Document Title

Summary of the ecotoxicological studies for Fluopyram

Data Requirement(s)

Regulation (EC) No 1107/2009 & Regulation (EU) No 283/2013
Document MCA
Section 8: Ecotoxicological studies – Part 2

According to the Guidance Document SANCO/10181/2013 for applicants on preparing dossiers for the approval of a chemical active substance

Date

2021-03-15

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M-766357-01-2

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Version history

Date [yyyy-mm-dd]	Data points containing amendments or additions[1] and brief description	Document identifier and version number

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4, 'How to revise an Assessment Report'.

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CA 8 ECOTOXICOLOGICAL STUDIES ON THE ACTIVE SUBSTANCE

Fluopyram was included in Annex I to Council Directive 91/414/EEC in 2013 (Regulation (EU), Entry into Force on August 22, 1013). This Supplementary Dossier contains only data which were not submitted at the time of the Annex I inclusion of Fluopyram under Council Directive 91/414/EEC and which were therefore not evaluated during the first EU review. All data which were already submitted by Bayer AG (former Bayer CropScience) for the Annex I inclusion under Council Directive 91/414/EEC are contained in the Draft Assessment Report (DAR) and its Addenda and are included in the Baseline Dossier provided by Bayer AG.

Relevant information for classification as detailed in the "*Combined Draft (Renewal) Assessment Report prepared according to Regulation (EC) N° 1107/2009 and Proposal for Harmonised Classification and Labelling (CLH Report) according to Regulation (EC) N° 1272/2008 – Volume 1, Level 2*" is provided in Document N1, Section 9.2, and highlighted in light grey.

The document MCA Section 8 summarizes all ecotoxicological data and classification proposal, which are relevant for the approval of Fluopyram and the proposed intended uses, including the representative uses, under Regulation (EC) No 1107/2009 in accordance with the requirements laid down in the Commission Regulation (EU) No 283/2013 and under Classification Regulation (EC) No 1272/2008.

The ecotoxicology MCA was split into two parts, of which this document represents Part 2.

It comprises of section CA 8.9, sections while CA 8 to CA 8.8 are shown in Part 1.

CA 8.9 Monitoring data

In this section, studies are submitted and summarised which provide information on residue decline in matrices relevant for bird and mammal risk assessment:

- **Residue decline in arthropods: 5 studies** delivering 12 DT_{50} values for foliage dwelling arthropods (3 DT_{50}s in vines, 3 DT_{50}s in OSR and 6 DT_{50}s in apple orchards), 9 DT_{50} values for flying insects (3 DT_{50}s in vines, 1 DT_{50} in OSR and 5 DT_{50}s in apple) and ground dwelling arthropods (1 DT_{50} extended lab, 6 DT_{50}s in apple).
- **Residue decline in foliage: 143 trials** delivering DT_{50} for various types of vegetables (surrogates for non-grass weeds: 118 DT_{50}s) and young cereals (surrogates for grass and cereals: 25 DT_{50}s). Due to the size of the kinetic evaluation reports, these DT_{50}s are reported in 4 reports for the vegetables and 2 reports for the cereals.

The arthropod residue studies in this evaluation were especially conducted for the purpose to inform the bird and mammal risk assessment.

The plant residue trials for this evaluation have been compiled from all potentially relevant residue decline trials conducted with fluopyram in the EU (eg, irrespective of the applied formulated product).

However, only trials were selected where the sampled matrix corresponds with the EFSA bird and mammal food categories “grass & cereals” and “non-grass weeds”, and where the type of plant matrix and growth stage matched those behind the RUDs for these matrices in the EFSA GD 2009 App. F (e.g., cereals only up to BBCH 30 at application).

It should be noted that the data set of surrogates for non-grass weeds also includes onions and leek, which are monocots. However, onion and leek are not grasses (do not belong to the botanical order Poales which includes both grasses and cereals), and were conducted under conditions more similar to the other vegetables. For these reasons it is proposed to include onions and leek with the other vegetables into the group of surrogates for non-grass weeds.

In the summaries for these studies, an attempt is made to visualize and assess the influence of rainfall on the residue time course according to the recommendations of EFSA 2019. For that purpose, the DT_{50} values from the trials have been assigned to 3 categories:

Category 1: no discernible influence of precipitation

Category 2: influence possible, slight

Category 3: marked influence

Influence of rainfall on arthropod residue decline

The evaluation of the arthropod residue decline trials demonstrated that rainfall occurred in the majority of trials. Thus, rainfall (and/or irrigation) is a typical element for exposure assessment in realistic bird and wild mammal scenarios under EFSA GD 2009. However, there was hardly any discernible impact of rainfall on the insect residue decline, so that nearly all trials can be assigned to rainfall category 1. The difference between the geomean DT_{50} for category 1 trials and for both category 1 & 2 trials is negligible (< 5%). Therefore it is proposed to pool all trials per foliage dwelling arthropods (n= 12), flying insects (n= 9) or ground dwelling arthropods (n= 7), respectively.

DT_{50} of fluopyram in arthropods

The geometric mean DT_{50} for foliage dwellers is 3.10 days (n= 12), for flying insects it is 3.03 days (n= 9) and for ground dwellers it is 6.39 days (n= 7).

Table 8.9- 1: DT$_{50}$ of fluopyram in arthropods per stratum and rainfall category

Group Plot Edition no.	Crop	Zone	Kinetic model	DT50	Cat	Rainfall	Source DT$_{50}$
Ground dweller M-545010-02-1	Bare soil	na	HS slow phase	5.58	1	none	M-545010-02-1
Foliage dweller plot 1 M-453376-01-2	Vines	N	FOMC DT$_{90}$/3.32	5.94 [a)]	1	No discernible influence of rainfall on residue time course	EnSa-15-0934
Foliage dweller plot 2 M-453376-01-2	Vines	N	SFO	5.57	1	No discernible influence of rainfall on residue time course	EnSa-15-0934
Foliage dweller plot 3 M-453376-01-2	Vines	N	FOMC DT$_{90}$/3.32	2.37	2	Frequent early rainfall without consistent correlation with the residue time course	EnSa-15-0934
Flying insects plot 1 M-453376-01-2	Vines	N	SFO	5.55	1	No discernible influence of rainfall on residue time course	EnSa-15-0934
Flying insects plot 2 M-453376-01-2	Vines	N	HS DT$_{90}$/3.32	2.85 [b)]	1	No discernible influence of rainfall on residue time course	EnSa-15-0934
Flying insects plot 3 M-453376-01-2	Vines	N	DFOP DT$_{90}$/3.32	3.38 [c)]	2	Frequent early rainfall without consistent correlation with the residue time course	EnSa-15-0934
Foliage dweller plot 1 M-544190-01-1	Oilseed rape	N	SFO	0.685	1	No discernible influence of rainfall on residue time course	EnSa-16-0035
Foliage dweller plot 2 M-544190-01-1	Oilseed rape	N	HS DT$_{90}$/3.32	1.078	1	No discernible influence of rainfall on residue time course	EnSa-16-0035
Foliage dweller plot 3 M-544190-01-1	Oilseed rape	N	HS DT$_{90}$/3.32	1.594	1	No discernible influence of rainfall on residue time course	EnSa-16-0035
Flying insects plots 1+2+3 M-544190-01-1	Oilseed rape	N	SFO	2.13	1	Very little rain	EnSa-16-0035
Foliage dweller plot 1 M-644049-01-1	Apple orchard	N	SFO	4.1	1	No discernible influence of rainfall on residue time course	M-644049-01-1
Foliage dweller plot 2 M-644049-01-1	Apple orchard	N	FOMC DT$_{90}$/3.32	2.7	1	No discernible influence of rainfall on residue time course	M-644049-01-1
Foliage dweller plot 3 M-644049-01-1	Apple orchard	N	FOMC DT$_{90}$/3.32	5.3	2	Slight influence of rainfall from day 8	M-644049-01-1
Flying insects plot 1 M-644049-01-1	Apple orchard	N	FOMC DT$_{90}$/3.32	2.4	1	No discernible influence of rainfall on residue time course	M-644049-01-1
Flying insects plot 2 M-644049-01-1	Apple orchard	N	SFO	2.2	1	No discernible influence of rainfall on residue time course	M-644049-01-1
Flying insects plot 3 M-644049-01-1	Apple orchard	N	SFO	1.9	1	No discernible influence of rainfall on residue time course	M-644049-01-1
Ground dweller plot 1	Apple orchard	N	Pseudo SFO DT$_{50}$	8.3	1	No discernible influence of rainfall on residue time course	EnSa-20-0891

Group Plot Edition no.	Crop	Zone	Kinetic model	DT50	Cat	Rainfall	Source DT_{50}
M-644049-01-1							
Ground dweller plot 2 M-644049-01-1	Apple orchard	N	Pseudo SFO DT_{50}	4.4	1	No discernible influence of rainfall on residue time course	EnSa-20-0891
Ground dweller plot 3 M-644049-01-1	Apple orchard	N	Pseudo SFO DT_{50}	9.4	1	No discernible influence of rainfall on residue time course	EnSa-20-0891
Foliage dweller plot 1 M-644048-01-1	Apple orchard	S	SFO	6.1	1	No discernible influence of rainfall on residue time course	M-644048-01-1
Foliage dweller plot 2 M-644048-01-1	Apple orchard	S	FOMC $DT_{90}/3.32$	5.5	1	No discernible influence of rainfall on residue time course	M-644048-01-1
Foliage dweller plot 3 M-644048-01-1	Apple orchard	S	SFO	4.4	1	No discernible influence of rainfall on residue time course	M-644048-01-1
Flying insects plot 1 M-644048-01-1	Apple orchard	S	SFO	4.9	1	No discernible influence of rainfall on residue time course	M-644048-01-1
Flying insects plot 3 M-644048-01-1	Apple orchard	S	SFO	3.8	1	No discernible influence of rainfall on residue time course	M-644048-01-1
Ground dweller plot 1 M-644048-01-1	Apple orchard	S	Pseudo SFO DT_{50}	7.1	1	No discernible influence of rainfall on residue time course	EnSa-20-0890
Ground dweller plot 2 M-644048-01-1	Apple orchard	S	Pseudo SFO DT_{50} [d]	5.5	2	Moderate rainfalls on days 4 and 5 coincide with a visible drop in residues, influence likely	EnSa-20-0890
Ground dweller plot 3 M-644048-01-1	Apple orchard	S	Pseudo SFO DT_{50}	5.8	1	No discernible influence of rainfall on residue time course	EnSa-20-0890

([a] it is proposed to use FOMC as the best fit (instead of DFOP as selected in EnSa-15-0934) because the visual fit rating is identical but the χ^2 -error is lower

([b]: it is proposed to use HS as the best fit for flying insects on plot 2 (instead of DFOP as selected in EnSa-15-0934) because the visual fit rating is identical but the χ^2 -error is lower

([c]: it is proposed to use DFOP as the best fit for flying insects on plot 2 (instead of SFO as selected in EnSa-15-0934) because the visual fit rating is identical but the χ^2 -error is lower

([d] it is proposed to use the pseudo-SFO DT_{50} of 5.5 days instead of the FOMC $DT_{90}/3.32$ of 7.9 days as suggested in the original report. Justification: both the pseudo-SFO of 5.5 days and the FOMC $DT_{90}/3.32$ of 7.9 days are used here as surrogate for the real best fit kinetic with the FOMC parameter alpha = 1.6093 and beta = 3.4342 (which is difficult to apply without a suitable calculator like TREC, Ebeling & Hammel 2020). However, the surrogate SFO-DT_{50} calculated as FOMC $DT_{90}/3.32$ of 7.9 days is an overestimation as it results in a 21-d f_{TWA} much larger than the 21-d f_{TWA} calculated with the FOMC parameter alpha and beta. The 21-d f_{TWA} calculation with the pseudo SFO-DT_{50} of 5.5 days still overestimates the 21-d f_{TWA} but is much closer to the best fit 21-d f_{TWA} with the FOMC parameter alpha and beta:

Approach	Calculated with	Parameter values	Resulting 21-d f_{TWA}
FOMC-DT_{90}/ 3.32	Surrogate SFO DT_{50}	7.9 days	0.46
Pseudo SFO-DT_{50}	Surrogate SFO DT_{50}	5.5 days	0.35
Best fit parameter	FOMC alpha & beta	1.0693 & 3.4342	0.30

Therefore, the pseudo SFO-DT_{50} = 5.5 days can be considered as a more accurate kinetic parameter than the FOMC-DT_{90}/3.32 = 7.9 days, which is still conservative compared with the best fit FOMC kinetic.

Influence of rainfall on foliage residue decline

The evaluation of the foliage residue decline trials demonstrated that rainfall occurred in the majority of trials (in vegetables often supplemented by irrigation). Thus, rainfall (and/or irrigation) is a typical element for exposure assessment in realistic bird and wild mammal scenarios under EFSA GD 2009. The comparison of DT_{50}s for the 3 rainfall categories indicate slower residue dissipation in category 1 than in categories 2 or 3, which is not surprising since rainfall may influence residue decline by various mechanisms beside wash-off (e.g., allowing dilution by plant growth, promoting metabolic activity of microflora on leaf surfaces).

Table 8.9- 2: Summary of DT_{50}s in plant foliage per rainfall category and feed category

Category 1		Category 2		Category 3		
young cereals	non-grass herbs	young cereals	non-grass herbs	young cereals	non-grass herbs	
4.60 d	3.39 d	3.58 d	3.22 d	2.50 d	2.76	DT_{50} geomean
11	34	6	36	8	48	n
44%	29%	24%	31%	32%	34%	% of trials

Table 8.9- 3: Overview on foliage residue decline DT_{50} sorted per rainfall influence categories

Trial Edition no.	Crop	Zone	Kinetic model	DT_{50} mod	Cat	Influence rain and/or irrigation	Source DT_{50}
R 2006 0655/9 M-290825-01-1	Beans	N	SFO	2.729	1	late rain, no influence	Ensa-20-8029
R 2006 0722/9 M-291180-01-1	Beans	N	SFO	13.88	1	very little rain, no influence	Ensa-20-8029
R 2006 0723/7 M-291180-01-1	Beans	N	SFO	3.636	1	late rain, no influence	Ensa-20-8029
08-2096-01 T1 M-365542-01-1	Beans	S	SFO	2.969	1	irrigation d5 and d11, no discernible influence	Ensa-20-8029
R 2006 0378/9 M-290827-01-1	Beans	S	SFO	8.872	1	no rain, no influence	Ensa-20-8029
R 2006 0657/5 M-290827-01-1	Beans	S	HS	0.883	1	no rain, no influence	Ensa-20-8029
R 2006 0658/3 M-290827-01-1	Beans	S	SFO	3.548	1	no rain, late irrigation, no influence	Ensa-20-8029
R 2007 0550/6 M-297564-01-1	Beans	S	SFO	0.7695	1	no rainfall, no influence	Ensa-20-8030
R 2007 0551/4 M-297564-01-1	Beans	S	SFO	8.169	1	no rainfall, no influence	Ensa-20-8030
R 2007 0552/2 M-297564-01-1	Beans	S	DFOP	11.166	1	nearly no rainfall (1.2mm day 7), no influence	Ensa-20-8030

Trial Edition no.	Crop	Zone	Kinetic model	DT_{50} mod	Cat	Influence rain and/or irrigation	Source DT_{50}
R 2007 0599/9 M-302101-01-1	Cabbage	N	SFO	1.979	1	marked decline, unlikely to be influenced by very little early rainfall	EnSa-20-0832
R 2006 0544/7 M-293182-01-1	Cabbage	S	FOMC	3.148	1	Little rainfall until day 14, no influence discernible	EnSa-20-0832
R 2006 0605/2 M-292048-01-1	Lettuce	N	HS	3.587	1	very little rain, no influence	Ensa-20-8029
R 2007 0244/2 M-304280-01-1	Lettuce	N	SFO	3.09	1	late rain, no marked influence	Ensa-20-8030
R 2007 0540/9 M-304280-01-1	Lettuce	N	SFO	1.368	1	late rain, no discernible influence	Ensa-20-8030
14-2029-02 M-534202-01-1	Lettuce	N	SFO	2.892	1	little rainfall, irrigation without discernible impact. Influence unlikely.	Ensa-20-8031
14-2029-04 M-534202-01-1	Lettuce	N	SFO	2.034	1	no rainfall until day 6, without discernible impact. Influence unlikely	Ensa-20-8031
18-2086-01-T1 M-675005-01-1	Lettuce	S	SFO	8.248	1	nearly no rain, no influence	Ensa-20-8029
18-2086-01-T2 M-675005-01-1	Lettuce	S	SFO	7.754	1	nearly no rain, no influence	Ensa-20-8029
18-2086-02-T1 M-675005-01-1	Lettuce	S	SFO	3.419	1	nearly no rain, no influence	Ensa-20-8029
18-2086-02-T2 M-675005-01-1	Lettuce	S	SFO	4.04	1	nearly no rain, no influence	Ensa-20-8029
18-2086-03-T1 M-675005-01-1	Lettuce	S	SFO	4.378	1	no rain, no influence	Ensa-20-8029
18-2086-03-T2 M-675005-01-1	Lettuce	S	SFO	4.339	1	no rain, no influence	Ensa-20-8029
18-2086-04-T1 M-675005-01-1	Lettuce	S	SFO	1.186	1	nearly no rain until d7, no influence	Ensa-20-8029
18-2086-04-T2 M-675005-01-1	Lettuce	S	SFO	1.174	1	nearly no rain until d7, no influence	Ensa-20-8029
R 2006 0376/2 M-292050-01-1	Lettuce	S	SFO	1.52	1	little rain, late irrigation, no influence	Ensa-20-8029
R 2006 0608/7 M-292050-01-1	Lettuce	S	SFO	2.57	1	very little rain, no influence	Ensa-20-8029
R 2006 0610/9 M-292050-01-1	Lettuce	S	SFO	3.529	1	late rain, no influence	Ensa-20-8029
R 2006 0611/7 M-292050-01-1	Lettuce	S	SFO	3.02	1	late rain, no influence	Ensa-20-8029
14-2030-01 M-534595-01-1	Lettuce	S	SFO	4.804	1	Virtually no rain, no influence	Ensa-20-8031
14-2030-02 M-534595-01-1	Lettuce	S	SFO	5.522	1	no rain, no influence	Ensa-20-8031
14-2185-02 M-536963-01-1	Lettuce	S	SFO	4.578	1	virtually no rain, no influence	Ensa-20-8031
14-2185-03 M-536963-01-1	Lettuce	S	SFO	4.78	1	no rain until day 9, no influence	Ensa-20-8031
R 2007 0568/9 M-302325-01-1	Onion	S	SFO	4.203	1	No rainfall and no influence from irrigation day 10	EnSa-20-0832
18-2951-02 M-678413-01-1	Young cereals	N	SFO	3.214	1	very little rain, no influence	EnSa-20-0834
18-2951-03 M-678413-01-1	Young cereals	N	SFO	3.523	1	no rain, no influence	EnSa-20-0834

Trial Edition no.	Crop	Zone	Kinetic model	DT_{50} mod	Cat	Influence rain and/or irrigation	Source DT_{50}
E19RP102-01 M-758824-01-1	Young cereals	N	SFO	6.419	1	no rain, no influence	EnSa-20-0834
E19RP102-02 M-758824-01-1	Young cereals	N	SFO	8.185	1	no rain, no influence	EnSa-20-0834
15-2952-01 M-566830-01-1	Young cereals	N	SFO	3.37	1	rain only late, no influence	EnSa-17-0484
15-2952-02 M-566830-01-1	Young cereals	N	SFO	7.59	1	no rain, no influence	EnSa-17-0484
18-2954-03 M-675129-02-1	Young cereals	S	SFO	3.607	1	no rain, no influence	EnSa-20-0834
E19RP087-01 M-758649-01-1	Young cereals	S	SFO	10.18	1	no rain, no influence	EnSa-20-0834
E19RP087-02 M-758649-01-1	Young cereals	S	SFO	1.782	1	rain d4 and d5 but no discernible influence	EnSa-20-0834
15-2952-04 M-566830-01-1	Young cereals	S	SFO	4.19	1	very little rain, no influence	EnSa-17-0484
15-2953-03 M-566828-01-1	Young cereals	S	SFO	4.64	1	no rain, no influence	EnSa-17-0484
R 2006 0377/0 M-290825-01-1	Beans	N	SFO	4.674	2	late rain, influence possible	Ensa-20-8029
R 2006 0656/7 M-290825-01-1	Beans	N	SFO	2.84	2	frequent rainfall, slight influence possible	Ensa-20-8029
R 2007 0546/8 M-297562-01-1	Beans	N	SFO	2.969	2	frequent but little rain, influence possible	Ensa-20-8030
R 2007 0547/6 M-297562-01-1	Beans	N	SFO	2.744	2	late irrigation and rainfall, possibly slight influence	Ensa-20-8030
R 2007 0548/4 M-297562-01-1	Beans	N	HS	3.639	2	little early and more rain on day 6, no marked influence	Ensa-20-8030
R 2006 0347/9 M-292103-01-1	Cabbage	N	HS	4.729	2	frequent rainfall but in small amounts which are unlikely to have markedly influenced residue levels.	EnSa-20-0832
R 2006 0543/9 M-292103-01-1	Cabbage	N	SFO	5.78	2	Little rainfall until day 8, no influence discernible	EnSa-20-0832
R 2006 0348/7 M-293182-01-1	Cabbage	S	FOMC	3.693	2	Little rainfall until day 8, no influence discernible	EnSa-20-0832
R 2007 0079/2 M-302044-01-1	Cabbage	S	FOMC	4.084	2	marked decline until 2nd sampling but little early rain until day 7 (influence questionable)	EnSa-20-0832
R 2007 0600/6 M-302044-01-1	Cabbage	S	SFO	3.981	2	Moderate early rainfall but no marked decline (influence unlikely)	EnSa-20-0832
10-2099-01 M-423901-01-1	Endive	N	SFO	2.252	2	frequent heavy rainfall, influence not discernible but likely	Ensa-20-8029
R 2006 0343/6 M-292101-02-1	Leek	N	SFO	8.282	2	frequent rainfall after day 5 did not seem to have any discernible influence on residue dissipation	EnSa-20-0832
R 2006 0466/1 M-292101-02-1	Leek	N	SFO	5.836	2	frequent rainfall after day 7 did not seem to have any discernible influence	EnSa-20-0832
R 2006 0468/8 M-292101-02-1	Leek	N	SFO	8.99	2	Frequent late rainfall and heavy irrigation coincide with a	EnSa-20-0832

Trial Edition no.	Crop	Zone	Kinetic model	DT_{50} mod	Cat	Influence rain and/or irrigation	Source DT_{50}
						moderate drop of residue levels on day 15	
R 2006 0344/4 M-292082-01-1	Leek	S	SFO	6.01	2	rainfall on day 6 and 7 may have slightly influenced residue dissipation	EnSa-20-0832
R 2006 0469/6 M-292082-01-1	Leek	S	SFO	7.054	2	frequent irrigation and occasional rainfall may have markedly influenced residue dissipation, although this is not discernible in the decline pattern	EnSa-20-0832
R 2006 0604/4 M-292048-01-1	Lettuce	N	SFO	1.409	2	rain after 75% already declined, at most slight influence	Ensa-20-8029
R 2006 0606/0 M-292048-01-1	Lettuce	N	SFO	2.452	2	some rain after 2nd sampling but no visible influence	Ensa-20-8029
R 2007 0011/3 M-304280-01-1	Lettuce	N	SFO	1.048	2	little rain during first days, influence possible	Ensa-20-8030
R 2007 0537/9 M-304280-01-1	Lettuce	N	FOMC /DFOP	1.949	2	Little but early rain, influence possible	Ensa-20-8030
R 2007 0539/5 M-304280-01-1	Lettuce	N	SFO	2.129	2	Very early rainfall, no influence discernible	Ensa-20-8030
14-2029-01 M-534202-01-1	Lettuce	N	SFO	2.921	2	frequent irrigation and rainfall. Slight influence possible	Ensa-20-8031
14-2029-03 M-534202-01-1	Lettuce	N	SFO	1.682	2	little rainfall until day 6 (8 mm). Slight influence possible.	Ensa-20-8031
14-2029-05 M-534202-01-1	Lettuce	N	SFO	1.8	2	several rainfalls without discernible impact, slight influence cannot be excluded	Ensa-20-8031
14-2184-02 M-536965-01-1	Lettuce	N	SFO	4.71	2	rainfall coincides with slight drop of residue levels. Influence possible.	Ensa-20-8031
14-2184-03 M-536965-01-1	Lettuce	N	SFO	2.406	2	irrigation coincides with slight drop of residue levels. Influence possible	Ensa-20-8031
R 2006 0609/5 M-292050-01-1	Lettuce	S	SFO	0.8444	2	little rain during first days, but influence possible	Ensa-20-8029
R 2007 0012/1 M-304278-01-1	Lettuce	S	SFO	1.813	2	no rain but daily irrigation. Influence likely.	Ensa-20-8030
R 2007 0245/0 M-304278-01-1	Lettuce	S	SFO	1.204	2	little but very early rain after application, influence possible	Ensa-20-8030
R 2007 0541/7 M-304278-01-1	Lettuce	S	SFO	5.797	2	frequent but little rain, influence possible	Ensa-20-8030
14-2030-03 M-534595-01-1	Lettuce	S	SFO	3.233	2	Frequent rainfall and regular sprinkler irrigation. Marked influence not discernible but slight impact likely	Ensa-20-8031
14-2185-04 M-536963-01-1	Lettuce	S	SFO	2.403	2	Several rainfalls around 2nd sampling, no influence discernible	Ensa-20-8031
R 2006 0339/8 M-292098-01-1	Onion	S	SFO	4.448	2	Irrigation coincides with a moderate drop of residue levels, slight influence likely	EnSa-20-0832
R 2007 0555/7 M-298639-01-1	Peas	N	SFO	5.468	2	Only little rainfall but coinciding with residue decline. Influence possible.	Ensa-20-8030

Trial Edition no.	Crop	Zone	Kinetic model	DT_{50} mod	Cat	Influence rain and/or irrigation	Source DT_{50}
R 2007 0556/5 M-298639-01-1	Peas	N	SFO	7.032	2	many days with little rainfall. Influence possible	Ensa-20-8030
R 2007 0557/3 M-297487-01-1	Peas	S	SFO	3.275	2	early irrigation and rainfall, influence possible	Ensa-20-8030
E19RP102-03 M-758824-01-1	Young cereals	N	SFO	7.01	2	moderate rain d4, slight influence	EnSa-20-0834
E19RP102-04 M-758824-01-1	Young cereals	N	FOMC	4.319	2	moderate rain d2, slight influence	EnSa-20-0834
13-2950-01 M-471216-01-1	Young cereals	N	SFO	1.95	2	little early rainfall, very little impact on DT50	EnSa-17-0484
15-2953-02 M-566828-01-1	Young cereals	N	SFO	4.23	2	heavy rain day 5, visible but slight influence	EnSa-17-0484
E19RP087-04 M-758649-01-1	Young cereals	S	SFO	2.956	2	"moderate rain d3, d4, slight influence"	EnSa-20-0834
15-2952-03 M-566830-01-1	Young cereals	S	SFO	2.86	2	no rain before day 5, only slight influence	EnSa-17-0484
08-2034-01 T1 M-365530-01-1	Beans	N	SFO	4.053	3	moderate rain d3, d5, marked influence	Ensa-20-8029
08-2034-02 T2 M-365530-01-1	Beans	N	SFO	3.992	3	moderate rain d3, d5, marked influence	Ensa-20-8029
R 2006 0380/0 M-291180-01-1	Beans	N	SFO	17.32	3	late rain but influence likely	Ensa-20-8029
R 2006 0654/0 M-290825-01-1	Beans	N	SFO	0.7187	3	marked influence by early heavy rain	Ensa-20-8029
R 2007 0014/8 M-297562-01-1	Beans	N	SFO	2.733	3	Heavy rain on days around 2nd sampling, influence likely	Ensa-20-8030
R 2007 0549/2 M-297562-01-1	Beans	N	SFO	3.172	3	marked influence of rainfall days 3 and 4 likely	Ensa-20-8030
08-2096-02 T2 M-365542-01-1	Beans	S	SFO	3.648	3	irrigation d5 and d11, marked influence	Ensa-20-8029
R 2006 0620/6 M-290827-01-1	Beans	S	SFO	0.7254	3	marked influence of early rainfall likely	Ensa-20-8029
R 2007 0035/0 M-297564-01-1	Beans	S	SFO	3.176	3	large rainfall days 4 and 5, influence likely	Ensa-20-8030
R 2007 0078/4 M-302101-01-1	Cabbage	N	SFO	2.062	3	early rainfall coincides with marked drop (influence possible)	EnSa-20-0832
10-2099-02 M-423901-01-1	Endive	N	FOMC	2.659	3	early rainfall, marked decline, influence likely	Ensa-20-8029
10-2099-03 M-423901-01-1	Endive	N	SFO	1.228	3	early rainfall, marked decline, influence likely	Ensa-20-8029
10-2099-04 M-423901-01-1	Endive	N	SFO	1.481	3	early rainfall, marked decline, influence likely	Ensa-20-8029
11-2029-01 M-442996-01-1	Leek	N	SFO	2.279	3	Heavy rainfall coincides with a marked drop of residue levels, influence likely	EnSa-20-0832
11-2029-02 M-442996-01-1	Leek	N	SFO	2.657	3	Heavy rainfall coincides with a marked drop of residue levels, influence likely	EnSa-20-0832
11-2029-03 M-442996-01-1	Leek	N	SFO	2.620	3	Early rainfall coincides with a marked drop of residue levels, influence likely	EnSa-20-0832
11-2029-04 M-442996-01-1	Leek	N	SFO	2.543	3	Early rainfall coincides with a marked drop of residue levels, influence likely	EnSa-20-0832

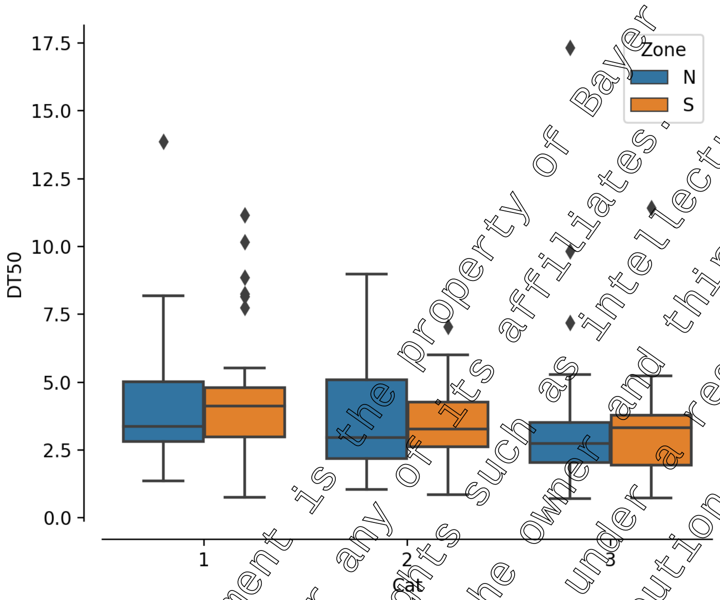
Trial Edition no.	Crop	Zone	Kinetic model	DT_{50} mod	Cat	Influence rain and/or irrigation	Source DT_{50}
R 2006 0465/3 M-292101-02-1	Leek	N	SFO	2.346	3	Frequent early rainfall coincides with a marked drop of residue levels, influence likely.	EnSa-20-0832
R 2007 0056/3 M-304288-01-1	Leek	N	DFOP	4.184	3	Early rainfall coincided with a moderate drop (influence likely).	EnSa-20-0832
R 2007 0249/3 M-304276-01-1	Leek	N	HS	3.392	3	early rainfall coincides with marked drop (influence likely)	EnSa-20-0832
R 2007 0569/7 M-304288-01-1	Leek	N	FOMC	3.551	3	early rainfall coincides with marked drop (influence likely)	EnSa-20-0832
R 2007 0570/0 M-304288-01-1	Leek	N	FOMC	3.675	3	early rainfall coincides with marked drop (influence likely)	EnSa-20-0832
R 2007 0571/9 M-304288-01-1	Leek	N	SFO	2.557	3	early rainfall coincides with marked drop (influence likely)	EnSa-20-0832
R 2007 0573/5 M-304276-01-1	Leek	N	SFO	3.321	3	early rainfall coincides with marked drop (influence likely)	EnSa-20-0832
R 2007 0574/3 M-304276-01-1	Leek	N	SFO	2.916	3	early rainfall coincides with marked drop (influence likely)	EnSa-20-0832
R 2007 0057/1 M-302775-01-1	Leek	S	FOMC	5.241	3	early irrigation coincides with marked drop (influence likely	EnSa-20-0832
R 2007 0250/7 M-302780-01-1	Leek	S	HS	11.434	3	early irrigation coincides with moderate drop (influence likely)	EnSa-20-0832
R 2007 0572/7 M-302775-01-1	Leek	S	SFO	1.952	3	early irrigation coincides with marked drop (influence likely)	EnSa-20-0832
R 2006 0375/4 M-292048-01-1	Lettuce	N	HS	2.198	3	early rainfall and sprinkler irrigation, marked influence	Ensa-20-8029
R 2006 0607/9 M-292048-01-1	Lettuce	N	SFO	1.129	3	marked influence by sprinkler irrigation	Ensa-20-8029
R 2007 0538/7 M-304280-01-1	Lettuce	N	SFO	0.7255	3	marked influence of early rainfall	Ensa-20-8030
14-2184-01 M-536965-01-1	Lettuce	N	SFO	1.095	3	Early rainfall coincides with marked drop of residue levels. Influence likely	Ensa-20-8031
14-2184-04 M-536965-01-1	Lettuce	N	SFO	1.592	3	frequent early rainfall may have markedly influenced residue levels	Ensa-20-8031
R 2007 0246/9 M-304278-01-1	Lettuce	S	SFO	0.8952	3	early rain and irrigation, influence likely	Ensa-20-8030
14-2030-04 M-534595-01-1	Lettuce	S	FOMC	4.918	3	Early heavy rainfall, marked influence likely	Ensa-20-8031
14-2030-05 M-534595-01-1	Lettuce	S	SFO	3.779	3	Heavy rainfall before 3rd sampling, marked influence likely	Ensa-20-8031
14-2185-01 M-536963-01-1	Lettuce	S	SFO	1.057	3	early rainfall and irrigation, marked influence likely.	Ensa-20-8031
R 2006 0337/1 M-292996-01-1	Onion	N	FOMC	7.184	3	Irrigation and rainfall coincide with a moderate drop of residue levels, influence likely	EnSa-20-0832
R 2006 0504/8 M-292996-01-1	Onion	N	SFO	4.91	3	Irrigation coincides with moderate drops of residue levels, influence likely.	EnSa-20-0832
R 2007 0567/0 M-302330-01-1	Onion	N	SFO	2.992	3	early rainfall coincides with marked drop (influence likely)	EnSa-20-0832

Trial Edition no.	Crop	Zone	Kinetic model	DT_{50} mod	Cat	Influence rain and/or irrigation	Source DT_{50}
R 2006 0505/6 M-292098-01-1	Onion	S	SFO	3.282	3	Irrigation coincides with moderate drops of residue levels, influence likely.	EnSa-20-0832
R 2007 0043/1 M-302325-01-1	Onion	S	FOMC	4.584	3	Likely marked influence from irrigation at day 3	EnSa-20-0832
R 2007 0036/9 M-298639-01-1	Peas	N	SFO	5.287	3	large rainfall days 4 and 5, influence likely	Ensa-20-8030
R 2007 0553/0 M-298639-01-1	Peas	N	HS	3.401	3	Rain on day 2, influence likely	Ensa-20-8030
R 2007 0554/9 M-298639-01-1	Peas	N	FOMC	9.837	3	Large rainfall on days 2 and 3, influence likely	Ensa-20-8030
15-2030-01 M-566823-03-1	Peas	N	SFO	3.346	3	Heavy rainfall coincides with a marked drop in residue levels, impact likely	Ensa-20-8031
R 2007 0037/7 M-297487-01-1	Peas	S	SFO	3.329	3	Large rainfall on day 3, influence likely.	Ensa-20-8030
15-2030-04 M-566823-03-1	Peas	S	SFO	2.928	3	Rainfall on days 3 and 4 coincides with a drop in residue levels, influence likely.	Ensa-20-8031
18-2951-01 M-678413-01-1	Young cereals	N	SFO	2.747	3	early rain, marked decline	EnSa-20-0834
13-2950-02 M-471216-01-1	Young cereals	N	HS	2.03	3	rainfall day0, marked decline	EnSa-17-0484
13-2950-03 M-471216-01-1	Young cereals	N	HS	1.2	3	early rainfall, marked decline	EnSa-17-0484
13-2950-04 M-471216-01-1	Young cereals	N	SFO	1.25	3	early rainfall, marked decline	EnSa-17-0484
15-2953-01 M-566828-01-1	Young cereals	N	HS	3.48	3	early rain, marked decline	EnSa-17-0484
18-2954-01 M-675129-02-1	Young cereals	S	SFO	4.201	3	heavy rain d4, marked decline	EnSa-20-0834
18-2954-02 M-675129-02-1	Young cereals	S	SFO	3.599	3	heavy rain d4, marked decline	EnSa-20-0834
E19RP087-03 M-758649-01-1	Young cereals	S	SFO	3.415	3	heavy rain d3, marked decline	EnSa-20-0834

Influence of the residue zone on foliage DT_{50}

A comparison of the DT_{50} values from trials conducted in the Northern EU residue zone with the DT_{50} values from trials conducted in the Southern EU residue zone shows comparability within each of the rainfall categories.

It is therefore proposed to pool the foliage residue decline DT_{50}s from trials conducted in the Northern EU residue zone with the DT_{50} values from trials conducted in the Southern EU residue zone.



Influence of metabolite fluopyram-benzamide on the DT_{50} in foliage

In a part of the residue trials evaluated here for the purpose of informing the bird and mammal risk assessment, the metabolite fluopyram-benzamide (BNZ) was included as analyte since it is part of the residue definition in the toxicological assessment for plant material.

Based on the metabolism data and field residue trials, the definitions of residues in plants were established by EFSA:

	Residue definition		Reference
Food of plant origin	Monitoring	fluopyram (parent only)	EFSA Scientific Report EFSA Journal 2013;11(4):3052
	Risk assessment	fluopyram and fluopyram-benzamide (M25) expressed as fluopyram	

However, the comparison of the foliage DT_{50} of fluopyram alone with the foliage DT_{50} of the combined residues of fluopyram and its benzamide-metabolite shows that this metabolite contributes very little to the potential exposure of herbivorous birds and mammals in foliage (typically less than 5%) which may be considered negligible.

It is therefore proposed that the definition of the residue for herbivorous birds and mammals can be limited to fluopyram alone.

Kinetic evaluation report	**Matrix**	**# of trials with analysis for BNZ**	**Geomean DT_{50} FLU**	**Geomean DT_{50} FLU+BNZ**	**Difference in DT_{50}**
EnSa-20-0829	Vegetables	37	2.765	2.857	~ 3%
EnSa-20-0830	Vegetables	26	2.845	2.926	~ 3%
EnSa-20-0831	Vegetables	20	2.673	2.697	~ 1%
EnSa-20-0832	Vegetables	35	3.921	4.144	~ 5%
EnSa-20-0834	Young cereals	8	4.820	4.821	< 1%

Studies relevant to address residues in invertebrates as prey for insectivorous birds and mammals

Data Point:	KCA 8.9/01
Report Author:	[redacted]
Report Year:	2017
Report Title:	Amendment no. 1 to determination of residues of fluopyram in Poecilus cupreus (Coleoptera: Carabidae) using an extended laboratory test
Report No:	CW15/045
Document No:	M-545010-02-1
Guideline(s) followed in study:	Heimbach et al. (2000) modified US EPA OCSPP Guideline No. 850.SUPP
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	yes, evaluated and accepted in the Addendum No. 4 to the DAR (rev 2017)
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	No

Executive Summary

The present summary reflects the Amendment No. 1 to the original study report in which the LOQ and LOD as well as the kinetic evaluation have been revised.

Residues of fluopyram in carabid beetles (*Poecilus cupreus*) after one application of Fluopyram SC 500 g/L at an application rate of 250 g a.s./ha were determined in an extended laboratory study. Fluopyram concentrations on carabid beetles declined over the sampling period of 10 days. According to the best fitting kinetic model (Hockey-Stick), the DT_{50} of fluopyram was 0.607 days in the fast phase and 5.58 days in the slow phase (tb = 2 d).

I. Material and Methods

Materials.

1. Test Item: Fluopyram SC 500 g/L
   Batch no.: EZ01217101
   Active Ingredient: Fluopyram
   Storage: recommended storage conditions from +2 °C to +30 °C
   Expiry date: 2018-01-30
2. Sampled matrix: *Poecilus cupreus* (Coleoptera: Carabidae)

Methods:

The purpose of the study was to determine the residue decline of fluopyram in carabid beetles (*Poecilus cupreus*) following an application of the formulated product Fluopyram SC 500 g/L at a rate of 250 g a.s./ha in an extended laboratory test following Heimbach et al. (2000).

Test organisms and test units: Adult *Poecilus cupreus* beetles were transferred in groups of three males and three females to exposure units filled with 250 ± 1 g (dry weight) natural soil (LUFA 2.1 silty sand, particle sizes <0.002-2.0 mm, organic carbon content = 0.67 ± 0.11%). According to the test guideline, the soil was moistened with deionized water and kept at a 55 ± 5% saturation of the water holding capacity during the experiment. The beetles were kept in a laboratory at a temperature of 19.5-20.5°C, a relative humidity of 70-83%, and a light:dark cycle of 16:8 h with a light intensity range of 290-550 lux.

Test design: Directly before application, beetles were transferred to a fresh exposure unit. The test item Fluopyram SC 500 g/L was applied on the beetles, the food (*Musca domestica* pupae) and the soil substrate at a rate corresponding to 250 g a.s./ha in 400 L deionized water using a linear cabinet track sprayer. Beetles were kept in the exposure units over a period of 10 days after application. After application, six treated pupae were put into each exposure unit (one punctured pupa per beetle). The remaining treated pupae were deep-frozen and fed to the beetles 3 times per week. Old food was removed.

Sampling: At the day of application as well as 1, 2, 3, 5, 7, and 10 days after application, beetles from two treated exposure units were sampled for each sampling day. The samples were combined and the total fresh weight of all 12 beetles was determined before they were stored deep-frozen until residue analysis. The same was done for two untreated exposure units at the application day only.

Residue analysis: Samples were analyzed for residues of fluopyram according to method 00984/M002 (Schöning 2011) by reversed phase HPLC-MS/MS. Residues are reported as µg active substance/kg fresh weight.

The method validation was done with a full set of recoveries at the 10 µg/kg, 100 µg/kg, 1000 µg/kg, and 2000 µg/kg levels by spiking control samples with the defined amounts of fluopyram. As control material for the validation, deep-frozen larvae and beetles from an internal insect breeding were used. Due to contamination in the measuring system and residues found in the control material at the level of 10 µg/kg, recovery values at the fortification level of 10 µg/kg were considered invalid in the amendment. Thus, the limit of quantification (LOQ), defined as the lowest validated fortification level, was set to 100 µg/kg. The limit of detection (LOD) was defined as 30 µg/kg.

Analytical method:

Full details and acceptable validation data to support the analytical method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

Data evaluation: The residue decline (DT_{50}) of the active substance in arthropods was calculated to quantify the time course of the residue concentration in potential food items of insectivorous and omnivorous birds or mammals over time. The residue decline data were evaluated using SFO, FOMC, DFOP and HS kinetic models. The selection of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment, $\chi 2$ statistics, randomness of residuals, and t-test significance following the FOCUS guidance (2006, 2014). For the kinetic evaluation, measured values between LOD and LOQ were set to 0.5 x (LOQ + LOD).

Calculation tool: DT_{50} calculations were performed with the Bayer AG CropScience software KinGUI version 2.1 (Heinemann 2012, Meyer & Witt, 2014).

II. Results and Discussion

Individual values of validation samples ranged between 85% and 88%, with an overall mean recovery of 87% and a relative standard deviation (RSD) of 1.5% (n = 5).

Table 8.9- 4: Analytical information

Fortification level [µg/kg]	Recoveries – Single values [%]	Mean [%]	RSD [%]
100	86 88 85	86	1.8
1000	87	-	-
2000	88	-	
Overall Mean and RSD [%]		**87**	**1.5**

Detected fluopyram residues in the carabid beetles at study end were < 10% of the initial values. The measured residues in the samples of the carabid beetles are presented below.

Table 8.9- 5: Analytical findings

Sample	DAA	Residues of fluopyram [µg a.s./kg f.w.] as measured	Residues of fluopyram [µg a.s./kg f.w.] used in kinetic evaluation
Control	0	<LOD	-
Treated	0	1749	1749
Treated	1	578	578
Treated	2	100	100
Treated	3	192	192
Treated	5	134	134
Treated	7	<LOQ [L]	65
Treated	10	<LOQ [L]	65

DAA Days after application
LOD 30 µg/kg
LOQ 100 µg/kg
[L] Values between LOD and LOQ were set to 0.5 x (LOQ+LOD) = 65 µg/kg (FOCUS, 2014)

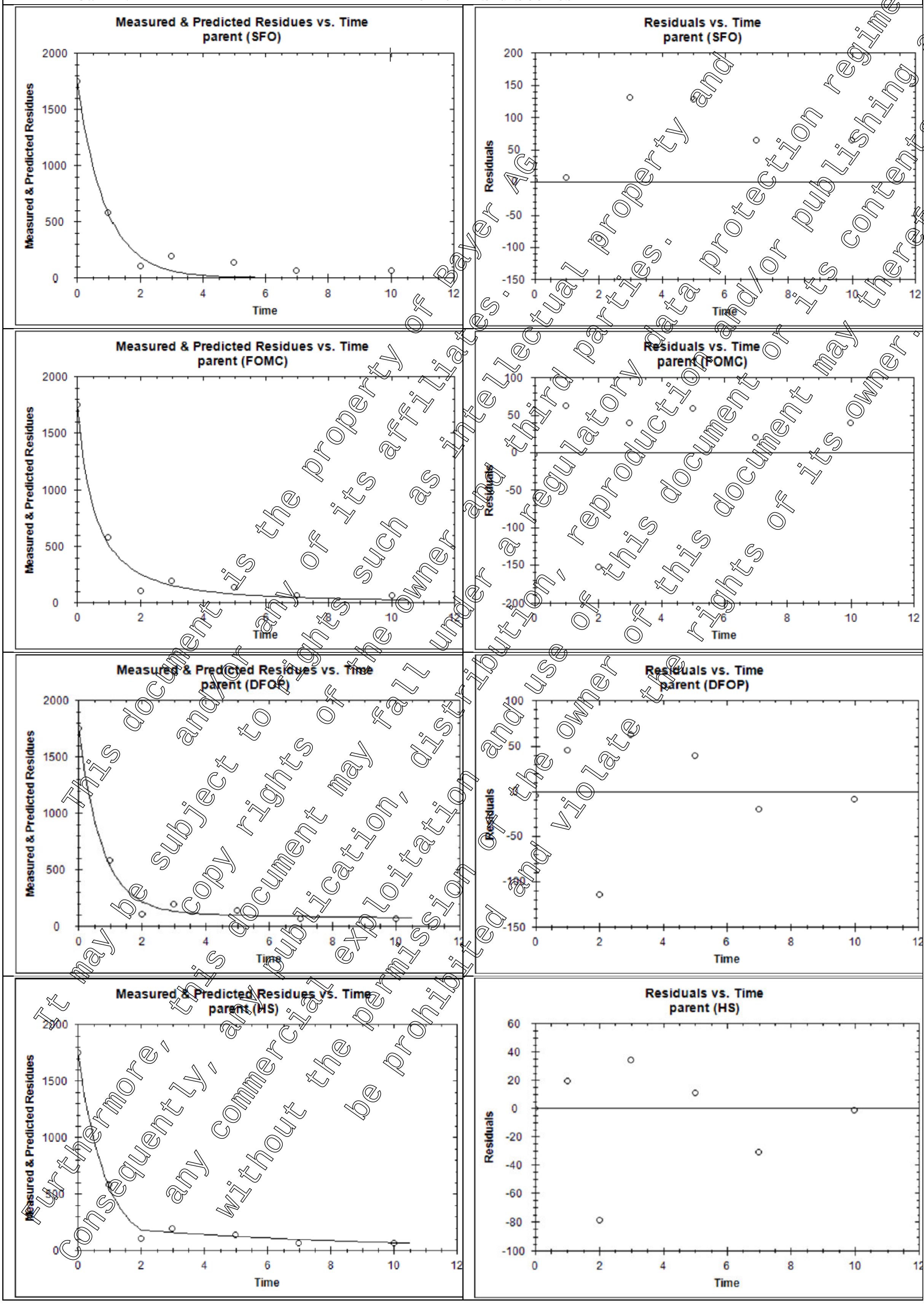
Based on a kinetic evaluation of the data, the best fit for ecotoxicological purposes was obtained with the Hockey-stick model (HS). It should be noted that the slow phase of this HS fit may not be appropriate to describe the decline of fluopyram in carabid beetles alone, because the slow phase is based only on a very small portion of the initial residues (~ 10%).

Table 8.9- 6: Kinetic evaluation

Kinetic model							
SFO	Visual fit	χ^2 - error	DT_{50}	DT_{90}		DT_{50} recalc	t-test k
FOMC			DT_{50}	DT_{90}	α / β	= DT_{90} /	
DFOP			DT_{50} fast	DT_{50} slow	g	3.32	
HS			DT_{50} fast	DT_{50} slow	tb, in d		
		[%]	[d]	[d]		[d]	
SFO	o	16.21	0.620	2.06		0.620	k: < 0.001
FOMC	+	14.58	0.480	2.70	1.743/0.983	0.814	
DFOP	+	12.64	0.510	15.17	0.9336	0.697	k2: 0.419
HS [E]	+	8.14	0.607	5.58	2.0	0.652	k2: 0.151

visual acceptability: + good o medium - bad
[E] best approach for ecotoxicological purpose recommended by the authors of the kinetic evaluation

8.9- 1: am on carabid beetles



III. Conclusion

The study provides ground dwelling insect residue decline data from an extended laboratory test system following an application of fluopyram at 250 g a.s./ha. Fluopyram concentrations on carabid beetles reached initial concentrations of 1749 µg/kg and declined to < 100 µg/kg within the sampling period of 10 days.

Acceptable fits for the dissipation kinetics of fluopyram were provided by a Hockey-stick model with a DT_{50} of 0.607 days in the fast phase and a DT_{50} of 5.58 days in the slow phase.

<u>Assessment and conclusion by applicant</u>:

The study and its data are considered as acceptable and reliable for use in risk assessment.

This study provides information on the residue decline of fluopyram on ground beetles, an important taxon often dominating the captures in pitfall traps in field studies. The study adapted an extended laboratory testing guideline for non-target arthropods. Food chain effects are simulated by offering exclusively treated feed additional to the overspray of the beetles and the soil in the testing arena.

Therefore, the results of this study can be considered as supplemental information to the field studies on insect residue decline with fluopyram. A conservative approach would be to select the slow-phase DT_{50} from the HS fit (5.58 days).

Data Point:	KCA 8.9/02
Report Author:	[redacted]
Report Year:	2013
Report Title:	Residue decline of fluopyram on arthropods after spray application in vines in Germany
Report No:	M-453376-01-2
Document No:	M-453376-01-2
Guideline(s) followed in study:	Regulation (EC) No 1107/2009, EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) US EPA OCSPP Guideline No. 850.SUPP
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	yes, evaluated and accepted in the Addendum No. 4 to the DAR (rev 2017)
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

A field study with three invertebrate residue decline trials was conducted in vineyards in Germany during the 2012 season. One application with Fluopyram SC 500, containing 500 g/L fluopyram was conducted at 0.5 kg product/ha. Foliage dwelling invertebrates were sampled with inventory sprays and flying insects were sampled with Malaise traps.

Acceptable fits for fluopyram provided an SFO-DT_{50} of 5.63 days for foliage dwellers and of 2.23 and 5.55 days in Malaise traps.

I. MATERIAL AND METHODS

Materials:

1. Test Item: Fluopyram SC 500 g/L
   Batch no.: 300066
   Active Ingredient: Fluopyram
   Storage: 25°C +/- 5°C, from +2°C to +30°C are also acceptable
   Expiry date: 2014-03-12
2. Sampled matrix: Invertebrates
   Crop: Vineyards

Methods:

The purpose of the study was to determine the residue decline of fluopyram following an application of the formulated product LUNA® Privilege (SC formulation, containing 500 g/L fluopyram) at a rate of nominal 0.5 L product/ha in vineyards in Germany, following the recommendations of the guidance document on risk assessment for birds & mammals on request from EFSA. EFSA Journal 2009; 7(12):1438.

Study sites: The study was conducted in the vicinity of Neustadt an der Weinstrasse, Rhineland-Palatinate in southern Germany. Three plots (1.1, 1.2 and 1.2 ha) in three vineyards were selected.

Test item and application: The test item Luna® Privilege was applied in each vineyard at growth stages BBCH 71-79, at a nominal application rate of 0.5 L product/ha, corresponding to nominal 250 g fluopyram per ha with a spray volume of 400 L tap water according to Good Laboratory Practice and Good Agricultural Practice. Deviations from the target rate were < 3%.

Arthropod sampling: Foliage dwelling arthropods by inventory spraying and flying insects with Malaise traps. For inventory spraying, whole trees within the sample area were sprayed with a ‘knock down’ insecticide (Aquapy®) at approx. 25 mL product in 1 L water with a motor driven knapsack sprayer (non-GLP application). One Malaise trap per orchard was placed between the tree rows. Targeted biomass per sample was ≥ 1.0 g for all sampling methods.

Sampling period was until 21 days after the application. After identification and quantification of the main taxonomic groups, the samples were stored deep frozen until residue analysis.

Residue analysis: All samples were analysed for their content of fluopyram via HPLC-MS/MS. Residues are reported in terms of mg active substance/kg fresh weight (mg a.s./kg fw). The Limit of quantification (LOQ) value was 0.01 mg/kg, the limit of detection (LOD) was 0.003 mg/kg.

Full details and acceptable validation data to support the analytical method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

Data evaluation:

The residue decline (DT_{50}) of the active substance in arthropods was calculated to quantify the time course of the residue concentration in potential food items of insectivorous and omnivorous birds or mammals over time. The residue decline data were evaluated with a first-order kinetic (SFO).

It was considered that the residue declines in arthropods followed a first-order kinetic. Following FOCUS kinetics (2011, p. 157), the decline curve was fitted from its observed maximum. On plot 1, the residue decline on flying insects was fitted without the outlier on DAT +21, in order to obtain a realistic fit. Before the residue data was subjected to half-life calculation, residue values before the application (DAT -3 to DAT -1) which were not < LOD were deducted from residue values.

Calculation tools: DT_{50} calculation was performed with the Bayer CropScience software KinGUI version 2 (Gao et al., 2011) as improvement of version 1 by Schäfer et al., 2007.

II. Results and Discussion

The measured residue values are presented below.

Day -1 depicts residues measured before the first application on each plot. Low day -1 residues in foliage dwelling invertebrates and flying insects in replicate 2 and 3 may be due to the application on plot 1 which was earlier than on plot 2 and 3, or the use of fluopyram on other vineyards in the area. However, these residues were very low and not considered to compromise the results of this study.

Table 8.9- 7: Residues in foliage dwelling invertebrates

Residues of fluopyram on foliage dwelling invertebrates								
Sample ID	DAT	Residues mg/kg	Sample ID	DAT	Residues mg/kg	Sample ID	DAT	Residues mg/kg
Plot 1			Plot 2			Plot 3		
IS001	-3	<LOD	IS018	-1	0.012	IS012	-3	0.014
IS004	0	3.4	IS020	0	2.2	IS013	0	1.2
IS005	1	1.9	IS021	1	3.5	IS014	1	3.4
IS006	2	1.8	IS023	2	2.9	IS015	2	1.6
IS007	3	1.0	IS024	3	2.3	IS017	3	4.5
IS008	5	1.0	IS025	5	2.6	IS019	5	2.0
IS009	7	0.53	IS027	7	1.6	IS022	7	0.63
IS010	10	0.34	IS028	10	0.97	IS026	10	0.54
IS011	15	0.58	IS030	15	0.50	IS029	15	0.42
IS016	21	0.39	IS032	21	0.28	IS031	21	0.26

Table 8.9- 8: Residues in flying insects

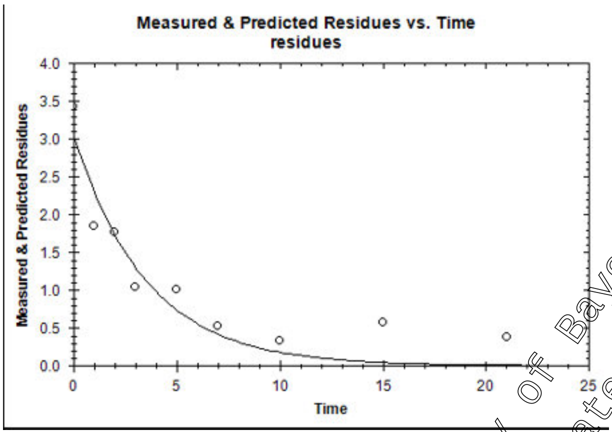
Residues of fluopyram on flying insects								
Sample ID	DAT	Residues mg/kg	Sample ID	DAT	Residues mg/kg	Sample ID	DAT	Residues mg/kg
Plot 1			Plot 2			Plot 3		
M001	-2	<LOD	M016	-1	0.010	M011	-3	0.020
M004	1	0.19	M018	1	1.2	M012	1	0.36
M005	2	0.19	M020	2	0.67	M014	2	0.58
M006	3	0.08	M021	3	0.30	M015	3	0.19
M007	5	0.13	M022	5	0.21	M017	5	0.31
M008	7	0.11	M024	7	0.22	M019	7	0.15
M009	10	0.03	M025	10	0.17	M023	10	0.02
M010	15	0.04	M027	15	0.02	M026	15	0.04
M013	21	0.22	M029	21	0.03	M028	21	0.02

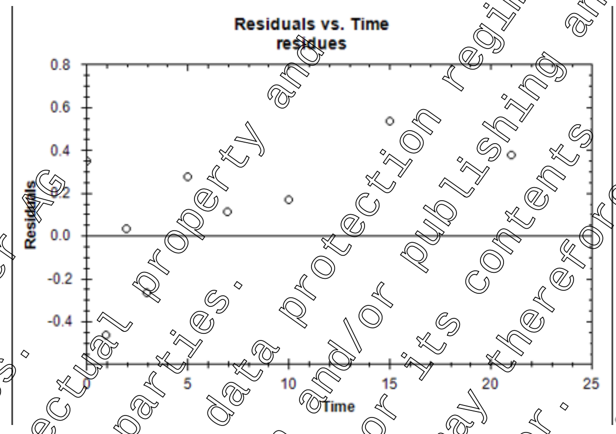
Table 8.9- 9: Kinetic evaluation of the residue decline of fluopyram on arthropods in vineyards

Fluopyram								
Replicate	**Kinetic model**	**DT_{50} (days)**	**DT_{90} (days)**	**chi² error**	**visual fit**	**t-test of k (SFO)**	**Start of decline fit**	**Excluded outliers**
Foliage dwelling invertebrates								
1	SFO	**2.43**	8.06	21.44	o	0.001	DAT0	None
2	SFO	**5.63**	18.69	10.89	+	< 0.001	DAT1	None
3	SFO	**1.66**	5.51	13.42	o	0.001	DAT3	None
Flying insects								
1	SFO	**5.55**	18.44	27.21	o	0.055	DAT2	DAT21
2	SFO	**1.27**	4.21	21.30	o	0.001	DAT1	None
3	SFO	**2.23**	7.41	41.26	o	0.030	DAT2	None

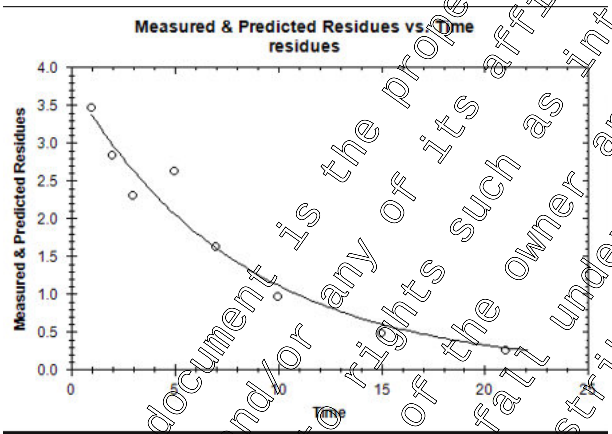
SFO = single first order (no other kinetic model employed in original report)
k = rate constant for SFO
+: good fit o: medium fit -: bad fit
(visual fit assessment not in original report, instead added here following M-544286-01-1)

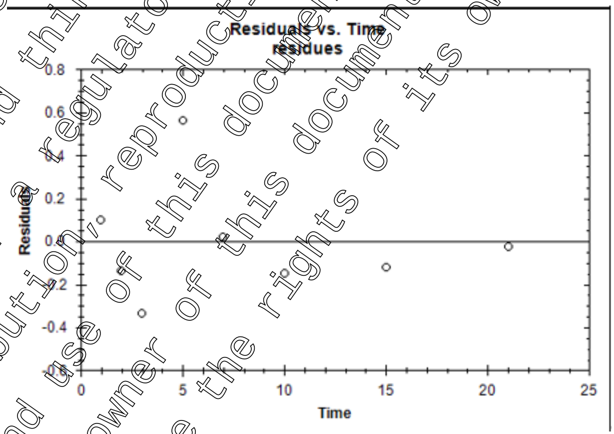
Figure 8.9- 2: Fitted SFO decline curves and corresponding residuals for fluopyram on foliage dwellers



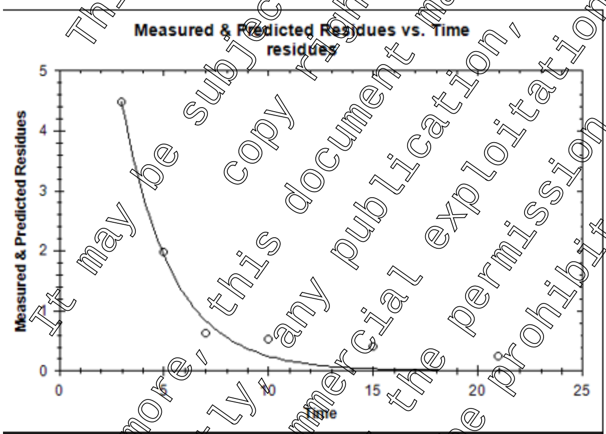


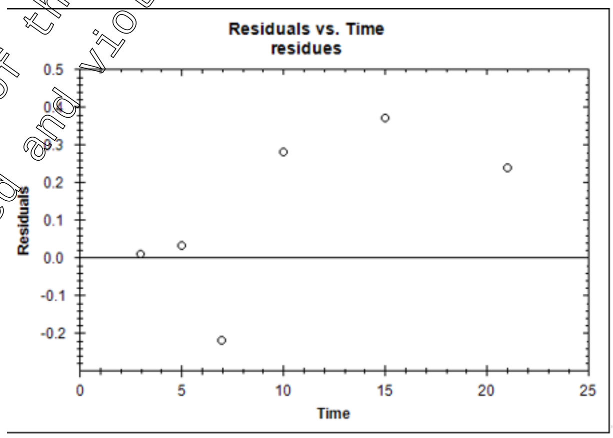
Foliage dweller on replicate 1; SFO fit borderline





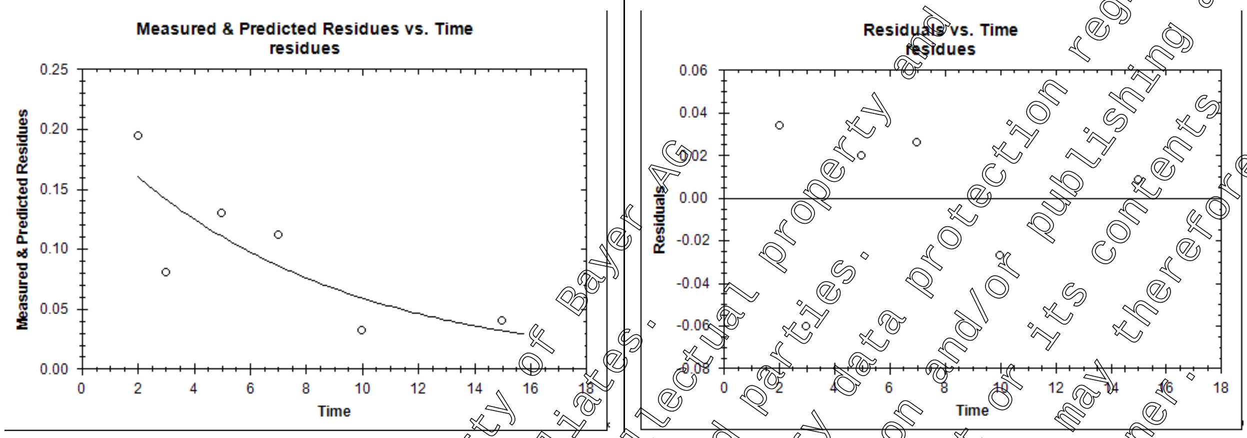
Foliage dweller on replicate 2; SFO good fit



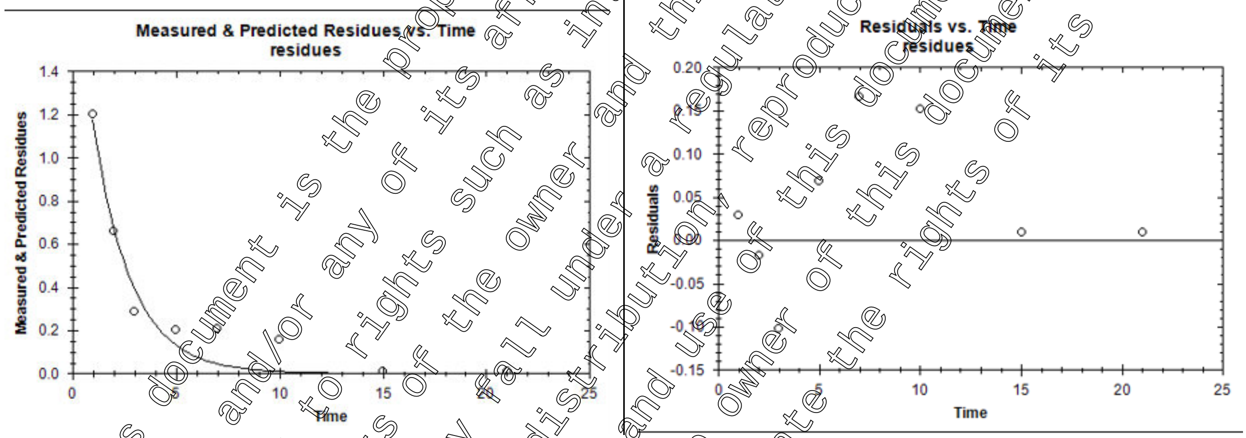


Foliage dweller on replicate 3; SFO fit borderline

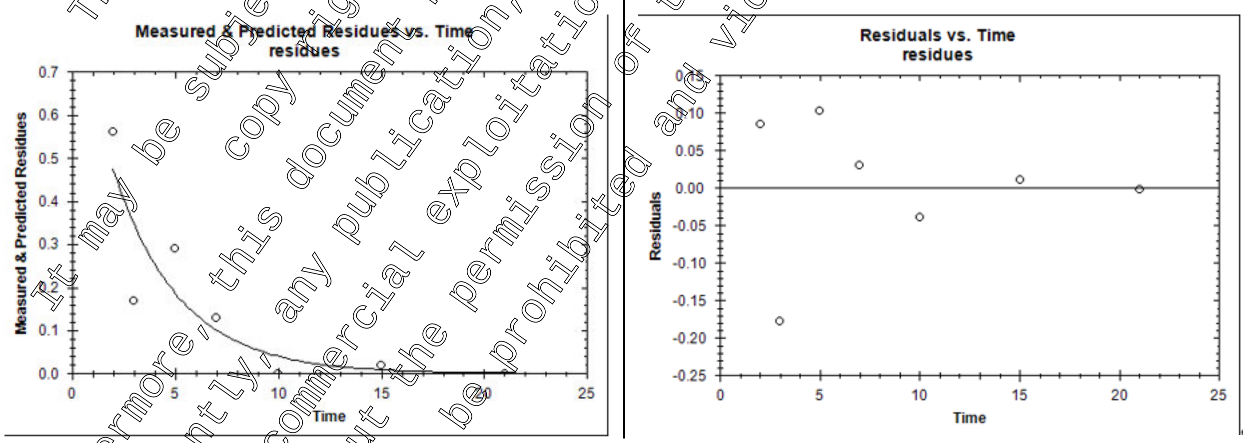
Figure 8.9- 3: Fitted SFO decline curves and corresponding residuals for fluopyram on flying insects



Flying insects on replicate 1; SFO fit acceptable



Flying insects on replicate 2; SFO fit borderline



Flying insects on replicate 3; SFO fit acceptable

Figure 8.9- 4: Proportion [%] of different arthropod groups in inventory spray samples (foliage dwellers)

*Arachnida without Opiliones and Acari, ** Hymenoptera without Formicidae

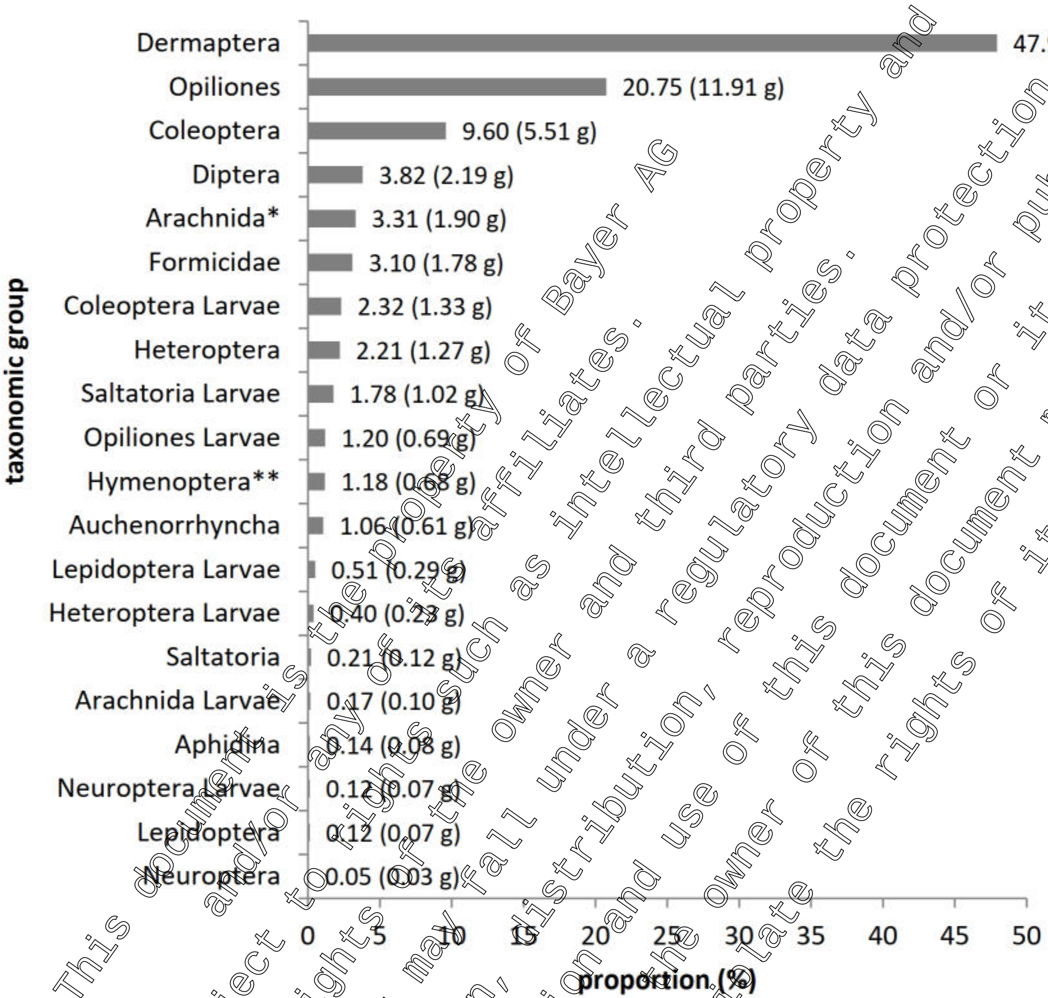
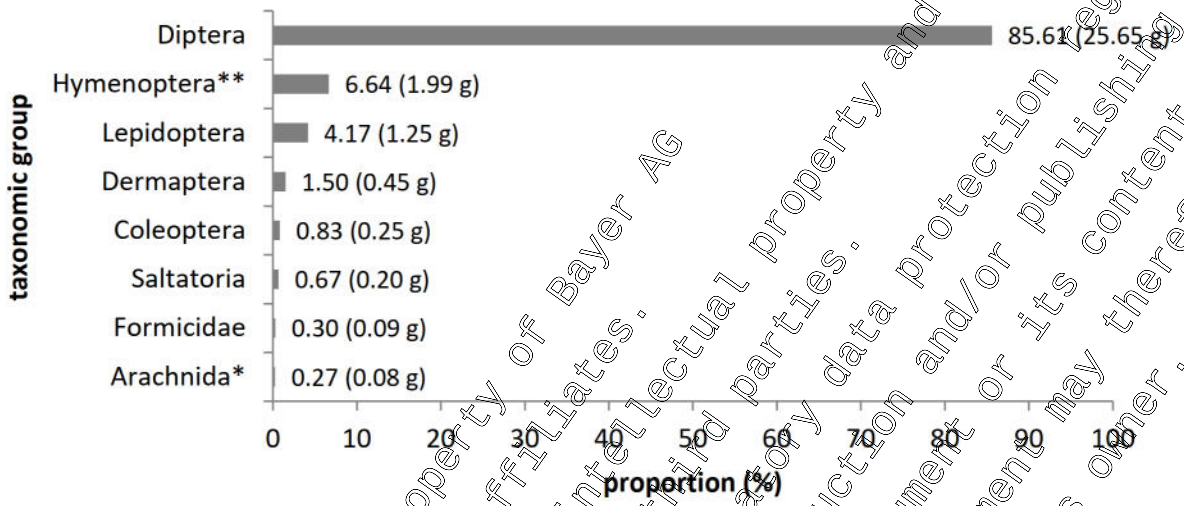


Figure 8.9- 5: Proportion [%] of different arthropod groups of the whole sample weight in Malaise samples

* Arachnida without Opiliones and Acari, ** Hymenoptera without Formicidae



Weather conditions

The rainfall at the Study Site during the study period is shown below for Plot 1 and for Plot 2 (next to plot 3). The weather was unpredictable during the study with localised thunderstorms and unreliable weather forecasts. However, it was relatively dry after the application on plot 1 with only 4 mm on DAT+3, and completely dry after application on plot 2 up to DAT+6. On plot 3, slightly more rainfall was recorded in the first days after the application with maximum 10 mm on DAT+2.

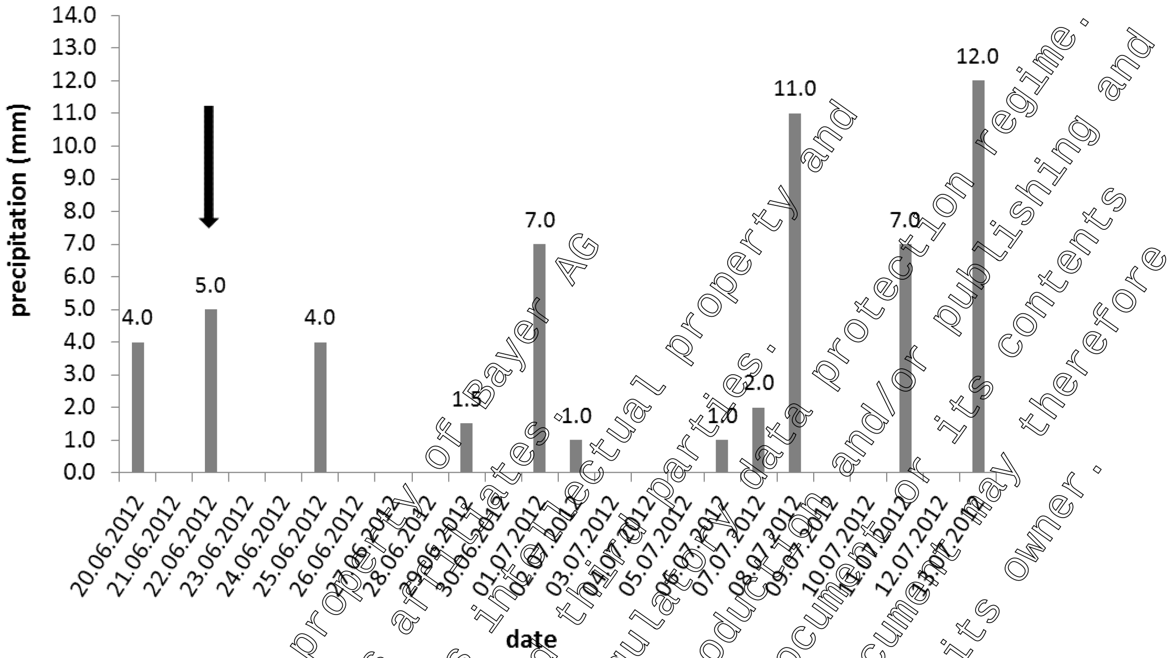


Figure 8.9- 6: Measured precipitation with a conventional rain gauge on plot 1
Arrow indicates the day of application (Rainfall recorded on this day was <u>before</u> the application)

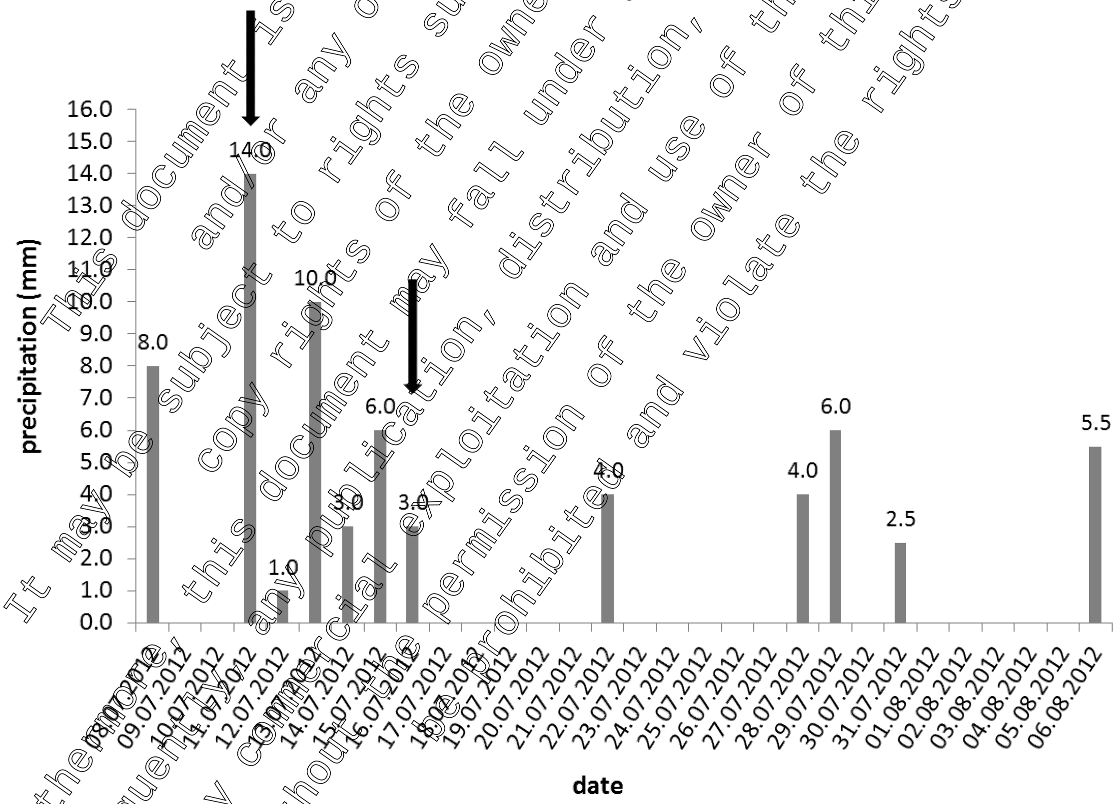


Figure 8.9- 7: Measured precipitation with a conventional rain gauge on plot 2 next to plot 3
Arrows indicate the days of application. Left arrow: application on plot 3, right arrow application on plot 2. (Rainfall recorded on these days was <u>before</u> the applications)

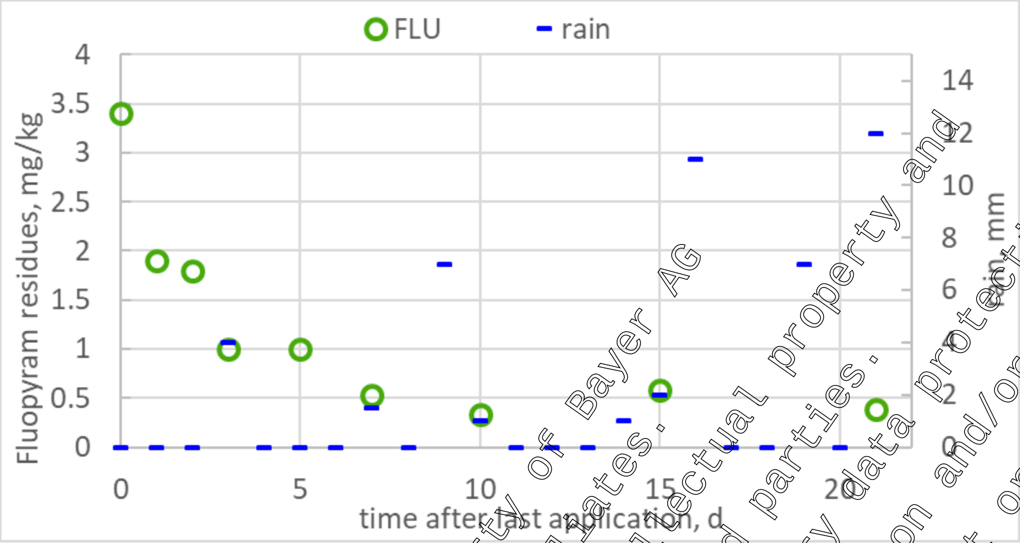


Figure 8.9- 8: Rainfall and residues for plot 1, foliage dwelling invertebrates

No discernible influence of rainfall on the residue time course

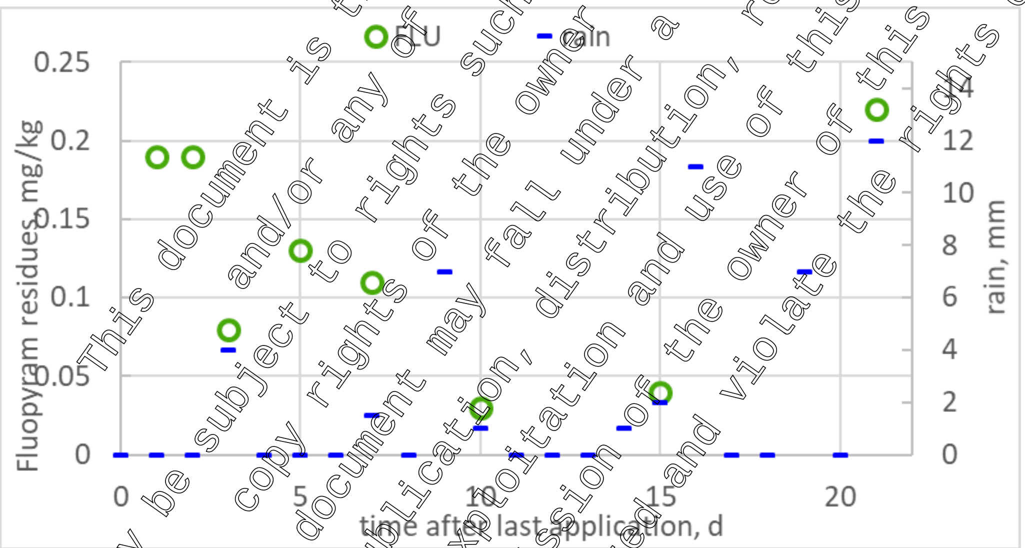


Figure 8.9- 9: Rainfall and residues for plot 1, flying insects

No discernible influence of rainfall on the residue time course

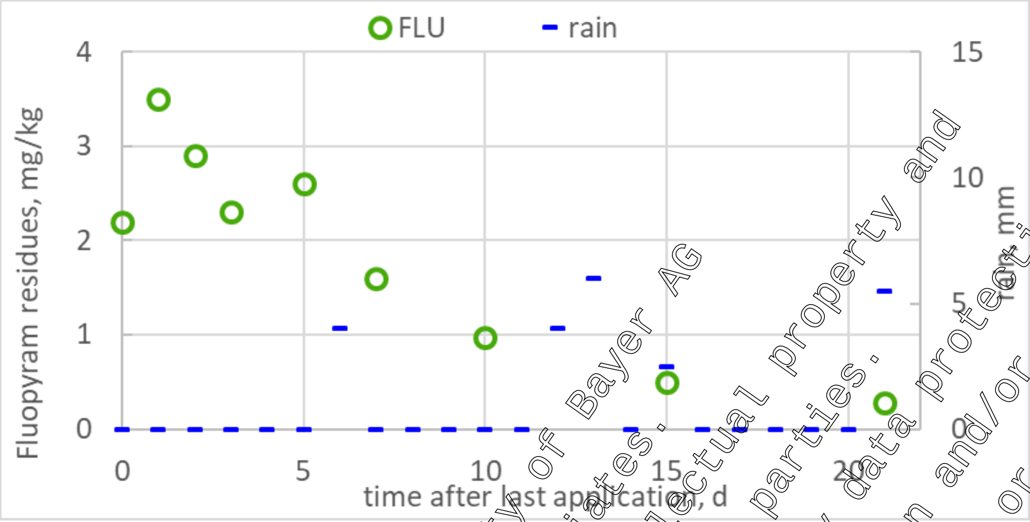


Figure 8.9- 10: Rainfall and residues for plot 2, foliage dwelling invertebrates

No discernible influence of rainfall on the residue time course

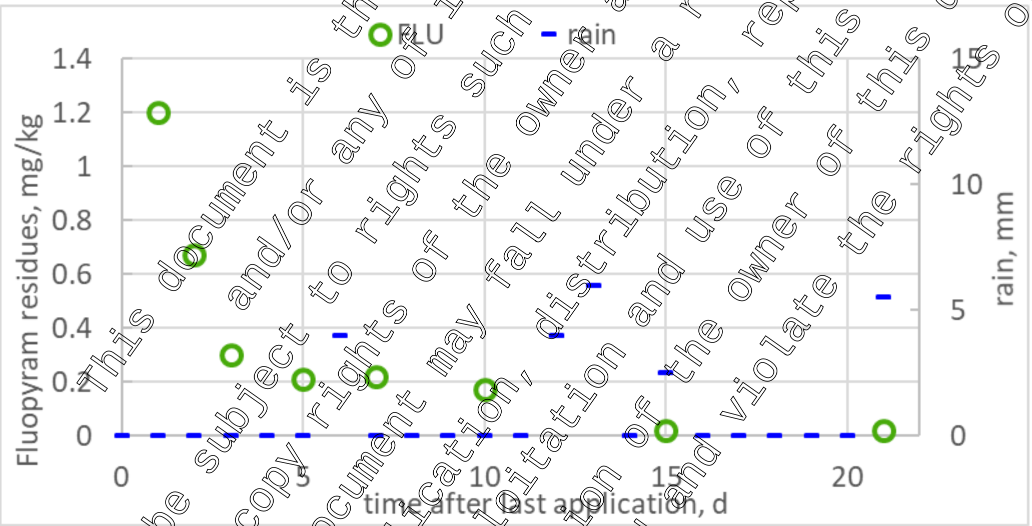


Figure 8.9- 11: Rainfall and residues for plot 2, flying insects

No discernible influence of rainfall on the residue time course

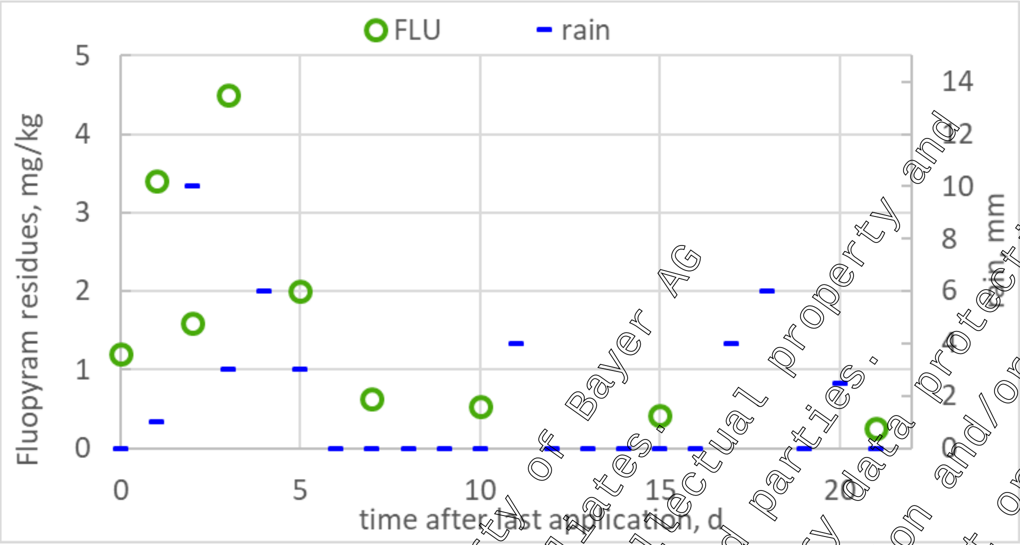


Figure 8.9- 12: Rainfall and residues for plot 3, foliage dwelling invertebrates

Frequent early rainfall without consistent correlation with the residue time course

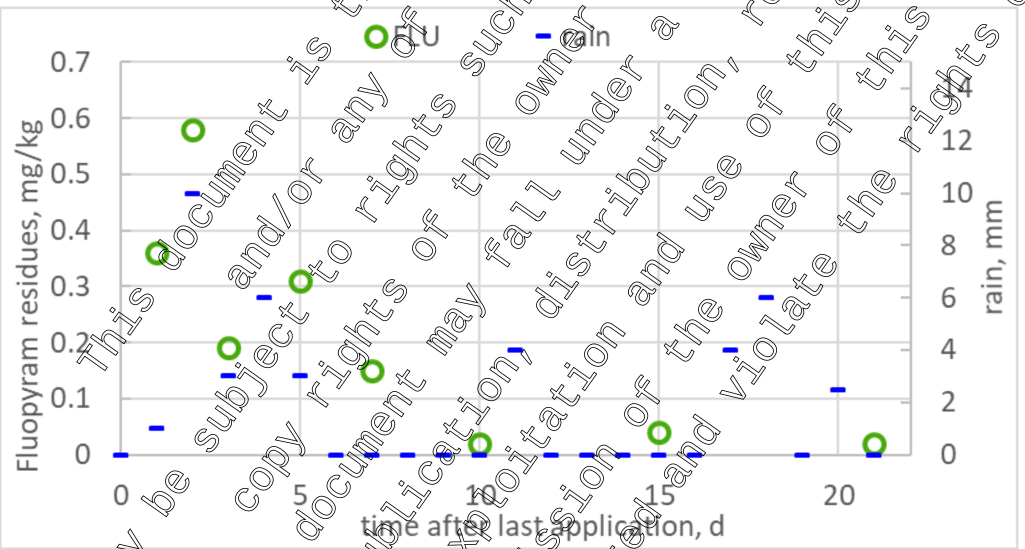


Figure 8.9- 13: Rainfall and residues for plot 3, flying insects

Frequent early rainfall without consistent correlation with the residue time course.

III. Conclusion

The study provides realistic field residue data for fluopyram on invertebrates in vineyards following an application with 250 g a.s./ha.

Fluopyram concentrations fluctuated due to interaction of different influencing factors like sample compositions over time, food web interactions and in addition mobility of the arthropod communities.

SFO DT_{50} values were calculated for residue data on foliage dwellers and arthropods caught in Malaise traps.

Acceptable fits for fluopyram provided an SFO-DT$_{50}$ of 5.63 days for foliage dwellers and of 2.23 and 5.55 days in Malaise traps.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment.

Acceptable fits for fluopyram provided an SFO-DT$_{50}$ of 5.63 days for foliage dwellers and of 2.23 and 5.55 days in Malaise traps.

Data Point:	KCA 8.9/03
Report Author:	[redacted]
Report Year:	2016
Report Title:	Kinetic evaluation of fluopyram residues in foliage dwellers and flying insects in vines - Fluopyram (AE C656948)
Report No:	EnSa-15-0934
Document No:	M-544286-01-1
Guideline(s) followed in study:	not applicable
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	yes, evaluated and accepted in the Addendum No. 4 to the DAR (rev 2017)
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

The purpose of this evaluation was the determination of the dissipation kinetics of residues of fluopyram on foliage dwelling and flying arthropods as determined under field conditions in German vineyards (M-453376-01-2).

The model fit as well as the statistical evaluation of the results were carried out with the in-house developed software KinGUI, version 2.1 which employs SFO, FOMC, DFOP and HS kinetic models. The selection of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment, χ^2 statistics, randomness of residuals, and t-test significance following the FOCUS guidance (2006, 2014).

The most appropriate models and parameters for further use in ecotoxicological risk assessments for each trial are summarised in the following table:

Table 8.9- 10: Kinetic information

	Kinetic model:					
	SFO	DT_{50}			**DT_{50} recalc.**	Residue
	FOMC	DT_{50}	DT_{90}	α / β	= DT_{90} /3.32	at end
	DFOP	DT_{50} fast	DT_{50} slow	g		< 10 %?
	HS	DT_{50} fast	DT_{50} slow	tb, in d		
		[d]	[d]		[d]	
Foliage dwelling arthropods						
Plot 1	DFOP	1.107	17.38	0.75204	6.86	no
Plot 2	SFO	5.567			5.57	yes
Plot 3	FOMC	1.402	7.86	1.7542 / 2.894	2.37	yes
Flying insects						
Plot 1	SFO	5.551			5.551	no
Plot 2	FOMC	1.018	7.849	1.1557 / 1.2393	2.36	yes
Plot 3	SFO	2.543			2.543	yes

I. MATERIAL AND METHODS

The residues of fluopyram observed in foliage dwelling arthropods and flying insects samples in vineyards are tabled below. In cases, where the maximum occurred later than the day of application, the time scale was shifted such, that the kinetic evaluation always starts at day 0.

Table 8.9- 11: Fluopyram residues in foliage dwelling arthropods and values used for kinetic evaluation

Plot 1 time after treatment [d]	residues [mg/kg]	**Plot 2** original time [d]	shifted time [d]	residues [mg/kg]	**Plot 3** original time [d]	shifted time [d]	residues [mg/kg]
0	**3.43**	0		*2.2*	0		*1.2*
1	1.85	1	0	**3.5**	1		*3.4*
2	1.77	2	1	2.9	2		*1.6*
3	1.04	3	2	2.3	3	0	**4.5**
5	1.01	5	4	2.6	5	2	2.0
7	0.528	7	6	1.6	7	4	0.63
10	0.343	10	9	0.97	10	7	0.54
15	0.579	15	14	0.50	15	12	0.42
21	0.385	21	20	0.28	21	18	0.26
Remaining of max	11.2 %			2.3%			1.3%

Table 8.9- 12: Fluopyram residues in flying insects and values used for kinetic evaluation

Plot 1 original time [d]	shifted time [d]	residues [mg/kg]	**Plot 2** original time [d]	shifted time [d]	residues [mg/kg]	**Plot 3** original time [d]	shifted time [d]	residues [mg/kg]
1		*0.190*	1	0	**1.2**	1		*0.56*
2	0	**0.194**	2	1	0.67	2	0	**0.58**
3	1	0.081	3	2	0.30	3	1	0.19
5	3	0.130	5	4	0.21	5	3	0.31
7	5	0.112	7	6	0.22	7	5	0.15
10	8	0.032	10	9	0.17	10	8	0.02
15	13	0.040	15	14	0.02	15	13	0.04
21		0.22 *	21	20	0.02	21	19	0.02
Remaining of max		20.6%			4.7%			5.9%

* considered as outlier, not used for evaluation, as in original study report

For the kinetical and statistical analysis of the experimental data the numerical software package KinGUI 2.1 (v. 2.2014) was employed. KinGUI 2 uses the statistical computing language R.

The appropriateness of a kinetic fit was primarily assessed based on the visual inspection of the fit quality. Residuals have to be small compared to the data values and should be randomly distributed around zero. Systematic variations of the residuals are a sign of the choice of an inappropriate kinetic model or the lack of sufficient data points to support an appropriate fit. However, in case of sufficiently small but systematic deviations, a fit is still qualified as visually acceptable.

The second factor for fit assessment is the χ^2 value. FOCUS kinetics suggests for soil studies conducted in the laboratory that "ideally, the error value at which the χ2-test is passed by the best-fit model … should be below 15% and the fit must be visually acceptable. However, this value should not be considered as an absolute cut-off criterion. There will be cases where the error value to pass the χ^2-test is higher, but the fit still represents a reasonable description of the degradation behaviour". For field studies it is acknowledged that "the individual data points are often scattered around the curve, which results in a large error value." Thus, a χ^2 value of up to 25% is often accepted for field studies if the visual fit is acceptable.

Finally a t-test is employed to identify the probability that a parameter is not significantly different from zero. Normally, a probability of 0.05 - 0.1 is considered as sufficiently small, but with limited data sets, may be relaxed to 0.15. It should be stressed that the t-test is more a guide to considering the assessment of curve fit, and is not in itself a reason to reject a fit.

II. RESULTS AND DISCUSSION

The results of the kinetic evaluations are presented below.

Table 8.9- 13: Dissipation parameters for fluopyram in foliage dwelling arthropods in vine

Kinetic SFO FOMC DFOP HS	model: Visual fit	χ^2 - error	DT$_{50}$ DT$_{50}$ DT$_{50}$ fast DT$_{50}$ fast	 DT$_{90}$ DT$_{50}$ slow DT$_{50}$ slow	 α / β g tb, in d	**DT$_{50}$ recalc** = DT$_{90}$ / 3.32	t-test k
		[%]	[d]	[d]		[d]	
Plot 1							
SFO	o	21.44	2.425			2.425	k: 0.001
FOMC	++	11.73	1.455	19.7	0.7487 /0.9550	5.94	
DFOP [E]	++	13.76	1.107	17.38	0.75204	6.86	k2: 0.230
HS	+	15.56	1.77	12.2	3.46	6.08	k2: 0.149
Plot 2							
SFO [E]	+	10.40	5.567			5.567	k: < 0.001
FOMC	+	11.09	5.567	18.49	7474 / 60020	5.57	
DFOP	+	11.98	5.567	na	1.0	5.567	k1: 0.037
HS	+	11.70	3.59	5.81	0.806	5.66	k2: 0.004
Plot 3							
SFO	o	13.92	1.68			1.68	k: 0.001
FOMC [E]	++	11.76	1.402	7.86	1.7542 / 2.894	2.37	
DFOP	+	9.52	1.36	171	0.925	2.09	k2: 0.487
HS	+	5.76	1.58	11.0	4.43	3.02	k2: 0.162

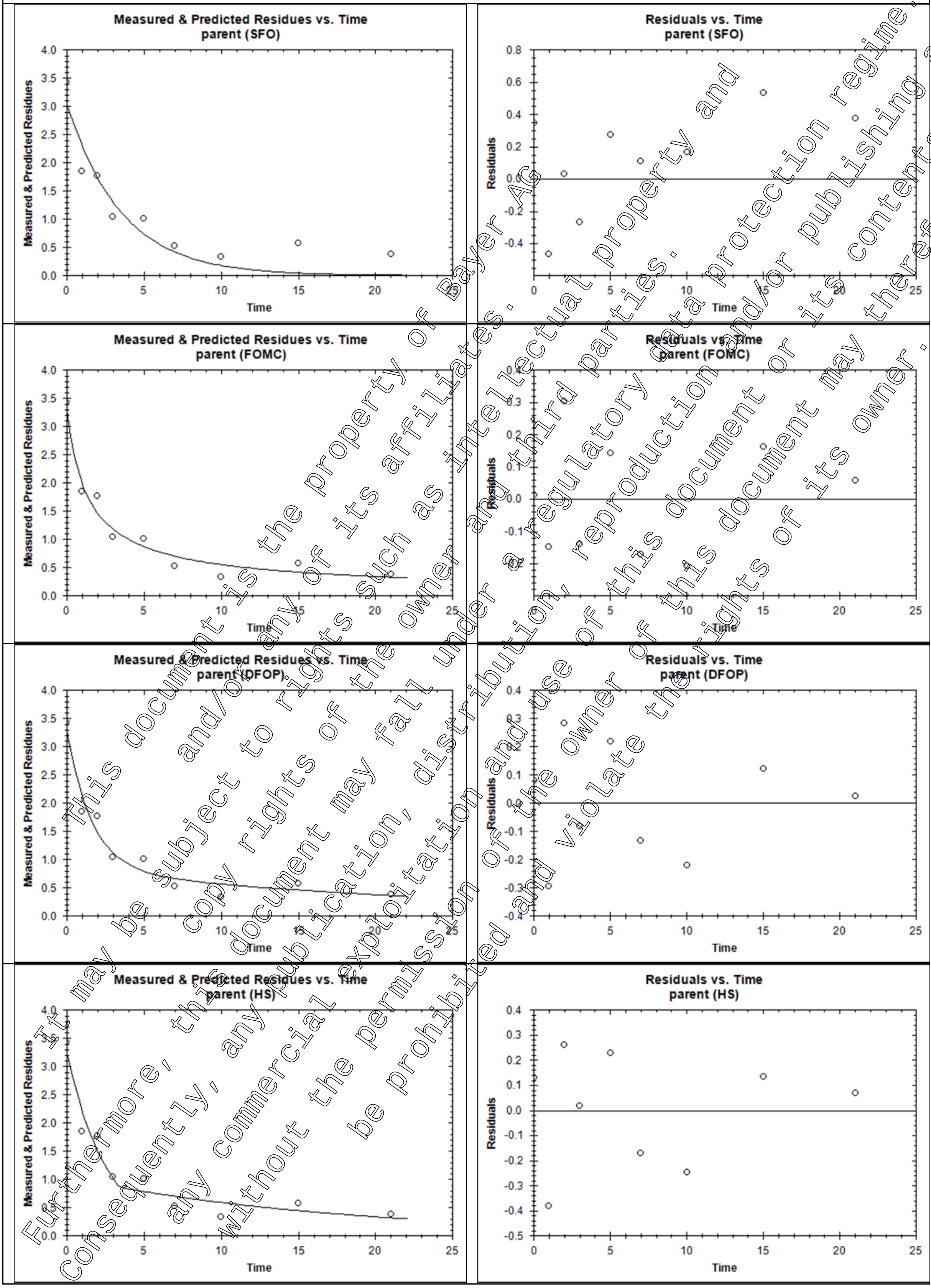
visual acceptability: ++ very good + good o medium - bad
[E] best approach for ecotoxicological purpose recommended by the authors of the kinetic evaluation

Table 8.9- 14: Dissipation parameters for fluopyram in flying insects in vine

Kinetic SFO FOMC DFOP HS	model: Visual fit	 χ^2 - error	 DT$_{50}$ DT$_{50}$ DT$_{50}$ fast DT50 fast	 DT$_{90}$ DT$_{50}$ slow DT$_{50}$ slow	 α / β g tb, in d	**DT$_{50}$ recalc** = DT$_{90}$ / 3.32	t-test k
		[%]	[d]	[d]		[d]	
Plot 1							
SFO [E]	o	27.01	5.551			5.551	k: 0.055
FOMC	-	27.78	1.74	> 1000	0.2408/0.1035	442	
DFOP	o	33.96	4.80	> 1000	0.929	> 1000	k2: 0.5
HS	o	26.73	1.27	8.74	1.0	6.97	k2: 0.263
Plot 2							
SFO	o	21.66	1.33			1.33	k: 0.001
FOMC [E]	++	13.41	1.018	7.849	1.1557/1.2393	2.36	
DFOP	++	12.13	0.692	6.59	0.739	2.75	k2: 0.114
HS	++	8.61	1.076	5.47	2.13	2.85	k2: 0.032
Plot 3							
SFO [E]	o	37.05	2.543			2.543	k: 0.030
FOMC	-	33.62	0.789	19.4	0.5591/0.3214	5.85	
DFOP	o	29.46	3.46E-04	4.78	0.491	3.38	k2: 0.115
HS	o	43.68	2.49	8.91	8.0	2.69	k2: 0.460

visual acceptability: ++ very good + good o medium - bad
[E] best approach for ecotoxicological purpose recommended by the authors of the kinetic evaluation

- 14:


Measured & Predicted Residues vs. Time
parent (SFO)
Measured & Predicted Residues
Time
Residuals vs. Time
parent (SFO)
Residuals
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Measured & Predicted Residues vs. Time
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Residuals vs. Time
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Measured & Predicted Residues vs. Time
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Measured & Predicted Residues
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Residuals vs. Time
parent (HS)
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Time

Figure 8.9- 15: Residue decline of fluopyram on foliage dwelling invertebrates (plot 2)

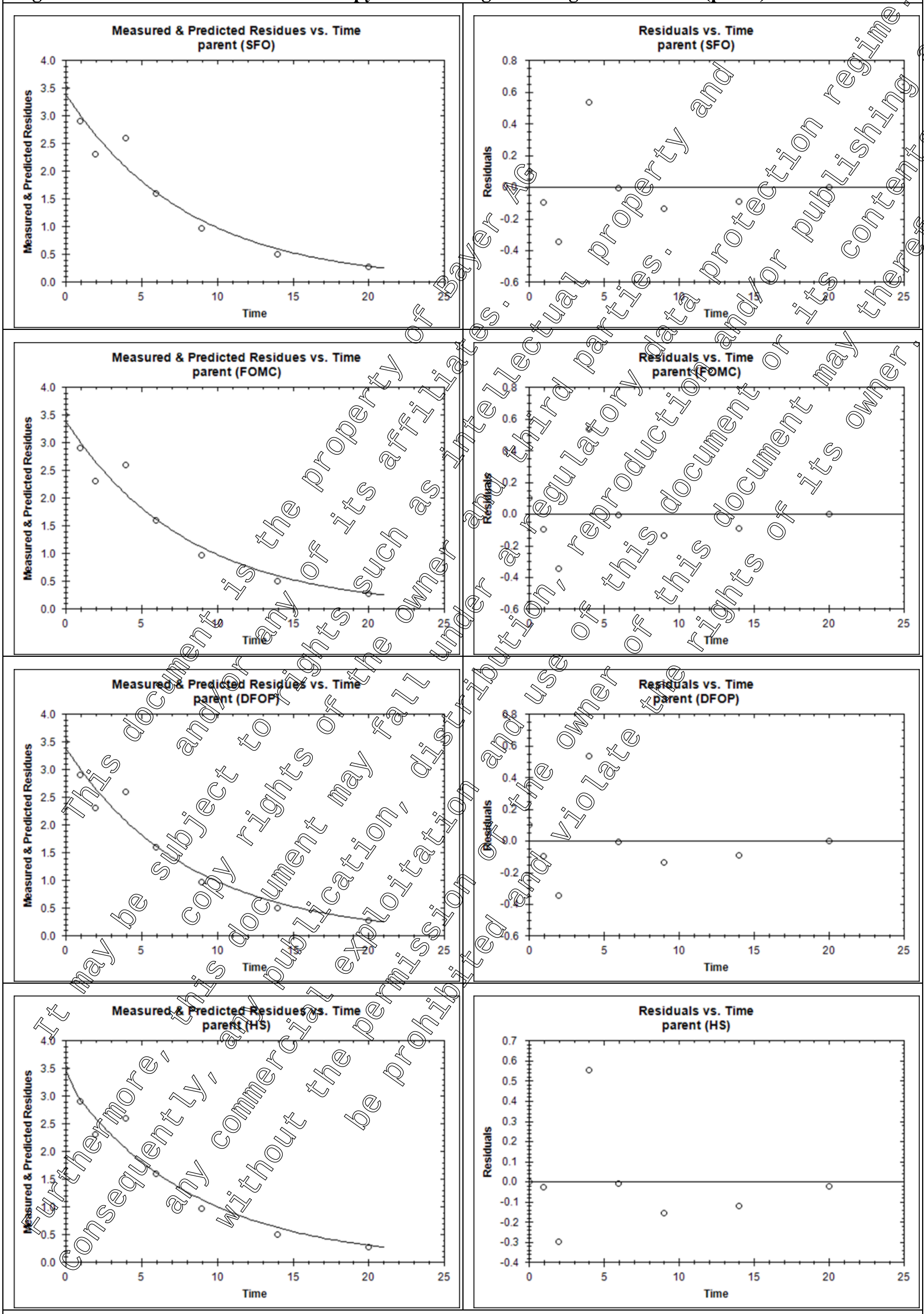


Figure 8.9- 16: Residue decline of fluopyram on foliage dwelling invertebrates (plot 3)

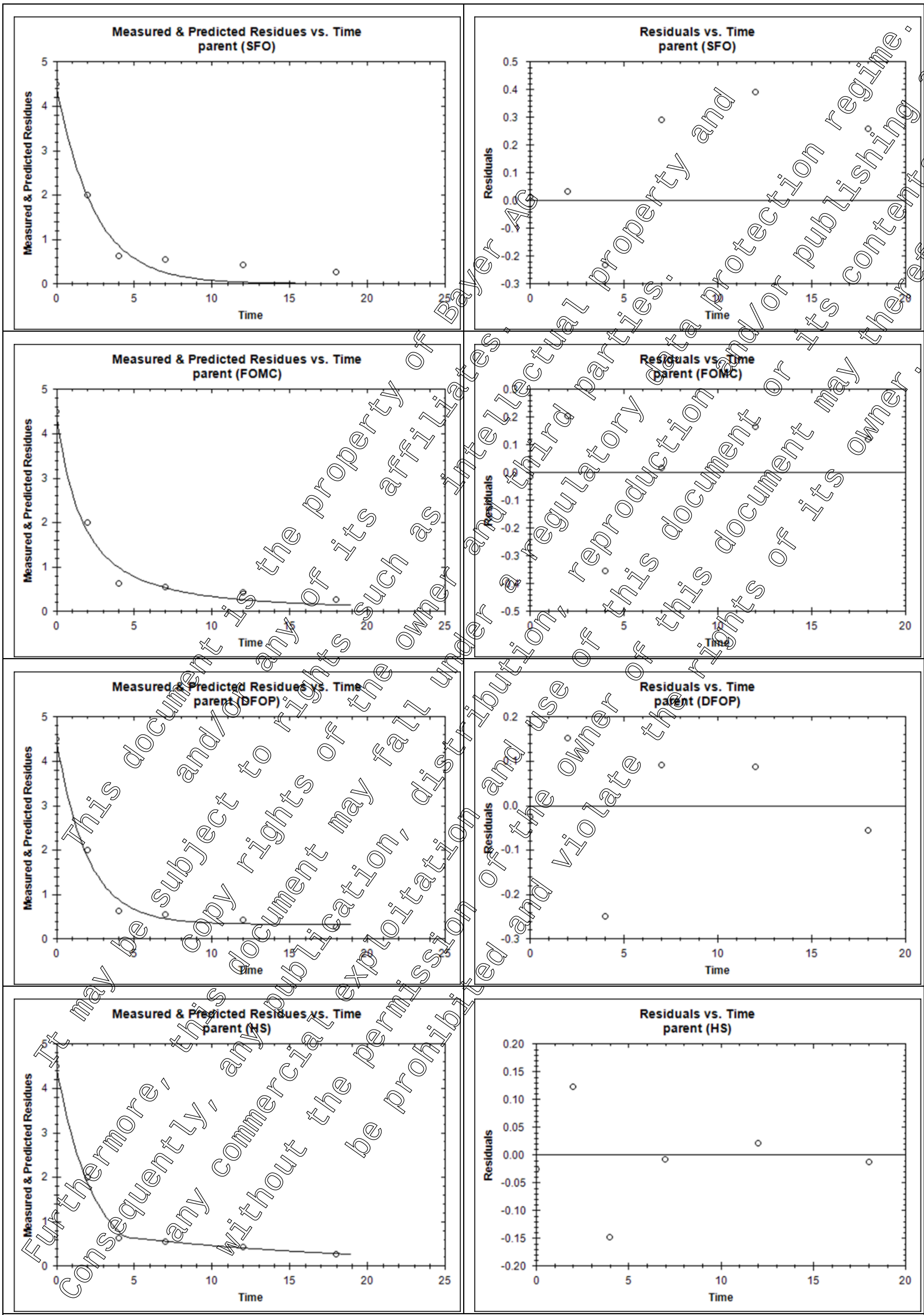


Figure 8.9- 17: Residue decline of fluopyram on flying insects (plot 1)

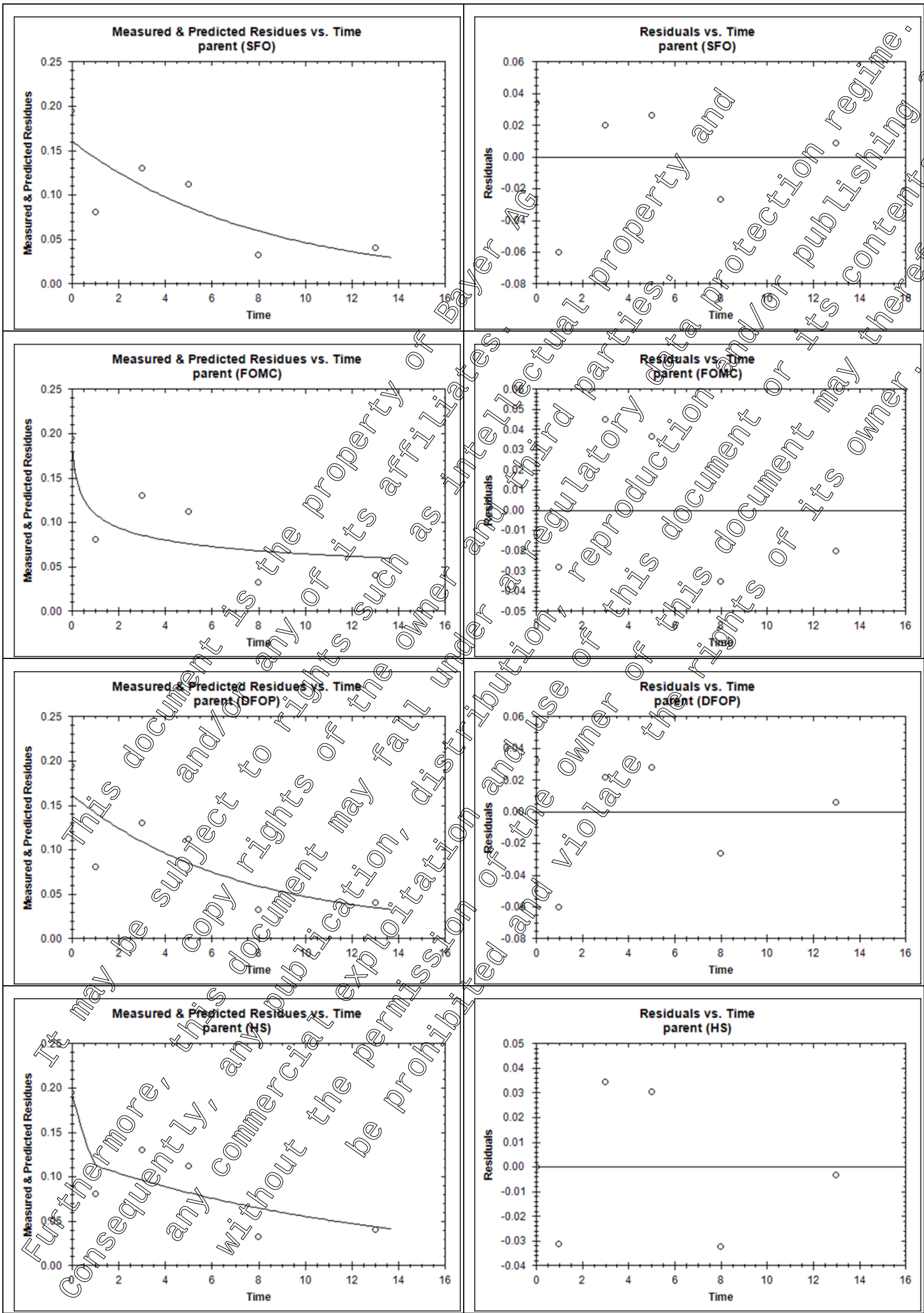


Figure 8.9- 18: Residue decline of fluopyram on flying insects (plot 2)

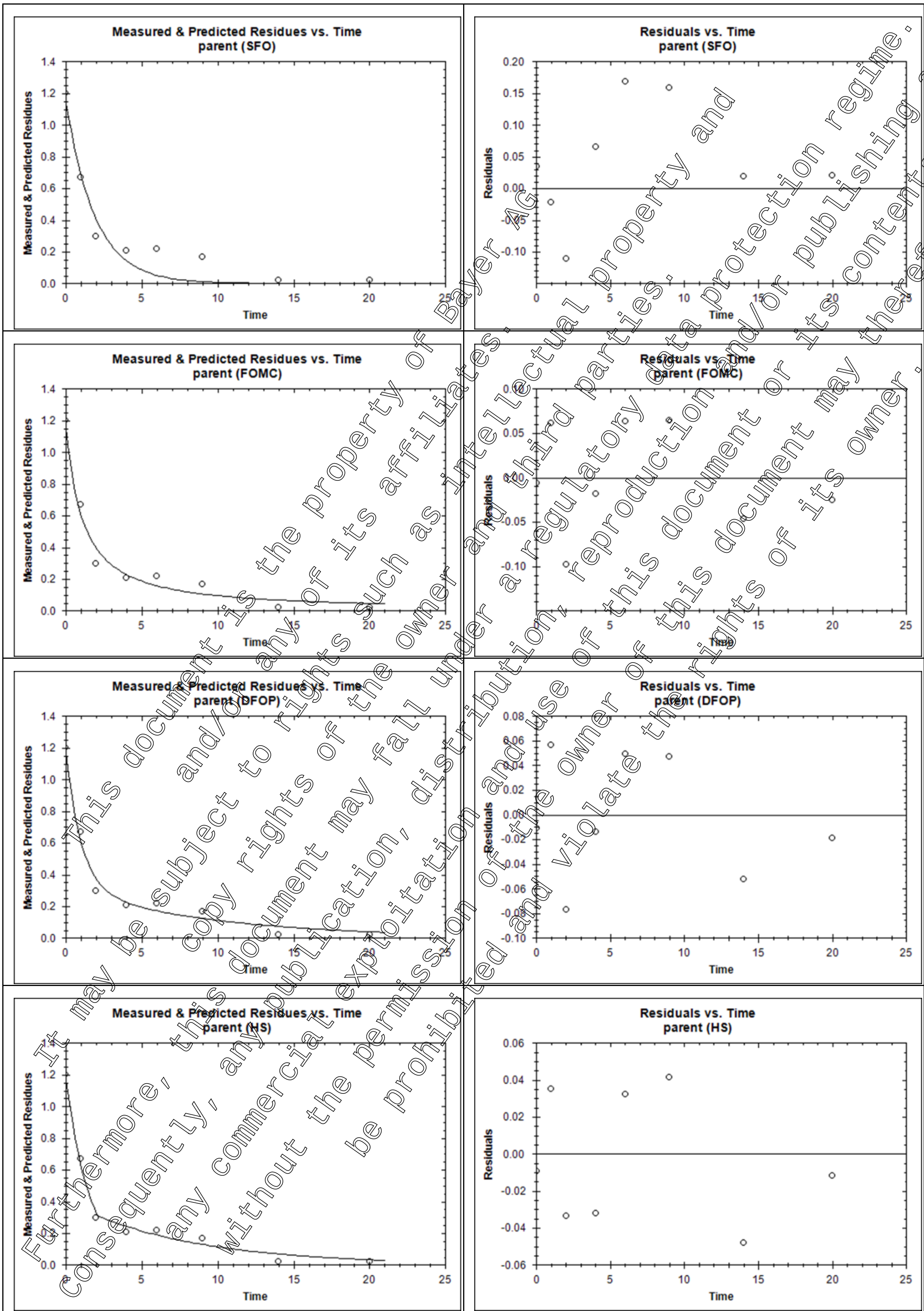
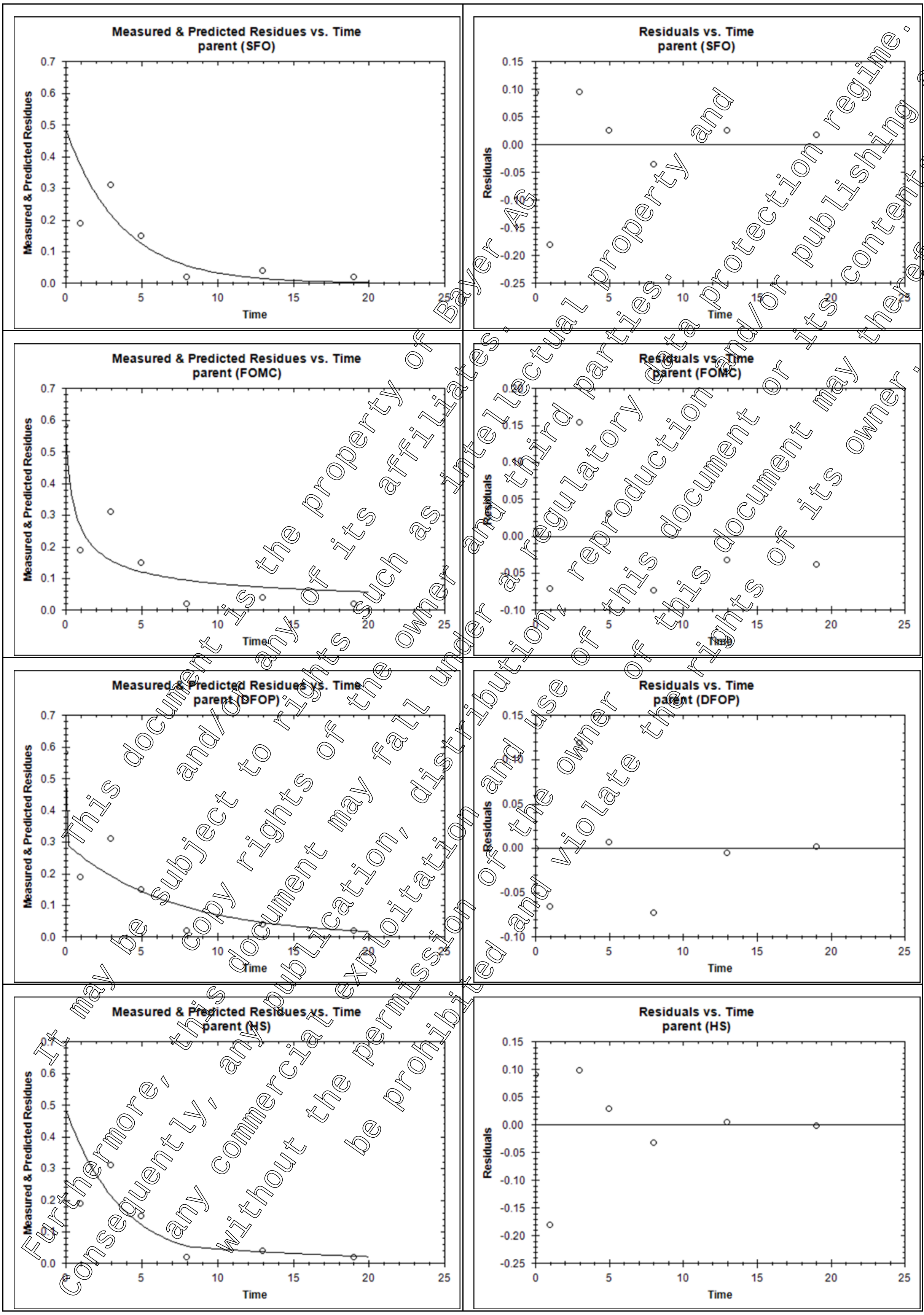


Figure 8.9- 19: Residue decline of fluopyram on flying insects (plot 3)


Measured & Predicted Residues vs. Time
parent (SFO)
Measured & Predicted Residues
Time
Residuals vs. Time
parent (SFO)
Residuals
Time
Measured & Predicted Residues vs. Time
parent (FOMC)
Measured & Predicted Residues
Time
Residuals vs. Time
parent (FOMC)
Residuals
Time
Measured & Predicted Residues vs. Time
parent (DFOP)
Measured & Predicted Residues
Time
Residuals vs. Time
parent (DFOP)
Residuals
Time
Measured & Predicted Residues vs. Time
parent (HS)
Measured & Predicted Residues
Time
Residuals vs. Time
parent (HS)
Residuals
Time

III. CONCLUSION

The study provides kinetic evaluations for the residue decline data of fluopyram on foliage dwelling invertebrates and flying insects in vineyards in Germany, complementing the original evaluation with non-SFO kinetic models (FOMC, DFOP, HS).

Recommended DT_{50}s (for non-SFO calculated as $DT_{90}/3.32$) were 6.860, 5.567 and 2.370 days for foliage dwellers and 5.551, 2.360 and 2.543 days in flying insects.

Deviating from the assessment in the original kinetic evaluation report presented above, the author of this summary would consider a different selection of the best fits in the following cases FOMC as the best fit for foliage dwellers on plot 1 (instead of DFOP): DT_{50} = 5.94 days

- HS as the best fit for flying insects on plot 2 (instead of FOMC): DT_{50} = 2.85 days
- DFOP as the best fit for flying insects on plot 3 (instead of SFO): DT_{50} = 3.38 days

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment.

Recommended DT_{50}s (for non-SFO calculated as $DT_{90}/3.32$) are 5.94, 5.57 and 3.02 days for foliage dwellers and 5.55, 2.85 and 3.38 days in flying insects

Data Point:	KCA 8.9/04
Report Author:	[redacted]
Report Year:	2015
Report Title:	Residue decline of fluopyram and prothioconazole on arthropods after spray application on oilseed rape fields in Western Germany
Report No:	R13067
Document No:	M-544190-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009, EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)
Deviations from current test guideline:	Current Guideline not applicable
Previous evaluation:	yes, evaluated and accepted in the Addendum No. 4 to the DAR (rev 2017)
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

A field study with three invertebrate residue decline trials was conducted in oilseed rape fields in Germany during the 2012 season. One application with Propulse® (SE formulation containing 125 g fluopyram + 125 g prothioconazole per L) at the application rate of 1 L product/ha. Foliage dwelling invertebrates were sampled with inventory sprays and flying insects were sampled with Malaise traps.

Only the parameters and results relevant to fluopyram have been reported within this study summary.

Fluopyram concentrations on foliage dwelling invertebrates reached very high initial levels (RUD 238) and declined then very rapidly with DT_{50} < 1 day. More typical DT_{50} values ranging 1 to 5 days were obtained when fitting started on day 1 after application, i.e. after the peculiar high residues had reached a more typical level (RUD 62).

The DT_{50} of fluopyram on flying insects was 2.1 days.

I. MATERIALS AND METHODS

Materials:

1.	Test Item:	Fluopyram & Prothioconazole SE 125 + 125 g/L
	Batch no.:	EM4L012612
	Active Ingredient:	Fluopyram, prothioconazole
	Storage:	recommended storage conditions from +2° C to +30° C
	Expiry date:	2016-02-13
2.	Sampled matrix:	Invertebrates
3.	Crop:	Oilseed rape fields (BBCH 65 at application)

METHODS

The purpose of the study was to determine the residue decline of fluopyram following an application of the formulated product Propulse® (SE formulation, containing 125 g/L fluopyram and 125 g/L prothioconazole) at a rate of nominal 1.0 L product/ha in oilseed rape fields in Germany, following the recommendations of the guidance document on risk assessment for birds & mammals on request from EFSA. EFSA Journal 2009; 7(12):1438.

Study sites: The study was conducted in the vicinity of Zuelpich, North Rhine-Westphalia in western Germany. Three plots (1.0, 1.0 and 0.73 ha) in three oilseed rape fields were selected.

Test item and application: The test item Propulse® was applied in each oilseed rape field at growth stage BBCH 65, at a nominal application rate of 1.0 L product/ha, corresponding to nominal 125 g fluopyram and 125 g prothioconazole per ha with a spray volume of 400 L tap water according to Good Laboratory Practice and Good Agricultural Practice. Deviations from the target rate were ≤ ±8%.

Arthropod sampling: Foliage dwelling arthropods were collected by inventory spraying and flying insects with Malaise traps. For inventory spraying, plants within the sample area were sprayed with a 'knock down' insecticide (Aquapy®) at approx. 30 mL product in 1 L water with a motor driven knapsack sprayer (non-GLP application). Before the insecticide application, 80 to 150 gutters (10 cm x 200 cm) with an area of approx. 32 m^2 -60 m^2 were placed on the ground between plant rows in a way that arthropods falling from the plants dropped into the gutter.

Two Malaise traps were placed per plot.

Targeted biomass per sample was ≥ 1.5 g for all sampling methods.

Sampling period was until 10 days after the application. After identification and quantification of the main taxonomic groups, the samples were stored deep frozen until residue analysis.

Residue analysis: All samples were analysed for their content of fluopyram, prothioconazole and the metabolite JAU 6476-desthio via HPLC-MS/MS. Residues are reported in terms of mg active substance/kg fresh weight (mg a.s./kg fw). The Limit of quantification (LOQ) value was 0.01 mg/kg, the limit of detection (LOD) was 0.001 mg/kg.

Full details and acceptable validation data to support the analytical method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

Data evaluation:

The residue decline (DT_{50}) of the active substance in arthropods was calculated to quantify the time course of the residue concentration in potential food items of insectivorous and omnivorous birds or mammals over time. The residue decline data were evaluated with a first-order kinetic (SFO).

It was considered that the residue declines in arthropods followed a first-order kinetic. Maximum residue concentrations occurred directly after application (DAT 0 for foliage dweller, DAT +1 for flying insects) for all compounds. The biomass of flying insects was insufficient for analysis and samples had to be pooled over the 3 plots.

Calculation tools: DT_{50} calculation was performed with the Bayer CropScience software KinGUI version 2.1 (Heinemann 2012, Meyer & Witt, 2014).

II. RESULTS AND DISCUSSION

The measured residue values are presented below. For fluopyram, the initial residues on foliage dwelling invertebrates were much higher than predicted with the RUDs, i.e. when normalized with the application rate in kg a.s./ha: the average maximum residue concentrations of fluopyram of 29.80 mg/kg would correspond with a RUD = (1000/125) x 29.8 = 238. However, these high initial concentrations also decreased extremely fast. Presumably, this can be explained by a high proportion of small beetles (mainly pollen beetles *Meligethes aeneus*) dominating the foliage dwelling invertebrate samples. These small beetles may have received a full overspray and thus presented high initial surface residues, which were then also rapidly lost (DT_{50} < 1 day). The mean measured residues of fluopyram after 1 day had declined to 7.72 mg/kg (RUD = 62). In the original report, the DT_{50} for foliage dweller was therefore additionally calculated with only the decline following day 1, in order to exclude the particular influence of these extremely high and extremely rapidly declining initial residues.

Table 8.9- 15: Residues in foliage dwelling arthropods and flying insects

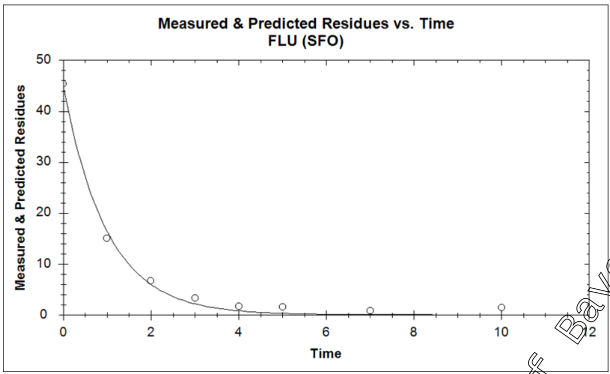
DAT	Residues of fluopyram [mg a.s./kg f.w.]					
	Foliage dwelling arthropods					Flying insects
	Replicate 1	Replicate 2	Replicate 3	Mean	SD	Replicate 1-3
-1	<LOD	<LOD	<LOD	-	-	0.03*
0	**45.40**	**29.19**	**14.81**	**29.80**	15.30	-**
+1	15.11	4.67	3.37	7.72	6.44	0.91
+2	6.72	3.11	4.02	4.62	1.88	0.57
+3	3.26	2.62	3.02	2.97	0.32	0.29
+4	1.70	4.15	-	2.92	1.74	0.46
+5	1.57	2.70	1.08	1.78	0.83	0.14
+7	0.82	1.40	0.83	1.02	0.33	0.26
+10	1.44	1.15	0.29	0.96	0.60	0.07

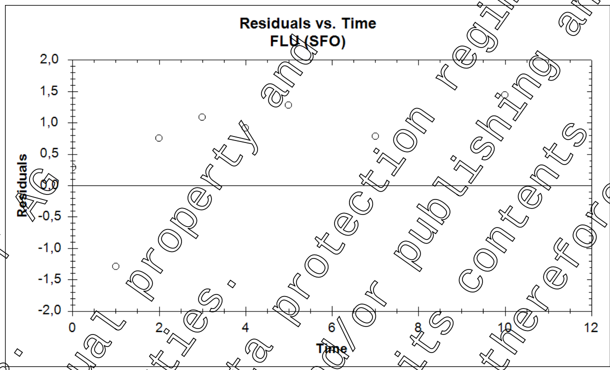
*contamination of pre-application sample probably due to insects flying in from nearby fields treated with fluopyram-containing products
**no sampling

Table 8.9- 16: Kinetic information

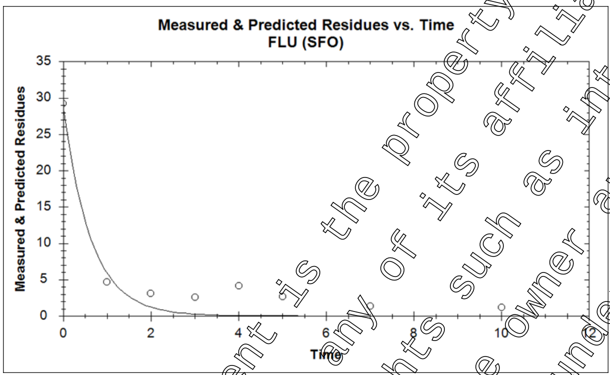
Fluopyram								
Replicate	**Kinetic model**	**DT_{50} (days)**	**DT_{90} (days)**	**chi² error**	**visual fit**	**t-test of k (SFO)**	**Start of decline fit**	**Excluded outliers**
Foliage dwelling invertebrates								
1	SFO	**0.68**	2.275	8.735	+	< 0.01	DAT0	None
2	SFO	**0.44**	1.445	28.43	-	< 0.01	DAT0	None
3	SFO	**0.79**	2.612	29.50	-	< 0.01	DAT0	None
Flying insects								
1-3	SFO	**2.13**	7.077	21.61	o	< 0.01	DAT1	None
SFO = single first order (no other kinetic model employed in original report) k = rate constant for SFO +: good fit o: medium fit -: bad fit (visual fit assessment not in original report, instead added here following M-545077-01-1								

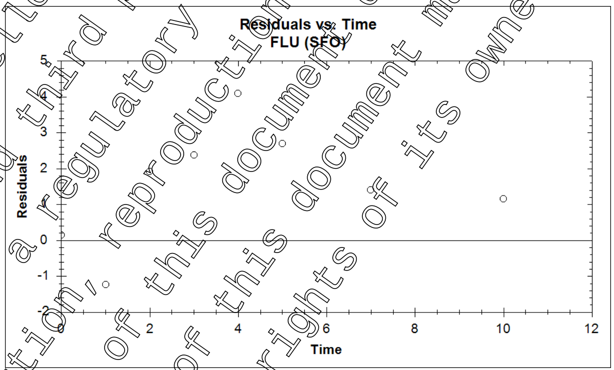
Figure 8.9- 20: Fitted SFO decline curves and corresponding residuals for fluopyram on foliage dwellers



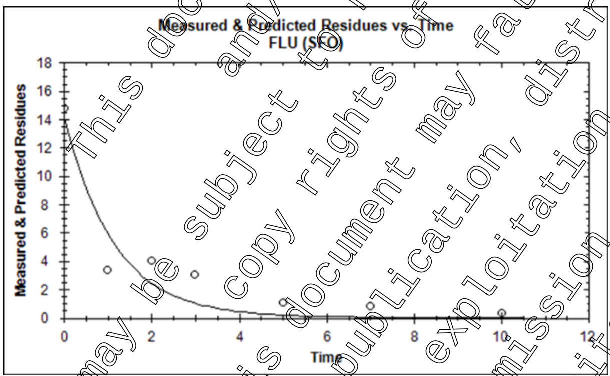


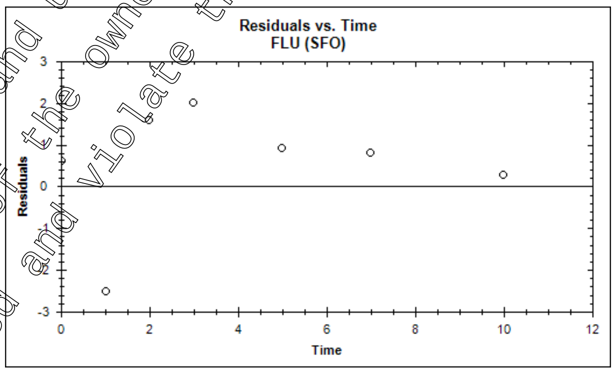
Foliage dweller on replicate 1; SFO fit acceptable (systematic deviations but very small)





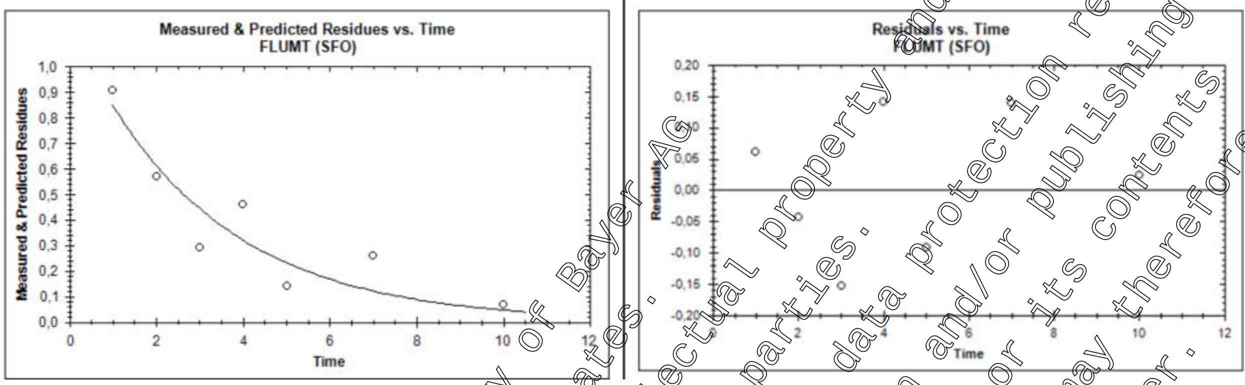
Foliage dweller on replicate 2; SFO fit not acceptable (systematic deviations of considerable magnitude)





Foliage dweller on replicate 3; SFO fit not acceptable (systematic deviations of considerable magnitude)

Figure 8.9- 21: Fitted SFO decline curves and corresponding residuals for flying insects



Fluopyram, replicates combined; SFO fit acceptable (deviations of considerable magnitude but not systematic)

Alternative DT_{50} evaluation for fluopyram (without DAT0)

The similarity in decline curves for fluopyram foliage dwelling invertebrates resulted in similar half-lives with SFO-DT_{50}s less than one day for foliage dwellers on all 3 plots. This was considered as untypical for fluopyram and not seen in the flying insects which usually present similar or shorter DT_{50}s than foliage dweller.

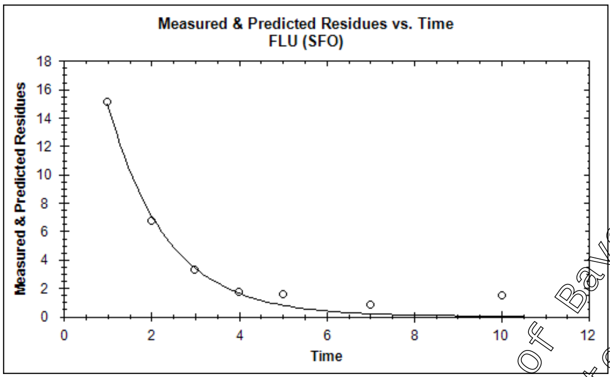
If the decline curve for fluopyram is fitted from DAT 1 onwards instead of DAT 0, more typical SFO-DT_{50} values between 1 and 5 days are calculated. Fits are visually acceptable (non-systematic scatter), and chi^2-errors in acceptable ranges for field studies.

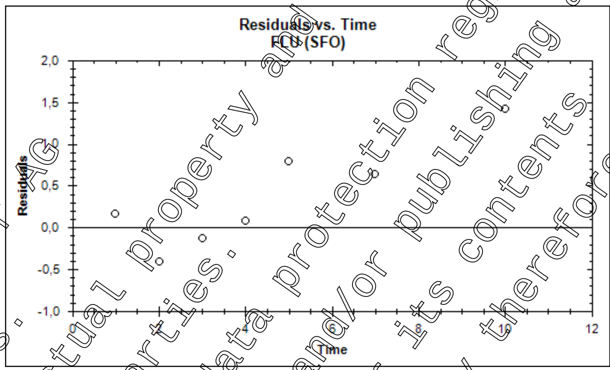
Table 8.9-17: Kinetic information

Fluopyram								
Replicate	Kinetic model	DT_{50} (days)	DT_{90} (days)	chi^2 error	visual fit	t-test of k (SFO)	Start of decline fit	Excluded outliers
Foliage dwelling invertebrates								
1	SFO	**0.935**	3.107	12.46	o	< 0.01	DAT1	DAT0
2	SFO	**4.977**	16.53	18.25	o	< 0.01	DAT1	DAT0
3	SFO	**2.955**	9.815	20.07	o	< 0.01	DAT1	DAT0

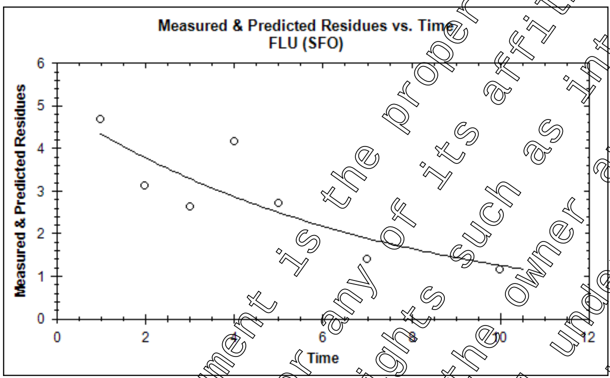
SFO = single first order (no other kinetic model employed in original report)
k = rate constant for SFO
+: good fit o: medium fit -: bad fit
(visual fit assessment not in original report, instead added here as the view by the author of this summary)

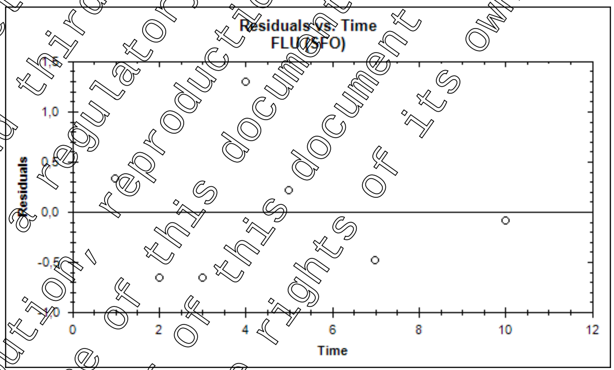
Figure 8.9- 22: Fitted SFO decline curves and corresponding residuals for fluopyram on foliage dwellers (fitted from DAT1)



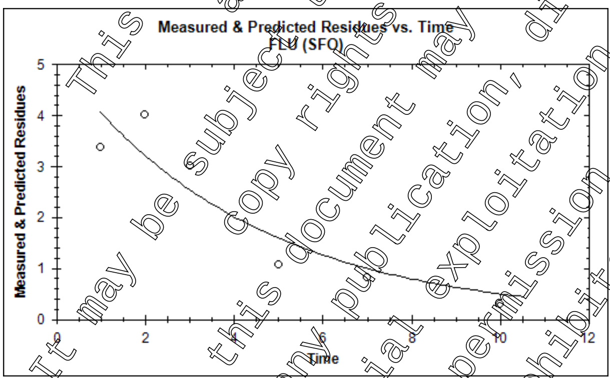


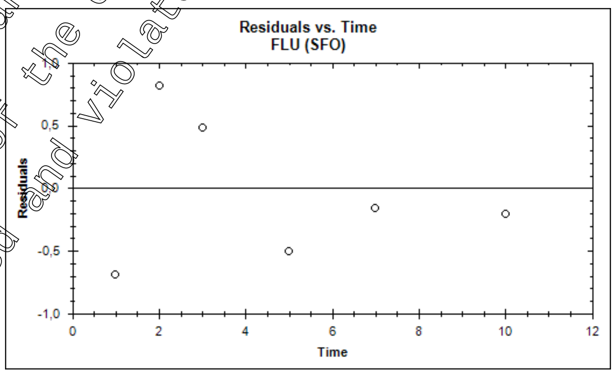
Foliage dweller on replicate 1; SFO fit acceptable (systematic deviations but small)





Foliage dweller on replicate 2; SFO fit acceptable (deviations of considerable magnitude but non-systematic)





Foliage dweller on replicate 3; SFO fit acceptable (deviations of considerable magnitude but non-systematic)

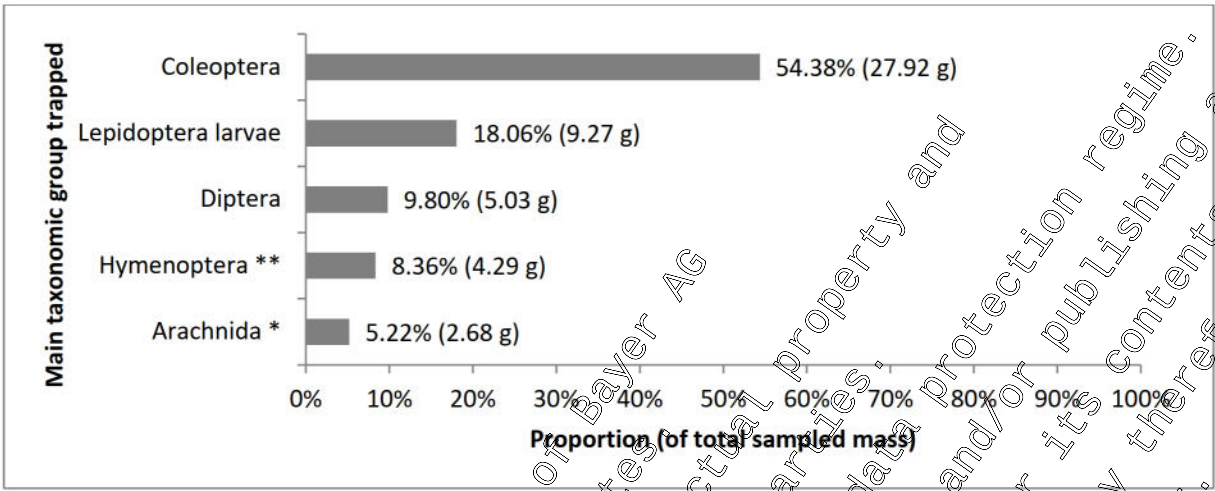


Figure 8.9- 23: Proportion of sampled mass for main foliage-dwelling arthropod groups

* without Opiliones and Acari, ** without Formicidae

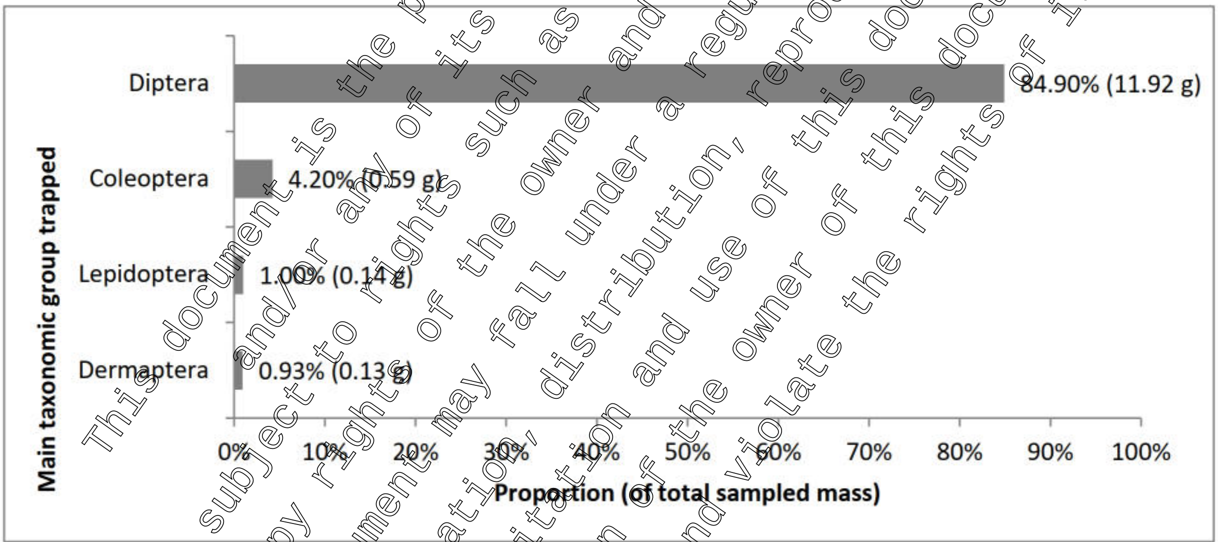


Figure 8.9- 24: Proportion of sampled mass for main arthropod groups trapped in Malaise traps

Within inventory samples most dominant taxonomic groups (54.4 %) were Coleoptera (predominately *Meligethes aeneus*), followed by Lepidoptera larvae (18.1 %) and Diptera (9.8 %). Most dominant taxonomic groups in Malaise traps were Diptera (84.9 %).

Weather conditions

The weather conditions during the field phase were predominantly dry. During the whole field phase only four days were recorded with slight rainfall, with the maximum of 4.5 mm on 21 April 2014. During the field phase from the 09 April until 26 April 2014 in total 11.2 mm rainfall was measured. This amount of precipitation indicates an arid April in 2014 compared to the long-term precipitation recordings for the study region.

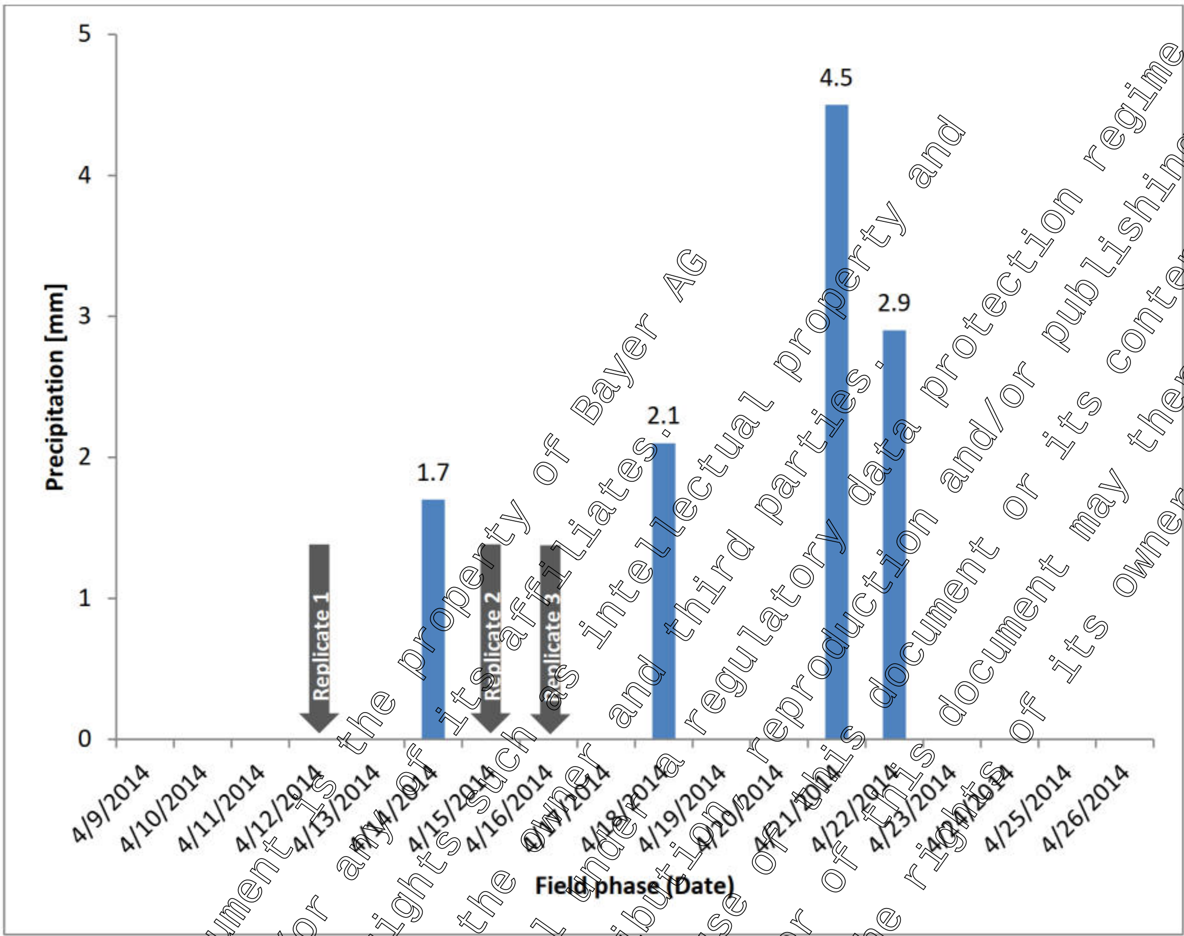


Figure 8.9- 25: Measured precipitation with a conventional rain gauge (arrows indicate the days of application)

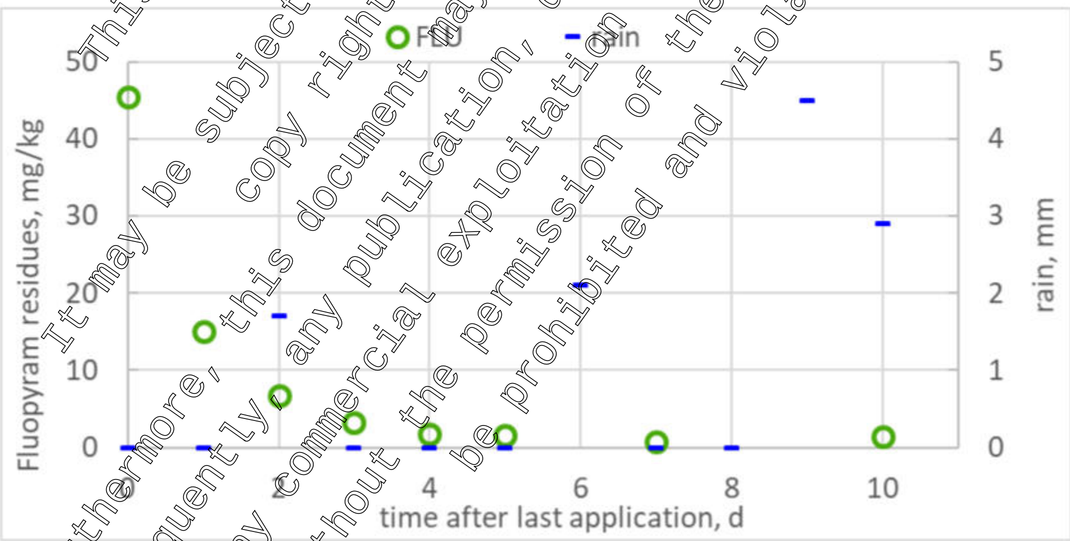


Figure 8.9- 26: Rainfall and residues for plot 1, foliage dwelling arthropods

No discernible influence of rainfall on the residue time course

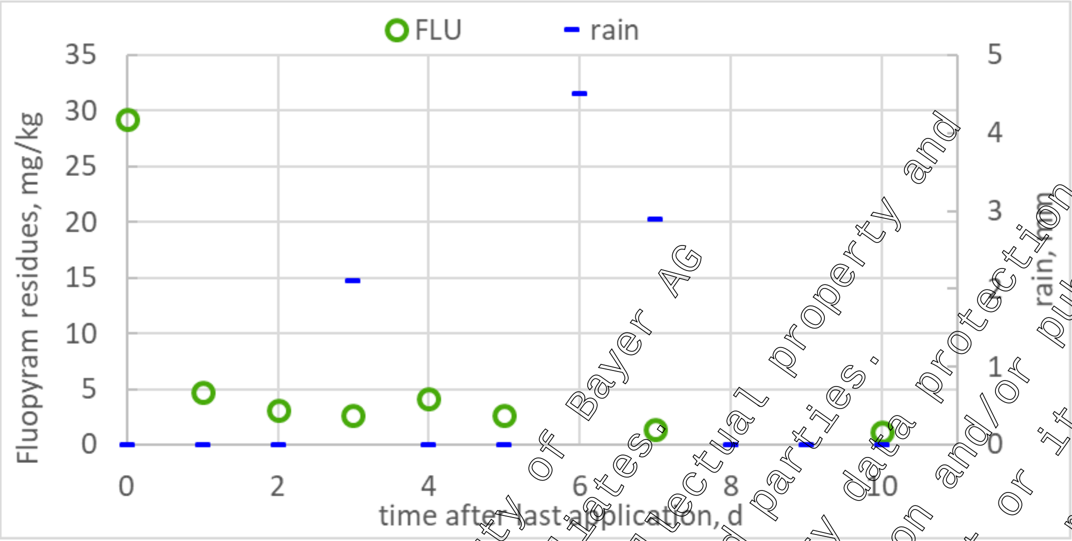


Figure 8.9- 27:Rainfall and residues for plot 2, foliage dwelling arthropods

No discernible influence of rainfall on the residue time course

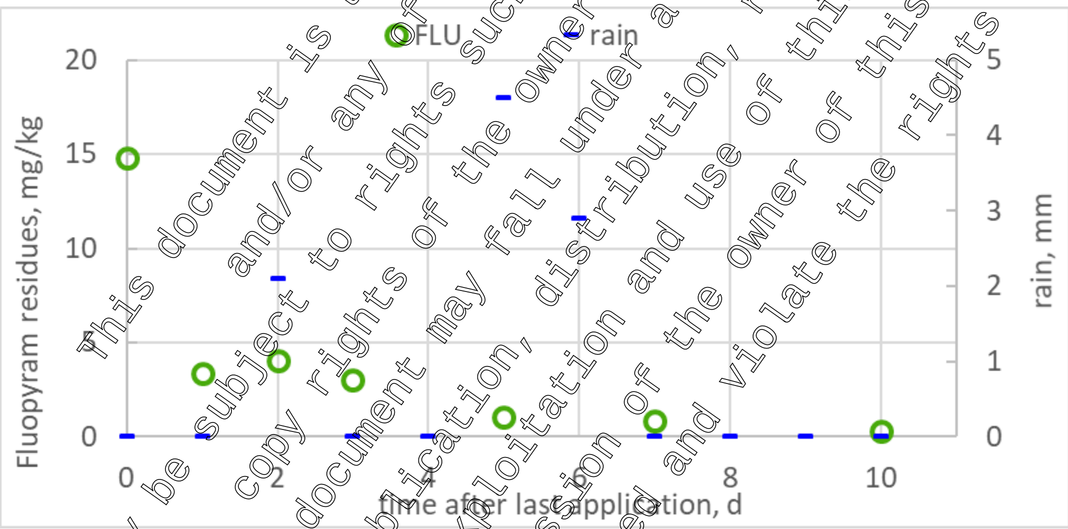


Figure 8.9- 28:Rainfall and residues for plot 3, foliage dwelling arthropods

No discernible influence of rainfall on the residue time course

Mean daily temperature fluctuated between 7.5°C and 16.0°C (mean 11.5°C). The mean temperature was similar to the long-term weather data (1981-2010) as given for the meteorological station Bonn-Roleber (36 km to study fields).

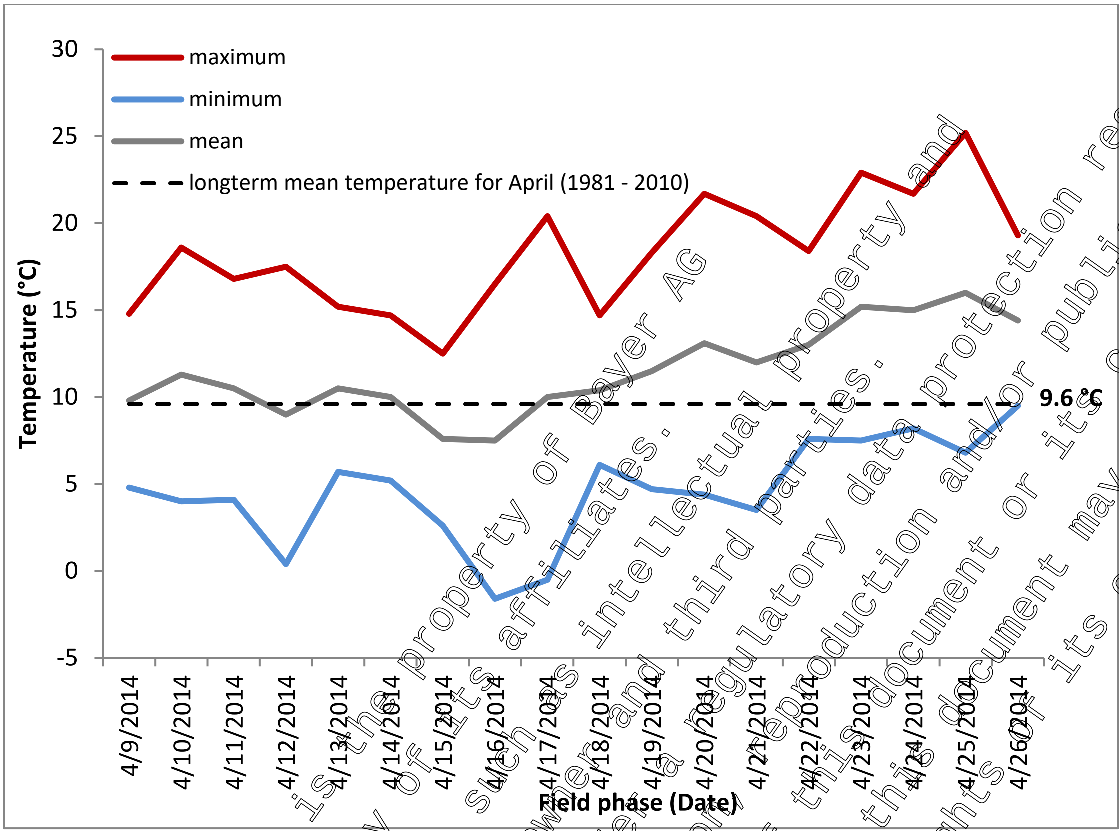


Figure 8.9- 29:Recorded daily temperatures during field phase

III. Conclusion

The study provides field residue data on invertebrates in oilseed rape fields following an application of fluopyram and prothioconazole at 125 g a.s./ha each.

SFO DT_{50} values were calculated for residue data on foliage dwellers (inventory spray sampling) and on flying insects caught in Malaise traps.

Fluopyram concentrations on foliage dwelling invertebrates reached very high initial levels (RUD 238) and declined then very rapidly with $DT_{50} < 1$ day. More typical DT_{50} values ranging from 1 to 5 days were obtained when fitting started on day 1 after application, i.e. after the peculiar high residues had reached a more typical level (RUD 62).

The DT_{50} of fluopyram on flying insects was 2.1 days.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment.

SFO DT_{50} values were calculated for residue data on foliage dwellers (inventory spray sampling) and on flying insects caught in Malaise traps.

The DT_{50} of fluopyram on flying insects was 2.1 days.

Data Point:	KCA 8.9/05
Report Author:	[redacted]
Report Year:	2016
Report Title:	Kinetic evaluation of fluopyram residues in foliage dwellers and flying insects in oilseed rape
Report No:	EnSa-16-0035
Document No:	M-545077-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	yes, evaluated and accepted in the Addendum No. 4 to the DAR (rev 2017)
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

The purpose of this evaluation was the determination of the dissipation kinetics of residues of fluopyram on foliage dwelling and flying arthropods as determined under field conditions in German oilseed rape fields (M-544190-01-1).

The model fit as well as the statistical evaluation of the results were carried out with the in-house developed software KinGUI, version 2.1 which employs SFO, FOMC, DFOP and HS kinetic models. The selection of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment, χ^2 statistics, randomness of residuals, and t-test significance following the FOCUS guidance (2006, 2014).

The most appropriate models and parameters for further use in ecotoxicological risk assessments for each trial are summarised in the following table:

Table 8.9- 18: Kinetic information

	Kinetic model:					
	SFO	DT_{50}			**DT_{50} recalc.**	Residue
	FOMC	DT_{50}	DT_{90}	α / β	= DT_{90} /3.32	at end
	DFOP	DT_{50} fast	DT_{50} slow	g		< 10 %?
	HS	DT_{50} fast	DT_{50} slow	tb, in d		
		[d]	[d]		[d]	
Foliage dwelling arthropods						
Plot 1	SFO	0.685			0.685	yes
Plot 2	HS	0.378	5.876	1.0966	1.078	yes
Plot 3	HS	0.488	2.954	0.8957	1.594	yes
Flying insects						
Plots 1- 3	SFO	2.13			2.13	yes

I. Material and Methods

The residues of fluopyram observed in foliage dwelling arthropods and flying insects samples in oilseed rape fields are tabled below. In cases, where the maximum occurred later than the day of application, the time scale was shifted such, that the kinetic evaluation always starts at day 0.

Table 8.9- 19: Fluopyram residues in foliage dwelling arthropods and values used for kinetic evaluation

time after treatment [d]	**Plot 1** residues [mg/kg]	**Plot 2** residues [mg/kg]	**Plot 3** residues [mg/kg]
0	**45.4**	**29.19**	**14.81**
1	15.11	4.67	3.37
2	6.72	3.11	4.02
3	3.26	2.62	3.02
4	1.70	4.15	-
5	1.57	2.70	1.08
7	0.82	1.40	0.83
10	1.44	1.15	0.29
Remaining of max	3%	4%	2%

Table 8.9- 20: Fluopyram residues in flying dwelling arthropods and values used for kinetic evaluation

time after treatment [d]	shifted time [d]	**Plot 1-3** residues [mg/kg]
0		-
1	0	**0.91**
2	1	0.57
3	2	0.29
4	3	0.46
5	4	0.14
7	6	0.26
10	9	0.07
Remaining of max		8%

For the kinetical and statistical analysis of the experimental data the numerical software package KinGUI 2.1 (v. 2.2014) was employed. KinGUI 2 uses the statistical computing language R.

The appropriateness of a kinetic fit was primarily assessed based on the visual inspection of the fit quality. Residuals have to be small compared to the data values and should be randomly distributed around zero. Systematic variations of the residuals are a sign of the choice of an inappropriate kinetic model or the lack of sufficient data points to support an appropriate fit. However, in case of sufficiently small but systematic deviations, a fit is still qualified as visually acceptable.

The second factor for fit assessment is the χ^2 value. FOCUS kinetics suggests for soil studies conducted in the laboratory that "ideally, the error value at which the χ2-test is passed by the best-fit model … should be below 15 % and the fit must be visually acceptable. However, this value should not be considered as an absolute cut-off criterion. There will be cases where the error value to pass the χ^2-test is higher, but the fit still represents a reasonable description of the degradation behaviour". For field studies it is acknowledged that "the individual data points are often scattered around the curve, which results in a large error value." Thus, a χ^2 value of up to 25% is often accepted for field studies if the visual fit is acceptable.

Finally a t-test is employed to identify the probability that a parameter is not significantly different from zero. Normally, a probability of 0.05 - 0.1 is considered as sufficiently small, but with limited data sets, may be relaxed to 0.15. It should be stressed that the t-test is more a guide to considering the assessment of curve fit, and is not in itself a reason to reject a fit.

II. Results and Discussion

The results of the kinetic evaluations are presented below.

Table 8.9- 21: Dissipation parameters for fluopyram in foliage dwelling arthropods in oilseed rape

Kinetic model: SFO FOMC DFOP HS	Visual fit	χ^2 - error	 DT_{50} DT_{50} DT_{50} fast DT_{50} fast	 DT_{90} DT_{50} slow DT_{50} slow	 α / β g tb, in d	**DT_{50} recalc** = DT_{90} / 3.32	t-test k
		[%]	[d]	[d]		[d]	
Plot 1							
SFO [E]	+	8.74	0.685			0.685	k: < 0.001
FOMC	+	4.10	0.581	2.589	2.9684 / 2.209	0.780	
DFOP	+	3.60	0.595	8.024	0.9485	0.719	k2: 0.197
HS	+	5.51	0.630	1.211	1.5168	0.790	k2: 0.007
Plot 2							
SFO	-	28.4	0.435			0.435	k: 0.004
FOMC	+	9.25	0.060	3.046	0.4348/ 0.0153	0.917	
DFOP	+	8.75	0.193	5.837	0.8469	1.081	k2: 0.072
HS [E]	+	8.72	0.378	5.876	1.0966	1.078	k2: 0.069
Plot 3							
SFO	-	29.5	0.786			0.786	k: 0.006
FOMC	o	16.3	0.327	5.429	0.6701/ 0.1806	1.635	
DFOP	+	11.9	0.017	2.955	0.6539	1.594	k2: 0.032
HS [E]	+	11.9	0.488	2.954	0.8957	1.594	k2: 0.032

visual acceptability: + good o medium - bad
[E] best approach for ecotoxicological purpose recommended by the authors of the kinetic evaluation

Plot 1: SFO decay can be considered appropriate for further use in ecotoxicological risk assessments. Systematic but small deviation of residuals from the modelled curve occurs only very late when ≥ 90 % of fluopyram is already dissipated.

Plot 2, 3: SFO fit is considered not acceptable (visually, χ^2). Most biphasic fits resulted in a good to very good fit, with low and random deviations of the residuals. Finally, the HS is considered most appropriate for further use in ecotoxicological risk assessments, as it shows the best visual fit.

Table 8.9- 22: Dissipation parameters for fluopyram in flying insects in oilseed rape

Kinetic model: SFO / FOMC / DFOP / HS	Visual fit	χ^2 - error	DT_{50} / **DT_{50}** / **DT_{50} fast** / DT_{50} fast	**DT_{90}** / **DT_{50} slow** / DT_{50} slow	α / β / g / tb, in d	**DT_{50} recalc** = DT_{90} / 3.32	t-test k
		[%]	[d]	[d]		[d]	
Plot 1-3							
SFO [E]	o	21.6	**2.13**			2.13	k: 0.005
FOMC	o	20.0	1.52	12.76	1.0638/ 1.6544	3.843	
DFOP	o	21.7	0.549	4.141	0.454	3.054	k2: 0.247
HS	o	20.8	1.482	4.352	1.997	3.190	k2: 0.157

visual acceptability: + good o medium - bad
[E] best approach for ecotoxicological purpose recommended by the authors of the kinetic evaluation

In case of flying insects, the visual inspection of SFO resulted in a good to moderate acceptability. In this trial, a biphasic fit did not improve the visual acceptability, as the moderate fit is mainly based on randomly scattering residues. Finally, in this case the SFO fit is considered most appropriate for further use in ecotoxicological risk assessments.
In addition, it should be noted, that the slow phase of a DFOP or HS fit is mostly not appropriate for a solely use to describe the decline of fluopyram in insects if the slow phase is based mainly on a small portion of the totally degrading amount (< 25 %).

8.9- 30:

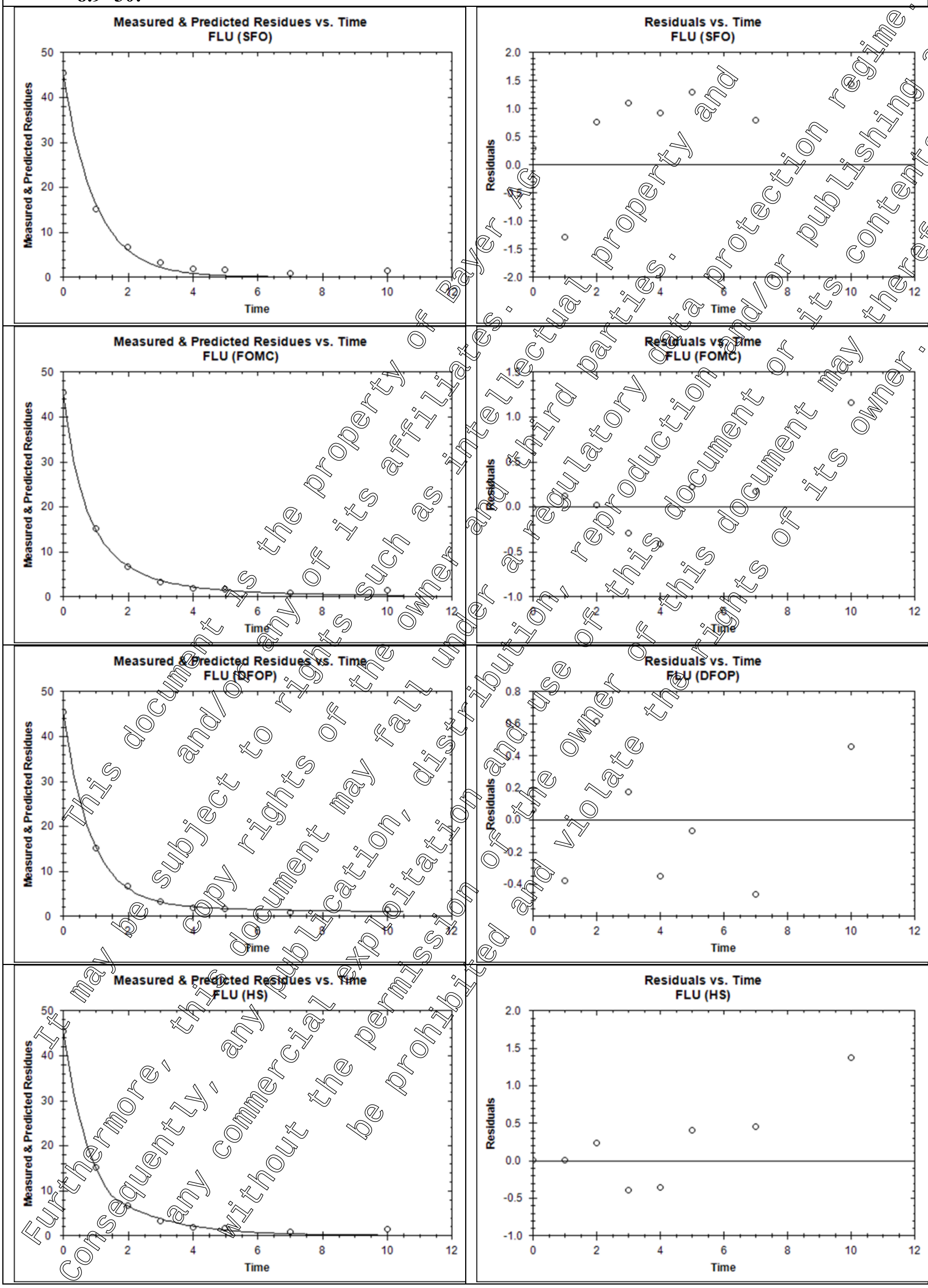

Measured & Predicted Residues vs. Time
FLU (SFO)
Residuals vs. Time
FLU (SFO)
Measured & Predicted Residues vs. Time
FLU (FOMC)
Residuals vs. Time
FLU (FOMC)
Measured & Predicted Residues vs. Time
FLU (DFOP)
Residuals vs. Time
FLU (DFOP)
Measured & Predicted Residues vs. Time
FLU (HS)
Residuals vs. Time
FLU (HS)
Measured & Predicted Residues
Residuals
Time

Figure 8.9- 31: Residue decline of fluopyram on foliage dwelling invertebrates (plot 2)

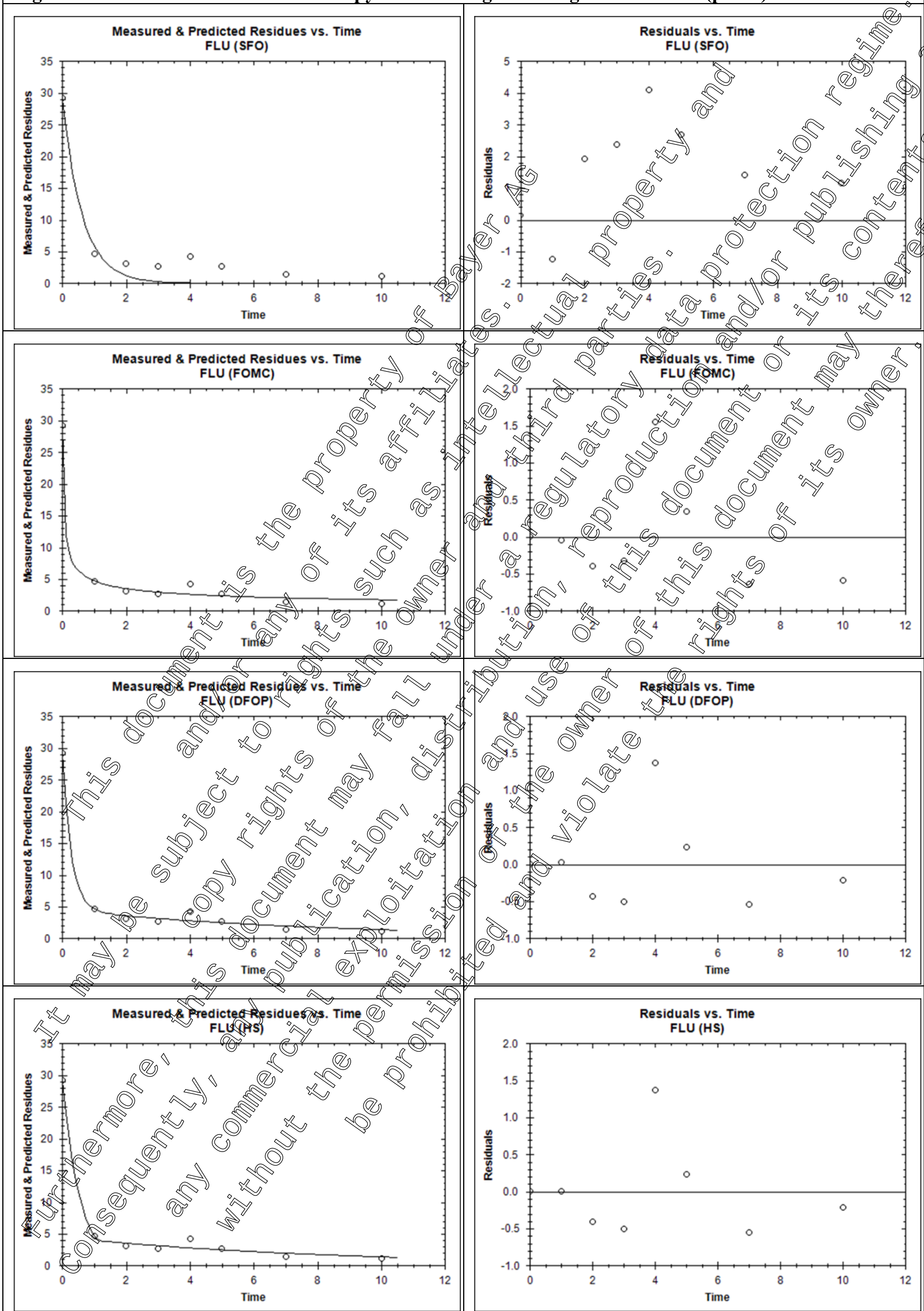


Figure 8.9- 32: Residue decline of fluopyram on foliage dwelling invertebrates (plot 3)

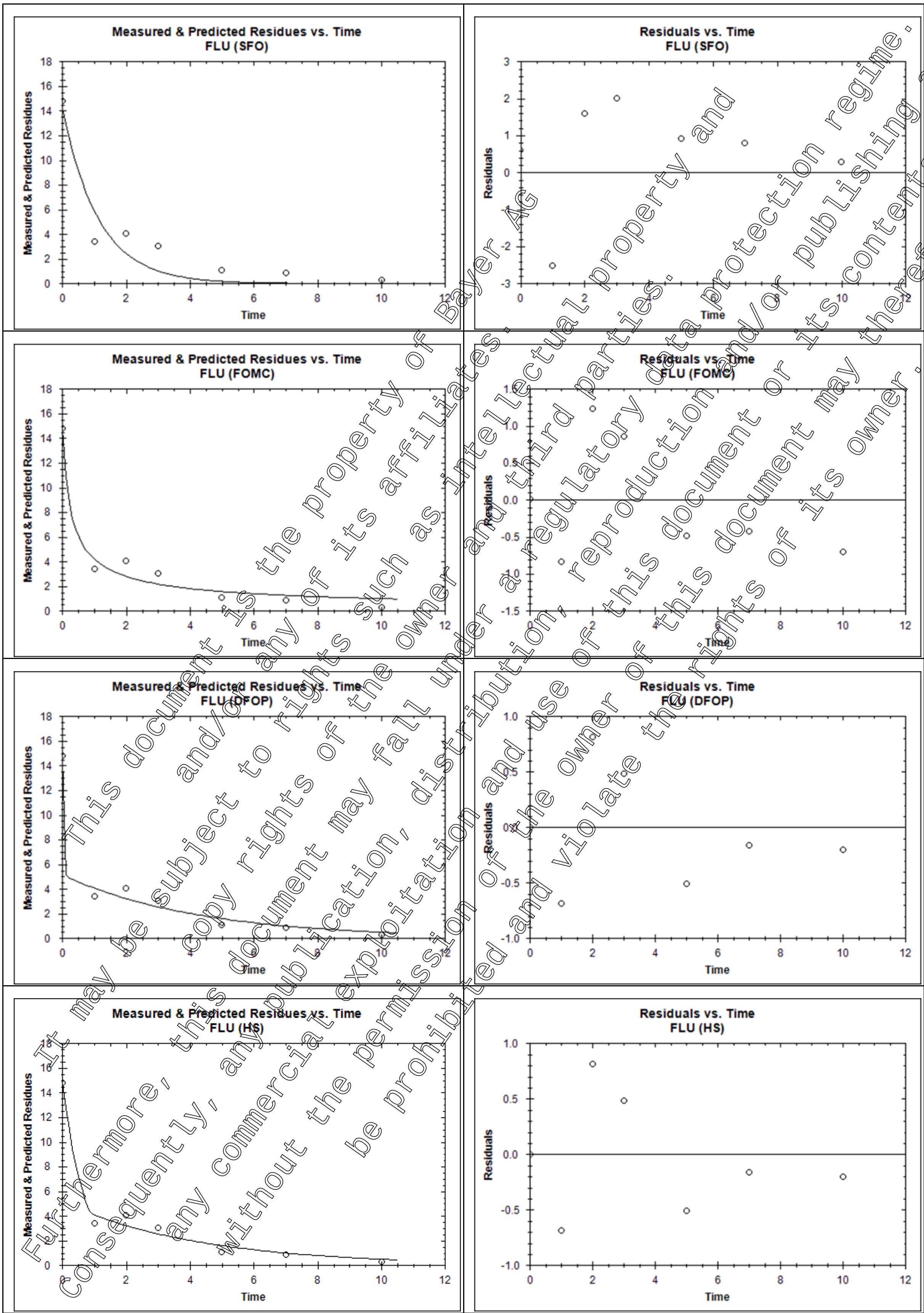
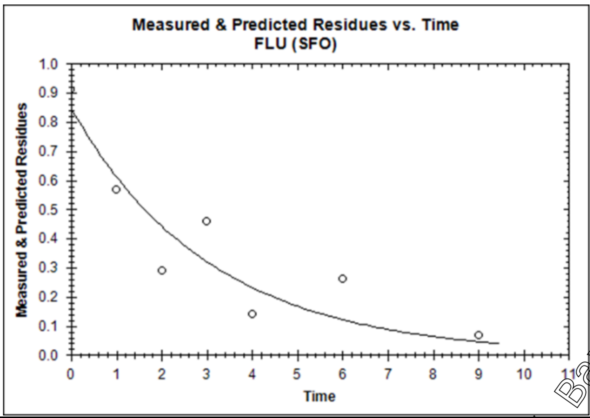
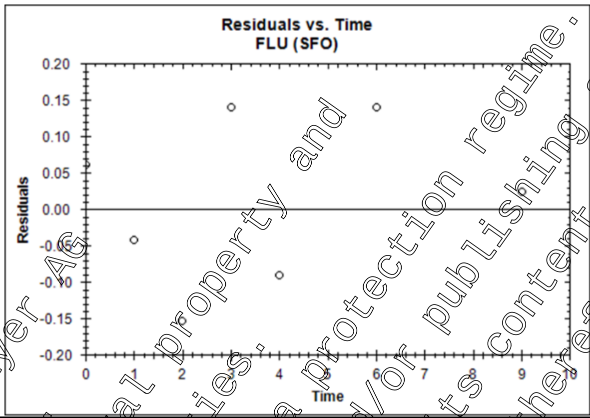
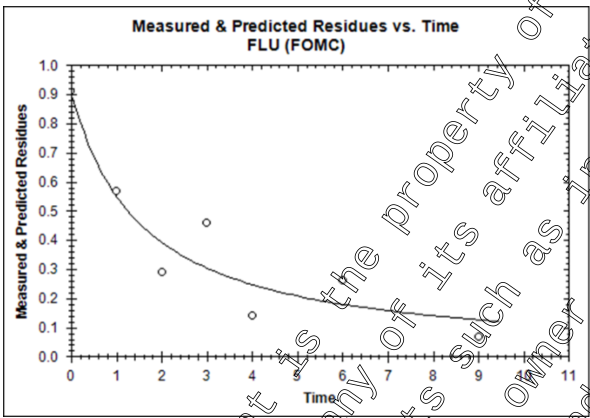
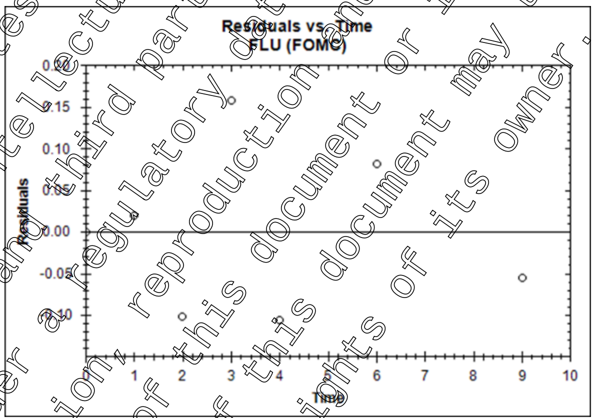


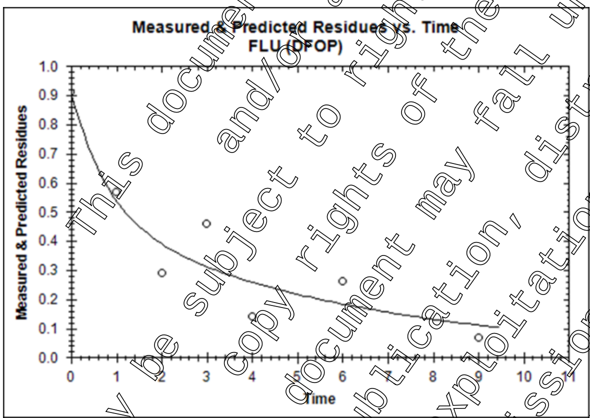
Figure 8.9- 33: Residue decline of fluopyram on flying insects (plot 1-3)

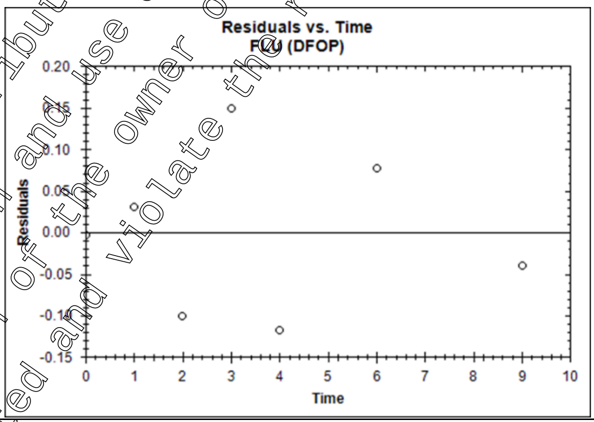

Measured & Predicted Residues vs. Time
FLU (SFO)
Measured & Predicted Residues
Time

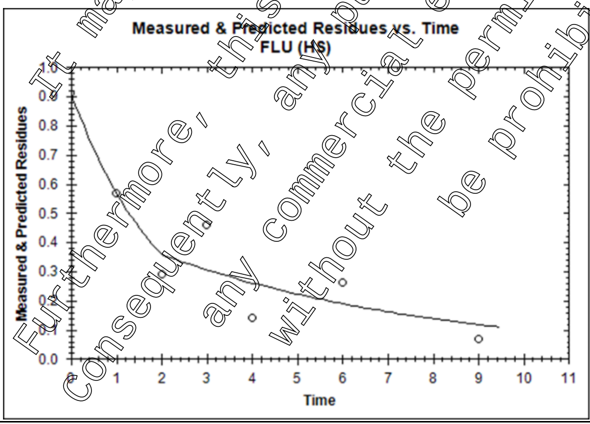

Residuals vs. Time
FLU (SFO)
Residuals
Time

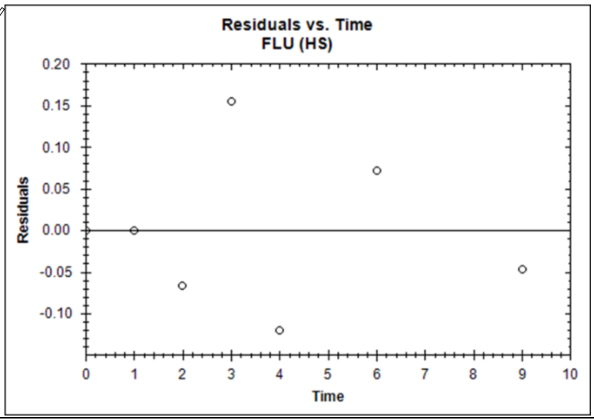

Measured & Predicted Residues vs. Time
FLU (FOMC)
Measured & Predicted Residues
Time


Residuals vs. Time
FLU (FOMC)
Residuals
Time


Measured & Predicted Residues vs. Time
FLU (DFOP)
Measured & Predicted Residues
Time


Residuals vs. Time
FLU (DFOP)
Residuals
Time


Measured & Predicted Residues vs. Time
FLU (HS)
Measured & Predicted Residues
Time


Residuals vs. Time
FLU (HS)
Residuals
Time

III. CONCLUSION

The study provides kinetic evaluations for the residue decline data of fluopyram on foliage dwelling invertebrates and flying insects in oil seed rape fields in Germany, complementing the original evaluation with non-SFO kinetic models (FOMC, DFOP, HS).

Recommended DT_{50}s (for non-SFO calculated as $DT_{90}/3.32$) were 0.685, 1.078 and 1.594 days for foliage dwellers and 2.13 days in flying insects.

Assessment and conclusion by applicant: The study and its data are considered as acceptable and reliable for use in risk assessment. Recommended DT_{50}s (for non-SFO calculated as $DT_{90}/3.32$) were 0.685, 1.078 and 1.594 days for foliage dwellers and 2.13 days in flying insects.

Data Point:	KCA 8.9/06
Report Author:	[redacted]
Report Year:	2018
Report Title:	Residue decline of fluopyram and tebuconazole on arthropods after spray applications in pome fruit orchards in Germany
Report No:	EBGM0105
Document No:	M-644049-01-1
Guideline(s) followed in study:	No official test guideline available for this type of study. The study was conducted under consideration of the EFSA Guidance Document on Risk Assessment for Birds & Mammals (EFSA 2009). Regulation (EC) No 1107/2009 Directive 2003-01 (Canada/PMRA) US EPA OCSPP Not Applicable
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

A field study with three invertebrate residue decline trials was conducted in pome fruit orchards in Germany during the 2017 season. Two applications with Fluopyram + Tebuconazole SC 400 (200+200), containing 200 g/L fluopyram and 200 g/L tebuconazole were conducted. Only the parameters and results relevant to fluopyram have been reported within this study summary.

The residues of fluopyram on foliage dwelling invertebrates (DT_{50}s 2.7-5.3d) and flying insects (DT_{50}s 1.9-2.4d) declined during the sampling period. Calculation of a DT_{50} on ground invertebrates was not attempted (only calculation of C_{TWA})

I. Material and Methods

Materials:

1.	Test Item:	Fluopyram + Tebuconazole SC 400 (200 + 200 g/L)
	Batch no.:	EM4L021490
	Active Ingredient:	Fluopyram and Tebuconazole
	Storage:	25°C +/-5°C, from +2°C to +30°C are also acceptable
	Expiry date:	2020-05-15
2.	Sampled matrix:	Invertebrates
	Crop:	Apple orchards

Methods:

The purpose of the study was to determine the residue decline of fluopyram and tebuconazole following two applications (application interval: minimum 7 days) of the formulated product LUNA® Experience (SC formulation, containing 200 g/L fluopyram and 200 g/L tebuconazole) at a rate of nominal 0.25 L product/ha/m crown height in pome fruit orchards in Germany, following the recommendations of the guidance document on risk assessment for birds & mammals on request from EFSA. EFSA Journal 2009; 7(12):1438.

Study sites: The study was conducted in the vicinity of Leichlingen, Northrhine-Westphalia in western Germany. Three pome fruit orchards with sizes of 1.57, 1.76 and 0.78 ha were selected.

Test item and application: The test item Luna® Experience was applied in each orchard at a nominal application rate of 0.25 L product/ha/m crown height, corresponding to nominal 50 g fluopyram and 50 g tebuconazole per ha and m crown height with a spray volume of 500 L tap water according to Good Laboratory Practice and Good Agricultural Practice. Two applications with an interval of 7 days in two orchards and 14 days in the third orchard were conducted. With the actual canopy height of 2.21 m, 2.36 m and 2.31 m for Replicate 1, 2 and 3 respectively, the nominal application rate was 110.5, 118 and 115.5 g a.s./ha.

Arthropod sampling: Ground dwelling arthropods were collected with pitfall traps, foliage dwelling arthropods by inventory spraying and flying insects with Malaise traps. Pitfall traps were placed within the apple rows, in the middle of two trees in an adequate, evenly distributed set-up. For inventory spraying, whole trees within the sample area were sprayed with a 'knock down' insecticide (Aquapy®) at approx. 20 mL product in 1 L water with a motor driven knapsack sprayer (non-GLP application). Two Malaise traps per orchard were placed between the tree rows. Targeted biomass per sample was ≥ 1.5 g for all sampling methods.

Sampling period was until 21 days after the second application (with exception of inventory spray, replicate 3, last sampling shifted to 22 days). After identification and quantification of the main taxonomic groups, the samples were stored deep frozen until residue analysis.

Residue analysis: All samples were analysed for their content of fluopyram and tebuconazole via HPLC-MS/MS. Residues are reported in terms of mg active substance/kg fresh weight (mg a.s./kg fw). The Limit of quantification (LOQ) value was 0.01 mg/kg. This summary focuses only on the residues of fluopyram.

Full details and acceptable validation data to support the analytical method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

Data evaluation: In the report, time weighted average (TWA) concentrations over a 21 day period with a moving time window across the entire sampling period were calculated via interpolation of concentrations on days without residue data (not included in this summary). The residue concentrations were also expressed as RUDs in the report (not included in this summary because not intended for the risk assessment). Instead, the TWA concentrations on ground dwelling invertebrates after the second application are included in this summary because they may be employed to calculate a pseudo-DT_{50} as surrogate for a kinetic DT_{50} which cannot be derived from the residue data obtained in this group.

The residue decline (DT_{50}) of the active substance in arthropods was calculated to quantify the time course of the residue concentration in potential food items of insectivorous and omnivorous birds or mammals over time. The residue decline data were evaluated with a first-order kinetic (SFO) and additionally first-order multi compartment (FOMC) kinetic. To account for FOMC kinetics, Malaise trapping data were re-scaled to start on DALT 0 (day after last application) for both models.

The FOMC DT_{50} was back-calculated with DT_{90}/3.32 (EFSA GD for Birds and Mammals, Appendix H (2009)). The constant parameters α and β for FOMC would allow a more precise residue decline calculation than the back-calculation from the FOMC-DT_{90}. but this was not done within the scope of this report.

Due to fluctuations in residue decline, focus of best-fit evaluation was on visual judgement as acceptability criterion.

Calculation tools: TWA calculations were conducted with MS Excel 2010. DT_{50} calculation was performed with KineticEval 1.0.3 (based on Bayer CropScience software KinGUI version 2.1).

II. RESULTS AND DISCUSSION

The measured residue values and the 21-d $C_{TWA\ max}$ are presented below. The 21-d $C_{TWA\ max}$ is calculated with a moving time window and with interpolated data on DAFTs/DALTs without residue data (DAFT=Day after first treatment, DALT=Day after last treatment). DAFT 14 on replicate 3 was not considered for TWA calculations.

Day -1 depicts residues measured before the first application on each plot. Low day -1 residues in foliage dwelling invertebrates and flying insects in replicate 2 and 3 may be due to the application on plot 1 which was earlier than on plot 2 and 3. However, these residues were low and not considered to compromise the results from this study.

Table 8.9- 23: Residues in foliage dwelling invertebrates

Residues of fluopyram on foliage dwelling invertebrates [mg/kg]			
DAFT/*DALT*	Replicate 1	Replicate 2	Replicate 3
-1	< 0.01	0.17	0.055
0	1.27	1.58	4.79
1	1.76	1.94	1.85
2	2.02	2.19	1.64
4	1.16	1.15	0.58
6	1.38	0.88	0.91
14	-	-	0.13
0	3.05	9.40	3.18
1	2.84	2.64	1.61
3	2.09	2.65	1.17
5	0.76	2.64	0.96
7	0.94	0.80	0.81
10	0.84	0.35	0.30
14	0.41	0.21	0.29
17	0.29	0.32	0.28
21	0.23	0.12	0.077

Table 8.9- 24: Residues in ground dwelling invertebrates

Residues of fluopyram on ground dwelling invertebrates [mg/kg]			
DAFT/*DALT*	Replicate 1	Replicate 2	Replicate 3
-1	< 0.01	< 0.01	< 0.01
1	0.033	0.049	0.15
2	0.096	0.035	0.10
4	0.075	0.035	0.056
6	0.025	0.041	0.11
14	-	-	0.010
1	0.15	0.14	0.10
3	0.062	0.10	0.078
5	0.16	0.36	0.043
7	0.038	0.99	0.065
10	0.097	0.018	0.021
14	0.31	0.61	0.092
17	0.16	0.079	0.017
21	0.13	0.020	0.036

Table 8.9- 25: Residues in flying insects

Residues of fluopyram on flying insects [mg/kg]			
DAFT/*DALT*	**Replicate 1**	**Replicate 2**	**Replicate 3**
-1	< 0.01	0.013	0.052
1	0.34	1.1	1.12
2	0.13	0.3	0.61
4	0.20	0.33	0.31
6	0.11	0.17	0.37
14	-	-	0.017
1	0.42	0.57	0.63
3	0.20	0.25	0.26
5	0.065	0.19	0.13
7	0.065	0.081	0.12
10	0.025	0.058	0.036
14	0.016	0.018	0.039
17	0.043	0.019	0.019
21	0.034	0.024	0.01

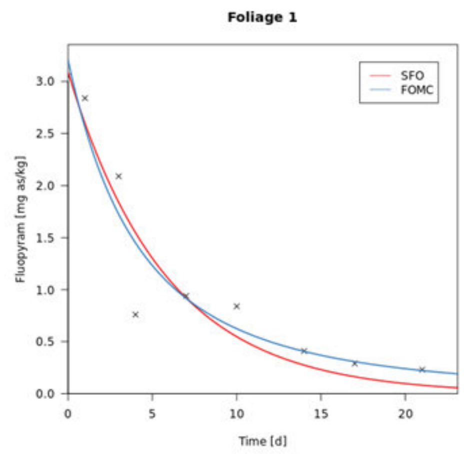
Table 8.9- 26: Kinetic evaluation of the residue decline of fluopyram on arthropods in pome fruit orchards after the second application

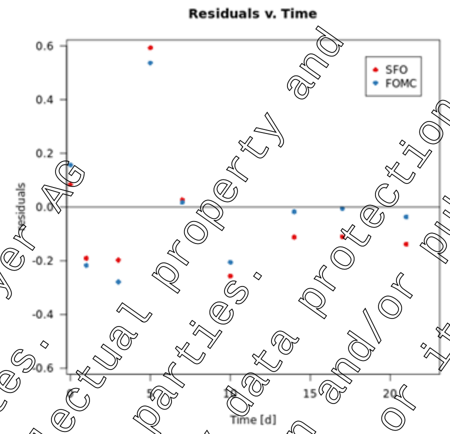
Fluopyram								
Replicate	**Kinetic model**	**DT_{50} (days)**	**DT_{90} (days)**	**chi² error**	**visual fit**	**α (FOMC)**	**β (FOMC)**	**t-test of k (SFO)**
Foliage dwelling invertebrates								
1	SFO	**4.1**	13.7	15.45	+	-	-	<0.001
2	FOMC	**2.7**	9.0	25.63	o	0.6052	0.2056	-
3	FOMC	**5.3**	17.8	13.37	+	0.7650	0.922	-
Flying insects								
1	FOMC	**2.4**	8.1	15.30	+	1.9251	3.5175	-
2	SFO	**2.2**	7.4	12.98	+	-	-	<0.001
3	SFO	**1.9**	6.2	14.05	+	-	-	<0.001
Ground dwelling invertebrates								
1	No acceptable kinetic fit							
2	No acceptable kinetic fit							
3	No acceptable kinetic fit							

SFO = single first order (preferred where feasible)
FOMC = first order multi-compartment (Gustafson and Holden); $DT_{50} = DT_{90}/3.32$
k = rate constant for SFO; α, β = constant parameters for FOMC
+: good fit o: acceptable fit (small systematic deviation or large random scatter)

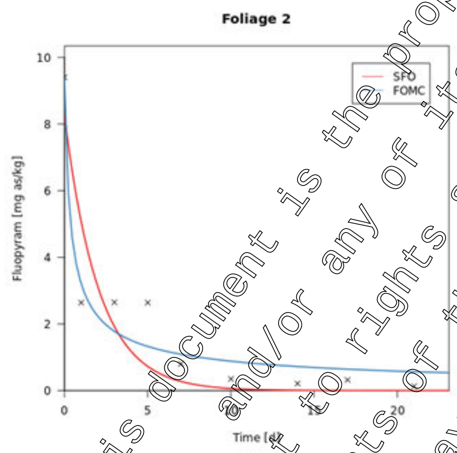
It should be noted that the constant parameters α and β for FOMC allow a more precise residue decline calculation than the back-calculation with FOMC-$DT_{50} = DT_{90}/3.32$ mentioned in the EFSA GD (2009).

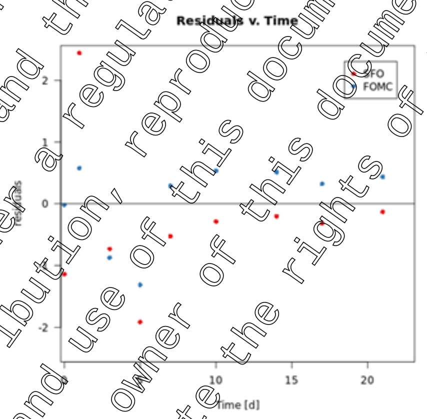
Figure 8.9- 34: Fitted SFO and FOMC decline curves and corresponding residuals for fluopyram on foliage dwellers



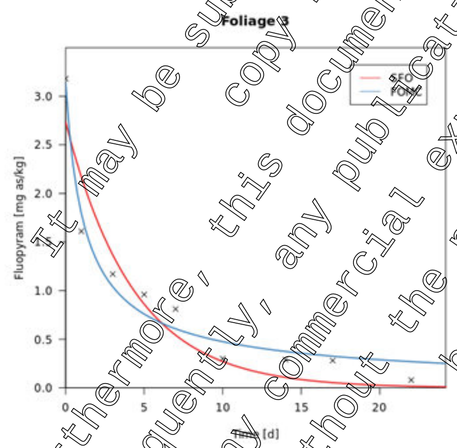


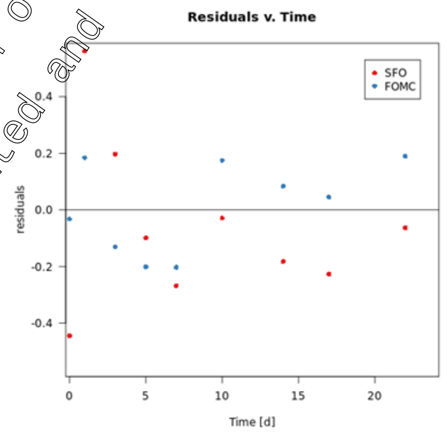
Foliage dweller on replicate 1; SFO visually good fit





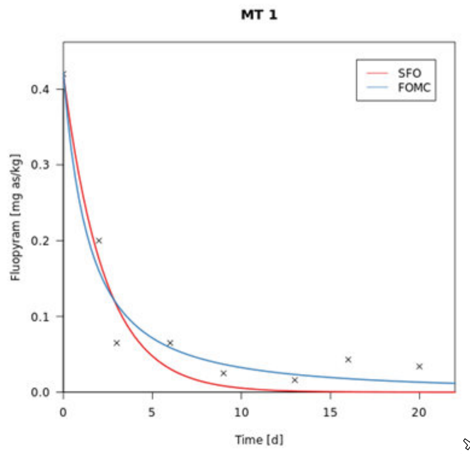
Foliage dweller on replicate 2; FOMC visually acceptable fit

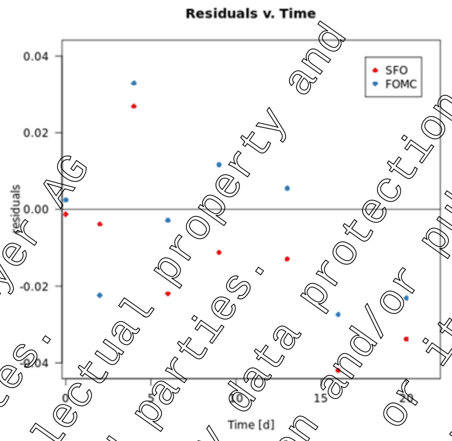




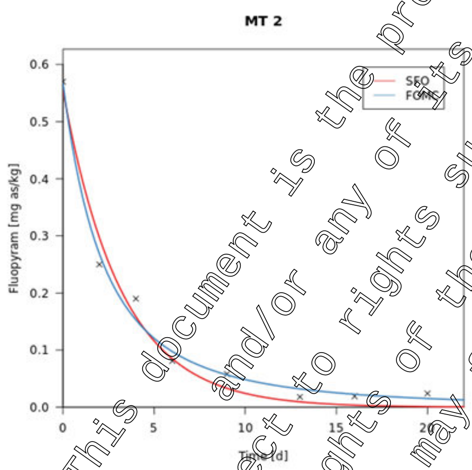
Foliage dweller on replicate 3; FOMC visually good fit

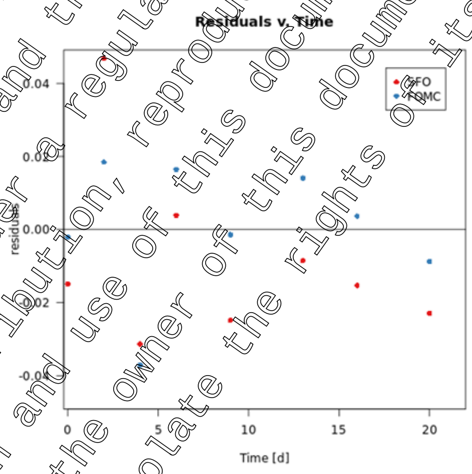
Figure 8.9- 35: Fitted SFO and FOMC decline curves and corresponding residuals for fluopyram on flying insects



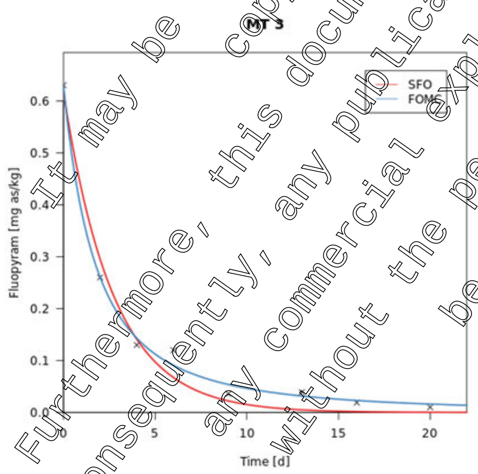


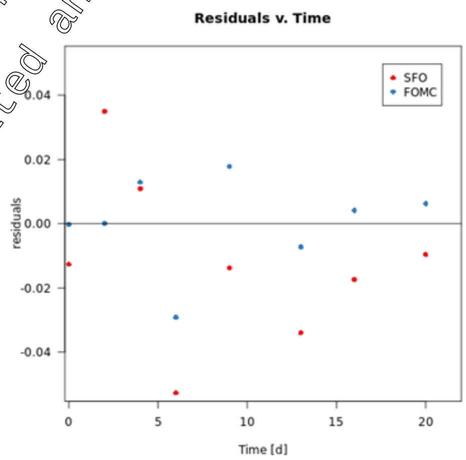
Malaise traps on replicate 1; FOMC visually good fit





Malaise traps on replicate 2, SFO visually good fit





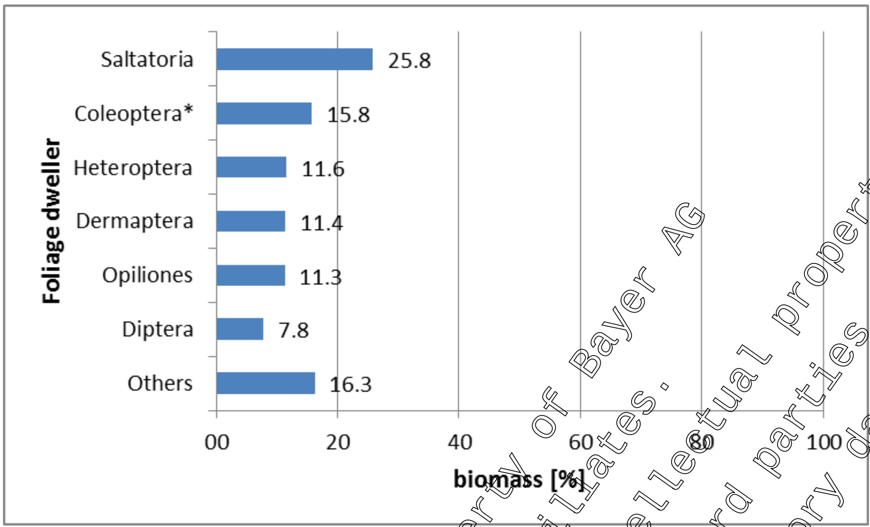
Malaise traps on replicate 3, SFO visually good fit

Table 8.9- 27: Calculation of 21-day f_{TWA}

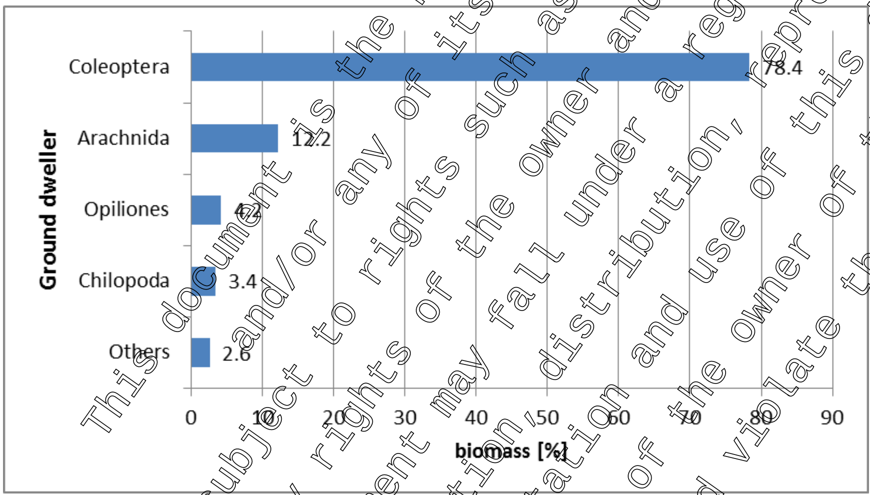
Calculation of 21-d f_{TWA} for fluopyram in ground dwelling arthropods after the 2nd application			
DALT	**Replicate 1**	**Replicate 2**	**Replicate 3**
1	0.15	0.14	0.10
2	*0.10*	*0.12*	*0.090*
3	0.062	0.10	0.078
4	0.11	*0.23*	*0.060*
5	0.16	0.36	0.043
6	*0.10*	*0.675*	*0.054*
7	0.038	0.99	0.065
8	*0.058*	*0.664*	*0.050*
9	*0.077*	*0.341*	*0.036*
10	0.097	0.018	0.021
11	*0.149*	*0.165*	*0.039*
12	*0.201*	*0.312*	*0.056*
13	*0.254*	*0.459*	*0.074*
14	0.31	0.61	0.092
15	*0.256*	*0.430*	*0.067*
16	*0.207*	*0.255*	*0.042*
17	0.16	0.079	0.017
18	*0.15*	*0.064*	*0.021*
19	*0.14*	*0.050*	*0.026*
20	*0.14*	*0.035*	*0.031*
21	0.13	0.020	0.036
21-d C_{TWA}	0.14	0.29	0.05

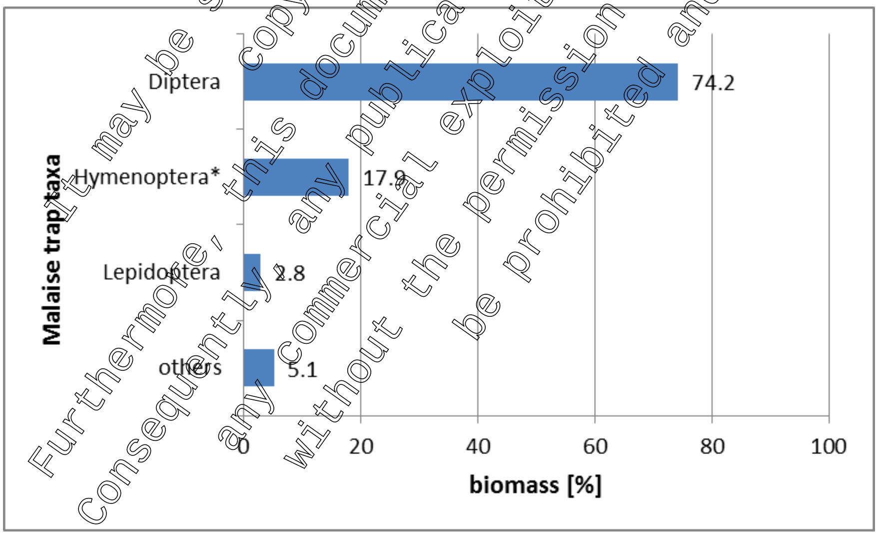
In *italics*: interpolated residue concentrations on days without sampling

Figure 8.9- 36: Arthropod composition



* adults





* without Formicidae

Weather conditions

Total rainfall during the sampling phase (01 Jun 2017 – 27 Jul 2017) was 181 mm (41.2 mm in June and 139.8 mm in July) with the highest precipitation towards the end after the sampling phase of the first two replicates (102.6 mm). The mean air temperature ranged between minimum 7.8°C and 18.2°C and maximum 16.1°C and 33.6°C (mean 14°C and 24°C).

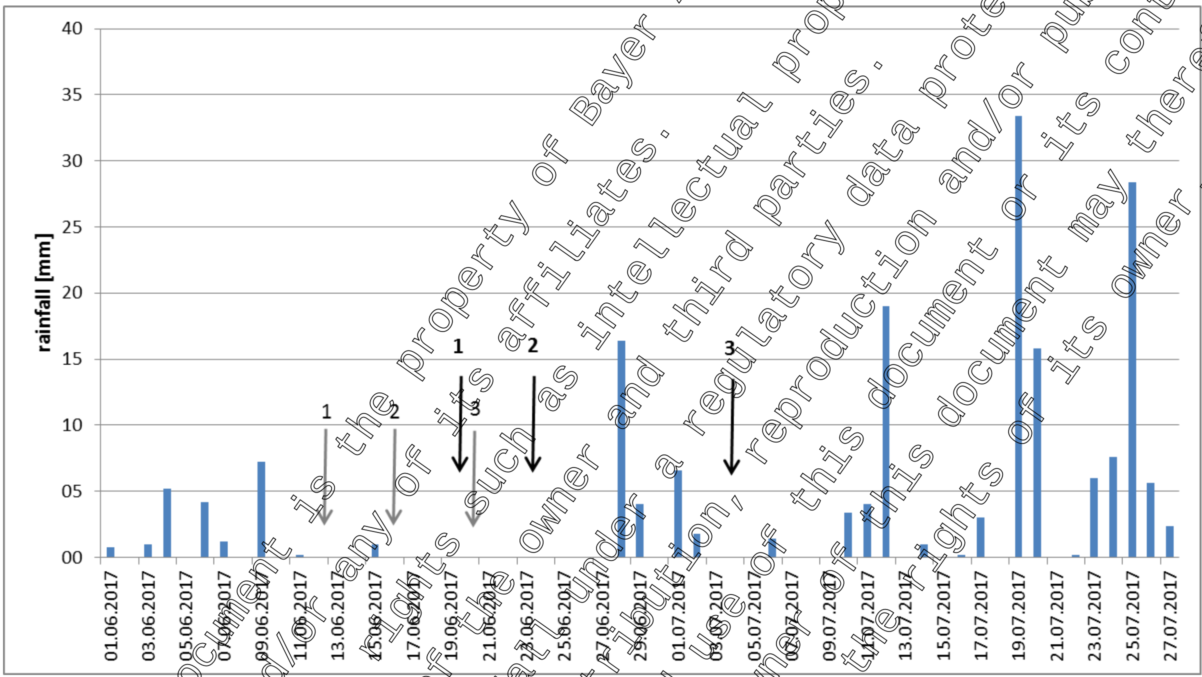


Figure 8.9- 37: Weather conditions

Grey arrows indicate the first application on Replicates 1 (12 Jun 2017), 2 (16 Jun 2017) and 3 (20 Jun 2017), respectively. Black arrows indicate the second application on Replicates 1 (19 Jun 2017), 2 (23 Jun 2017) and 3 (04 Jul 2017), respectively.

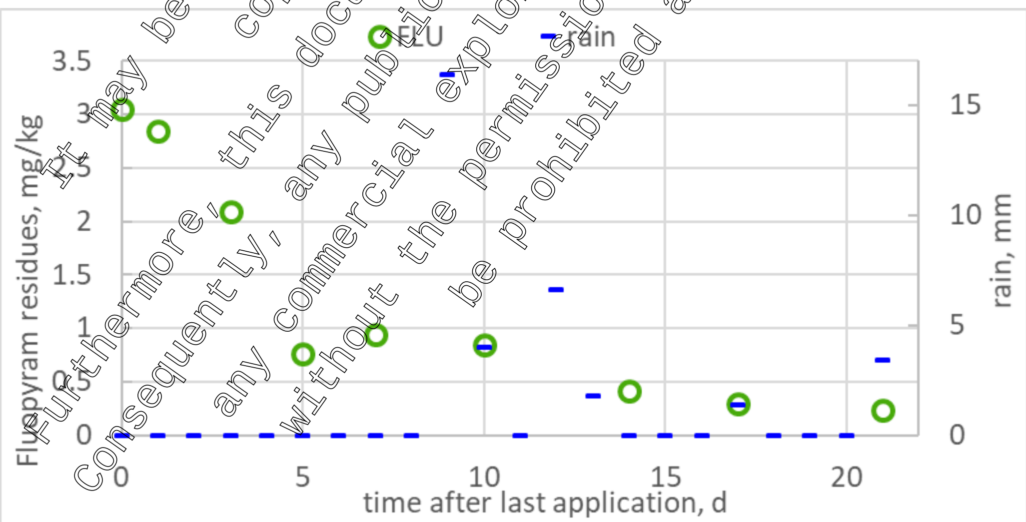


Figure 8.9- 38: Rainfall and residues for plot 1, foliage dwelling arthropods

No discernible influence of rainfall on the residue time course

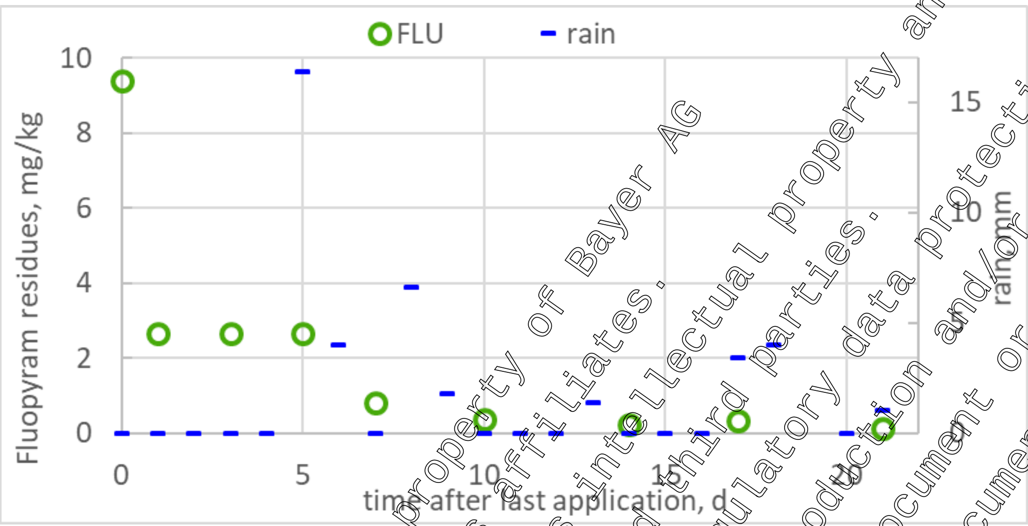


Figure 8.9- 39: Rainfall and residues for plot 2, foliage dwelling arthropods

No discernible influence of rainfall on the residue time course

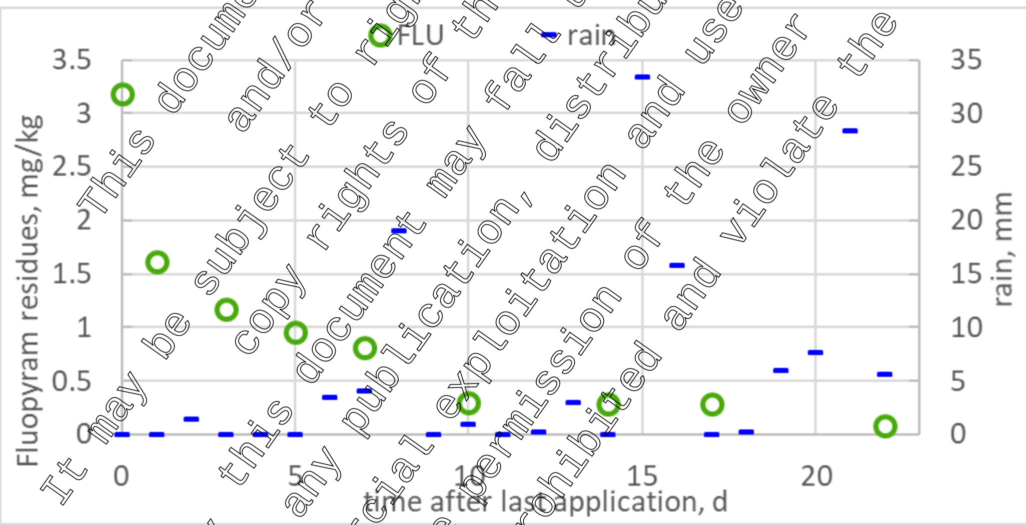


Figure 8.9- 40: Rainfall and residues for plot 3, foliage dwelling arthropods

Slight influence of rainfall from day 8

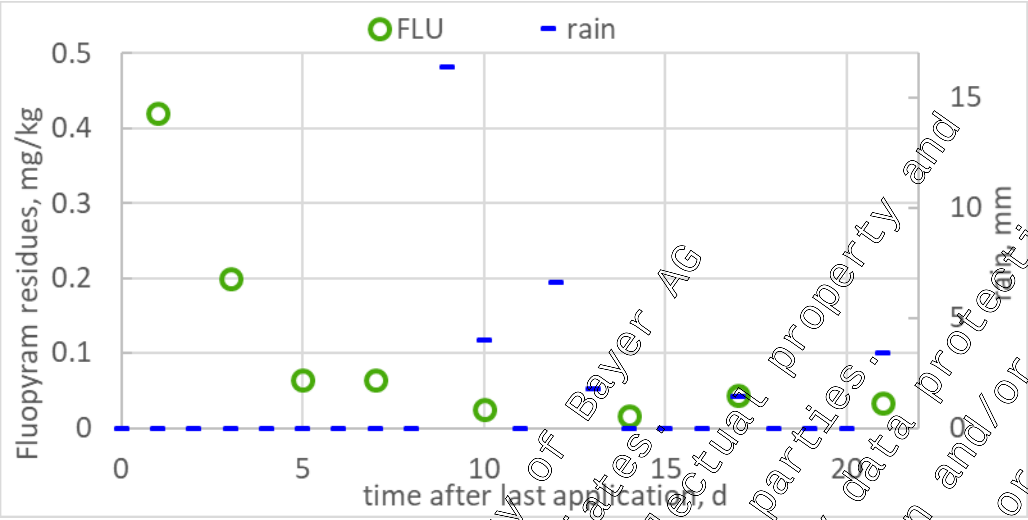


Figure 8.9- 41: Rainfall and residues for plot 1, flying insects

No discernible influence of rainfall on the residue time course

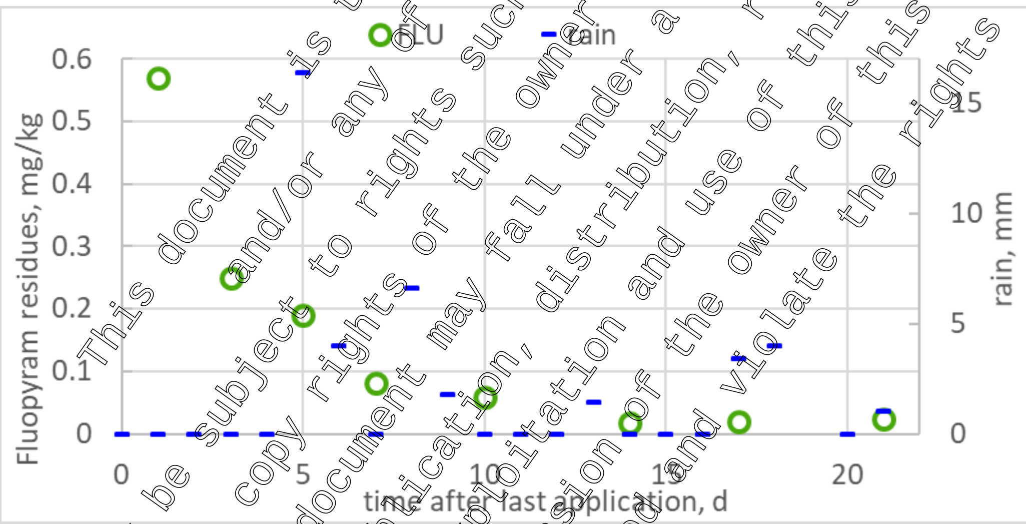


Figure 8.9- 42: Rainfall and residues for plot 2, flying insects

No discernible influence of rainfall on the residue time course

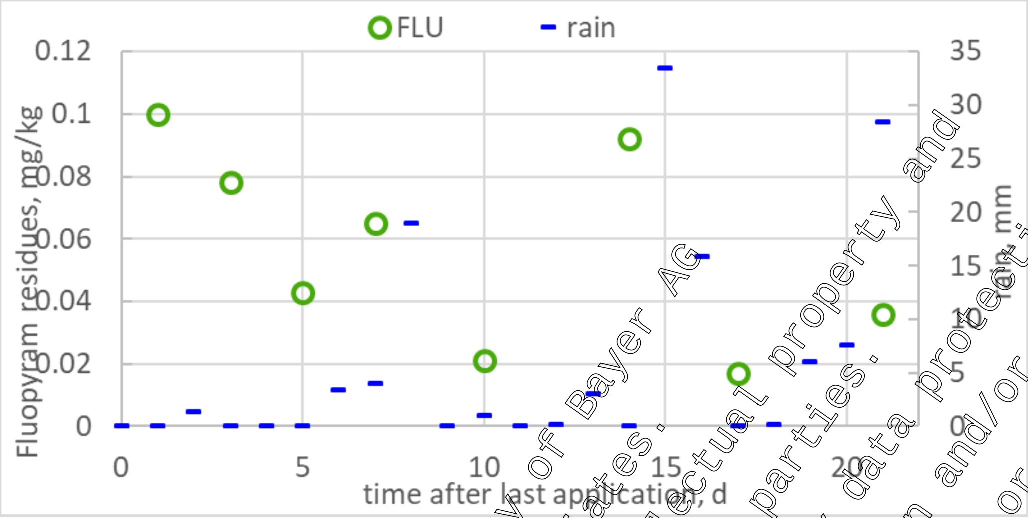


Figure 8.9- 43: **Rainfall and residues for plot 3, flying insects**

No discernible influence of rainfall on the residue time course

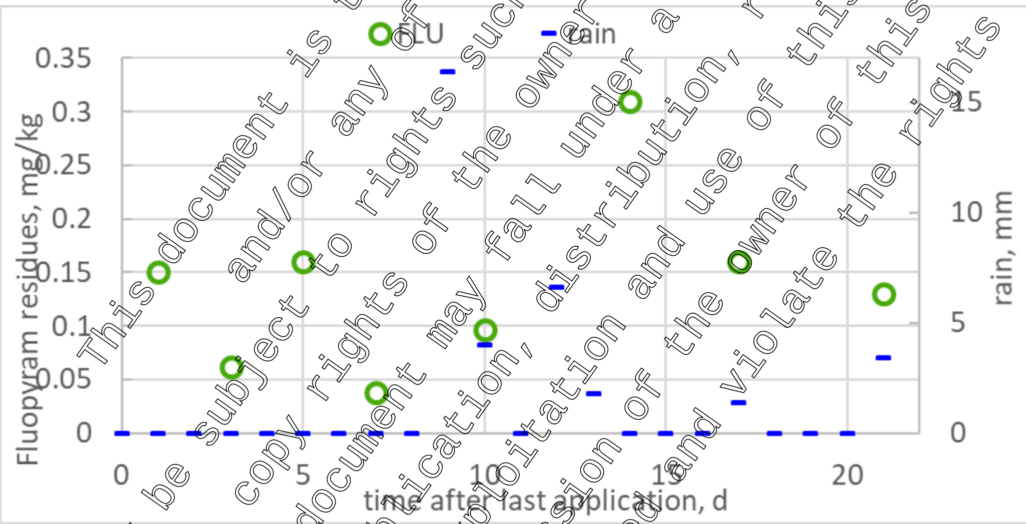


Figure 8.9- 44: **Rainfall and residues for plot 1, ground dwelling arthropods**

No discernible influence of rainfall on the residue time course

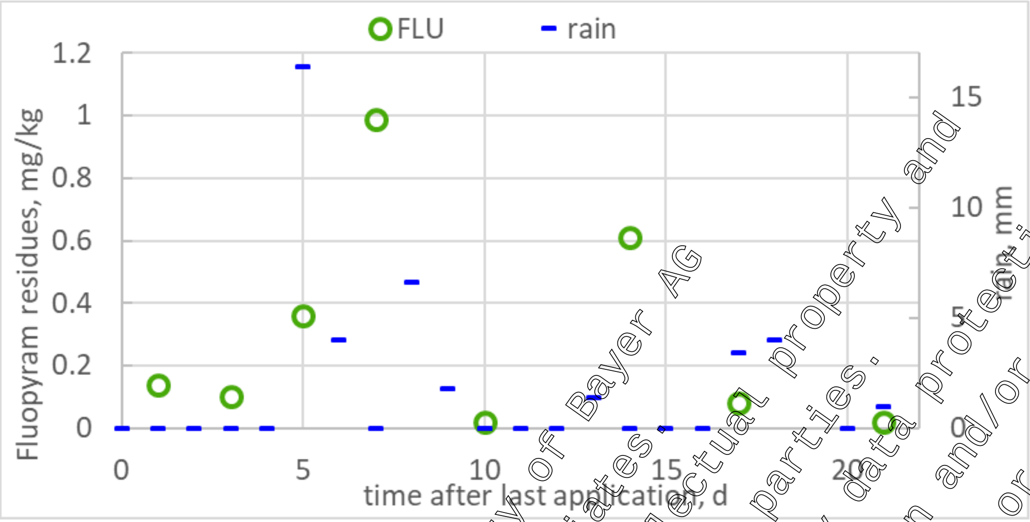


Figure 8.9- 45: **Rainfall and residues for plot 2, ground dwelling arthropods**

No discernible influence of rainfall on the residue time course

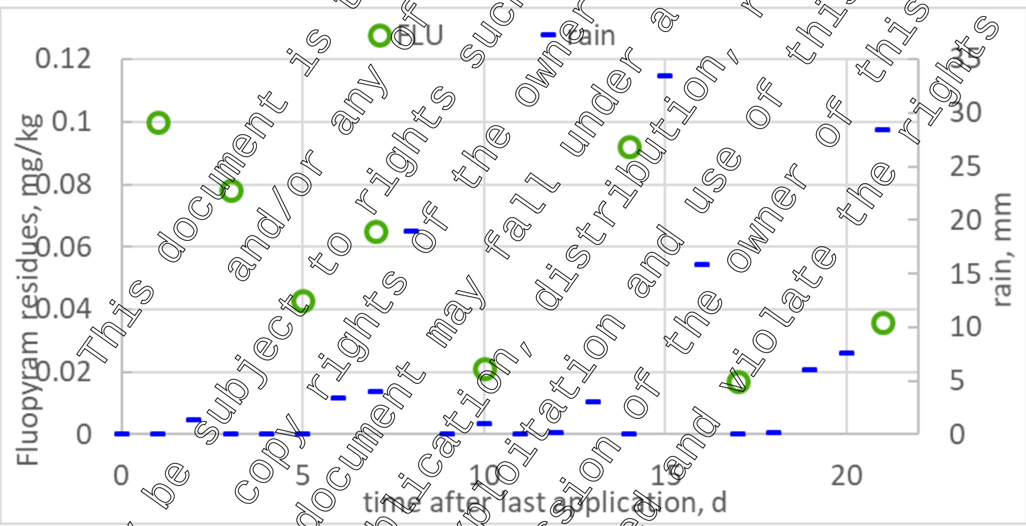


Figure 8.9- 46: **Rainfall and residues for plot 3, ground dwelling arthropods**

No discernible influence of rainfall on the residue time course

III. Conclusion

The study provides realistic field residue data for fluopyram on invertebrates in pome fruit orchards following 2 applications with 110.5, 118 and 115.5 g a.s./ha.

Fluopyram concentrations fluctuated due to interaction of different influencing factors like sample compositions over time, food web interactions and in addition mobility of the arthropod communities.

SFO and FOMC DT_{50} values were calculated for residue data on foliage dwellers and arthropods caught in Malaise traps. An acceptable fit for the use of DT_{50} values in risk assessments was determined by visual comparison of both kinetic models.

The FOMC DT_{50}s were back-calculated with $DT_{90}/3.32$ and represent a conservative approach for the residue decline. A more precise representation of the residue decline curve is obtained when the kinetic parameters α and β are employed in a suitable calculation program. However, this was not done within the scope of this report.

Kinetic evaluation of the residue time course on ground dwellers was not possible. Instead, a 21d C_{TWA} was calculated.

DT_{50}s with acceptable fits for fluopyram ranged from 2.7 to 5.3 days for foliage dwellers and 1.9 to 2.4 days in Malaise traps.

<u>**Assessment and conclusion by applicant:**</u> The study and its data are considered as acceptable and reliable for use in risk assessment. DT_{50}s with acceptable fits for fluopyram ranged from 2.7 to 5.3 days for foliage dwellers and 1.9 to 2.4 days in Malaise traps.

Data Point:	KCA 8.9/07
Report Author:	[redacted].
Report Year:	2020
Report Title:	Calculation of pseudo-SFO-DT50 values for residues of fluopyram on ground-dwelling invertebrates in apple orchards in Germany
Report No:	EnSa-20-0891
Document No:	M-760161-01-1
Guideline(s) followed in study:	--
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	not applicable
Acceptability/Reliability:	Yes

EXECUTIVE SUMMARY

A field study with three invertebrate residue decline trials was conducted in pome fruit orchards in Germany during the 2017 season (M-644049-01-1). Two applications with the Fluopyram + Tebuconazole SC 400 (200+200), containing 200 g/L fluopyram and 200 g/L tebuconazole, were conducted. Due to the time course of the residue concentrations measured on ground dwelling invertebrates, no kinetic DT_{50} could be generated for this group in the original report. Instead, pseudo-DT_{50} values ranging 4.4-9.4 days are calculated here for fluopyram on ground dwelling invertebrates, according to the procedure described in EFSA (2009), appendix H.

I. MATERIALS AND METHODS

A field study with three invertebrate residue decline trials was conducted in pome fruit orchards in Germany during the 2017 season (M-644049-01-1). Two applications with the Fluopyram + Tebuconazole SC 400 (200+200), containing 200 g/L fluopyram and 200 g/L tebuconazole, were conducted. The time course of the residues in ground dwelling invertebrates did not allow a kinetic evaluation. Instead, calculation of a pseudo-DT_{50} for fluopyram is proposed according to EFSA GD App. H, where the 21-d f_{TWA} is estimated as the ratio between C_{max} and 21-d C_{TWA}. The pseudo-SFO-DT_{50} is then derived by back-calculation of the SFO DT_{50} that would correspond with the respective 21-d f_{TWA}. This pseudo-SFO-DT_{50} is calculated with the residue data after the second application, because the sampling after the first application was shorter than 21 days and because the back-calculation of the SFO-DT_{50} is not trivial for repeated applications.

Calculation tools: TWA calculations were conducted with MS Excel 2010.

II. RESULTS AND DISCUSSION

Table 8.9- 28: Calculation of 21-day f_{TWA}

Calculation of 21-d f_{TWA} for fluopyram in ground dwelling arthropods after the second application			
DALT	Replicate 1	Replicate 2	Replicate 3
1	0.15	0.14	0.10
2	*0.10*	*0.12*	*0.090*
3	0.062	0.10	0.078
4	*0.11*	*0.23*	*0.060*
5	0.16	0.36	0.043
6	*0.10*	*0.675*	*0.054*
7	0.038	0.99	0.065
8	*0.058*	*0.664*	*0.050*
9	*0.077*	*0.341*	*0.036*
10	0.097	0.018	0.021
11	*0.149*	*0.165*	*0.039*
12	*0.201*	*0.312*	*0.056*
13	*0.254*	*0.459*	*0.074*
14	0.31	0.61	0.092
15	*0.256*	*0.430*	*0.067*
16	*0.207*	*0.255*	*0.042*
17	0.16	0.079	0.017
18	*0.15*	*0.064*	*0.021*
19	*0.14*	*0.050*	*0.026*
20	*0.14*	*0.035*	*0.031*
21	0.13	0.020	0.036
21-d C_{TWA}	0.14	0.29	0.05
21-d C_{max}	0.31	0.99	0.10
21-d f_{TWA}	0.47	0.29	0.51

In *italics*: interpolated residue concentrations on days without sampling

SFO-DT_{50} (8.25, 4.35 and 9.35 days) that would result in 21-d f_{TWA} corresponding to the values determined for plots 1, 2 and 3 (0.47, 0.29 and 0.51) can be estimated by iterative back-calculation:

Table 8.9- 29: Calculation of DT_{50} and 21-day f_{TWA}

	Plot 1	Plot 2	Plot 3
DT_{50} [d]	**8.3**	**4.4**	**9.4**
k = ln(2)/DT_{50}	0.084	0.159	0.074
No. of applications	1	1	1
Interval [d]	n.a.	n.a.	n.a.
MAF	1.00	1.00	1.00
Averaging Time [d]	21	21	21
21-d f_{TWA}	**0.47**	**0.29**	**0.51**

Table 8.9- 30: Calculation of 21-day f_{TWA} and Pseudo SFO-DT_{50}

Ground dwelling invertebrates Residue data were not suitable for kinetic evaluation. Instead, a pseudo-SFO DT_{50} corresponding to the 21-d f_{TWA} (ratio between 21-d C_{TWA} and the C_{max}) may be considered (EFSA GD 2009, App. H). This assessment has not been done in the original report and is provided with this document.				
Replicate	**21d- $C_{TWA\ max}$ [mg/kg]**	**C_{max} [mg/kg]**	**21-d f_{TWA}**	**Pseudo SFO-DT_{50} [d]**
1	0.14	0.31	0.47	8.3
2	0.29	0.99	0.29	4.4
3	0.05	0.10	0.51	9.4

III. CONCLUSION

A field study with three invertebrate residue decline trials was conducted in pome fruit orchards in Germany during the 2017 season (M-644049-01-1). Two applications with Fluopyram + Tebuconazole SC 400 (200+200) were conducted. Due to the time course of the residue concentrations measured on ground dwelling invertebrates, no kinetic DT_{50} could be generated for this group in the original report. Therefore, pseudo-DT_{50} values are calculated here for fluopyram residues in this group, according to the procedure described in EFSA (2009), appendix H.

These pseudo-DT_{50} values for ground dwellers ranged from 4.4 to 9.4 days.

Assessment and conclusion by applicant: The study and its data are considered as acceptable and reliable for use in risk assessment. Pseudo-DT_{50} values for ground dwellers ranged from 4.4 to 9.4 days.

Data Point:	KCA 8.9/08
Report Author:	[redacted]
Report Year:	2018
Report Title:	Residue decline of fluopyram and tebuconazole on arthropods after spray applications in pome fruit orchards in Spain
Report No:	EBGM0106
Document No:	M-644048-01-1
Guideline(s) followed in study:	No official test guideline available for this type of study. The study was conducted under consideration of the EFSA Guidance Document on Risk Assessment for Birds & Mammals (EFSA 2009).
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

A field study with three invertebrate residue decline trials was conducted in pome fruit orchards in Spain during the 2017 season. Two applications with Fluopyram + Tebuconazole SC 400 (200+200), containing 200 g/L fluopyram and 200 g/L tebuconazole were conducted. Only the parameters and results relevant to fluopyram have been reported within this study summary.

The residues of fluopyram on foliage dwelling invertebrates (DT_{50}s 4.4-6.1d) and flying insects (DT_{50}s 3.8-4.9) declined during the sampling period. Calculation of a DT_{50} on ground invertebrates was not attempted (only calculation of C_{TWA}).

I. MATERIAL AND METHODS

Materials:

1. Test Item: Fluopyram + Tebuconazole SC 400 (200 + 200 g/L)

   Batch no.: EM4L021490

   Active Ingredient: Fluopyram and Tebuconazole

   Storage: 25°C +/-5°C, from +2°C to +30° C are also acceptable

   Expiry date: 2020-05-15

2. Sampled matrix: Invertebrates

   Crop: Apple orchards

METHODS

The purpose of the study was to determine the residue decline of fluopyram and tebuconazole following two applications (application interval: minimum 7 days) of the formulated product LUNA® Experience (SC formulation, containing 200 g/L fluopyram and 200 g/L tebuconazole) at a rate of nominal 0.25 L product/ha/m crown height in pome fruit orchards in Spain, following the recommendations of the guidance document on risk assessment for birds & mammals on request from EFSA. EFSA Journal 2009; 7(12):1438.

Study sites: The study was conducted in the vicinity of Figueres, province of Girona, Catalonia in northern Spain. Three pome fruit orchards with sizes of 1.62, 1.62 and 1.06 ha were selected.

Test item and application: The test item Luna® Experience was applied in each orchard at a nominal application rate of 0.25 L product/ha/m crown height, corresponding to nominal 50 g fluopyram and 50 g tebuconazole per ha and m crown height with a spray volume of 500 L tap water according to Good Laboratory Practice and Good Agricultural Practice. Two applications with an interval of 7 days in two orchards and 12 days in the third orchard were conducted. With the actual canopy height of 2.2 m, 1.9 m and 2.03 m for Replicate 1, 2 and 3 respectively, the nominal application rate was 110, 95 and 102 g a.s./ha.

Arthropod sampling: Ground dwelling arthropods were collected with pitfall traps, foliage dwelling arthropods by inventory spraying and flying insects with Malaise traps. Pitfall traps were placed within the apple rows, in the middle of two trees in an adequate, evenly distributed set-up. For inventory spraying, whole trees within the sample area were sprayed with a 'knock down' insecticide (Pyrethrum 5 EC®) at approx. 5 mL product in 1 L water with a motor driven knapsack sprayer (non-GLP application). Two Malaise traps per orchard were placed between the tree rows. Targeted biomass per sample was ≥ 1.5 g for all sampling methods.

Sampling period was until 21 days after the second application. After identification and quantification of the main taxonomic groups, the samples were stored deep frozen until residue analysis.

Residue analysis: All samples were analysed for their content of fluopyram and tebuconazole via HPLC-MS/MS. Residues are reported in terms of mg active substance/kg fresh weight (mg a.s./kg fw). The Limit of quantification (LOQ) value was 0.01 mg/kg. This summary focuses only on the residues of fluopyram.

Full details and acceptable validation data to support the analytical method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830 Rev.1

Data evaluation: In the report, time weighted average (TWA) concentrations over a 21 day period with a moving time window across the entire sampling period were calculated via interpolation of concentrations on days without residue data (not included in this summary). The residue concentrations were also expressed as RUDs in the report (not included in this summary because not intended for the risk assessment). Instead, the TWA concentrations on ground dwelling invertebrates after the second application are included in this summary because they may be employed to calculate a pseudo-DT_{50} as surrogate for a kinetic DT_{50} which cannot be derived from the residue data obtained in this group.

The residue decline (DT_{50}) of the active substance in arthropods was calculated to quantify the time course of the residue concentration in potential food items of insectivorous and omnivorous birds or mammals over time. The residue decline data were evaluated with a first-order kinetic (SFO) and additionally first-order multi compartment (FOMC) kinetic. To account for FOMC kinetics, Malaise trapping data were re-scaled to start on DALT 0 (day after last application) for both models.

The FOMC DT_{50} was back-calculated with $DT_{90}/3.32$ (EFSA GD for Birds and Mammals, Appendix H (2009)). The constant parameters α and β for FOMC would allow a more precise residue decline calculation than the back-calculation from the FOMC-DT_{90}. but this was not done within the scope of this report.

Due to fluctuations in residue decline, focus of best-fit evaluation was on visual judgement as acceptability criterion.

Calculation tools: TWA calculations were conducted with MS Excel 2010. DT_{50} calculation was performed with KinetcEval 1.0.3 (based on Bayer CropScience software KinGUI version 2.1).

II. RESULTS AND DISCUSSION

The measured residue values and the 21-d $C_{TWA\ max}$ are presented below. The 21-d $C_{TWA\ max}$ is calculated with a moving time window and with interpolated data on DAFTs/DALTs without residue data (DAFT=Day after first treatment, DALT=Day after last treatment). DAFT 10 on replicate 3 was not considered for TWA calculations.

Table 8.9- 31: Residues on foliage dwelling invertebrates

Residues of fluopyram on foliage dwelling invertebrates [mg/kg]			
DAFT/*DALT*	**Replicate 1**	**Replicate 2**	**Replicate 3**
-1*	<0.01	<0.01	<0.01
0	0.97	1.15	1.30
1	0.56	1.35	0.49
2	0.72	1.21	1.16
4	0.45	0.64	0.41
6	0.56	0.50	0.23
10	-	-	0.24
0	1.12	1.58	1.22
1	1.23	1.07	1.01
3	0.97	0.66	0.73
4	0.63	-	-
5	-	0.38	0.38
7	0.50	0.31	0.39
10	0.43	0.16	0.20
14	0.28	0.42	0.20
17	0.079	0.13	0.30
21	0.20	0.14	0.16

Table 8.9- 32: Residues on ground dwelling invertebrates

Residues of fluopyram on ground dwelling invertebrates [mg/kg]			
DAFT/*DALT*	Replicate 1	Replicate 2	Replicate 3
-1*	<0.01	<0.01	<0.01
1	0.062	0.19	0.056
2	0.20	0.11	0.11
4	0.078	0.088	0.073
6	0.064	0.12	0.072
10	-	-	0.046
1	0.34	0.29	0.15
3	0.21	0.25	0.045
4	0.14	-	-
5	-	0.095	0.028
7	0.26	0.046	0.083
10	0.030	0.086	0.064
14	0.096	0.046	0.035
17	0.083	0.052	0.048
21	0.14	0.089	0.020

Table 8.9- 33: Residues on flying insects

Residues of fluopyram on flying insects [mg/kg]			
DAFT/*DALT*	Replicate 1	Replicate 2	Replicate 3
-1*	<0.01	<0.01	<0.01
1	0.29	0.84	0.61
2	0.35	0.34	0.091
3	-	0.064	-
4	0.12	0.063	0.16
6	0.12	0.13	0.089
10	-	-	0.020
1	0.64	0.44	0.31
3	0.14	0.35	0.28
4	0.37	-	-
5	-	0.66	0.16
7	0.37	0.063	0.034
10	0.18	0.053	0.10
14	0.054	0.13	0.035
17	0.038	0.020	0.021
21	0.01	0.041	0.013

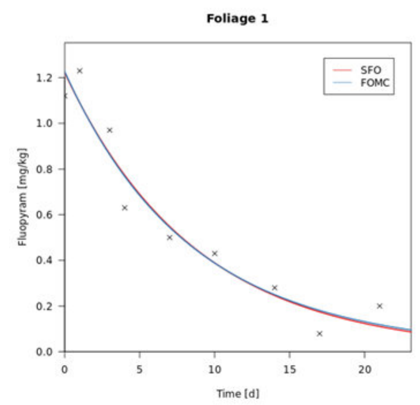
Table 8.9- 34: Kinetic evaluation of the residue decline of fluopyram on arthropods in pome fruit orchards after the second application

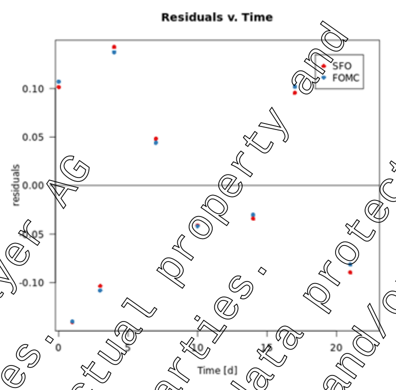
Fluopyram								
Replicate	**Kinetic model**	**DT_{50} (days)**	**DT_{90} (days)**	**chi² error**	**visual fit**	**α (FOMC)**	**β (FOMC)**	**t-test of k (SFO)**
Foliage dwellers								
1	SFO	**6.1**	20.1	12.74	+	-	-	<0.001
2	FOMC	**5.5**	18.2	13.74	+	0.9596	1.8203	-
3	SFO	**4.4**	14.8	16.07	+	-	-	<0.001
Flying insects								
1	SFO	**4.9**	16.3	40.17	o	-	-	0.0275
2	No acceptable kinetic fit							
3	SFO	**3.8**	12.5	23.87	+	-	-	0.0018
Ground dwellers								
1	No acceptable kinetic fit							
2	FOMC	**7.9**	26.1	27.28	o	1.0693	3.4342	-
3	No acceptable kinetic fit							

SFO = single first order (preferred where feasible)
FOMC = first order multi-compartment (Gustafson and Holden); $DT_{50} = DT_{90}/3.32$
k = rate constant for SFO; α, β = constant parameters for FOMC
+: good fit o: acceptable fit (small systematic deviation or large random scatter)

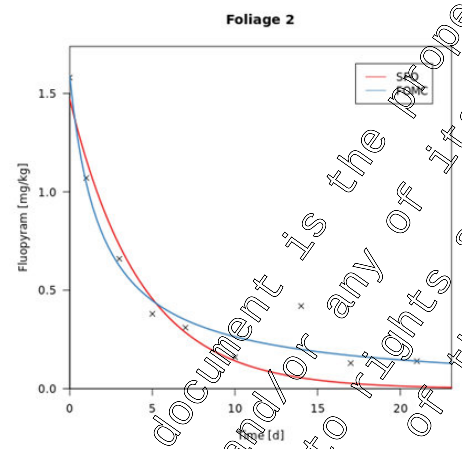
It should be noted that the constant parameters α and β for FOMC allow a more precise residue decline calculation than the back-calculation with FOMC-$DT_{50} = DT_{90}/3.32$ mentioned in the EFSA GD (2009).

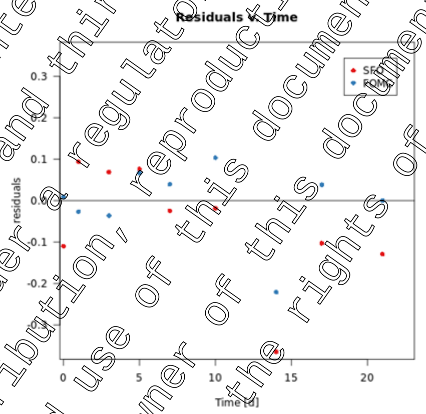
Figure 8.9- 47: Fitted SFO and FOMC decline curves and corresponding residuals for fluopyram on foliage dwellers



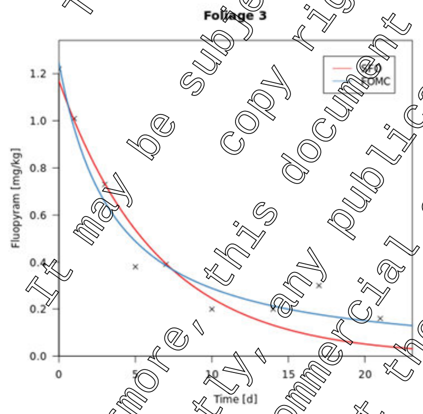


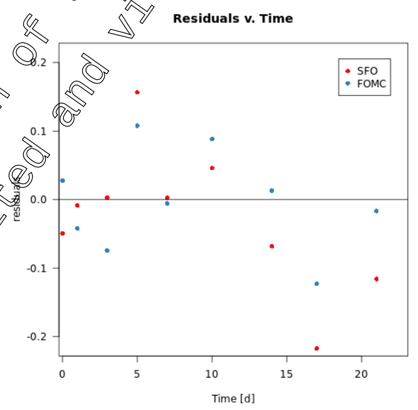
Foliage dweller on replicate 1; SFO and FOMC visually good fit





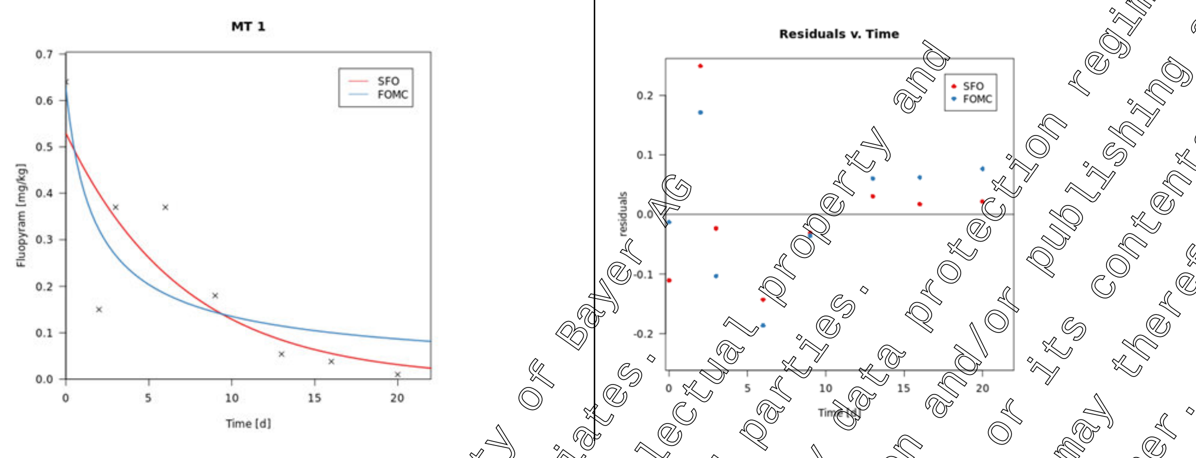
Foliage dweller on replicate 2, FOMC visually good fit



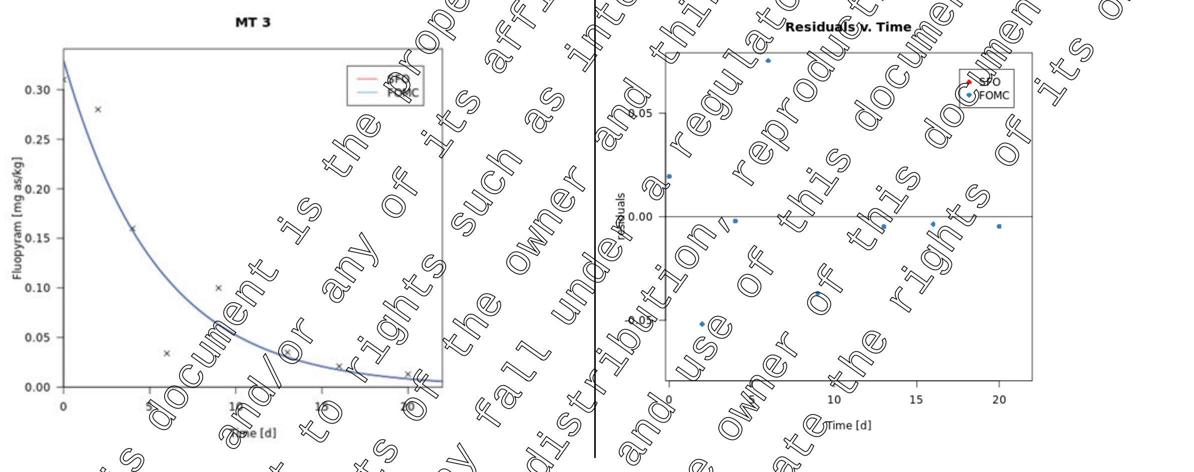


Foliage dweller on replicate 3; SFO visually good fit

Figure 8.9- 48: Fitted SFO and FOMC decline curves and corresponding residuals for fluopyram on flying insects after the second application

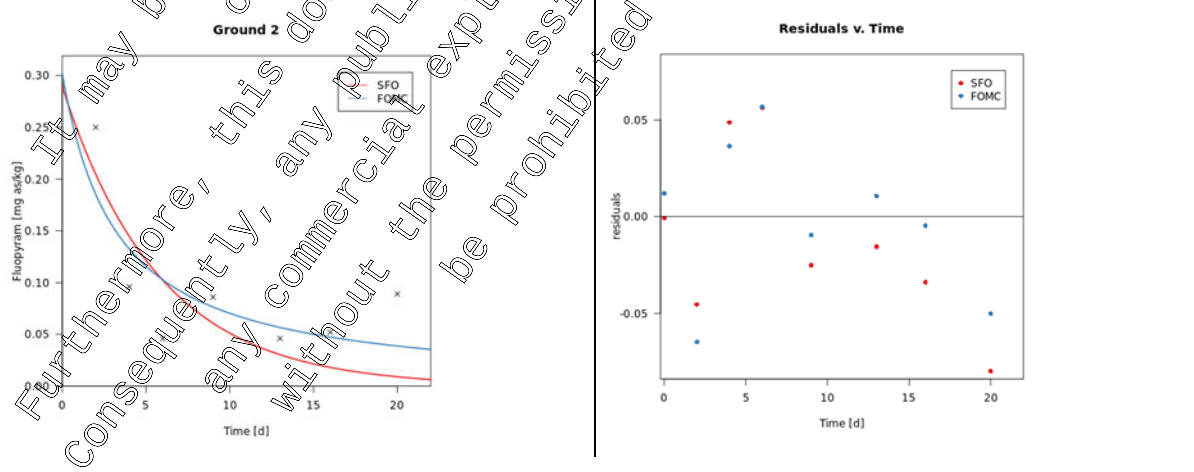


Malaise traps on replicate 1, SFO visually acceptable fit



Malaise traps on replicate 3, SFO and FOMC visually good fit

Figure 8.9- 49: Fitted SFO and FOMC decline curves and corresponding residuals for fluopyram on ground dwelling invertebrates after the second application



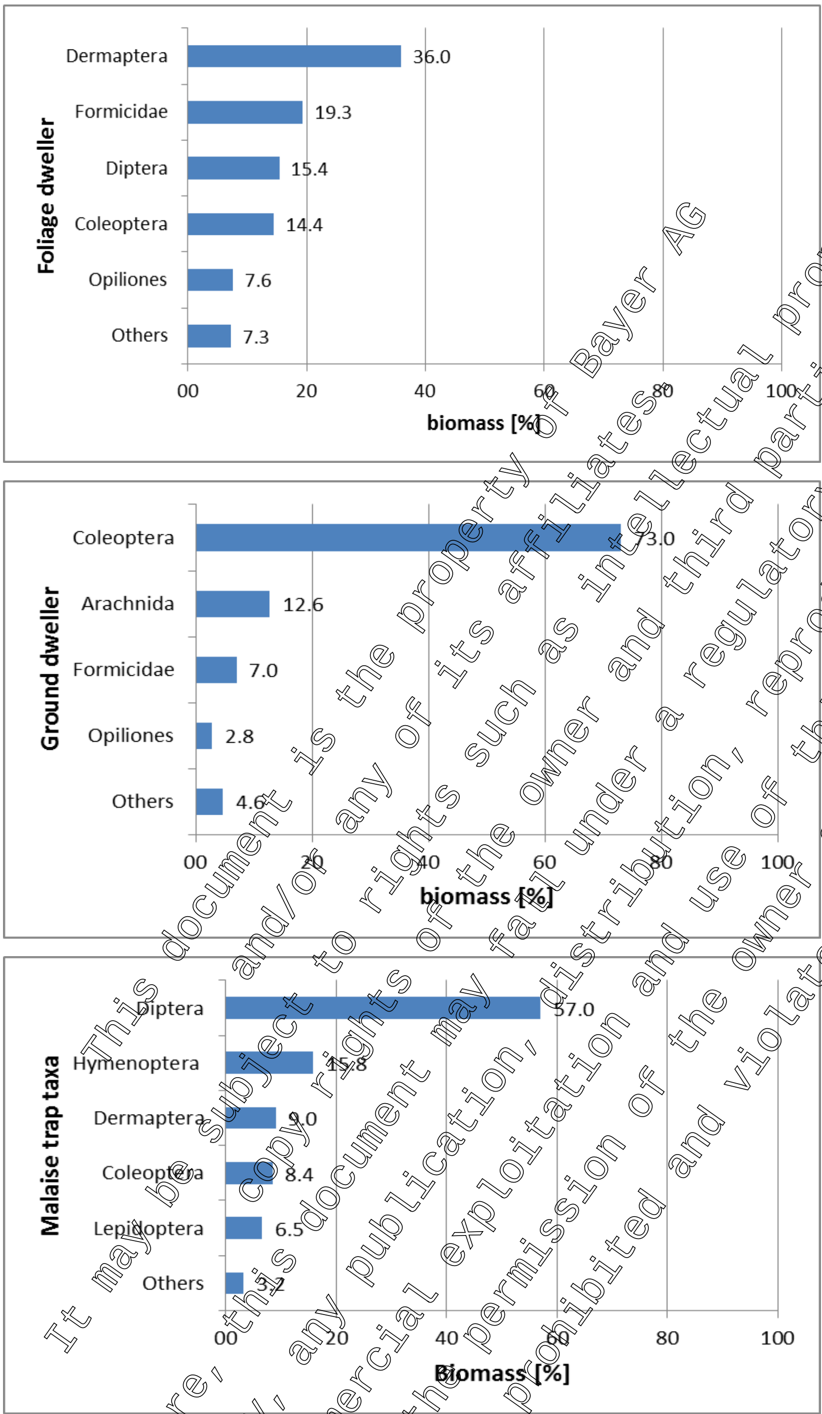
Ground dwellers on replicate 2, FOMC acceptable fit

Table 8.9- 35: Calculation of 21-d f_{TWA}

Calculation of 21-d f_{TWA} for fluopyram in ground dwelling arthropods after the 2nd application			
DALT	**Replicate 1**	**Replicate 2**	**Replicate 3**
1	0.34	0.29	0.15
2	*0.28*	*0.27*	*0.10*
3	0.21	0.25	0.045
4	0.14	*0.17*	*0.037*
5	*0.18*	0.095	0.028
6	*0.22*	*0.071*	*0.056*
7	0.26	0.046	0.083
8	*0.18*	*0.059*	*0.077*
9	*0.11*	*0.073*	*0.070*
10	0.030	0.086	0.064
11	*0.047*	*0.076*	*0.057*
12	*0.063*	*0.066*	*0.050*
13	*0.080*	*0.056*	*0.042*
14	0.096	0.046	0.035
15	*0.092*	*0.048*	*0.039*
16	*0.087*	*0.050*	*0.044*
17	0.083	0.052	0.048
18	*0.10*	*0.061*	*0.041*
19	*0.11*	*0.071*	*0.034*
20	*0.13*	*0.080*	*0.027*
21	0.14	0.089	0.020
21-d C_{TWA}	0.142	0.100	0.055

In *italics*: interpolated residue concentrations on days without sampling

Figure 8.9- 50: Arthropod composition



Note: Earwigs are not flying insects. Individuals climbed up the nets of the Malaise traps and were trapped in the collecting vessel. The term “flying insects” is however maintained in this summary because it applies to the vast majority of the trapped individuals.

Weather conditions

Time and amount of rainfall were similar at study orchards 1+2 and 3. No rainfall occurred after the first applications. During the time period, when the second applications were scheduled weather conditions became unstable with unpredictable thunderstorms. However, at all study sites very little precipitation was measured with maximum 4 mm. Total rainfall during the entire sampling phase was about 7 mm at both locations.

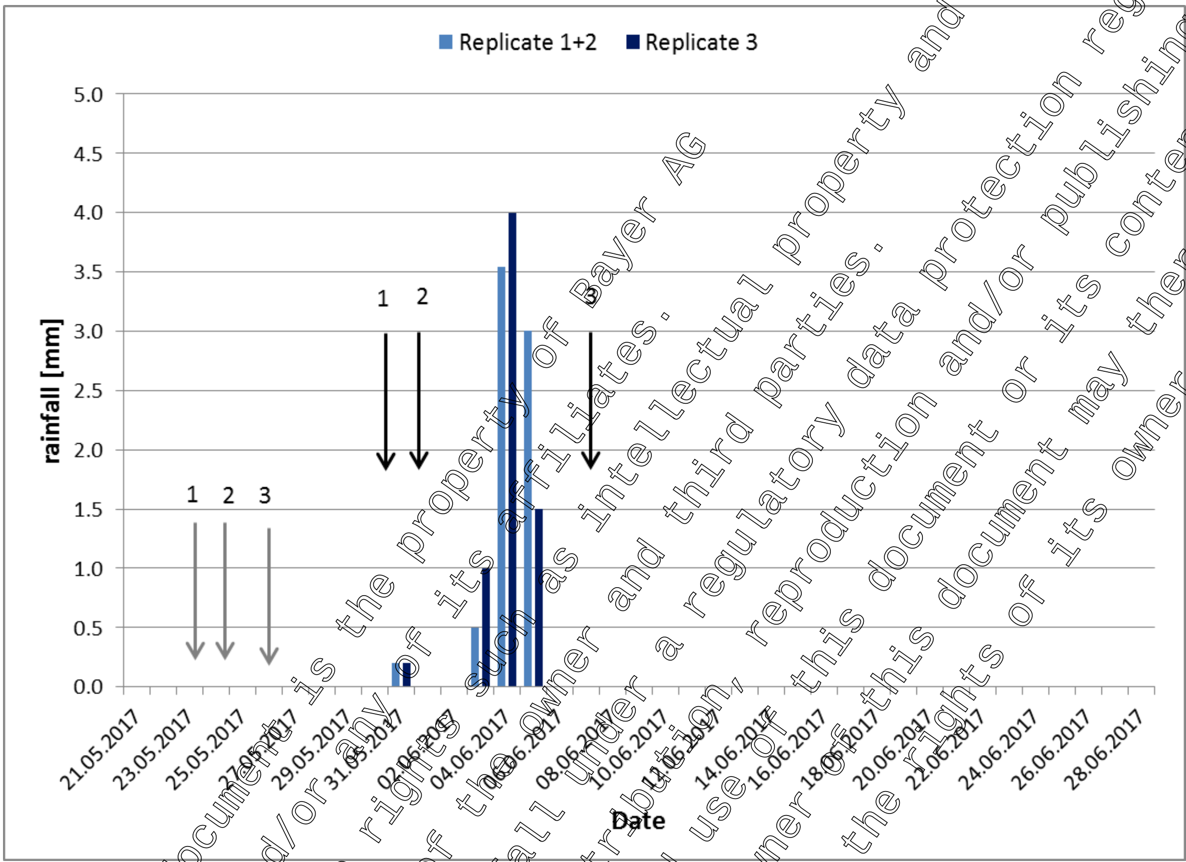


Figure 8.9- 51: Rainfall during the sampling phase

Grey arrows indicate the first application on Replicates 1 (23 May 2017), 2 (24 May 2017) and 3 (26 May 2017). Black arrows indicate the second application on Replicates 1 (30 May 2017), 2 (31 May 2017) and 3 (07 Jun 2017), respectively.

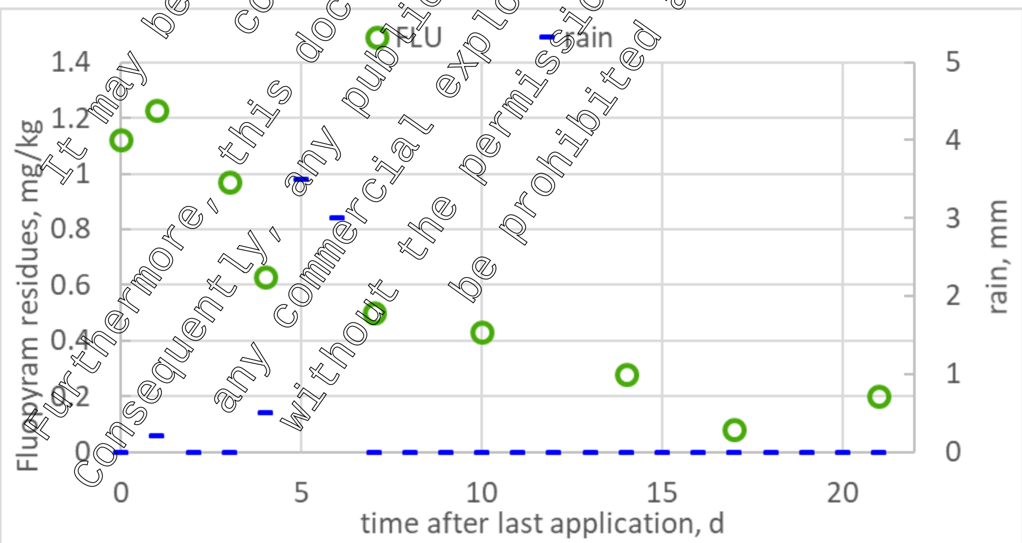


Figure 8.9- 52: Rainfall and residues for plot 1, foliage dwelling arthropods

No discernible influence of rainfall on the residue time course

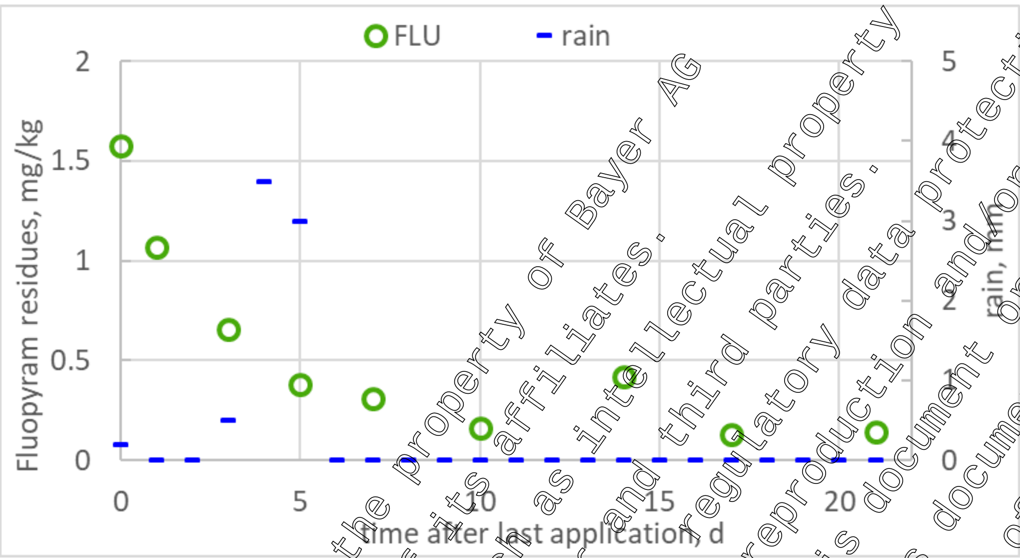


Figure 8.9- 53: Rainfall and residues for plot 2, foliage dwelling arthropods

No discernible influence of rainfall on the residue time course

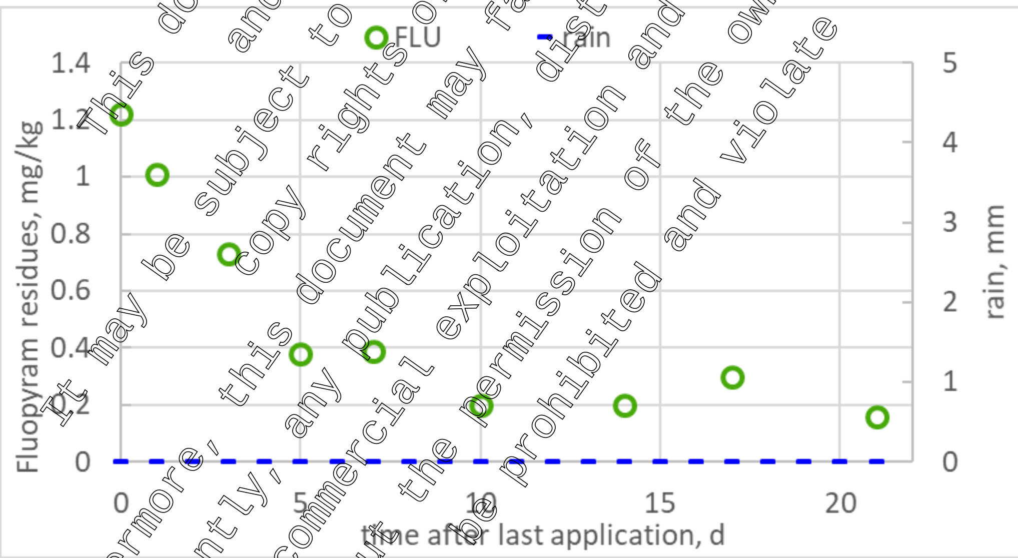


Figure 8.9- 54: Rainfall and residues for plot 3, foliage dwelling arthropods

No discernible influence of rainfall on the residue time course

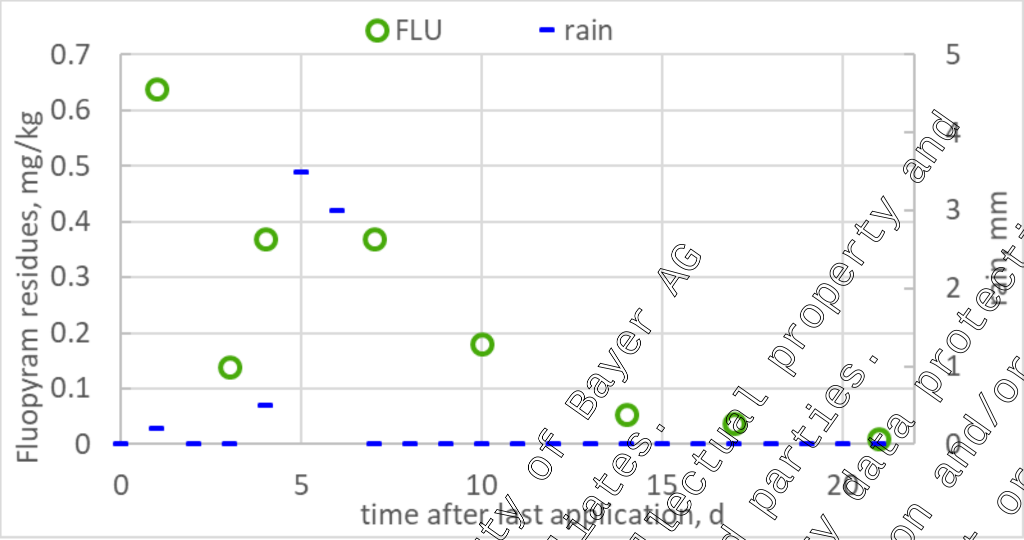


Figure 8.9- 55: **Rainfall and residues for plot 1, flying insects**

No discernible influence of rainfall on the residue time course.

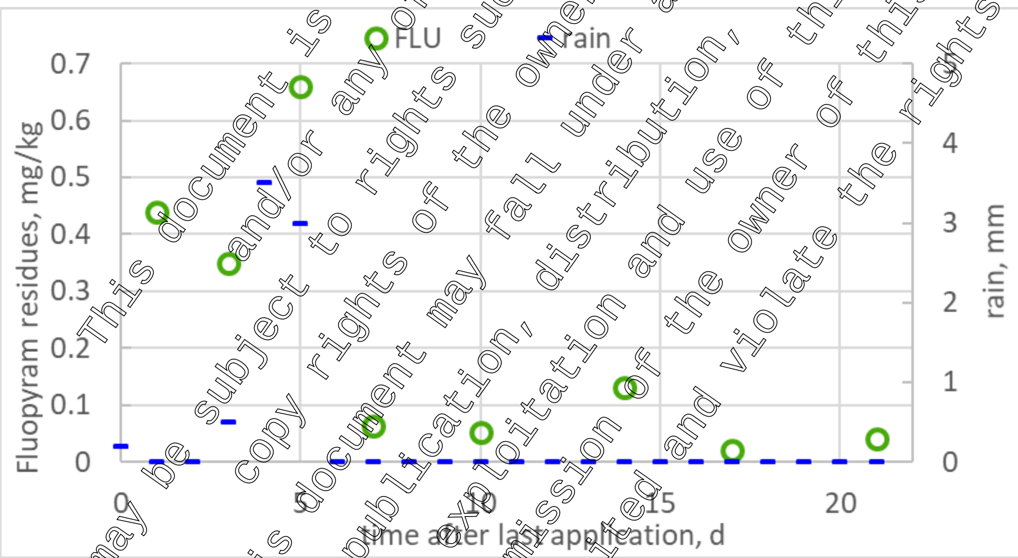


Figure 8.9- 56: **Rainfall and residues for plot 2, flying insects**

Rainfalls on day 4 and 5 coincide with a marked decline, influence possible.

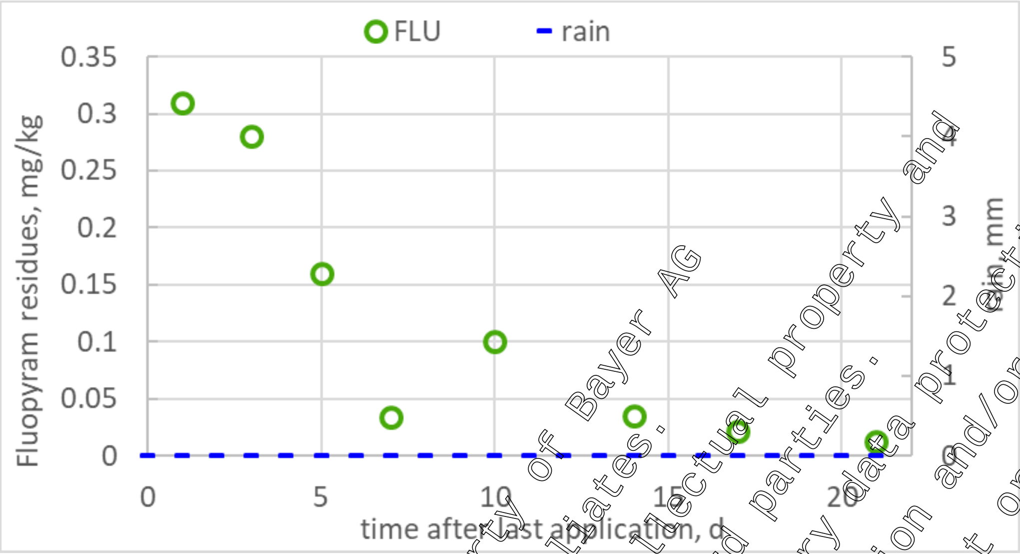


Figure 8.9- 57: **Rainfall and residues for plot 3, flying insects**

No discernible influence of rainfall on the residue time course

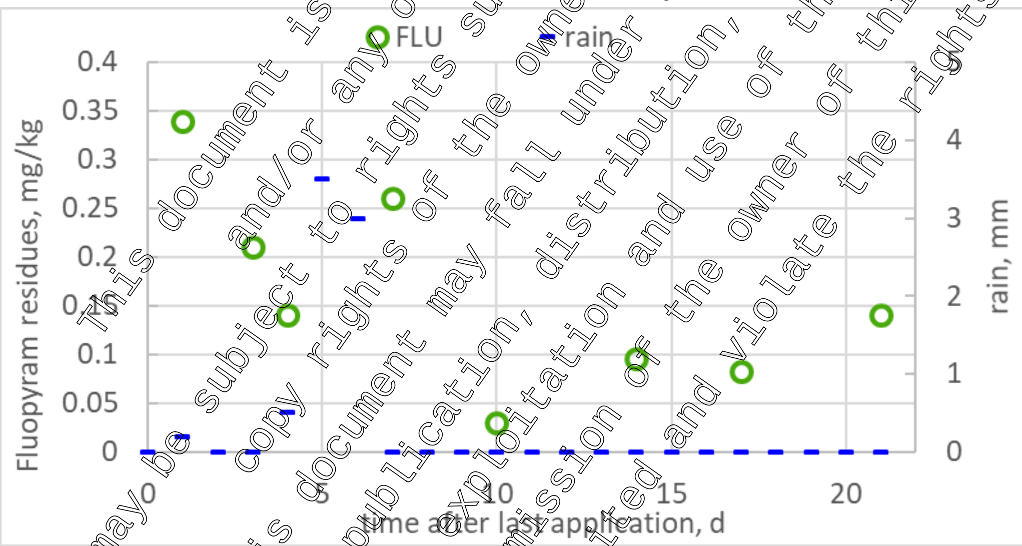


Figure 8.9- 58: **Rainfall and residues for plot 1, ground dwelling invertebrates**

No discernible influence of rainfall on the residue time course

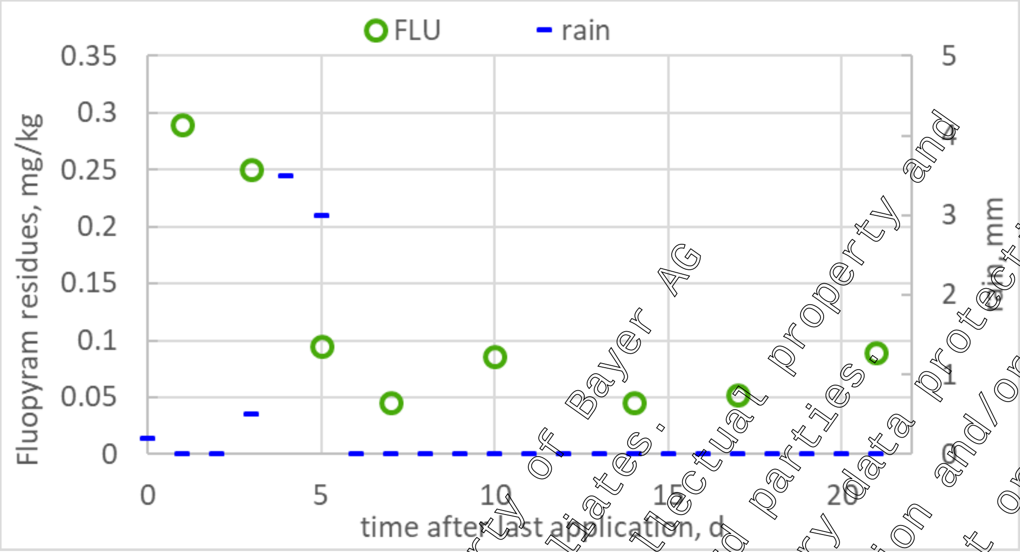


Figure 8.9- 59: Rainfall and residues for plot 2, ground dwelling invertebrates

Moderate rainfalls on days 4 and 5 coincide with a visible drop in residues, influence likely

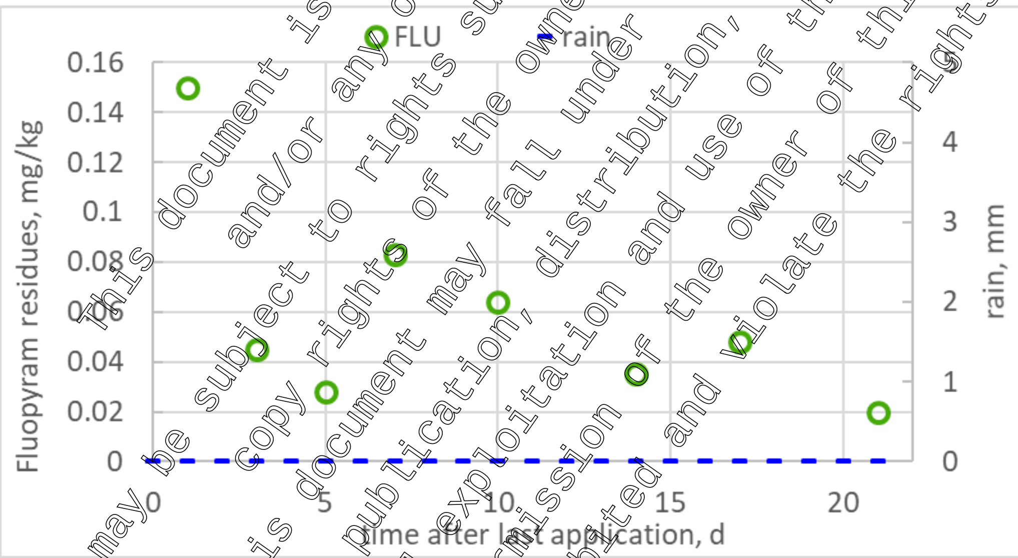


Figure 8.9- 60: Rainfall and residues for plot 3, ground dwelling invertebrates

No discernible influence of rainfall on the residue time course

III. Conclusion

The study provides realistic field residue data for fluopyram on invertebrates in pome fruit orchards following 2 applications with 110, 95 and 102 g a.s./ha.

Fluopyram concentrations fluctuated due to interaction of different influencing factors like sample compositions over time, food web interactions and in addition mobility of the arthropod communities.

SFO and FOMC DT_{50} values were calculated for residue data on arthropods. An acceptable fit for the use of DT_{50} values in risk assessments was determined by visual comparison of both kinetic models.

The FOMC DT_{50}s were back-calculated with $DT_{90}/3.32$ and represent a conservative approach for the residue decline. A more precise representation of the residue decline curve is obtained when the kinetic parameters α and β are employed in a suitable calculation program. However, this was not done within the scope of this report.

Taking into account the complexity of the interactions studied, the fit of most of decline curves was considered visually acceptable.

DT_{50}s with acceptable fits for fluopyram ranged from 4.4 to 6.1 days for foliage dwellers. For ground dwellers, one acceptable fit with 7.9 days was determined, and DT_{50}s of 3.8 and 4.9 days were considered acceptable for Malaise traps.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment.

DT_{50}s with acceptable fits for fluopyram ranged from 4.4 to 6.1 days for foliage dwellers. For ground dwellers, one acceptable fit with 7.9 days was determined, and DT_{50}s of 3.8 and 4.9 days were considered acceptable for Malaise traps.

Data Point:	KCA 8.9/09
Report Author:	[redacted]
Report Year:	2021
Report Title:	Calculation of pseudo-SFO-DT50 values for residues of fluopyram on ground-dwelling invertebrates in apple orchards in Spain
Report No:	EnSa-20-0890
Document No:	M-760160-02-1
Guideline(s) followed in study:	--
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	not applicable
Acceptability/Reliability:	Yes

EXECUTIVE SUMMARY

A field study with three invertebrate residue decline trials was conducted in pome fruit orchards in Spain during the 2017 season (M-644048-01-1). Two applications with the Fluopyram + Tebuconazole SC 400 (200+200), containing 200 g/L fluopyram and 200 g/L tebuconazole, were conducted. Due to the time course of the residue concentrations measured on ground dwelling invertebrates, no kinetic DT_{50} could be generated for this group for two of the three plots in the original report. Instead, pseudo-DT_{50}

values ranging 5.5-7.1 days, are calculated here for fluopyram on ground dwelling invertebrates, according to the procedure described in EFSA (2009), appendix H.

I. MATERIALS AND METHODS

A field study with three invertebrate residue decline trials was conducted in pome fruit orchards in Spain during the 2017 season (M-644048-01-1). Two applications with the Fluopyram + Tebuconazole SC 400 (200+200), containing 200 g/L fluopyram and 200 g/L tebuconazole, were conducted. The time course of the residues in ground dwelling invertebrates did not allow a kinetic evaluation for two of the three plots. Instead, calculation of a pseudo-DT_{50} for fluopyram is proposed according to EFSA GD App. H, where the 21-d f_{TWA} is estimated as the ratio between C_{max} and 21-d C_{TWA}. The pseudo-SFO-DT_{50} is then derived by back-calculation of the SFO-DT_{50} that would correspond with the respective 21-d f_{TWA}. This pseudo-SFO-DT_{50} is calculated with the residue data after the second application, because the sampling after the first application was shorter than 21 days and because the back-calculation of the SFO-DT_{50} is not trivial for repeated applications.

Calculation tools: TWA calculations were conducted with MS Excel 2010.

II. RESULTS AND DISCUSSION

Table 8.9- 36: Calculation of 21-d f_{TWA}

Calculation of 21-d f_{TWA} for fluopyram in ground dwelling arthropods after the 2nd application			
DALT	Replicate 1	Replicate 2	Replicate 3
1	0.34	0.29	0.15
2	*0.28*	*0.27*	*0.10*
3	0.21	0.25	0.045
4	0.14	*0.17*	*0.037*
5	*0.18*	0.095	0.028
6	*0.22*	*0.071*	*0.056*
7	0.26	0.046	0.083
8	*0.18*	*0.059*	*0.077*
9	*0.11*	*0.073*	*0.070*
10	0.030	0.086	0.064
11	*0.047*	*0.076*	*0.057*
12	*0.063*	*0.066*	*0.050*
13	*0.080*	*0.056*	*0.042*
14	0.096	0.046	0.035
15	*0.092*	*0.048*	*0.039*
16	*0.087*	*0.050*	*0.044*
17	0.083	0.052	0.048
18	*0.10*	*0.061*	*0.041*
19	*0.11*	*0.071*	*0.034*
20	*0.13*	*0.080*	*0.027*
21	0.14	0.089	0.020
21-d C_{TWA}	0.142	0.100	0.055
21-d C_{max}	0.34	0.29	0.15
21-d f_{TWA}	0.42	0.35	0.36

In *italics*: interpolated residue concentrations on days without sampling

Pseudo-SFO-DT_{50} (7.1, 5.5 and 5.8 days) that would result in 21-d f_{TWA} corresponding to the values determined for plots 1, 2 and 3 (0.42, 0.35 and 0.37) can be estimated by iterative back-calculation:

Table 8.9- 37: Calculation of 21-d f_{TWA} and DT_{50}

	Plot 1	Plot 2	Plot 3
DT_{50} [d]	**7.1**	**5.5**	**5.8**
$k = \ln(2)/DT_{50}$	0.098	0.126	0.120
No. of applications	1	1	1
Interval [d]	n.a.	n.a.	n.a.
MAF	1.00	1.00	1.00
Averaging Time [d]	21	21	21
21-d f_{TWA}	**0.42**	**0.35**	**0.37**

Table 8.9- 38: Calculation of Pseudo SFO-DT$_{50}$

Ground dwelling invertebrates				
Residue data in replicates 1 and 3 were not suitable for kinetic evaluation. Instead, a pseudo-SFO DT$_{50}$ corresponding to the 21-d f$_{TWA}$ (ratio between 21-d C$_{TWA}$ and the C$_{max}$) may be considered (EFSA GD 2009, App. H). This assessment has not been done in the original report and is provided with this document.				
Replicate	**21d-C$_{TWA\ max}$ [mg/kg]**	**C$_{max}$ [mg/kg]**	**21-d f$_{TWA}$**	**Pseudo SFO-DT$_{50}$ [d]**
1	0.142	0.34	0.42	7.1
2	0.100	0.29	0.35	5.5
3	0.055	0.15	0.36	5.8

The pseudo SFO-DT$_{50}$ of 5.5 days for replicate 2 according to EFSA (2008) App. H is lower than the back-calculated DT$_{50}$ from the FOMC-DT$_{90}$ (7.9 days) in the original report. However, this is a typical and systematic error (overestimation of the true DT$_{50}$) when using the FOMC-DT$_{90}$/3.32, as demonstrated by Ebeling & Hammel (2020 [1]) using the TWA calculator TREC which can employ the kinetic parameter α and β instead of the back-calculated FOMC-DT$_{50}$.

Using TREC with the kinetic FOMC parameter α = 1.0693 and β = 3.4342 from replicate 2 allows to generate a 21-d f$_{TWA}$ = 0.30, which is close to the 21-d f$_{TWA}$ = 0.35 used to estimate the pseudo-DT$_{50}$ of 5.5 days for replicate 2. Thus, the pseudo-SFO-DT$_{50}$s may be considered as acceptable estimates to calculate f$_{TWA}$ for other application scenarios than those in season (M-644048-01-1).

III. CONCLUSION

A field study with three invertebrate residue decline trials was conducted in pome fruit orchards in Germany during the 2017 season (M-644048-01-1). Two applications with Fluopyram + Tebuconazole SC 400 (200+200) were conducted. Due to the time course of the residue concentrations measured on ground dwelling invertebrates, no kinetic DT$_{50}$ could be generated for this group in the original report for two of the replicates. Therefore, pseudo-DT$_{50}$ values are calculated here for fluopyram residues in this group, according to the procedure described in EFSA (2009), appendix H.

These pseudo-DT$_{50}$ values for ground dwellers ranged from 5.5 to 7.1 days.

Assessment and conclusion by applicant:
The study and its data are considered as acceptable and reliable for use in risk assessment.
Pseudo-DT$_{50}$ values for ground dwellers ranged from 5.5 to 7.1 days.

[1] Ebeling M & Hammel K (2020) Evaluating plant residue decline data with KinGUII and TREC: results from case studies involving also non-SFO kinetic models. *Environ Sci Eur* 32, 116. https://doi.org/10.1186/s12302-020-00386-

Kinetic evaluation reports for residues in/on plant material for cereals and grass

Data Point:	KCA 8.9/10
Report Author:	[redacted]
Report Year:	2018
Report Title:	Fluopyram (FLU) - Kinetic evaluation of green plant residues in cereals
Report No:	EnSa-17-0484
Document No:	M-617837-01-1
Guideline(s) followed in study:	none
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

EXECUTIVE SUMMARY

Kinetic evaluations were conducted for the residue decline of fluopyram after application on young cereals. Additional to a standard evaluation using all data points of the residue decline of each trial (termed "for ecotoxicological purposes"), an alternative evaluation was performed in which only that part of a decline series was maintained which was not considered as marked influenced by rainfall (termed "for modelling purposes").
For the evaluation with all data points, 4 kinetic models were fitted (SFO, FOMC, DFOP and HS), with a preference for selecting SFO where the fit was considered visually and statistically acceptable. Otherwise, the best-fit of the other models was selected. To facilitate the use of the selected kinetic parameter, a surrogate SFO DT_{50} was estimated as DT_{90}/3.32 for the non SFO kinetics.
For the evaluation of the reduced data sets, only SFO kinetics were employed because the lower number of data points for each decline series typically prevented the use of non-SFO kinetics.
Geometric mean DT_{50} values for total trial periods ("for ecotoxicological purpose") and for periods without potential precipitation impact ("for modelling purpose") were 2.60 and 3.99 days, respectively.

The outcome of the evaluation for ecotoxicological purposes is presented below.

Table 8.9- 39: Dissipation parameters of fluopyram in green material of cereals, all residue data, for ecotoxicological purpose

	Kine-tic model	DT_{50} recalc	DT_{90} trigger	visual fit (link)	χ^2 error	k1 (DFOP, HS) / α (FOMC)	k2 (SFO/ DFOP, HS) / β (FOMC)	g_{fast} (DFOP) / t_b (HS)	DT_{50} 1 fast	DT_{50} 2 slow
		(d)	(d)		(%)	(1/d / -)	(1/d / d)	(- / d)	(d)	(d)
13-2950-01 Burscheid, DE	SFO	**1.95**	6.47	+	10.0		0.3557			
13-2950-02 Langförden, DE	HS	2.03	6.74	+	1.9	1.5450	0.1332	**0.995**	**0.45**	**5.20**
13-2950-03 Saint-Amand, BE	HS	1.20	3.99	+	2.8	1.6415	0.2310	**0.979**	**0.42**	**3.00**
13-2950-04 Middenmeer, NL	SFO	**1.25**	4.14	o	23.0		0.5566			
15-2952-01 Wieringerwerf, NL	SFO	**3.37**	11.2	+	8.6		0.2060			
15-2952-02 Vieille Maison, BE	SFO	**7.59**	25.2	o	12.8		0.0913			
15-2952-03 Andria, IT	SFO	**2.86**	9.51	+	12.1		0.2422			
15-2952-04 Brenes, ES	SFO	**4.19**	13.9	o	11.3		0.1655			
15-2953-01 Chambourg sur Indre, FR	HS	1.05	3.48	+	2.8	1.0098	0.2810	**1.818**	**0.69**	**2.47**
15-2953-02 Great Chishill, UK	SFO	**4.23**	14.1	o	18.1		0.1637			
15-2953-03 C. da Reitana, IT	SFO	**4.64**	15.4	o	12.7		0.1495			
Geomean [M]		**2.60**								

visual fit: + good, o acceptable, - not acceptable
DT_{50} recalc = DT_{90} trigger / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT_{90} trigger: time for first 90 % of residues to dissipate
DT_{50} 1 fast: = ln(2)/k1
DT_{50} 2 slow: = ln(2)/k2 (DFOP, HS)
[M] DT_{50} recalc used for geomean

I. MATERIALS AND METHODS

Fluopyram has been analysed in several crop residue decline studies in the field, based on total residues,

not only washable residues. Trials carried out on green material of cereals, spring barley and wheat, have been selected.
A spray application has been carried out in all trials. It took place in spring and early summer, March - June. Average temperatures ranged between 6.3 and 18.7°C.
The BBCH growth stages at application have been mainly 29 to 30, in a single case already starting from 24.
A kinetic modelling analysis of crop residue data of fluopyram was conducted using the software tool KinGUI 2.1, implementing the IRLS error model (Iteratively reweighted least square). The identification of the appropriate kinetic model, SFO, FOMC, DFOP or HS, is based primarily upon the recommendations given by FOCUS kinetics, i.e. detailed statistical analysis including visual assessment, χ^2 2 statistic, significance t-test and correlation analysis.

The kinetic evaluation can be appropriate for 2 different purposes:

1. In an ecotoxicological context, plant foliage residue trials are used to describe the dissipation or decline behaviour of fluopyram in potential food for birds and mammals. Dissipation curves can be used to estimate the exposure of herbivorous birds or mammals, mainly by calculating the area under the dissipation curve.

To allow for calculation of time weighted averaged residues or area under the curve, after single or multiple applications, it is most appropriate to use a full kinetic parameter set of SFO or biphasic models.

2. In general in a modelling context, for certain predictive leaching, soil or surface water models, a foliar half-life of a fluopyram on plant surfaces is needed which is valid in combination with a wash-off process. Such DT_{50} values can be estimated conservatively based on total residues, not only washable residues. There, the total green plant above soil surface should be analysed for its residues. However, the total residues in the plant should not be influenced or washed off by rain or irrigation during the evaluated period. Otherwise the decline might be caused by wash-off and not only by foliar dissipation.

II. RESULTS AND DISCUSSION

Based on the crop residue decline studies available, 11 trials have been identified for an appropriate foliar kinetic evaluation in green material of cereals. In this section all available residue data points per trial have been included in the evaluation.
One remaining trial needed to be disregarded, due to very scattering unrealistic residue data for reasons detailed in the original report.
The results of the kinetic evaluation for all crop residue decline studies are summarised in the table further below. Justifications for the appropriate fit are given there, if needed. Details and degradation curves of the kinetic evaluation for each trial are given in detail in the report.
In 8 of 11 trials, the SFO decay was considered visually and statistically acceptable and reasonably describing dissipation processes of fluopyram in green material of cereals.
In 3 of 11 trials, the hockey stick (HS) decay was considered visually and statistically most appropriate. In these, cases, the first fast phase was most likely caused by a significant rain event of equal or more than 9 mm at day 0 and day 1 after application. Nevertheless, such rain events will regularly occur under realistic environmental conditions and should be part of an ecotoxicological risk assessment.
In general it should be noted, that occasionally increased values of scaled error or t-test probability are often caused by the limited extent of the data available from individual trials.
In addition, it should be noted, that the slow phase of a DFOP or HS fit is often not appropriate for a solely use to describe the decline of a substance in foliage or insects. This might be obvious, if the slow phase is based mainly on a small portion of the totally degrading amount (< 25 %), which can be also reflected in the fact, that the slow degradation rate k2 is not significantly different from 0 (t-test).

Total residue data

Table 8.9- 40: Dissipation parameters of fluopyram in green material of barley, all residue data

Kinetic model	DT_{50} trigger	DT_{90} trigger	visual fit (link)	χ^2 error	k1 (DFOP, HS) / α (FOMC)	k2 (SFO, DFOP, HS) / β (FOMC)	g_{fast} (DFOP) / t_b (HS)	t-test of k1 / k2	DT_{50} 1 fast	DT_{50} 2 slow
	(d)	(d)		(%)	(1/d / -)	(1/d / d)	(- / d)		(d)	(d)
13-2950-01 Burscheid, DE										
SFO [E]	**1.95**	6.47	+	10.0		0.3557		< 0.001		**1.95**
FOMC	1.58	5.23	+	14.9	1985	4510		-	-	-
DFOP	1.95	6.47	+	12.0	0.3557	0.0112	1.0	0.011/ 0.417	1.95	62.0
HS	1.95	6.47	+	12.0	0.3557	0.0017	10.0	0.004/ 0.498	1.95	399.5
SFO visually and statistically good fit. DFOP, HS are de-facto SFO as well.										
13-2950-02 Langförden, DE										
SFO	0.61	2.04	-	29.1		1.1315		0.017		0.61
FOMC	0.13	7.49	+	5.8	0.4174	0.0302		-	-	-
DFOP	0.09	6.74	+	1.9	11.487	0.1332	0.7545	0.386/ 0.001	0.06	5.20
HS [E]	0.45	6.74	+	1.9	1.5450	0.1332	**0.995**	< 0.001	**0.45**	**5.20**
HS visually and statistically good fit, including t-tests										
13-2950-03 Saint-Amand, BE										
SFO	0.53	1.77	-	24.3		1.2998		0.006		0.53
FOMC	0.20	3.35	+	7.5	0.6586	0.1048		-	-	-
DFOP	0.08	3.99	+	2.8	13.845	0.2310	0.7486	0.427/ 0.001	0.05	3.00
HS [E]	0.42	3.99	+	2.8	1.6415	0.2310	**0.979**	< 0.001	**0.42**	**3.00**
HS visually and statistically good fit, including t-tests										
13-2950-04 Middenmeer, NL										
SFO [E]	**1.25**	4.14	o	23.0		0.5566		0.002		**1.25**
FOMC	1.01	3.56	o	27.6	2570	3750		-	-	-
DFOP	1.23	4.21	o	27.4	0.5700	1.625E-06	0.9901	0.157/ 0.5	1.22	>1000
HS	1.22	4.06	o	27.0	0.5672	0.2430	4.070	0.014/ 0.405	1.22	2.85
SFO visually and statistically acceptable fit; biphasic fits not better.										
15-2952-01 Wieringerwerf, NL										
SFO [E]	**3.37**	11.2	+	8.6		0.2060		< 0.001		**3.37**
FOMC	2.86	15.3	+	7.9	1.9150	6.5665		-	-	-
DFOP	2.85	13.1	+	8.1	0.8479	0.1528	0.2631	0.314/ 0.090	0.82	4.54
HS	2.70	13.2	+	7.0	0.2802	0.1533	2.195	0.007/ 0.019	2.47	4.52

Kinetic model	DT_{50} trigger	DT_{90} trigger	visual fit (link)	χ^2 error	k1 (DFOP, HS) / α (FOMC)	k2 (SFO, DFOP, HS) / β (FOMC)	g fast (DFOP) / t_b (HS)	t-test of k1 / k2	DT_{50} 1 fast	DT_{50} 2 slow
	(d)	(d)		(%)	(1/d / -)	(1/d / d)	(- / d)		(d)	(d)
SFO visually and statistically good, no significant improvement with biphasic fits										
15-2952-02 Vieille Maison, BE										
SFO [E]	**7.59**	25.2	°	12.8		0.0913		0.010		**7.59**
FOMC	7.57	26.3	°	13.9	18.631	199.7		-	-	-
DFOP	7.53	34.2	°	15.3	0.1028	2.248E-14	0.9275	0.483/ 0.500	6.74	>1000
HS	7.59	22.3	°	14.8	0.0638	0.1094	3	0.318/ 0.135	10.87	6.33
SFO visually and statistically acceptable, no improvement with biphasic fits										
15-2952-03 Andria, IT										
SFO [E]	**2.86**	9.51	+	12.1		0.2422		0.001		**2.86**
FOMC	2.86	9.51	+	13.0	6789	28030		-	-	-
DFOP	2.86	9.51	+	14.4	0.2422	2.22E-14	1	0.066/ < 0.001	2.86	>1000
HS	2.82	9.65	+	14.2	0.2638	0.2358	1	0.268/ 0.035	2.63	2.94
SFO visually and statistically good fit										
15-2952-04 Brenes, ES										
SFO [E]	**4.19**	13.9	°	11.3		0.1655		0.001		**4.19**
FOMC	4.19	13.9	°	12.2	5926	35800		-	-	-
DFOP	4.19	13.9	°	13.5	0.1655	0.0529	1	0.209/ < 0.001	4.19	13.10
HS	4.76	10.7	+	6.20	0.0300	0.2695	2.457	0.282/ 0.017	23.11	2.57
SFO visually and statistically acceptable. HS assumed a lag phase at beginning, which is not appropriate here.										
15-2953-01 Chambourg sur Indre, FR										
SFO	0.75	2.49	°	11.8		0.9248		< 0.001		0.75
FOMC	0.60	3.20		5.9	1.9218	1.3805		-	-	-
DFOP	0.64	3.18	+	5.5	1.3753	0.2324	0.8119	0.008/ 0.084	0.50	2.98
HS [E]	0.69	3.48	+	2.8	1.0098	0.2810	**1.818**	< 0.001/ 0.003	**0.69**	**2.47**
HS visually and statistically good fit, including t-tests										
15-2953-02 Great Chishill, UK										
SFO [E]	**4.23**	14.1	°	18.1		0.1637		0.010		**4.23**
FOMC	4.23	14.1	°	19.5	6354	38810		-	-	-

Kinetic model	DT50 trigger	DT90 trigger	visual fit (link)	χ^2 error	k1 (DFOP, HS) / α (FOMC)	k2 (SFO, DFOP, HS) / β (FOMC)	g fast (DFOP) / t_b (HS)	t-test of k1 / k2	DT50 1 fast	DT50 2 slow
	(d)	(d)		(%)	(1/d / -)	(1/d / d)	(- / d)		(d)	(d)
DFOP	4.23	14.1	o	21.5	0.1637	0.0642	1	0.340/ < 0.001	4.23	10.80
HS	4.76	8.70	+	11.7	0.0361	0.4090	3.365	0.297/ 0.062	19.18	1.69
SFO visually and statistically acceptable. HS assumed a lag phase at beginning, which is not appropriate here.										
15-2953-03 C. da Reitana, IT										
SFO [E]	**4.64**	15.4	o	12.7		0.1495		0.002		**4.64**
FOMC	4.59	15.9	o	13.7	18.84	122.4		-	-	-
DFOP	4.58	15.9	o	15.1	0.1981	0.1229	0.4185	0.495/ 0.494	3.50	5.64
HS	4.32	17.1	o	14.7	0.1757	0.1256	3	0.105/ 0.142	3.95	5.52
SFO visually and statistically acceptable, no improvement with biphasic fits										
15-2953-04 Kristoni village, Kilkis, Gr not evaluable due to scattering data, potentially samples mixed up in the field										

E best approach for ecotoxicological purpose
visual fit + good, o acceptable, - not acceptable
DT_{50} trigger time for first 50 % of residues to dissipate
DT_{90} trigger time for first 90 % of residues to dissipate
DT_{50} 1 fast = ln(2)/k1
DT_{50} 2 slow = ln(2)/k2 (DFOP, HS)

Residue data without precipitation impact

Table 8.9- 41: Dissipation parameters of fluopyram in green material of barley, without precipitation impact

Kinetic model	DT50 trigger	DT90 trigger	visual fit (link)	χ^2 error	k1 (DFOP, HS) / α (FOMC)	k2 (SFO, DFOP, HS) / β (FOMC)	g fast (DFOP) / t_b (HS)	t-test of k1 / k2	DT50 1	DT50 2
	(d)	(d)		(%)	(1/d / -)	(1/d / d)	(- / d)		(d)	(d)
13-2950-01 Burscheid, d0 - d2 excluded										
SFO [E]	**2.28**	7.57	+	10.1		0.3044		0.015		**2.28**
FOMC	2.28	7.57	+	12.7	7023	23070		-	-	-
DFOP	2.28	7.57	+	na	0.3044	0	1	na	2.28	na

Kinetic model	DT_{50} trigger	DT_{90} trigger	visual fit (link)	χ^2 error	k1 (DFOP, HS) / α (FOMC)	k2 (SFO, DFOP, HS) / β (FOMC)	g_{fast} (DFOP) / t_b (HS)	t-test of k1 / k2	DT_{50} 1	DT_{50} 2
	(d)	(d)		(%)	(1/d / -)	(1/d / d)	(- / d)		(d)	(d)
HS	2.32	7.04	+	na	0.2984	0.5190	6.114	na	2.32	1.34
SFO visually and statistically acceptable. Due to 4 data points only, DFOP and HS are not evaluable reliably.										
13-2950-02 Langförden, d0 excluded										
SFO [E]	**5.20**	17.3	+	3.2		0.1332		< 0.001		**5.20**
FOMC	5.20	17.3	+	3.5	18750	140700		-	-	-
DFOP	5.20	17.3	+	4.0	0.2765	0.1332	4.43E-14	na/ 0.096	2.51	5.20
HS	5.61	14.2	+	1.4	0.1136	0.1884	4.861	0.002/ 0.008	6.10	3.68
SFO visually and statistically good. HS shows visually and phenologically no improvement.										
13-2950-03 Saint-Amand, d0 excluded										
SFO [E]	**3.00**	9.97	+	5.6		0.2310		< 0.001		**3.00**
FOMC	3.00	9.97	+	6.2	5668	24540		-	-	-
DFOP	3.00	9.97	+	7.0	0.2310	0	1	0.051/ na	3.0	na
HS	3.00	infinite	+	7.0	0.2310	0	9.672	0.007/ na	3.0	na
SFO visually and statistically good fit.										
13-2950-04 Middenmeer, d0 - d1 excluded										
SFO [E]	**2.69**	8.93	+	8.8		0.2580		0.003		**2.69**
FOMC	2.69	8.93	+	10.1	10870	42110		-	-	-
DFOP	2.69	8.93	+	12.6	0.2580	2.22E-14	1	0.202/ < 0.001	2.69	> 1000
HS	2.91	8.00	+	5.2	0.0900	0.3163	1	0.403/ 0.087	7.70	2.19
SFO visually and statistically acceptable. HS assumed a lag phase at beginning, which is not appropriate here.										
15-2952-01 Wieringerwerf, d10 excluded										
SFO [E]	**3.44**	11.4	+	8.1		0.2016		0.001		**3.44**
FOMC	2.83	28.2	+	4.9	0.9204	2.5204		-	-	-
DFOP	2.68	> 1000	+	4.6	0.4427	2.232E-14	0.7201	0.188/ 0.5	1.57	> 1000
HS	2.47	19.2	+	3.1	0.2802	0.0933	2.739	0.006/ 0.044	2.47	7.43
SFO statistically and visually acceptable. HS statistically slightly better. However, as rain impact is already eliminated, biphasic behaviour is phenologically very unlikely, especially in comparison with other trials. Based on simplicity, SFO is considered appropriate.										
15-2952-02 Vieille Maison, B										

Kinetic model	DT50 trigger	DT90 trigger	visual fit (link)	χ^2 error	k1 (DFOP, HS) / α (FOMC)	k2 (SFO, DFOP, HS) / β (FOMC)	g fast (DFOP) / t_b (HS)	t-test of k1 / k2	DT50 1	DT50 2
	(d)	(d)		(%)	(1/d / -)	(1/d / d)	(- / d)		(d)	(d)
SFO [E]	**7.59**	25.2	○	12.8		0.0913		0.010		**7.59**
FOMC	7.57	26.3	○	13.9	18.631	199.7		-	-	-
DFOP	7.53	34.2	○	15.3	0.1028	2.248E-14	0.9275	0.483/ 0.500	6.74	>1000
HS	7.59	22.3	○	14.8	0.0638	0.1094	3	0.318/ 0.135	10.87	6.33
SFO visually and statistically acceptable, no improvement with biphasic fits										
15-2952-03 Andria, d7 - d10 excluded										
SFO [E]	**3.47**	11.52	+	7.1		0.1998		0.006		**3.47**
FOMC	3.17	69.33	++	5.6	0.5881	1.4101		-	-	-
DFOP	3.34	14.36	++	5.97	2694	0.1459	0.1864	na/0.109	2.6E-4	4.75
HS	3.47	11.52	+	10.1	0.1998	2.22E-14	2095	0.097/ < 0.001	3.47	>1000
SFO visually and statistically acceptable. FOMC or DFOP not more appropriate due to worse t-test.										
15-2952-04 Brenes, d11 excluded										
SFO [E]	**4.52**	15.0	○	9.7		0.1534		0.004		**4.52**
FOMC	4.52	15.0	○	10.7	5061	32987		-	-	-
DFOP	4.52	15.0	○	12.2	0.1534	0.0817	1	0.428/ < 0.001	4.52	8.48
HS	4.52	14.0	○	12.2	0.1534	0.1773	7.651	0.037/ < 0.001	4.52	3.91
SFO visually and statistically acceptable, no improvement with biphasic fits										
15-2953-01 Chambourg sur Indre, d0 - d1 excluded										
SFO [E]	**2.47**	8.20	+	9.3		0.2810		0.003		**2.47**
FOMC	2.47	8.20	+	10.6	7192	25590		-	-	-
DFOP	2.47	8.20	+	13.3	0.2810	2.22E-14	1	0.192/ < 0.001	2.47	>1000
HS	2.47	8.20	+	13.3	0.2810	0.8228	25.4	0.081/ < 0.001	2.47	0.84
SFO visually and statistically good fit. DFOP and HS result de facto in SFO.										
15-2953-02 Great Chishill, d7 - d10 excluded										
SFO [E]	**9.12**	30.3	○	9.6		0.0760		0.110		**9.12**
FOMC	493.9	> 1000	-	10.4	0.0828	0.1143		-	-	-

Kinetic model	DT_{50} trigger	DT_{90} trigger	visual fit (link)	χ^2 error	k1 (DFOP, HS) / α (FOMC)	k2 (SFO, DFOP, HS) / β (FOMC)	g_{fast} (DFOP) / t_b (HS)	t-test of k1 / k2	DT_{50} 1	DT_{50} 2
	(d)	(d)		(%)	(1/d / -)	(1/d / d)	(- / d)		(d)	(d)
DFOP	12.7	49.8	○	12.7	10820	0.0434	0.1331	< 0.001/ 0.388	6.4E-5	15.98
HS	7.62	22.5	○	13.6	0.0760	0.1084	4.093	0.268/ < 0.001	9.12	6.40
SFO visually and statistically acceptable. Scattering data set, no improvement with biphasic fits. Day3 data point might be an outlier, but was not eliminated here.										
15-2953-03 C. da Reitana, I										
SFO [E]	**4.64**	15.4	○	12.7		0.1495		0.002		**4.64**
FOMC	4.59	15.9	○	13.7	18.84	122.4			-	-
DFOP	4.58	15.9	○	15.1	0.1981	0.1229	0.4185	0.495/ 0.494	3.50	5.64
HS	4.32	17.1	○	14.7	0.1757	0.1256	3	0.105/ 0.142	3.95	5.52
SFO visually and statistically acceptable, no improvement with biphasic fits										
15-2953-04 Kristoni village, Kilkis, Gr not evaluable due to scattering data, potentially samples mixed up in the field										

E best approach for ecotoxicological purpose
visual fit + good, o acceptable, - not acceptable
DT_{50} trigger time for first 50 % of residues to dissipate
DT_{90} trigger time for first 90 % of residues to dissipate
DT_{50} 1 fast = ln(2)/k1
DT_{50} 2 slow = ln(2)/k2 (DFOP, HS)

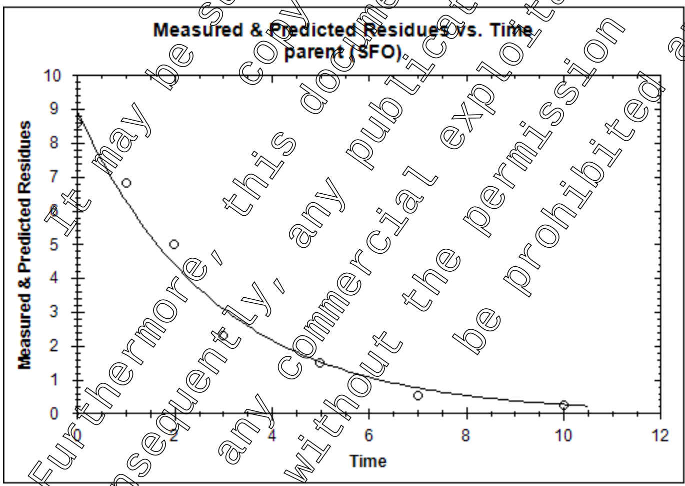


Figure 8.9- 61: Dissipation of fluopyram in cereals in Burscheid, 13-2950-01, all residue data (mg/kg)

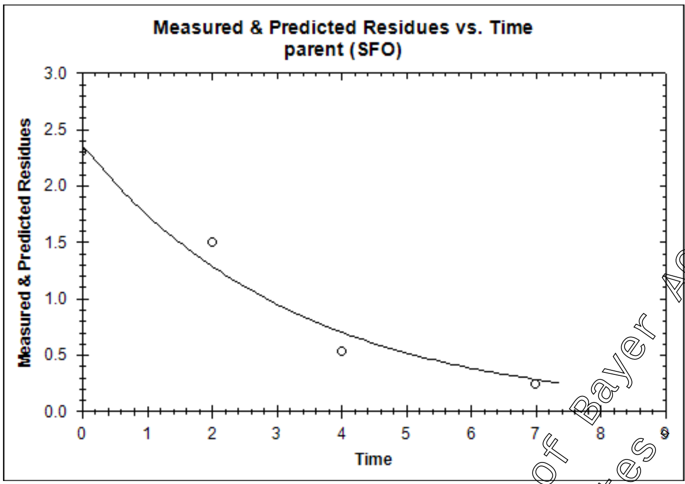


Figure 8.9- 62: **Dissipation of fluopyram in cereals in Burscheid, 13-2950-01, without precipitation impact (mg/kg)**

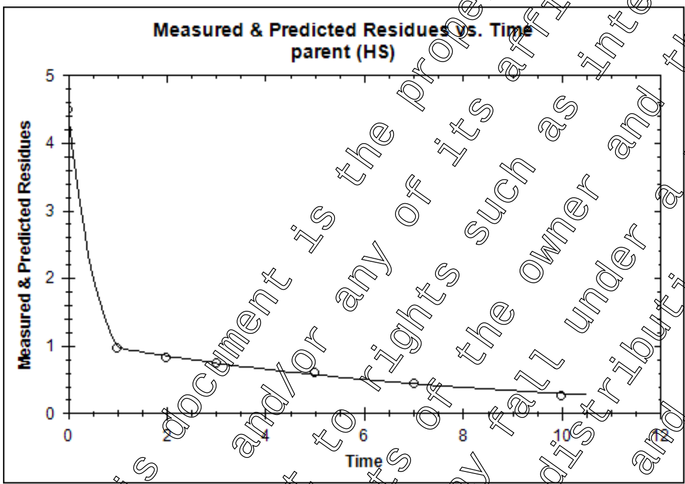


Figure 8.9- 63: **Dissipation of fluopyram in cereals in Langförden, 13-2950-02, all residue data (mg/kg)**

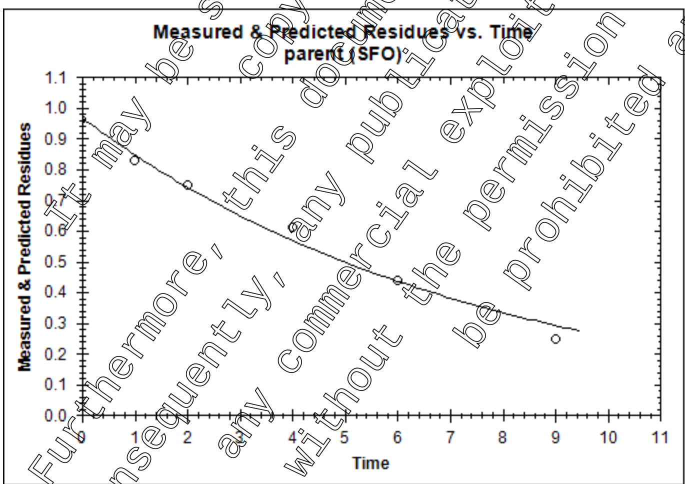


Figure 8.9- 64: **Dissipation of fluopyram in cereals in Langförden, 13-2950-02, without precipitation impact (mg/kg)**

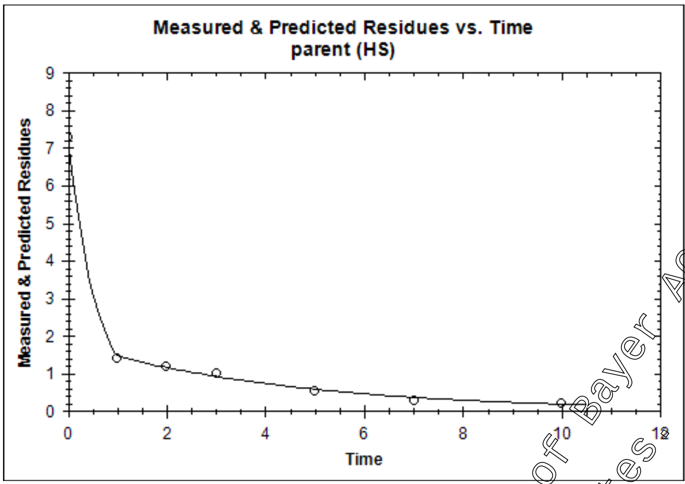


Figure 8.9- 65: Dissipation of fluopyram in cereals in Saint-Amand, 13-2950-03, all residue data (mg/kg)

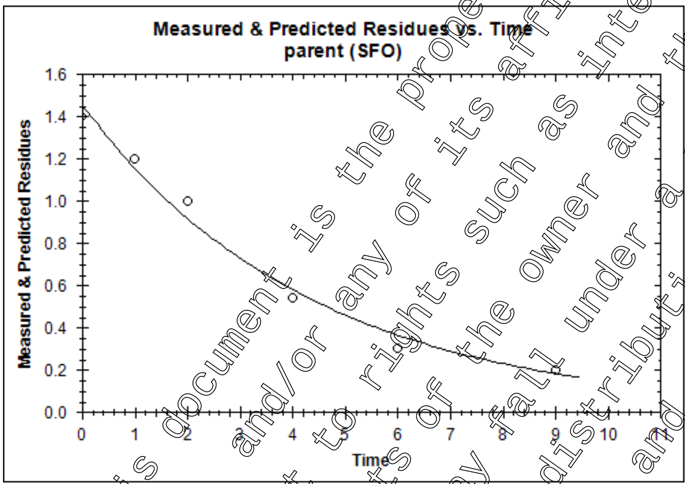


Figure 8.9- 66: Dissipation of fluopyram in cereals in Saint-Amand, 13-2950-03, without precipitation impact (mg/kg)

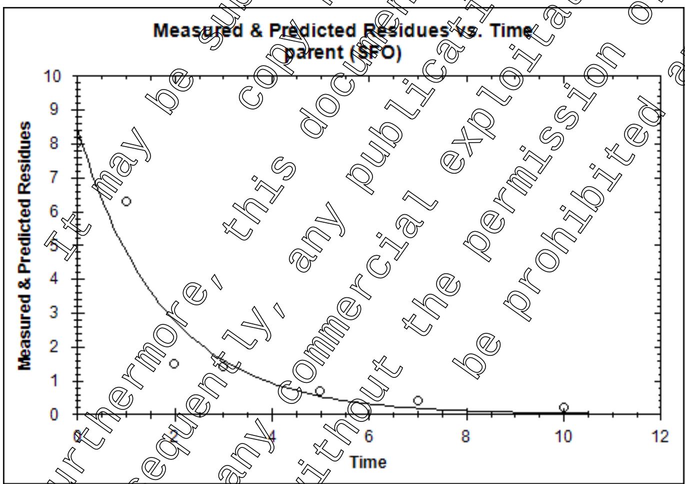


Figure 8.9- 67: Dissipation of fluopyram in cereals in Middenmeer, 13-2950-04, all residue data (mg/kg)

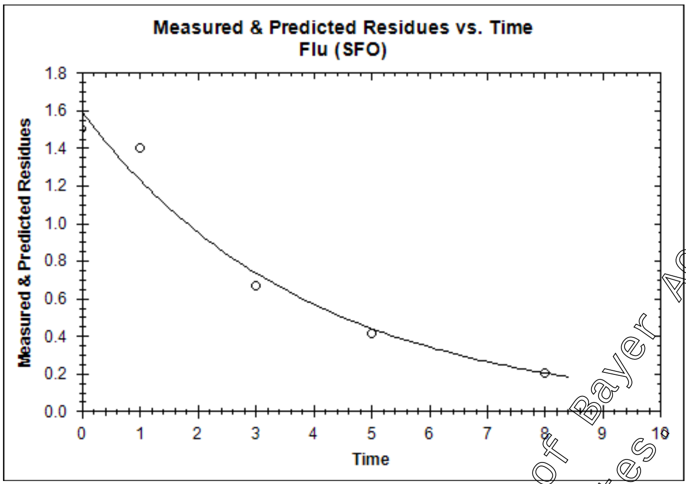


Figure 8.9- 68: Dissipation of fluopyram in cereals in Middenmeer, 13-2950-04, without precipitation impact (mg/kg)

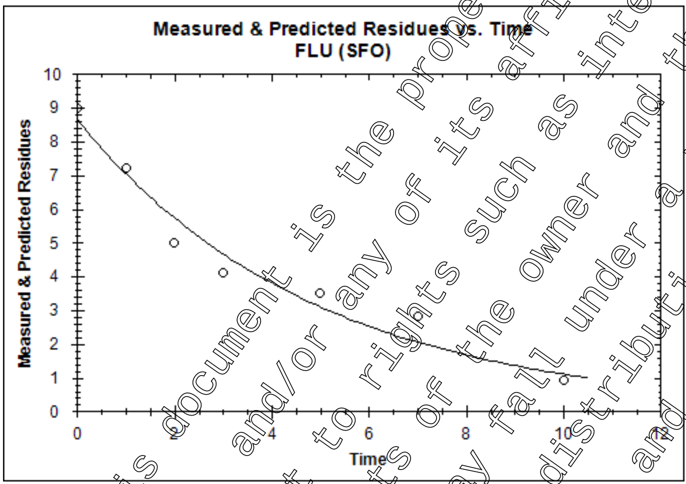


Figure 8.9- 69: Dissipation of fluopyram in cereals in Wieringerwerf, 15-2952-01, all residue data (mg/kg)

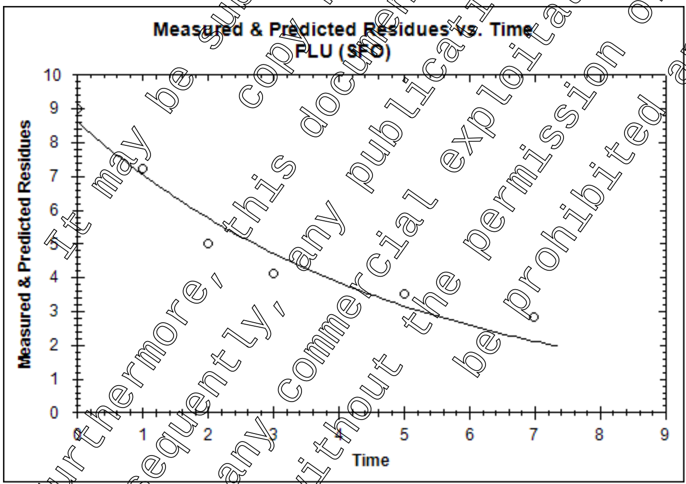


Figure 8.9- 70: Dissipation of fluopyram in cereals in Wieringerwerf, 15-2952-01, without precipitation impact (mg/kg)

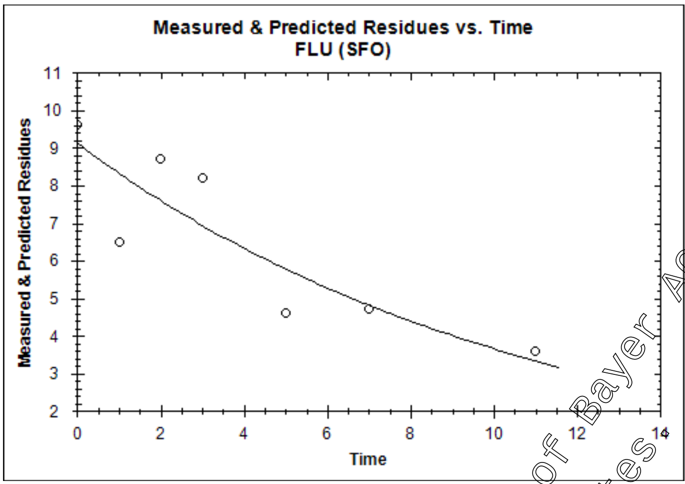


Figure 8.9- 71: Dissipation of fluopyram in cereals in Vielle Maison, 15-2952-02, all residue data, without precipitation impact (mg/kg)

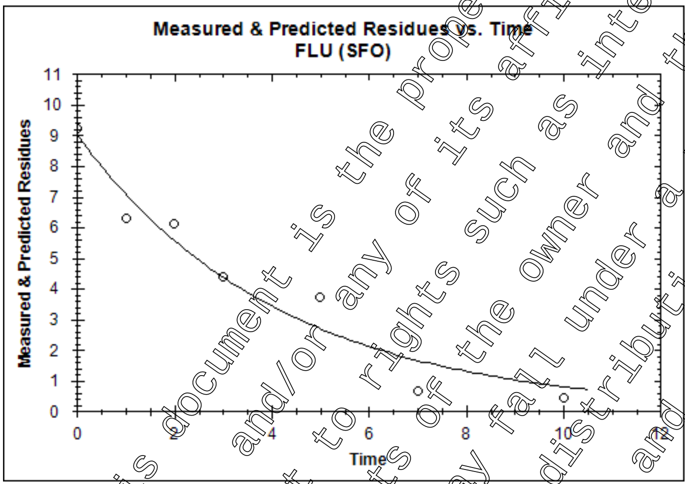


Figure 8.9- 72: Dissipation of fluopyram in cereals in Andria, 15-2952-03, all residue data (mg/kg)

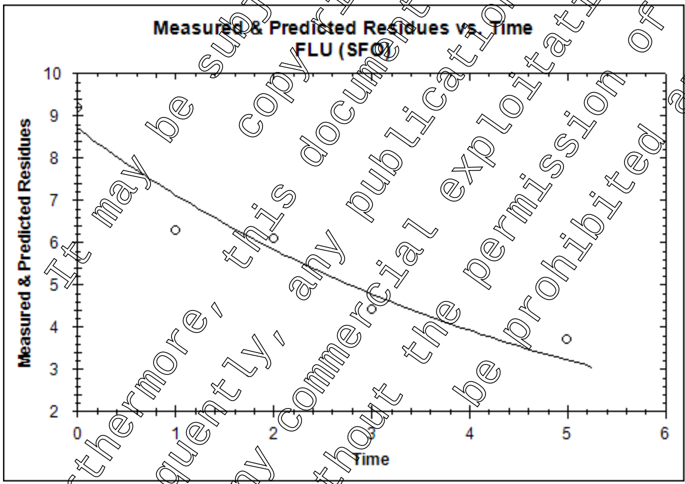


Figure 8.9- 73: Dissipation of fluopyram in cereals in Andria, 15-2952-03, without precipitation impact (mg/kg)

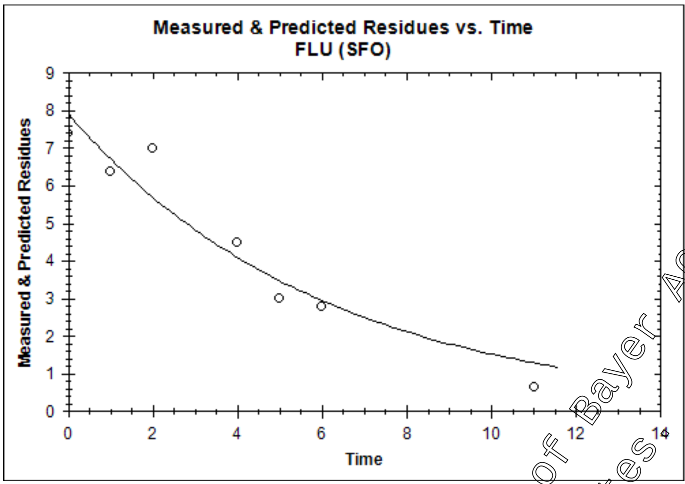


Figure 8.9- 74: Dissipation of fluopyram in cereals in Brenes, 15-2952-04, all residue data (mg/kg)

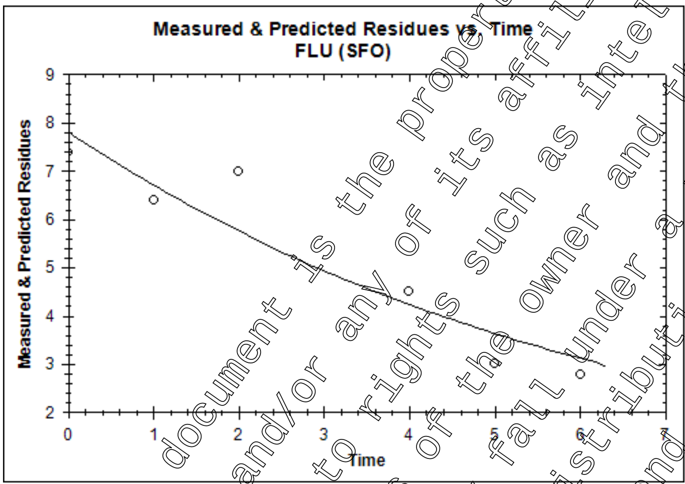


Figure 8.9- 75: Dissipation of fluopyram in cereals in Brenes, 15-2952-04, without precipitation impact (mg/kg)

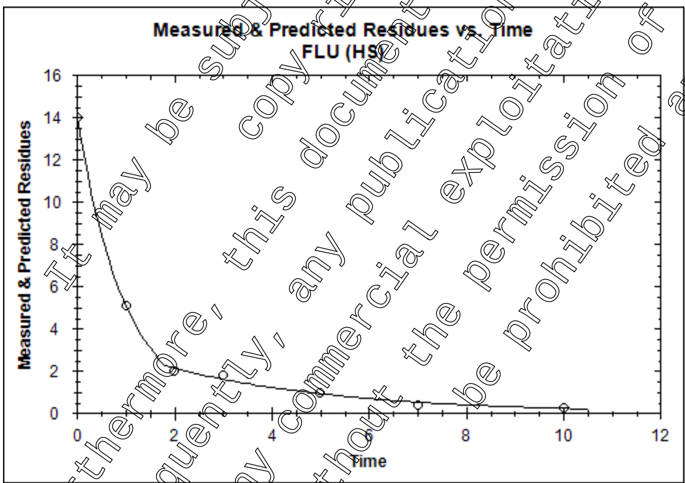


Figure 8.9- 76: Dissipation of fluopyram in cereals in Chambourg sur Indre, 15-2953-01, all residue data (mg/kg)

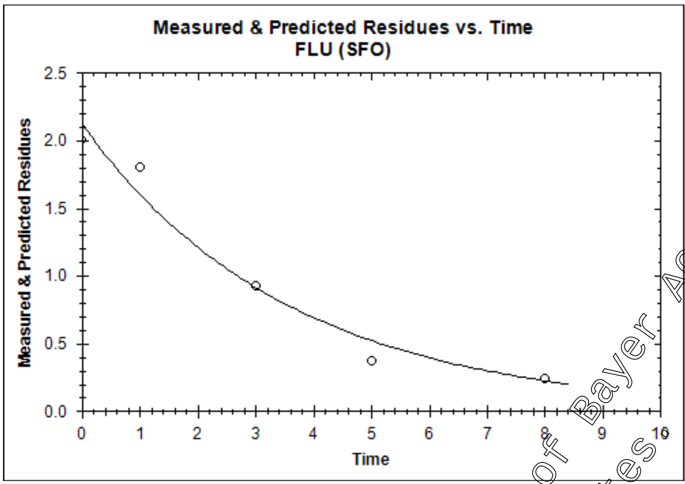


Figure 8.9- 77: Dissipation of fluopyram in cereals in Chambourg sur Indre, 15-2953-01, without precipitation impact (mg/kg)

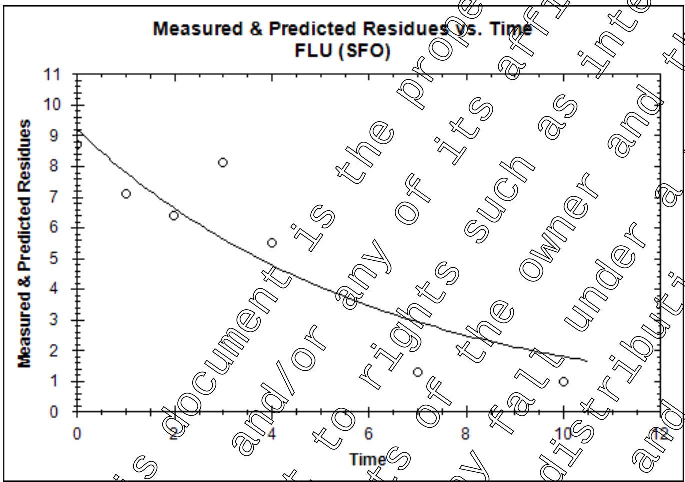


Figure 8.9- 78: Dissipation of fluopyram in cereals in Great Chishill, 15-2953-02, all residue data (mg/kg)

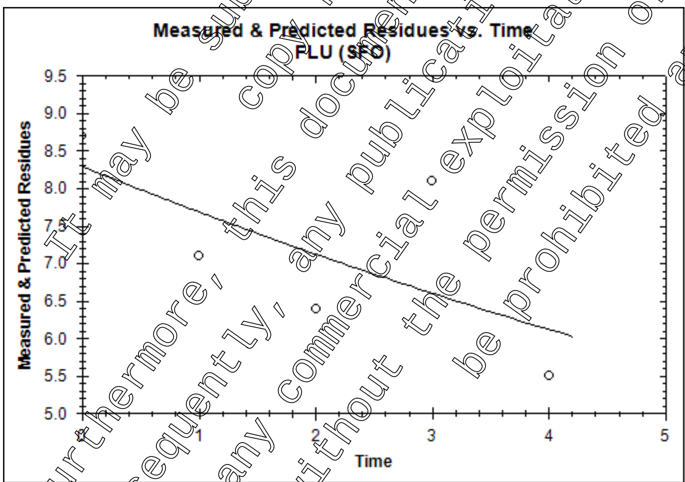


Figure 8.9- 79: Dissipation of fluopyram in cereals in Great Chishill, 15-2953-02, without precipitation impact (mg/kg)

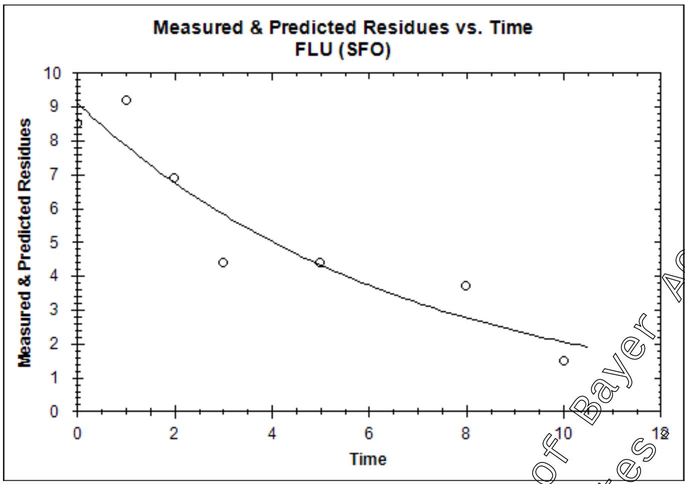


Figure 8.9- 80: Dissipation of fluopyram in cereals in C. da Reitana, 15-2953-03, all residue data, without precipitation impact (mg/kg)

III. CONCLUSION

Based on evaluations of foliar half-lives of fluopyram for total trial periods, as well as evaluations without a potential precipitation impact, geometric mean DT_{50} values for total trial periods ("for ecotoxicological purpose") and for periods without potential precipitation impact ("for modelling purpose") were 2.60 and 3.99 days, respectively.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment.

The geometric mean DT_{50} for ecotoxicological purpose (all data) for 11 trials on young cereals was 2.60 days for fluopyram.

Data Point:	KCA 8.9/11
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolite - Kinetic evaluation of green plant residues in young wheat, applying Propulse (SE250 FLU+PTZ)
Report No:	EnSa-20-0834
Document No:	M-763188-01-1
Guideline(s) followed in study:	not applicable
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

EXECUTIVE SUMMARY

Kinetic evaluations were conducted for the residue decline of fluopyram after application on young cereals. For the evaluation, 4 kinetic models were fitted (SFO, FOMC, DFOP and HS), with a preference for selecting SFO where the fit was considered visually and statistically acceptable. Otherwise, the best-fit of the other models was selected. To facilitate the use of the selected kinetic parameter, a surrogate SFO DT_{50} was estimated as DT_{90}/3.32 for the non SFO kinetics.
In total, 14 trials were evaluated (6 trials where only fluopyram was analysed plus 8 trials where also the metabolite fluopyram-benzamide was included as analyte).
The geometric mean of the DT_{50} for fluopyram alone was 4.178 days (n=14).
Additionally, an evaluation was made of the decline kinetics of the combined residues of fluopyram and its metabolite fluopyram-benzamide (for the 8 trials where the metabolite was included as analyte).
In these 8 trials, where the metabolite was included as analyte, the geometric mean DT_{50} of fluopyram alone was 4.820 days and the geometric mean DT_{50} of the combined residue was 4.821 days. Thus, the contribution of the metabolite fluopyram-benzamide is negligible for risk assessment.

The outcome of the evaluations is presented below.

Table 8.9- 42: Comparison of foliar DT_{50s} of fluopyram and fluopyram + FLU-benzamide in green material of young cereals

Fluopyram and FLU + FLU-benzamide	Foliar dissipation, residue decline studies in young cereals			
Trial	**EU zone**	**Kinetic model**	**DT_{50} FLU (d)**	**DT_{50} FLU + benzamide (d)**
18-2951-01, Burscheid, DE, M-678413-01-1	N	SFO	2.747	
18-2951-02, Eschau, DE, M-678413-01-1	N	SFO	3.214	-
18-2951-03, Mellet, BE, M-678413-01-1	N	SFO	3.523	-
18-2954-01, Fonfria, ES, M-675129-02-1	S	SFO	4.201	-
18-2954-02, Torralba de los Frailes, ES, M-675129-02-1	S	SFO	3.599	-
18-2954-03, Smilets, BG, M-675129-02-1	S	SFO	3.607	-
E19RP087-01, Bouloc, FR, M-758649-01-1	S	SFO	10.18	*10.18*
E19RP087-02, Antequera, ES, M-758649-01-1	S	SFO	1.782	*1.782*
E19RP087-03, Cento, IT, M-758649-01-1	S	SFO	3.415	*3.415*
E19RP087-04, Gravina di Puglia, IT, M-758649-01-1	S	SFO	2.956	*2.956*
E19RP102-01 Athee sur Cher, FR, M-758824-01-1	N	SFO	6.419	*6.419*
E19RP102-02, Great Chishill, Near Royston, GB, M-758824-01-1	N	SFO	8.185	*8.185*
E19RP102-03, Burscheid, DE, M-758824-01-1	N	SFO	7.010	7.027
E19RP102-04 Roellbach, DE, M-758824-01-1	N	FOMC	4.319	*4.319*
Geomean			**4.178 (n=14)**	**4.821 (n=8) [a)]**

DT_{50} = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed

a) geomean of n = 8 as in the other trials 6 trials FLU-benzamide was not analysed. For a better estimation of the relaive contribution from the metabolite to the combined DT_{50}, compare only the 8 trials where the metabolite was analysed. There the geometric mean DT_{50} for fluopyram alone was 4.820 days and the geometric mean DT_{50} for the combined residues was 4.821 days, suggesting that the metabolite contributes less than 1% to the exposure.

I. MATERIALS AND METHODS

A kinetic modelling analysis of European total crop residue decline study data of fluopyram (FLU) and fluopyram + fluopyram-benzamide (FLU-benzamide, M25) was conducted in order to derive kinetic parameters suitable for an ecotoxicological risk assessment, e.g. on birds and mammals, using the software tool KinGUI 2.1. The identification of the appropriate kinetic model followed the recommendations given by FOCUS Kinetics for modelling purpose (FOCUS kinetics, 2006, 2014) and EFSA (2019), based on a detailed statistical analysis including visual assessment, χ^2 statistic, significance t-test and correlation analysis.

In an ecotoxicological context, plant foliage residue trials are used to describe the dissipation or decline behaviour of fluopyram in potential food for birds and mammals. Dissipation curves can be used to estimate the exposure of herbivorous birds or mammals, mainly by calculating the area under the dissipation curve.

To allow for calculation of time weighted averaged residues or area under the curve, after single or multiple applications, it is most appropriate to use a full kinetic parameter set of SFO or biphasic models.

The modelling analysis is based on European crop residue data on green plant material of young wheat (cereals), after spray application of Propulse (SE250 FLU+PTZ). All available residue data points per trial starting with the last application have been included in the evaluation. The plant metabolite fluopyram-benzamide has been analysed in some of the trials, but not always detected > LOD. Foliar DT_{50} values are carried out for fluopyram, and in cases, where FLU-benzamide was detected > LOD, also for the sum of fluopyram and FLU-benzamide.

Trials took place in both regulatory zones (N- and S-EU) with a timely variance from March - May. The BBCH growth stages at application have been 28 - 30 (wheat).

Daily temperature and precipitation data (rain + irrigation over leaf surfaces, e.g. by sprinkler) are reported (e.g. based on raw data or publicly available weather station data).

In general, all 4 model fits have been carried out, but only those graphs are presented which are needed for model decision.

II. RESULTS AND DISCUSSION

The following units are used in the following tables:

Confidence Interval (CI)	same unit as parameter itself
initial mass M0	mg/kg plant
k	1/d
β, tb	d
α, g	none

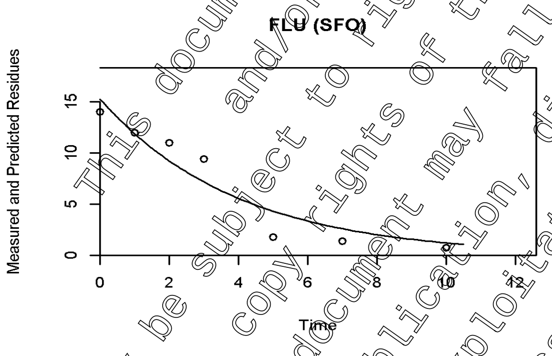
Fluopyram

2951-01, Burscheid, M-678413-01-1, DE, wheat, Propulse

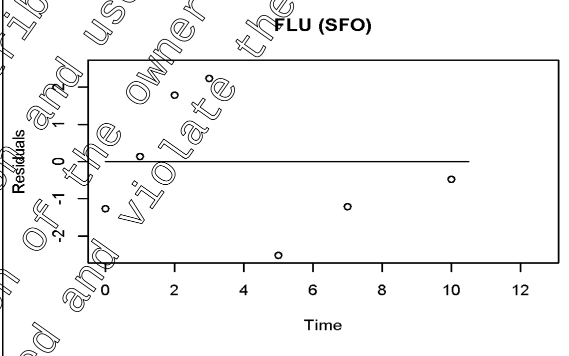
Table 8.9- 43: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial 18-2951-01, Burscheid, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	15.3	k: 0.25232	17.7	k: 0.003	k: 0.14	k: 0.36	**2.747**	9.13
FOMC	o	15.3	α: 8104.414 β: 32116.588	19.1	-	β: 31196.24	β: 33036.94	2.747	9.13
DFOP	o	15.3	k1: 0.2523 k2: 2.22e-14 g: 1.0	21.0	k1: 0.114 k2: <0.001	k1: -0.08 k2: 0.00	k1: 0.58 k2: 0.00	2.747	9.13
HS	o	15.3	k1: 0.25232 k2: 0.02997 tb: 10.718	21.0	k1: 0.019 k2: <0.001	k1: 0.11 k2: 0.03	k1: 0.39 k2: 0.03	2.747	9.13

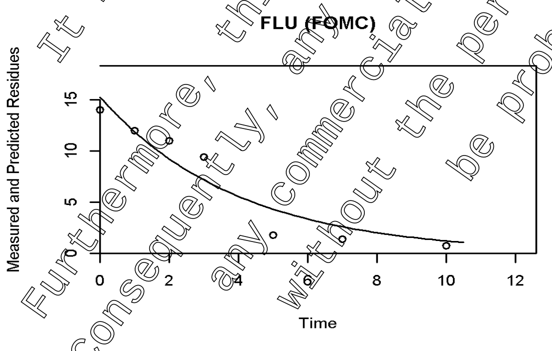
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2 err is slightly > 15 %, which is mainly reflecting the scattering data. FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



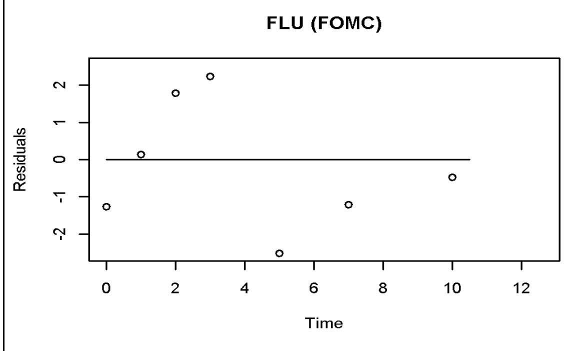
SFO



SFO



FOMC



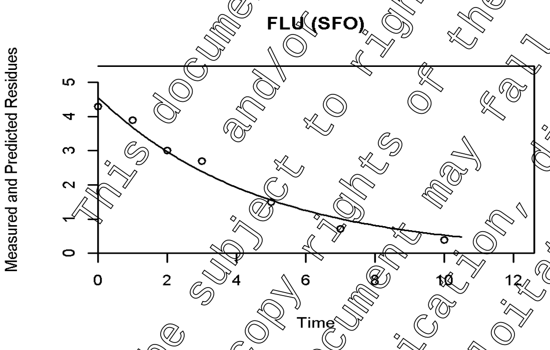
FOMC

18-2951-02, Eschau, M-678413-01-1, DE, wheat, Propulse

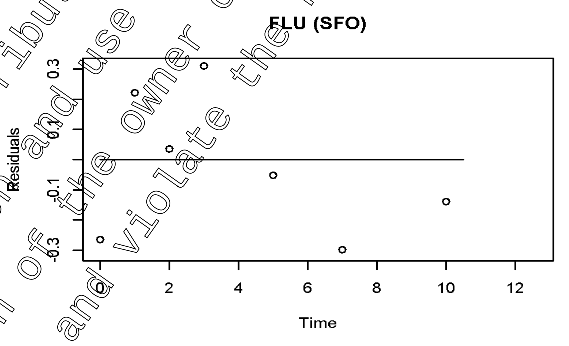
Table 8.9- 44: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial 18-2951-02, Eschau, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	4.6	k: 0.21565	7.3	k: <0.001	k: 0.17	k: 0.26	**3.214**	10.68
FOMC	+	4.6	α: 587200 β: 2723000	7.9	-	β: 2723000	β: 2723000	3.214	10.68
DFOP	+	4.6	k1: 0.2157 k2: 2.22e-14 g: 1.0	8.7	k1: 0.032 k2: <0.001	k1: 0.07 k2: 0.00	k1: 0.36 k2: 0.00	3.214	10.68
HS	+	4.6	k1: 0.21565 k2: 0.31308 tb: 13.11	8.7	k1: 0.002 k2: <0.001	k1: 0.16 k2: 0.31	k1: 0.27 k2: 0.31	3.214	10.68

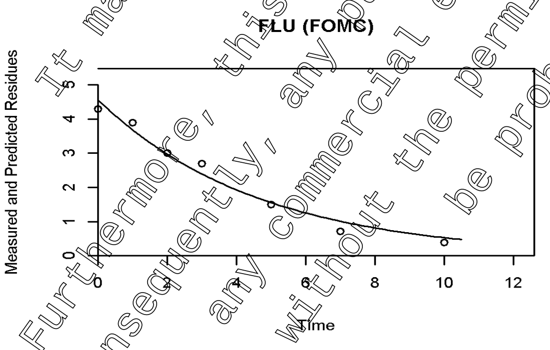
SFO fit is statistically and visually acceptable (χ^2err < 15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



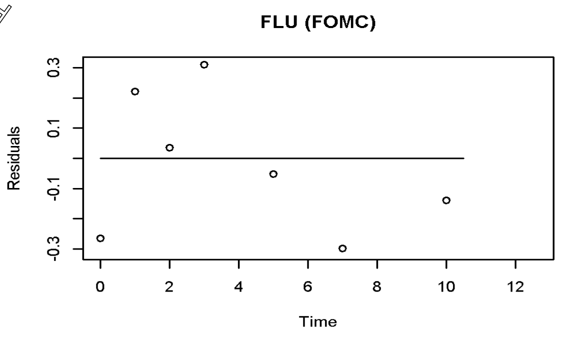
SFO



SFO



FOMC



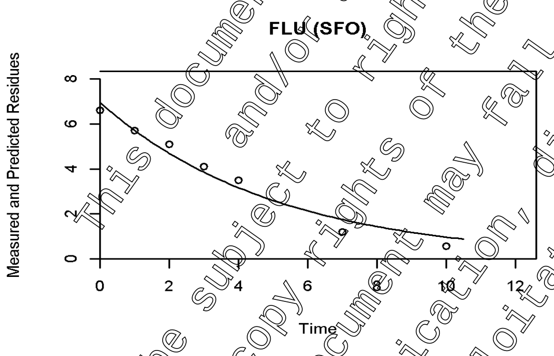
FOMC

18-2951-03, Mellet, M-678413-01-1, BE, wheat, Propulse

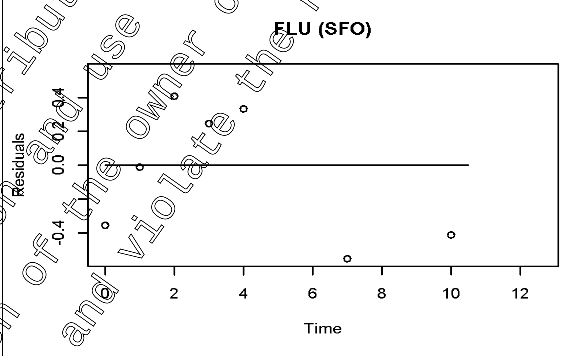
Table 8.9- 45: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial 18-2951-03, Mellet, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	7.0	k: 0.19675	7.6	k: <0.001	k: 0.15	k: 0.24	**3.523**	11.70
FOMC	+	7.0	α: 16640 β: 84560	8.2	-	β: 83780	β: 85345.19	3.523	11.70
DFOP	+	7.0	k1: 0.19675 k2: 0.05149 g: 1.0	9.1	k1: 0.088 k2: <0.001	k1: -0.02 k2: 0.05	k1: 0.42 k2: 0.05	3.523	11.70
HS	+	7.0	k1: 0.19675 k2: 0.16406 tb: 13.939	9.1	k1: 0.003 k2: <0.001	k1: 0.14 k2: 0.16	k1: 0.25 k2: 0.16	3.523	11.70

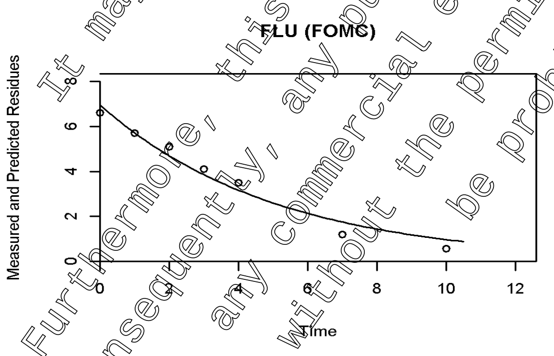
SFO fit is statistically and visually acceptable (χ^2err < 15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



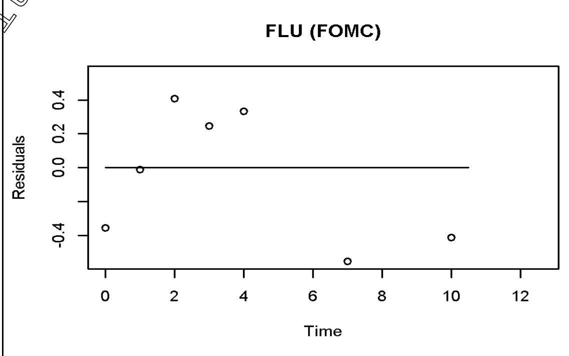
SFO



SFO



FOMC



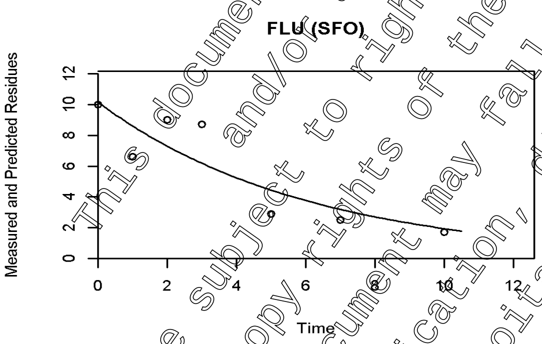
FOMC

18-2954-01, Fonfria, M-675129-02-1, ES, wheat, Propulse

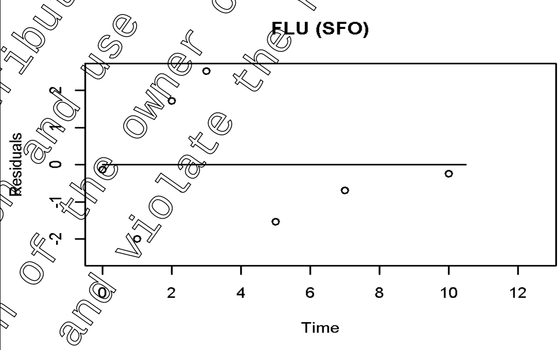
Table 8.9- 46: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial 18-2954-01, Fonfria, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	10.1	k: 0.16499	20.5	k: 0.013	k: 0.06	k: 0.27	**4.201**	13.96
FOMC	o	10.1	α: 5703.071 β: 34563.664	22.1	-	β: 33921.82	β: 35205.51	4.201	13.96
DFOP	o	10.1	k1: 0.165 k2: 0.06417 g: 1.0	24.4	k1: 0.358 k2: <0.001	k1: -0.64 k2: 0.06	k1: 0.97 k2: 0.06	4.201	13.96
HS	o	10.1	k1: 0.16499 k2: 0.0918 tb: 11.487	24.4	k1: 0.047 k2: <0.001	k1: 0.03 k2: 0.09	k1: 0.30 k2: 0.09	4.201	15.92

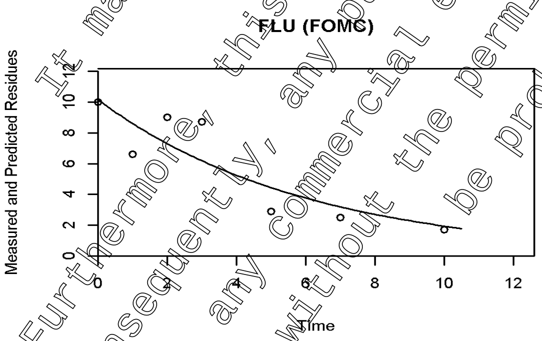
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2 err is > 15 %, which is mainly reflecting the scattering data. FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



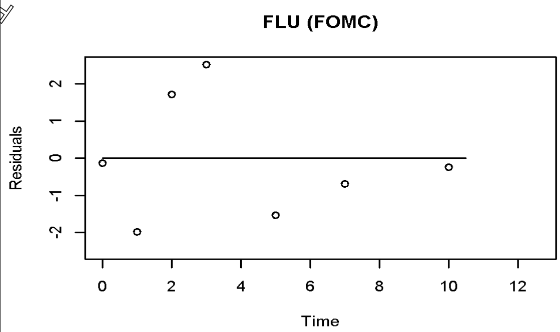
SFO



SFO



FOMC



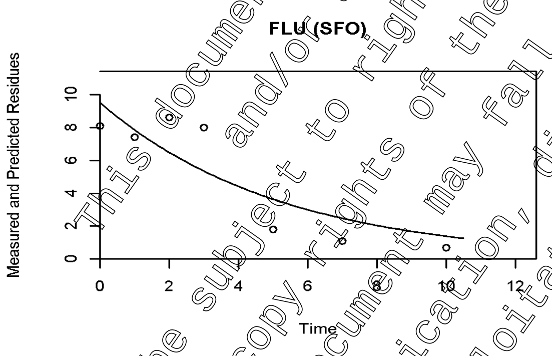
FOMC

18-2954-02, Torralba de los Frailes, M-675129-02-1, ES, wheat, Propulse

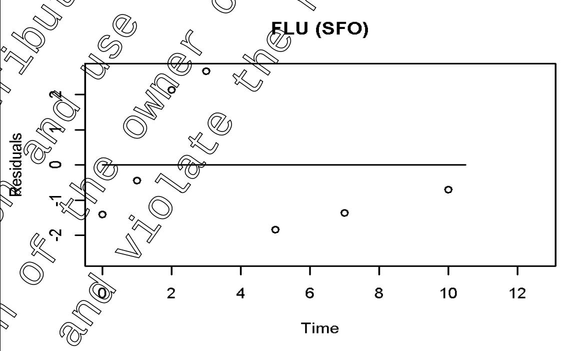
Table 8.9- 47: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial 18-2954-02, Torralba de los Frailes, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	9.5	k: 0.19259	26.1	k: 0.021	k: 0.05	k: 0.33	**3.599**	11.96
FOMC	o	9.5	α: 11921.841 β: 61899.530	28.1	-	β: 60115.53	β: 63683.53	3.599	11.96
DFOP	o	9.5	k1: 0.19259 k2: 0.07479 g: 1.0	31.0	k1: 0.355 k2: <0.001	k1: -0.73 k2: 0.07	k1: 1.12 k2: 0.08	3.599	11.96
HS	o	9.5	k1: 0.19259 k2: 0.04362 tb: 16.839	31.0	k1: 0.063 k2: <0.001	k1: 0.01 k2: 0.04	k1: 0.37 k2: 0.04	3.599	11.96

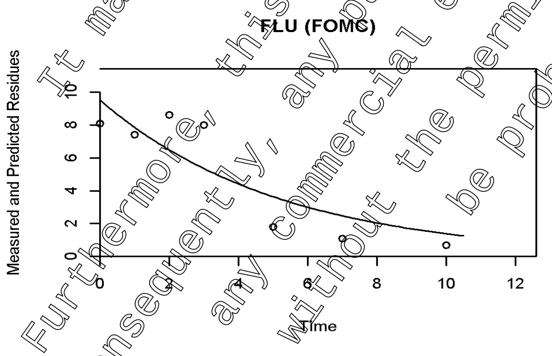
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %, which is mainly reflecting the scattering data. FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



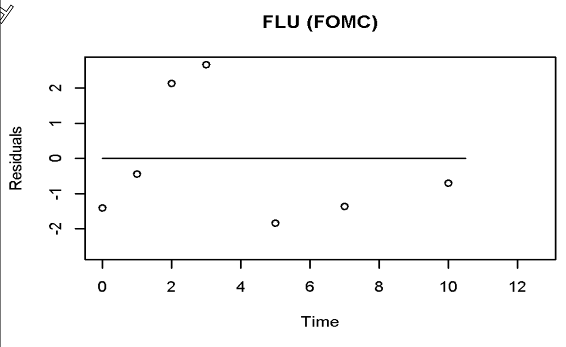
SFO



SFO



FOMC



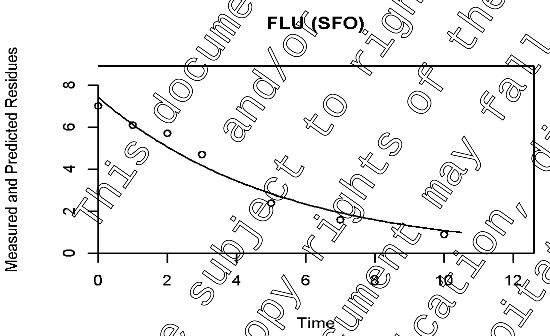
FOMC

18-2954-03, Smilets, M-675129-02-1, BG, wheat, Propulse

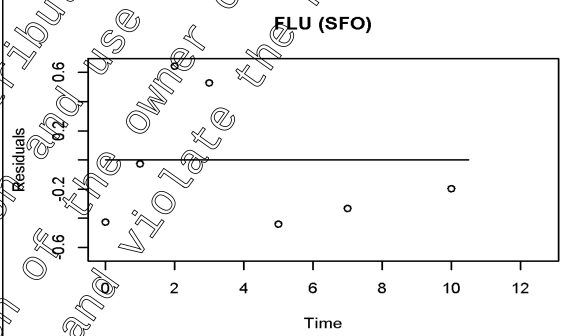
Table 8.9- 48: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial 18-2954-03, Smilets, BG

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.4	k: 0.19217	8.2	k: <0.001	k: 0.15	k: 0.24	**3.607**	11.98
FOMC	o	7.4	α: 15360 β: 79910	8.8	-	β: 79180.00	β: 80647.12	3.607	11.98
DFOP	o	7.4	k1: 0.192172 k2: 0.013494 g: 1.0	9.7	k1: 0.071 k2: <0.001	k1: 0.00 k2: 0.01	k1: 0.38 k2: 0.01	3.607	11.98
HS	o	7.4	k1: 0.1922 k2: 2.22e-14 tb: 14.8	9.7	k1: 0.004 k2: <0.001	k1: 0.13 k2: 0.00	k1: 0.25 k2: 0.00	3.607	11.98

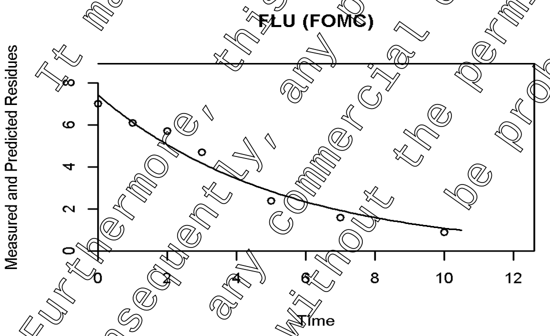
SFO fit is statistically and visually acceptable (χ^2err < 15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



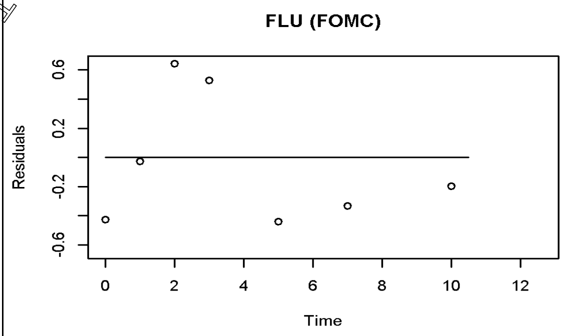
SFO



SFO



FOMC



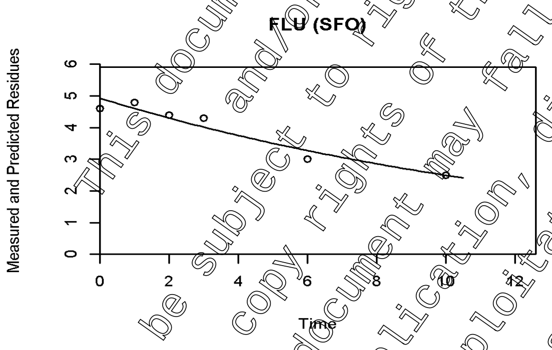
FOMC

E19RP087-01, Bouloc, M-758649-01-1, FR, wheat, Propulse

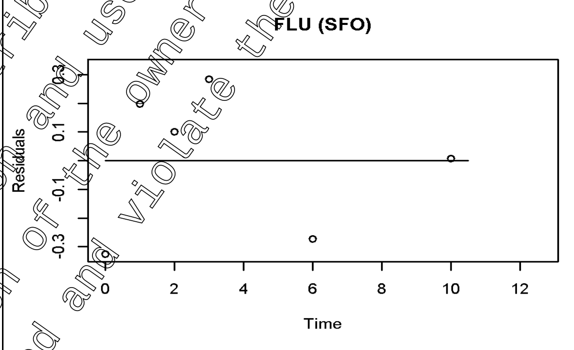
Table 8.9- 49: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial E19RP087-01, Bouloc, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	4.9	k: 0.06811	4.6	k: 0.002	k: 0.05	k: 0.09	**10.18**	33.81
FOMC	+	4.9	α: 4682 β: 68740	5.1	-	β: 68630	β: 68852.68	10.18	33.81
DFOP	+	4.9	k1: 0.06811 k2: 0.06811 g: 1.0	5.8	k1: 0.023 k2: <0.001	k1: 0.04 k2: 0.07	k1: 0.10 k2: 0.07	10.18	33.81
HS	+	4.7	k1: 0.02128 k2: 0.08279 tb: 2.149	4.3	k1: 0.340 k2: 0.026	k1: -0.07 k2: 0.04	k1: 0.11 k2: 0.12	9.969	29.41

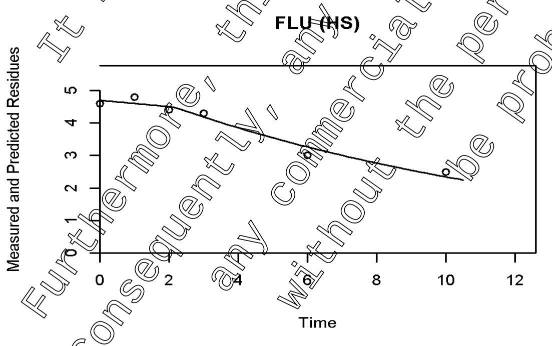
SFO fit is statistically and visually good (χ^2err < 15%, t-test <0.05). FOMC and DFOP did not result in an improved statistical or visual fit. HS resulted in a lag phase with very low inprovement, which is considered not appropriate for the intended purpose. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



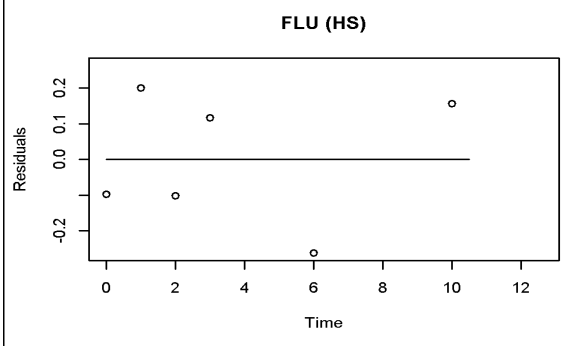
SFO



SFO



HS



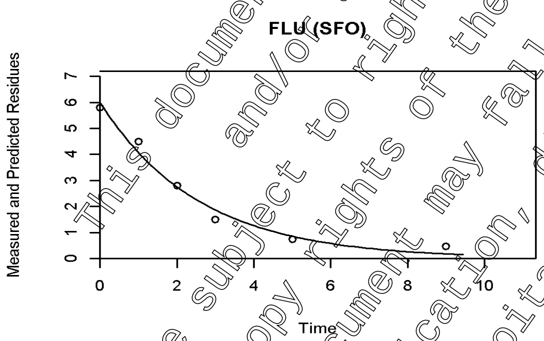
HS

E19RP087-02, Antequera, M-758649-01-1, ES, wheat, Propulse

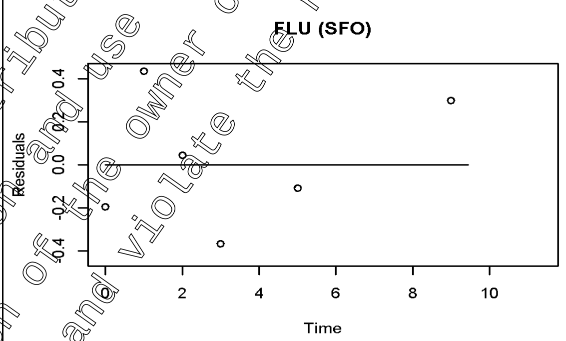
Table 8.9- 50: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial E19RP087-02, Antequera, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	6.0	k: 0.38902	8.4	k: <0.001	k: 0.31	k: 0.47	**1.782**	5.92
FOMC	o	6.0	α: 4356 β: 11200	9.3	-	β: -32350000	β: 32370000	1.782	5.92
DFOP	o	6.0	k1: 0.4096 k2: 2.22e-14 g: 0.977	10.4	k1: 0.182 k2: 0.50	k1: -0.28 k2: -6.40	k1: 1.10 k2: 6.40	1.751	6.21
HS	o	6.0	k1: 0.39559 k2: 0.39559 tb: 6.122	9.5	k1: 0.009 k2: 0.460	k1: 0.29 k2: -0.60	k1: 0.50 k2: 0.67	1.752	5.82

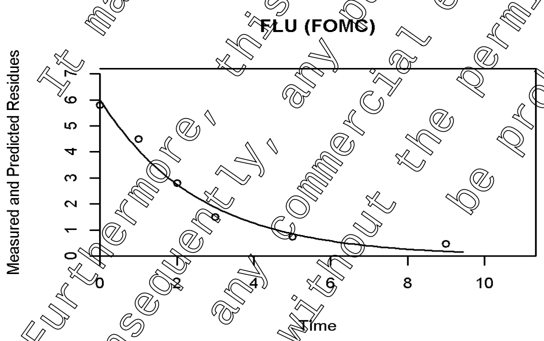
SFO fit is statistically and visually acceptable (χ^2err < 15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



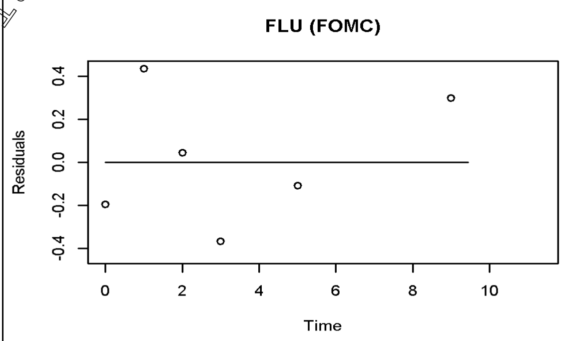
SFO



SFO



FOMC



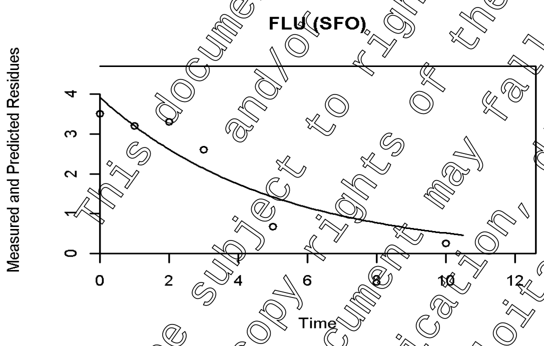
FOMC

E19RP087-03, Cento, M-758649-01-1, IT, wheat, Propulse

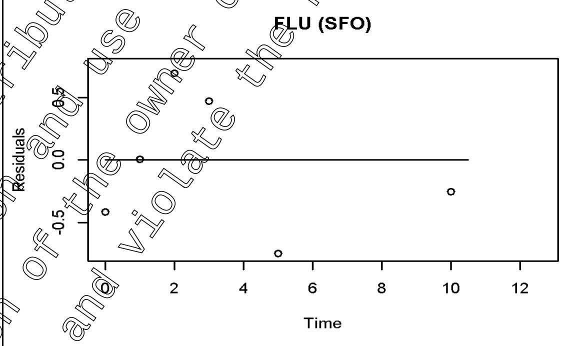
Table 8.9- 51: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial E19RP087-03, Cento, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.9	k: 0.20295	17.6	k: 0.017	k: 0.08	k: 0.33	**3.415**	11.35
FOMC	o	3.9	α: 5539 β: 27290	19.4	-	β: 26520.00	β: 28066.19	3.415	11.35
DFOP	o	3.9	k1: 0.20294 k2: 0.05543 g: 1.0	22.2	k1: 0.298 k2: <0.001	k1: -0.43 k2: 0.06	k1: 0.84 k2: 0.06	3.415	11.35
HS	o	3.9	k1: 0.20294 k2: 0.04122 tb: 11.301	22.2	k1: 0.077 k2: <0.001	k1: 0.03 k2: 0.04	k1: 0.38 k2: 0.04	3.415	11.52

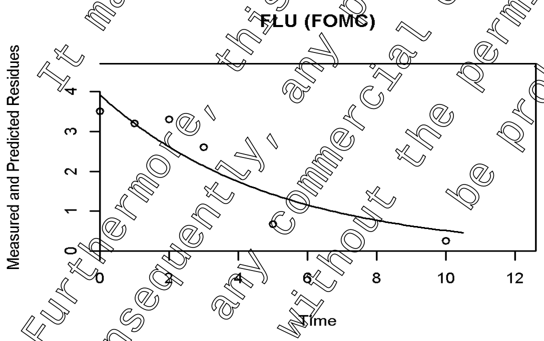
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2 err is > 15 %, which is mainly reflecting the scattering data. FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



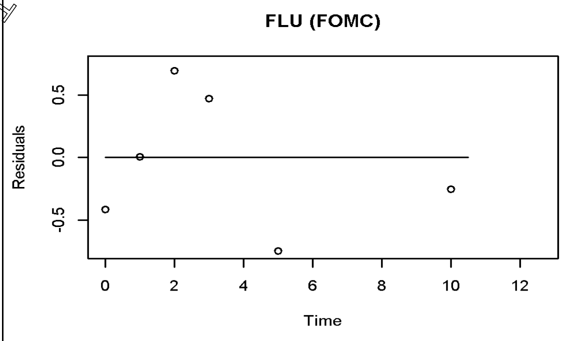
SFO



SFO



FOMC



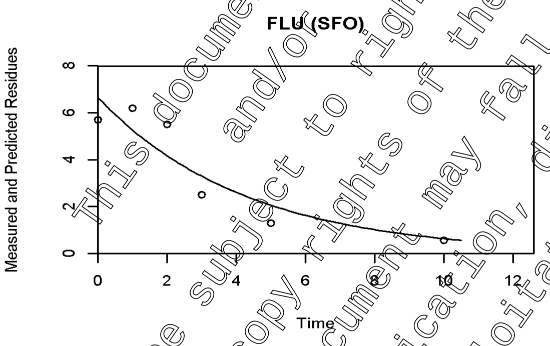
FOMC

E19RP087-04, Gravina di Puglia, M-758649-01-1, IT, wheat, Propulse

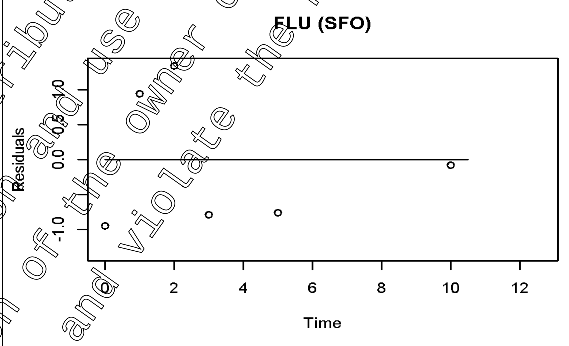
Table 8.9- 52: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial E19RP087-04, Gravina di Puglia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	6.6	k: 0.23452	19.6	k: 0.019	k: 0.08	k: 0.39	**2.956**	9.82
FOMC	o	6.6	α: 8979.690 β: 38288.117	21.6	-	β: 36809.86	β: 39766.37	2.956	9.82
DFOP	o	6.6	k1: 0.2345 k2: 2.22e-14 g: 1.0	24.7	k1: 0.218 k2: <0.001	k1: -0.24 k2: 0.00	k1: 0.71 k2: 0.00	2.956	9.82
HS	o	6.6	k1: 0.23452 k2: 0.74082 tb: 27.086	24.7	k1: 0.082 k2: <0.001	k1: 0.02 k2: 0.74	k1: 0.45 k2: 0.74	2.956	9.82

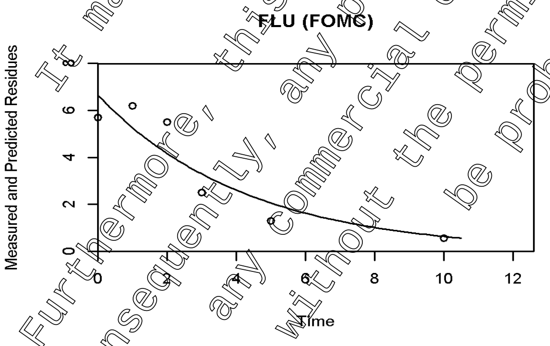
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15%, which is mainly reflecting the scattering data. FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



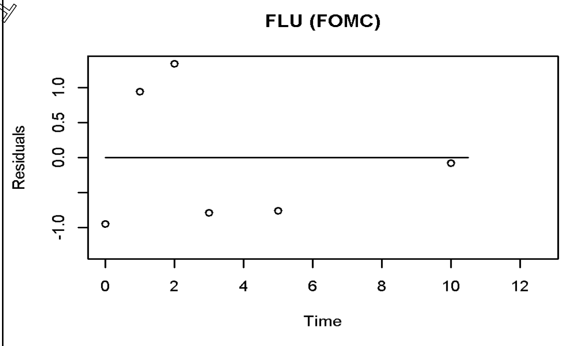
SFO



SFO



FOMC



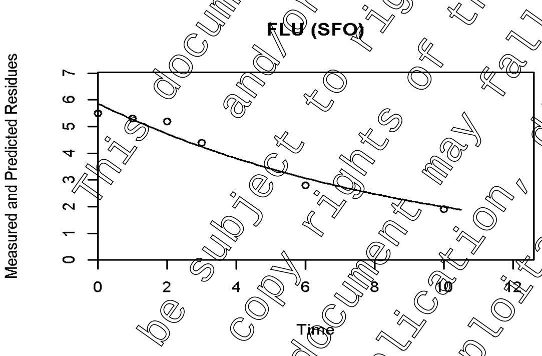
FOMC

E19RP102-01, Athée sur Cher, M-758824-01-1, FR, wheat, Propulse

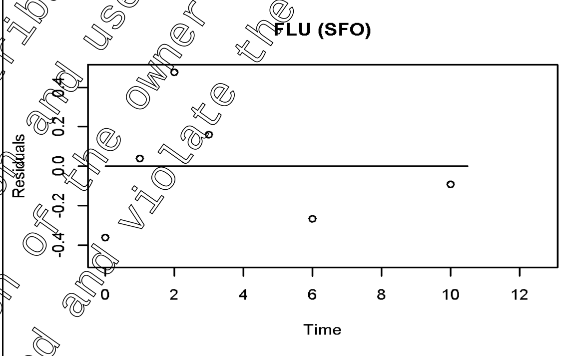
Table 8.9- 53: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial E19RP102-01, Athée sur Cher, FR

Kinetic model	**Visual assess-ment**	**M_0**	**Kinetic parameters**	**X^2 error (%)**	**Prob > t**	**Lower 95% CI**	**Upper 95% CI**	**DT_{50} actual (d)**	**DT_{90} actual (d)**
SFO	+	5.9	k: 0.10798	5.3	k: <0.001	k: 0.08	k: 0.14	**6.419**	21.32
FOMC	+	5.9	α: 7449.548 β: 68986.317	5.8	-	β: 68751.80	β: 69220.84	6.419	21.33
DFOP	+	5.9	k1: 0.10798 k2: 0.079 g: 1.000	6.7	k1: 0.408 k2: <2e-16	k1: -0.69 k2: 0.08	k1: 0.90 k2: 0.08	6.419	21.32
HS	+	5.5	k1: 0.03704 k2: 0.13509 tb: 1.994	2.6	k1: 0.266 k2: 0.004	k1: -0.06 k2: 0.11	k1: 0.13 k2: 0.16	6.578	18.49

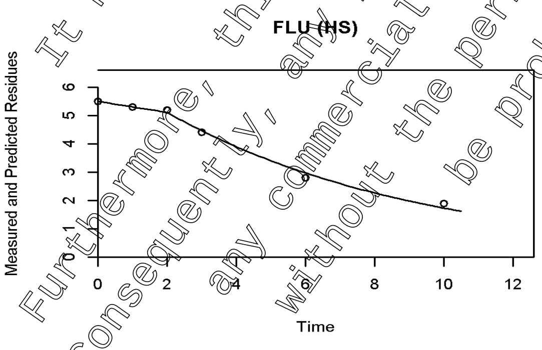
SFO fit is statistically and visually good (χ^2err < 15%, t-test <0.05). FOMC and DFOP did not result in an improved statistical or visual fit. . HS resulted in a lag phase with very low improvement, which is considered not appropriate for the intended purpose. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



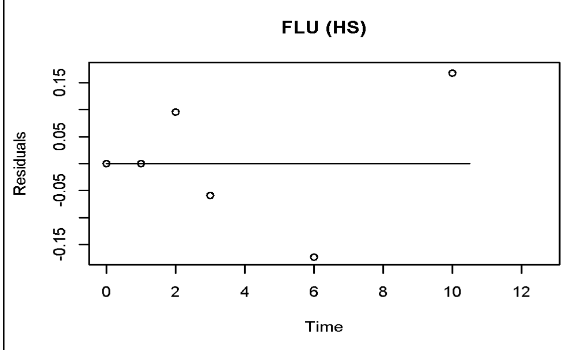
SFO



SFO



HS



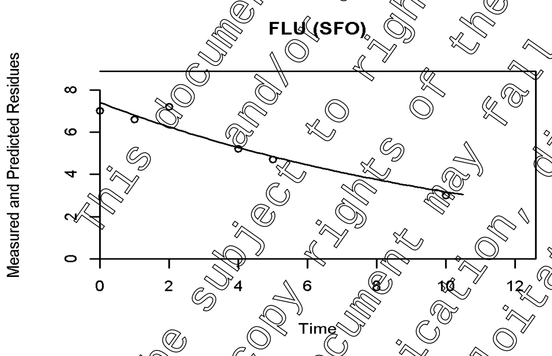
HS

E19RP102-02, Great Chishill, Near Royston, M-758824-01-1, GB, wheat, Propulse

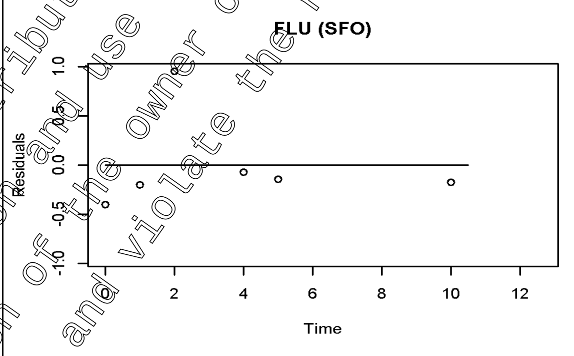
Table 8.9- 54: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial E19RP102-02, Great Chishill, Near Royston, GB

Kinetic model	**Visual assess-ment**	**M_0**	**Kinetic parameters**	**X^2 error (%)**	**Prob > t**	**Lower 95% CI**	**Upper 95% CI**	**DT_{50} actual (d)**	**DT_{90} actual (d)**
SFO	+	7.4	k: 0.08469	6.2	k: 0.003	k: 0.05	k: 0.12	**8.185**	27.19
FOMC	+	7.4	α: 5442 β: 64260	6.9	-	β: 64070.00	β: 64448.90	8.185	27.19
DFOP	+	7.4	k1: 0.08469 k2: 0.08469 g: 0.209	7.8	k1: 0.003 k2: 0.041	k1: 0.07 k2: 0.03	k1: 0.10 k2: 0.14	8.185	27.19
HS	+	7.3	k1: 0.07741 k2: 0.24786 tb: 9.307	7.6	k1: 0.063 k2: 0.322	k1: 0.02 k2: -0.66	k1: 0.14 k2: 1.15	8.955	15.69

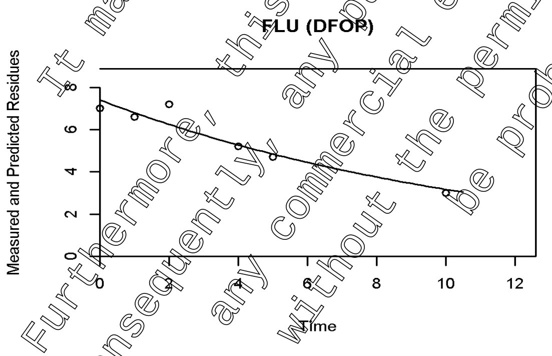
SFO fit is statistically and visually acceptable (χ^2err < 15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



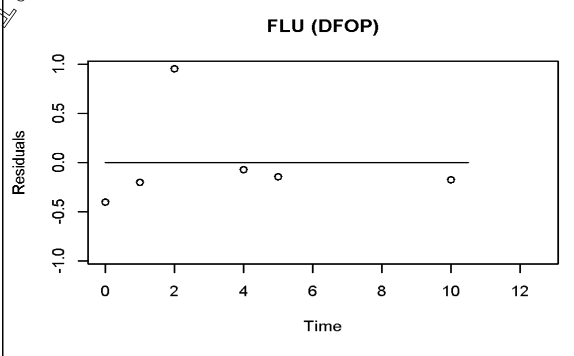
SFO



SFO



DFOP



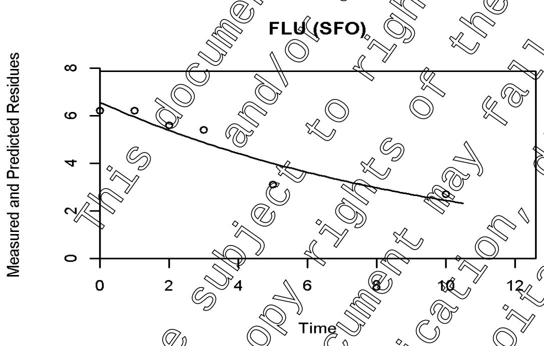
DFOP

E19RP102-03, Burscheid, M-758824-01-1, DE, wheat, Propulse

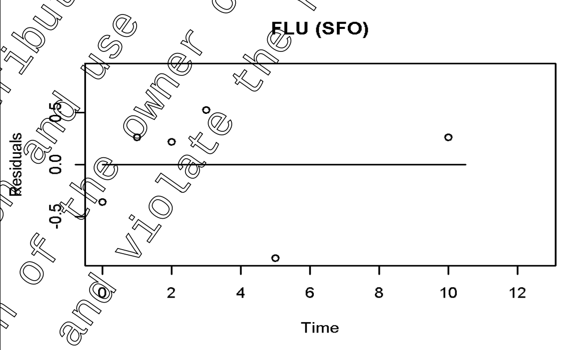
Table 8.9- 55: models and goodness-of-fit statistics of fluopyram fits for wheat of trial E19RP102-03, Burscheid, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	6.6	k: 0.09889	7.9	k: 0.005	k: 0.06	k: 0.14	**7.010**	23.29
FOMC	o	6.6	α: 24.120 β: 240.000	8.7	-	β: -16200.00	β: 16678.76	6.998	24.04
DFOP	o	6.6	k1: 0.1151 k2: 0.000 g: 0.909	9.9	k1: 0.482 k2: 0.50	k1: -4.30 k2: -26.01	k1: 4.53 k2: 26.01	6.937	40.04
HS	o	6.2	k1: 2.22e-14 k2: 0.1429 tb: 1.031	8.9	k1: 0.50 k2: 0.057	k1: -0.34 k2: 0.03	k1: 0.34 k2: 0.20	7.171	21.43

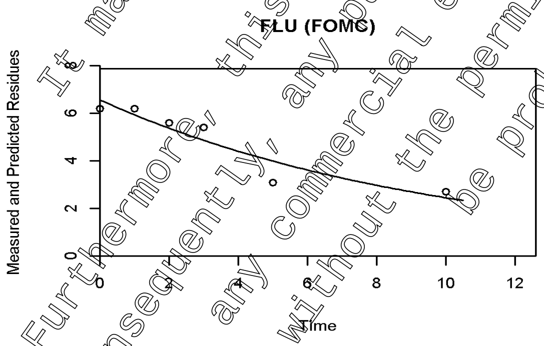
SFO fit is statistically and visually good (χ^2err < 15%, t-test ≤0.05). FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



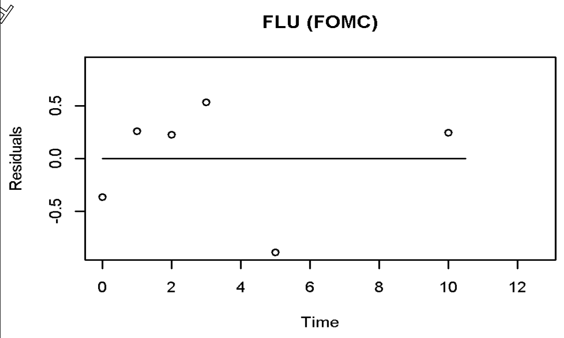
SFO



SFO



FOMC



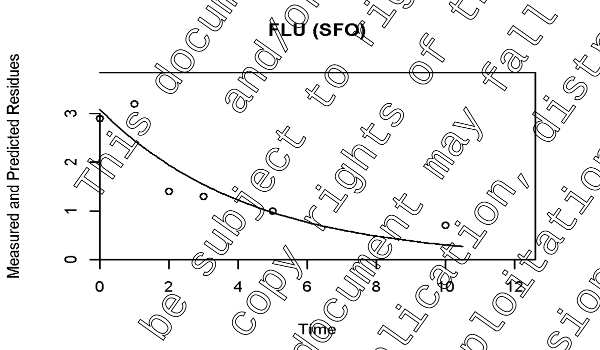
FOMC

E19RP102-04, Roellbach, M-758824-01-1, DE, wheat, Propulse

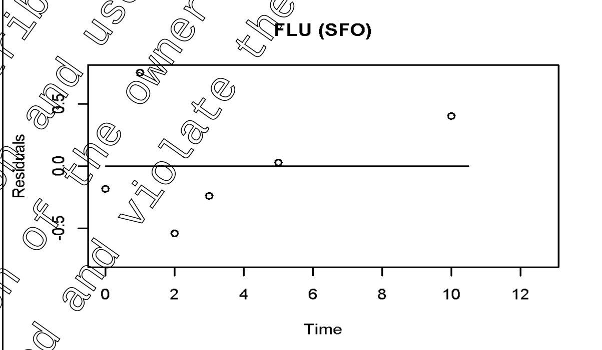
Table 8.9- 56: Kinetic models and goodness-of-fit statistics of fluopyram fits for wheat of trial E19RP102-04, Roellbach, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	3.1	k: 0.2313	19.6	k: 0.021	k: 0.08	k: 0.39	2.997	9.96
FOMC	o	3.2	α: 2.0393 β: 6.8502	20.7	-	β: -40.22	β: 53.92	2.773	14.34
DFOP	o	3.2	k1: 0.3591 k2: 2.027e-12 g: 0.826	22.8	k1: 0.387 k2: 0.50	k1: -1.79 k2: -2.33	k1: 2.51 k2: 2.33	2.587	>1000
HS	o	3.2	k1: 0.28183 k2: 0.068498 tb: 3.862	22.0	k1: 0.097 k2: 0.397	k1: -0.01 k2: -0.38	k1: 0.57 k2: 0.52	2.459	21.59

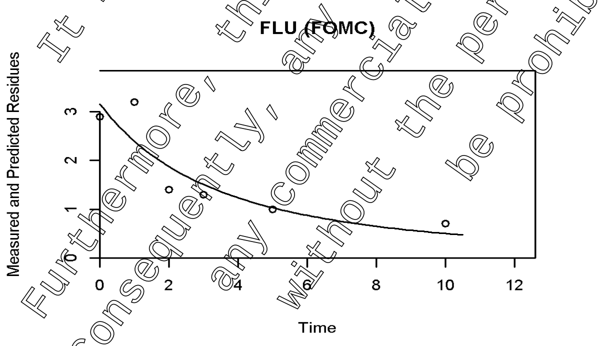
SFO fit is statistically and visually poor (χ^2err > 15%). FOMC, DFOP and HS fits were alternatively tested, which show a visuall improvement. The t-test of DFOP and HS show a low reliability especially of the slow degradation rates k2 (t-test > 0.05). FOMC has the lowest χ^2err of the biphasic fits and its extrapolation until DT90 is not too far beyond the study duration. Therefore, **FOMC** model is considered most appropriatet.



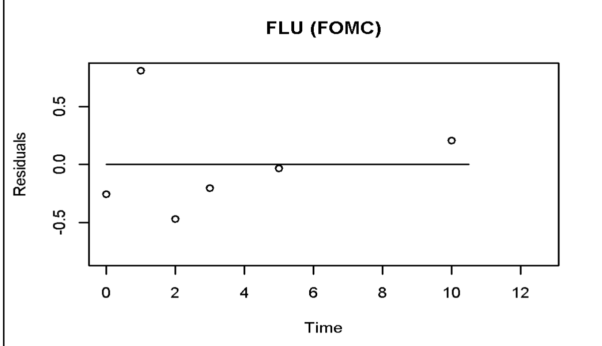
SFO



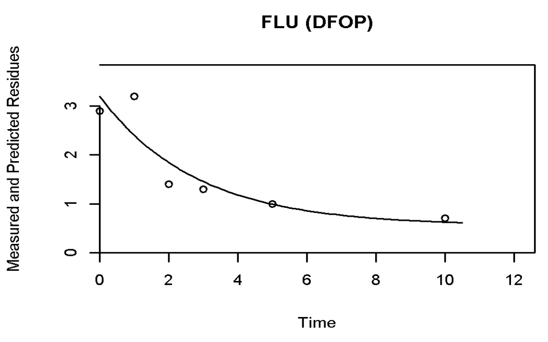
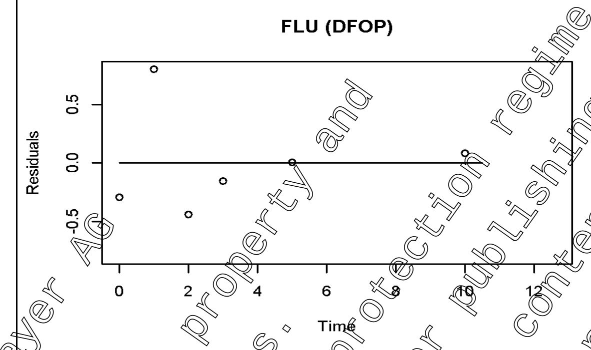
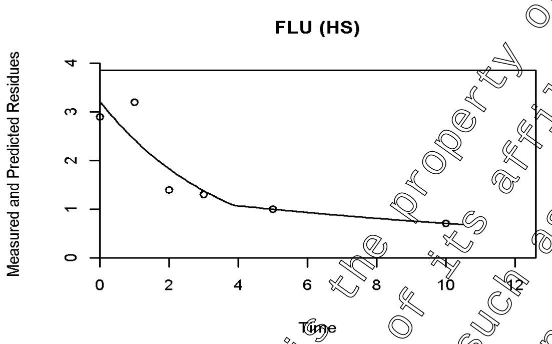
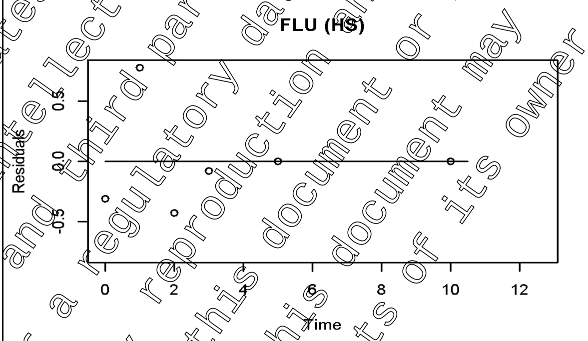
SFO



FOMC



FOMC

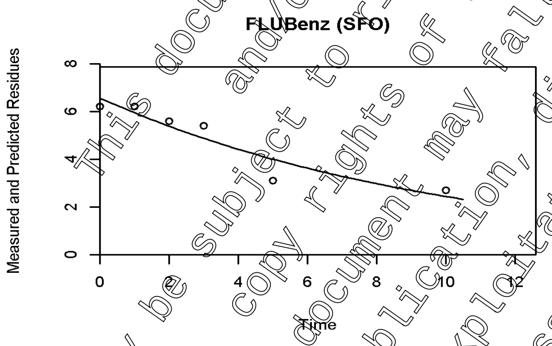
 DFOP	 DFOP
 HS	 HS

Fluopyram + FLU-benzamide

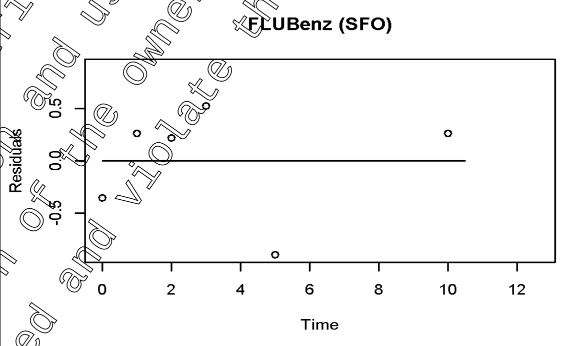
E19RP102-03, Burscheid, M-758824-01-1, DE, wheat, Propulse

Table 8.9- 57: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for wheat of trial E19RP102-03, Burscheid, DE

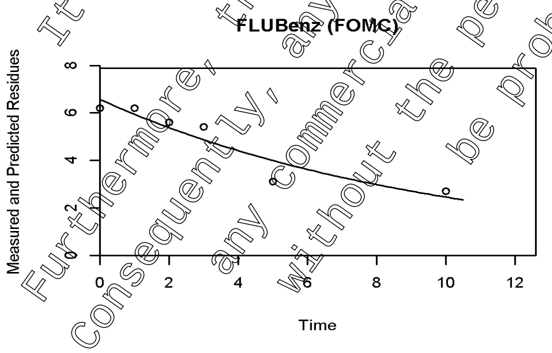
Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	6.6	k: 0.09864	7.9	k: 0.005	k: 0.06	k: 0.14	**7.027**	23.34
FOMC	o	6.6	α: 21.150 β: 210.500	8.7	-	β: -12520.00	β: 12944.76	7.014	24.21
DFOP	o	6.6	k1: 0.1155 k2: 4.523e-09 g: 0.906	9.9	k1: 0.482 k2: 0.500	k1: -4.29 k2: -24.86	k1: 4.52 k2: 24.86	6.952	44.06
HS	o	6.2	k1: 1.139e-08 k2: 0.1125 tb: 1.025	8.9	k1: 0.500 k2: 0.057	k1: -0.34 k2: 0.03	k1: 0.34 k2: 0.19	7.189	21.50
SFO fit is statistically and visually good (χ^2err < 15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.									



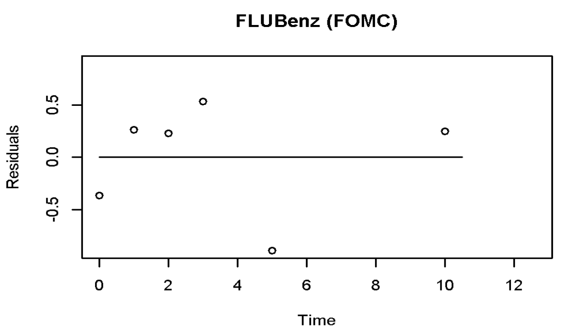
SFO



SFO



FOMC



FOMC

III. CONCLUSION

The following units are used in the following tables:

k	1/d
β, tb	d
α, g	none

Table 8.9- 58: Foliar DT_{50} parameters of fluopyram in green material of young wheat, cereals, after application of Propulse (SE250 FLU+PTZ), based on time points after last application; for modelling purpose

Fluopyram	Foliar dissipation, crop residue decline studies, young wheat								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**$DT_{50\ pseudo}$ (d)**	**$DT_{90\ actual}$ (d)**	**$DT_{50\ fast}$ (d)**	**$DT_{50\ slow}$ (d)**
18-2951-01 Burscheid, DE, M-678413-01-1	N	**SFO**	k: 0.25232	17.7	k: 0.003	**2.747**	9.13		
18-2951-02, Eschau, DE, M-678413-01-1	N	**SFO**	k: 0.21565	7.3	k: <0.001	**3.214**	10.68		
18-2951-03, Mellet, BE, M-678413-01-1	N	**SFO**	k: 0.19675	7.6	k: <0.001	**3.523**	11.70		
18-2954-01, Fonfria, ES, M-675129-02-1	S	**SFO**	k: 0.16499	20.5	k: 0.013	**4.201**	13.96		
18-2954-02, Torralba de los Frailes, ES, M-675129-02-1	S	**SFO**	k: 0.19259	26.1	k: 0.021	**3.599**	11.96		
18-2954-03, Smilets, BG, M-675129-02-1	S	**SFO**	k: 0.19217	8.2	k: <0.001	**3.607**	11.98		
E19RP087-01, Bouloc, FR, M-758649-01-1	S	**SFO**	k: 0.06811	4.6	k: 0.002	**10.18**	33.81		
E19RP087-02 Antequera, ES, M-758649-01-1	S	**SFO**	k: 0.38902	8.4	k: <0.001	**1.782**	5.92		
E19RP087-03 Cento, IT, M-758649-01-1	S	**SFO**	k: 0.20295	17.6	k: 0.017	**3.415**	11.35		
E19RP087-04, Gravina di Puglia, IT, M-758649-01-1	S	**SFO**	k: 0.23452	19.6	k: 0.019	**2.956**	9.82		
E19RP102-01 Athee sur Cher, FR, M-758824-01-1	N	**SFO**	k: 0.10798	5.3	k: <0.001	**6.419**	21.32		

Fluopyram	Foliar dissipation, crop residue decline studies, young wheat								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**DT_{90} actual (d)**	**DT_{50} fast (d)**	**DT_{50} slow (d)**
E19RP102-02 Great Chishill, Near Royston, GB, M-758824-01-1	N	**SFO**	k: 0.08469	6.2	k: 0.003	**8.185**	27.19		
E19RP102-03, Burscheid, DE, M-758824-01-1	N	**SFO**	k: 0.09889	7.9	k: 0.005	**7.010**	23.29		
E19RP102-04 Roellbach, DE, M-758824-01-1	N	**FOMC**	α: 2.0393 β: 6.8502	20.7	-	**4.319**	14.34		
Geomean (n=14) [M]						**4.178**[M]			

DT_{50} pseudo = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT_{90} actual time for first 90 % of residues to dissipate
DT_{50} fast = ln(2)/k1
DT_{50} slow = ln(2)/k2 (DFOP, HS)
M geomean of DT_{50} pseudo of fits for modelling purpose

Table 8.9- 59: Foliar DT_{50} parameters of fluopyram + FLU-benzamide in green material of young wheat, cereals, after application of Propulse (SE250 FLU+PTZ), based on time points after last application; for modelling purpose

Fluopyram + FLU-benzamide	Foliar dissipation, crop residue decline studies, in young wheat, Propulse								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**DT_{90} actual (d)**	**DT_{50} fast (d)**	**DT_{50} slow (d)**
E19RP102-03 Burscheid, DE, M-758824-01-1	N	**SFO**	k: 0.09864	7.9	k: 0.005	**7.027**	23.34		

DT_{50} pseudo = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT_{90} actual time for first 90 % of residues to dissipate
DT_{50} fast = ln(2)/k1
DT_{50} slow = ln(2)/k2 (DFOP, HS)

III. CONCLUSION

In total, 14 trials were evaluated (6 trials where only fluopyram was analysed plus 8 trials where also the metabolite fluopyram-benzamide was included as analyte).
The geometric mean of the DT_{50} for fluopyram alone was 4.178 days (n=14).
Additionally, an evaluation was made of the decline kinetics of the combined residues of fluopyram and its metabolite fluopyram-benzamide (for the 8 trials where the metabolite was included as analyte).
In these 8 trials, where the metabolite was included as analyte, the geometric mean DT_{50} of fluopyram alone was 4.820 days and the geometric mean DT_{50} of the combined residue was 4.821 days. Thus, the contribution of the metabolite fluopyram-benzamide is negligible for risk assessment.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment.

The geometric mean DT_{50} for fluopyram over 14 residue decline trials in young cereals was 4.178 days. In 8 of these trials, the metabolite fluopyram-benzamide was also included as analyte, but was found in only one of these trials in very low concentrations. This finding suggests that the contribution of fluopyram-benzamide is negligible for risk assessment.

Kinetic evaluation reports for residues in/on vegetables

Data Point:	KCA 8.9/12
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolite - Kinetic evaluation of green plant residues in lettuce, endive, beans and peas, applying Luna Privilège (SC500, SC250) part 1
Report No:	EnSa-20-0829
Document No:	M-763335-01-1
Guideline(s) followed in study:	not applicable
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

EXECUTIVE SUMMARY

Kinetic evaluations were conducted for the residue decline of fluopyram from foliage after application on various vegetables. All trials were evaluated with SFO and FOMC kinetics. Where the number of sampling points allowed the evaluation, 2 biphasic kinetic models were fitted additionally (DFOP and HS), with a preference for selecting SFO where the fit was considered visually and statistically acceptable. Otherwise, the best-fit of the other models was selected. To facilitate the use of the selected kinetic parameter, a surrogate SFO DT_{50} was estimated as $DT_{90}/3.32$ for the non SFO kinetics.
The geometric mean of the DT_{50} for fluopyram was 2.765 days (n=37).

Additionally, an evaluation was made of the decline kinetics of the combined residues of fluopyram and its metabolite fluopyram-benzamide (in all trials the metabolite was included as analyte).
The geometric mean DT_{50} of the combined residue was 2.857 days (~3% longer than for fluopyram alone. Thus, the contribution of the metabolite fluopyram-benzamide is negligible for risk assessment.

The outcome of the evaluations is presented below.

Table 8.9- 60: Comparison of foliar DT_{50}s of fluopyram and fluopyram + FLU-benzamide in green material of lettuce, endive, beans, peas

Fluopyram and FLU + FLU-benzamide	Foliar residue decline studies in lettuce, endive, beans, peas			
Trial	EU zone	Kinetic model	DT_{50} FLU (d)	DT_{50} FLU + benzamide (d)
08-2034-01, Damery, FR, M-365530-01-1	N	SFO	4.053	4.12
08-2034-02, Damery, FR, M-365530-01-1	N	SFO	3.992	4.058
08-2096-01, Ladispoli, IT, M-365542-01-1	S	SFO	2.969	3.052
08-2096-02, Ladispoli, IT, M-365542-01-1	S	SFO	3.648	3.748

Fluopyram and FLU + FLU-benzamide	**Foliar residue decline studies in lettuce, endive, beans, peas**			
Trial	**EU zone**	**Kinetic model**	**DT50 FLU (d)**	**DT50 FLU + benzamide (d)**
10-2099-01, Wieringerwerf, NL, M-423901-01-1	N	SFO	2.252	2.252
10-2099-02, Langenfeld-Reusrath, DE, M-423901-01-1	N	FOMC	2.659	2.690
10-2099-03, Villers-Perwin, BE, M-423901-01-1	N	SFO	1.228	1.232
10-2099-04, Fondettes, FR, M-423901-01-1	N	SFO	1.481	*1.481*
18-2086-01-T1, Palidoro Fiumicino, IT, M-675005-01-1	S	SFO	8.248	8.91
18-2086-01-T2, Palidoro Fiumicino, IT, M-675005-01-1	S	SFO	7.754	8.847
18-2086-02-T1, Terlizzi , IT, M-675005-01-1	S	SFO	3.419	3.436
18-2086-02-T2, Terlizzi , IT, M-675005-01-1	S	SFO	4.04	4.056
18-2086-03-T1, Alginet, ES, M-675005-01-1	S	SFO	4.378	4.402
18-2086-03-T2, Alginet, ES, M-675005-01-1	S	SFO	4.339	4.373
18-2086-04-T1, Vasilika Thessaloniki, GR, M-675005-01-1	S	SFO	1.186	1.191
18-2086-04-T2, Vasilika Thessaloniki, GR, M-675005-01-1	S	SFO	1.174	1.179
R 2006 0375/4, Cergy, FR, M-292048-01-1	N	HS	2.198	2.322
R 2006 0376/2, St. Jory, FR, M-292050-01-1	S	SFO	1.52	1.559
R 2006 0377/0, Lampertheim, DE, M-290825-01-1	N	SFO	4.674	4.814
R 2006 0378/9, Alginet, ES, M-290827-01-1	S	SFO	8.872	9.653
R 2006 0380/0, Machern, DE, M-291180-01-1	N	SFO	17.32	17.95
R 2006 0604/4, Meckenbeuren, DE, M-292048-01-1	N	SFO	1.409	1.413
R 2006 0605/2, Langenfeld-Reusrath, D, M-292048-01-1	N	HS	3.587	3.705
R 2006 0606/0, Zwaagdijk, NL, M-292048-01-1	N	SFO	2.452	2.469
R 2006 0607/9, Ely, GB, M-292048-01-1	N	SFO	1.129	1.131
R 2006 0608/7, Vilanova del Valles, ES, M-292050-01-1	S	SFO	2.57	2.592
R 2006 0609/5, Andria, IT, M-292050-01-1	S	SFO	0.8444	*0.8444*
R 2006 0610/9, Catania, IT, M-292050-01-1	S	SFO	3.529	3.561
R 2006 0611/7, Katerini / Paralia, GR, M-292050-01-1	S	SFO	3.02	3.04
R 2006 0620/6, Pradelle di Nogarole Rocca, IT, M-290827-01-1	S	SFO	0.7254	0.7439
R 2006 0654/0, Langenfeld-Reusrath, D, M-290825-01-1	N	SFO	0.7187	0.7368

Fluopyram and FLU + FLU-benzamide	**Foliar residue decline studies in lettuce, endive, beans, peas**			
Trial	**EU zone**	**Kinetic model**	**DT_{50} FLU (d)**	**DT_{50} FLU + benzamide (d)**
R 2006 0655/9, Zwaagdijk, NL, M-290825-01-1	N	SFO	2.729	2.857
R 2006 0656/7, Villers-Perwin, BE, M-290825-01-1	N	SFO	2.84	2.858
R 2006 0657/5, Malgrat de Mar, ES, M-290827-01-1	S	HS	0.883	1.288
R 2006 0658/3, Ladispoli, IT, M-290827-01-1	S	SFO	3.548	3.676
R 2006 0722/9, Needham, GB, M-291180-01-1	N	SFO	13.88	14.37
R 2006 0723/7, Meckenbeuren, DE, M-291180-01-1	N	SFO	3.636	3.708
Geomean (n=37)			**2.765**	**2.857**

Surrogate DT_{50} = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed

I. MATERIALS AND METHODS

A kinetic modelling analysis of European total crop residue decline study data of fluopyram (FLU) and fluopyram + fluopyram-benzamide (FLU-benzamide, M25) was conducted in order to derive kinetic parameters suitable for an ecotoxicological risk assessment, e.g. on birds and mammals, using the software tool KinGUI 2.1. The identification of the appropriate kinetic model followed the recommendations given by FOCUS Kinetics for modelling purpose (FOCUS kinetics, 2006, 2014) and EFSA (2019), based on a detailed statistical analysis including visual assessment, χ^2 statistic, significance t-test and correlation analysis.

In an ecotoxicological context, plant foliage residue trials are used to describe the dissipation or decline behaviour of fluopyram in potential food for birds and mammals. Dissipation curves can be used to estimate the exposure of herbivorous birds or mammals, mainly by calculating the area under the dissipation curve.

To allow for calculation of time weighted averaged residues or area under the curve, after single or multiple applications, it is most appropriate to use a full kinetic parameter set of SFO or biphasic models.

The modelling analysis is based on European crop residue data on green plant material of lettuce, endive, beans and peas (dicotyledons), after spray application of Luna Privilege (SC 500, SC 250). All available residue data points per trial starting with the last application have been included in the evaluation. The plant metabolite fluopyram-benzamide has been analysed in the trials, but not always detected > LOQ. Foliar DT_{50} values are carried out for fluopyram, and in cases, where FLU-benzamide was detected > LOQ, also for the sum of fluopyram and FLU-benzamide.

Trials took place in both regulatory residue zones (N- and S-EU) with a timely variance from April - October. The BBCH growth stages at application have been 41 - 49 (lettuce), 44 - 47 (endive), 71 - 85 (beans) and 71 - 79 (peas).

Daily temperature and precipitation data (rain + irrigation over leaf surfaces, e.g. by sprinkler) were collected, (e.g. based on raw data or publicly available weather station data).

In case of trials with 4 sampling points, DFOP and HS fits cannot deliver statistical information and are not appropriate, due to a too low degree of freedom (3 fitted parameters based on 4 data points). In these cases, such fits were not selected and summarised in the conclusion section. Nevertheless, reliable dissipation kinetics can be derived with 4 data points, e.g. when a clear decline can be seen, or the latest points are close to 0.

In case of trials with > 4 sampling points, all 4 model fits have been carried out, but only those graphs are presented in the summary which are needed for model decision.

II. RESULTS AND DISCUSSION

The following units are used in the following tables:

k	1/d
β, tb	d
α, g	none

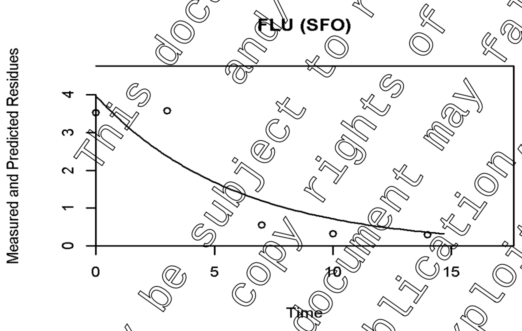
Fluopyram

Trial 08-2034-01, Damery, M-365530-01-1, FR, beans

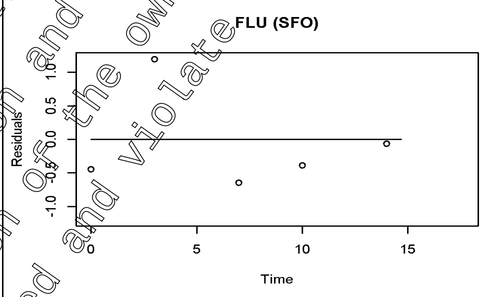
Table 8.9- 61: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial 08-2034-01, Damery, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.0	k: 0.17101	32.1	k: 0.0046	k: 0.03	k: 0.31	**4.053**	13.46
FOMC	o	4.0	α: 13115.89 β: 76693.81	36.7	-	β: 74546.59	β: 78841.03	4.053	13.47
DFOP	o	4.0	k1: 0.171 k2: 0.043 g: 1.00	45.8	k1: 0.380 k2: <0.001	k1: -0.68 k2: 0.04	k1: 1.02 k2: 0.04	4.053	13.46
HS	o	4.0	k1: 0.171 k2: 0.182 tb: 14.597	45.8	k1: 0.197 k2: <0.001	k1: -0.07 k2: 0.18	k1: 0.41 k2: 0.18	4.053	13.46

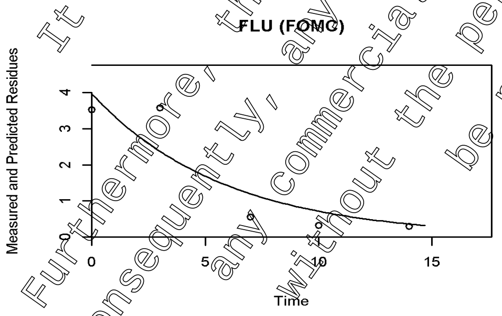
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



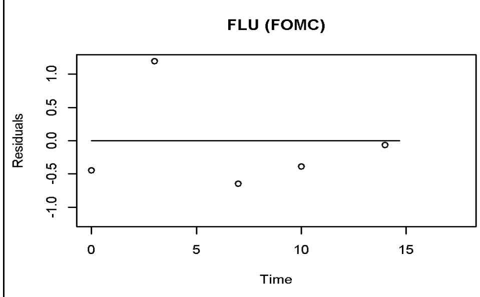
SFO



SFO



FOMC

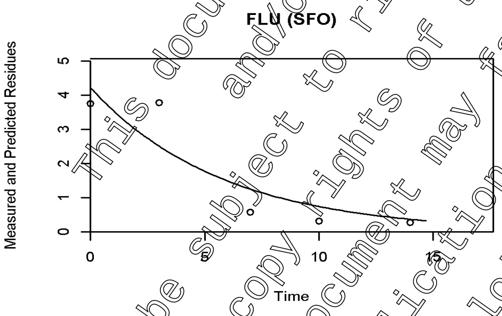


08-2034-02, Damery, M-365530-01-1, FR, beans

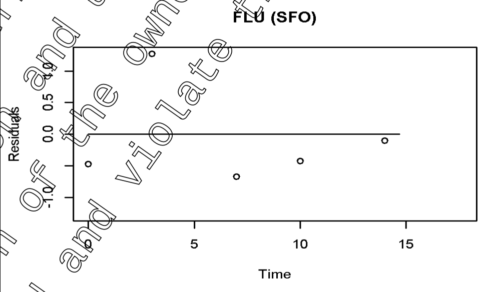
Table 8.9- 62: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial 08-2034-02, Damery, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.2	k: 0.17365	32.4	k: 0.046	k: 0.03	k: 0.31	**3.992**	13.26
FOMC	o	4.2	α: 9026.15 β: 51976.05	37.0	-	β: 50477.44	β: 53474.67	3.992	13.26
DFOP	o	4.2	k1: 0.174 k2: 0.044 g: 1.00	46.2	k1: 0.379 k2: <0.001	k1: -0.68 k2: 0.04	k1: 1.03 k2: 0.04	3.992	13.26
HS	+	3.8	k1:<0.0005 k2: 0.428 tb: 3.00	8.5	k1: 0.5 k2: 0.271	k1: -1.38 k2: -0.53	k1: 1.38 k2: 1.39	4.620	8.38

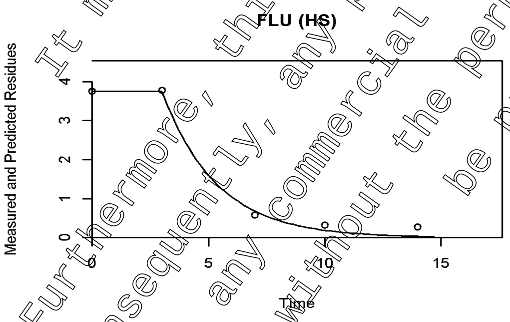
SFO fit is statistically and visually acceptable (t-test < 0.05), although χ^2 err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. The HS resulted in a lag phase, which is considered not appropriate for the intended purpose. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.

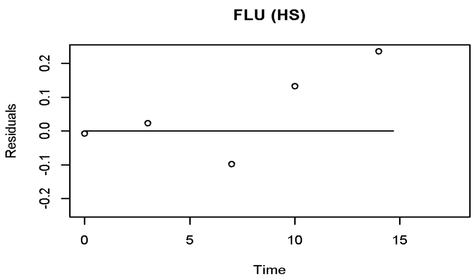


SFO



SFO



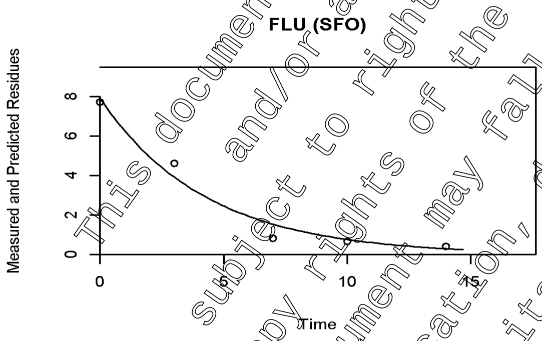


08-2096-01, Ladispoli, M-365542-01-1, IT, beans

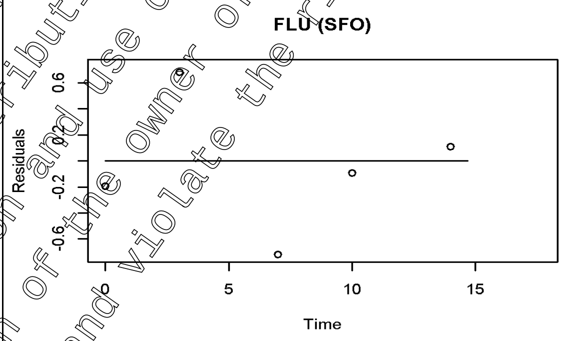
Table 8.9- 63: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial 08-2096-01, Ladispoli, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.9	k: 0.23348	12.9	k: 0.004	k: 0.16	k: 0.30	**2.969**	9.86
FOMC	o	7.9	α: 10300 β: 44120	14.7	-	β: 43280	β: 44958.03	2.969	9.86
DFOP	o	7.9	k1: 0.2335 k2: 2.2 E-14 g: 1.00	18.3	k1: 0.151 k2: <0.001	k1: -0.0023 k2: 2.2 E-14	k1: 0.47 k2: 0.0005	2.969	9.86
HS	o	7.9	k1: 0.235 k2: 0.031 tb: 12.38	18.2	k1: 0.085 k2: 0.494	k1: 0.11 k2: -3.05	k1: 0.36 k2: 3.11	2.950	9.80

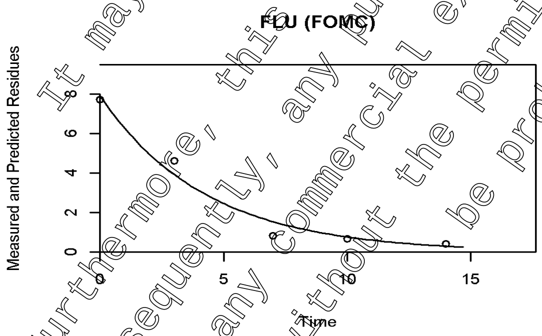
SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, SFO model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



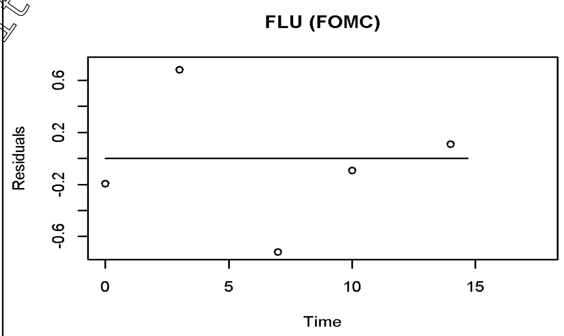
SFO



SFO



FOMC



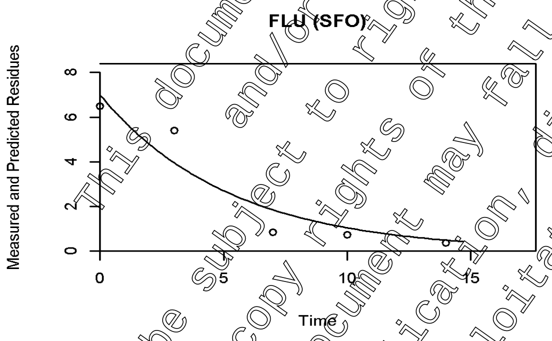
FOMC

08-2096-02, Ladispoli, M-365542-01-1, IT, beans

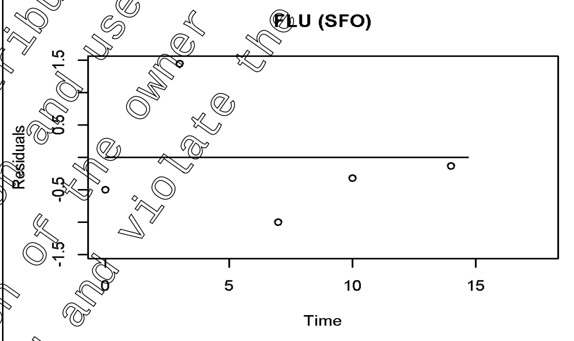
Table 8.9- 64: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial 08-2096-02, Ladispoli, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.0	k: 0.19003	24.0	k: 0.022	k: 0.08	k: 0.30	**3.648**	12.12
FOMC	o	7.0	α: 16727.04 β: 88019.25	27.4	-	β: 85830.3	β: 90208.21	3.647	12.12
DFOP	o	7.0	k1: 0.190 k2: 2.2 E-14 g: 1.00	34.2	k1: 0.280 k2: <0.001	k1: -0.26 k2: 2.2 E-14	k1: 0.64 k2: 0.0005	3.648	12.12
HS	o	7.0	k1: 0.188 k2: 0.450 tb: 12.73	34.1	k1: 0.159 k2: 0.464	k1: -0.01 k2: -7.35	k1: 0.39 k2: 8.25	3.687	12.25

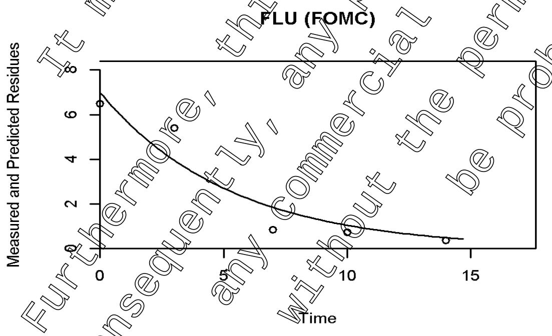
SFO fit is statistically and visually acceptable (t-test < 0.05), although χ^2 err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



SFO



SFO



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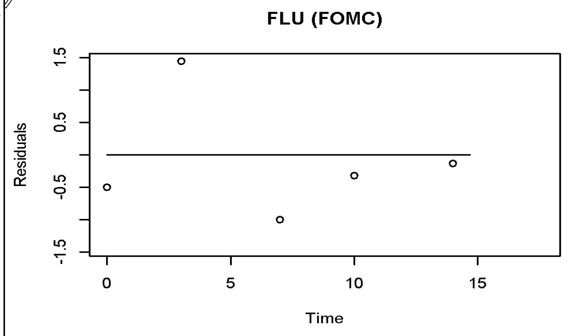


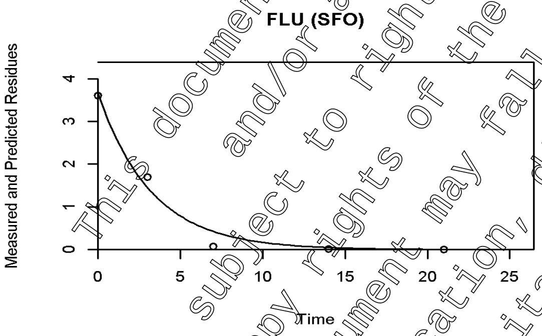
FOMC

10-2099-01, Wieringerwerf, M-423901-01-1, NL, endive

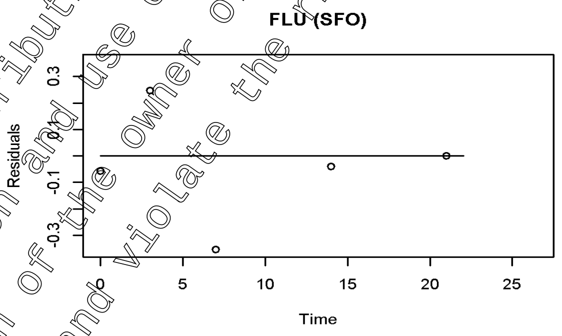
Table 8.9- 65: Kinetic models and goodness-of-fit statistics of fluopyram fits for endive of trial 10-2099-01, Wieringerwerf, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.7	k: 0.30776	14.5	k: 0.005	k: 0.21	k: 0.41	**2.252**	7.48
FOMC	o	3.7	α: 13630 β: 44300	16.6	-	β: 44300	β: 44301.89	2.252	7.48
DFOP	o	3.7	k1: 0.815 k2: 0.3078 g: 3.1 E-14	20.7	k1: NA k2: 0.253	k1: NA k2: -0.31	k1: NA k2: 0.92	2.252	7.48
HS	o	3.7	k1: 0.308 k2: 0.458 tb: 20.125	20.7	k1: 0.089 k2: 0.499	k1: 0.13 k2: -189.89	k1: 0.48 k2: 190.81	2.252	7.48

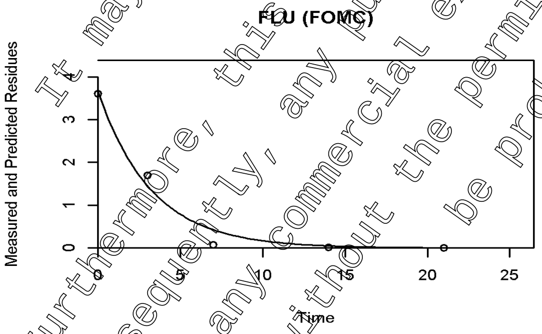
SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



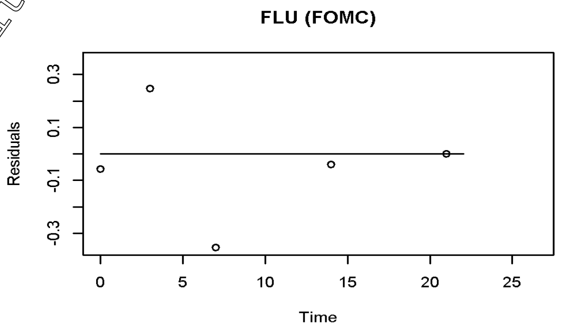
SFO



SFO



FOMC



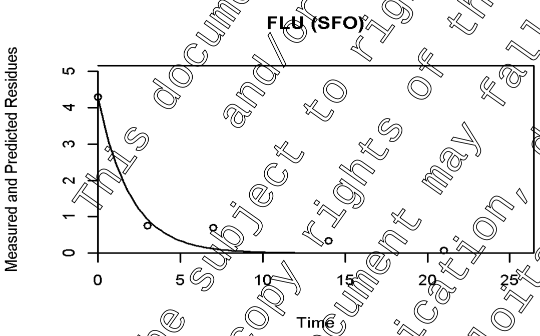
FOMC

10-2099-02, Langenfeld-Reusrath, M-423901-01-1, DE, endive

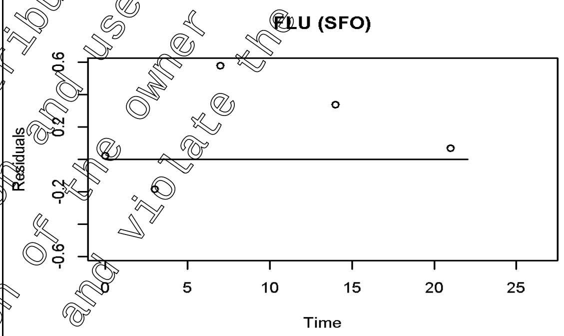
Table 8.9- 66: Kinetic models and goodness-of-fit statistics of fluopyram fits for endive of trial 10-2099-02, Langenfeld-Reusrath, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	4.3	k: 0.5076	20.2	k: 0.018	k: 0.23	k: 0.78	1.366	4.54
FOMC	+	4.3	α: 0.63521 β: 0.24175	9.4	-	β: -0.63	β: 1.12	0.478	8.829
DFOP	+	4.3	k1: 11.67542 k2: 0.085029 g: 0.7545	7.2	k1: <0.001 k2: 0.137	k1: 11.68 k2: 0.01	k1: 11.68 k2: 0.16	0.092	10.56
HS	+	4.3	k1: 0.617 k2: 0.085 tb: 2.639	7.2	k1: 0.038 k2: 0.137	k1: 0.47 k2: 0.01	k1: 0.76 k2: 0.16	1.123	10.56

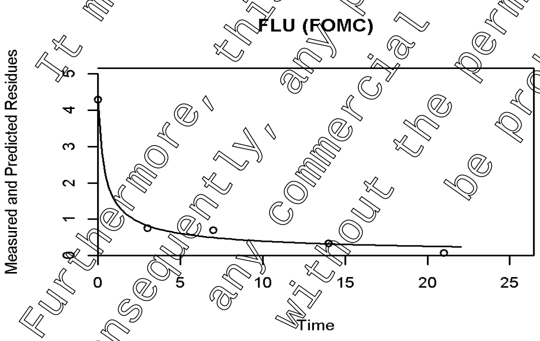
SFO fit is statistically (χ^2err ~15%, t-test <0.05) and visually poor. FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in χ2 error and visual assessment. However, the t-test of DFOP and HS show a low reliability especially of the slow degradation rates k2 (t-test > 0.05). Therefore, **FOMC** model is considered best appropriate for modelling endpoints (FOCUS kinetics) and as well as best visual fit.



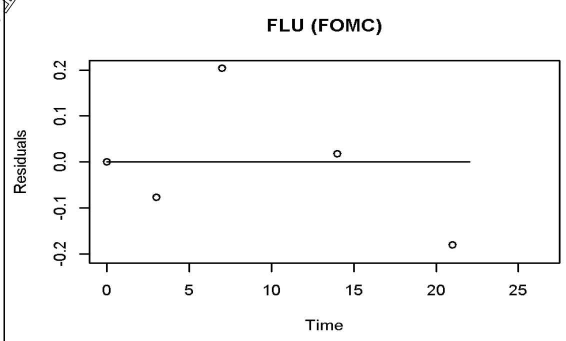
SFO



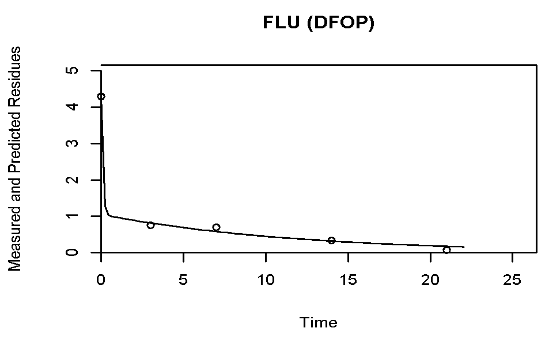
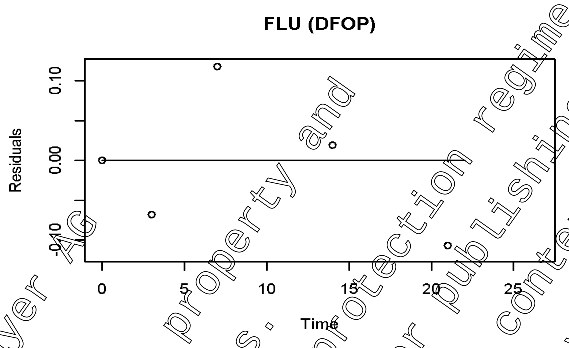
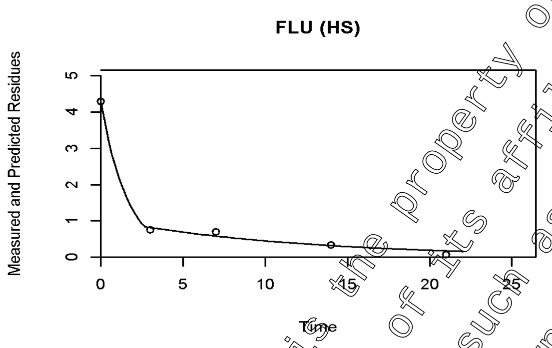
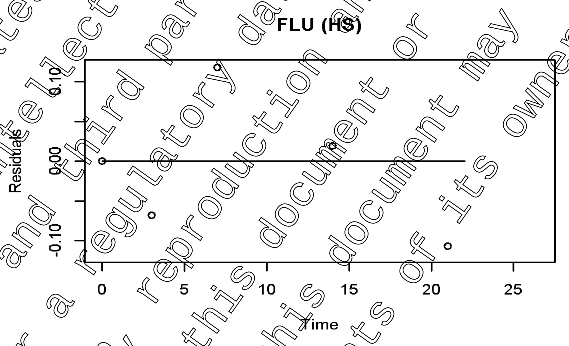
SFO



FOMC



FOMC

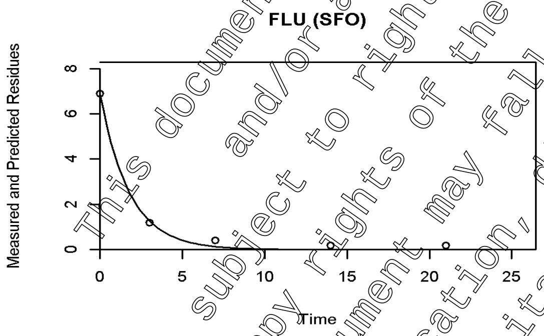
 DFOP	 DFOP
 HS	 HS

10-2099-03, Villers-Perwin, M-423901-01-1, BE, endive

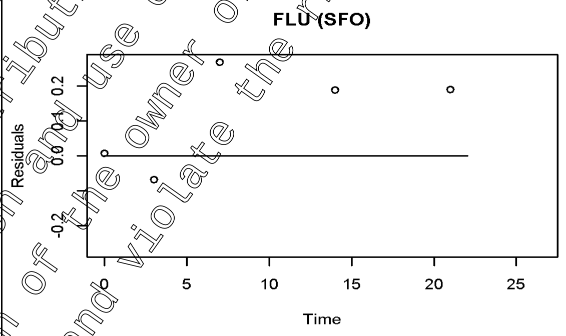
Table 8.9- 67: Kinetic models and goodness-of-fit statistics of fluopyram fits for endive of trial 10-2099-03, Villers-Perwin, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	$DT_{50\ actual}$ (d)	$DT_{90\ actual}$ (d)
SFO	+	6.9	k: 0.56460	7.7	k: 0.001	k: 0.45	k: 0.68	**1.228**	4.078
FOMC	+	6.9	α: 1.42878 β: 1.23192	2.3	-	β: 0.38	β: 2.08	0.769	4.941
DFOP	+	6.9	k1: 0.697195 k2: 0.051759 g: 0.9307	1.6	k1: 0.023 k2: 0.158	k1: 0.60 k2: -0.0032	k1: 0.794 k2: 0.107	1.093	4.356
HS	+	6.9	k1: 0.583 k2: 0.067 tb: 4.686	1.9	k1: 0.010 k2: 0.132	k1: 0.55 k2: 0.01	k1: 0.62 k2: 0.13	1.189	3.949

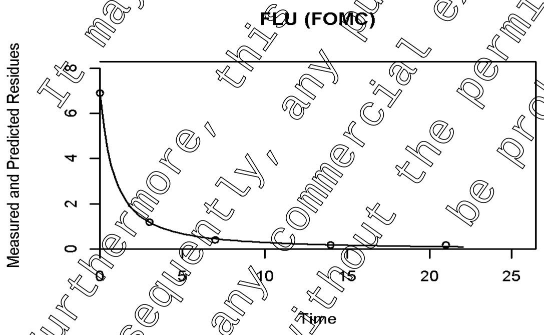
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached, is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



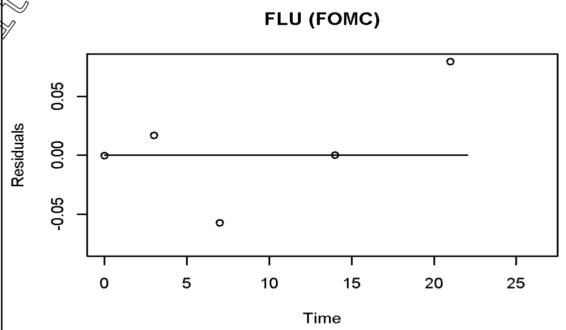
SFO



SFO



FOMC



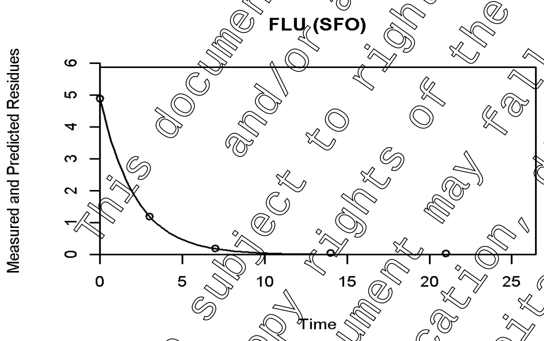
FOMC

10-2099-04, Fondettes, M-423901-01-1, FR, endive

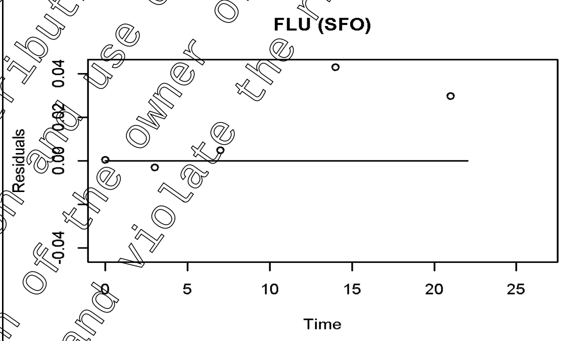
Table 8.9- 68: Kinetic models and goodness-of-fit statistics of fluopyram fits for endive of trial 10-2099-04, Fondettes, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	4.9	k: 0.468101	1.5	k: <0.001	k: 0.45	k: 0.48	**1.481**	4.919
FOMC	+	4.9	α: 29.767 β: 61.879	1.6	-	β: -179.83	β: 303.59	1.458	4.976
DFOP	+	4.9	k1: 0.4771 k2: 2.2 E-14 g: 0.994	0.8	k1: 0.007 k2: 0.5	k1: 0.456 k2: -0.17	k1: 0.498 k2: 0.17	1.467	4.953
HS	+	4.9	k1: 0.46897 k2: 0.170 tb: 6.911	0.6	k1: 0.003 k2: 0.060	k1: 0.46 k2: 0.11	k1: 0.48 k2: 0.23	1.478	4.91

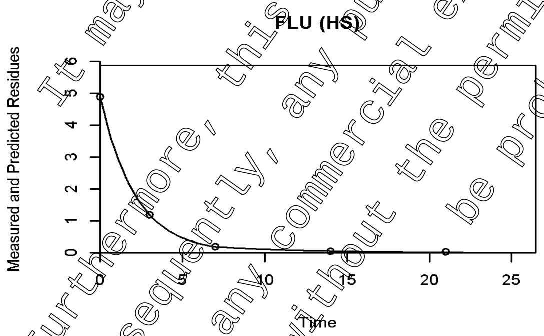
SFO fit is statistically and visually very good (χ^2err <15%, t-test <0.05). DFOP and HS would result in a very marginally improved χ^2err. However, parameters g and tb show, that both fits are almost equal to SFO. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



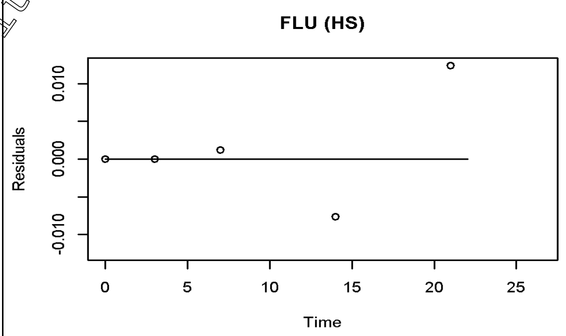
SFO



SFO



HS



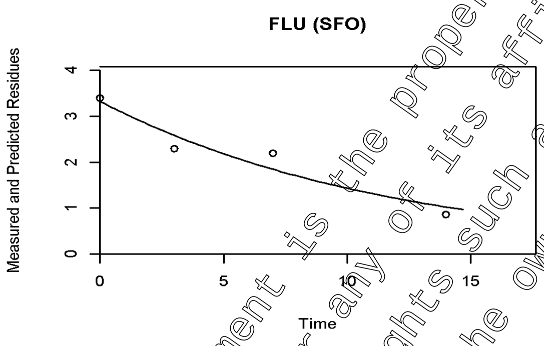
HS

18-2086-01-T1, Palidoro Fiumicino, M-675005-01-1, IT, lettuce

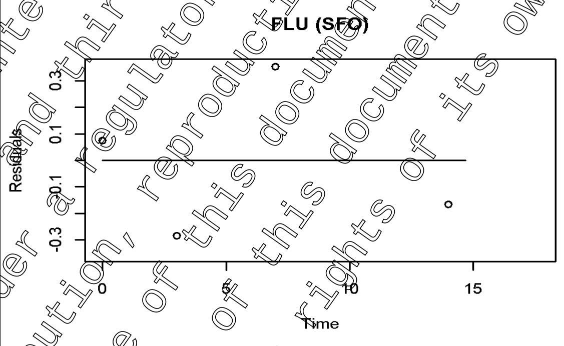
Table 8.9- 69: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 18-2086-01-T1, Palidoro Fiumicino, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.3	k: 0.08404	9.1	k: 0.028	k: 0.04	k: 0.13	**8.248**	27.40
FOMC	+	3.3	α: 6832 β: 81290	11.4	-	β: 80900	β: 81682.74	8.248	27.40

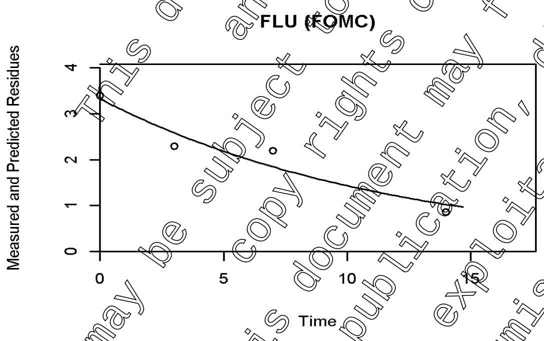
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). FOMC did not result in an improved fit, mainly due to scattering data. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



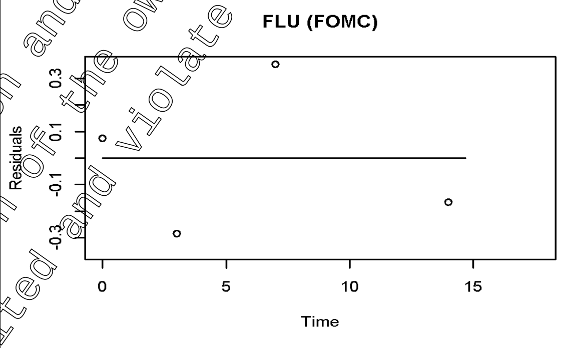
SFO



SFO



FOMC



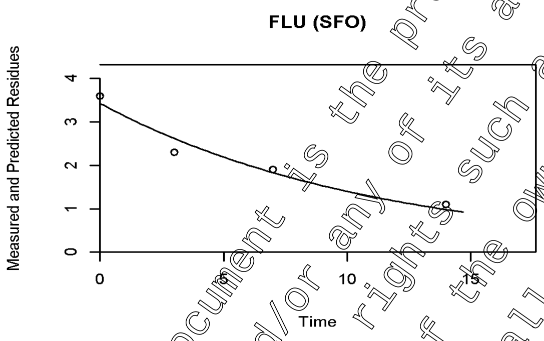
FOMC

18-2086-01-T2, Palidoro Fiumicino, M-675005-01-1, IT, lettuce

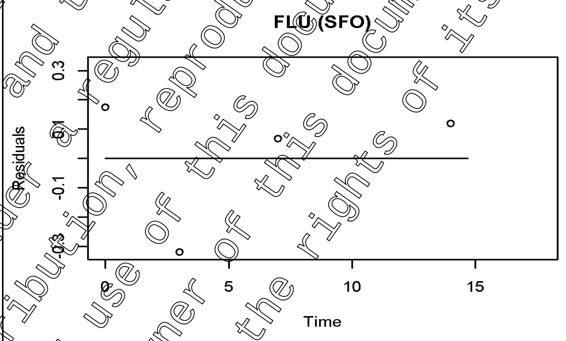
Table 8.9- 70: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 18-2086-01-T2, Palidoro Fiumicino, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.4	k: 0.0894	7.2	k: 0.017	k: 0.06	k: 0.12	**7.754**	25.76
FOMC	+	3.6	α: 0.7763 β: 4.4732	5.2	-	β: -6.27	β: 15.22	6.450	82.36

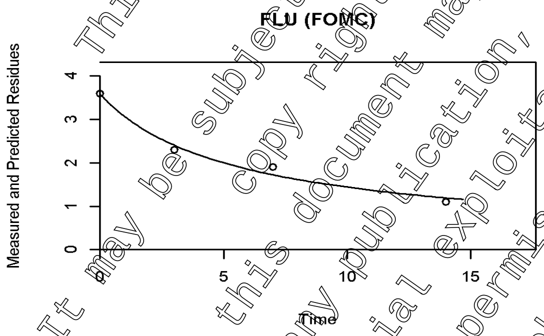
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics). FOMC shows a lower χ^2err. However, FOMC is not fully appropriate in cases where 10 % of the initial residues have not been reached during study duration, as an unrealistic tailing may occur. DFOP and HS are not appropriate in case of 4 data points, due to a too low degree of freedom. Consequently, SFO is therefore considered appropriate for modelling purpose (FOCUS kinetics) and as best visual fit.



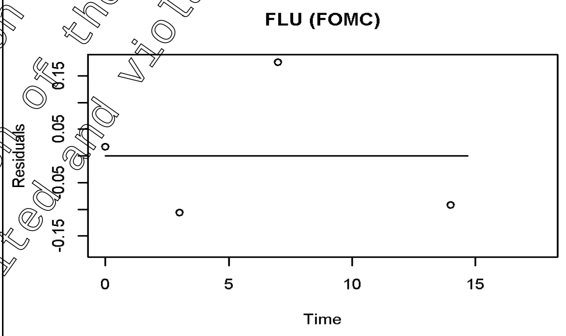
SFO



SFO



FOMC



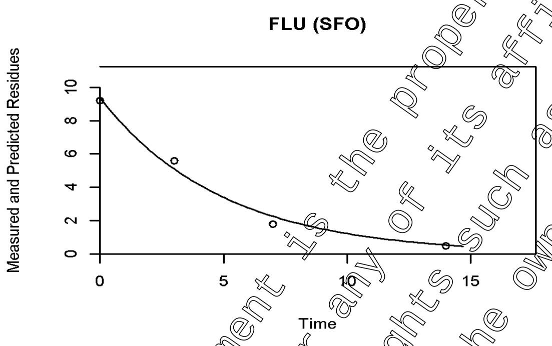
FOMC

18-2086-02-T1, Terlizzi , M-675005-01-1, IT, lettuce

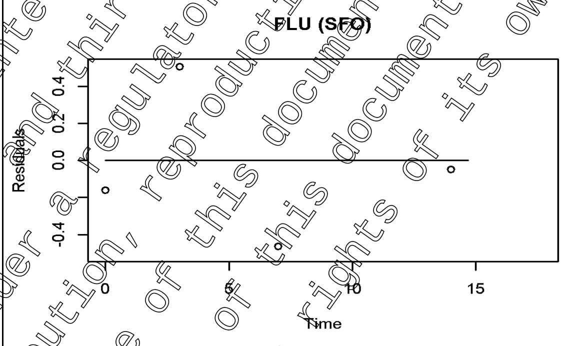
Table 8.9- 71: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 18-2086-02-T1, Terlizzi , IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	9.4	k: 0.20275	6.7	k: 0.007	k: 0.16	k: 0.25	**3.419**	11.36
FOMC	+	9.4	α: 5569 β: 27460	8.4	-	β: 27110	β: 27822.5	3.419	11.36

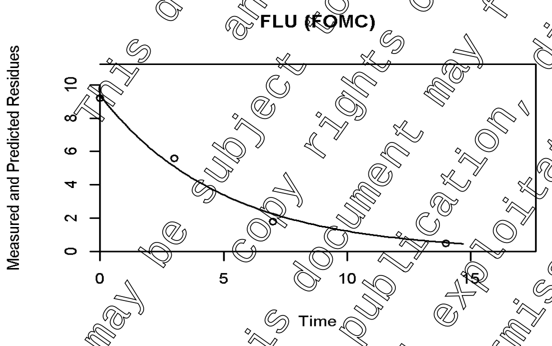
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



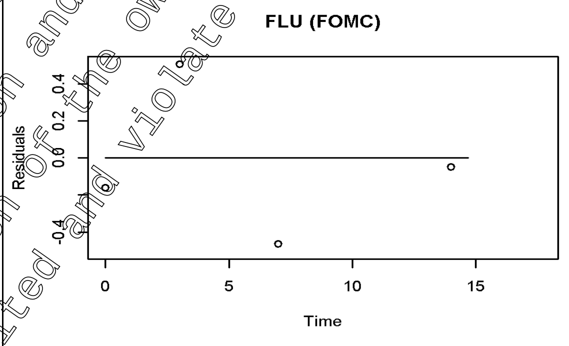
SFO



SFO



FOMC



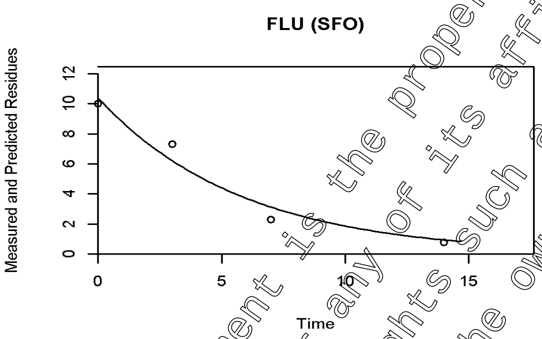
FOMC

18-2086-02-T2, Terlizzi , M-675005-01-1, IT, lettuce

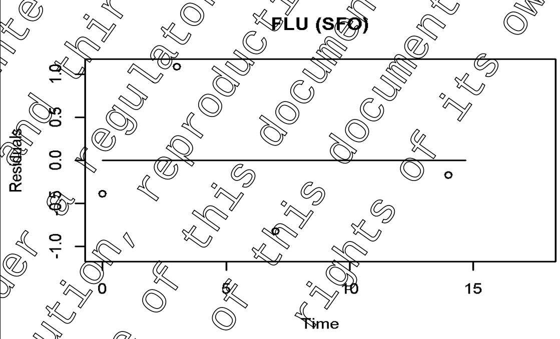
Table 8.9- 72: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 18-2086-02-T2, Terlizzi , IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	10.4	k: 0.17156	11.5	k: 0.022	k: 0.10	k: 0.24	**4.040**	13.42
FOMC	o	10.4	α: 7285.173 β: 42461.29	14.4	-	β: 41737.38	β: 43185.20	4.040	13.42

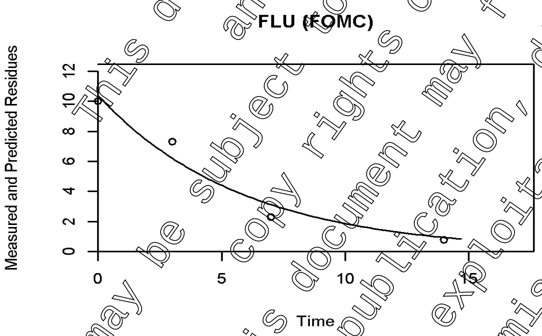
SFO fit is statistically and visually acceptable (χ^2 err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit



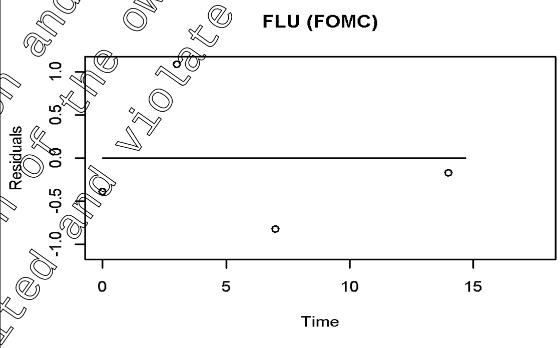
SFO



SFO



FOMC

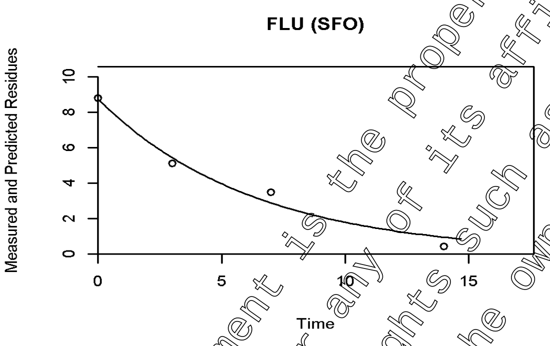


FOMC

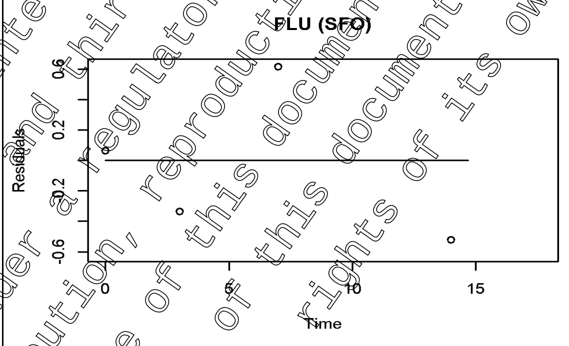
18-2086-03-T1, Alginet, M-675005-01-1, ES, lettuce

Table 8.9- 73: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 18-2086-03-T1, Alginet, ES

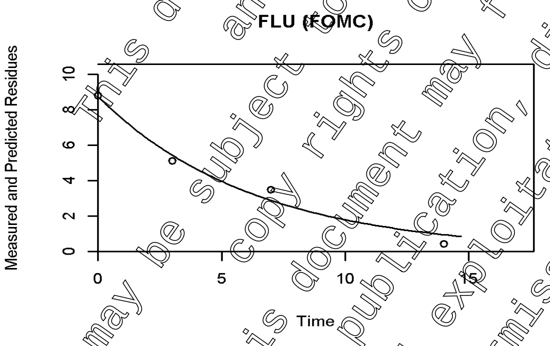
Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	$DT_{50\ actual}$ (d)	$DT_{90\ actual}$ (d)
SFO	o	8.7	k: 0.15831	8.0	k: 0.012	k: 0.11	k: 0.21	**4.378**	14.54
FOMC	o	8.7	α: 11086.197 β: 70024.008	10.0	-	β: 69284.56	β: 70763.45	4.378	14.55
SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.									



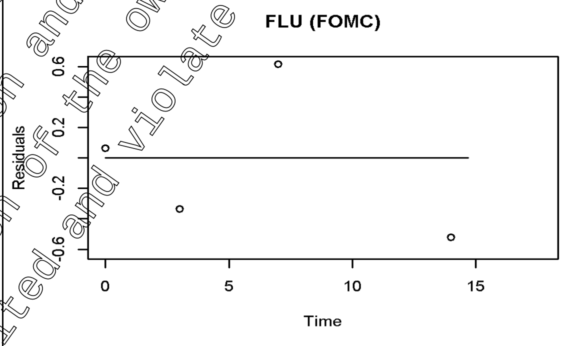
SFO



SFO



FOMC



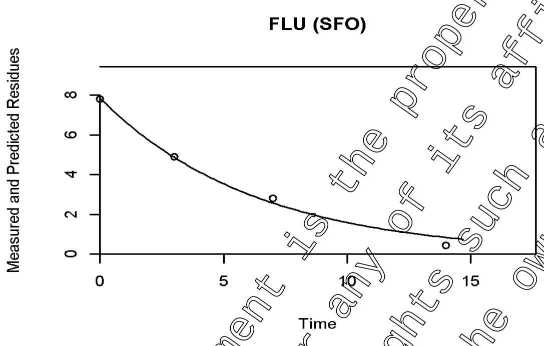
FOMC

18-2086-03-T2, Alginet, M-675005-01-1, ES, lettuce

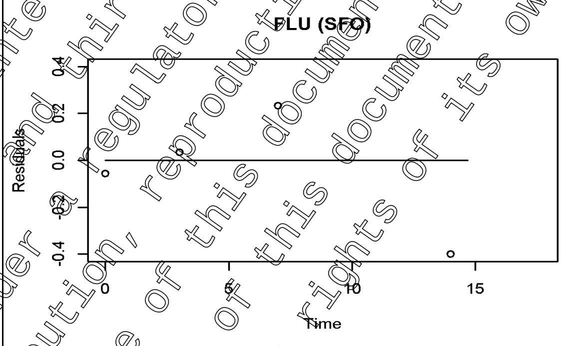
Table 8.9- 74: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 18-2086-03-T2, Alginet, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	7.9	k: 0.15974	4.8	k: 0.004	k: 0.13	k: 0.19	**4.339**	14.41
FOMC	+	7.9	α: 8493 β: 53170	6.0	-	β: 52830	β: 53505.29	4.339	14.42

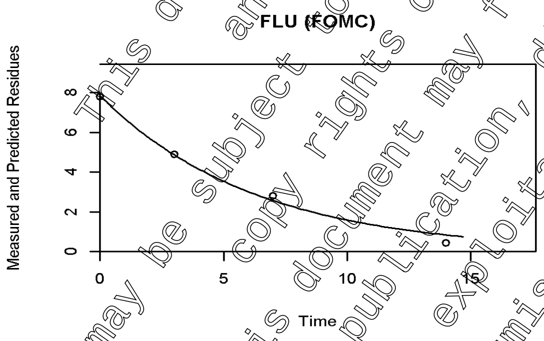
SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



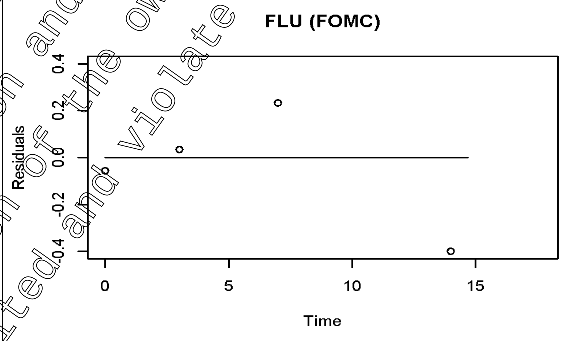
SFO



SFO



FOMC



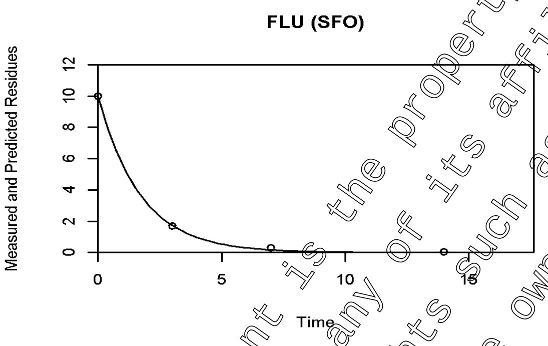
FOMC

18-0286-04-T1, Vasilika Thessaloniki, M-675005-01-1, GR, lettuce

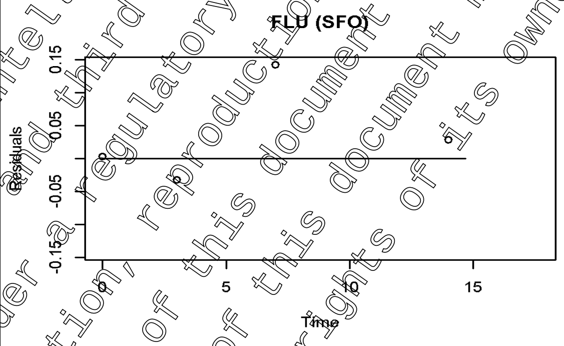
Table 8.9- 75: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 18-0286-04-T1, Vasilika Thessaloniki, GR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	10.0	k: 0.58426	2.0	k: <0.001	k: 0.54	k: 0.62	**1.186**	3.941
FOMC	+	10.0	α: 5.388963 β: 7.707201	0.1	-	β: 6.84	β: 8.58	1.058	4.109

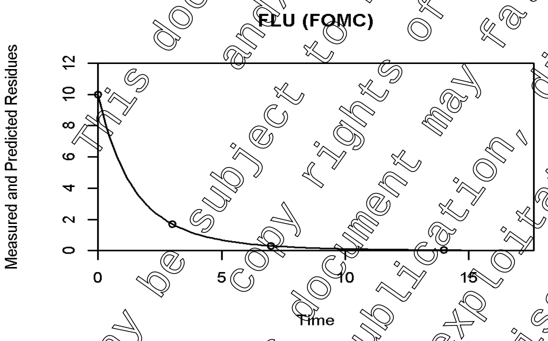
SFO fit is statistically and visually very good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



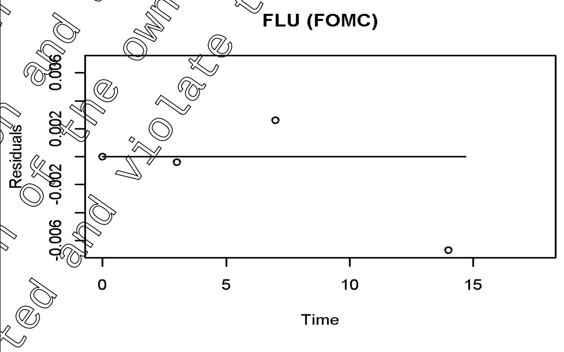
SFO



SFO



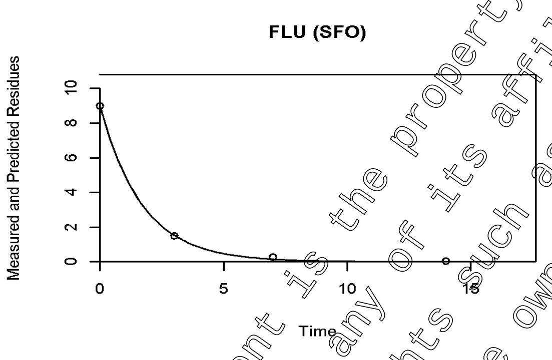
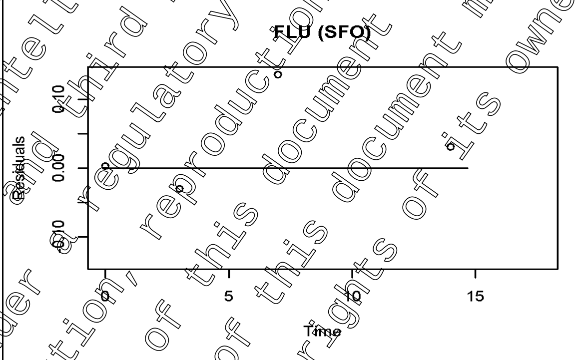
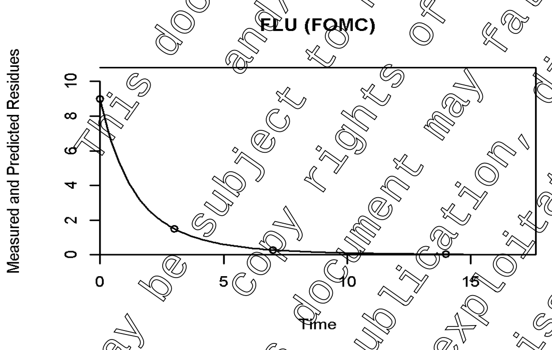
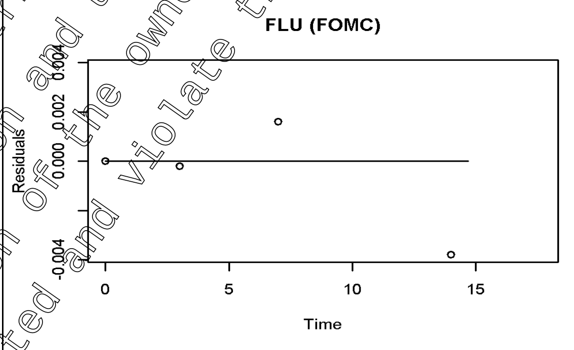
FOMC



FOMC

18-0286-04-T2, Vasilika Thessaloniki, M-675005-01-1, GR, lettuce

Table 8.9- 76: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 18-0286-04-T2, Vasilika Thessaloniki, GR

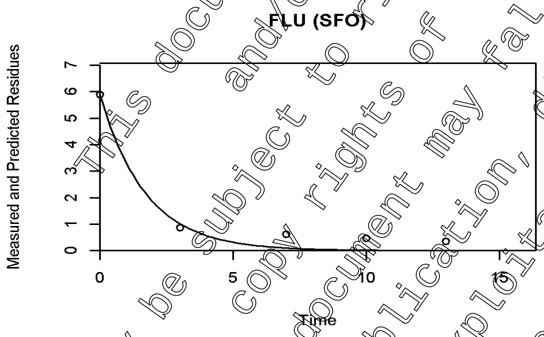
Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	9.0	k: 0.59053	2.2	k: <0.001	k: 0.55	k: 0.63	**1.174**	3.899
FOMC	+	9.0	α: 4.963166 β: 6.900881	0.1	-	β: 6.43	β: 7.37	1.034	4.074
SFO fit is statistically and visually very good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).									
 SFO					 SFO				
 FOMC					 FOMC				

R 2006 0375/4, Cergy, M-292048-01-1, FR, lettuce

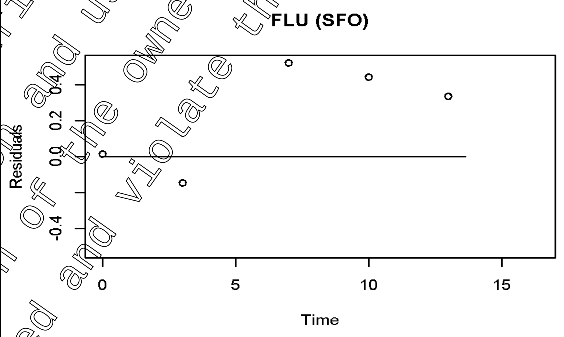
Table 8.9- 77: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2006 0375/4, Cergy, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	5.9	k: 0.5856	17.0	k: 0.014	k: 0.30	k: 0.87	1.184	3.932
FOMC	+	5.9	α: 0.565 β: 0.109	2.1	-	β: -0.04	β: 0.25	0.262	6.303
DFOP	+	5.9	k1: 433800 k2: 0.092 g: 0.805	0.5	k1: NA k2: 0.015	k1: NA k2: 0.08	k1: NA k2: 0.10	7.43 E-5	7.297
HS	+	5.9	k1: 0.640819 k2: 0.091899 tb: 2.973	0.5	k1: 0.003 k2: 0.015	k1: 0.63 k2: 0.08	k1: 0.65 k2: 0.10	1.082	7.297

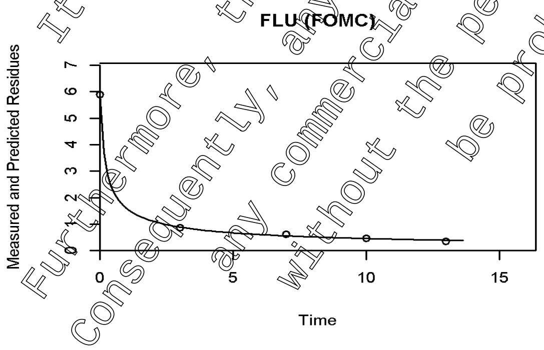
SFO fit is statistically acceptable (χ^2err ~15%, t-test <0.05), but visually poor. DFOP, FOMC and HS fits were alternatively tested. HS fit is statistically (χ^2err, t-test) and visually good, with a lowest χ2 err and most reliable degradation rates (of DFOP or HS). Consequently, **HS** model is considered appropriate according to modelling purpose (FOCUS kinetics) and as best visual fit. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT50 is an adequate option.



SFO



SFO



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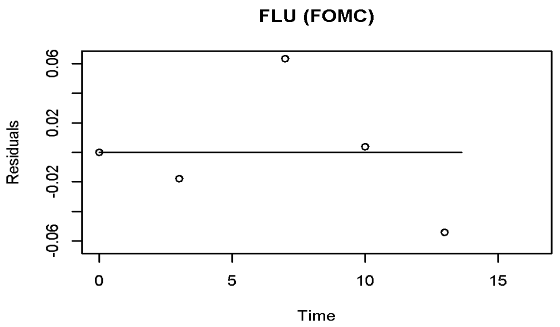
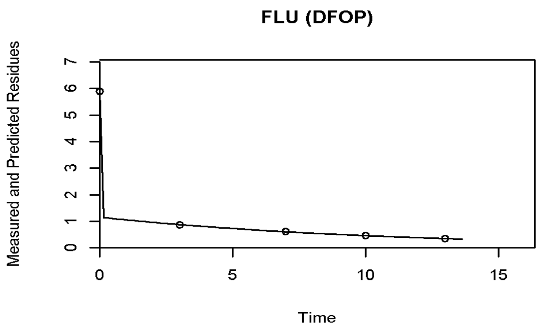
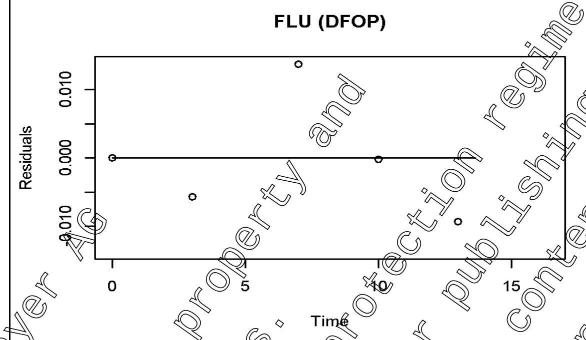
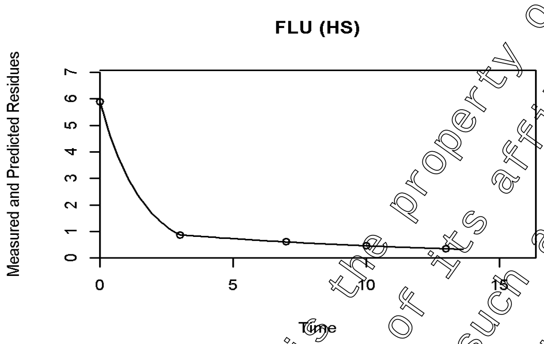
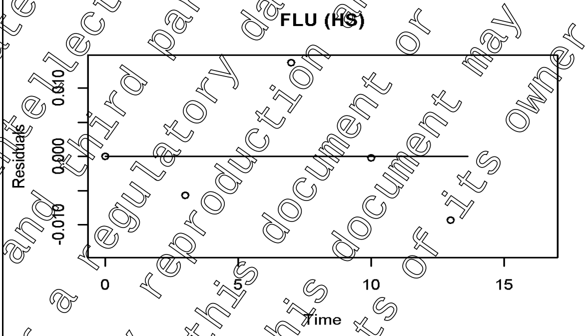


FOMC

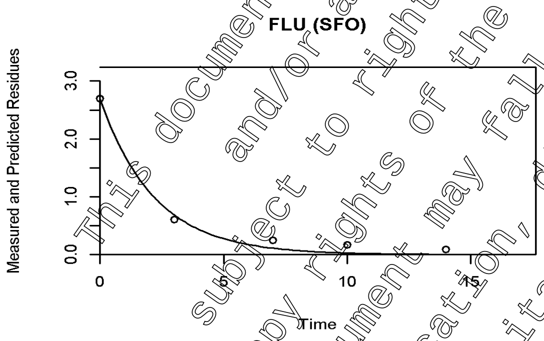
 DFOP	 DFOP
 HS	 HS

R 2006 0376/2, St. Jory, M-292050-01-1, FR, lettuce

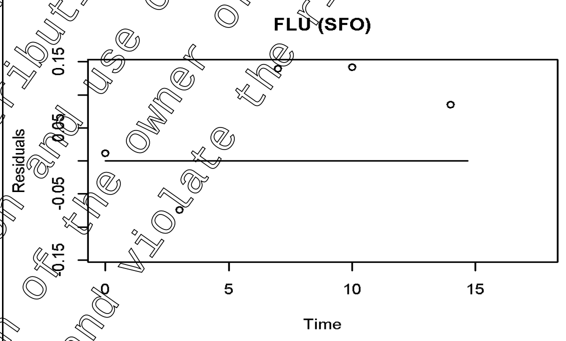
Table 8.9- 78: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2006 0376/2, St. Jory, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	2.7	k: 0.45594	10.7	k: 0.003	k: 0.34	k: 0.58	**1.520**	5.050
FOMC	+	2.7	α: 1.47734 β: 1.73192	0.9	-	β: 1.34	β: 2.13	1.037	6.498
DFOP	+	2.7	k1: 1793000 k2: 0.194 g: 0.60	2.5	k1: NA k2: 0.039	k1: NA k2: 0.15	k1: NA k2: 0.24	0.000	7.144
HS	+	2.7	k1: 0.495849 k2: 0.141111 tb: 3.902	0.4	k1: 0.002 k2: 0.022	k1: 0.49 k2: 0.12	k1: 0.50 k2: 0.16	1.398	6.508

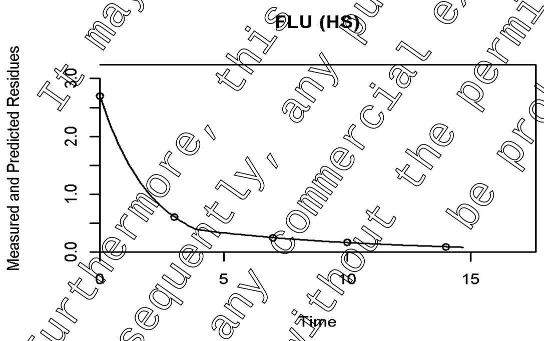
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 7), is described visually acceptable. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



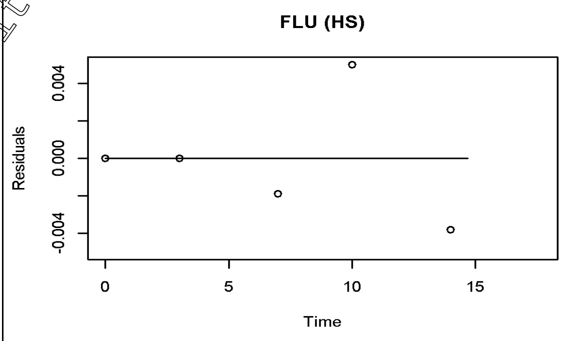
SFO



SFO



HS



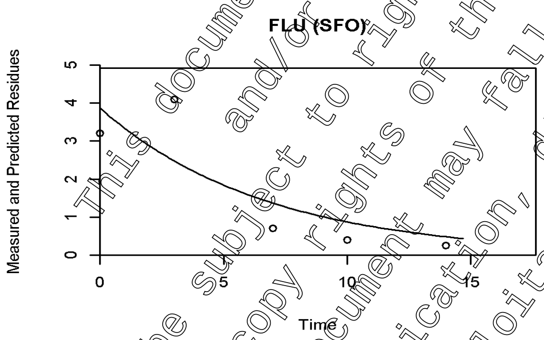
HS

R 2006 0377/0, Lampertheim, M-290825-01-1, DE, beans

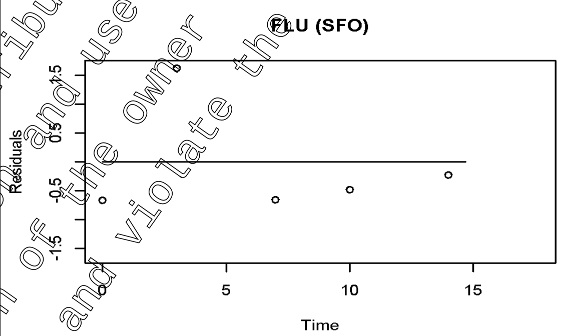
Table 8.9- 79: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2006 0377/0, Lampertheim, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.9	k: 0.148291	40.2	k: 0.081	k: -0.01	k: 0.31	**4.674**	15.53
FOMC	o	3.9	α: 16950 β: 114300	45.9	-	β: 114300	β: 114300	4.674	15.53
DFOP	o	3.9	k1: 0.14829 k2: 0.056 g: 1.00	57.3	k1: 0.434 k2: <0.001	k1: -1.22 k2: 0.06	k1: 1.52 k2: 0.06	4.674	15.53
HS	o	3.9	k1: 0.1483 k2: 0.147 tb: 19.804	57.3	k1: 0.240 k2: <0.001	k1: -0.12 k2: 0.15	k1: 0.42 k2: 0.15	4.674	15.53

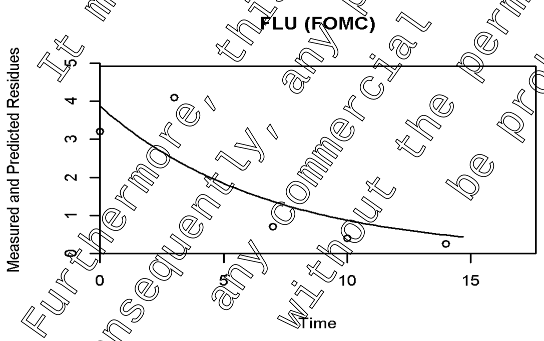
SFO fit is visually acceptable and at least conservative, but statistically not very good (χ^2err >15%, t-test >0.05). FOMC, DFOP and HS did not result in an improved fit, due to the scattering data. No further explanation for the scattering residue data is given in the experimental report. However, as residues reach 10% of the initial amount, the SFO fit is finally considered appropriate and conservative to describe the residue decay.



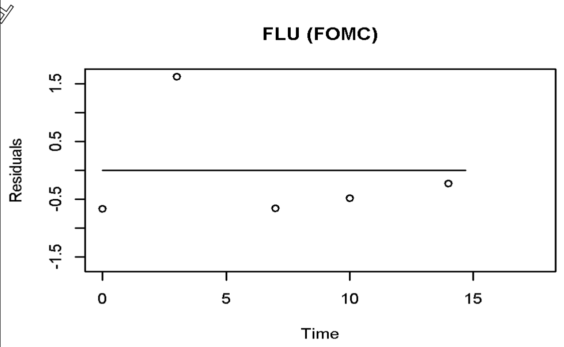
SFO



SFO



FOMC



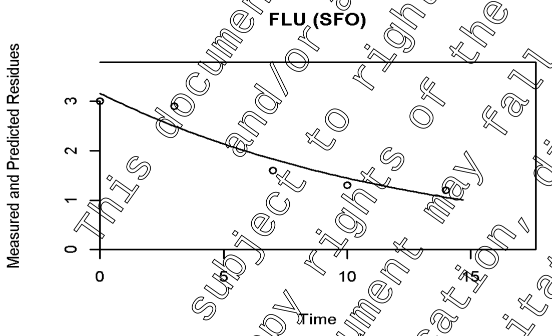
FOMC

R 2006 0378/9, Alginet, M-290827-01-1, ES, beans

Table 8.9- 80: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2006 0378/9, Alginet, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.2	k: 0.07813	9.5	k: 0.008	k: 0.05	k: 0.11	**8.872**	29.47
FOMC	o	3.2	α: 1254 β: 16050	10.8	-	β: 16000	β: 16093.53	8.871	29.49
DFOP	o	3.2	k1: 0.07813 k2: 0.033 g: 1.00	13.5	k1: 0.415 k2: <0.001	k1: -0.48 k2: 0.0329	k1: 0.64 k2: 0.033	8.872	29.47
HS	o	3.2	k1: 0.084 k2: 0.039 tb: 10.0	12.7	k1: 0.155 k2: 0.446	k1: -0.0033 k2: -0.41	k1: 0.17 k2: 0.49	8.268	47.30

SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



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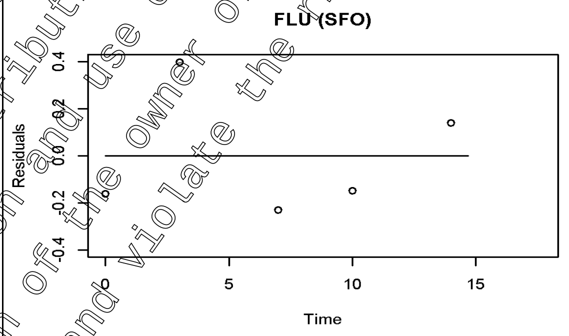
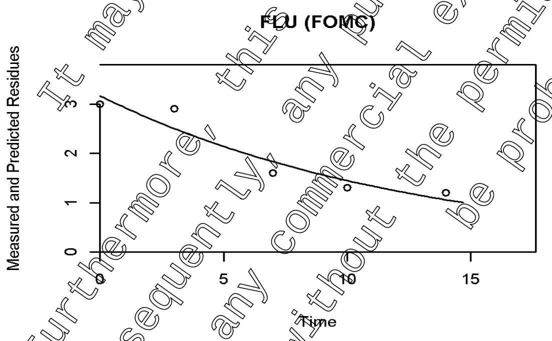
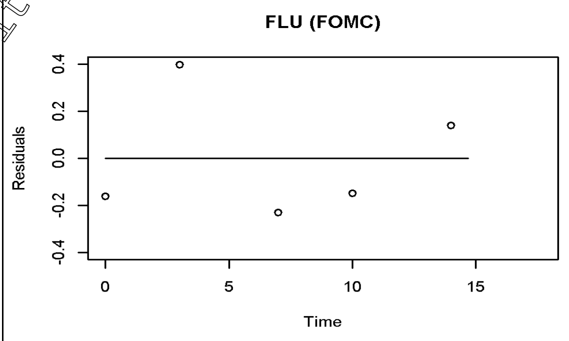


SFO



FOMC



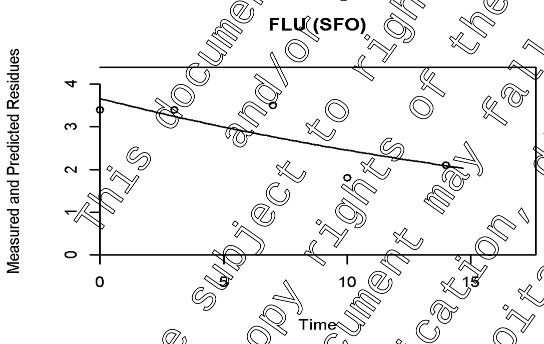
FOMC

R 2006 0380/0, Machern, M-291180-01-1, DE, peas

Table 8.9- 81: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial R 2006 0380/0, Machern, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.7	k: 0.040021	13.0	k: 0.067	k: 0.00149	k: 0.079	**17.32**	57.53
FOMC	o	3.7	α: 4172 β: 104200	14.8	-	β: 104000	β: 104428.6	17.32	57.55
DFOP	o	3.7	k1: 0.04002 k2: 0.040 g: 0.531	18.5	k1: 0.233 k2: 0.214	k1: -0.03 k2: -0.02	k1: 0.11 k2: 0.10	17.32	57.53
HS	o	3.4	k1: 2.2 E-14 k2: 0.091 tb: 6.398	14.6	k1: 0.5 k2: 0.218	k1: -0.22 k2: -0.05	k1: 0.22 k2: 0.24	14.00	31.65

SFO fit is visually and statistically not very good (χ^2err <15%, t-test >0.05). FOMC, DFOP and HS did not result in an improved fit, due to scattering data. No further explanation for the scattering residue data is given in the experimental report (after analytical double check). However, as initial and final residues are covered sufficiently well and further data points scatter equally around the fit, the SFO fit is finally considered appropriate and conservative to describe the residue decay.



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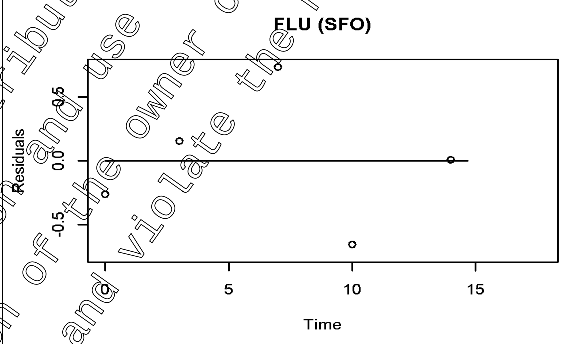

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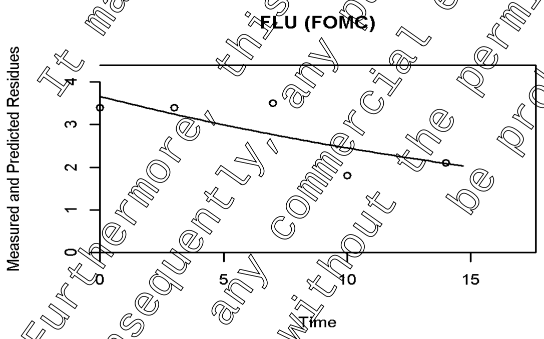

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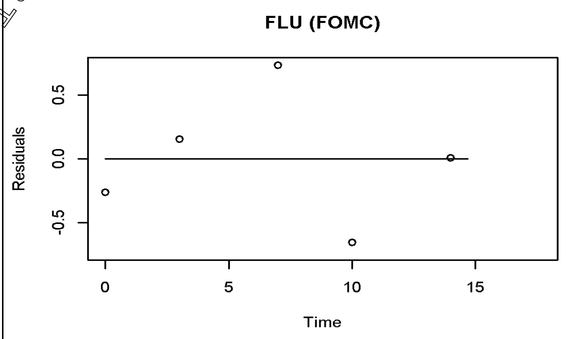


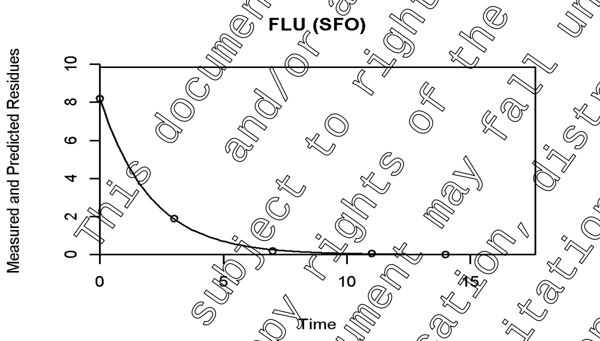
FOMC

R 2006 0604/4, Meckenbeuren, M-292048-01-1, DE, lettuce

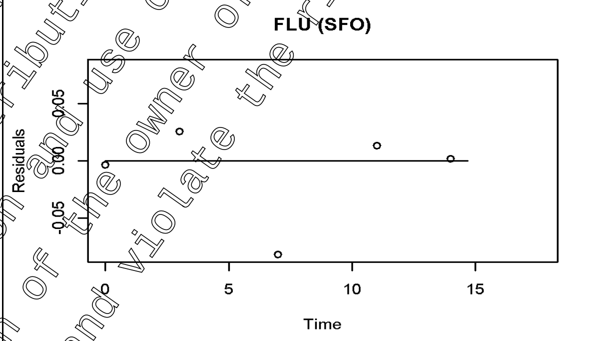
Table 8.9- 82: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2006 0604/4, Meckenbeuren, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	8.2	k: 0.492096	1.5	k: <0.001	k: 0.48	k: 0.51	**1.409**	4.679
FOMC	+	8.2	α: 55460 β: 112700	1.7	-	β: 112700	β: 112700	1.409	4.68
DFOP	+	8.2	k1: 0.4896 k2: 0.4921 g: <0.0005	2.1	k1: <2e-16 k2: 0.010	k1: 0.49 k2: 0.46	k1: 0.49 k2: 0.52	1.409	4.68
HS	+	8.2	k1: 0.492 k2: 0.422 tb: 7.00	2.1	k1: 0.010 k2: 0.252	k1: 0.46 k2: -0.41	k1: 0.52 k2: 1.26	1.408	4.68

SFO fit is statistically and visually very good (χ^2 err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit



SFO



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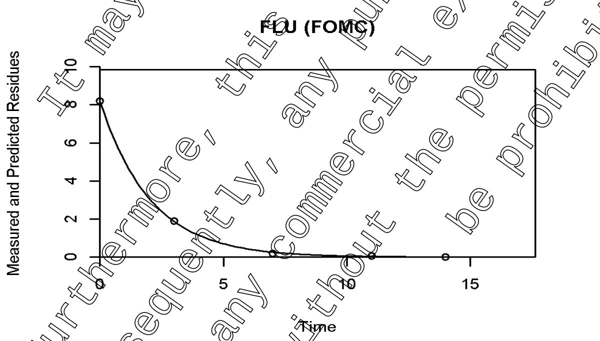

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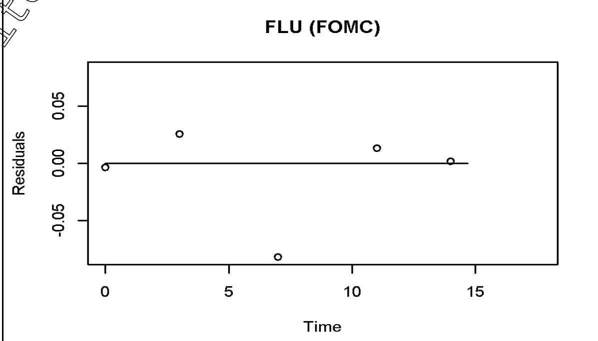


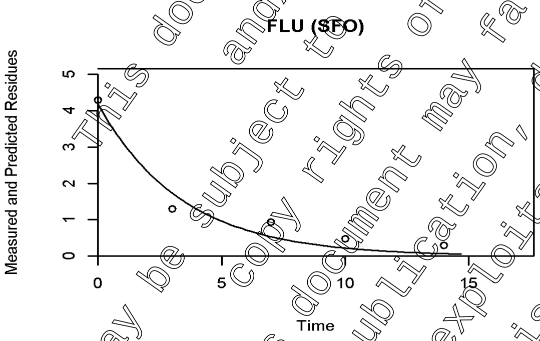
FOMC

R 2006 0605/2, Langenfeld-Reusrath, M-292048-01-1, DE, lettuce

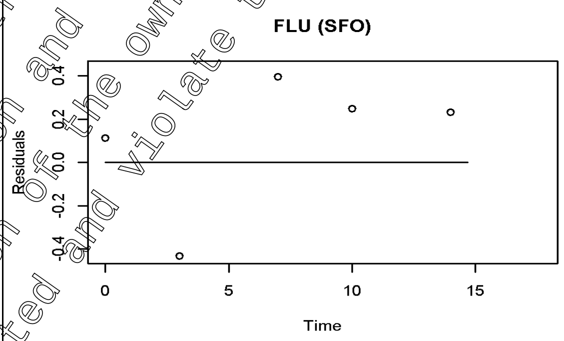
Table 8.9- 83: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2006 0605/2, Langenfeld-Reusrath, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	$DT_{50\ actual}$ (d)	$DT_{90\ actual}$ (d)
SFO	o	4.2	k: 0.2941	16.8	k: 0.009	k: 0.17	k: 0.42	2.357	7.828
FOMC	+	4.3	α: 0.9549 β: 1.2816	6.9	-	β: -0.83	β: 3.40	1.367	13.06
DFOP	+	4.3	k1: 13.23889 k2: 0.12732 g: 0.545	5.5	k1: <0.001 k2: 0.075	k1: 13.24 k2: 0.07	k1: 13.24 k2: 0.19	0.174	11.91
HS	+	4.3	k1: 0.420695 k2: 0.127324 tb: 2.680	5.5	k1: 0.034 k2: 0.075	k1: 0.33 k2: 0.07	k1: 0.51 k2: 0.19	1.648	11.91

SFO fit is statistically still acceptable (χ^2err ~15%, t-test <0.05), but visually borderline to poor. FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in χ2 error and visual assessment. The t-test of DFOP and HS show only a slightly reduced reliability of the slow degradation rates k2 (t-test > 0.05). However, HS shows the best visual fit and one of the lowest χ^2err. Therefore, **HS** model is considered best appropriate for modelling endpoints (FOCUS kinetics) and as well as best visual fit. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT50 is an adequate option.



SFO



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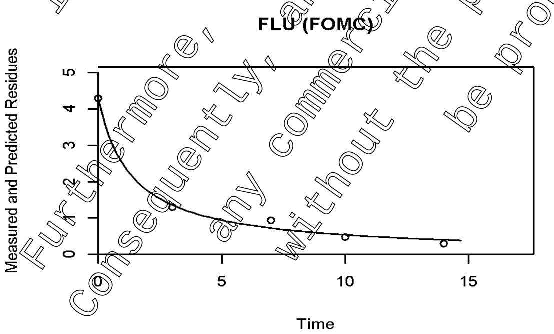

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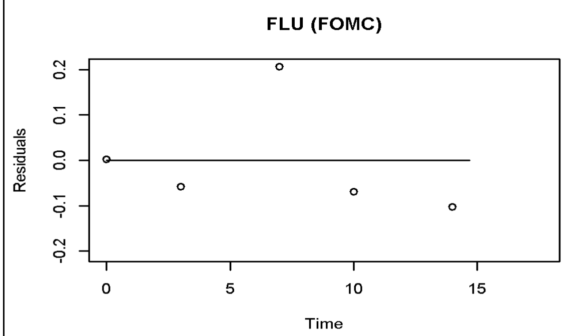
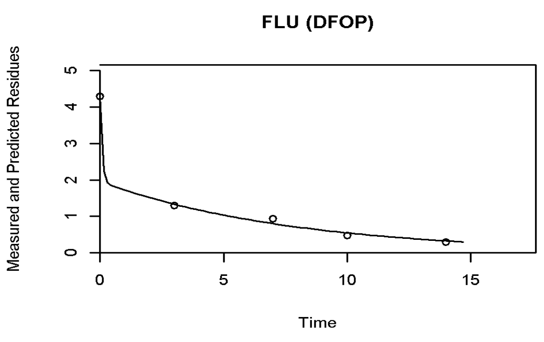
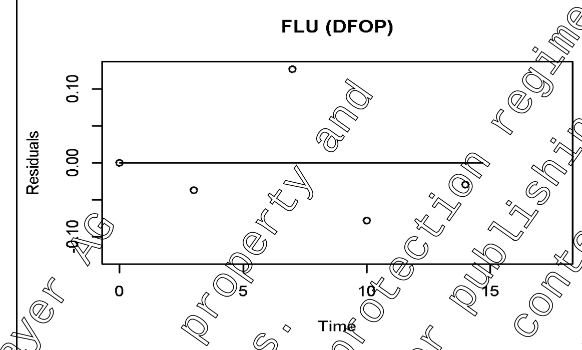


FOMC



DFOP



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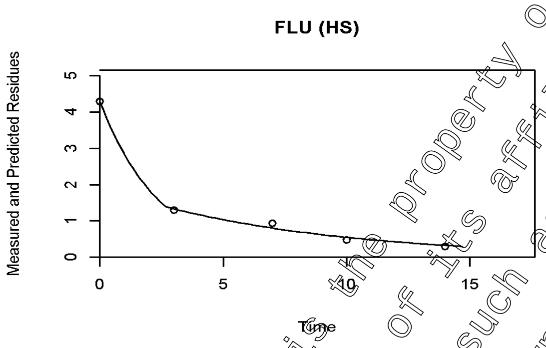

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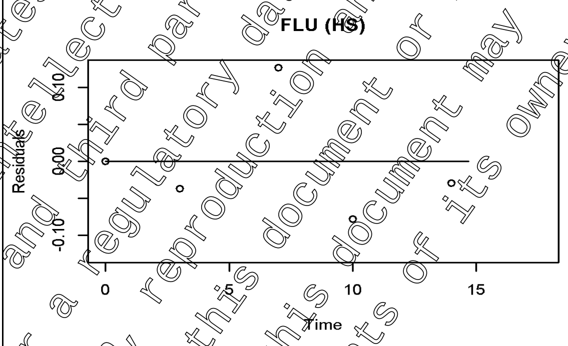


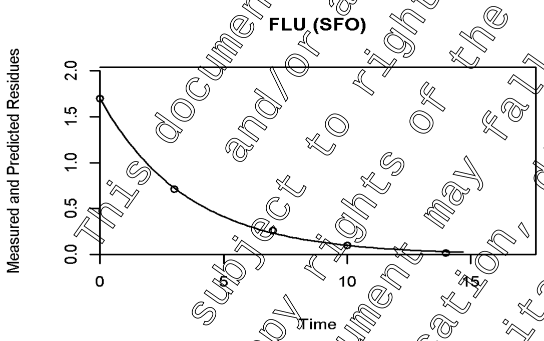
HS

R 2006 0606/0, Zwaagdijk, M-292048-01-1, NL, lettuce

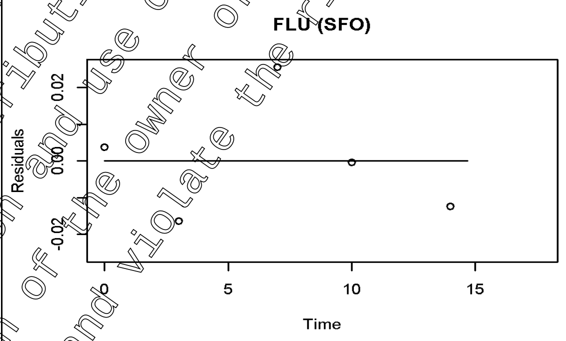
Table 8.9- 84: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2006 0606/0, Zwaagdijk, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	1.7	k: 0.28268	2.1	k: <0.001	k: 0.27	k: 0.30	**2.452**	8.15
FOMC	+	1.7	α: 27.36925 β: 94.04367	2.2	-	β: -250.57	β: 438.66	2.412	8.25
DFOP	+	1.7	k1: 6.738 k2: 0.2672 g: 0.065	2.3	k1: <0.001 k2: 0.025	k1: 6.74 k2: 0.23	k1: 6.74 k2: 0.31	2.341	8.37
HS	+	1.7	k1: 0.2917284 k2: 0.2671934 tb: 2.757	2.3	k1: 0.016 k2: 0.025	k1: 0.26 k2: 0.23	k1: 0.32 k2: 0.31	2.376	8.37

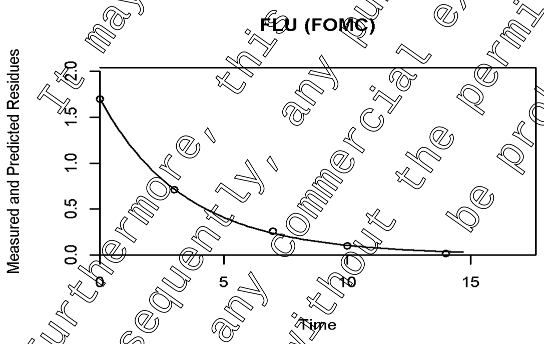
SFO fit is statistically and visually very good (χ² err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



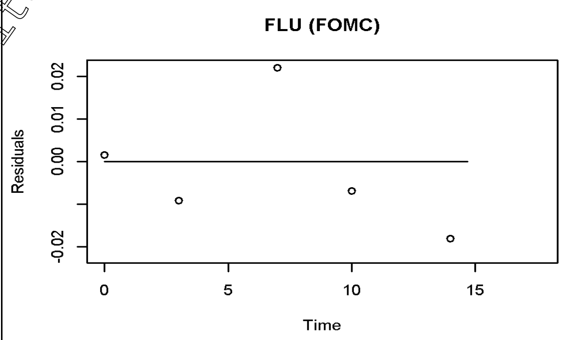
SFO



SFO



FOMC



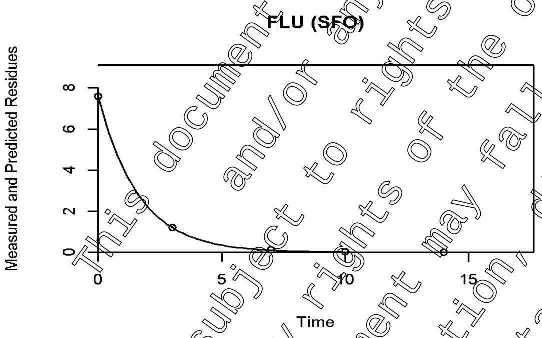
FOMC

R 2006 0607/9, Ely, M-292048-01-1, GB, lettuce

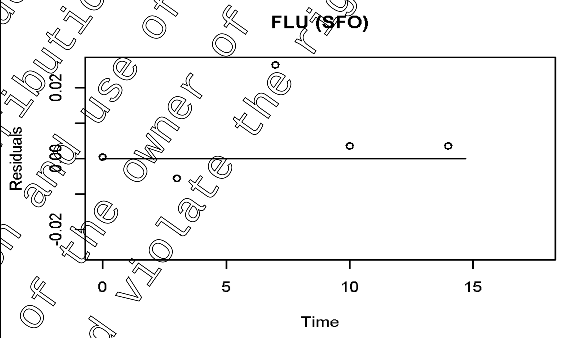
Table 8.9- 85: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2006 0607/9, Ely, GB

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	7.6	k: 0.613732	0.5	k: <0.001	k: 0.61	k: 0.62	**1.129**	3.752
FOMC	+	7.6	α: 22.625687 β: 35.298489	0.175	-	β: 20.69	β: 49.91	1.098	3.781
DFOP	+	7.6	k1: 7.981 k2: 0.558 g: 0.158	0.14	k1: <0.001 k2: 0.005	k1: 7.98 k2: 0.54	k1: 7.98 k2: 0.58	0.935	3.819
HS	+	7.6	k1: 0.6156 k2: 0.558 tb: 2.980	0.14	k1: <0.001 k2: 0.005	k1: 0.61 k2: 0.54	k1: 0.62 k2: 0.58	1.126	3.819

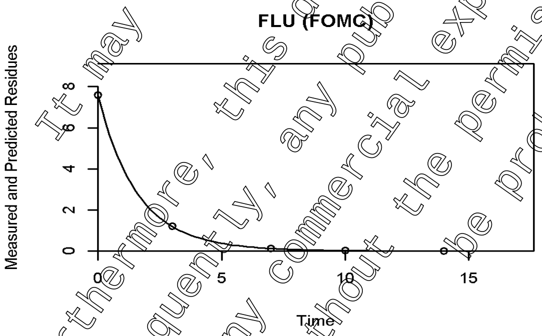
SFO fit is statistically and visually very good (χ^2 err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



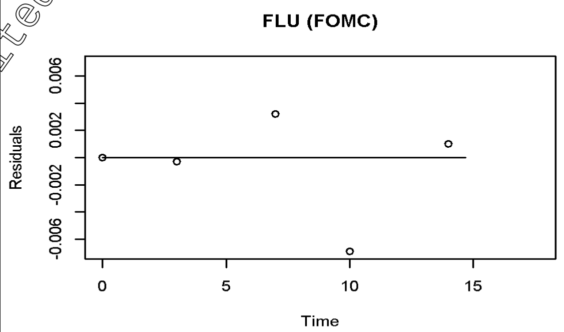
SFO



SFO



FOMC



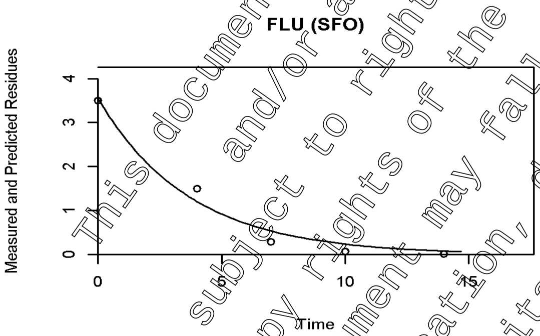
FOMC

R 2006 0608/7, Vilanova del Valles, M-292050-01-1, ES, lettuce

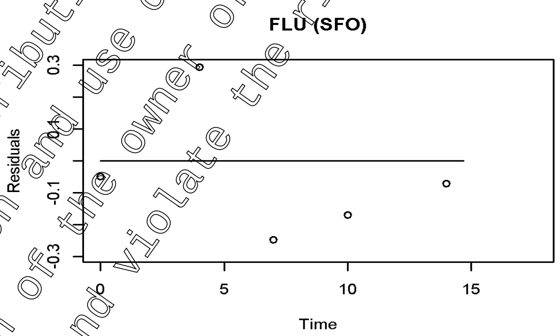
Table 8.9- 86: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2006 0608/7, Vilanova del Valles, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.5	k: 0.26972	14.3	k: 0.003	k: 0.19	k: 0.35	**2.570**	8.54
FOMC	+	3.5	α: 26250 β: 97330	16.3	-	β: 97330.00	β: 97331.22	2.570	8.54
DFOP	+	3.5	k1: 0.2697 k2: 2.2 E-14 g: 1.00	20.3	k1: 0.137 k2: <0.001	k1: 0.03 k2:2.2 E-14	k1: 0.51 k2: < 0.0005	2.570	8.54
HS	+	3.5	k1: 30.570 k2: 0.270 tb: 3 E-14	20.3	k1: <0.001 k2: 0.206	k1: 30.57 k2: -0.13	k1: 30.57 k2: 0.67	2.570	8.54

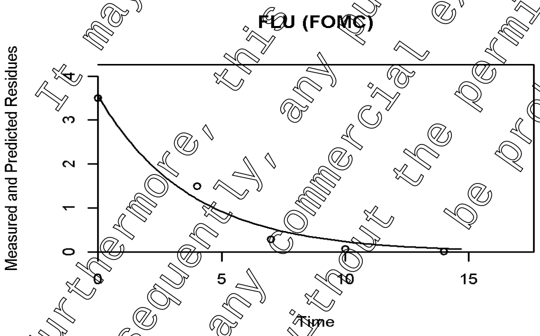
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



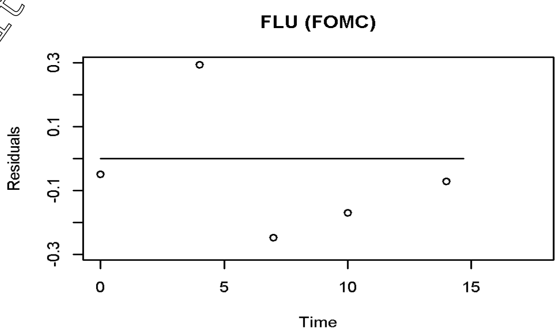
SFO



SFO



FOMC



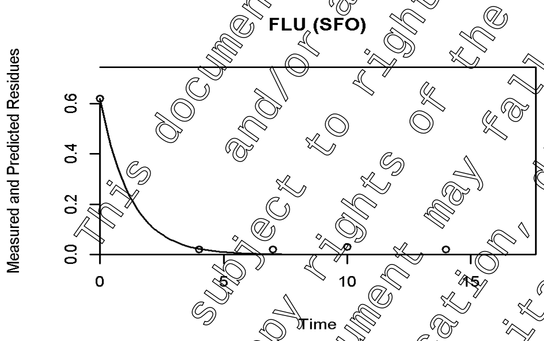
FOMC

R 2006 0609/5, Andria, M-292050-01-1, IT, lettuce

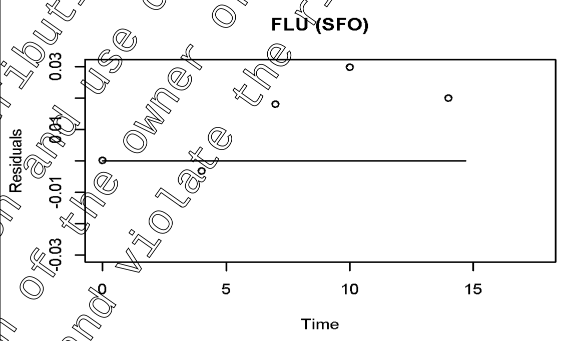
Table 8.9- 87: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2006 0609/5, Andria, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	0.6	k: 0.82085	10.2	k: 0.023	k: 0.34	k: 1.31	**0.844**	2.805
FOMC	o	0.6	α: 31000000 β: 37770000	11.6	-	β: 37770000	β: 37770000	0.844	2.805
DFOP	o	0.6	k1: 106200 k2: <0.0005 g: 0.964	3.1	k1: 0.001 k2: 0.5	k1: 106200 k2: -0.10	k1: 106200 k2: 0.10	6.9 E-6	2.6 E-5
HS	+	0.6	k1: 0.8382 k2: 2.22 E-14 tb: 3.957	3.1	k1: 0.029 k2: 0.5	k1: 0.69 k2: -0.10	k1: 0.99 k2: 0.10	0.827	2.747

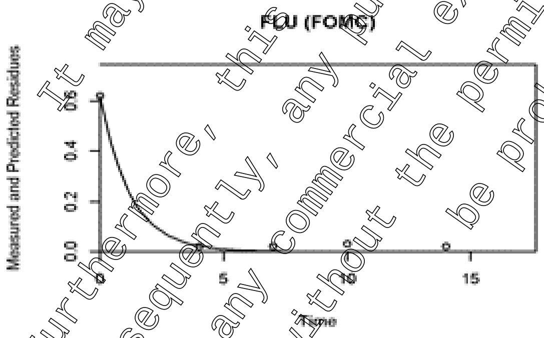
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached, is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



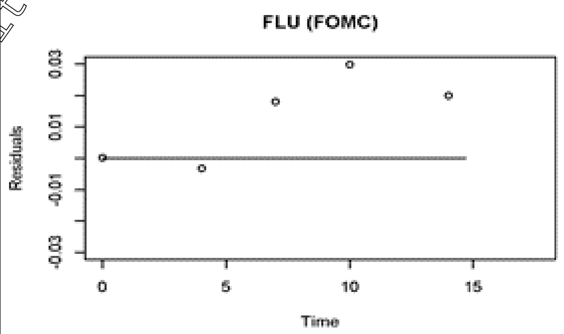
SFO



SFO



FOMC



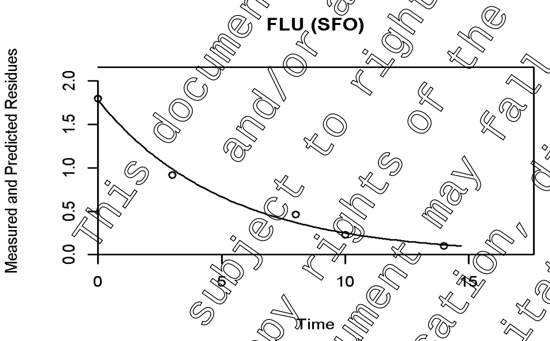
FOMC

R 2006 0610/9, Catania, M-292050-01-1, IT, lettuce

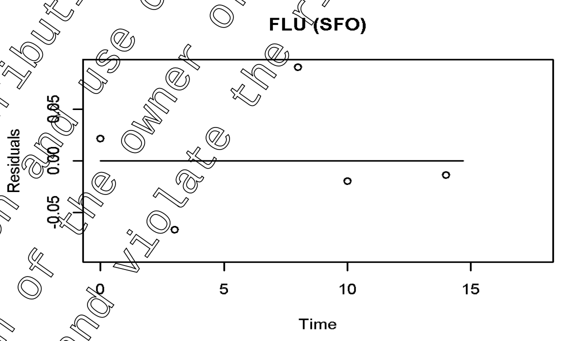
Table 8.9- 88: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2006 0610/9, Catania, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	1.8	k: 0.1964	6.0	k: <0.001	k: 0.17	k: 0.23	**3.529**	11.72
FOMC	+	1.8	α: 6.81696 β: 30.85691	6.3	-	β: -79.55	β: 141.26	3.303	12.40
DFOP	+	1.8	k1: 6.842 k2: 0.175 g: 0.126	6.7	k1: <0.001 k2: 0.060	k1: 6.84 k2: 0.11	k1: 6.84 k2: 0.24	3.197	12.40
HS	+	1.8	k1: 0.222 k2: 0.175 tb: 2.826	6.7	k1: 0.057 k2: 0.060	k1: 0.14 k2: 0.11	k1: 0.30 k2: 0.24	3.197	12.40

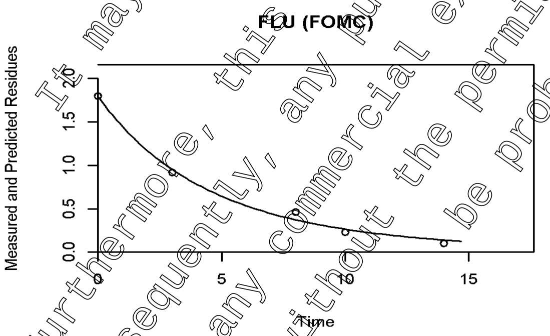
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



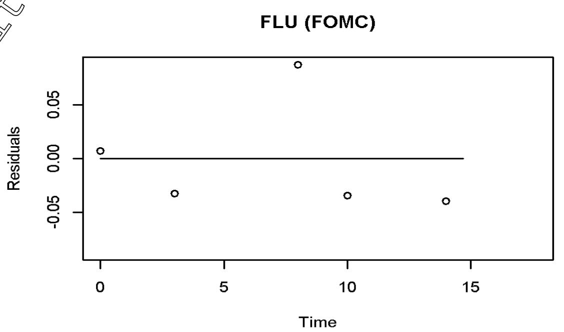
SFO



SFO



FOMC



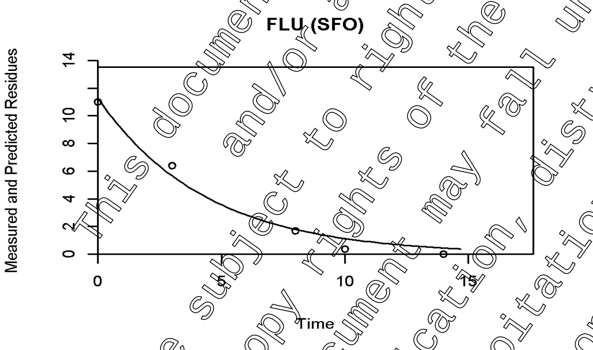
FOMC

R 2006 0611/7, Katerini / Paralia, M-292050-01-1, GR, lettuce

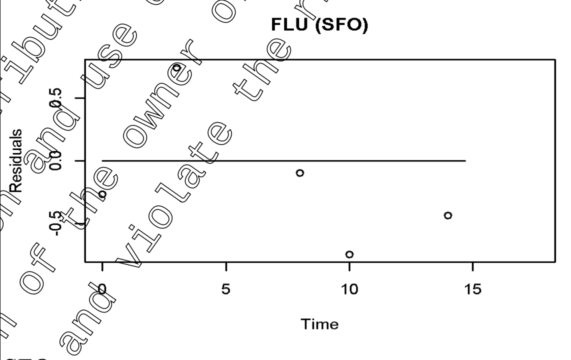
Table 8.9- 89: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2006 0611/7, Katerini / Paralia, GR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	11.3	k: 0.2295	10.7	k: 0.002	k: 0.17	k: 0.29	**3.020**	10.03
FOMC	o	11.3	α: 12360 β: 53860	12.3	-	β: 53050.00	β: 54678.51	3.020	10.03
DFOP	o	11.3	k1: 0.2295 k2: 2.22 E-14 g: 1.0	15.3	k1: 0.131 k2: <0.001	k1: 0.03 k2: < 0.001	k1: 0.43 k2: < 0.001	3.020	10.03
HS	-	11.0	k1: 0.1805 k2: 0.7362 tb: 7.239	0.007	k1: <0.001 k2: <0.001	k1: 0.18 k2: 0.73	k1: 0.18 k2: 0.74	3.839	8.59

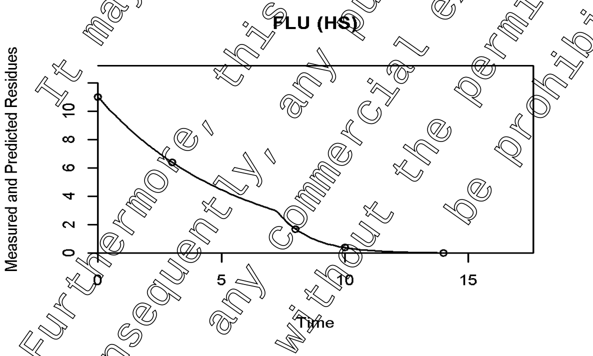
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. HS seems to show a lower χ^2err, however, the visual assessments does not justify to prefer this fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



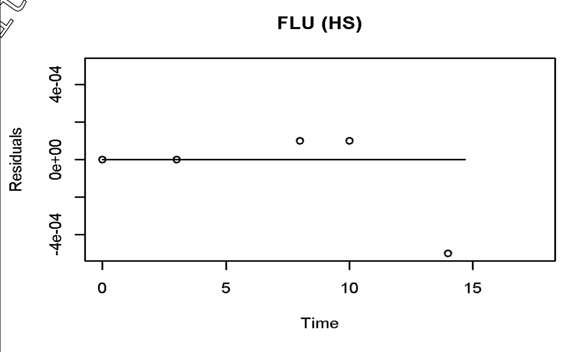
SFO



SFO



HS



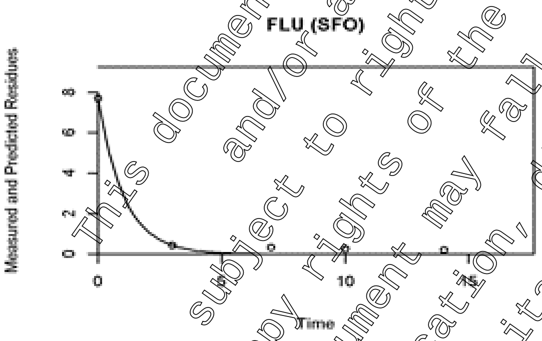
HS

R 2006 0620/6, Pradelle di Nogarole Rocca, M-290827-01-1, IT, beans

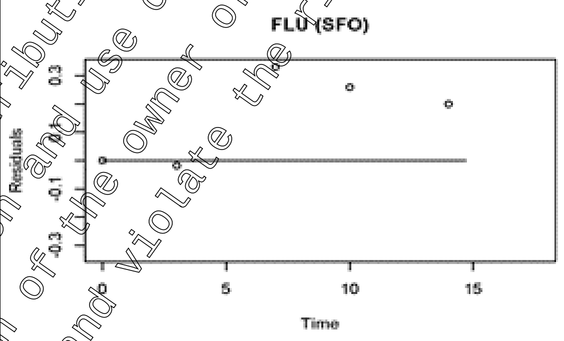
Table 8.9- 90: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2006 0620/6, Pradelle di Nogarole Rocca, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.7	k: 0.9556	9.3	k: 0.009	k: 0.55	k: 1.36	**0.7254**	2.41
FOMC	+	7.7	α: 0.41868 β: 0.00308	1.1	-	β: -0.01	β: 0.01	0.013	0.75
DFOP	+	7.7	k1: 29570 k2: 0.06714 g: 0.932	0.5	k1: <0.001 k2: 0.035	k1: 29570 k2: 0.05	k1: 29568.9 k2: 0.08	2.34 E-5	1.56 E-4
HS	+	7.7	k1: 1.03441 k2: 0.06714 tb: 2.785	0.5	k1: 0.004 k2: 0.035	k1: 1.01 k2: 0.05	k1: 1.06 k2: 0.08	0.670	2.226

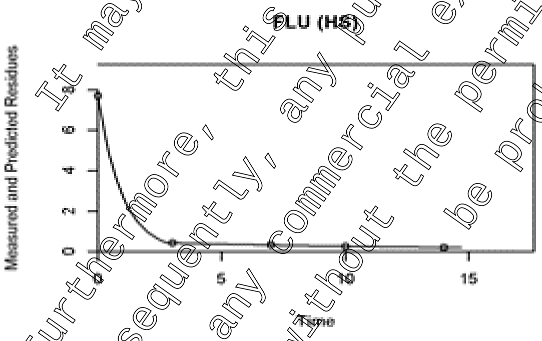
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 3), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



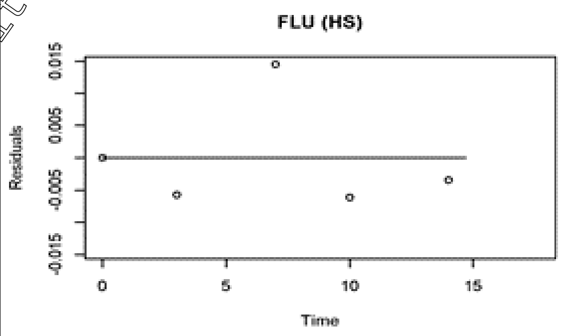
SFO



SFO



HS



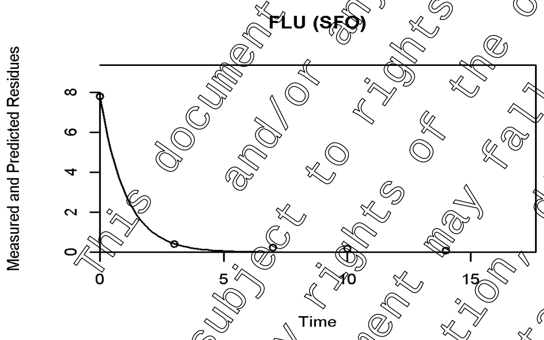
HS

R 2006 0654/0, Langenfeld-Reusrath, M-290825-01-1, DE, beans

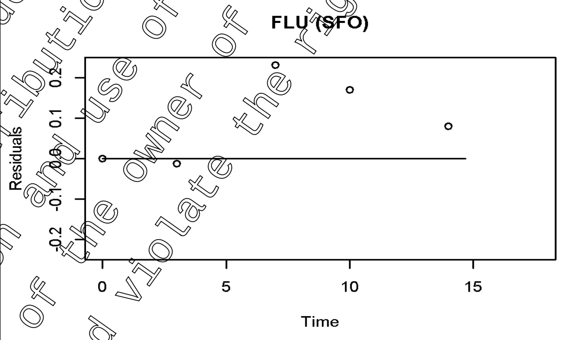
Table 8.9- 91: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2006 0654/0, Langenfeld-Reusrath, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	7.8	k: 0.9644	6.1	k: 0.003	k: 0.70	k: 1.22	**0.719**	2.39
FOMC	+	7.8	α: 0.84404 β: 0.09932	1.2	-	β: -0.03	β: 0.23	0.127	1.42
DFOP	+	7.8	k1: 22540 k2: 0.139 g: 0.918	0.5	k1: NA k2: 0.024	k1: NA k2: 0.12	k1: NA k2: 0.16	3.08 E-5	1.6 E-4
HS	+	7.8	k1: 0.97368 k2: 0.1392 tb: 2.998	0.5	k1: 0.004 k2: 0.024	k1: 0.95 k2: 0.12	k1: 1.00 k2: 0.16	0.712	2.365

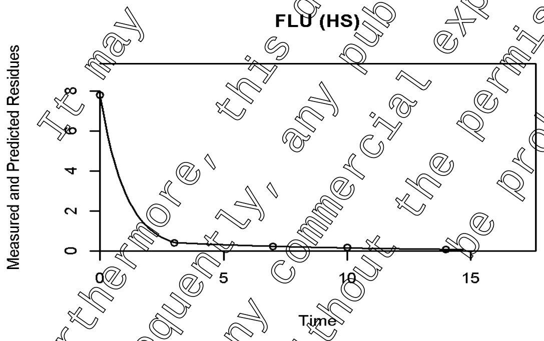
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



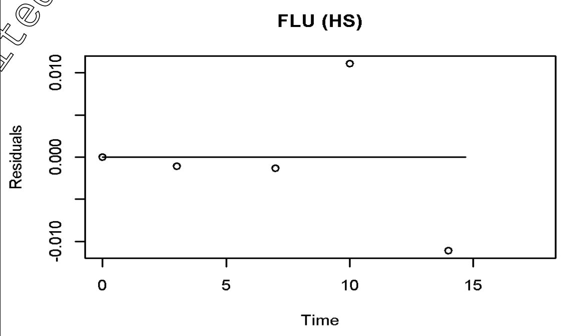
SFO



SFO



HS



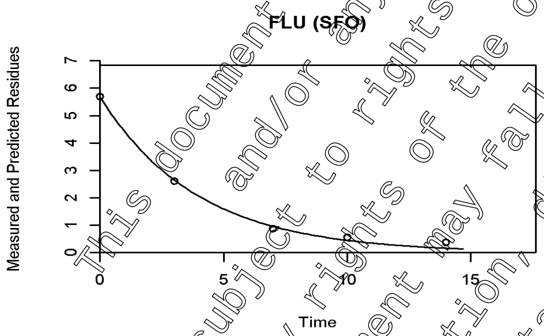
HS

R 2006 0655/9, Zwaagdijk, M-290825-01-1, NL, beans

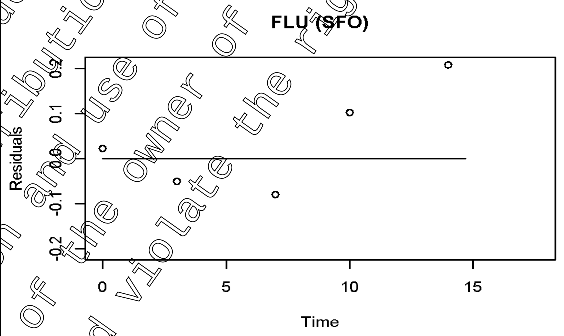
Table 8.9- 92: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2006 0655/9, Zwaagdijk, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	5.7	k: 0.25399	4.4	k: <0.001	k: 0.23	k: 0.28	**2.729**	9.066
FOMC	+	5.7	α: 5.9301 β: 20.5316	3.5	-	β: -11.61	β: 52.67	2.546	9.741
DFOP	+	5.7	k1: 0.287 k2: 2.22 E-14 g: 0.959	2.8	k1: 0.062 k2: 0.50	k1: 0.18 k2: -0.50	k1: 0.40 k2: 0.50	2.563	9.697
HS	+	5.7	k1: 0.2639 k2: 0.0991 tb: 8.180	0.6	k1: 0.003 k2: 0.065	k1: 0.26 k2: 0.06	k1: 0.27 k2: 0.14	2.627	9.632

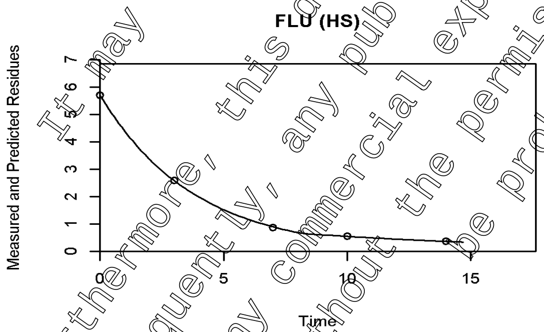
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



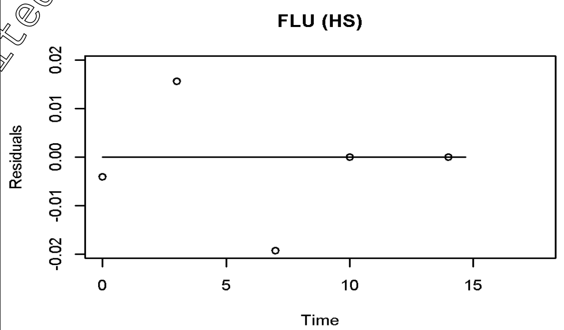
SFO



SFO



HS



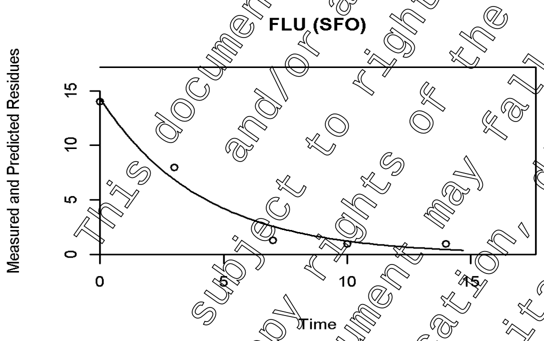
HS

R 2006 0656/7, Villers-Perwin, M-290825-01-1, BE, beans

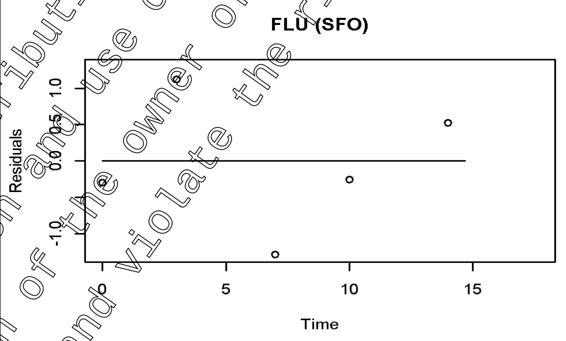
Table 8.9- 93: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2006 0656/7, Villers-Perwin, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	14.3	k: 0.24406	13.0	k: 0.004	k: 0.17	k: 0.32	**2.840**	9.44
FOMC	o	14.3	α: 6204.767 β: 25420.200	14.8	-	β: 24890.48	β: 25949.92	2.840	9.44
DFOP	o	14.3	k1: 0.244 k2: 2.2 E-14 g: 1.0	18.5	k1: 0.147 k2: <2 E-16	k1: 0.0056 k2: 2.2 E-14	k1: 0.48 k2: 0.0005	2.840	9.44
HS	o	14.0	k1: 0.178247 k2: 0.384067 tb: 2.852	10.8	k1: 0.096 k2: 0.110	k1: 0.07 k2: 0.41	k1: 0.29 k2: 0.65	3.333	7.52

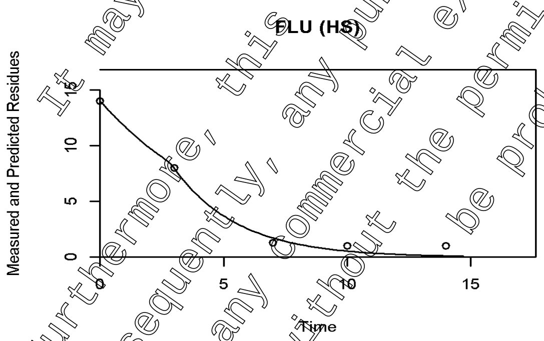
SFO fit is statistically and visually good (χ^2 err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



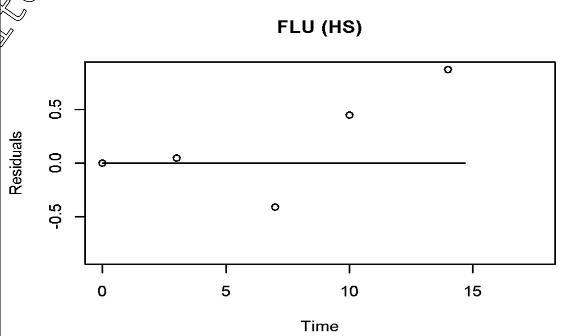
SFO



SFO



HS



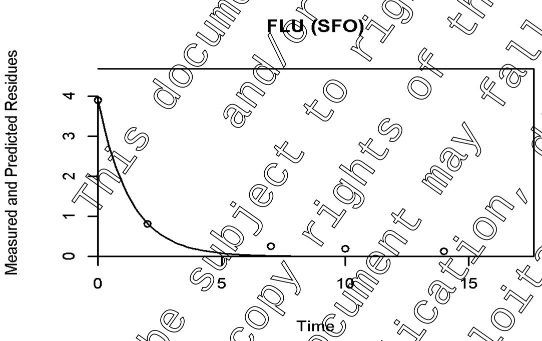
HS

R 2006 0657/5, Malgrat de Mar, M-290827-01-1, ES, beans

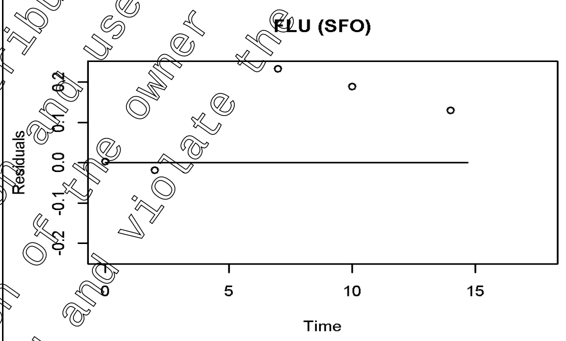
Table 8.9- 94: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2006 0657/5, Malgrat de Mar, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	3.9	k: 0.7739	11.1	k: 0.003	k: 0.55	k: 1.00	0.896	2.975
FOMC	+	3.9	α: 1.060063 β: 0.586678	0.5	-	β: 0.52	β: 0.65	0.542	4.563
DFOP	+	3.9	k1: 1001000 k2: 0.195 g: 0.697	3.8	k1: NA k2: 0.061	k1: NA k2: 0.12	k1: NA k2: 0.27	0.000	5.686
HS	+	3.9	k1: 0.78585 k2: 0.09311 tb: 3.023	0.04	k1: <0.001 k2: 0.004	k1: 0.78 k2: 0.09	k1: 0.79 k2: 0.10	0.882	2.93

SFO fit is statistically still acceptable (χ^2err <15%, t-test <0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. HS fit is statistically (χ^2err, t-test) and visually good, with the lowest $\chi2$ err. Consequently, **HS** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT50 is an adequate option.



SFO



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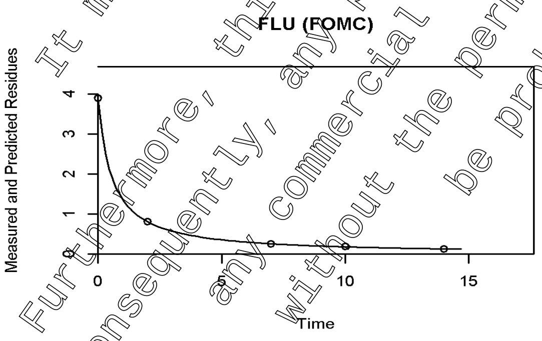
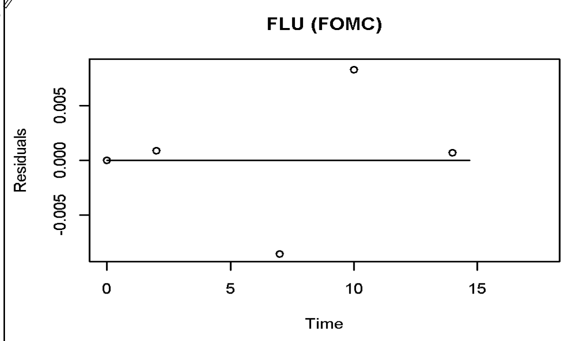
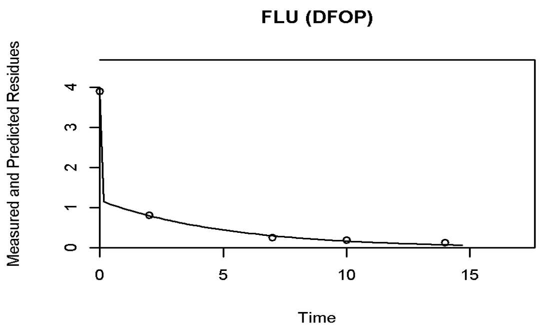
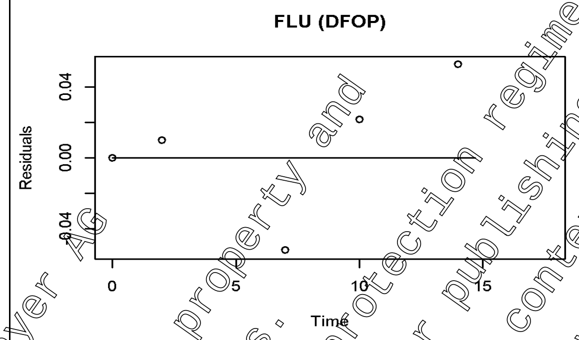
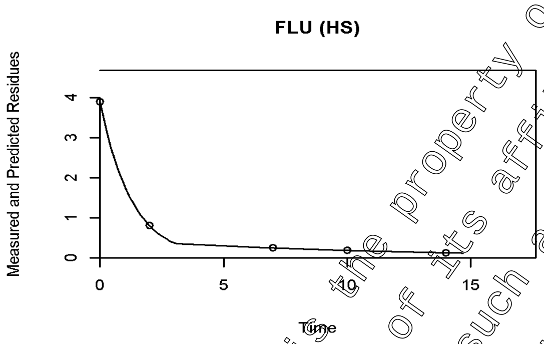
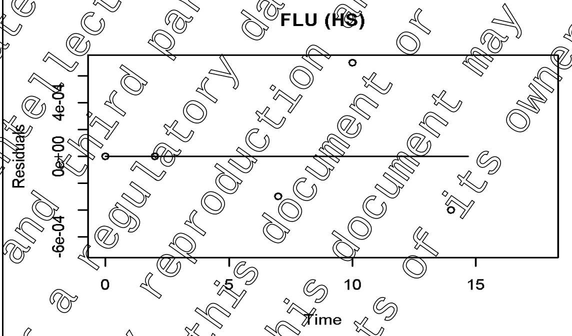


FOMC



FOMC

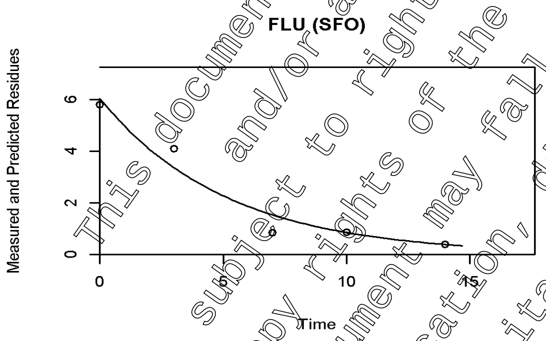
 DFOP	 DFOP
 HS	 HS

R 2006 0658/3, Ladispoli, M-290827-01-1, IT, beans

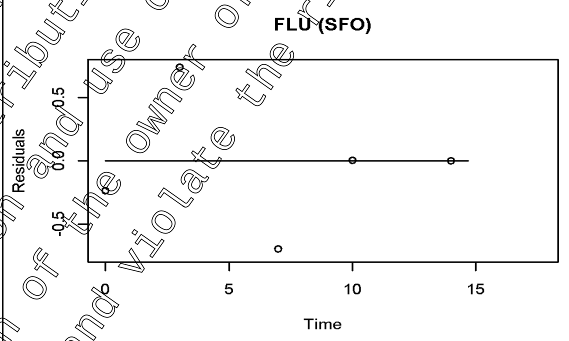
Table 8.9- 95: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2006 0658/3, Ladispoli, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	6.0	k: 0.19539	15.6	k: 0.007	k: 0.12	k: 0.27	**3.548**	11.78
FOMC	+	6.0	α: 8973 β: 45920	17.8	-	β: 45130.00	β: 46713.19	3.547	11.79
DFOP	+	6.0	k1: 0.1954 k2: 2.22 E-14 g: 1.0	22.2	k1: 0.210 k2: <0.001	k1: -0.10 k2: 2.2 E-14	k1: 0.49 k2:< 0.0005	3.548	11.78
HS	+	6.0	k1: 0.1954 k2: 2.22 E-14 tb: 17.61	22.2	k1: 0.104 k2: <0.001	k1: 0.07 k2: 2.2 E-14	k1: 0.33 k2:< 0.0005	3.548	11.78

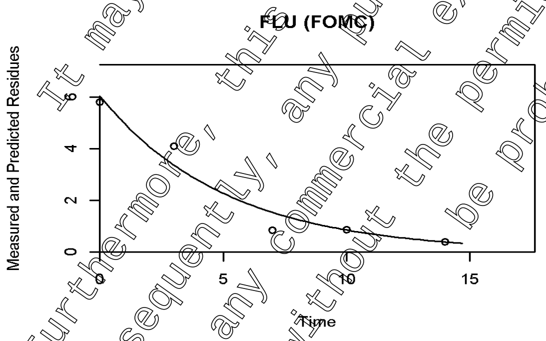
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



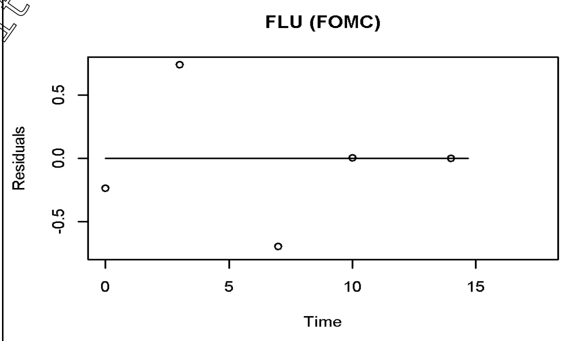
SFO



SFO



FOMC



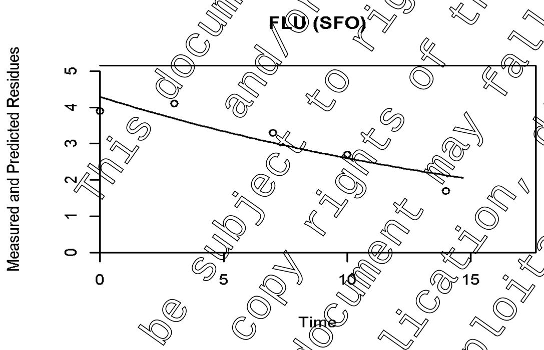
FOMC

R 2006 0722/9, Needham, M-291180-01-1, GB, pea

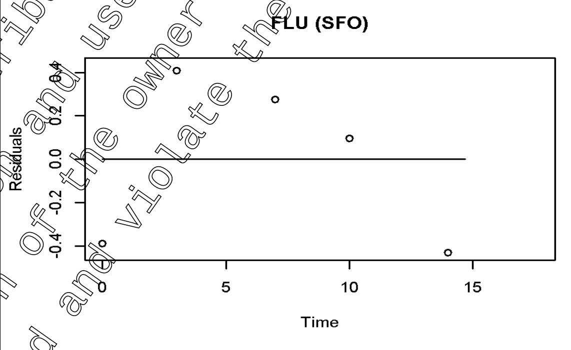
Table 8.9- 96: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial R 2006 0722/9, Needham, GB

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.3	k: 0.04995	8.7	k: 0.017	k: 0.02	k: 0.08	**13.880**	46.10
FOMC	o	4.3	α: 3593 β: 71930	10.0	-	β: 71810.00	β: 72046.69	13.880	46.11
DFOP	o	4.3	k1: 0.050 k2: 0.050 g: 0.259	12.5	k1: 0.062 k2: 0.163	k1: 0.03 k2: -0.01	k1: 0.07 k2: 0.11	13.880	46.10
HS	+	4.0	k1: 2.22 E-14 k2: 0.090 tb: 5.071	3.6	k1: 0.50 k2: 0.068	k1: -0.05 k2: 0.05	k1: 0.05 k2: 0.13	12.740	30.55

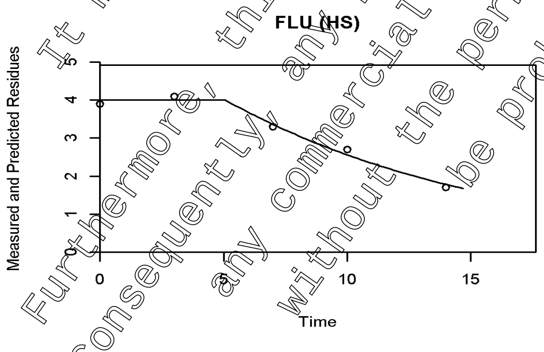
SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).
FOMC and DFOP did not result in an improved fit. The HS resulted in a lag phase, which is considered not appropriate for the intended purpose. As initial and final residues are covered sufficiently well and conservative, the SFO fit is finally considered appropriate and conservative to describe the residue decay.



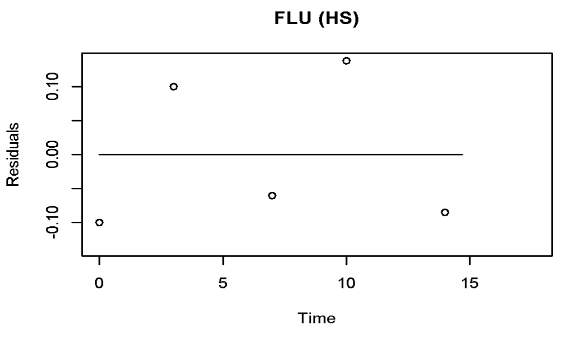
SFO



SFO



HS



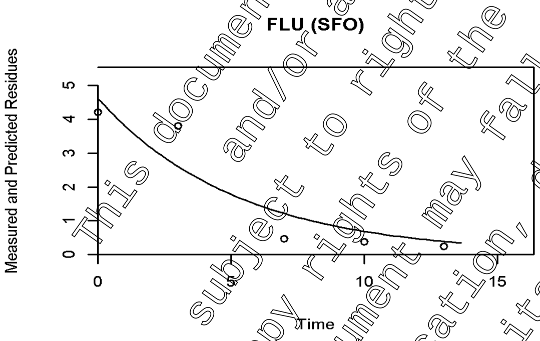
HS

R 2006 0723/7, Meckenbeuren, M-291180-01-1, DE, pea

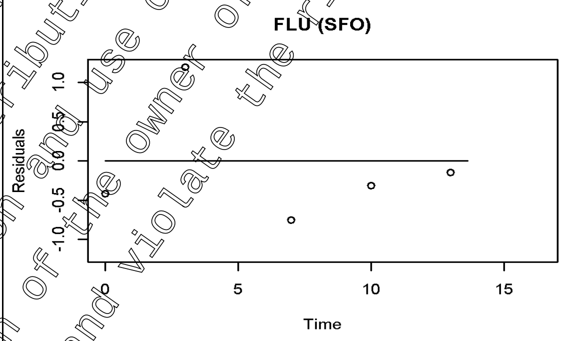
Table 8.9- 97: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial R 2006 0723/7, Meckenbeuren, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.6	k: 0.19063	29.9	k: 0.035	k: 0.06	k: 0.33	**3.636**	12.08
FOMC	o	4.6	α: 15399.163 β: 80775.735	34.1	-	β: 78308.27	β: 83243.20	3.636	12.08
DFOP	o	4.6	k1: 0.191 k2: 0.024 g: 1.0	42.6	k1: 0.341 k2: <0.001	k1: -0.49 k2: 0.02	k1: 0.88 k2: 0.02	3.636	12.08
HS	o	4.6	k1: 0.1906 k2: 0.2349 tb: 15.671	42.6	k1: 0.179 k2: <0.001	k1: -0.04 k2: 0.23	k1: 0.43 k2: 0.24	3.636	12.08

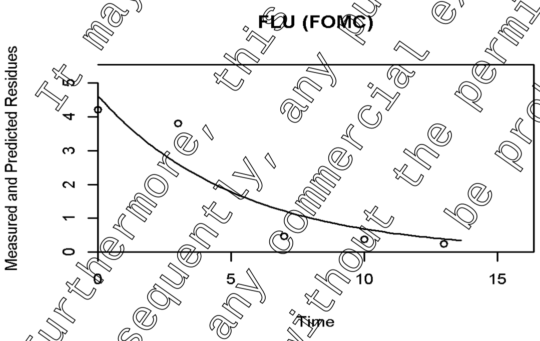
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



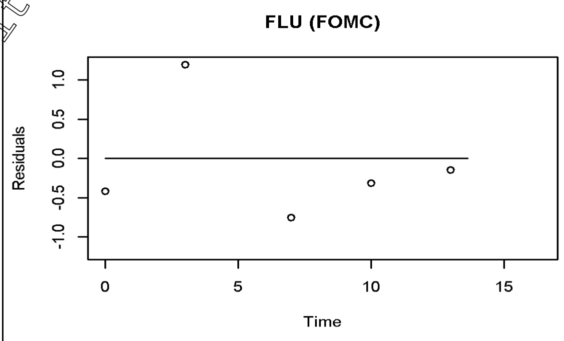
SFO



SFO



FOMC



FOMC

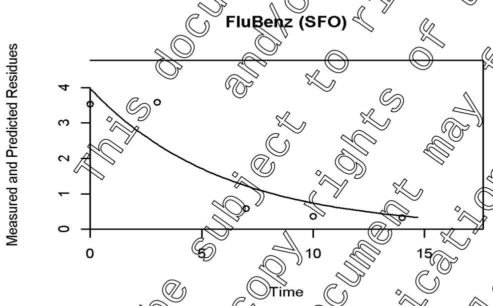
Fluopyram + FLU-benzamide

08-2034-01, Damery, M-365530-01-1, FR, beans

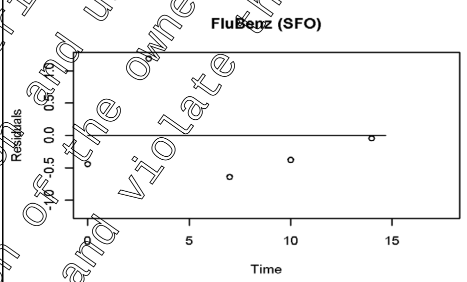
Table 8.9- 98: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial 08-2034-01, Damery, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.0	k: 0.1683	31.5	k: 0.0045	k: 0.03	k: 0.30	**4.120**	13.68
FOMC	o	4.0	α: 5654 β: 33600	35.9	-	β: 32700.00	β: 34502.59	4.119	13.69
DFOP	o	4.0	k1: 0.168 k2: 0.044 g: 1.000	44.9	k1: 0.383 k2: <2e-16	k1: -0.69 k2: 0.04	k1: 1.02 k2: 0.04	4.120	13.68
HS	o	4.0	k1: 0.168 k2: 0.140 tb: 15.148	44.9	k1: 0.195 k2: <2e-16	k1: -0.06 k2: 0.14	k1: 0.40 k2: 0.14	4.120	13.69

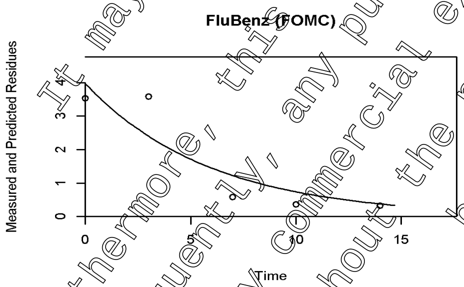
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.

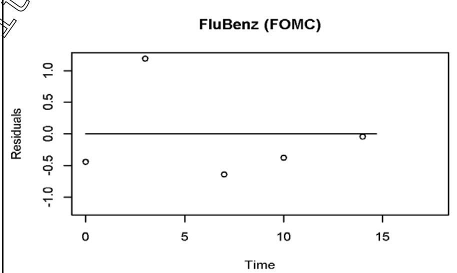


SFO



SFO



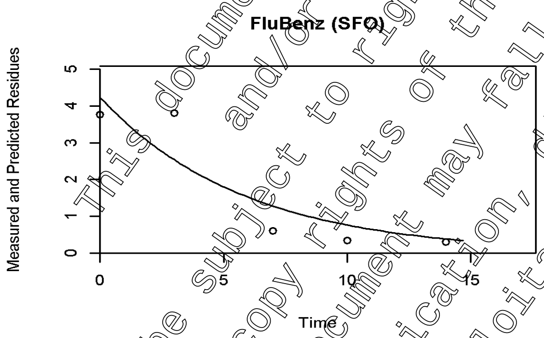


08-2034-02, Damery, M-365530-01-1, FR, beans

Table 8.9- 99: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial 08-2034-02, Damery, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.2	k: 0.17083	31.7	k: 0.045	k: 0.04	k: 0.31	**4.058**	13.48
FOMC	o	4.2	α: 6845.630 β: 40069.930	36.2	-	β: 38963.49	β: 41176.38	4.057	13.48
DFOP	o	4.2	k1: 0.171 k2: 0.045 g: 1.0	45.2	k1: 0.381 k2: <0.001	k1: -0.68 k2: 0.04	k1: 1.02 k2: 0.05	4.058	13.48
HS	o	4.2	k1: 0.171 k2: 0.013 tb: 14.604	45.2	k1: 0.195 k2: <0.001	k1: -0.06 k2: 0.01	k1: 0.41 k2: 0.01	4.058	13.48

SFO fit is statistically and visually acceptable (t-test < 0.05), although χ^2 err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



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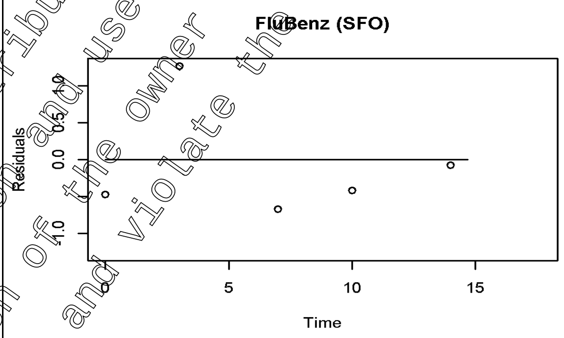

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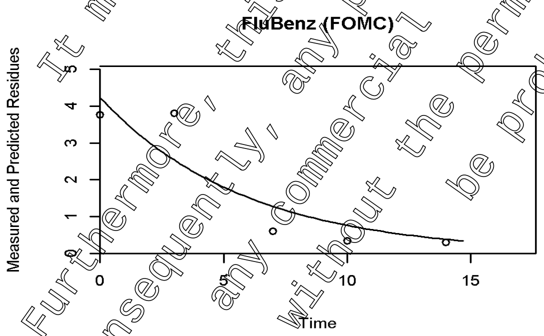
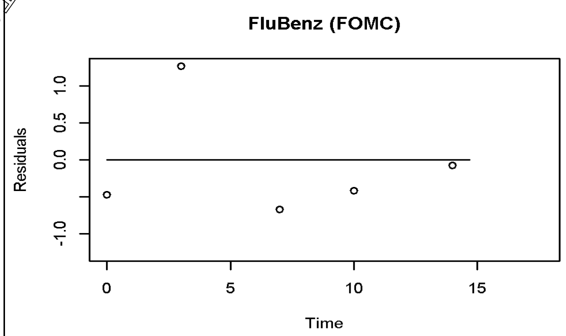


FOMC



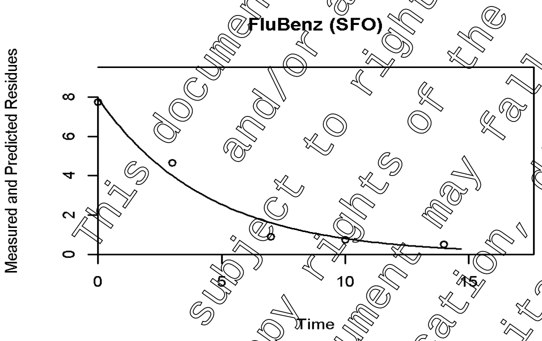
FOMC

08-2096-01, Ladispoli, M-365542-01-1, IT, beans

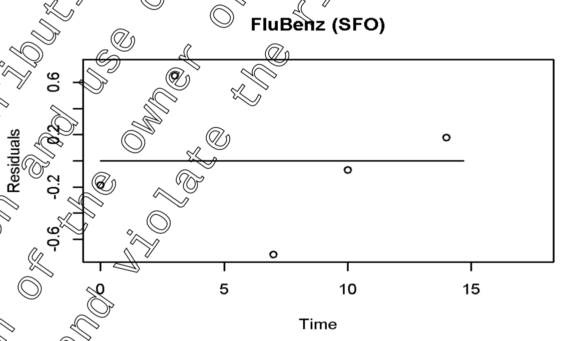
Table 8.9- 100: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial 08-2096-01, Ladispoli, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.9	k: 0.22709	12.3	k: 0.003	k: 0.16	k: 0.29	**3.052**	10.14
FOMC	o	7.9	α: 7888 β: 34730	14.1	-	β: 34120.00	β: 35342.05	3.052	10.14
DFOP	o	7.9	k1: 0.227 k2: 2.2 E-14 g: 1.0	17.6	k1: 0.151 k2: <0.001	k1: -0.0012 k2: 2.2 E-14	k1: 0.455 k2: 0.0005	3.052	10.14
HS	o	7.9	k1: 0.230 k2: 0.095 tb: 10.503	17.3	k1: 0.082 k2: 0.448	k1: 0.11 k2: -1.04	k1: 0.35 k2: 1.23	3.018	10.03

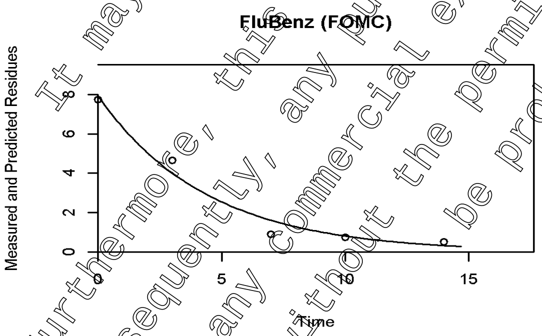
SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



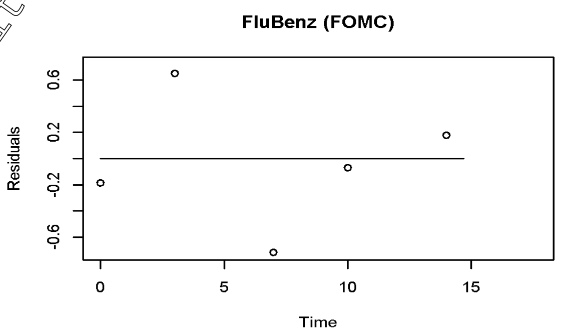
SFO



SFO



FOMC



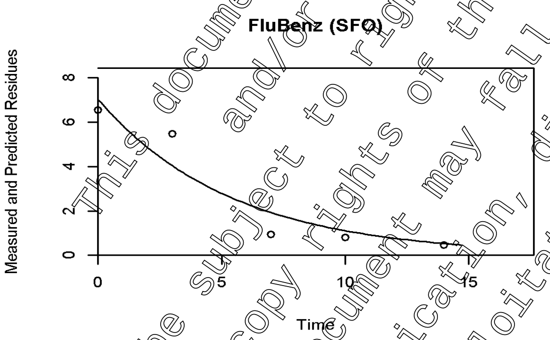
FOMC

08-2096-02, Ladispoli, M-365542-01-1, IT, beans

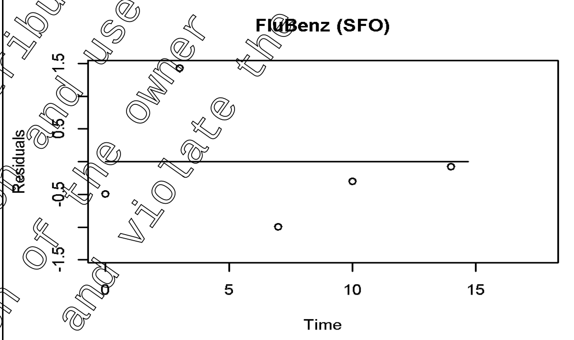
Table 8.9- 101: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial 08-2096-02, Ladispoli, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.0	k: 0.18493	23.2	k: 0.021	k: 0.08	k: 0.29	**3.748**	12.45
FOMC	o	7.0	α: 18106.919 β: 97910.752	26.5	-	β: 95649.38	β: 100200	3.748	12.45
DFOP	o	7.0	k1: 0.185 k2: 2.2 E-14 g: 1.0	33.0	k1: 0.281 k2: <2 E-16	k1: -0.26 k2: 2.2 E-14	k1: 0.63 k2: 0.0005	3.748	12.45
HS	o	6.8	k1: 0.131 k2: 0.230 tb: 3.0	23.1	k1: 0.438 k2: 0.327	k1: -1.17 k2: -0.51	k1: 1.44 k2: 0.97	4.312	11.31

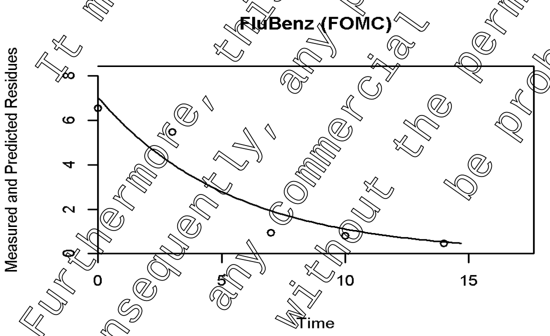
SFO fit is statistically and visually acceptable (t-test < 0.05), although χ^2 err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



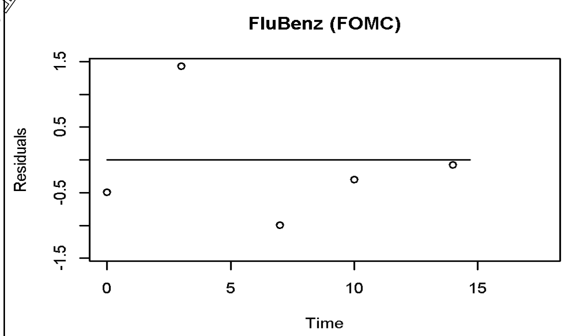
SFO



SFO



FOMC



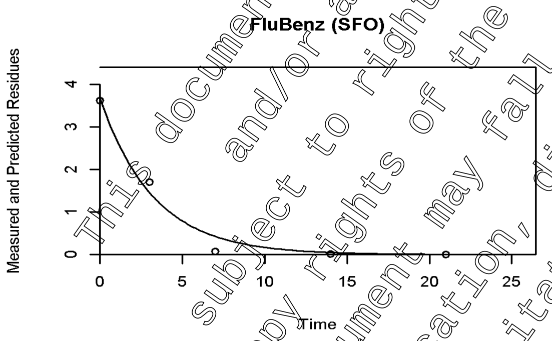
FOMC

10-2099-01, Wieringerwerf, M-423901-01-1, NL, endive

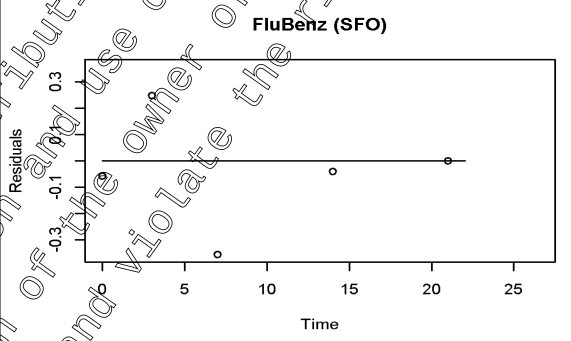
Table 8.9- 102: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for endive of trial 10-2099-01, Wieringerwerf, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	$DT_{50\ actual}$ (d)	$DT_{90\ actual}$ (d)
SFO	o	3.7	k: 0.30774	14.5	k: 0.005	k: 0.21	k: 0.41	**2.252**	7.48
FOMC	o	3.7	α: 4967000 β: 16140000	16.6	-	β: 16140000	β: 16140000	2.253	7.48
DFOP	o	3.7	k1: 0.815 k2: 0.308 g: 3 E-14	20.7	k1: NA k2: 0.253	k1: NA k2: -0.31	k1: NA k2: 0.92	2.252	7.48
HS	o	3.7	k1: 0.308 k2: 2.22 E-14 tb: 21.51	20.7	k1: 0.089 k2: <0.001	k1: 0.13 k2: 2.2 E-14	k1: 0.48 k2:< 0.0005	2.252	7.48

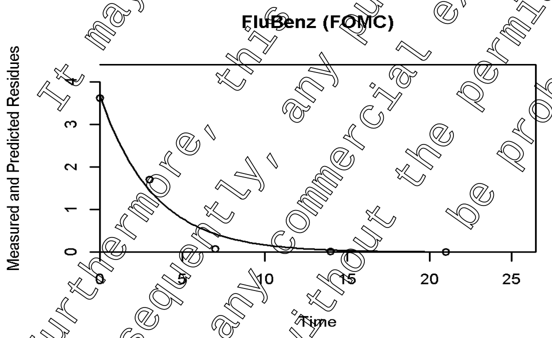
SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit



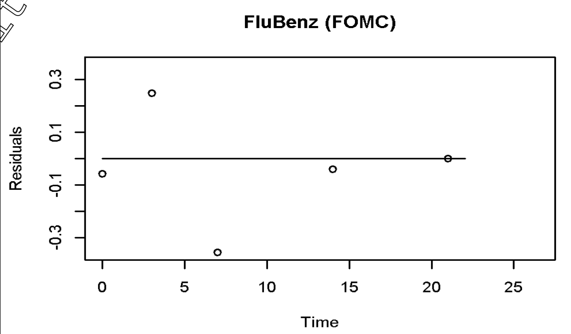
SFO



SFO



FOMC



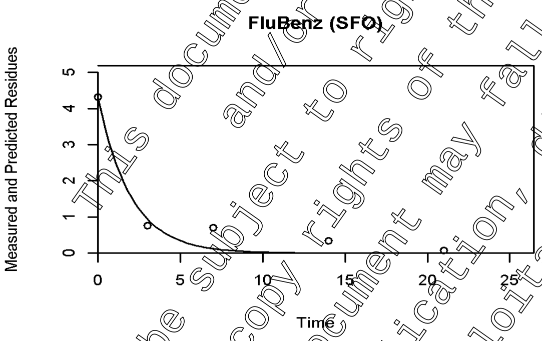
FOMC

10-2099-02, Langenfeld-Reusrath, M-423901-01-1, DE, endive

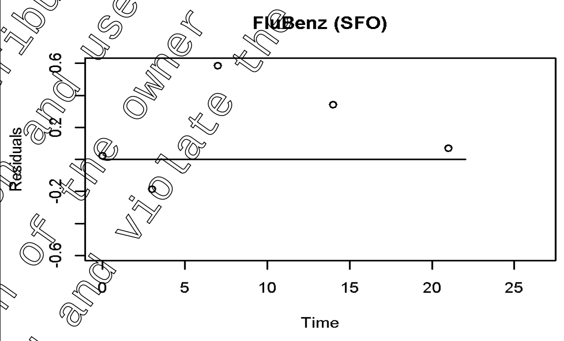
Table 8.9- 103: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for endive of trial 10-2099-02, Langenfeld-Reusrath, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	4.3	k: 0.5059	20.4	k: 0.019	k: 0.23	k: 0.78	1.370	4.55
FOMC	+	4.3	α: 0.63156 β: 0.23934	9.5	-	β: -0.64	β: 1.12	0.478	8.932
DFOP	+	4.3	k1: 10.030 k2: 0.08462 g: 0.754	7.4	k1: <0.001 k2: 0.14	k1: 10.03 k2: 0.01	k1: 10.03 k2: 0.16	0.108	10.65
HS	+	4.3	k1: 0.601508 k2: 0.084616 tb: 2.711	7.4	k1: 0.039 k2: 0.14	k1: 0.46 k2: 0.01	k1: 0.75 k2: 0.16	1.152	10.65

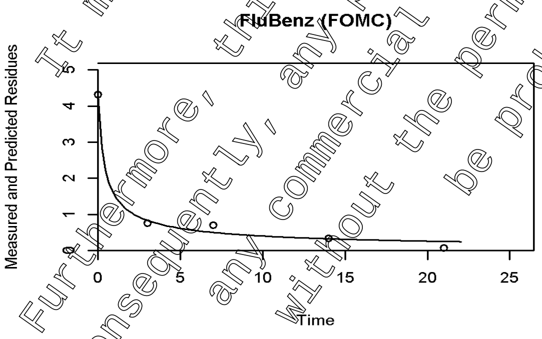
SFO fit is statistically (χ^2err ~15%, t-test <0.05) and visually poor. FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in χ2 error and visual assessment. However, the t-test of DFOP and HS show a low reliability especially of the slow degradation rates k2 (t-test >0.05). Therefore, **FOMC** model is considered best appropriate for modelling endpoints (FOCUS kinetics) and as well as best visual fit.



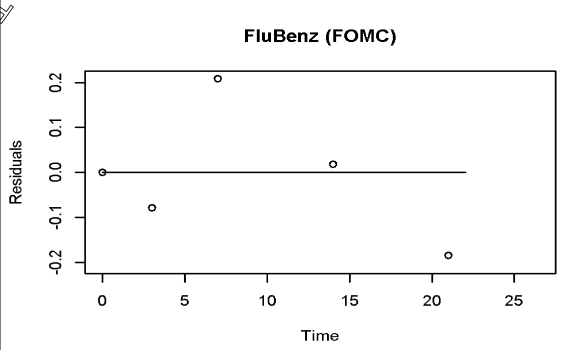
SFO



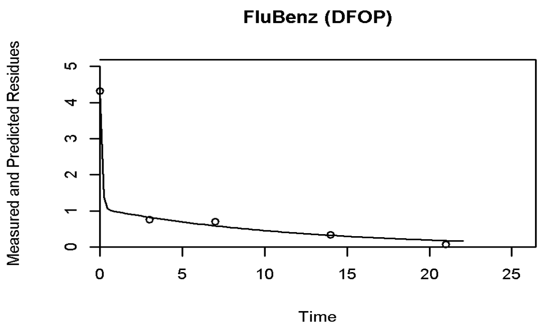
SFO



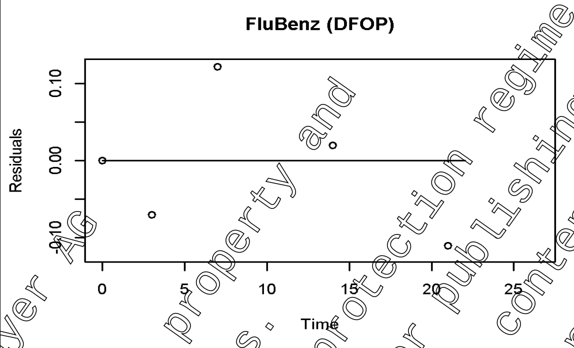
FOMC



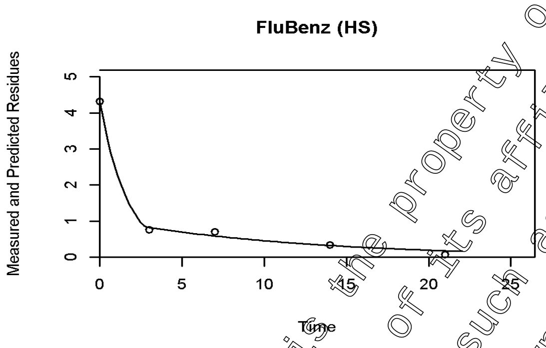
FOMC



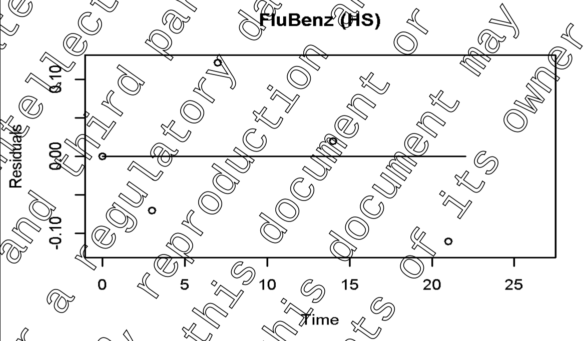
DFOP



DFOP



HS



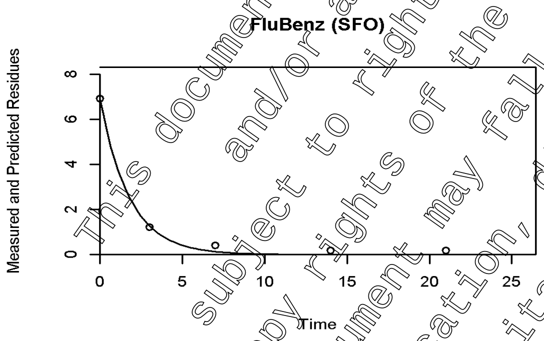
HS

10-2099-03, Villers-Perwin, M-423901-01-1, BE, endive

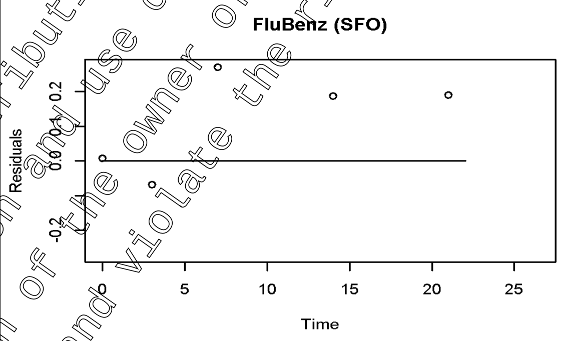
Table 8.9- 104: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for endive of trial 10-2099-03, Villers-Perwin,BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	6.9	k: 0.56261	7.7	k: 0.001	k: 0.45	k: 0.68	**1.232**	4.09
FOMC	+	6.9	α: 1.43377 β: 1.24652	2.2	-	β: 0.40	β: 2.09	0.775	4.97
DFOP	+	6.9	k1: 0.696726 k2: 0.05312 g: 0.929	1.6	k1: 0.023 k2: 0.158	k1: 0.60 k2: -0.003	k1: 0.80 k2: 0.11	1.095	4.38
HS	+	6.9	k1: 0.581265 k2: 0.068627 tb: 4.677	1.9	k1: 0.010 k2: 0.132	k1: 0.54 k2: 0.01	k1: 0.62 k2: 0.13	1.192	3.96

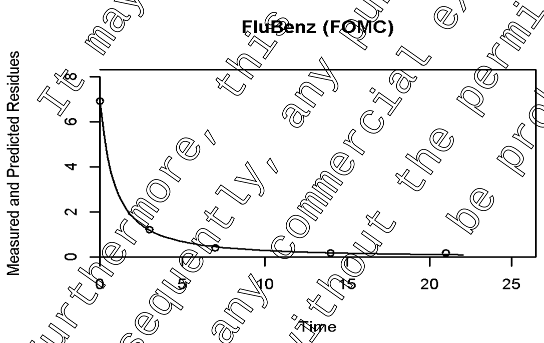
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached, is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



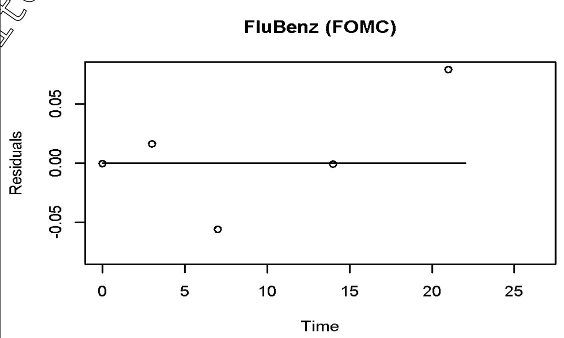
SFO



SFO



FOMC



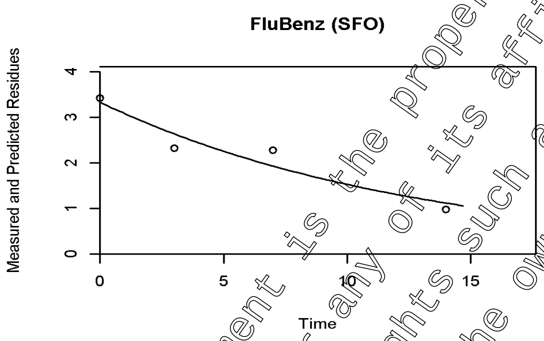
FOMC

18-2086-01-T1, Palidoro Fiumicino, M-675005-01-1, IT, lettuce

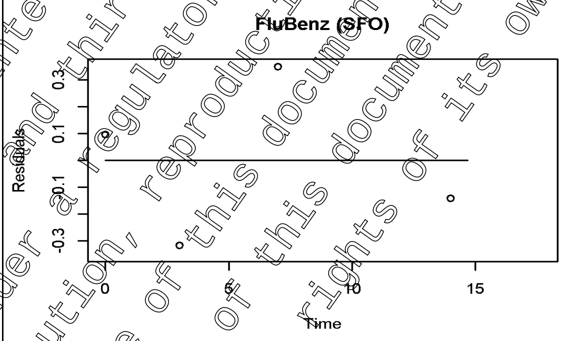
Table 8.9- 105: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial 18-2086-01-T1, Palidoro Fiumicino, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	$DT_{50\ actual}$ (d)	$DT_{90\ actual}$ (d)
SFO	+	3.3	k: 0.0778	9.1	k: 0.030	k: 0.04	k: 0.12	**8.910**	29.60
FOMC	+	3.3	α: 4224 β: 54290	11.3	-	β: 54060.06	β: 54524.81	8.909	29.60

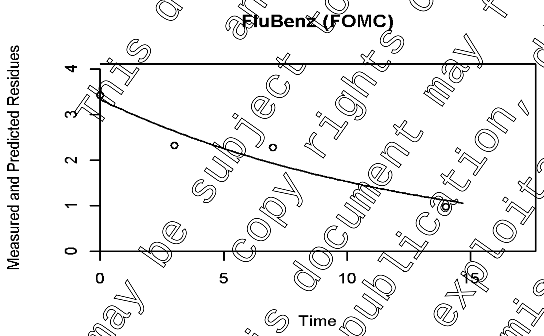
SFO fit is statistically and visually good to acceptable (χ^2 err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit, mainly due to scattering data. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



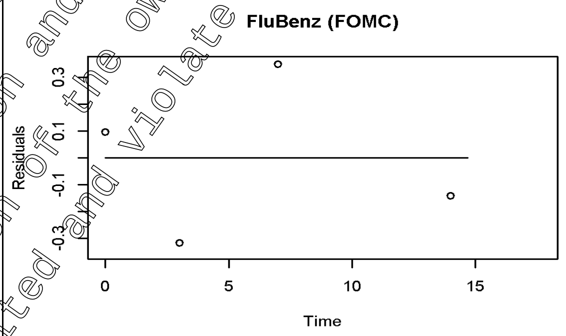
SFO



SFO



FOMC



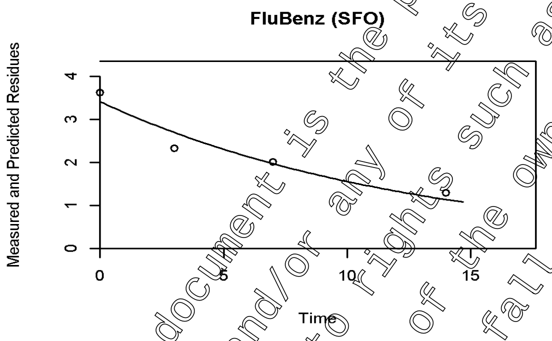
FOMC

18-2086-01-T2, Palidoro Fiumicino, M-675005-01-1, IT, lettuce

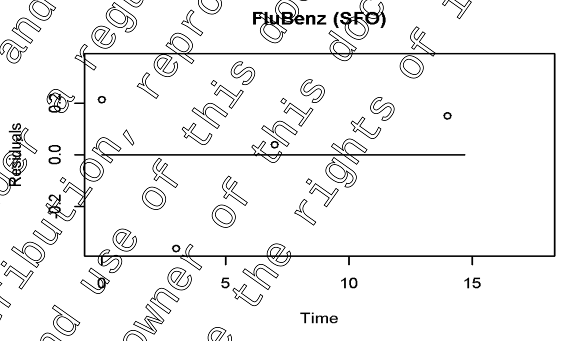
Table 8.9- 106: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial 18-2086-01-T2, Palidoro Fiumicino, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.4	k: 0.07835	7.9	k: 0.024	k: 0.04	k: 0.11	**8.847**	29.39
FOMC	+	3.6	α: 0.5178 β: 2.5959	4.8	-	β: -3.51	β: 8.70	7.305	219.00

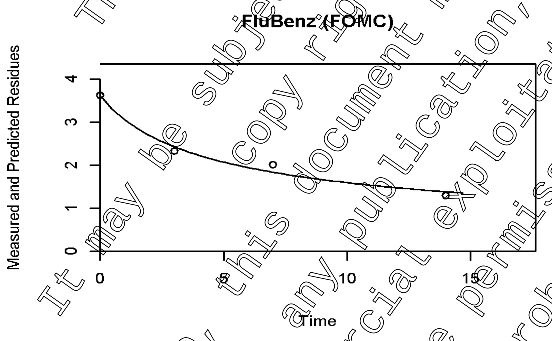
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics). FOMC shows a lower χ^2err. However, FOMC is not fully appropriate in cases where 10 % of the initial residues have not been reached during study duration, as an unrealistic tailing may occur. DFOP and HS are not appropriate in case of 4 data points, due to a too low degree of freedom. Consequently, SFO is therefore considered appropriate for modelling purpose (FOCUS kinetics) and as best visual fit (incl. all biphasic fits).



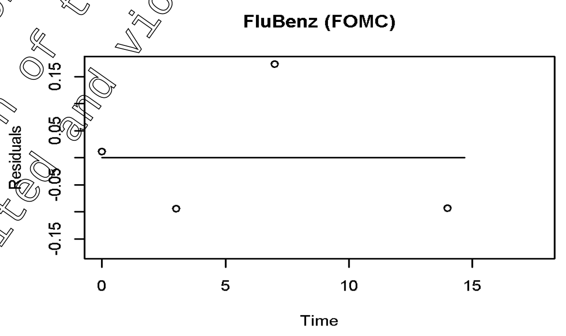
SFO



SFO



FOMC



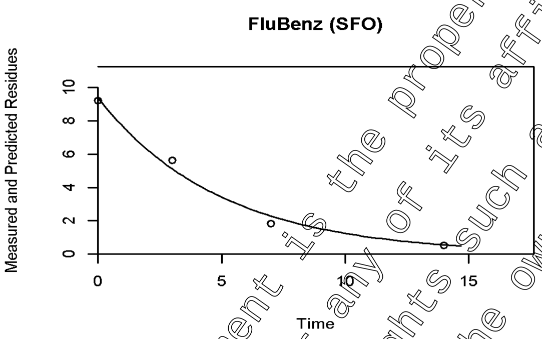
FOMC

18-2086-02-T1, Terlizzi, M-675005-01-1, IT, lettuce

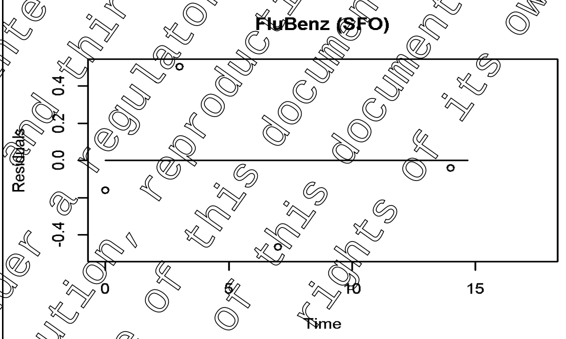
Table 8.9- 107: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial 18-2086-02-T1, Terlizzi, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	9.4	k: 0.20175	6.7	k: 0.007	k: 0.15	k: 0.25	**3.436**	11.41
FOMC	+	9.4	α: 10400 β: 51570	8.4	-	β: 50900.0	β: 52231.2	3.436	11.41

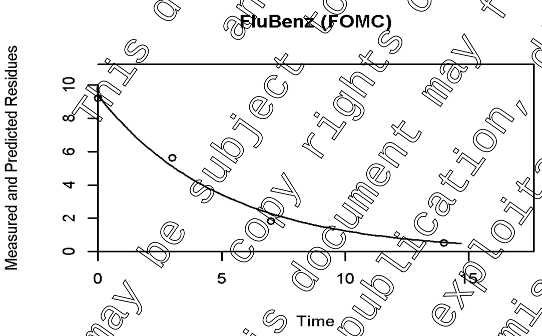
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



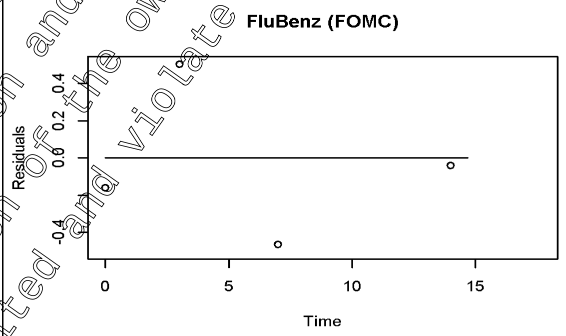
SFO



SFO



FOMC



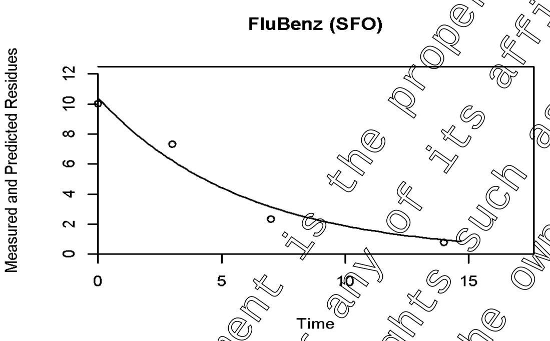
FOMC

18-2086-02-T2, Terlizzi, M-675005-01-1, IT, lettuce

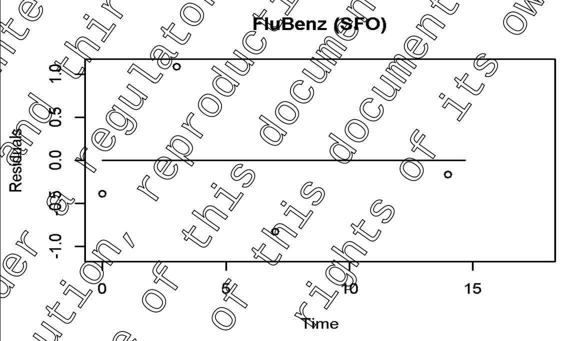
Table 8.9- 108: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial 18-2086-02-T2, Terlizzi, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	10.4	k: 0.17091	11.4	k: 0.021	k: 0.10	k: 0.24	**4.056**	13.47
FOMC	o	10.4	α: 10429.831 β: 61022.678	14.3	-	β: 59995.66	β: 62049.69	4.056	13.47

SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



SFO



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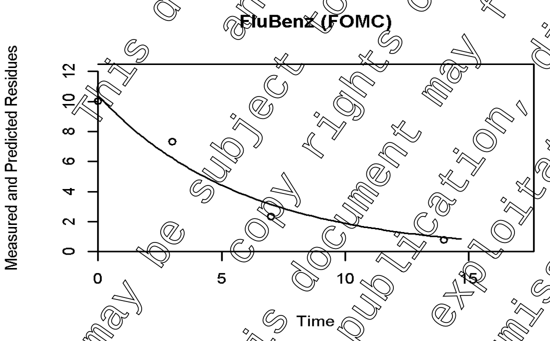
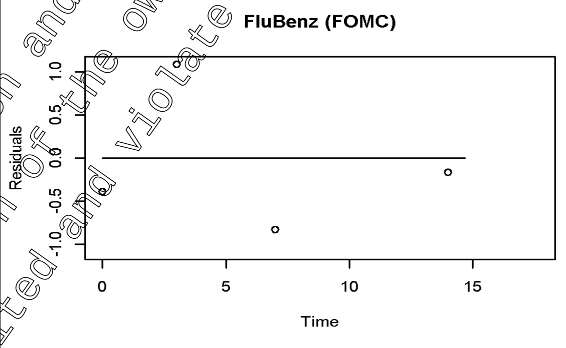


FOMC



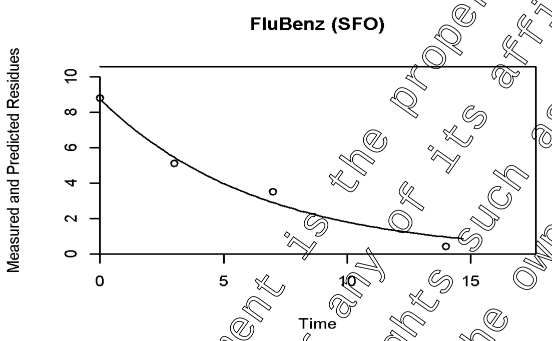
FOMC

18-2086-03-T1, Alginet, M-675005-01-1, ES, lettuce

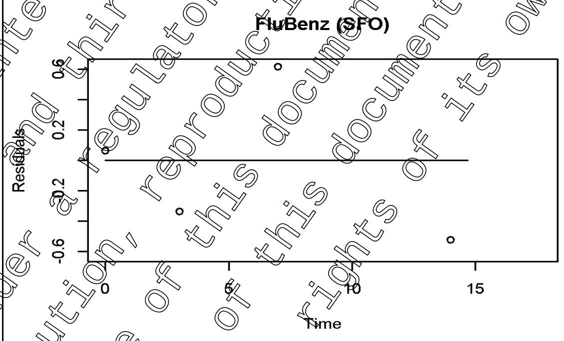
Table 8.9- 109: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial 18-2086-03-T1, Alginet, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	8.8	k: 0.15747	8.0	k: 0.012	k: 0.11	k: 0.21	**4.402**	14.62
FOMC	o	8.8	α: 17120 β: 108700	10.0	-	β: 107600.0	β: 109846.1	4.402	14.62

SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



SFO



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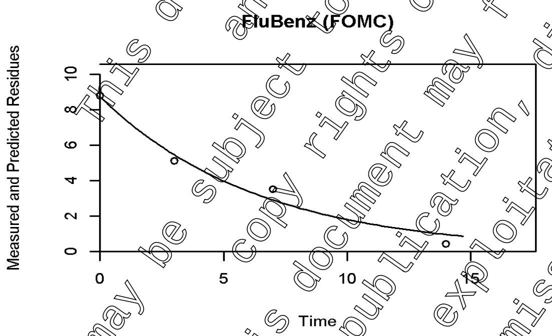
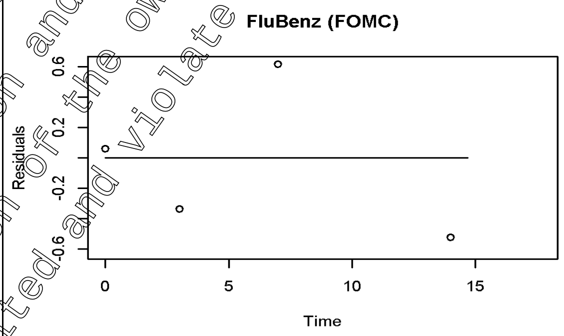


FOMC



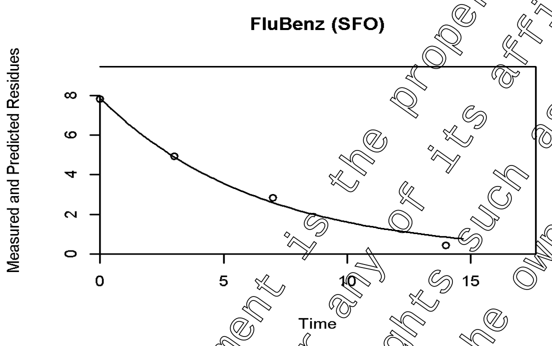
FOMC

18-2086-03-T2, Alginet, M-675005-01-1, ES, lettuce

Table 8.9- 110: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial 18-2086-03-T2, Alginet, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	7.9	k: 0.1585	4.8	k: 0.004	k: 0.13	k: 0.19	**4.373**	14.53
FOMC	+	7.9	α: 9806 β: 61860	6.0	-	β: 61470.06	β: 62255.39	4.373	14.53

SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



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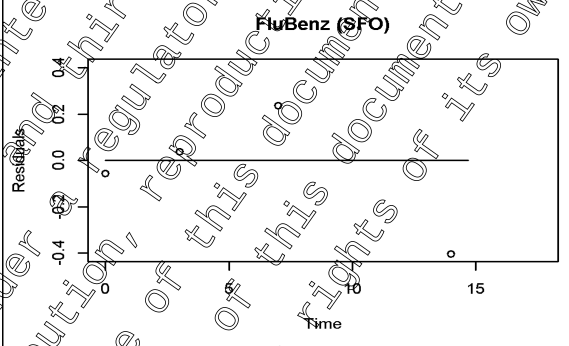

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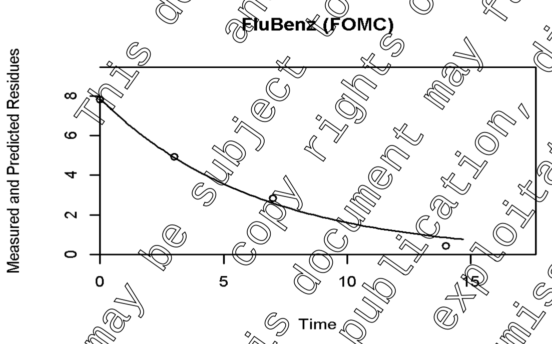
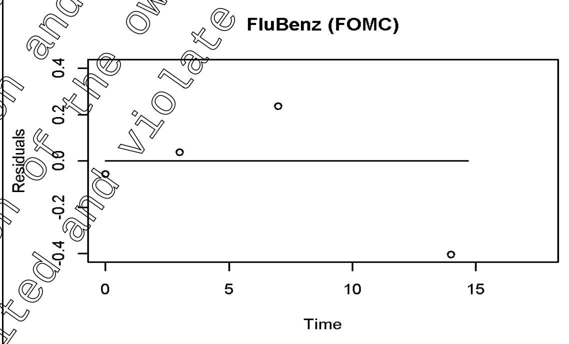


FOMC



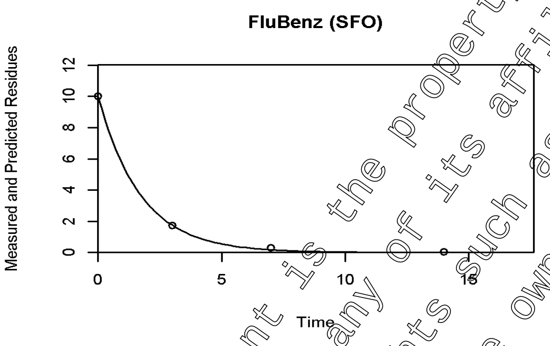
FOMC

18-0286-04-T1, Vasilika, Thessaloniki, M-675005-01-1, GR, lettuce

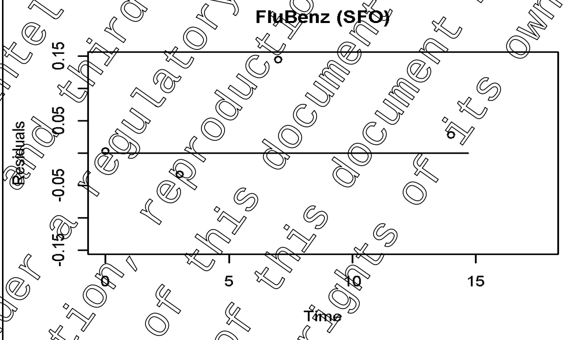
Table 8.9- 111: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial 18-0286-04-T1, Vasilika, Thessaloniki, GR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	10.0	k: 0.58201	2.0	k: <0.001	k: 0.54	k: 0.62	**1.191**	3.96
FOMC	+	10.0	α: 5.370547 β: 7.709606	0.1	-	β: 6.74	β: 8.68	1.062	4.13

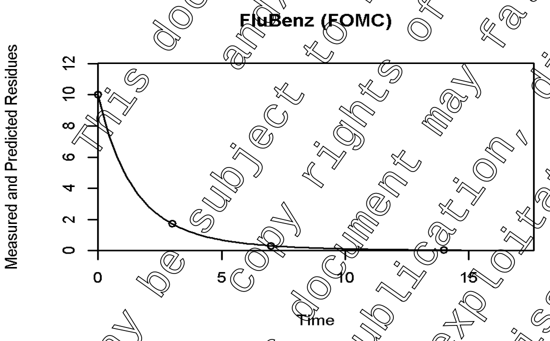
SFO fit is statistically and visually very good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



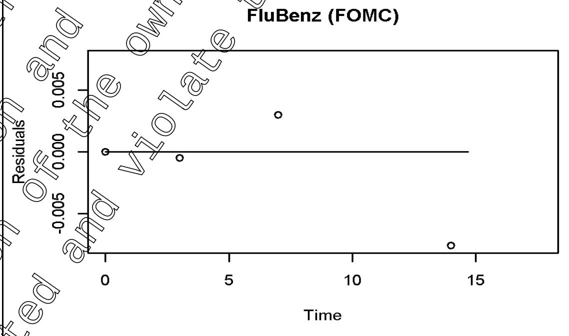
SFO



SFO



FOMC



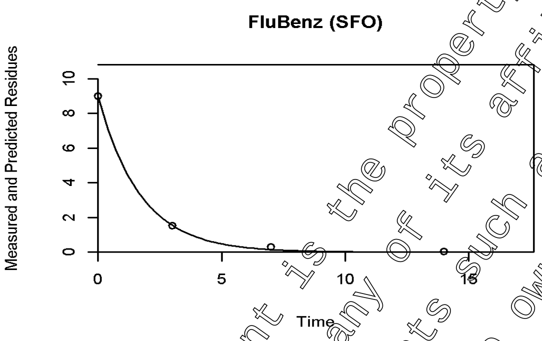
FOMC

18-0286-04-T2, Vasilika, Thessaloniki, M-675005-01-1, GR, lettuce

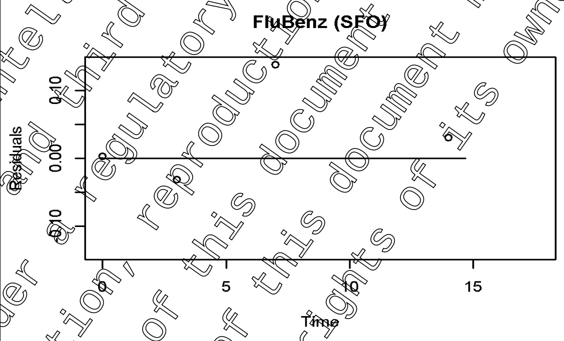
Table 8.9- 112: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial 18-0286-04-T2, Vasilika, Thessaloniki, GR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	9.0	k: 0.58795	2.2	k: <0.001	k: 0.55	k: 0.63	**1.179**	3.92
FOMC	+	9.0	α: 4.941914 β: 6.899856	0.1	-	β: 6.32	β: 7.48	1.039	4.095

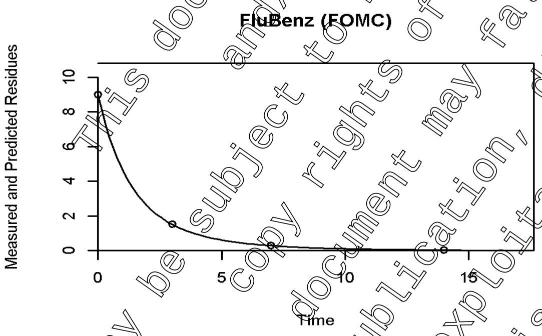
SFO fit is statistically and visually very good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



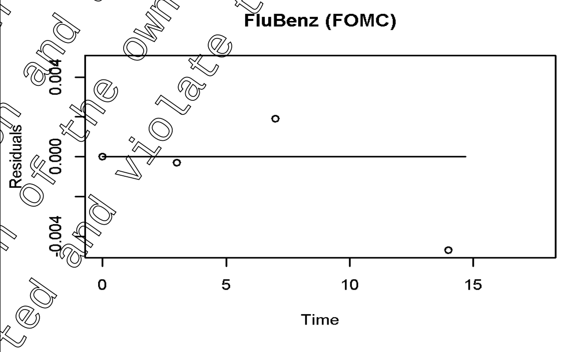
SFO



SFO



FOMC



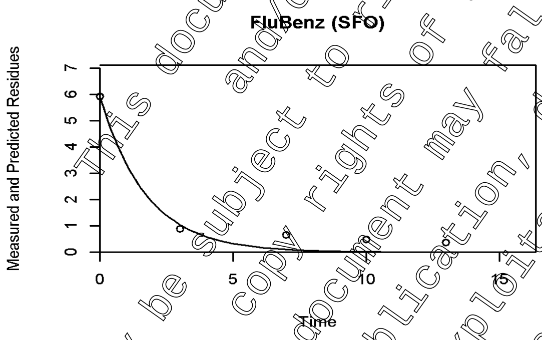
FOMC

R 2006 0375/4, Cergy, M-292048-01-1, FR, lettuce

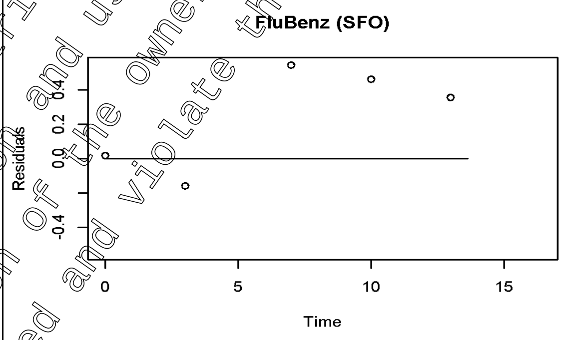
Table 8.9- 113: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce head of trial R 2006 0375/4, Cergy, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	5.9	k: 0.5765	17.5	k: 0.015	k: 0.29	k: 0.87	1.202	3.99
FOMC	+	5.9	α: 0.54276 β: 0.09796	2.3	-	β: -0.05	β: 0.24	0.253	6.72
DFOP	+	5.9	k1: 3354 k2: 0.0885 g: 0.803	0.7	k1: <0.001 k2: 0.020	k1: 3354.0 k2: 0.08	k1: 3353.67 k2: 0.10	0.000	7.69
HS	+	5.9	k1: 0.62833 k2: 0.08866 tb: 3.0	0.7	k1: 0.016 k2: 0.043	k1: 0.57 k2: 0.07	k1: 0.69 k2: 0.11	1.103	7.71

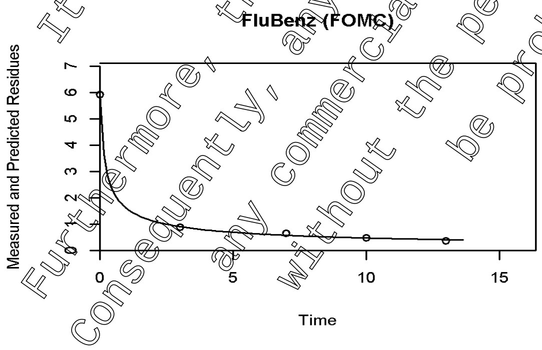
SFO fit is statistically acceptable (χ^2 err ~15%, t-test <0.05), but visually poor. DFOP, FOMC and HS fits were alternatively tested. HS fit is statistically good (χ^2 err, t-test) and visually better than DFOP, with a lowest $\chi2$ err. Consequently, **HS** model is considered appropriate according to modelling purpose (FOCUS kinetics) and as best visual fit. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT50 is an adequate option.



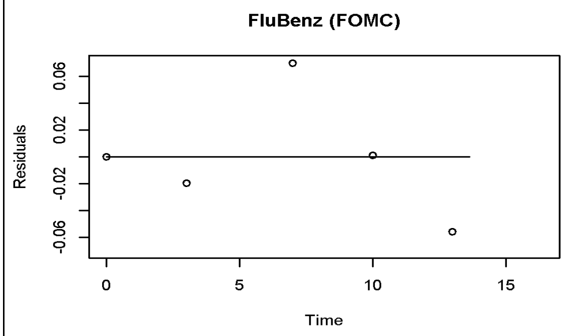
SFO



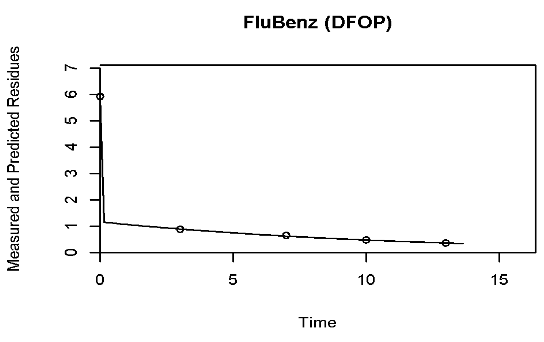
SFO



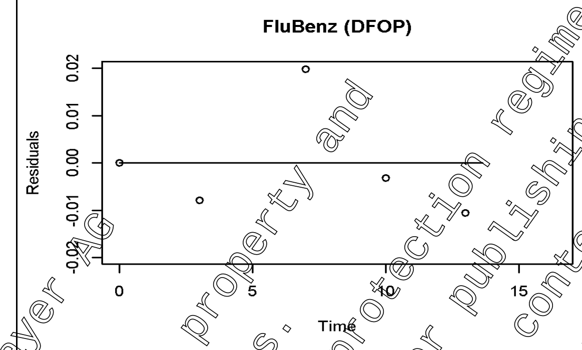
FOMC



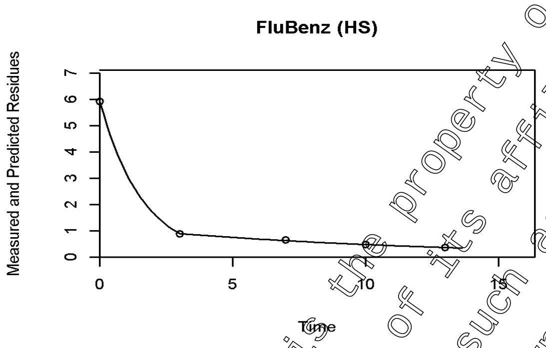
FOMC



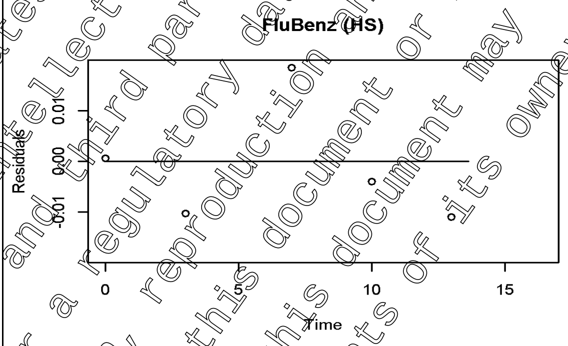
DFOP



DFOP



HS



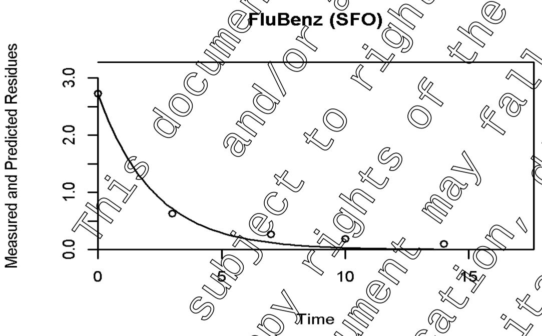
HS

R 2006 0376/2, St. Jory, M-292050-01-1, FR, lettuce

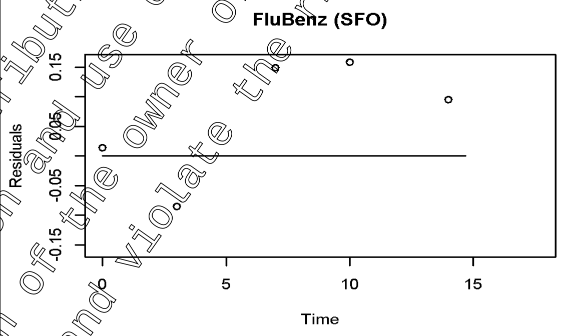
Table 8.9- 114: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce head of trial R 2006 0376/2, St. Jory, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	2.7	k: 0.44464	11.5	k: 0.003	k: 0.32	k: 0.57	**1.559**	5.18
FOMC	+	2.7	α: 1.3743 β: 1.5796	1.2	-	β: 1.13	β: 2.03	1.036	6.857
DFOP	+	2.7	k1: 13.571 k2: 0.183 g: 0.605	2.5	k1: NA k2: 0.039	k1: NA k2: 0.14	k1: NA k2: 0.23	0.123	7.511
HS	+	2.7	k1: 0.488779 k2: 0.135292 tb: 3.834	0.7	k1: 0.004 k2: 0.032	k1: 0.48 k2: 0.11	k1: 0.50 k2: 0.16	1.418	7.002

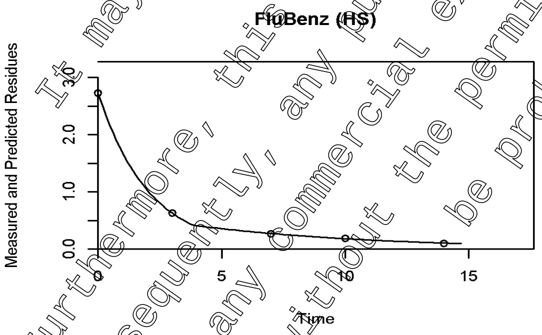
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 7), is described visually acceptable. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



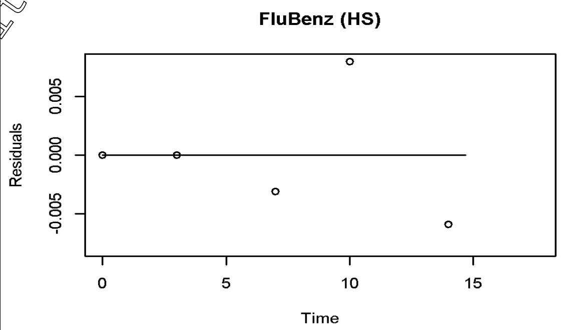
SFO



SFO



HS



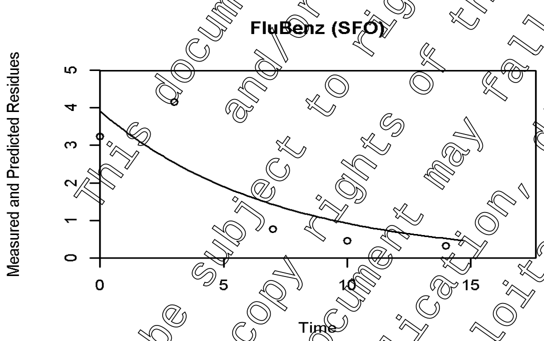
HS

R 2006 0377/0, Lampertheim, M-290825-01-1, DE, beans

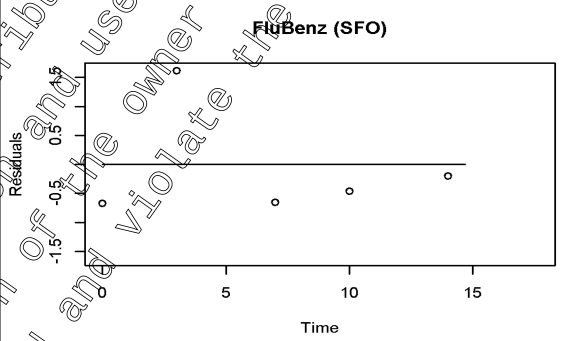
Table 8.9- 115: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2006 0377/0, Lampertheim, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.9	k: 0.143986	38.8	k: 0.079	k: -0.01	k: 0.30	**4.814**	15.99
FOMC	o	3.9	α: 13940 β: 96820	44.3	-	β: 96820.00	β: 96819.97	4.814	15.99
DFOP	o	3.9	k1: 0.144 k2: 0.1438 g: 1.0	55.3	k1: 0.238 k2: <0.001	k1: -0.12 k2: 0.14	k1: 0.41 k2: 0.14	4.814	15.99
HS	o	3.6	k1: 0 k2: 0.3322 tb: 3.0	20.9	k1: 0.50 k2: 0.345	k1: -1.88 k2: -0.89	k1: 1.88 k2: 1.56	5.086	9.93

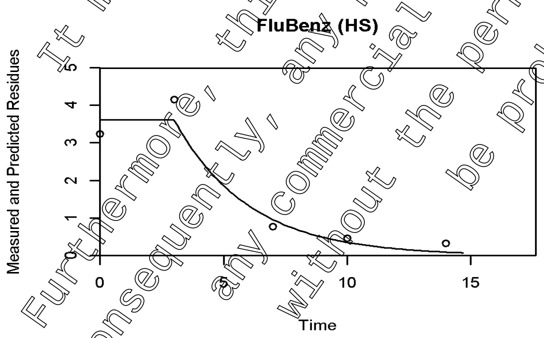
SFO fit is visually acceptable and at least conservative, but statistically not very good (χ² err >15%, t-test >0.05). FOMC and DFOP did not result in an improved fit, due to the scattering data. No further explanation for the scattering residue data is given in the experimental report. The HS resulted in a lag phase, which is considered not appropriate for the intended purpose. However, as residues reach 10 % of the initial amount, the SFO fit is finally considered appropriate and conservative to describe the residue decay.



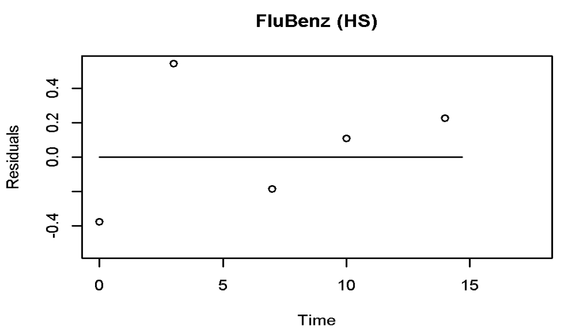
SFO



SFO



HS



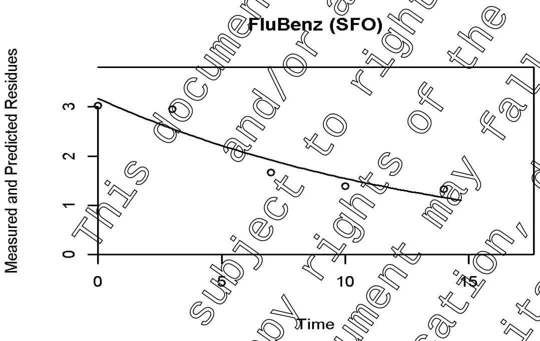
HS

R 2006 0378/9, Alginet, M-290827-01-1, ES, beans

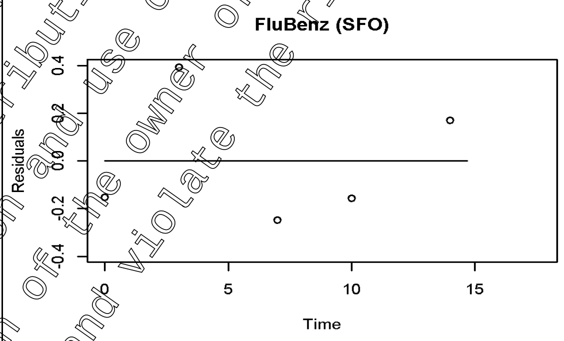
Table 8.9- 116: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2006 0378/9, Alginet, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.2	k: 0.07181	9.3	k: 0.009	k: 0.04	k: 0.10	**9.653**	32.07
FOMC	o	3.2	α: 630.3 β: 8771	10.7	-	β: -19190000	β: 19200000	9.652	32.10
DFOP	o	3.2	k1: 0.082 k2: 2.2 E-14 g: 0.920	13.3	k1: 0.485 k2: 0.5	k1: -3.36 k2: -22.88	k1: 3.52 k2: 22.88	9.558	46.46
HS	o	3.2	k1: 0.079573 k2: 0.012151 tb: 10.586	12.2	k1: 0.119 k2: 0.471	k1: 0.02 k2: -0.25	k1: 0.14 k2: 0.27	8.711	130.80

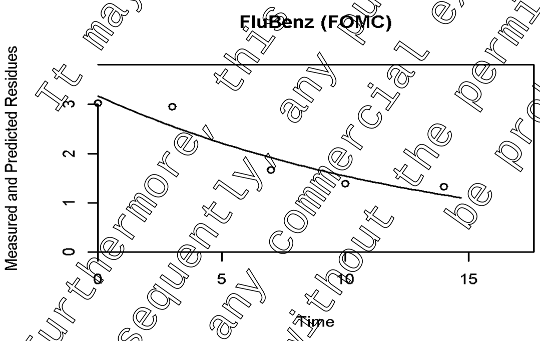
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



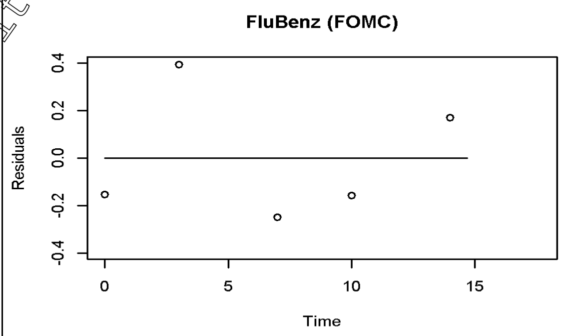
SFO



SFO



FOMC



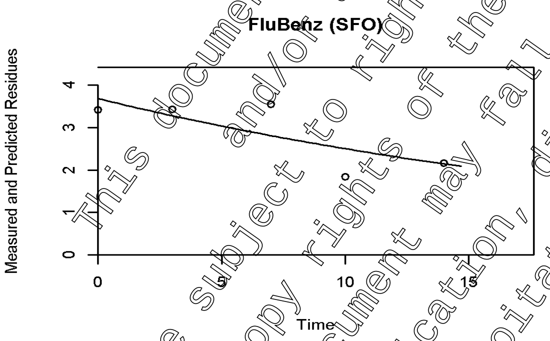
FOMC

R 2006 0380/0, Machern, M-291180-01-1, DE, pea

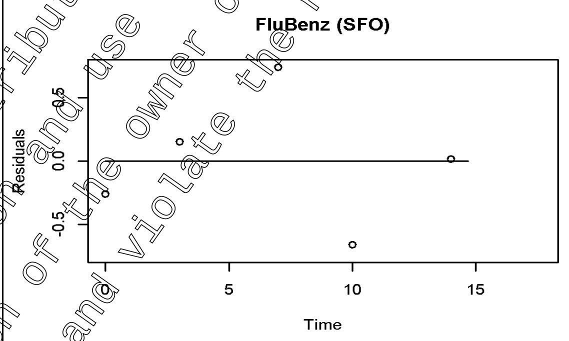
Table 8.9- 117: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for pea of trial R 2006 0380/0, Machern, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.7	k: 0.0386099	12.9	k: 0.071	k:< 0.001	k: 0.08	**17.95**	59.64
FOMC	o	3.7	α: 1574.3192 β: 40769.697	14.7	-	β: 40695.98	β: 40843.4	17.95	59.67
DFOP	o	3.7	k1: 0.03861 k2: 0.03861 g: 0.324	18.4	k1: 0.149 k2: 0.258	k1:<0.001 k2: -0.04	k1: 0.08 k2: 0.12	17.95	59.64
HS	o	3.4	k1: 2.2 E-14 k2: 0.08835 tb: 6.442	14.7	k1: 0.5 k2: 0.221	k1: -0.22 k2: -0.06	k1: 0.22 k2: 0.23	14.29	32.51

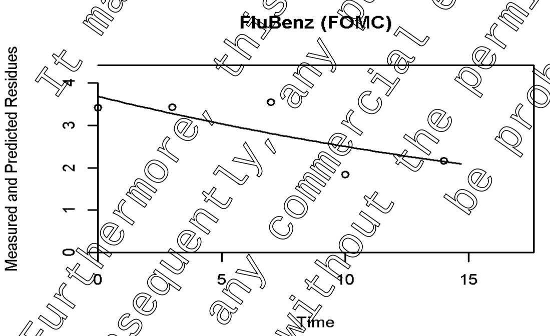
SFO fit is visually and statistically not very good (χ^2err <15%, t-test >0.05). FOMC, DFOP and HS did not result in an improved fit, due to scattering data. No further explanation for the scattering residue data is given in the experimental report (after analytical double check). However, as initial and final residues are covered sufficiently well and further data points scatter equally around the fit, the SFO fit is finally considered appropriate and conservative to describe the residue decay.



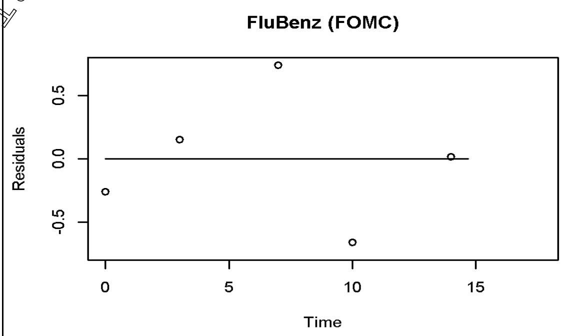
SFO



SFO



FOMC



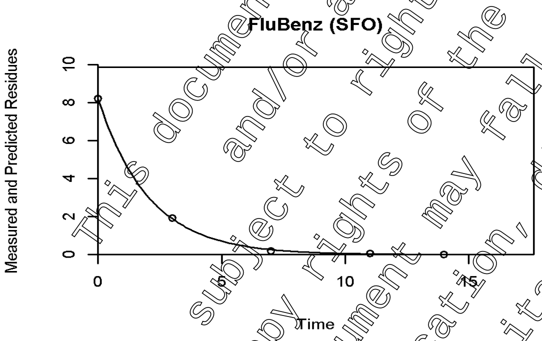
FOMC

R 2006 0604/4, Meckenbeuren, M-292048-01-1, DE, lettuce

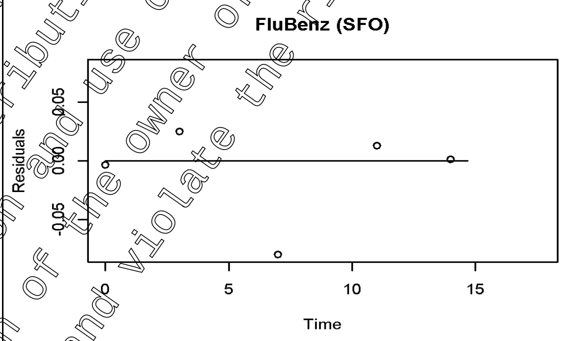
Table 8.9- 118: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce head of trial R 2006 0604/4, Meckenbeuren, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	8.2	k: 0.490644	1.5	k: <0.001	k: 0.47	k: 0.51	**1.413**	4.69
FOMC	+	8.2	α: 3751000 β: 7646000	1.7	-	β: 7646000	β: 7646000	1.413	4.69
DFOP	+	8.2	k1: 0 k2: 0.4907 g: 0	2.1	k1: NA k2: 0.012	k1: NA k2: 0.46	k1: NA k2: 0.53	1.413	4.69
HS	+	8.2	k1: 0.4908 k2: 0.42389 tb: 7.0	2.1	k1: 0.010 k2: 0.258	k1: 0.46 k2: -0.45	k1: 0.52 k2: 1.30	1.412	4.69

SFO fit is statistically and visually very good (χ^2 err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit



SFO



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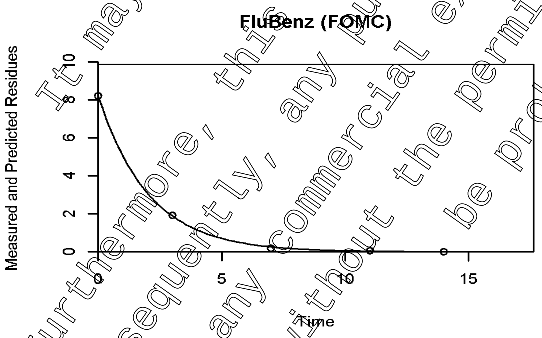

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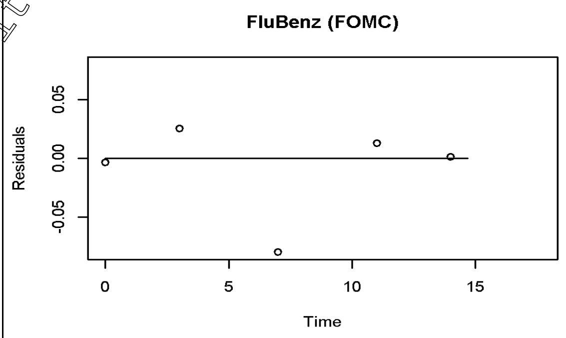


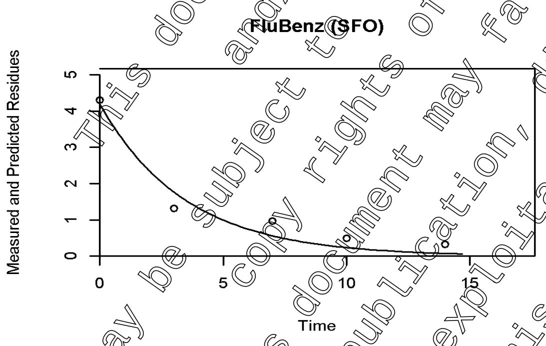
FOMC

R 2006 0605/2, Langenfeld-Reusrath, M-292048-01-1, DE, lettuce

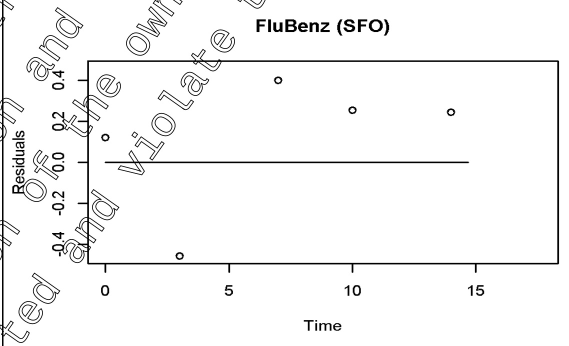
Table 1 **Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce head of trial R 2006 0605/2, Langenfeld-Reusrath, DE**

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.2	k: 0.28768	17.3	k: 0.010	k: 0.16	k: 0.41	2.409	8.00
FOMC	+	4.3	α: 0.9088 β: 1.188	7.1	-	β: -0.86	β: 3.23	1.359	13.78
DFOP	+	4.3	k1: 13.291 k2: 0.123 g: 0.548	5.7	k1: <0.001 k2: 0.079	k1: 13.29 k2: 0.06	k1: 13.29 k2: 0.18	0.170	12.30
HS	+	4.3	k1: 0.387 k2: 0.123 tb: 2.999	5.7	k1: 0.033 k2: 0.079	k1: 0.31 k2: 0.06	k1: 0.47 k2: 0.18	1.790	12.30

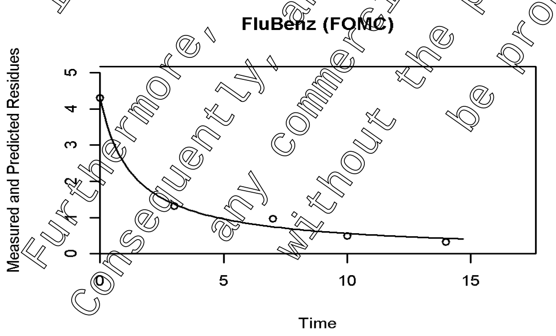
SFO fit is statistically still acceptable (χ^2err ~15%, t-test <0.05), but visually borderline to poor. FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in χ2 error and visual assessment. The t-test of DFOP and HS show only a slightly reduced reliability of the slow degradation rates k2 (t-test > 0.05). However, HS shows the best visual fit and one of the lowest χ^2err. Therefore, **HS** model is considered best appropriate for modelling endpoints (FOCUS kinetics) and as well as best visual fit. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT50 is an alternative option.



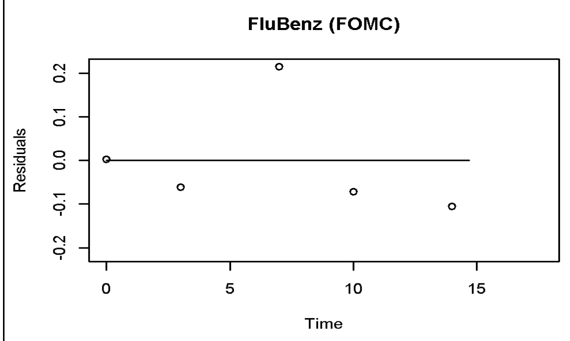
SFO



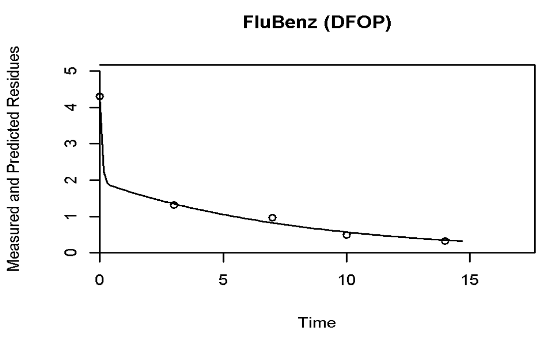
SFO



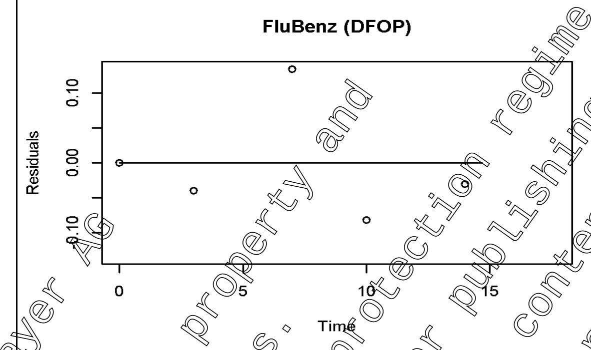
FOMC



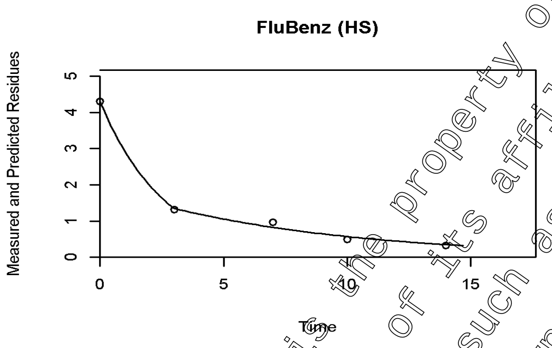
FOMC



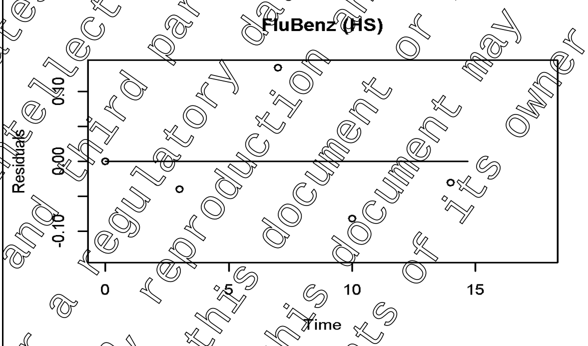
DFOP



DFOP



HS



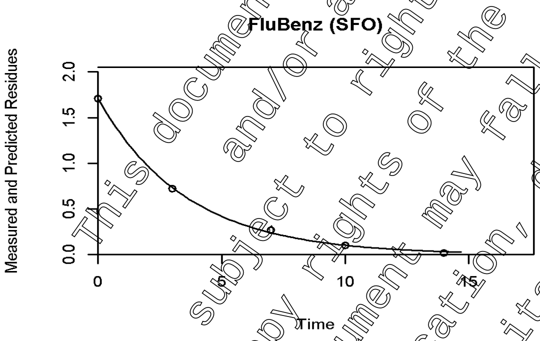
HS

R 2006 0606/0, Zwaagdijk, M-292048-01-1, NL, lettuce

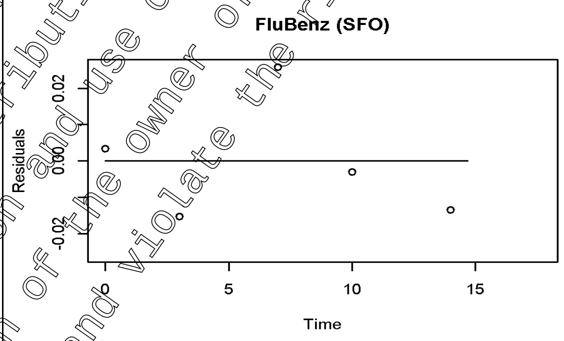
Table 8.9- 119: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce head of trial R 2006 0606/0, Zwaagdijk, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	1.7	k: 0.280685	2.1	k: <0.001	k: 0.27	k: 0.29	**2.469**	8.20
FOMC	+	1.7	α: 35.876 β: 125.009	2.3	-	β: -486.96	β: 736.97	2.439	8.29
DFOP	+	1.7	k1: 6.715 k2: 0.2672 g: 0.058	2.5	k1: <0.001 k2: 0.026	k1: 6.72 k2: 0.22	k1: 6.72 k2: 0.31	2.372	8.40
HS	+	1.7	k1: 0.2881462 k2: 0.2671836 tb: 2.828	2.5	k1: 0.017 k2: 0.026	k1: 0.26 k2: 0.22	k1: 0.32 k2: 0.31	2.406	8.40

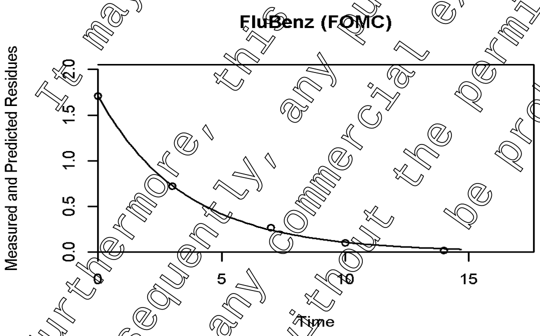
SFO fit is statistically and visually very good (χ^2 err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



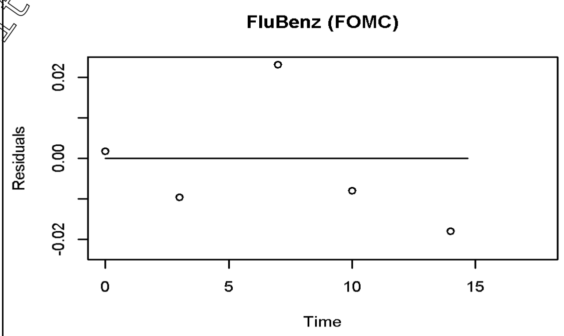
SFO



SFO



FOMC



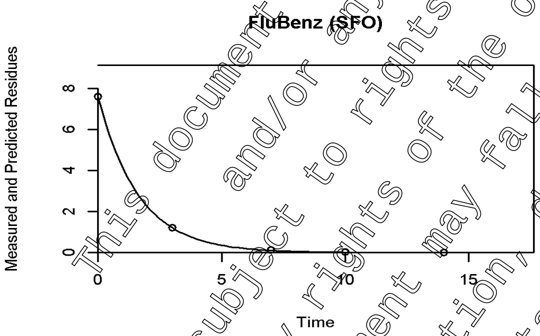
FOMC

R 2006 0607/9, Ely, M-292048-01-1, GB, lettuce

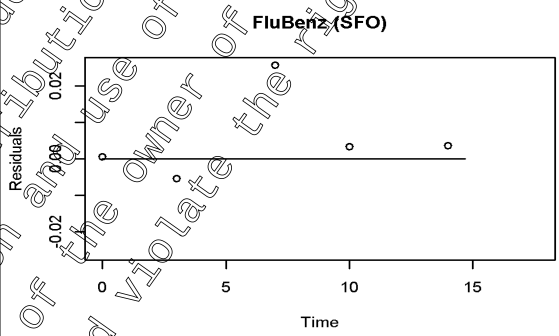
Table 8.9- 120: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce head of trial R 2006 0607/9, Ely, GB

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	7.6	k: 0.612832	0.5	k: <0.001	k: 0.60	k: 0.62	**1.131**	3.757
FOMC	+	7.6	α: 23.417932 β: 36.644124	0.17	-	β: 21.36	β: 51.93	1.101	3.786
DFOP	+	7.6	k1: 14960 k2: 0.559 g: 0.153	0.14	k1: NA k2: 0.005	k1: NA k2: 0.54	k1: NA k2: 0.58	0.943	3.822
HS	+	7.6	k1: 0.6152 k2: 0.559 tb: 2.951	0.14	k1: <0.001 k2: 0.005	k1: 0.61 k2: 0.54	k1: 0.62 k2: 0.58	1.127	3.822

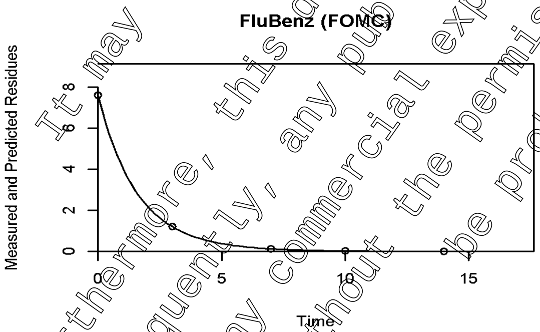
SFO fit is statistically and visually very good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



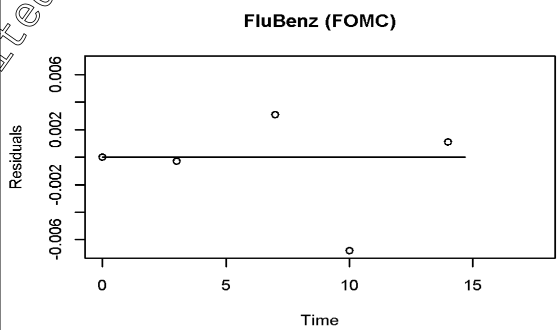
SFO



SFO



FOMC



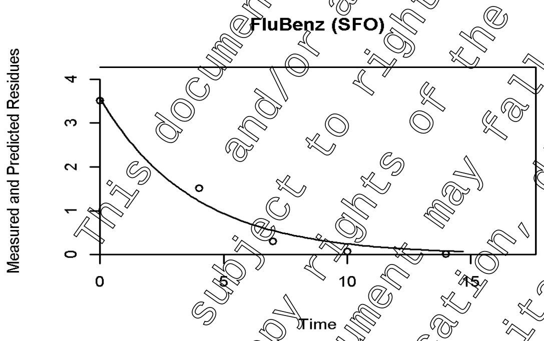
FOMC

R 2006 0608/7, Vilanova del Valles, M-292050-01-1, ES, lettuce

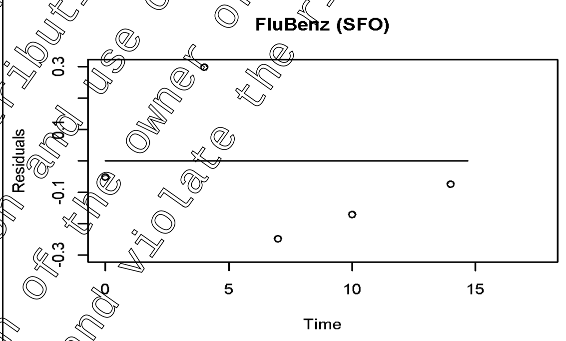
Table 8.9- 121: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce head of trial R 2006 0608/7, Vilanova del Valles, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.6	k: 0.26739	14.3	k: 0.003	k: 0.19	k: 0.34	**2.592**	8.61
FOMC	+	3.6	α: 39300 β: 147000	16.3	-	β: 147000	β: 147000	2.592	8.61
DFOP	+	3.6	k1: 0.267 k2: 2.2 E-14 g: 1.0	20.4	k1: 0.139 k2: <0.001	k1: 0.02 k2: 2.2 E-14	k1: 0.51 k2: < 0.0005	2.592	8.61
HS	+	3.6	k1: 0.26739 k2: 0.20496 tb: 17.055	20.4	k1: 0.079 k2: <0.001	k1: 0.13 k2: 0.20	k1: 0.40 k2: 0.21	2.592	8.61

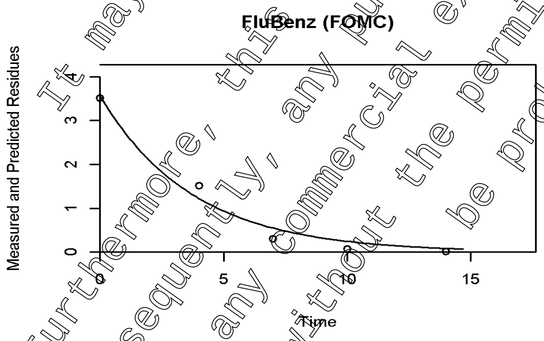
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



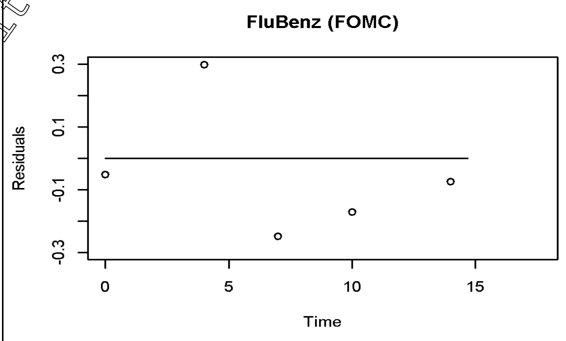
SFO



SFO



FOMC



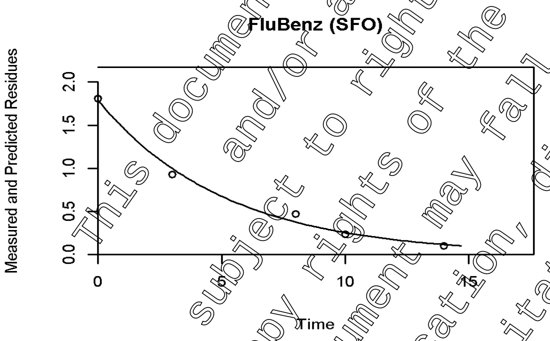
FOMC

R 2006 0610/9, Catania, M-292050-01-1, IT, lettuce

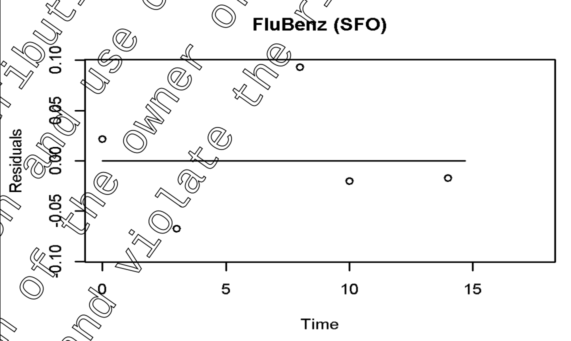
Table 8.9- 122: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce head of trial R 2006 0610/9, Catania, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	1.8	k: 0.19466	6.1	k: <0.001	k: 0.17	k: 0.22	**3.561**	11.83
FOMC	+	1.8	α: 7.12841 β: 32.72876	6.4	-	β: -93.43	β: 158.89	3.342	12.48
DFOP	+	1.8	k1: 7.287 k2: 0.1737 g: 0.124	6.9	k1: <0.001 k2: 0.062	k1: 7.29 k2: 0.11	k1: 7.29 k2: 0.24	3.232	12.50
HS	+	1.8	k1: 0.234706 k2: 0.173665 tb: 2.459	6.9	k1: 0.079 k2: 0.062	k1: 0.12 k2: 0.11	k1: 0.35 k2: 0.24	3.232	12.50

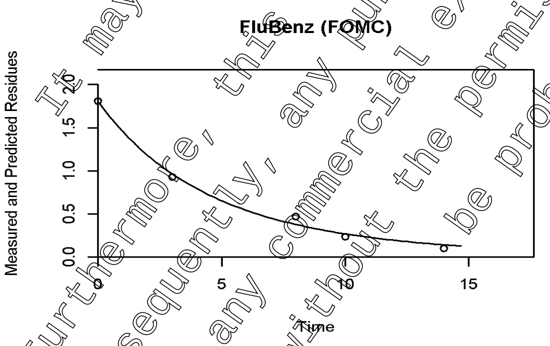
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



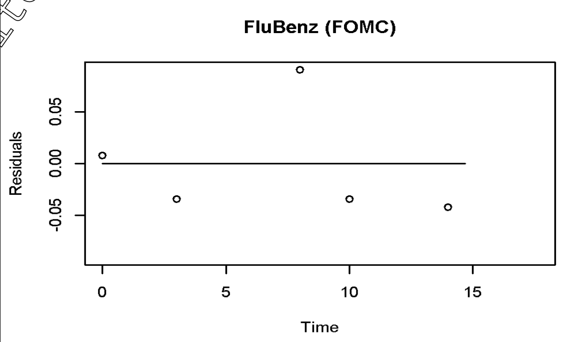
SFO



SFO



FOMC



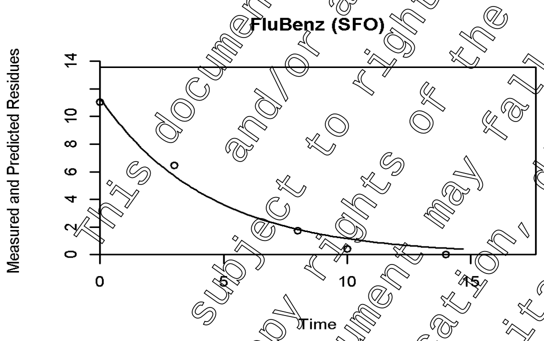
FOMC

R 2006 0611/7, Katerini / Paralia, M-292050-01-1, GR, lettuce

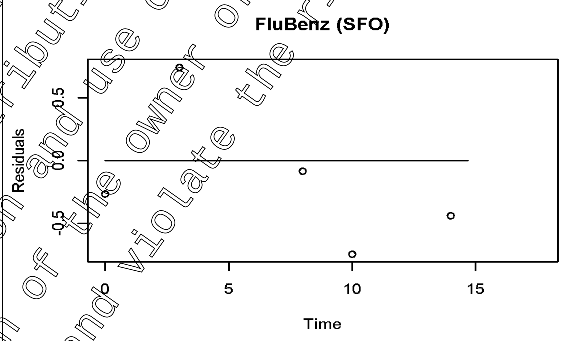
Table 8.9- 123: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce head of trial R 2006 0611/7, Katerini / Paralia, GR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	11.3	k: 0.22799	10.7	k: 0.002	k: 0.17	k: 0.28	**3.040**	10.10
FOMC	o	11.3	α: 19160 β: 84020	12.2	-	β: 82770.00	β: 85271.48	3.040	10.10
DFOP	o	11.3	k1: 0.228 k2: 2.2 E-14 g: 1.0	15.3	k1: 0.132 k2: <0.001	k1: 0.03 k2: 2.2 E-14	k1: 0.42 k2: < 0.0005	3.040	10.10
HS	o	11.3	k1: 0.22799 k2: 0.08447 tb: 28.634	15.3	k1: 0.068 k2: <0.001	k1: 0.13 k2: 0.08	k1: 0.33 k2: 0.08	3.040	10.10

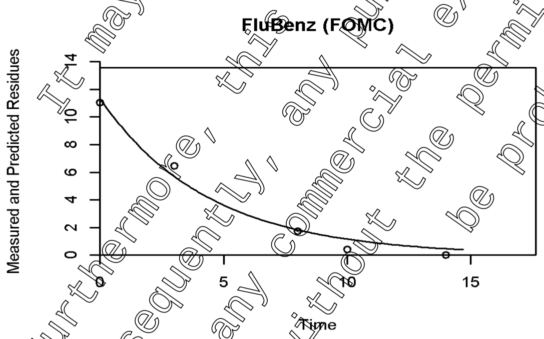
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



SFO



SFO



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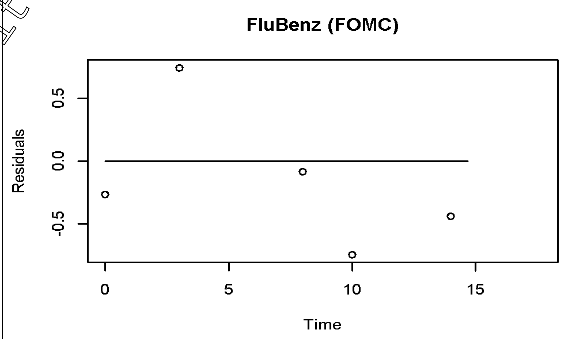


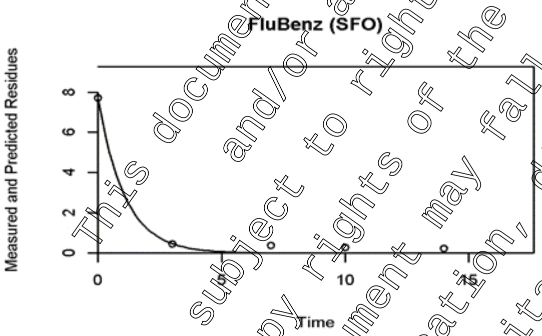
FOMC

R 2006 0620/6, Pradelle di Nogarole Rocca, M-290827-01-1, IT, beans

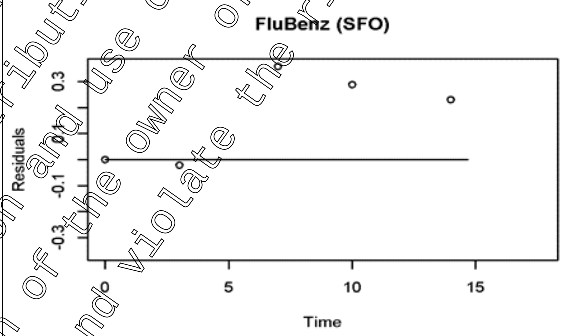
Table 8.9- 124: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2006 0620/6, Pradelle di Nogarole Rocca, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.7	k: 0.93180	10.2	k: 0.011	k: 0.52	k: 1.34	**0.7439**	2.471
FOMC	+	7.7	α: 0.38433 β: 0.00197	1.0	-[a]	β: 0.00	β: 0.01	0.010	0.79
DFOP	+	7.7	k1: 15.25607 k2: 0.06119 g: 0.92915	0.5	k1: NA k2: 0.032	k1: NA k2: 0.05	k1: NA k2: 0.07	0.051	0.22
HS	+	7.7	k1: 0.95908 k2: 0.06119 tb: 2.94827	0.5	k1: 0.003 k2: 0.032	k1: 0.94 k2: 0.05	k1: 0.98 k2: 0.07	0.7227	2.401

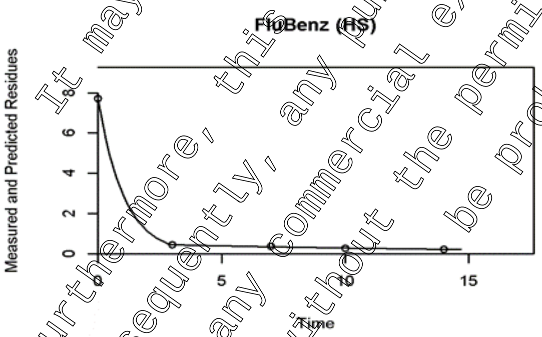
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 3), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



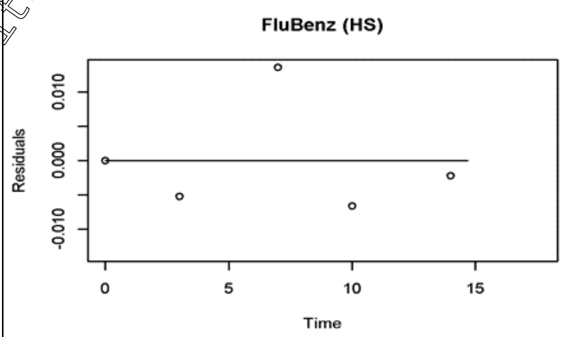
SFO



SFO



HS



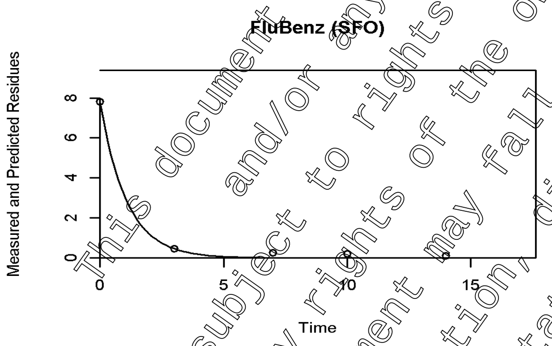
HS

R 2006 0654/0, Langenfeld-Reusrath, M-290825-01-1, DE, beans

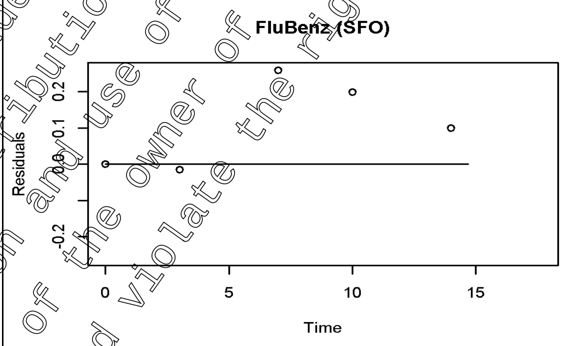
Table 8.9- 125: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2006 0654/0, Langenfeld-Reusrath, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	7.8	k: 0.9408	6.9	k: 0.003	k: 0.66	k: 1.22	**0.7368**	2.447
FOMC	+	7.8	α: 0.76988 β: 0.07727	1.3	-	β: -0.03	β: 0.19	0.113	1.46
DFOP	+	7.8	k1: 29210 k2: 0.1263 g: 0.916	0.5	k1: NA k2: 0.027	k1: NA k2: 0.11	k1: NA k2: 0.15	2.4 E-5	1.4 E-4
HS	+	7.8	k1: 0.9536 k2: 0.12632 tb: 2.990	0.5	k1: 0.004 k2: 0.027	k1: 0.93 k2: 0.11	k1: 0.98 k2: 0.15	0.7269	2.415

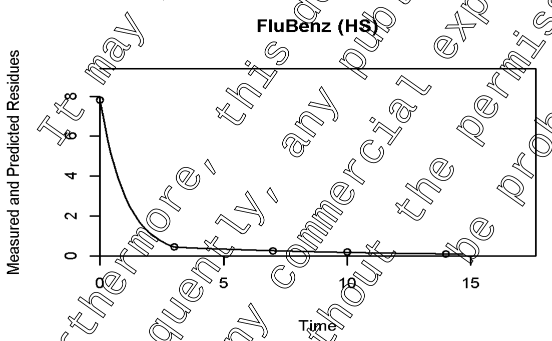
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



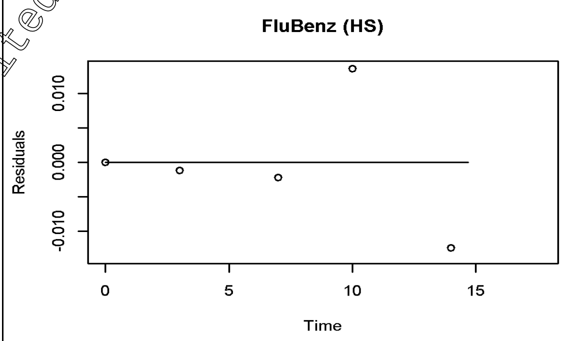
SFO



SFO



HS



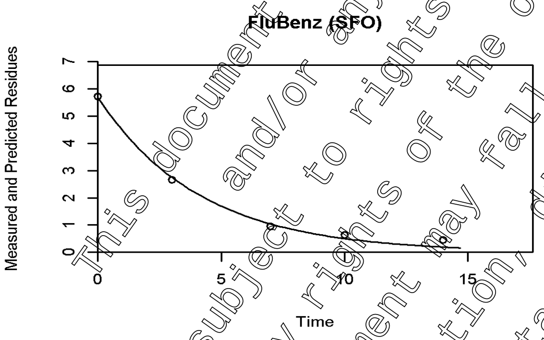
HS

R 2006 0655/9, Zwaagdijk, M-290825-01-1, NL, beans

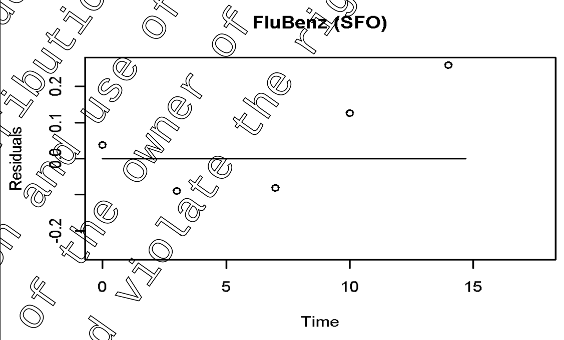
Table 8.9- 126: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2006 0655/9, Zwaagdijk, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	5.7	k: 0.2426	5.4	k: <0.001	k: 0.21	k: 0.27	**2.857**	9.49
FOMC	+	5.7	α: 4.1835 β: 14.3756	3.7	-	β: -4.26	β: 33.01	2.591	10.55
DFOP	+	5.7	k1: 0.2871 k2: 2.2 E-14 g: 0.945	2.6	k1: 0.061 k2: 0.5	k1: 0.18 k2: -0.36	k1: 0.40 k2: 0.36	2.623	10.61
HS	+	5.7	k1: 0.255536 k2: 0.084118 tb: 7.972	0.1	k1: <0.001 k2: 0.008	k1: 0.25 k2: 0.08	k1: 0.26 k2: 0.09	2.713	11.13

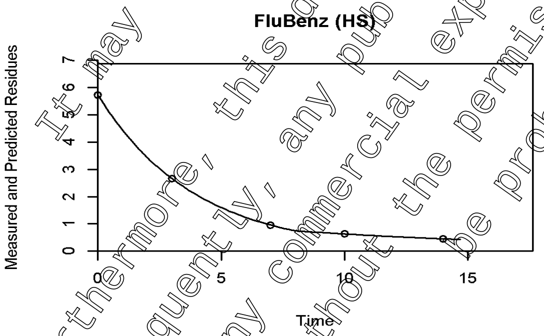
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



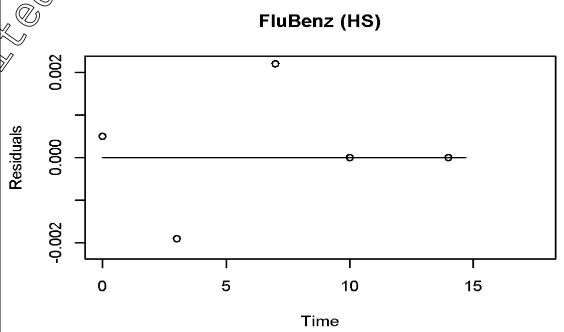
SFO



SFO



HS



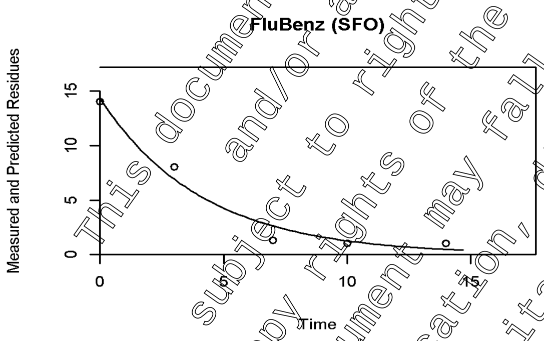
HS

R 2006 0656/7, Villers-Perwin, M-290825-01-1, BE, beans

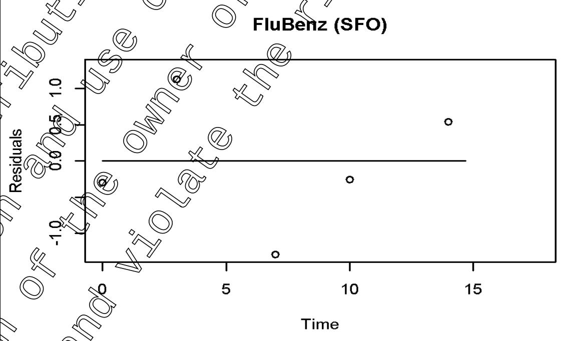
Table 8.9- 127: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2006 0656/7, Villers-Perwin, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	14.3	k: 0.2425	13.0	k: 0.004	k: 0.17	k: 0.32	**2.858**	9.49
FOMC	o	14.3	α: 10445.515 β: 43062.043	14.8	-	β: 42174	β: 43950.08	2.858	9.49
DFOP	o	14.3	k1: 0.2426 k2: 2.2 E-14 g: 1.0	18.5	k1: 0.148 k2: <0.001	k1: 0.004 k2: 2.2 E-14	k1: 0.481 k2: 0.0005	2.858	9.49
HS	o	14.0	k1: 0.186736 k2: 0.379403 tb: 2.993	10.9	k1: 0.087 k2: 0.110	k1: 0.08 k2: 0.11	k1: 0.29 k2: 0.65	3.347	7.59

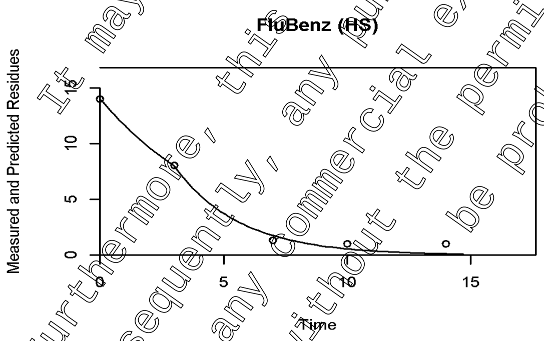
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



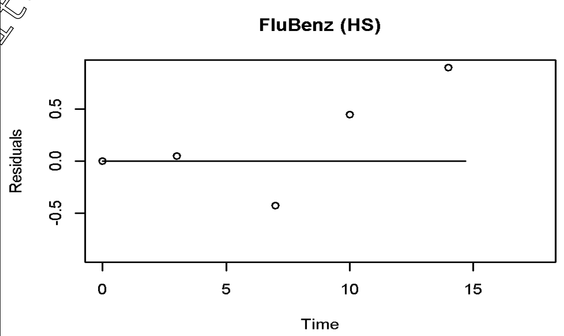
SFO



SFO



HS



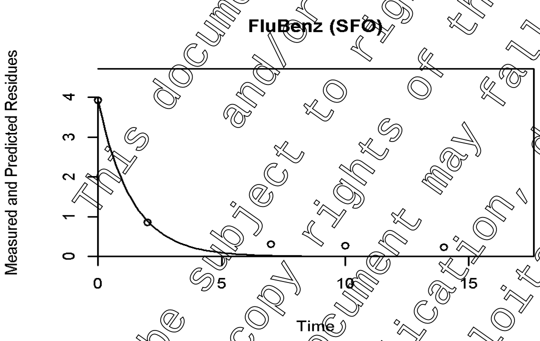
HS

R 2006 0657/5, Malgrat de Mar, M-290827-01-1, ES, beans

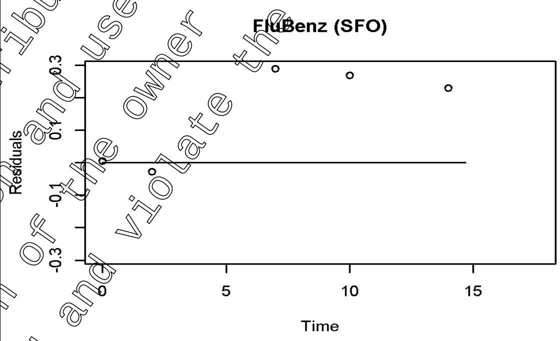
Table 8.9- 128: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2006 0657/5, Malgrat de Mar, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	3.9	k: 0.7429	14.6	k: 0.008	k: 0.45	k: 1.04	0.933	3.100
FOMC	+	3.9	α: 0.79482 β: 0.34362	1.7	-	β: 0.19	β: 0.50	0.478	5.883
DFOP	+	3.9	k1: 0.9923794 k2: 0.0411251 g: 0.896	0.05	k1: <0.001 k2: 0.006	k1: 0.988 k2: 0.0395	k1: 0.997 k2: 0.043	0.814	4.277
HS	+	3.9	k1: 0.759731 k2: 0.042797 tb: 3.429	0.10	k1: <0.001 k2: 0.013	k1: 0.76 k2: 0.04	k1: 0.76 k2: 0.05	0.912	3.031

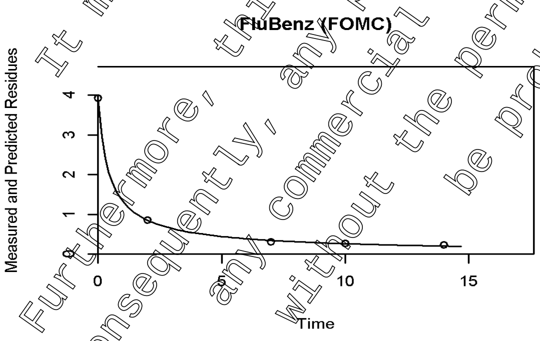
SFO fit is statistically still acceptable (χ^2err <15%, t-test <0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. DFOP fit is statistically (χ^2err, t-test) and visually good, with the lowest $\chi2$ err. Consequently, **DFOP** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT50 is an adequate option.



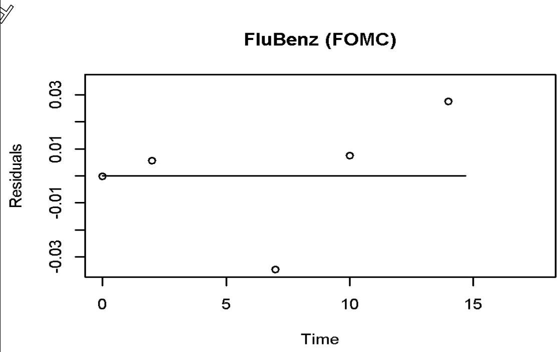
SFO



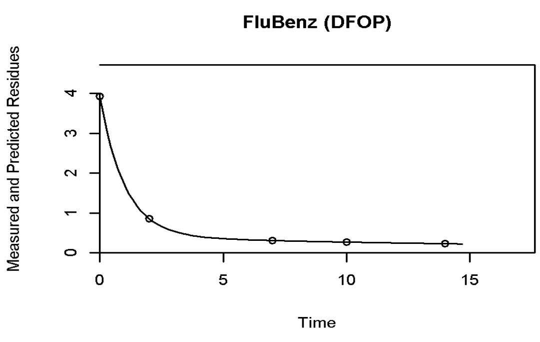
SFO



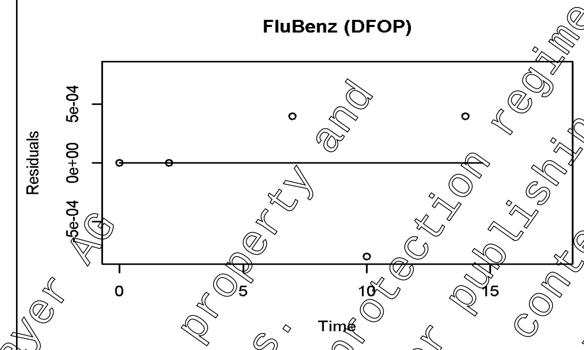
FOMC



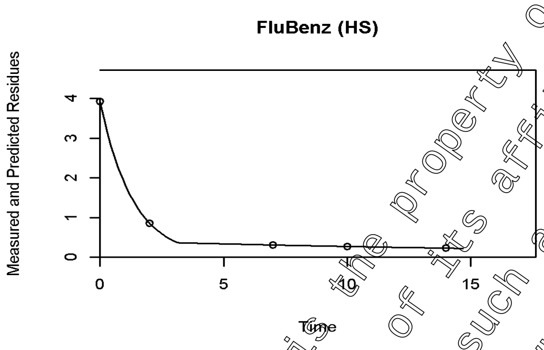
FOMC



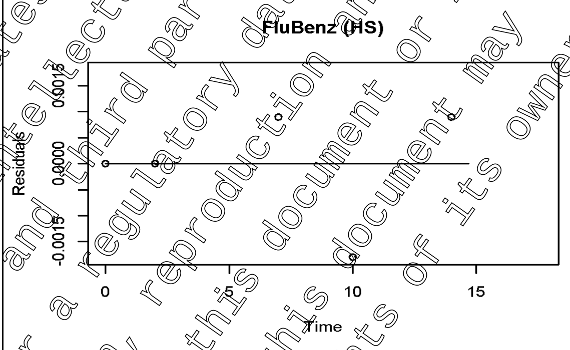
DFOP



DFOP



HS



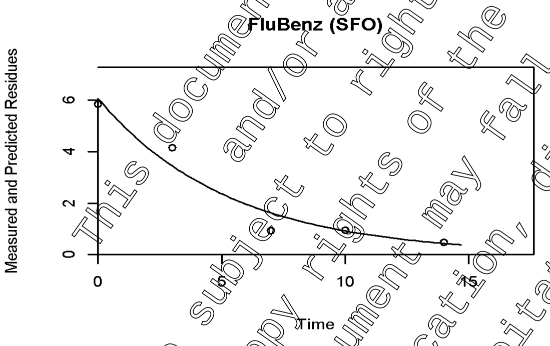
HS

R 2006 0658/3, Ladispoli, M-290827-01-1, IT, beans

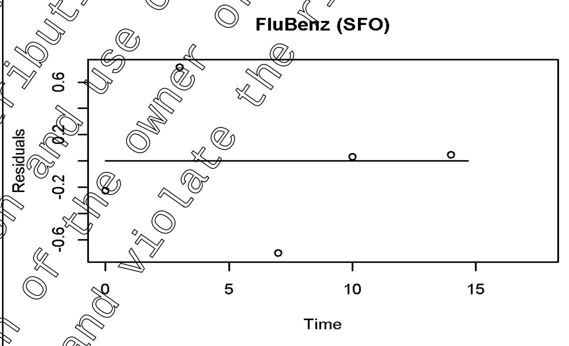
Table 8.9- 129: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2006 0658/3, Ladispoli, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	6.1	k: 0.18859	14.9	k: 0.007	k: 0.12	k: 0.26	**3.676**	12.21
FOMC	+	6.1	α: 18550 β: 98340	17.0	-	β: 96800	β: 99870.53	3.675	12.21
DFOP	+	6.1	k1: 0.1886 k2: 2.2 E-14 g: 1.0	21.2	k1: 0.21 k2: <0.001	k1: -0.10 k2: 2.2 E-14	k1: 0.48 k2: < 0.0005	3.676	12.21
HS	+	5.8	k1: 0.114779 k2: 0.282957 tb: 2.940	13.1	k1: 0.163 k2: 0.105	k1: -0.01 k2: 0.09	k1: 0.24 k2: 0.47	4.197	9.89

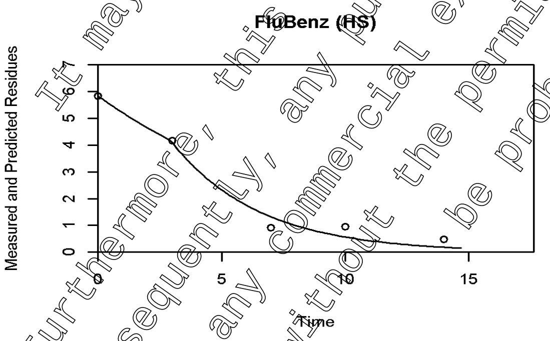
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



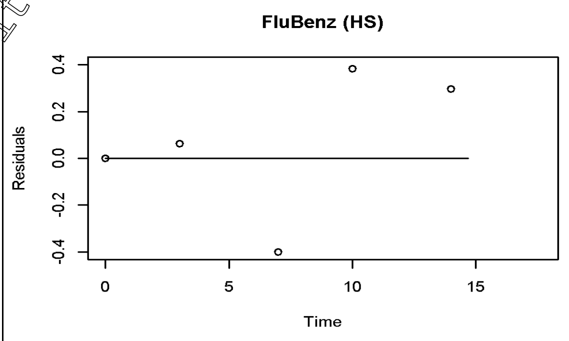
SFO



SFO



HS



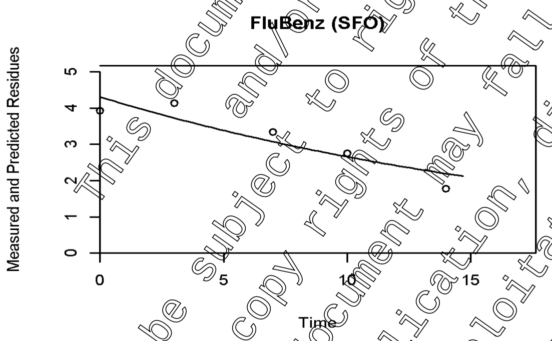
HS

R 2006 0722/9, Needham, M-291180-01-1, GB, pea

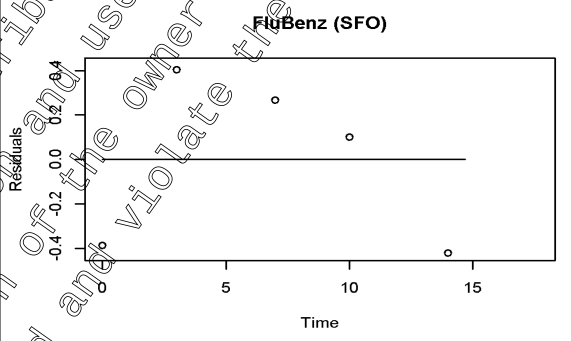
Table 8.9- 130: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for pea of trial R 2006 0722/9, Needham, GB

Kinetic model	Visual assess-ment	M₀	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.3	k: 0.04825	8.5	k: 0.017	k: 0.02	k: 0.07	**14.370**	47.72
FOMC	o	4.3	α: 4110 β: 85180	9.7	-	β: 85050.00	β: 85307.82	14.370	47.73
DFOP	o	4.3	k1: 0.04825 k2: 0.04825 g: 0.660	12.1	k1: 0.163 k2: 0.090	k1: <0.001 k2: 0.02	k1: 0.10 k2: 0.08	14.370	47.72
HS	+	4.0	k1: 2.2 E-14 k2: 0.08669 tb: 5.056	3.6	k1: 0.500 k2: 0.070	k1: -0.05 k2: 0.05	k1: 0.05 k2: 0.13	13.050	31.62

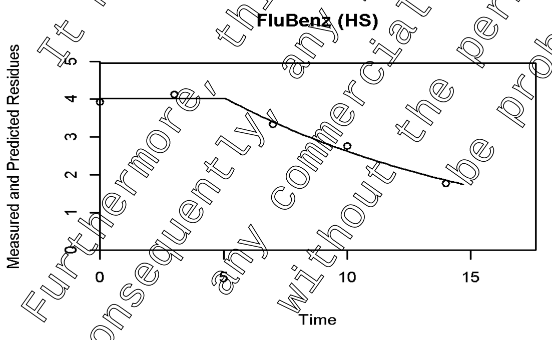
SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).
FOMC and DFOP did not result in an improved fit. The HS resulted in a lag phase, which is considered not appropriate for the intended purpose. As initial and final residues are covered sufficiently well and conservative, the SFO fit is finally considered appropriate and conservative to describe the residue decay.



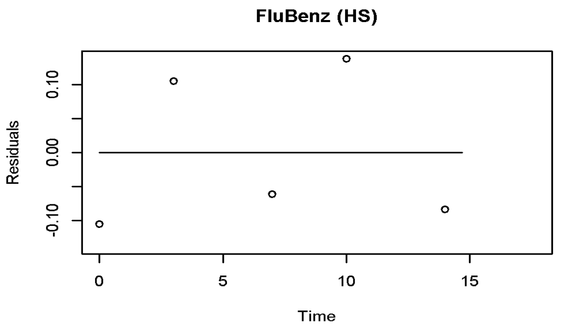
SFO



SFO



HS



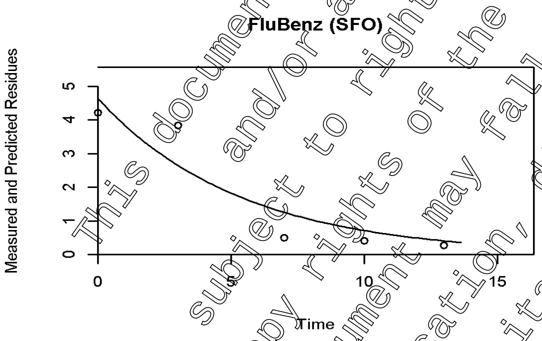
HS

R 2006 0723/7, Meckenbeuren, M-291180-01-1, DE, pea

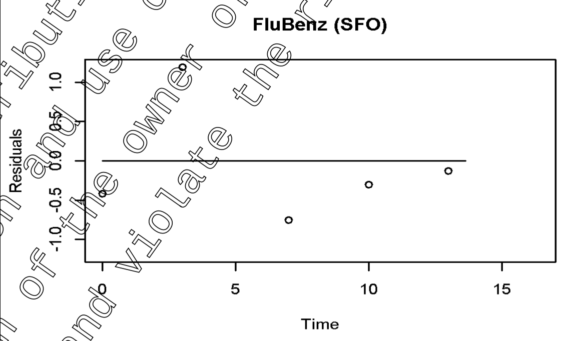
Table 8.9- 131: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for pea of trial R 2006 0723/7, Meckenbeuren, DE

Kinetic model	**Visual assess-ment**	**M_0**	**Kinetic parameters**	**X^2 error (%)**	**Prob > t**	**Lower 95% CI**	**Upper 95% CI**	**DT_{50} actual (d)**	**DT_{90} actual (d)**
SFO	o	4.6	k: 0.18696	29.2	k: 0.034	k: 0.06	k: 0.32	**3.708**	12.32
FOMC	o	4.6	α: 19890 β: 106400	33.3	-	β: 106400	β: 106400	3.707	12.32
DFOP	o	4.6	k1: 0.187 k2: 0.026 g: 1.0	41.6	k1: 0.344 k2: <0.001	k1: -0.50 k2: 0.03	k1: 0.87 k2: 0.03	3.708	12.32
HS	o	4.6	k1: 0.187 k2: 0.232 tb: 15.085	41.6	k1: 0.177 k2: <0.001	k1: -0.04 k2: 0.23	k1: 0.41 k2: 0.23	3.708	12.32

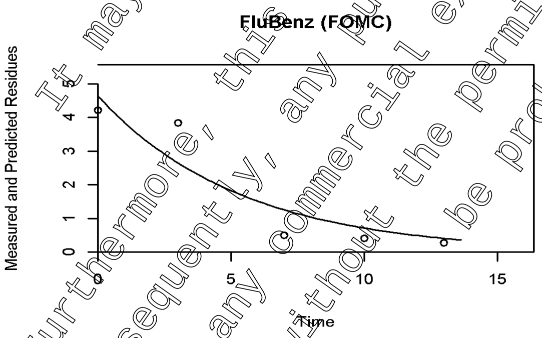
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



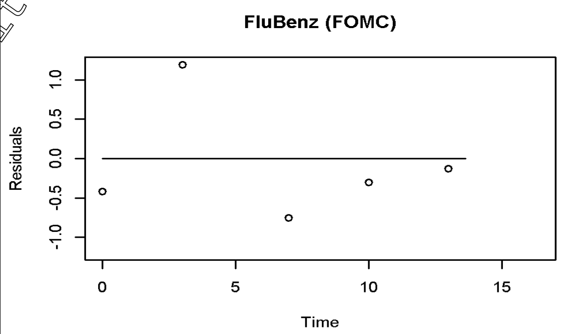
SFO



SFO



FOMC



FOMC

III. CONCLUSION

The following units are used in the following tables:

k	1/d
β, tb	d
α, g	none

Table 8.9- 132: Foliar DT_{50} parameters of fluopyram in green material of lettuce, endive, beans and peas, after application of Luna Privilege (SC 500, SC250), based on time points after last application, for modelling purpose

Fluopyram	Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, endive, beans, peas								
Trial	EU zone	Kinetic model	Kinetic parameters	X^2 err (%)	Prob > t	$DT_{50\ pseudo}$ (d)	$DT_{90\ actual}$ (d)	$DT_{50\ fast}$ (d)	$DT_{50\ slow}$ (d)
08-2034-01, Damery, FR, M-365530-01-1	N	**SFO**	k: 0.17101	32.1	k: 0.046	**4.053**	13.46		
08-2034-02, Damery, FR, M-365530-01-1	N	**SFO**	k: 0.17365	32.4	k: 0.046	**3.992**	13.26		
08-2096-01, Ladispoli, IT, M-365542-01-1	S	**SFO**	k: 0.23348	12.9	k: 0.004	**2.969**	9.86		
08-2096-02 Ladispoli, IT, M-365542-01-1	S	**SFO**	k: 0.19003	24.0	k: 0.022	**3.648**	12.12		
10-2099-01 Wieringerwerf, NL, M-423901-01-1	N	**SFO**	k: 0.30776	14.5	k: 0.005	**2.252**	7.48		
10-2099-02 Langenfeld-Reusrath, DE, M-423901-01-1	N	**FOMC**	α: 0.63521 β: 0.24175	9.4	-	**2.659**	8.829		
10-2099-03, Villers-Perwin, BE, M-423901-01-1	N	**SFO**	k: 0.5646	7.7	k: 0.001	**1.228**	4.078		
10-2099-04 Fondettes, FR, M-423901-01-1	N	**SFO**	k: 0.468101	1.5	k: <0.001	**1.481**	4.919		
18-2086-01-T1 Palidoro Fiumicino, IT, M-675005-01-1	S	**SFO**	k: 0.08404	9.1	k: 0.028	**8.248**	27.40		
18-2086-01-T2 Palidoro Fiumicino, IT, M-675005-01-1	S	**SFO**	k: 0.0894	7.2	k: 0.017	**7.754**	25.76		
18-2086-02-T1 Terlizzi, IT, M-675005-01-1	S	**SFO**	k: 0.20275	6.7	k: 0.007	**3.419**	11.36		

Fluopyram	Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, endive, beans, peas								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**DT_{90} actual (d)**	**DT_{50} fast (d)**	**DT_{50} slow (d)**
18-2086-02-T2 Terlizzi , IT, M-675005-01-1	S	**SFO**	k: 0.17156	11.5	k: 0.022	**4.040**	13.42		
18-2086-03-T1 Alginet, ES, M-675005-01-1	S	**SFO**	k: 0.15831	8.0	k: 0.012	**4.378**	14.54		
18-2086-03-T2 Alginet, ES, M-675005-01-1	S	**SFO**	k: 0.15974	4.8	k: 0.004	**4.339**	14.41		
18-2086-04-T1 Vasilika Thessaloniki, GR, M-675005-01-1	S	**SFO**	k: 0.58426	2.0	k: <0.001	**1.186**	3.941		
18-2086-04-T2 Vasilika Thessaloniki, GR, M-675005-01-1	S	**SFO**	k: 0.59053	2.2	k: <0.001	**1.174**	3.899		
R 2006 0375/4 Cergy, FR, M-292048-01-1	N	**HS**	k1: 0.640819 k2: 0.091899 tb: 2.973	0.5	k1: 0.003 k2: 0.015	**2.198**	7.297	1.082	7.542
R 2006 0376/2 St. Jory, FR, M-292050-01-1	S	**SFO**	k: 0.45594	10.7	k: 0.003	**1.520**	5.050		
R 2006 0377/0 Lampertheim, DE, M-290825-01-1	N	**SFO**	k: 0.148291	40.2	k: 0.081	**4.674**	15.53		
R 2006 0378/9 Alginet, ES, M-290827-01-1	S	**SFO**	k: 0.07813	9.5	k: 0.008	**8.872**	29.47		
R 2006 0380/0 Machern, DE, M-291180-01-1	N	**SFO**	k: 0.040021	13.0	k: 0.067	**17.32**	57.53		
R 2006 0604/4 Meckenbeuren, DE, M-292048-01-1	N	**SFO**	k: 0.492096	1.5	k: <0.001	**1.409**	4.679		
R 2006 0605/2 Langenfeld-Reusrath, DE, M-292048-01-1	N	**HS**	k1: 0.420695 k2: 0.127324 tb: 2.680	5.5	k1: 0.034 k2: 0.075	**3.587**	11.91	1.648	5.444
R 2006 0606/0 Zwaagdijk, NL, M-292048-01-1	N	**SFO**	k: 0.28268	2.1	k: <0.001	**2.452**	8.15		
R 2006 0607/9 Ely, GB, M-292048-01-1	N	**SFO**	k: 0.613732	0.5	k: <0.001	**1.129**	3.752		

Fluopyram	Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, endive, beans, peas								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**DT_{90} actual (d)**	**DT_{50} fast (d)**	**DT_{50} slow (d)**
R 2006 0608/7 Vilanova del Valles, ES, M-292050-01-1	S	**SFO**	k: 0.26972	14.3	k: 0.003	**2.570**	8.54		
R 2006 0609/5 Andria, IT, M-292050-01-1	S	**SFO**	k: 0.82085	10.2	k: 0.023	**0.844**	2.805		
R 2006 0610/9 Catania, IT, M-292050-01-1	S	**SFO**	k: 0.1964	6.0	k: <0.001	**3.529**	11.72		
R 2006 0611/7 Katerini / Paralia, GR, M-292050-01-1	S	**SFO**	k: 0.22953	10.7	k: 0.002	**3.020**	10.03		
R 2006 0620/6; Pradelle di Nogarole Rocca, IT, M-290827-01-1	S	**SFO**	k: 0.9556	9.3	k: 0.009	**0.7254**	2.41		
R 2006 0654/0 Langenfeld-Reusrath, DE, M-290825-01-1	N	**SFO**	k: 0.9644	6.1	k: 0.003	**0.719**	2.39		
R 2006 0655/9 Zwaagdijk, NL, M-290825-01-1	N	**SFO**	k: 0.25399	4.4	k: <0.001	**2.729**	9.066		
R 2006 0656/7 Villers-Perwin, BE, M-290825-01-1	N	**SFO**	k: 0.24406	13.0	k: 0.004	**2.840**	9.435		
R 2006 0657/5 Malgrat de Mar, ES, M-290827-01-1	S	**HS**	k1: 0.78585 k2: 0.09311 tb: 3.023	0.04	k1: <0.001 k2: 0.004	**0.883**	2.93	0.882	7.444
R 2006 0658/3 Ladispoli, IT, M-290827-01-1	S	**SFO**	k: 0.19539	15.6	k: 0.007	**3.548**	11.78		
R 2006 0722/9 Needham, GB, M-291180-01-1	N	**SFO**	k: 0.04995	8.7	k: 0.017	**13.88**	46.10		
R 2006 0723/7 Meckenbeuren, DE, M-291180-01-1	N	**SFO**	k: 0.19063	29.9	k: 0.035	**3.636**	12.08		
Geomean (n=37) M						**2.765** M			

DT_{50} pseudo = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT_{90} actual time for first 90 % of residues to dissipate
DT_{50} fast = ln(2)/k1
DT_{50} slow = ln(2)/k2 (DFOP, HS)

Fluopyram	Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, endive, beans, peas								
Trial	EU zone	Kinetic model	Kinetic parameters	X^2 err (%)	Prob > t	$DT_{50\ pseudo}$ (d)	$DT_{90\ actual}$ (d)	$DT_{50\ fast}$ (d)	$DT_{50\ slow}$ (d)

M geomean of DT_{50} pseudo of fits for modelling purpose

Table 8.9- 133: Foliar DT_{50} parameters of fluopyram + FLU-benzamide in green material of lettuce, endive, beans and peas, after application of Luna Privilege (SC 500, SC 250), based on time points after last application, for modelling purpose

Fluopyram + FLU-benzamide	Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, endive, beans, peas, Luna Privilege								
Trial	EU zone	Kinetic model	Kinetic parameters	X^2 err (%)	Prob > t	$DT_{50\ pseudo}$ (d)	$DT_{90\ actual}$ (d)	$DT_{50\ fast}$ (d)	$DT_{50\ slow}$ (d)
08-2034-01, Damery, FR, M-365530-01-1	N	**SFO**	k: 0.1683	31.5	k: 0.045	**4.120**	13.68		
08-2034-02, Damery, FR, M-365530-01-1	N	**SFO**	k: 0.17083	31.7	k: 0.045	**4.058**	13.48		
08-2096-01, Ladispoli, IT, M-365542-01-1	S	**SFO**	k: 0.22709	12.3	k: 0.003	**3.052**	10.14		
08-2096-02 Ladispoli, IT, M-365542-01-1	S	**SFO**	k: 0.18493	23.2	k: 0.021	**3.748**	12.45		
10-2099-01 Wieringerwerf, NL, M-423901-01-1	N	**SFO**	k: 0.30774	14.5	k: 0.005	**2.252**	7.48		
10-2099-02, Langenfeld-Reusrath, DE, M-423901-01-1	N	**FOMC**	α: 0.63156 β: 0.23934	9.5	-	**2.690**	8.932		
10-2099-03 Villers-Perwin, BE, M-423901-01-1	N	**SFO**	k: 0.56261	7.7	k: 0.001	**1.232**	4.09		
18-2086-01-T1 Palidoro Fiumicino, IT, M-675005-01-1	S	**SFO**	k: 0.0778	9.1	k: 0.030	**8.910**	29.60		
18-2086-01-T2 Palidoro Fiumicino, IT, M-675005-01-1	S	**SFO**	k: 0.07835	7.9	k: 0.024	**8.847**	29.39		
18-2086-02-T1 Terlizzi , IT, M-675005-01-1	S	**SFO**	k: 0.20175	6.7	k: 0.007	**3.436**	11.41		
18-2086-02-T2 Terlizzi , IT, M-675005-01-1	S	**SFO**	k: 0.17091	11.4	k: 0.021	**4.056**	13.47		

Fluopyram + FLU-benzamide	**Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, endive, beans, peas, Luna Privilege**								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**$DT_{90\ actual}$ (d)**	**$DT_{50\ fast}$ (d)**	**$DT_{50\ slow}$ (d)**
18-2086-03-T1 Alginet, ES, M-675005-01-1	S	**SFO**	k: 0.15747	8.0	k: 0.012	**4.402**	14.62		
18-2086-03-T2 Alginet, ES, M-675005-01-1	S	**SFO**	k: 0.1585	4.8	k: 0.004	**4.373**	14.53		
18-2086-04-T1 Vasilika, Thessaloniki, GR, M-675005-01-1	S	**SFO**	k: 0.58201	2.0	k: <0.001	**1.191**	3.96		
18-0286-04-T2 Vasilika, Thessaloniki, GR, M-675005-01-1	S	**SFO**	k: 0.58795	2.2	k: <0.001	**1.179**	3.92		
R 2006 0375/4 Cergy, FR, M-292048-01-1	N	**HS**	k1: 0.62833 k2: 0.08866 tb: 3.0	0.7	k1: 0.016 k2: 0.043	**2.322**	7.71	1.103	7.818
R 2006 0376/2 St. Jory, FR, M-292050-01-1	S	**SFO**	k: 0.44464	1.5	k: 0.003	**1.559**	5.18		
R 2006 0377/0 Lampertheim, DE, M-290825-01-1	N	**SFO**	k: 0.143986	38.8	k: 0.079	**4.814**	15.99		
R 2006 0378/9 Alginet, ES, M-290827-01-1	S	**SFO**	k: 0.07181	9.3	k: 0.009	**9.653**	32.07		
R 2006 0380/0 Machern, DE, M-291180-01-1	N	**SFO**	k: 0.0386099	12.9	k: 0.071	**17.95**	59.64		
R 2006 0604/4 Meckenbeuren, DE, M-292048-01-1	N	**SFO**	k: 0.490644	1.5	k: <0.001	**1.413**	4.69		
R 2006 0605/2 Langenfeld-Reusrath, DE, M-292048-01-1	N	**HS**	k1: 0.387 k2: 0.123 tb: 2.999	5.7	k1: 0.033 k2: 0.079	**3.705**	12.30	1.790	5.649
R 2006 0606/0 Zwaagdijk, NL, M-292048-01-1	N	**SFO**	k: 0.280685	2.1	k: <0.001	**2.469**	8.20		
R 2006 0607/9 Ely, GB, M-292048-01-1	N	**SFO**	k: 0.612832	0.5	k: <0.001	**1.131**	3.757		
R 2006 0608/7 Vilanova del Valles, ES, M-292050-01-1	S	**SFO**	k: 0.26739	14.3	k: 0.003	**2.592**	8.61		

Fluopyram + FLU-benzamide	Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, endive, beans, peas, Luna Privilege								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**$DT_{90\ actual}$ (d)**	**$DT_{50\ fast}$ (d)**	**$DT_{50\ slow}$ (d)**
R 2006 0610/9 Catania, IT, M-292050-01-1	S	**SFO**	k: 0.19466	6.1	k: <0.001	**3.561**	11.83		
R 2006 0611/7 Katerini / Paralia, GR, M-292050-01-1	S	**SFO**	k: 0.22799	10.7	k: 0.002	**3.040**	10.10		
R 2006 0620/6, Pradelle di Nogarole Rocca, IT, M-290827-01-1	S	**SFO**	k: 0.93180	10.2	k: 0.011	**0.7439**	2.471		
R 2006 0654/0 Langenfeld-Reusrath, DE, M-290825-01-1	N	**SFO**	k: 0.9408	6.9	k: 0.003	**0.7368**	2.447		
R 2006 0655/9 Zwaagdijk, NL, M-290825-01-1	N	**SFO**	k: 0.2426	5.4	k: <0.001	**2.857**	9.49		
R 2006 0656/7 Villers-Perwin, BE, M-290825-01-1	N	**SFO**	k: 0.2425	13.0	k: 0.004	**2.858**	9.49		
R 2006 0657/5 Malgrat de Mar, ES, M-290827-01-1	S	**DFOP**	k1: 0.9923794 k2: 0.0411251 g: 0.896	0.05	k1: <0.001 k2: 0.006	**1.288**	4.277	0.698	16.855
R 2006 0658/3 Ladispoli, IT, M-290827-01-1	S	**SFO**	k: 0.18859	14.9	k: 0.007	**3.676**	12.21		
R 2006 0722/9 Needham, GB, M-291180-01-1	N	**SFO**	k: 0.04825	8.5	k: 0.017	**14.37**	47.72		
R 2006 0723/7 Meckenbeuren, DE, M-291180-01-1	N	**SFO**	k: 0.18696	29.2	k: 0.034	**3.708**	12.32		
Geomean, trials with FLU-benz > LOQ (n=35) M						3.015 M			
Geomean, incl. all trials (n=37) A						**2.857** A			

DT_{50} pseudo = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT_{90} actual time for first 90 % of residues to dissipate
DT_{50} fast = ln(2)/k1
DT_{50} slow = ln(2)/k2 (DFOP, HS)
M geomean DT_{50} pseudo of fits for modelling purpose, for trials with FLU-benzamide > LOQ.
A geomean DT_{50} pseudo of fits for modelling purpose: for trials with FLU-benzamide > LOQ and remaining trials of FLU only from table above, where FLU-benzamide was < LOQ.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment.

The geometric mean of the DT_{50} values for fluopyram was 2.765 days (n=37).

The geometric mean DT_{50} of the combined residue was 2.875 days (~3% longer than for fluopyram alone. Thus, the contribution of the metabolite fluopyram-benzamide is negligible for risk assessment.

Data Point:	KCA 8.9/13
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolite - Kinetic evaluation of green plant residues in lettuce, beans and peas, applying Luna Privilege (SC500) part 2
Report No:	EnSa-20-0830
Document No:	M-763337-01-1
Guideline(s) followed in study:	not applicable
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

EXECUTIVE SUMMARY

Kinetic evaluations were conducted for the residue decline of fluopyram from foliage after application on various vegetables. All trials were evaluated with SFO and FOMC kinetics. Where the number of sampling points allowed the evaluation, 2 biphasic kinetic models were fitted additionally (DFOP and HS), with a preference for selecting SFO where the fit was considered visually and statistically acceptable. Otherwise, the best-fit of the other models was selected. To facilitate the use of the selected kinetic parameter, a surrogate SFO DT_{50} was estimated as $DT_{90}/3.32$ for the non SFO kinetics.
The geometric mean of the DT_{50} for fluopyram was 2.845 days (n=26).

Additionally, an evaluation was made of the decline kinetics of the combined residues of fluopyram and its metabolite fluopyram-benzamide (in all 26 trials the metabolite was included as analyte).
The geometric mean DT_{50} of the combined residue was 2.926 days (~3% longer than for fluopyram alone. Thus, the contribution of the metabolite fluopyram-benzamide is negligible for risk assessment.

The outcome of the evaluations is presented below.

Table 8.9- 134: Comparison of foliar DT50s of fluopyram and fluopyram + FLU-benzamide in green material of lettuce, beans, peas

Fluopyram and FLU + FLU-benzamide	**Foliar residue dissipation, in lettuce, beans, peas**			
Trial	**EU zone**	**Kinetic model**	**DT_{50} FLU (d)**	**DT_{50} FLU + benzamide (d)**
R 2007 0011/3, Barway, GB, M-304280-01-1	N	SFO	1.048	*1.048*
R 2007 0012/1, Olho Marinho, PT, M-304278-01-1	S	SFO	1.813	1.827
R 2007 0014/8, Villers-Perwin, BE, M-297562-01-1	N	SFO	2.733	2.754
R 2007 0035/0, Chazay d'Azergues, FR, M-297564-01-1	S	SFO	3.176	3.252

Fluopyram and FLU + FLU-benzamide	**Foliar residue dissipation, in lettuce, beans, peas**			
Trial	**EU zone**	**Kinetic model**	**DT_{50} FLU (d)**	**DT_{50} FLU + benzamide (d)**
R 2007 0036/9, Kopstukken, NL, M-298639-01-1	N	SFO	5.287	5.387
R 2007 0037/7, Chazay d'Azergues, FR, M-297487-01-1	S	SFO	3.329	3.497
R 2007 0244/2, Meckenbeuren, DE, M-304280-01-1	N	SFO	3.09	3.092
R 2007 0245/0, Agia Marina, GR, M-304278-01-1	S	SFO	1.204	1.215
R 2007 0246/9, Ouzilly, FR, M-304278-01-1	S	SFO	0.8952	0.91
R 2007 0537/9, Langenfeld Reusrath, DE, M-304280-01-1	N	FOMC / DFOP	1.949	1.971
R 2007 0538/7, Puzeaux, FR, M-304280-01-1	N	SFO	0.7255	0.7327
R 2007 0539/5, Villers-Perwin, BE, M-304280-01-1	N	SFO	2.129	2.142
R 2007 0540/9, Zwaagdijk, NL, M-304280-01-1	N	SFO	1.368	1.382
R 2007 0541/7, Manfredonia, IT, M-304278-01-1	S	SFO	5.797	5.837
R 2007 0546/8, Langenfeld-Reusrath, DE, M-297562-01-1	N	SFO	2.969	3.112
R 2007 0547/6, Fresnoy les Roye, FR, M-297562-01-1	N	SFO	2.744	2.794
R 2007 0548/4, Biddinghuizen, NL, M-297562-01-1	N	HS	3.639	3.898
R 2007 0549/2, Swisttal-Heimerzheim, DE, M-297562-01-1	N	SFO	3.172	3.221
R 2007 0550/6, Ladispoli, IT, M-297564-01-1	S	SFO	0.7695	0.7846
R 2007 0551/4, Alginet, ES, M-297564-01-1	S	SFO	8.169	8.617
R 2007 0552/2, Ribafria Peniche, PT, M-297564-01-1	S	DFOP	11.166	12.554
R 2007 0553/0, Burscheid, DE, M-298639-01-1	N	HS	3.401	3.494
R 2007 0554/9, Goyencourt, FR, M-298639-01-1	N	FOMC	9.837	10.702
R 2007 0555/7, Landenne-Sur-Meuse, BE, M-298639-01-1	N	SFO	5.468	5.685
R 2007 0556/5, Swisttal-Heimerzheim, DE, M-298639-01-1	N	SFO	7.032	7.18
R 2007 0557/3, Brenes, Sevilla, ES, M-297487-01-1	S	SFO	3.275	3.419
Geomean (n=26)			**2.845**	**2.926**

DT_{50} pseudo = DT90 actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed

I. MATERIALS AND METHODS

A kinetic modelling analysis of European total crop residue decline study data of fluopyram (FLU) and fluopyram + fluopyram-benzamide (FLU-benzamide, M25) was conducted in order to derive kinetic parameters suitable for an ecotoxicological risk assessment, e.g. on birds and mammals, using the software tool KinGUI 2.1. The identification of the appropriate kinetic model followed the recommendations given by FOCUS Kinetics for modelling purpose (FOCUS kinetics, 2006, 2014) and EFSA (2019), based on a detailed statistical analysis including visual assessment, χ^2 statistic, significance t-test and correlation analysis.

In an ecotoxicological context, plant foliage residue trials are used to describe the dissipation or decline behaviour of fluopyram in potential food for birds and mammals. Dissipation curves can be used to estimate the exposure of herbivorous birds or mammals, mainly by calculating the area under the dissipation curve.

To allow for calculation of time weighted averaged residues or area under the curve, after single or multiple applications, it is most appropriate to use a full kinetic parameter set of SFO or biphasic models.

The modelling analysis is based on European crop residue data on green plant material of lettuce, beans and peas (dicotyledons), after spray application of Luna Privilege (SC 500). All available residue data points per trial starting with the last application have been included in the evaluation. The plant metabolite fluopyram-benzamide has been analysed in the trials, but not always detected > LOQ. Foliar DT_{50} values are carried out for fluopyram, and in cases, where FLU-benzamide was detected > LOQ, also for the sum of fluopyram and FLU-benzamide.

Trials took place in both regulatory residue zones (N- and S-EU) with a timely variance from May - December. The BBCH growth stages at application have been 42 - 49 (lettuce), 69 - 78 (beans) and 74 - 79 (peas).

Daily temperature and precipitation data (rain + irrigation over leaf surfaces, e.g. by sprinkler) were collected, (e.g. based on raw data or publicly available weather station data).

In general, all 4 model fits have been carried out, but only those graphs are presented in the summary which are needed for model decision.

II. RESULTS AND DISCUSSION

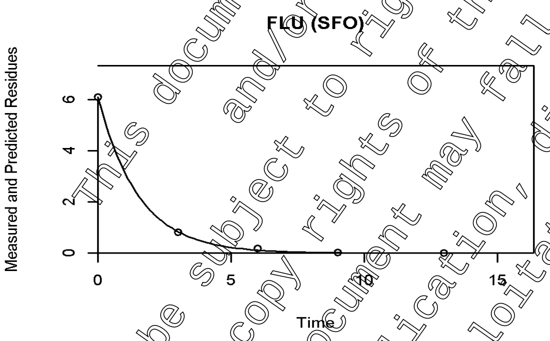
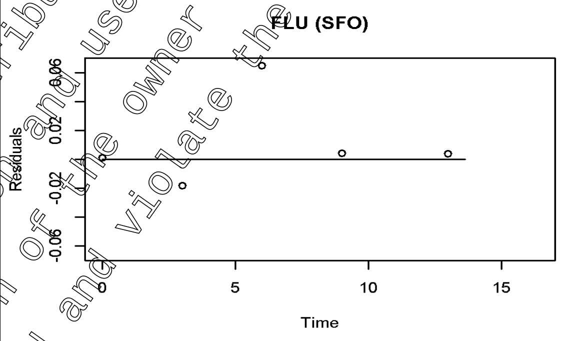
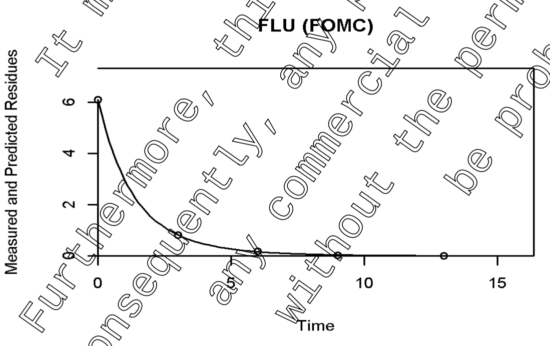
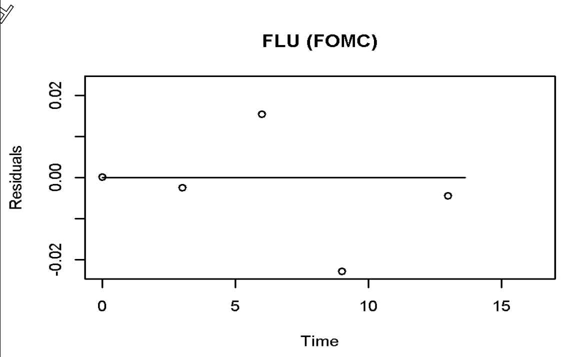
The following units are used in the following tables:

k	1/d
β, tb	d
α, g	none

Fluopyram

R 2007 0011/3, Barway, M-304280-01-1, GB, lettuce

Table 8.9- 135: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial R 2007 0011/3, Barway, GB

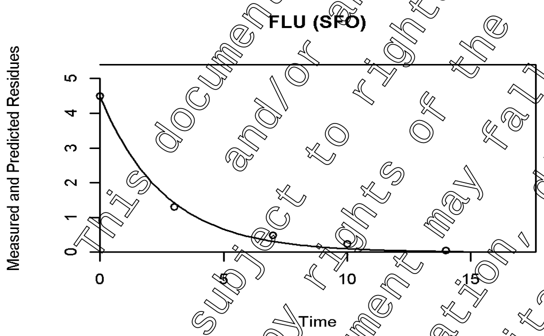
Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	$DT_{50\ actual}$ (d)	$DT_{90\ actual}$ (d)
SFO	+	6.1	k: 0.66158	1.7	k: <0.001	k: 0.63	k: 0.69	**1.048**	3.48
FOMC	+	6.1	α: 8.20101 β: 10.83956	0.8	-	β: 2.83	β: 18.85	0.956	3.514
DFOP	+	6.1	k1: 2608 k2: 0.5188 g: 0.362	0.6	k1: <0.001 k2: 0.020	k1: 2608.0 k2: 0.46	k1: 2607.61 k2: 0.58	0.470	3.572
HS	+	6.1	k1: 0.669989 k2: 0.5188165 tb: 2.973	0.6	k1: 0.004 k2: 0.020	k1: 0.66 k2: 0.46	k1: 0.69 k2: 0.58	1.035	3.572
SFO fit is statistically and visually very good (χ^2 err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).									
 SFO					 SFO				
 FOMC					 FOMC				

R 2007 0012/1, Olho Marinho, M-304278-01-1, PT, lettuce

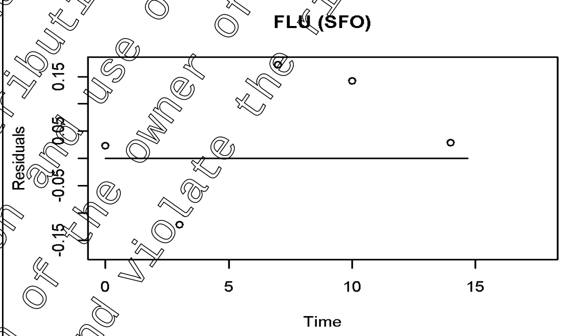
Table 8.9- 136: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2007 0012/1, Olho Marinho, PT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.5	k: 0.38236	7.0	k: <0.001	k: 0.32	k: 0.45	**1.813**	6.02
FOMC	+	4.5	α: 2.9938 β: 5.90395	2.6	-	β: 1.70	β: 10.11	1.538	6.84
DFOP	+	4.5	k1: 12.870 k2: 0.251 g: 0.386	1.4	k1: 0.001 k2: 0.019	k1: 12.87 k2: 0.22	k1: 12.87 k2: 0.28	0.819	7.23
HS	+	4.5	k1: 0.414 k2: 0.251 tb: 2.998	1.4	k1: 0.007 k2: 0.019	k1: 0.39 k2: 0.22	k1: 0.43 k2: 0.28	1.676	7.23

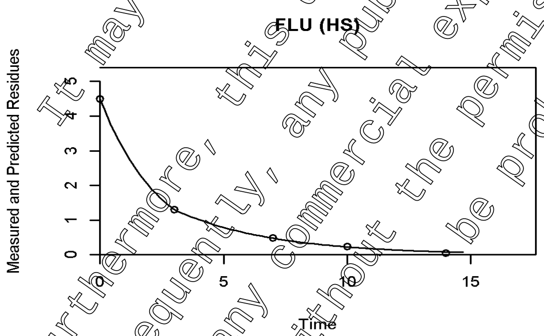
SFO fit is statistically good and overall visually acceptable (χ^2err <15%, t-test<0.05). Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



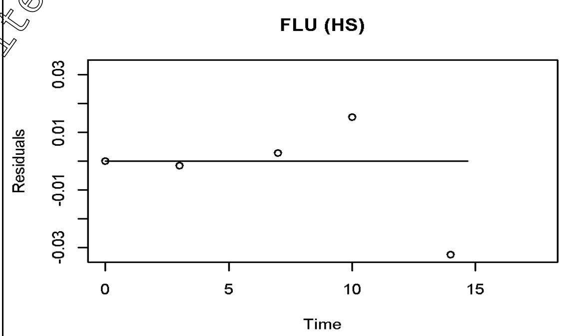
SFO



SFO



HS



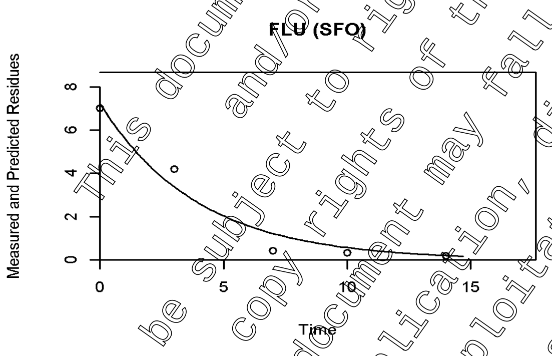
HS

R 2007 0014/8, Villers-Perwin, M-297562-01-1, BE, beans

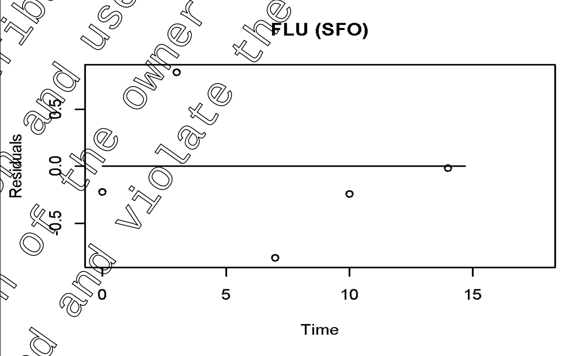
Table 8.9- 137: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2007 0014/8, Villers-Perwin, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.2	k: 0.25363	17.7	k: 0.008	k: 0.15	k: 0.35	**2.733**	9.08
FOMC	o	7.2	α: 27520 β: 108500	20.2	-	β: 108500	β: 108500	2.733	9.08
DFOP	o	7.2	k1: 0.254 k2: 2.2 E-14 g: 1.00	25.2	k1: 0.180 k2: <0.001	k1: -0.06 k2: 0.00	k1: 0.57 k2: 0.00	2.733	9.08
HS	o	7.2	k1: 0.254 k2: 2.2 E-14 tb: 14.88	25.2	k1: 0.107 k2: <0.001	k1: 0.08 k2: 0.00	k1: 0.43 k2: 0.00	2.733	9.08

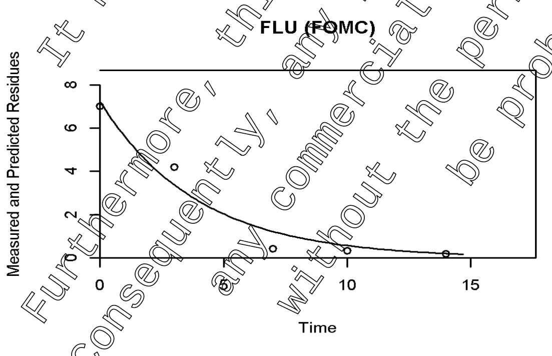
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is slightly > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



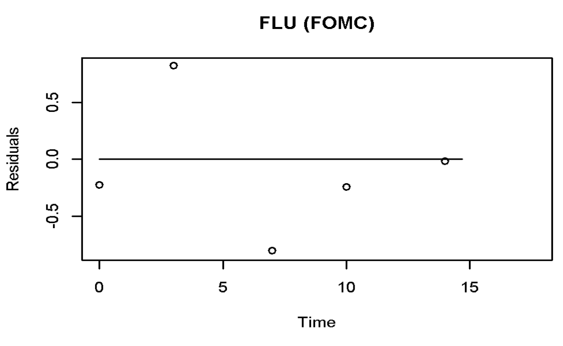
SFO



SFO



FOMC



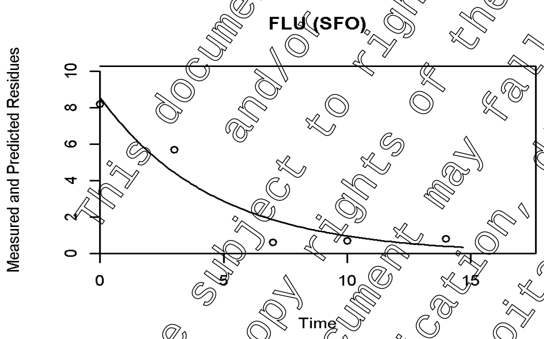
FOMC

R 2007 0035/0, Chazay d'Azergues, M-297564-01-1, FR, beans

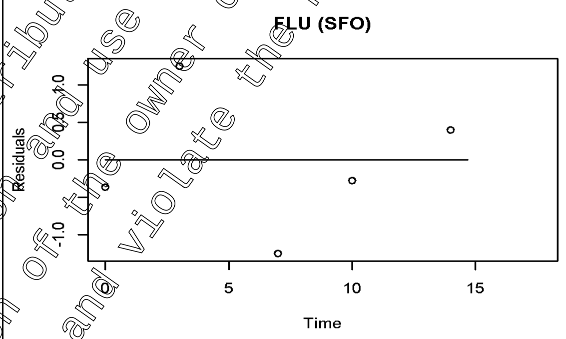
Table 8.9- 138: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2007 0035/0, Chazay d'Azergues,FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	8.6	k: 0.21824	20.9	k: 0.015	k: 0.11	k: 0.33	**3.176**	10.55
FOMC	o	8.6	α: 16690.299 β: 76475.787	23.9	-	β: 74360.53	β: 78591.04	3.176	10.55
DFOP	o	8.6	k1: 0.218 k2: 2.2 E-14 g: 1.00	29.8	k1: 0.234 k2: <0.001	k1: -0.17 k2: 2.2 E-14	k1: 0.61 k2: <0.0005	3.176	10.55
HS	-	8.3	k1: 0.1546 k2: 0.2997 tb: 3.00	19.8	k1: 0.446 k2: 0.346	k1: -1.61 k2: -0.81	k1: 1.92 k2: 1.41	3.765	9.14

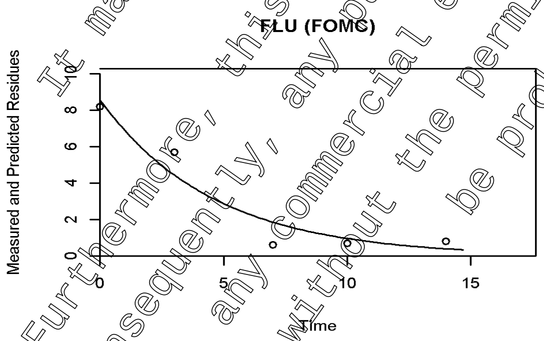
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved statistical or visual fit, mainly due to the partly scattering data. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



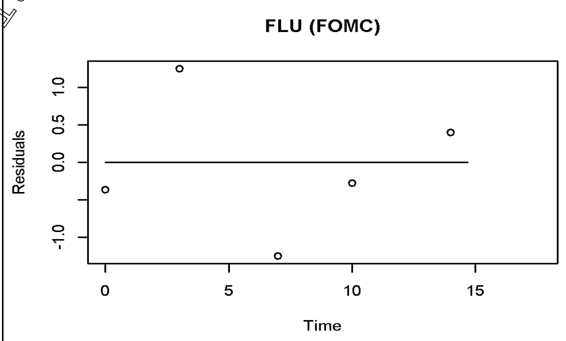
SFO



SFO



FOMC



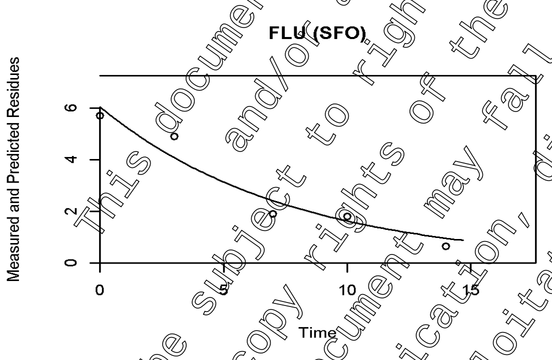
FOMC

R 2007 0036/9, Kopstukken, M-298639-01-1, NL, pea

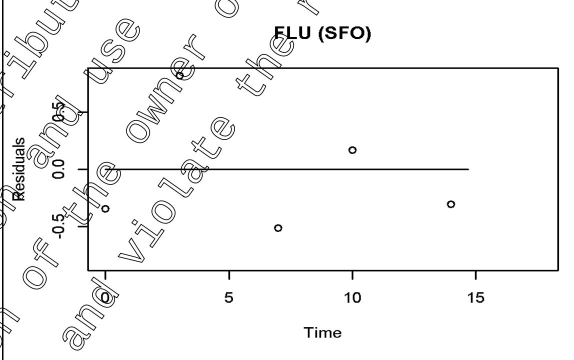
Table 8.9- 139: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial R 2007 0036/9, Kopstukken, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	6.0	k: 0.13109	13.0	k: 0.007	k: 0.08	k: 0.18	**5.287**	17.56
FOMC	o	6.0	α: 8973 β: 68440	14.8	-	β: 67910.06	β: 68980.32	5.287	17.57
DFOP	o	6.0	k1: 0.13109 k2: 0.038 g: 1.0	18.5	k1: 0.328 k2: <0.001	k1: -0.30 k2: 0.036	k1: 0.56 k2: 0.036	5.287	17.56
HS	o	6.0	k1: 0.13109 k2: 0.10719 tb: 20.729	18.5	k1: 0.103 k2: <0.001	k1: 0.05 k2: 0.107	k1: 0.22 k2: 0.107	5.287	17.56

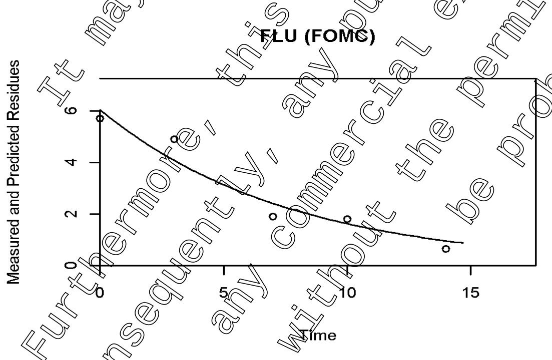
SFO fit is statistically and visually acceptable (χ^2err <15 %, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



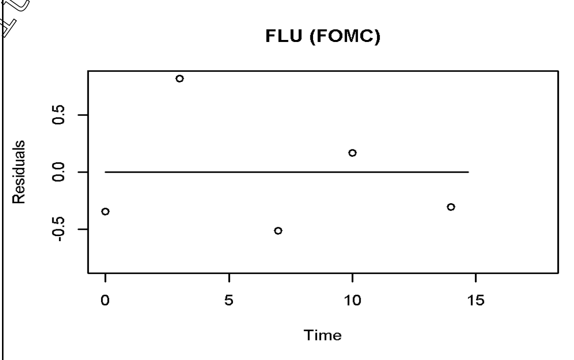
SFO



SFO



FOMC



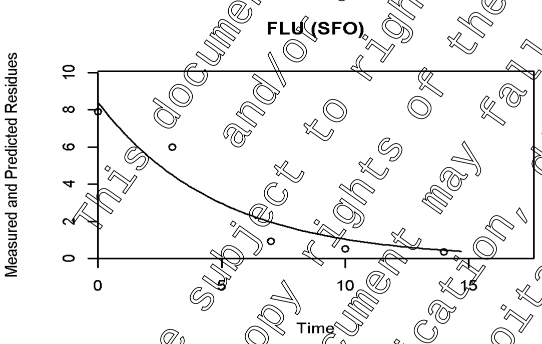
FOMC

R 2007 0037/7, Chazay d'Azergues, M-297487-01-1, FR, pea

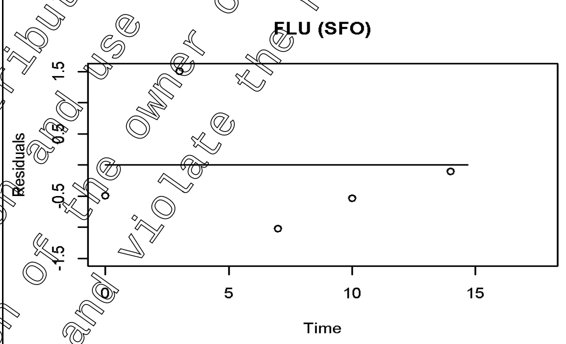
Table 8.9- 140: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial R 2007 0037/7, Chazay d'Azergues, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	8.4	k: 0.20822	22.4	k: 0.017	k: 0.10	k: 0.32	**3.329**	11.06
FOMC	o	8.4	α: 1084000 β: 5200000	25.6	-	β: 5200000	β: 5200000	3.326	11.05
DFOP	o	8.4	k1: 0.2082 k2: 2.2 E-14 g: 1.0	31.9	k1: 0.250 k2: <0.001	k1: -0.20 k2: 2.2 E-14	k1: 0.62 k2: <0.0005	3.329	11.06
HS	o	8.4	k1: 0.2082 k2: 2.2 E-14 tb: 15.42	31.9	k1: 0.139 k2: <0.001	k1: 0.02 k2: 0.00	k1: 0.40 k2: <0.0005	3.329	11.06

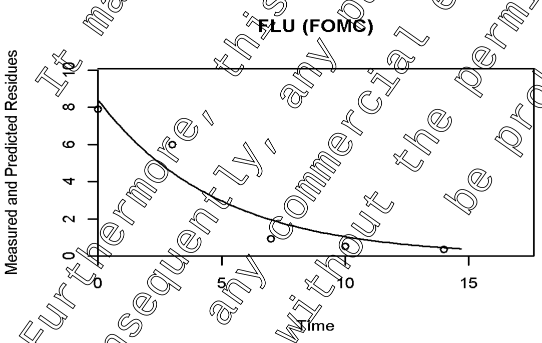
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved statistical or visual fit, mainly due to the partly scattering data. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



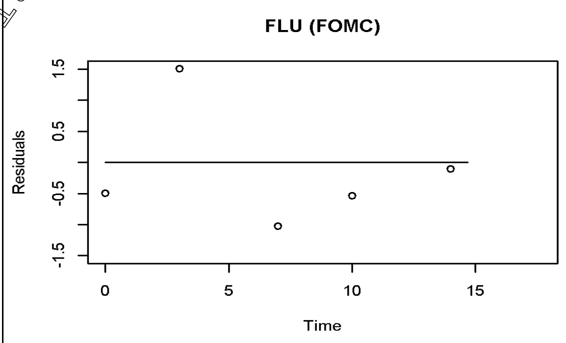
SFO



SFO



FOMC



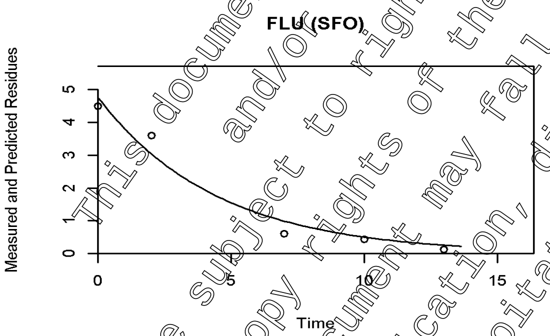
FOMC

R 2007 0244/2, Meckenbeuren, M-304280-01-1, DE, lettuce

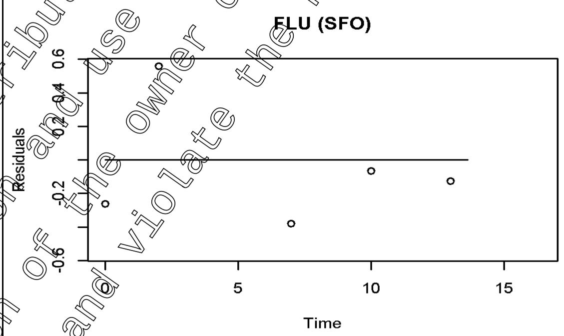
Table 8.9- 141: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2007 0244/2, Meckenbeuren, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.8	k: 0.22435	14.3	k: 0.007	k: 0.14	k: 0.31	**3.090**	10.26
FOMC	o	4.8	α: 5896 β: 26280	16.3	-	β: 25690	β: 26862.26	3.089	10.26
DFOP	o	4.8	k1: 0.2243 k2: 2.2 E-14 g: 1.0	20.3	k1: 0.202 k2: <0.001	k1: 0.10 k2: 2.2 E-14	k1: 0.35 k2: <0.0005	3.090	10.26
HS	o	4.8	k1: 0.2243 k2: 2.2 E-14 tb: 17.09	20.3	k1: 0.103 k2: <0.001	k1: 0.08 k2: 2.2 E-14	k1: 0.37 k2: <0.0005	3.090	10.26

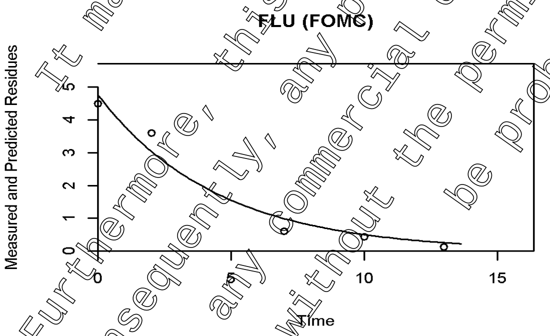
SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



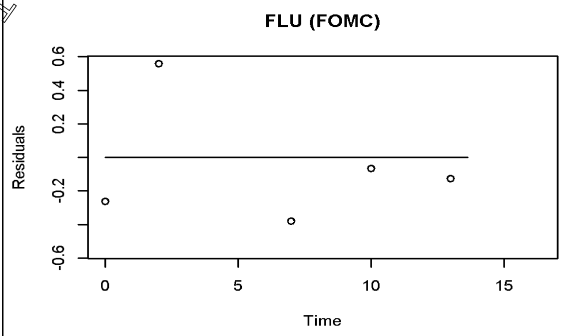
SFO



SFO



FOMC



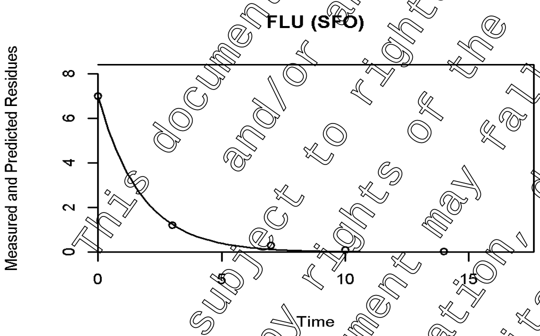
FOMC

R 2007 0245/0, Agia Marina, M-304278-01-1, GR, lettuce

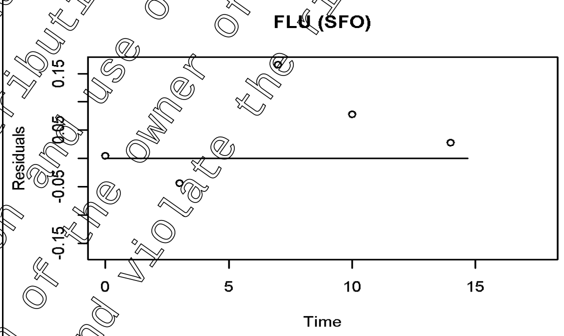
Table 8.9- 142: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial R 2007 0245/0, Agia Marina, GR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	7.0	k: 0.57578	3.9	k: <0.001	k: 0.52	k: 0.63	**1.204**	3.999
FOMC	+	7.0	α: 3.6609 β: 4.85781	0.8	-	β: 3.25	β: 6.47	1.013	4.254
DFOP	+	7.0	k1: 13.790 k2: 0.3542 g: 0.504	0.2	k1: <0.001 k2: 0.004	k1: 13.79 k2: 0.35	k1: 13.79 k2: 0.36	0.191	4.521
HS	+	7.0	k1: 0.587863 k2: 0.346017 tb: 3.457	0.1	k1: <0.001 k2: 0.014	k1: 0.59 k2: 0.32	k1: 0.59 k2: 0.38	1.179	4.448

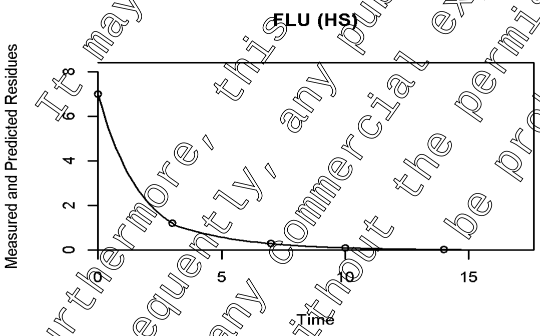
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



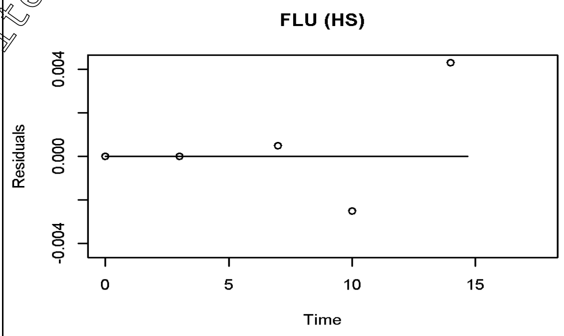
SFO



SFO



HS



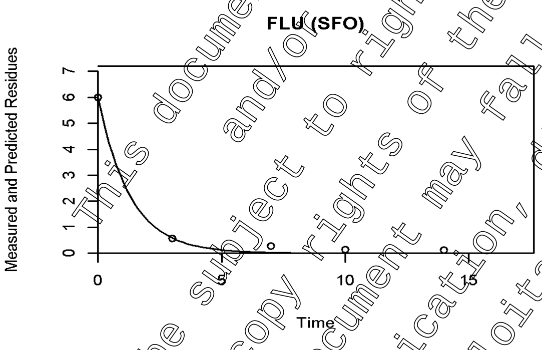
HS

R 2007 0246/9, Ouzilly, M-304278-01-1, FR, lettuce

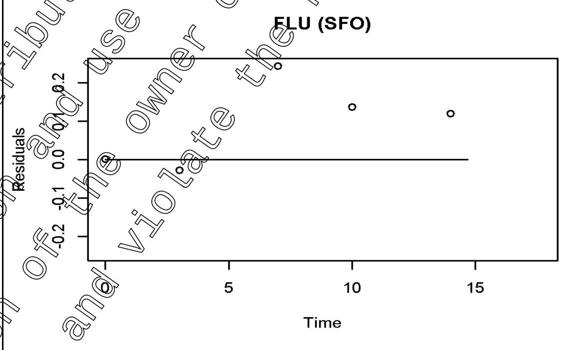
Table 8.9- 143: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial R 2007 0246/9, Ouzilly, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	6.0	k: 0.77429	7.7	k: 0.002	k: 0.58	k: 0.97	**0.895**	2.974
FOMC	+	6.0	α: 1.07795 β: 0.37645	1.1	-	β: 0.15	β: 0.60	0.340	2.811
DFOP	+	6.0	k1: 822500 k2: 0.1744 g: 0.844	1.7	k1: <0.001 k2: 0.052	k1: 822500 k2: 0.12	k1: 822500 k2: 0.23	8.4 E-7	2.557
HS	+	6.0	k1: 0.79053 k2: 0.13953 tb: 3.329	1.4	k1: 0.009 k2: 0.121	k1: 0.74 k2: 0.03	k1: 0.84 k2: 0.25	0.877	2.913

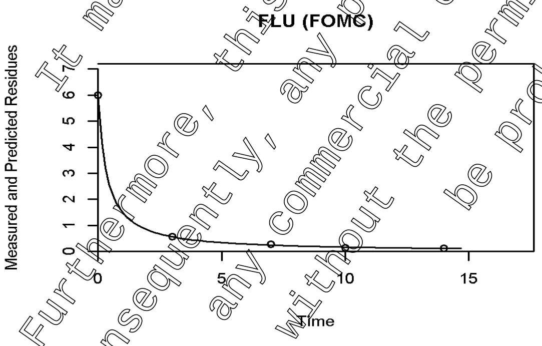
SFO fit is statistically and visually good to acceptable (χ^2 err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before 3 d), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



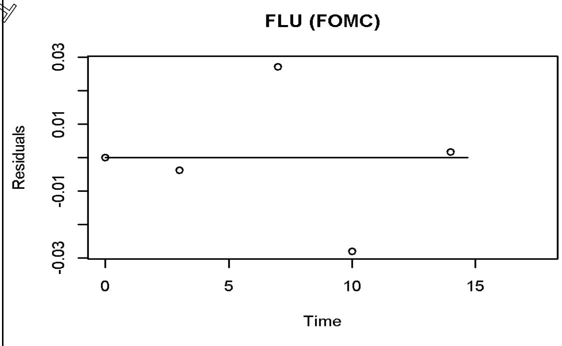
SFO



SFO



FOMC



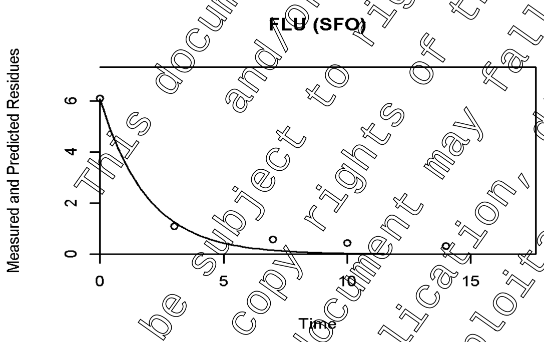
FOMC

R 2007 0537/9, Langenfeld Reusrath, M-304280-01-1, DE, lettuce

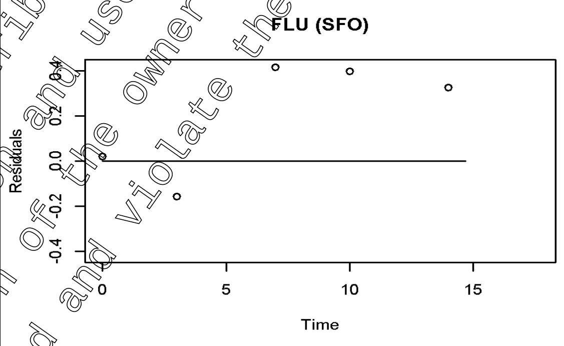
Table 8.9- 144: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial R 2007 0537/9, Langenfeld Reusrath, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	6.1	k: 0.5254	14.3	k: 0.007	k: 0.33	k: 0.73	1.319	4.382
FOMC	+	6.1	α: 0.847347 β: 0.457515	0.1	-	β: 0.44	β: 0.47	0.579	6.476
DFOP	+	6.1	k1: 14.07383 k2: 0.12864 g: 0.741	3.1	k1: NA k2: 0.062	k1: NA k2: 0.08	k1: NA k2: 0.18	0.079	7.384
HS	+	6.1	k1: 0.570993 k2: 0.080046 tb: 3.709	0.5	k1: 0.003 k2: 0.033	k1: 0.56 k2: 0.06	k1: 0.58 k2: 0.10	1.214	6.019

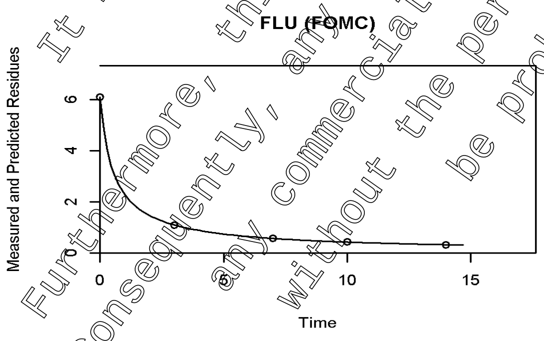
SFO fit is statistically acceptable (χ^2err <15%, t-test <0.05), but visually poor. DFOP, FOMC and HS fits were alternatively tested. FOMC fit is visually good, with lowest $\chi2$ err. Consequently, **FOMC** model is considered appropriate according to modelling purpose (FOCUS kinetics) and as best visual fit. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT50 is an adequate option.



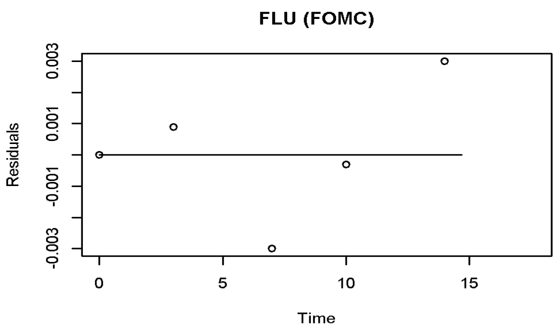
SFO



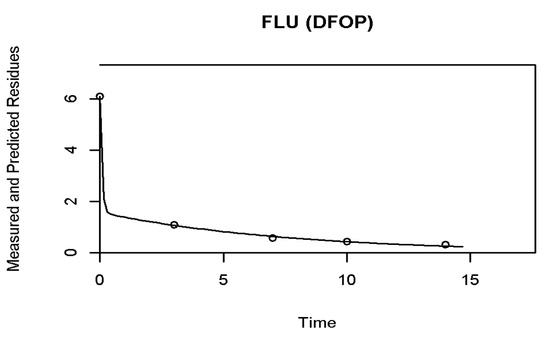
SFO



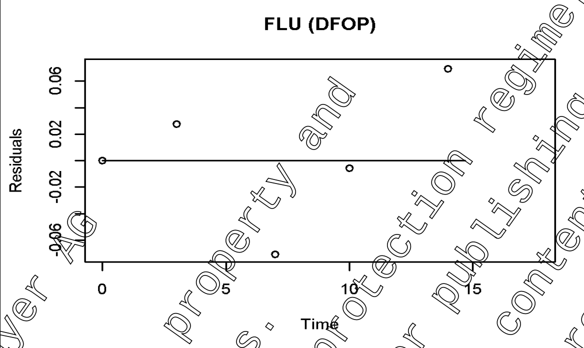
FOMC



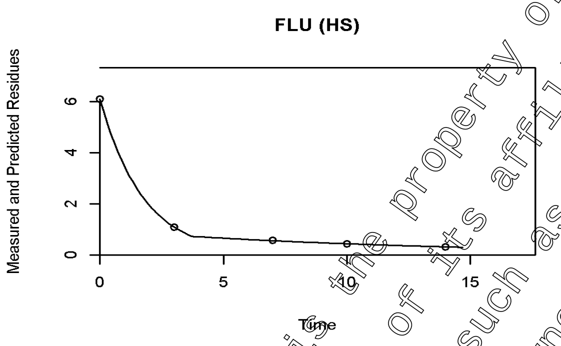
FOMC



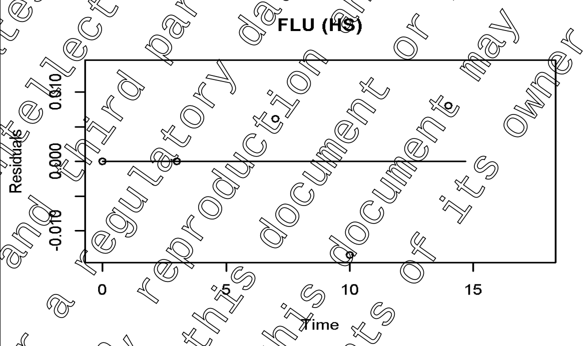
DFOP



DFOP



HS



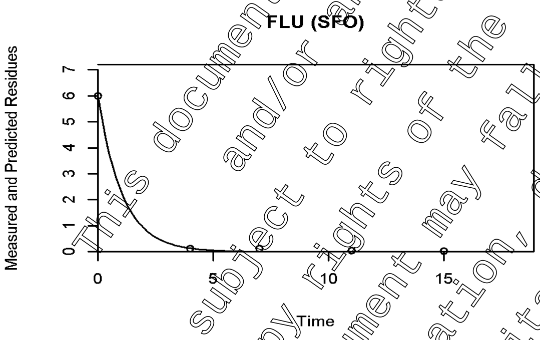
HS

R 2007 0538/7, Puzeaux, M-304280-01-1, FR, lettuce

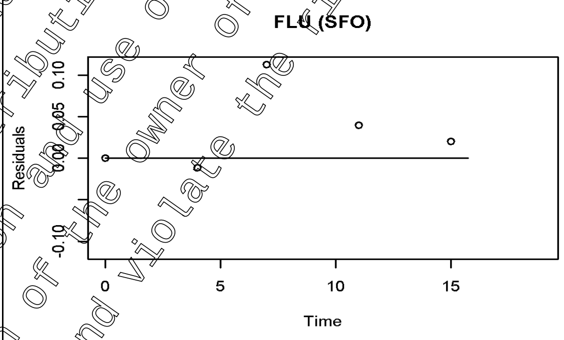
Table 8.9- 145: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial R 2007 0538/7, Puzeaux, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	6.0	k: 0.95542	3.5	k: 0.003	k: 0.69	k: 1.22	**0.726**	2.41
FOMC	o	6.0	α: 0.9157 β: 0.06335	1.6	-	β: -0.25	β: 0.37	0.0717	0.7197
DFOP	o	6.0	k1: 9524.709 k2: 0.13315 g: 0.962	1.5	k1: NA k2: 0.170	k1: NA k2: -0.02	k1: NA k2: 0.29	7.3 E-5	3.0 E-4
HS	+	6.0	k1: 0.93224 k2: 0.13826 tb: 4.0	1.6	k1: 0.077 k2: 0.250	k1: 0.48 k2: -0.13	k1: 1.38 k2: 0.41	0.744	2.47

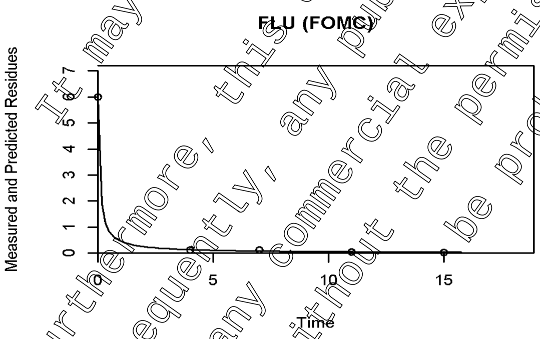
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



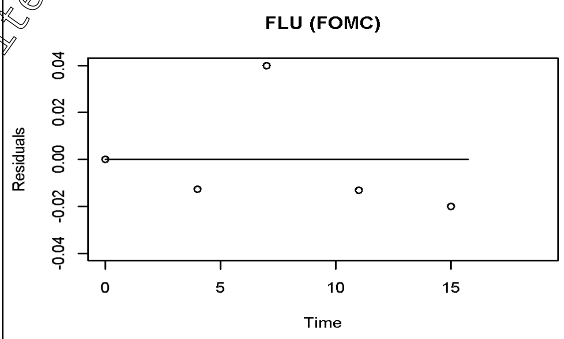
SFO



SFO



FOMC



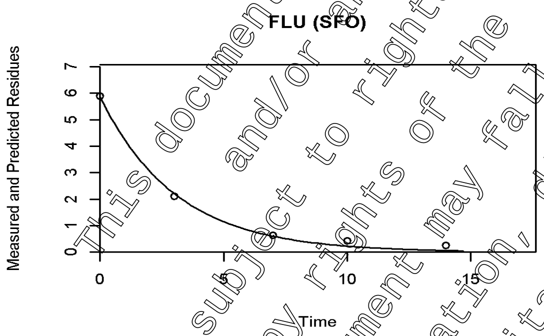
FOMC

R 2007 0539/5, Villers-Perwin, M-304280-01-1, BE, lettuce

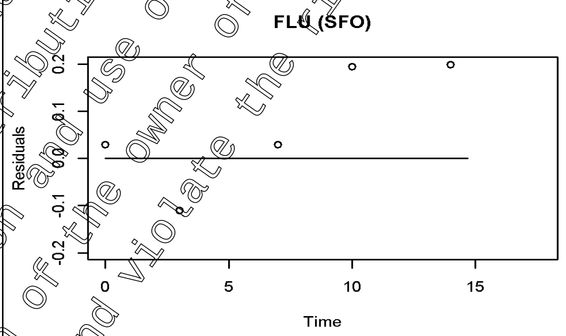
Table 8.9- 146: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial R 2007 0539/5, Villers-Perwin, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	5.9	k: 0.32562	5.8	k: <0.001	k: 0.28	k: 0.37	**2.129**	7.071
FOMC	+	5.9	α: 3.67246 β: 9.08683	2.7	-	β: 1.66	β: 16.52	1.888	7.923
DFOP	+	5.9	k1: 0.374842 k2: 0.006339 g: 0.955	1.4	k1: 0.024 k2: 0.475	k1: 0.32 k2: -0.15	k1: 0.43 k2: 0.17	1.975	7.516
HS	+	5.9	k1: 0.344338 k2: 0.128504 tb: 6.216	0.2	k1: 0.001 k2: 0.012	k1: 0.34 k2: 0.12	k1: 0.35 k2: 0.14	2.013	7.478

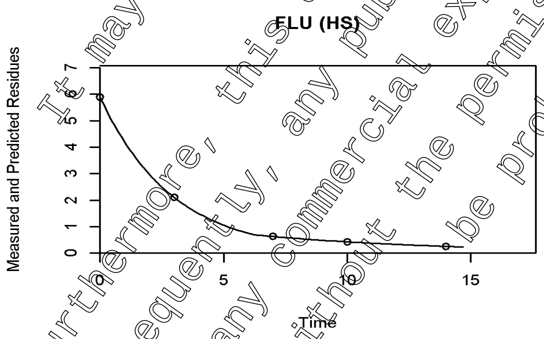
SFO fit is statistically and visually good (χ^2err <15%, t-test<0.05), and usable according modelling purpose (FOCUS kinetics).



SFO



SFO



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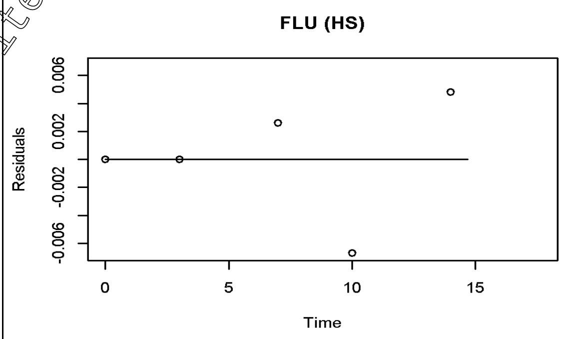


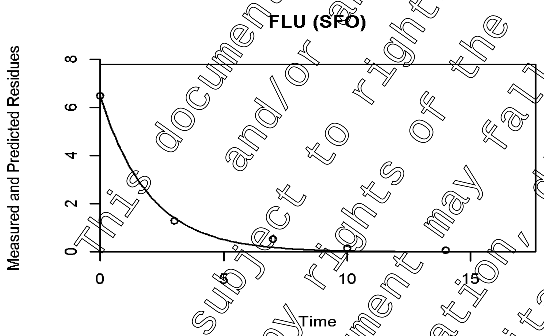
HS

R 2007 0540/9, Zwaagdijk, M-304280-01-1, NL, lettuce

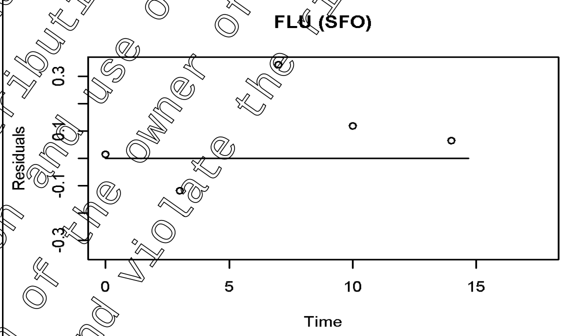
Table 8.9- 147: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial R 2007 0540/9, Zwaagdijk, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	6.5	k: 0.50672	8.1	k: 0.001	k: 0.41	k: 0.61	**1.368**	4.544
FOMC	+	6.5	α: 2.20425 β: 2.82946	3.5	-	β: 0.08	β: 5.58	1.046	5.213
DFOP	+	6.5	k1: 22530 k2: 0.2536 g: 0.569	2.5	k1: <0.001 k2: 0.043	k1: 22530.0 k2: 0.19	k1: 22528.61 k2: 0.32	1.09 E-4	5.76
HS	+	6.5	k1: 0.559552 k2: 0.253616 tb: 2.751	2.5	k1: 0.014 k2: 0.043	k1: 0.51 k2: 0.19	k1: 0.61 k2: 0.32	1.239	5.76

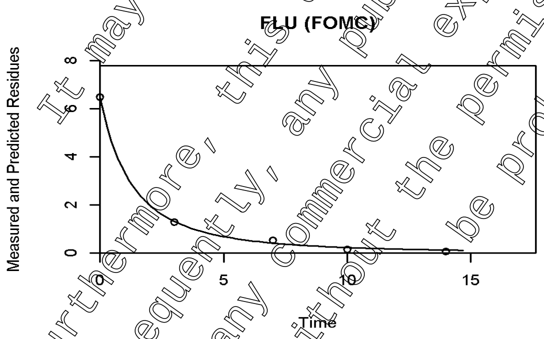
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



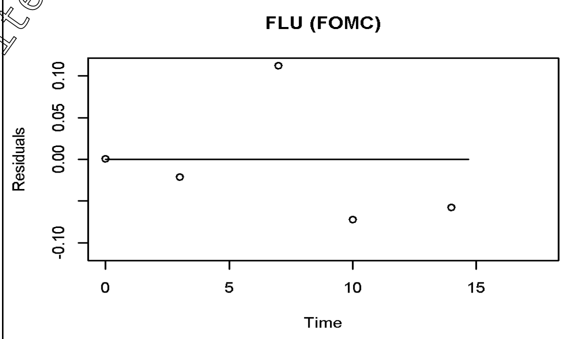
SFO



SFO



FOMC



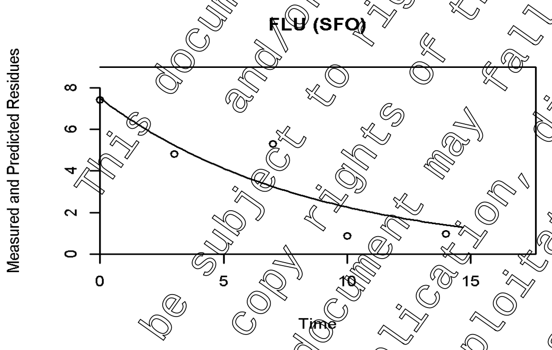
FOMC

R 2007 0541/7, Manfredonia, M-304278-01-1, IT, lettuce

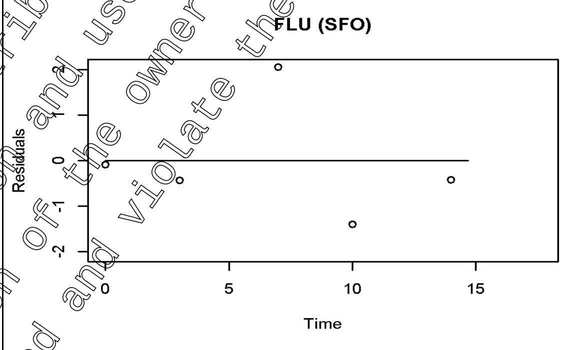
Table 8.9- 148: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial R 2007 0541/7, Manfredonia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.5	k: 0.11957	23.7	k: 0.037	k: 0.03	k: 0.21	**5.797**	19.26
FOMC	o	7.5	α: 5764.902 β: 48207.905	27.0	-	β: 47604.37	β: 48811.44	5.797	19.26
DFOP	o	7.5	k1: 0.11957 k2: 0.06524 g: 1.0	33.8	k1: 0.443 k2: <0.001	k1: -1.18 k2: 0.065	k1: 1.42 k2: 0.065	5.797	19.26
HS	o	7.5	k1: 0.142 k2: 0.120 tb: 4E-14	33.8	k1: NA k2: 0.254	k1: NA k2: -0.12	k1: NA k2: 0.36	5.797	19.26

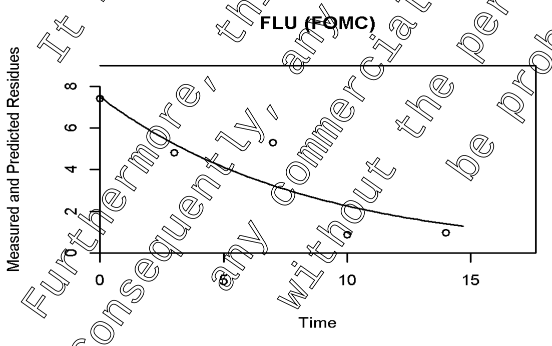
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



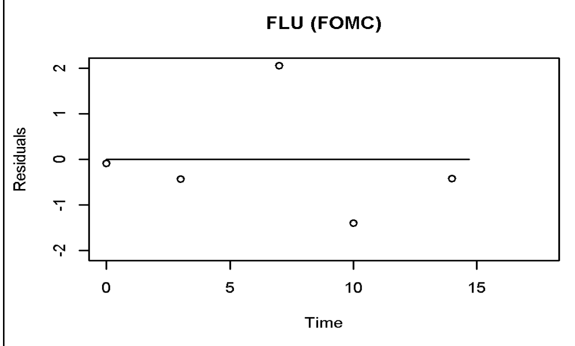
SFO



SFO



FOMC



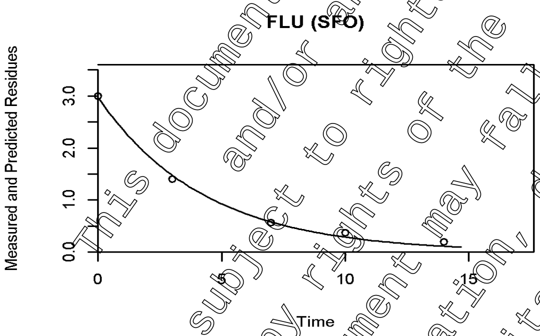
FOMC

R 2007 0546/8, Langenfeld-Reusrath, M-297562-01-1, DE, beans

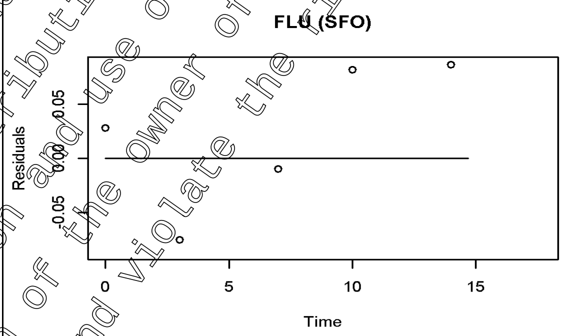
Table 8.9- 149: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2007 0546/8, Langenfeld-Reusrath, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.0	k: 0.23343	4.7	k: <0.001	k: 0.21	k: 0.26	**2.969**	9.864
FOMC	+	3.0	α: 3.96361 β: 13.97323	1.4	-	β: 7.29	β: 20.66	2.670	11.01
DFOP	+	3.0	k1: 0.30542 k2: 0.07412 g: 0.838	1.2	k1: 0.057 k2: 0.270	k1: 0.20 k2: -0.09	k1: 0.41 k2: 0.24	2.701	11.06
HS	+	3.0	k1: 0.254047 k2: 0.147999 tb: 5.870	0.2	k1: 0.002 k2: 0.007	k1: 0.25 k2: 0.14	k1: 0.26 k2: 0.15	2.728	11.35

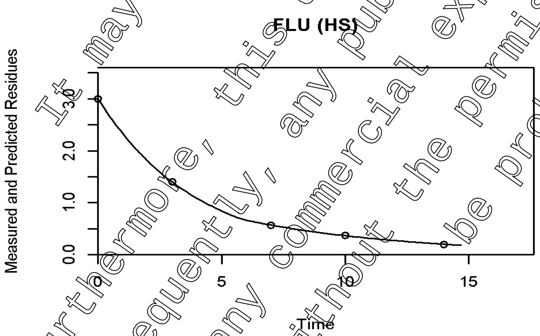
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



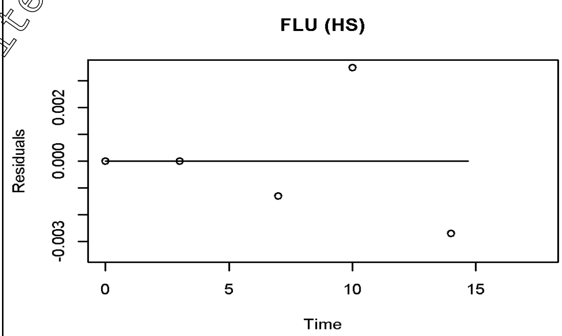
SFO



SFO



HS



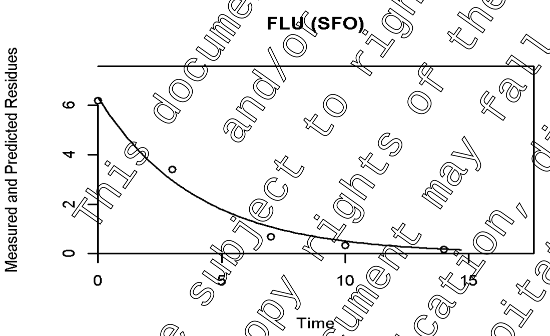
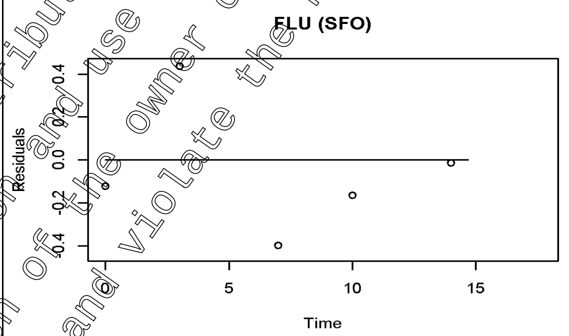
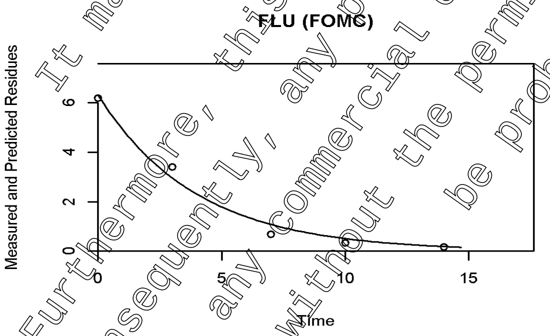
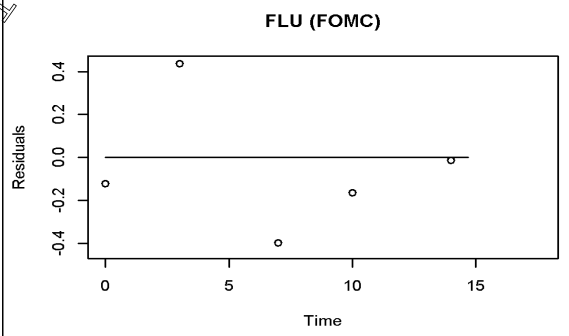
HS

R 2007 0547/6, Fresnoy les Roye, M-297562-01-1, FR, beans

Table 8.9- 150: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2007 0547/6, Fresnoy les Roye, FR

Kinetic model	Visual assessment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	6.3	k: 0.25264	10.4	k: 0.002	k: 0.19	k: 0.31	**2.744**	9.114
FOMC	o	6.3	α: 7591.357 β: 30045.313	11.9	-	β: 29522.02	β: 30568.61	2.743	9.115
DFOP	o	6.3	k1: 0.253 k2: 2.2 E-14 g: 1.0	14.8	k1: 0.115 k2: <0.001	k1: 0.06 k2: 2.2 E-14	k1: 0.44 k2: <0.0005	2.744	9.114
HS	o	6.3	k1: 0.252 k2: 0.282 tb: 11.189	14.8	k1: 0.067 k2: 0.433	k1: 0.15 k2: -2.32	k1: 0.36 k2: 2.88	2.746	9.122

SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.

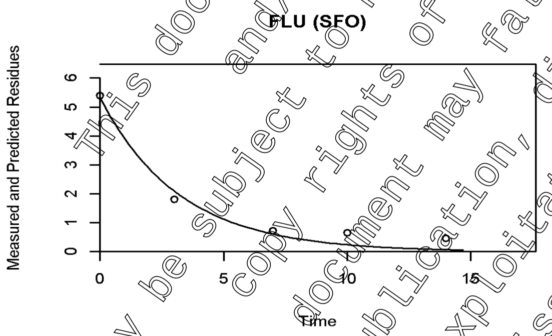
 SFO	 SFO
 FOMC	 FOMC

R 2007 0548/4, Biddinghuizen, M-297562-01-1, NL, beans

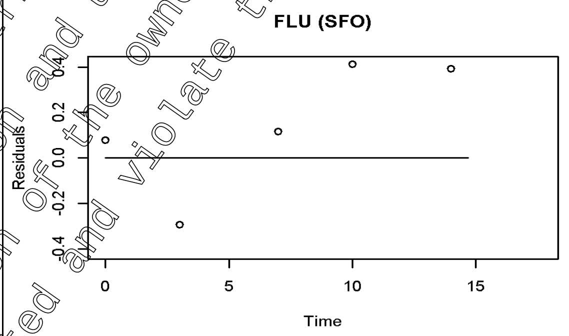
Table 8.9- 151: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2007 0548/4, Biddinghuizen, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	5.3	k: 0.31087	13.0	k: 0.004	k: 0.21	k: 0.41	2.230	7.407
FOMC	+	5.4	α: 1.2763 β: 2.1407	3.5	-	β: 0.50	β: 3.78	1.544	10.86
DFOP	+	5.4	k1: 0.480 k2: 0.03337 g: 0.858	2.4	k1: 0.047 k2: 0.310	k1: 0.34 k2: -0.06	k1: 0.62 k2: 0.13	1.773	11.49
HS	+	5.4	k1: 0.366204 k2: 0.061325 tb: 5.423	1.3	k1: 0.008 k2: 0.080	k1: 0.35 k2: 0.03	k1: 0.38 k2: 0.09	1.893	12.08

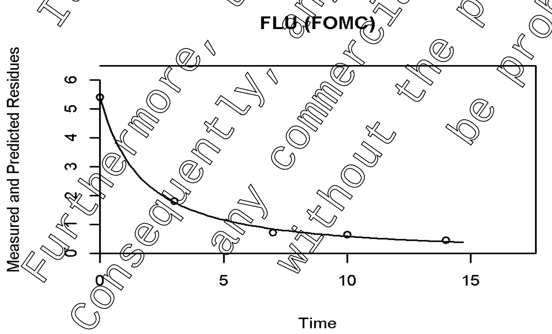
SFO fit is statistically acceptable (χ^2err <15%, t-test <0.05), but visually poor to borderline. DFOP, FOMC and HS fits were alternatively tested. HS fit is statistically (χ^2err, t-test) and visually good, with lowest $\chi2$ err and most reliable degradation rates (of DFOP or HS). Consequently, **HS** model is considered appropriate according to modelling purpose (FOCUS kinetics) and as best visual fit. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT50 is an adequate option.



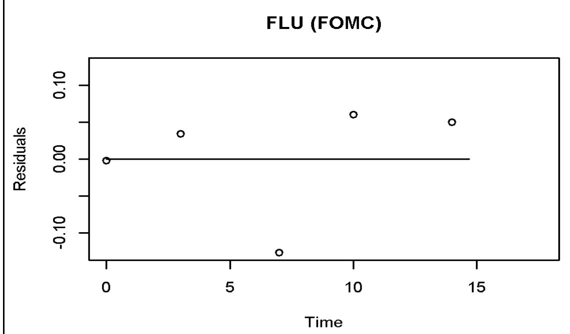
SFO



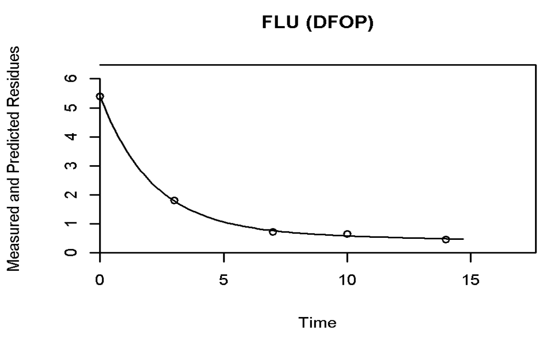
SFO



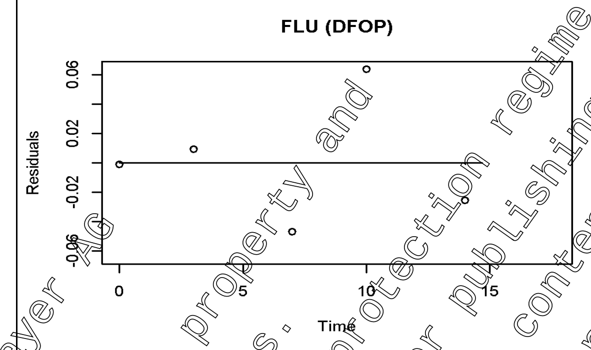
FOMC



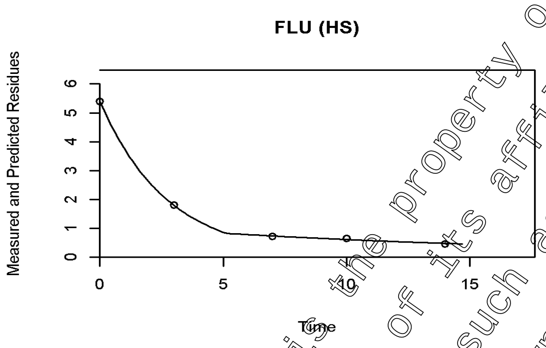
FOMC



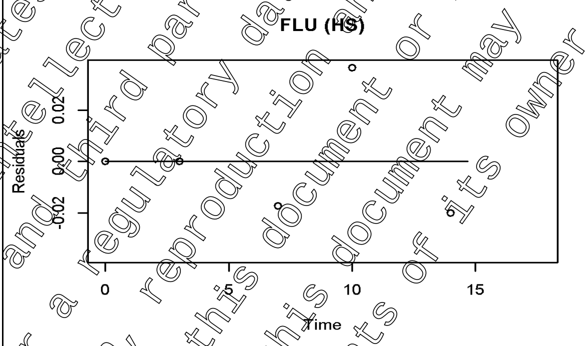
DFOP



DFOP



HS



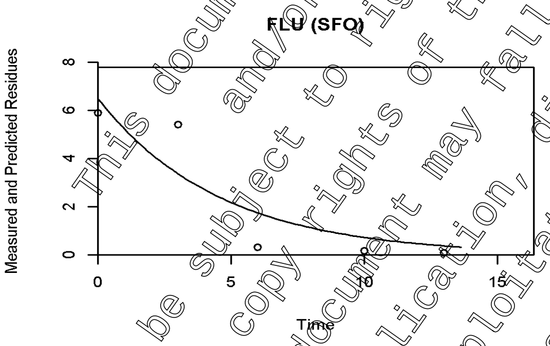
HS

R 2007 0549/2, Swisttal Heimerzheim, M-297562-01-1, DE, beans

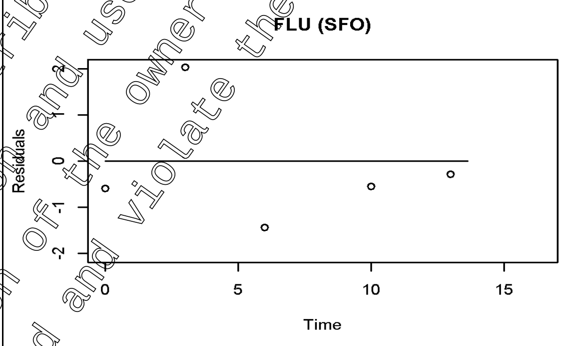
Table 8.9- 152: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2007 0549/2, Swisttal Heimerzheim, DE

Kinetic model	**Visual assess-ment**	**M_0**	**Kinetic parameters**	**X^2 error (%)**	**Prob > t**	**Lower 95% CI**	**Upper 95% CI**	**DT_{50} actual (d)**	**DT_{90} actual (d)**
SFO	o	6.5	k: 0.21851	39.6	k: 0.059	k: 0.02	k: 0.42	**3.172**	10.54
FOMC	o	6.5	α: 15521.467 β: 71028.856	45.3	-	β: 67446.83	β: 74610.88	3.172	10.54
DFOP	o	6.5	k1: 0.219 k2: 2.2 E-14 g: 1.0	56.5	k1: 0.329 k2: <0.001	k1: -0.50 k2: 2.2 E-14	k1: 0.94 k2: <0.0005	3.172	10.54
HS	o	6.5	k1: 0.219 k2: 0.231 tb: 16.793	56.5	k1: 0.214 k2: <0.001	k1: -0.12 k2: 0.23	k1: 0.56 k2: 0.23	3.172	10.54

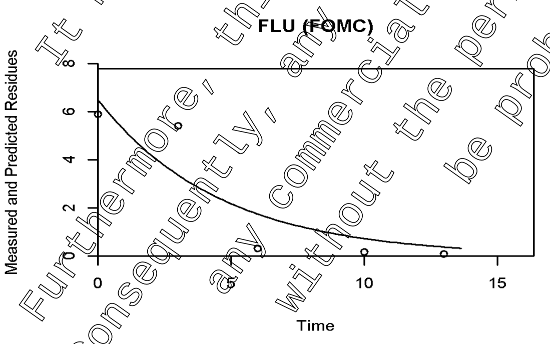
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



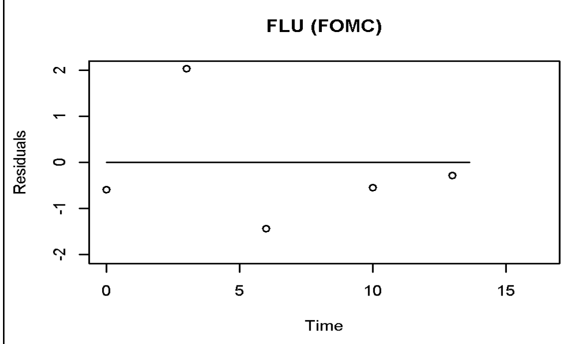
SFO



SFO



FOMC



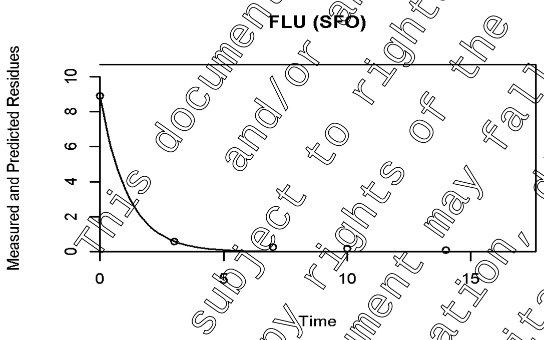
FOMC

R 2007 0550/6, Ladispoli, M-297564-01-1, IT, beans

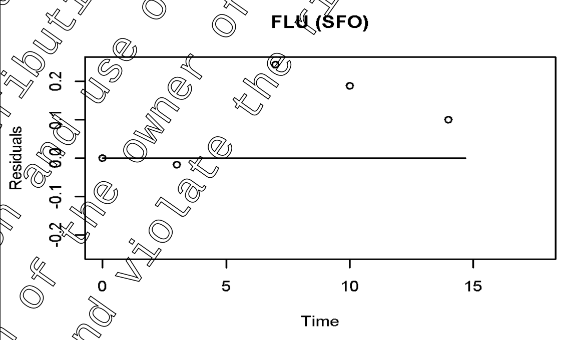
Table 8.9- 153: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2007 0550/6, Ladispoli, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	8.9	k: 0.9008	5.8	k: 0.002	k: 0.70	k: 1.11	**0.7695**	2.556
FOMC	+	8.9	α: 1.04287 β: 0.23711	0.6	-	β: 0.13	β: 0.35	0.224	1.92
DFOP	+	8.9	k1: 48250 k2: 0.1712 g: 0.893	0.9	k1: <0.001 k2: 0.040	k1: 48250.0 k2: 0.13	k1: 48250.43 k2: 0.21	<0.001	0.425
HS	+	8.9	k1: 0.910259 k2: 0.128445 tb: 3.349	0.3	k1: 0.003 k2: 0.043	k1: 0.90 k2: 0.09	k1: 0.93 k2: 0.16	0.762	2.53

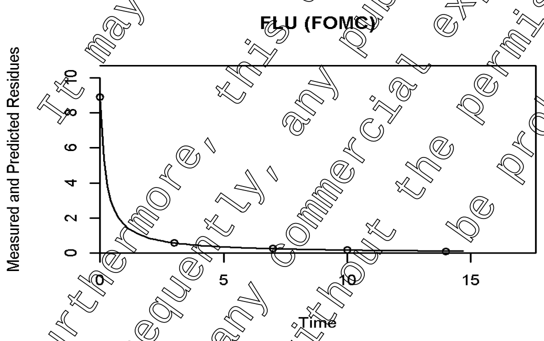
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



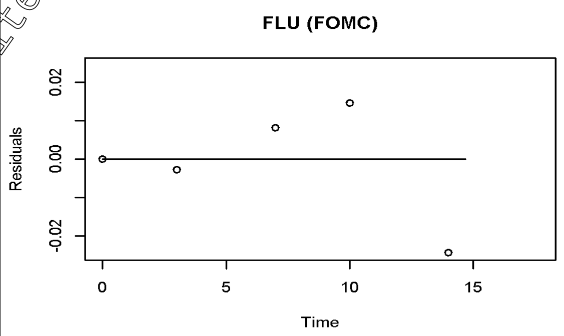
SFO



SFO



FOMC



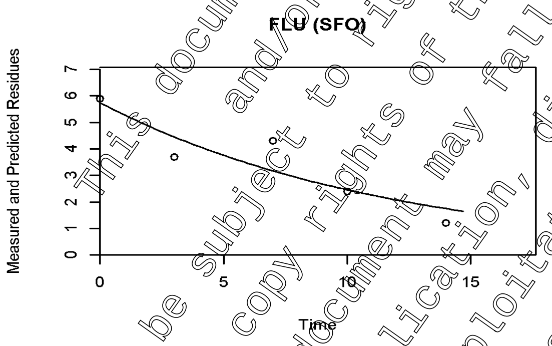
FOMC

R 2007 0551/4, Alginet, M-297564-01-1, ES, beans

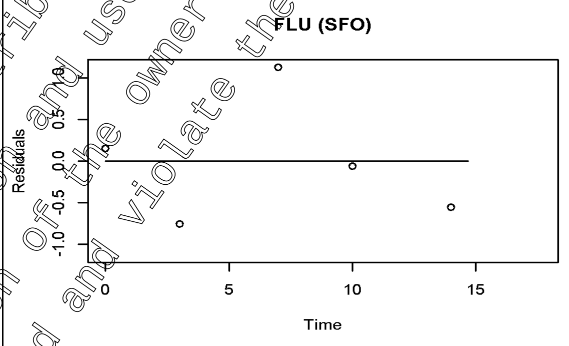
Table 8.9- 154: Kinetic models and goodness-of-fit statistics of fluopyram fits for beans of trial R 2007 0551/4, Alginet, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	5.7	k: 0.08485	15.1	k: 0.022	k: 0.04	k: 0.14	**8.169**	27.14
FOMC	o	5.7	α: 3332 β: 39260	17.2	-	β: 39060.00	β: 39462.37	8.169	27.14
DFOP	o	5.7	k1: 0.09161 k2: 0.08485 g: 2.2 E-14	21.5	k1: <0.001 k2: 0.152	k1: 0.0916 k2: -0.0014	k1: 0.092 k2: 0.171	8.169	27.14
HS	o	5.9	k1: 0.156 k2: 0.076 tb: 1.317	21.0	k1: 0.368 k2: 0.227	k1: -0.54 k2: -0.05	k1: 0.85 k2: 0.20	7.774	29.07

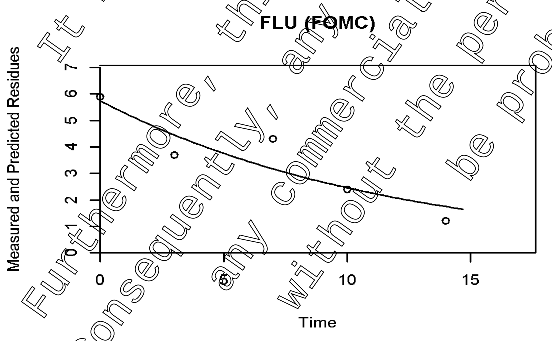
SFO fit is statistically and visually acceptable (χ^2err < 15 %, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit, mainly due to the scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



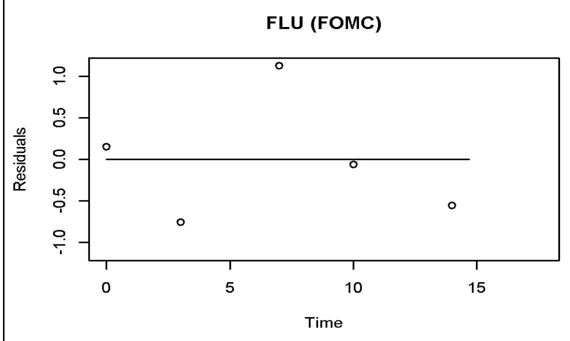
SFO



SFO



FOMC



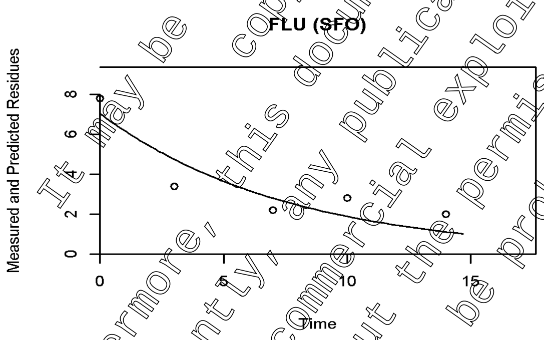
FOMC

R 2007 0552/2, Ribafria Peniche, M-297564-01-1, PT, beans

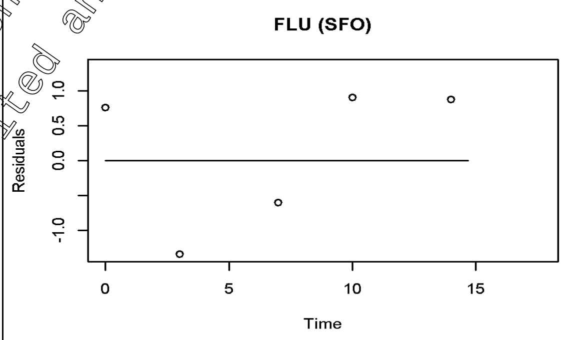
Table 8.9- 155: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce head of trial R 2007 0552/2, Ribafria Peniche, PT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	7.0	k: 0.13143	20.5	k: 0.026	k: 0.05	k: 0.21	5.274	17.52
FOMC	+	7.8	α: 0.29987 β: 0.1852	7.0	-	β: -0.55	β: 0.92	1.683	400.1
DFOP	+	7.8	k1: 11.88574 k2: 0.04164 g: 0.532	9.6	k1: <0.001 k2: 0.215	k1: 11.8857 k2: -0.02	k1: 11.886 k2: 0.11	0.226	37.07
HS	+	7.8	k1: 0.27678 k2: 0.01485 tb: 4.025	7.9	k1: 0.068 k2: 0.406	k1: 0.16 k2: -0.08	k1: 0.39 k2: 0.11	2.504	84.05

SFO fit is statistically and visually poor (χ^2err >15%, t-test <0.05). FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in χ2 error and visual assessment. However, FOMC is not fully appropriate as 10% of the initial residue was not reached during study duration (decay down to 25 %), leading to an uncertain extrapolation of the DT_{90} far beyond study end. Futheron, the t-test of DFOP and HS show a low reliability especially of the slow degradation rates k2 (t-test > 0.05). Nevertheless, a clear decay is seen and **DFOP** shows the less uncertain k rates (of HS and DFOP). Thus, the slow phase of DFOP with a $DT_{50\ slow}$ of 16.6 d could be used conservatively. However, this slow phase describes only half of the dissipation behaviour (g = 0.532, ratio of initial mass M0, which dissipates fast), and ignores the faster phase. As the DFOP DT_{90} (37.07 d) is not extrapolated far beyond the study end, a pseudo SFO DT50 (DT90 / 3.32 = 11.166 d) could be used alternatively, as the pseudo SFO curve lays always above the DFOP curve, until both curves meet at the DT90. So, either **DFOP** with full parameter set, or conservatively, a pseudo SFO DT50 of DFOP of 11.166 d is considered appropriate. An influence of precipitation on a biphasic decay can be excluded as almost no rain occurred.



SFO



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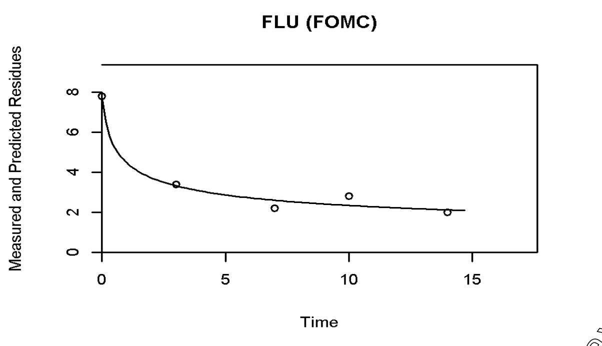
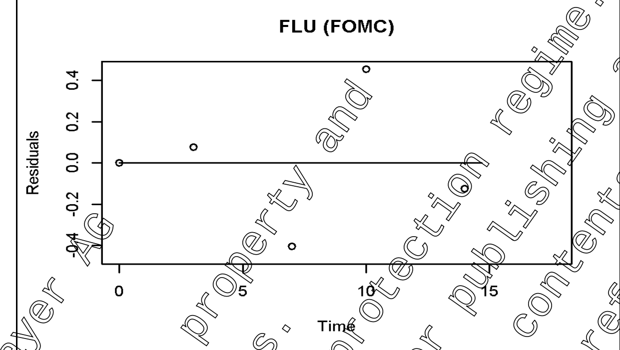


FOMC



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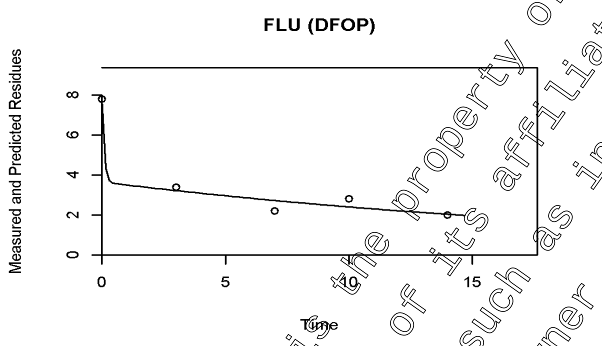
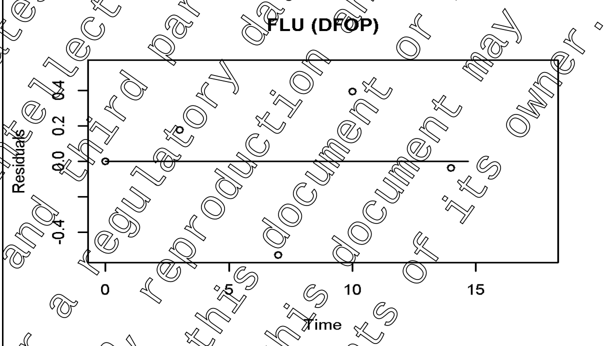


DFOP



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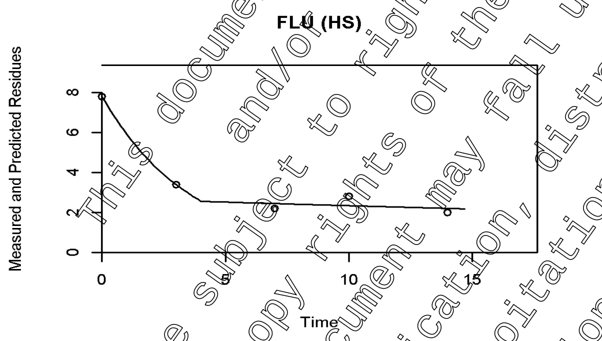
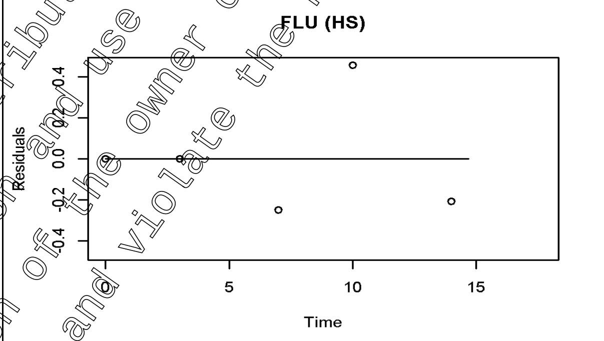


HS



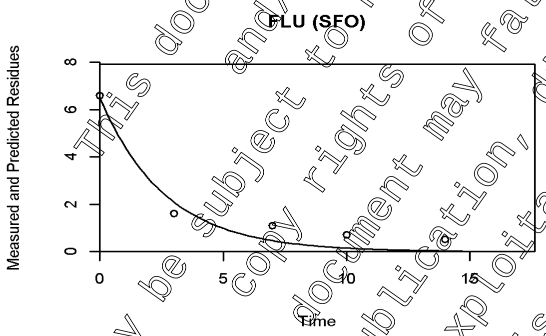
HS

R 2007 0553/0, Burscheid, M-298639-01-1, DE, pea

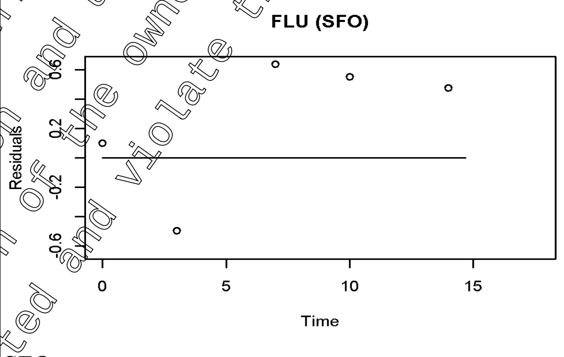
Table 8.9- 156: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial R 2007 0553/0, Burscheid, DE

Kinetic model	**Visual assess-ment**	**M_0**	**Kinetic parameters**	**X^2 error (%)**	**Prob > t**	**Lower 95% CI**	**Upper 95% CI**	**$DT_{50\ actual}$ (d)**	**$DT_{90\ actual}$ (d)**
SFO	-	6.5	k: 0.37762	18.6	k: 0.013	k: 0.20	k: 0.56	1.836	6.10
FOMC	+	6.6	α: 0.7204 β: 0.5081	3.5	-	β: -0.06	β: 1.08	0.822	11.91
DFOP	+	6.6	k1: 14.06731 k2: 0.10766 g: 0.663	2.0	k1: NA k2: 0.035	k1: NA k2: 0.08	k1: NA k2: 0.13	0.098	11.29
HS	+	6.6	k1: 0.476659 k2: 0.107659 tb: 2.945	2.0	k1: 0.011 k2: 0.035	k1: 0.44 k2: 0.08	k1: 0.51 k2: 0.13	1.454	11.29

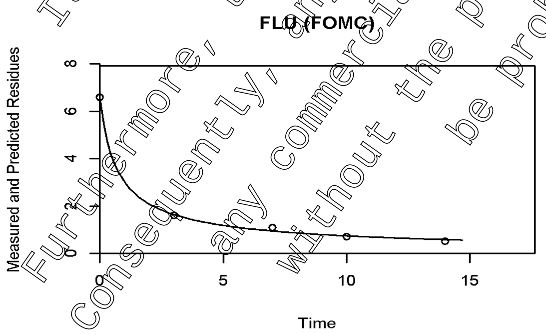
SFO fit is statistically acceptable (χ^2err <15%, t-test <0.05), but visually poor. DFOP, FOMC and HS fits were alternatively tested. HS fit is statistically (χ^2err, t-test) and visually good, with lowest χ^2 err and most reliable degradation rates (of DFOP or HS). Consequently, **HS** model is considered appropriate according to modelling purpose (FOCUS kinetics) and as best visual fit. As low residues < 10% are reached at study end, a recalculation of a pseudo SFO DT50 is an adequate option.



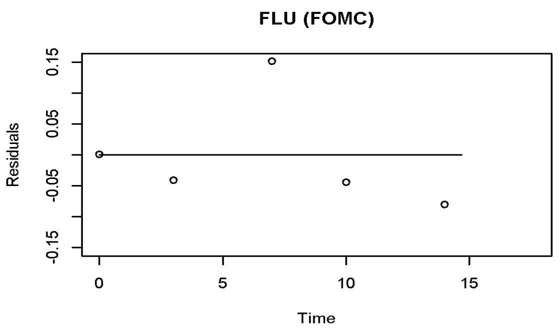
SFO



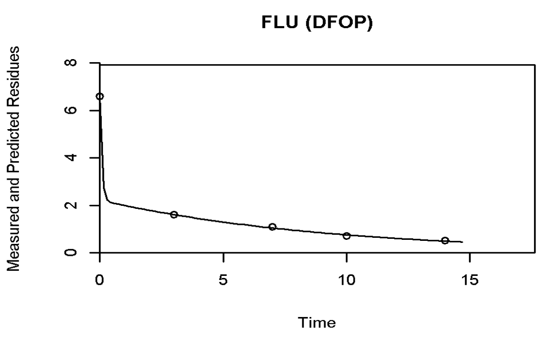
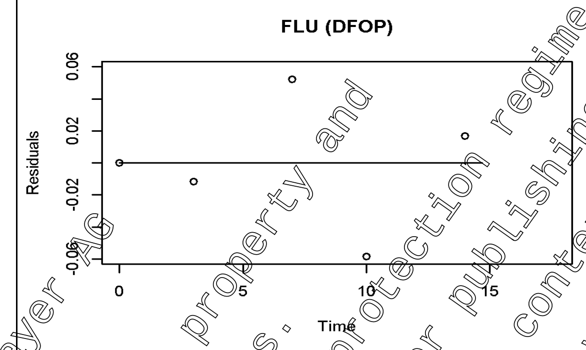
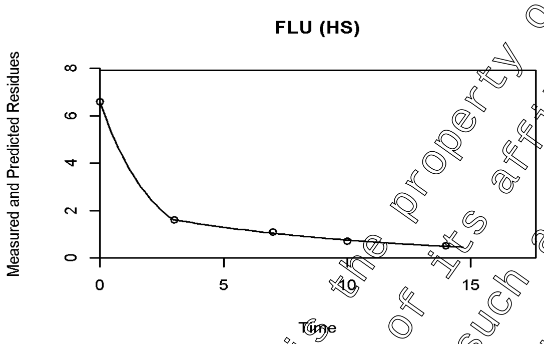
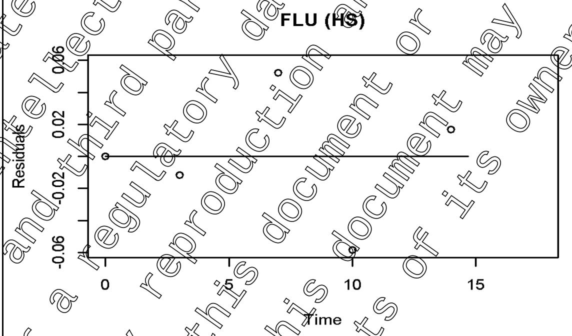
SFO



FOMC



FOMC

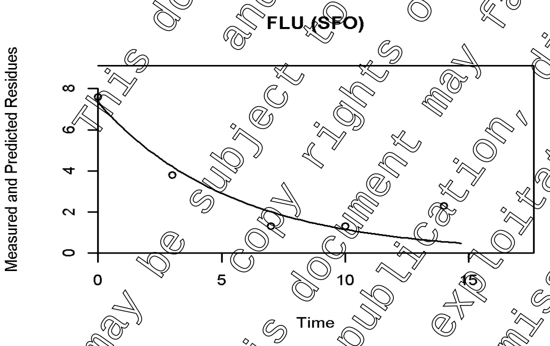
 DFOP	 DFOP
 HS	 HS

R 2007 0554/9, Goyencourt, M-298639-01-1, FR, pea

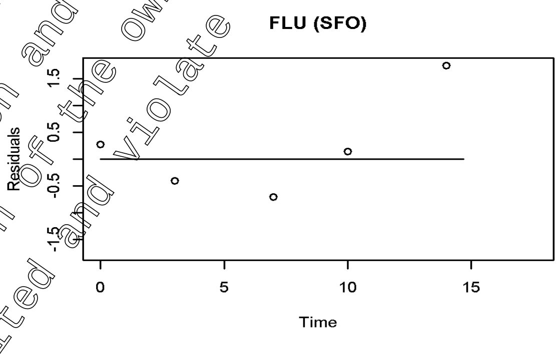
Table 8.9- 157: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial R 2007 0554/9, Goyencourt, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	7.3	k: 0.18463	21.5	k: 0.022	k: 0.08	k: 0.29	3.754	12.47
FOMC	o	7.6	α: 0.7393 β: 1.5174	17.2	-	β: -5.22	β: 8.26	2.358	32.66
DFOP	o	7.7	k1: 0.389 k2: 2.2 E-14 g: 0.798	17.2	k1: 0.298 k2: 0.50	k1: -0.64 k2: -0.51	k1: 1.42 k2: 0.51	2.529	>1000
HS	o	7.6	k1: 0.231 k2: 2.2 E-14 tb: 6.655	12.8	k1: 0.106 k2: 0.50	k1: 0.07 k2: -0.20	k1: 0.39 k2: 0.20	3.000	>1000

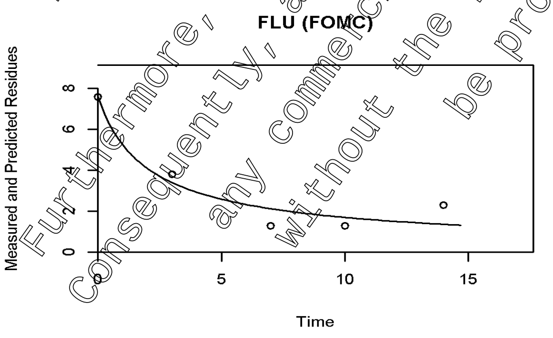
SFO fit is statistically (χ^2err >15%, t-test <0.05) and visually poor. FOMC, DFOP and HS fits were alternatively tested. The t-test of DFOP and HS show a very low reliability especially of the slow degradation rates k2 (t-test > 0.05). During study duration the lowest residues have been only slightly > 10 % (17 %) of initial mass, untypically increasing again at last data point. In addition, the FOMC DT_{90} (32.66 d) is not extrapolated far beyond the study end. Therefore, **FOMC** was considered best appropriate for modelling endpoints (FOCUS kinetics) and as well as best visual fit.



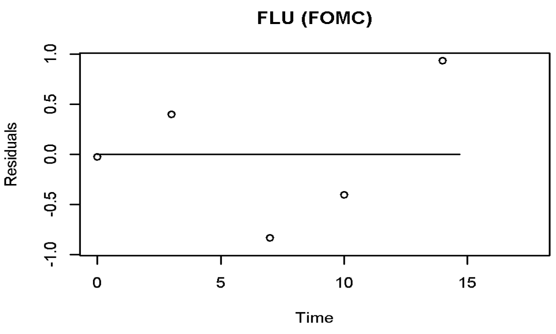
SFO



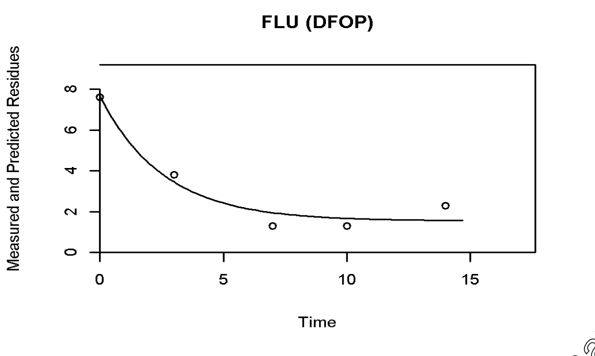
SFO



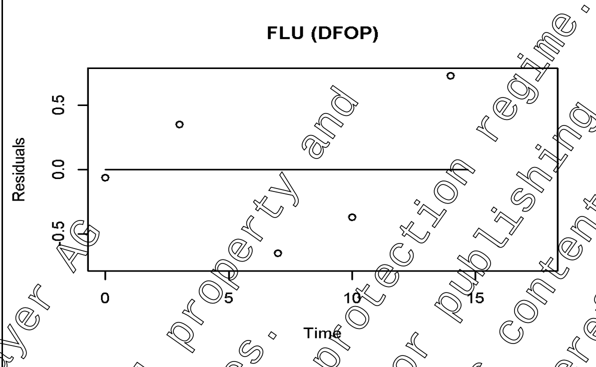
FOMC



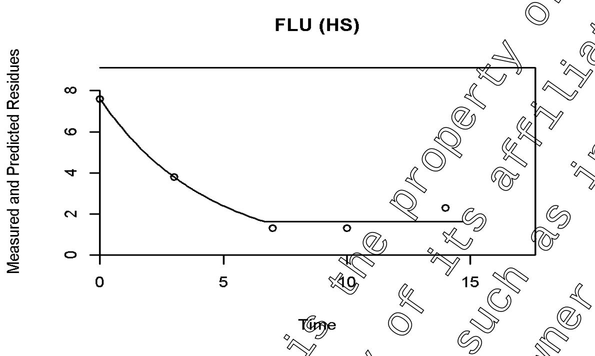
FOMC



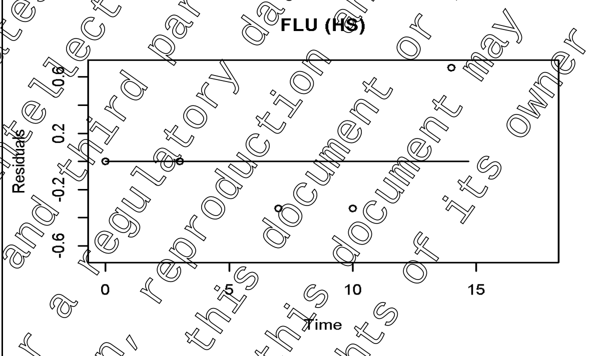
DFOP



DFOP



HS



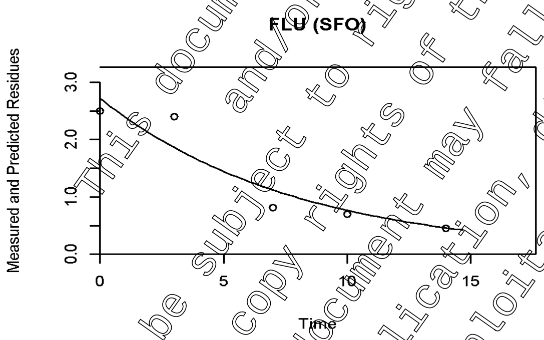
HS

R 2007 0555/7, Landenne-Sur-Meuse, M-298639-01-1, BE, pea

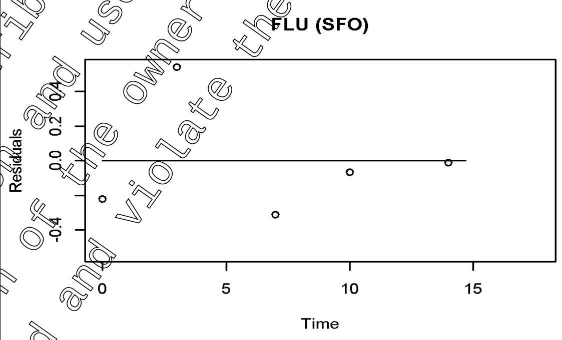
Table 8.9- 158: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial R 2007 0555/7, Landenne-Sur-Meuse, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	2.7	k: 0.12675	17.3	k: 0.016	k: 0.06	k: 0.19	**5.468**	18.17
FOMC	o	2.7	α: 8829 β: 69650	19.8	-	β: 68950.00	β: 70343.37	5.468	18.17
DFOP	o	2.7	k1: 0.1268 k2: 0.08052 g: 1.0	24.7	k1: 0.433 k2: <0.001	k1: -1.04 k2: 0.0805	k1: 1.29 k2: 0.081	5.468	18.17
HS	o	2.7	k1: 0.127 k2: 0.030 tb: 18.767	24.7	k1: 0.136 k2: <0.001	k1: 0.01 k2: 0.03	k1: 0.24 k2: 0.03	5.468	18.17

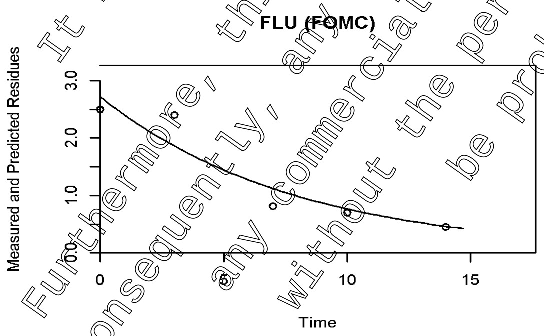
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



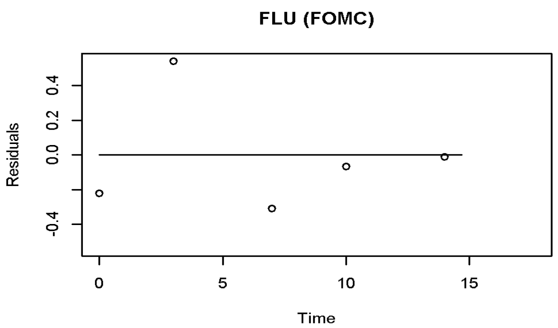
SFO



SFO



FOMC



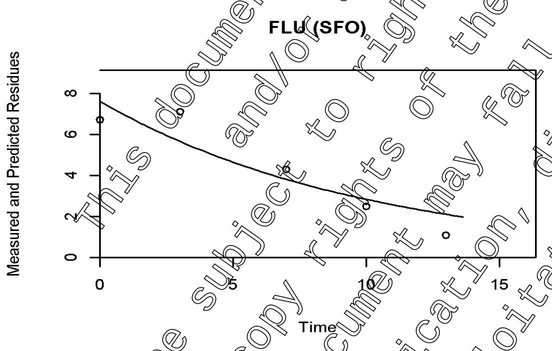
FOMC

R 2007 0556/5, Swisttal Heimerzheim, M-298639-01-1, DE, pea

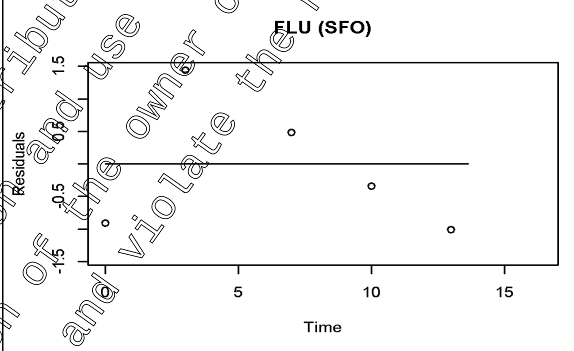
Table 8.9- 159: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial R 2007 0556/5, Swisttal Heimerzheim, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.6	k: 0.09858	17.0	k: 0.023	k: 0.04	k: 0.16	**7.032**	23.36
FOMC	o	7.6	α: 15310 β: 155300	19.5	-	β: 154200	β: 156387.16	7.032	23.36
DFOP	o	7.6	k1: 0.099 k2: 0.125 g: 1.0	24.3	k1: 0.471 k2: <0.001	k1: -2.03 k2: 0.12	k1: 2.23 k2: 0.13	7.032	23.36
HS	+	6.9	k1: 2.254e-14 k2: 0.2071 tb: 4.766	4.3	k1: 0.5 k2: 0.062	k1: -0.05 k2: 0.13	k1: 0.05 k2: 0.29	8.113	15.89

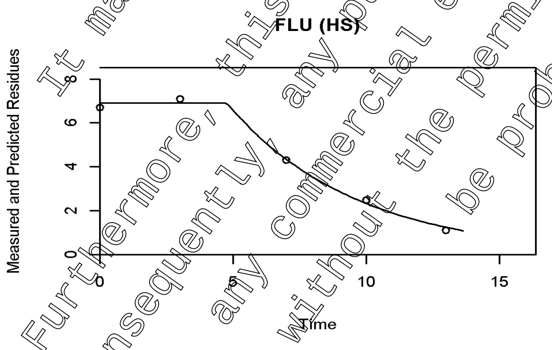
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. The HS resulted in a lag phase, which is considered not appropriate for the intended purpose. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



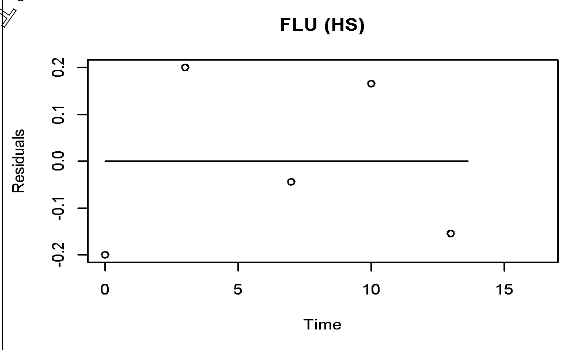
SFO



SFO



HS



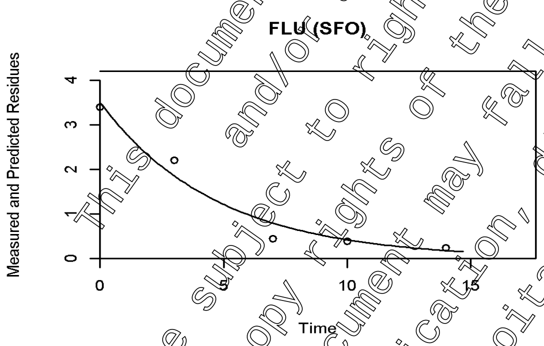
HS

R 2007 0557/3, Brenes, Sevilla, M-297487-01-1, ES, pea

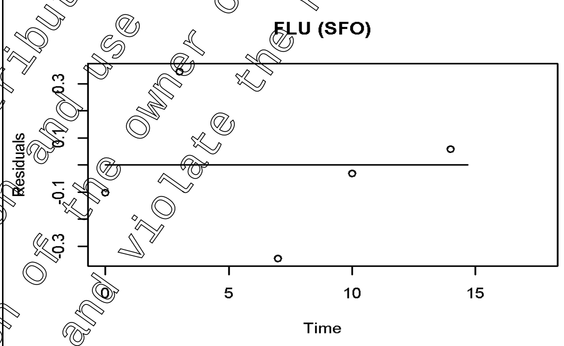
Table 8.9- 160: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial R 2007 0557/3, Brenes, Sevilla, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.5	k: 0.21165	13.5	k: 0.005	k: 0.14	k: 0.28	**3.275**	10.88
FOMC	o	3.5	α: 9374 β: 44290	15.4	-	β: 43530	β: 45042.55	3.275	10.88
DFOP	o	3.5	k1: 0.212 k2: 2.2 E-14 g: 1.0	19.2	k1: 0.174 k2: <0.001	k1: 0.04 k2: 2.2 E-14	k1: 0.46 k2: <0.0005	3.275	10.88
HS	o	3.5	k1: 0.212 k2: 2.2 E-14 tb: 15.86	19.2	k1: 0.089 k2: <0.001	k1: 0.09 k2: 2.2 E-14	k1: 0.33 k2: <0.0005	3.275	10.88

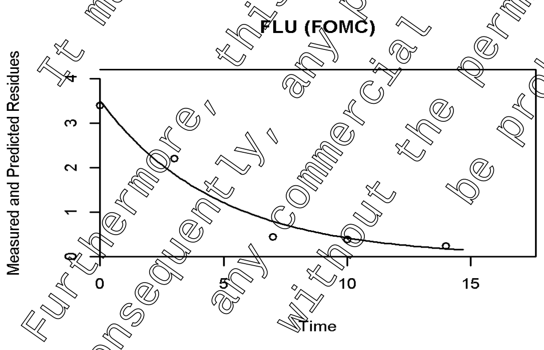
SFO fit is statistically and visually acceptable (χ^2err <15 %, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



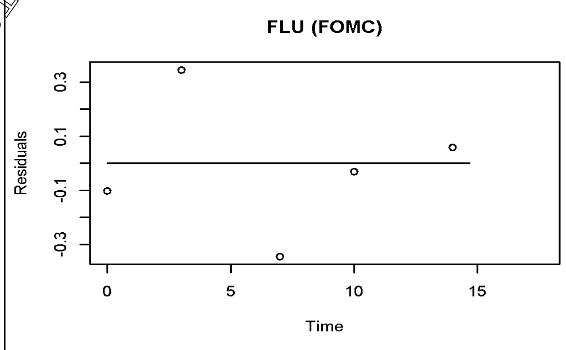
SFO



SFO



FOMC



FOMC

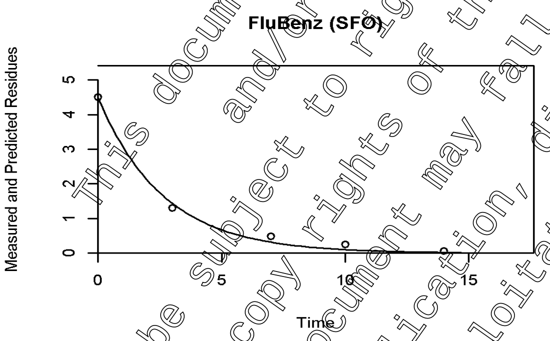
Fluopyram + FLU-benzamide

R 2007 0012/1, Olho Marinho, M-304278-01-1, PT, lettuce

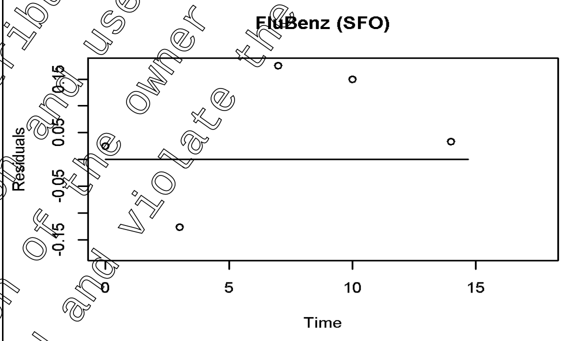
Table 8.9- 161: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce head of trial R 2007 0012/1, Olho Marinho, PT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.5	k: 0.37945	7.2	k: <0.001	k: 0.32	k: 0.44	**1.827**	6.068
FOMC	+	4.5	α: 2.89618 β: 5.70075	2.6	-	β: 1.70	β: 9.70	1.541	6.924
DFOP	+	4.5	k1: 12.87261 k2: 0.24682 g: 0.390	1.4	k1: <0.001 k2: 0.018	k1: 12.87 k2: 0.22	k1: 12.87 k2: 0.28	0.804	7.325
HS	+	4.5	k1: 0.41144 k2: 0.2472 tb: 3.0	1.4	k1: 0.101 k2: 0.055	k1: 0.15 k2: 0.16	k1: 0.68 k2: 0.33	1.685	7.322

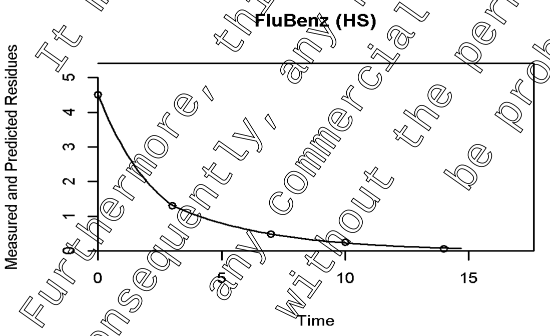
SFO fit is statistically good and overall visually acceptable (χ^2err <15%, t-test <0.05%). Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



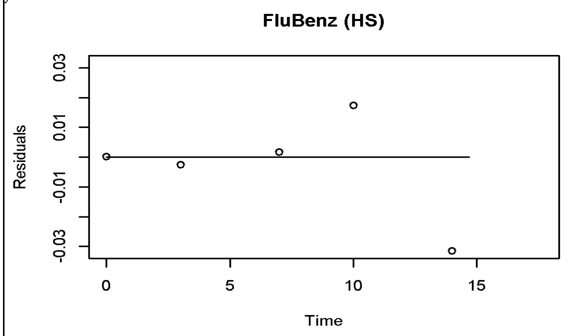
SFO



SFO



HS



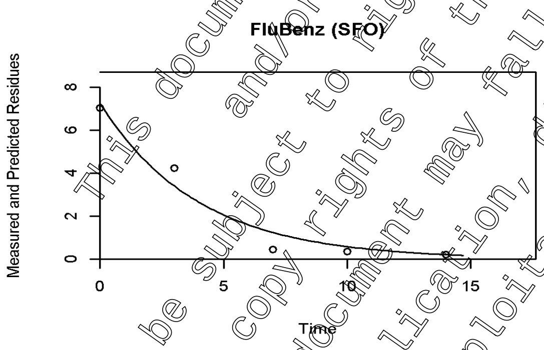
HS

R 2007 0014/8, Villers-Perwin, M-297562-01-1, BE, beans

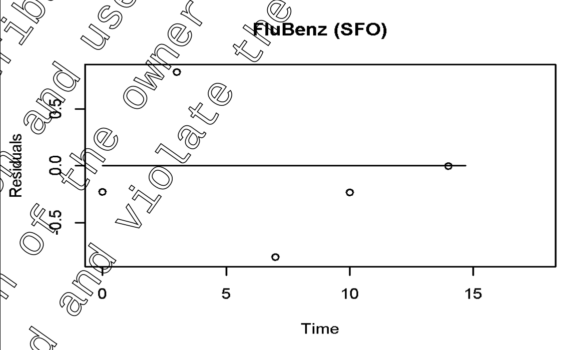
Table 8.9- 162: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2007 0014/8, Villers-Perwin, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.2	k: 0.25165	17.5	k: 0.008	k: 0.15	k: 0.35	**2.754**	9.15
FOMC	o	7.2	α: 12820 β: 50930	20.0	-	β: 49460.00	β: 52391.04	2.754	9.15
DFOP	o	7.2	k1: 0.252 k2: 2.2 E-14 g: 1.0	24.9	k1: 0.180 k2: <0.001	k1: -0.06 k2: 2.2 E-14	k1: 0.56 k2: < 0.0005	2.754	9.15
HS	-	7.1	k1: 0.1844 k2: 0.3906 tb: 3.0	10.0	k1: 0.431 k2: 0.309	k1: -1.45 k2: -0.73	k1: 1.82 k2: 1.51	3.359	7.48

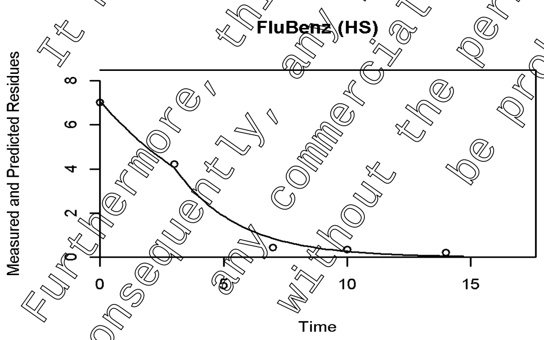
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is slightly > 15 %. FOMC, DFOP and HS did not result in an improved statistical or visual fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



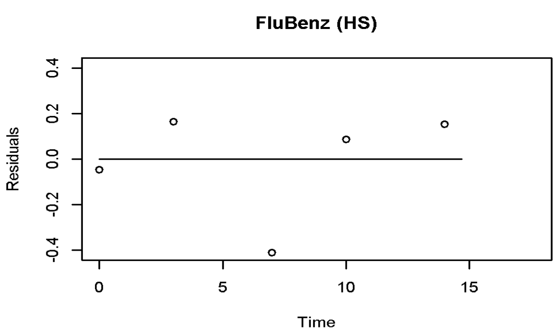
SFO



SFO



HS



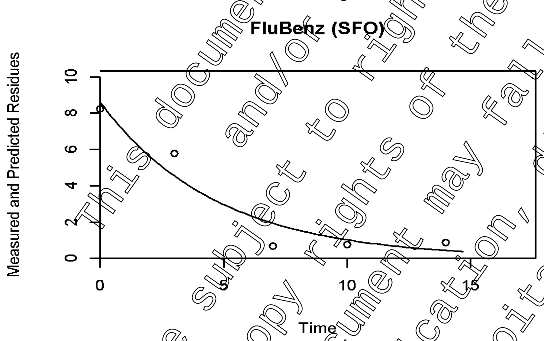
HS

R 2007 0035/0, Chazay d'Azergues, M-297564-01-1, FR, beans

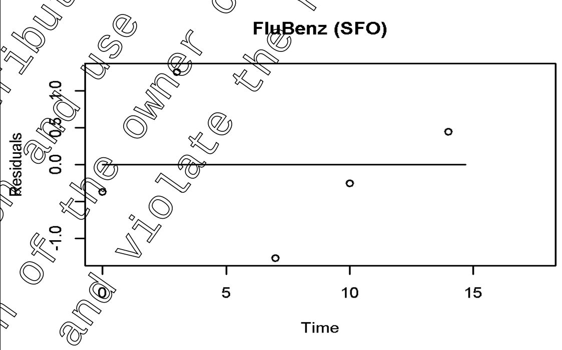
Table 8.9- 163: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2007 0035/0, Chazay d'Azergues, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	8.6	k: 0.21313	20.6	k: 0.014	k: 0.11	k: 0.32	**3.252**	10.80
FOMC	o	8.6	α: 10705.987 β: 50228.649	23.6	-	β: 48903.32	β: 51553.97	3.252	10.80
DFOP	o	8.6	k1: 0.213 k2: 2.2 E-14 g: 1.0	29.4	k1: 0.237 k2: <0.001	k1: -0.17 k2: 2.2 E-14	k1: 0.60 k2: < 0.0005	3.252	10.80
HS	o	8.6	k1: 0.219 k2: 0.019 tb: 10.101	28.5	k1: 0.133 k2: 0.490	k1: 0.03 k2: -1.12	k1: 0.41 k2: 1.16	3.169	14.97

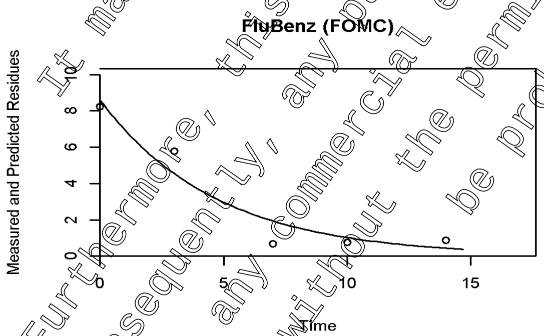
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved statistical or visual fit, mainly due to the partly scattering data. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



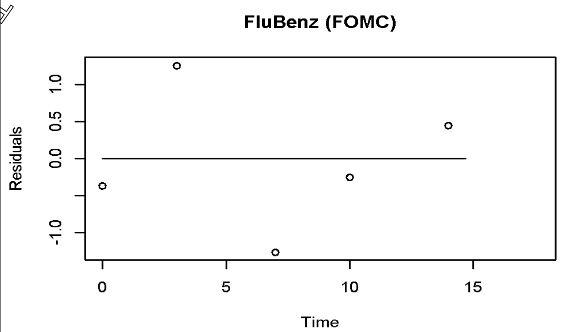
SFO



SFO



FOMC



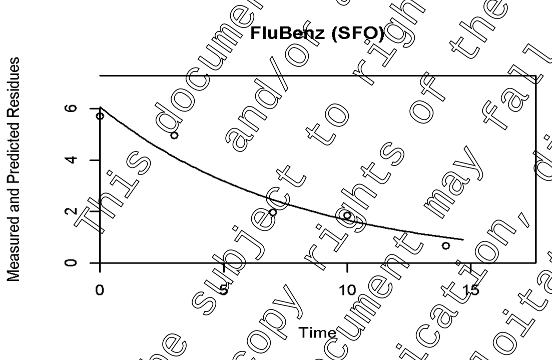
FOMC

R 2007 0036/9, Kopstukken, M-298639-01-1, NL, pea

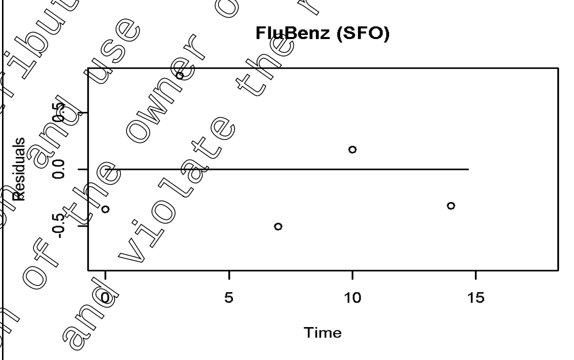
Table 8.9- 164: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for pea of trial R 2007 0036/9, Kopstukken, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	6.1	k: 0.12868	12.9	k: 0.007	k: 0.08	k: 0.18	**5.387**	17.89
FOMC	o	6.1	α: 633900 β: 4924000	14.8	-	β: 4924000	β: 4924000	5.385	17.89
DFOP	o	6.1	k1: 0.129 k2: 0.066 g: 1.0	18.4	k1: 0.380 k2: <0.001	k1: -0.51 k2: 0.07	k1: 0.76 k2: 0.07	5.387	17.89
HS	o	6.1	k1: 0.129 k2: 0.115 tb: 19.599	18.4	k1: 0.103 k2: <0.001	k1: 0.04 k2: 0.12	k1: 0.21 k2: 0.12	5.387	17.89

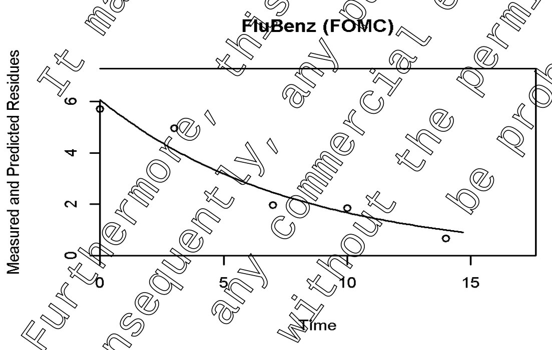
SFO fit is statistically and visually acceptable (χ^2err <15 %, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



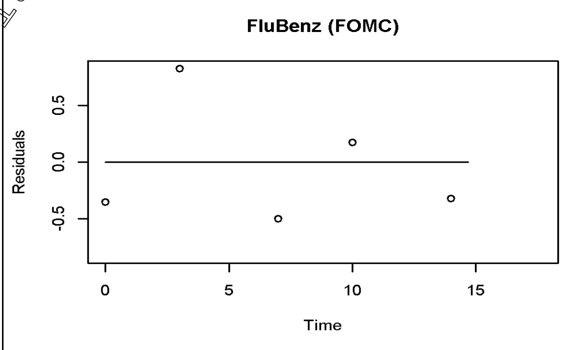
SFO



SFO



FOMC



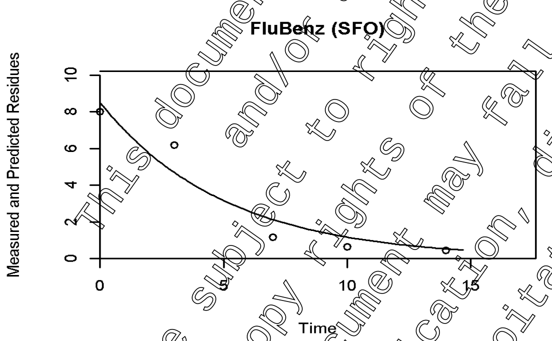
FOMC

R 2007 0037/7, Chazay d'Azergues, M-297487-01-1, FR, pea

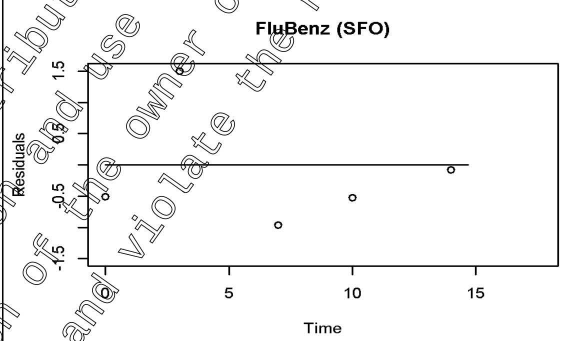
Table 8.9- 165: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for pea of trial R 2007 0037/7, Chazay d'Azergues, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	8.5	k: 0.19822	21.0	k: 0.015	k: 0.10	k: 0.30	**3.497**	11.62
FOMC	o	8.5	α: 7316.792 β: 36909.459	23.9	-	β: 36050.86	β: 37768.11	3.497	11.62
DFOP	o	8.5	k1: 0.198 k2: 2.2 E-14 g: 1.0	29.9	k1: 0.250 k2: <0.001	k1: -0.19 k2: 2.2 E-14	k1: 0.59 k2:< 0.0005	3.497	11.62
HS	o	8.5	k1: 0.198 k2: 2.2 E-14 tb: 17.03	29.9	k1: 0.133 k2: <0.001	k1: 0.03 k2: 2.2 E-14	k1: 0.37 k2:< 0.0005	3.497	11.62

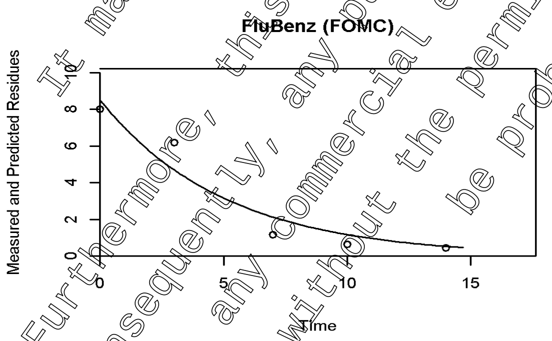
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved statistical or visual fit, mainly due to the partly scattering data. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



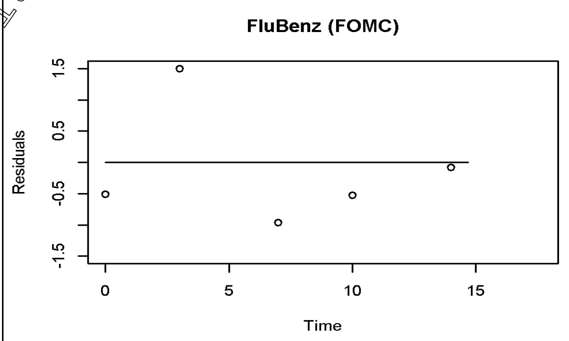
SFO



SFO



FOMC



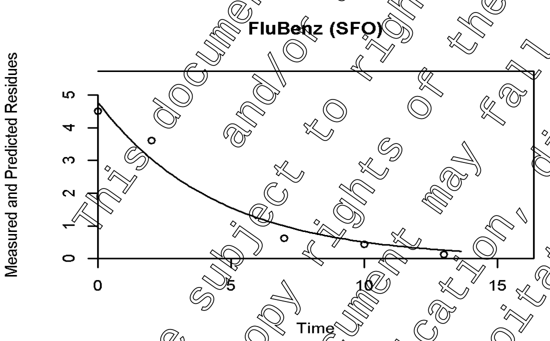
FOMC

R 2007 0244/2, Meckenbeuren, M-304280-01-1, DE, lettuce

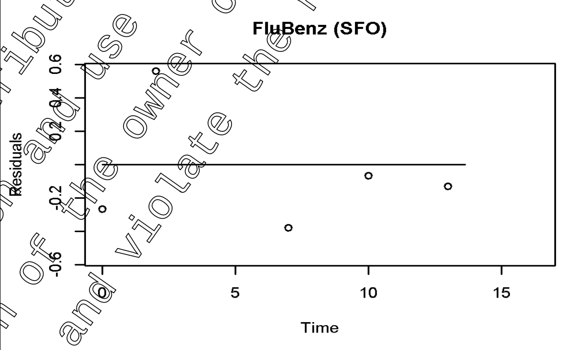
Table 8.9- 166: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce head of trial R 2007 0244/2, Meckenbeuren, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.8	k: 0.2241	14.2	k: 0.007	k: 0.14	k: 0.31	**3.092**	10.27
FOMC	o	4.8	α: 13380 β: 59680	16.3	-	β: 58350.00	β: 61000.08	3.092	10.27
DFOP	o	4.8	k1: 0.224 k2: 2.2 E-14 g: 1.0	20.3	k1: 0.202 k2: <0.001	k1: 0.10 k2: 2.2 E-14	k1: 0.55 k2: < 0.0005	3.092	10.27
HS	-	4.5	k1: 0.10978 k2: 0.32112 tb: 1.975	5.4	k1: 0.099 k2: 0.045	k1: 0.04 k2: 0.23	k1: 0.18 k2: 0.41	3.458	8.47

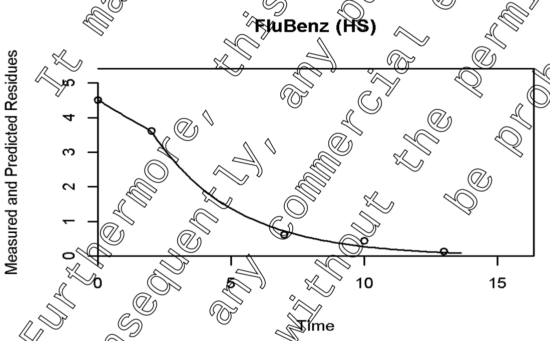
SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved statistical or visual fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



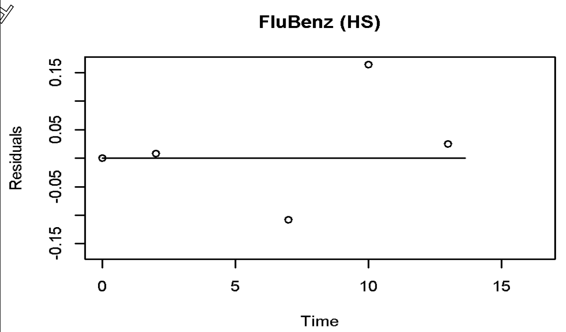
SFO



SFO



HS



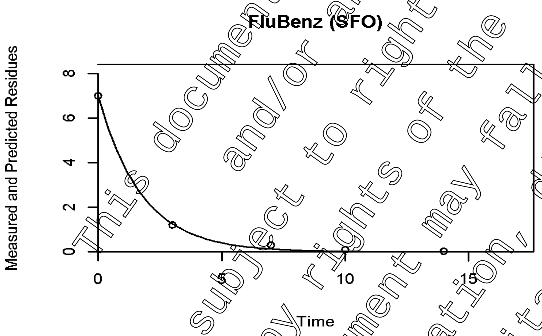
HS

R 2007 0245/0, Agia Marina, M-304278-01-1, GR, lettuce

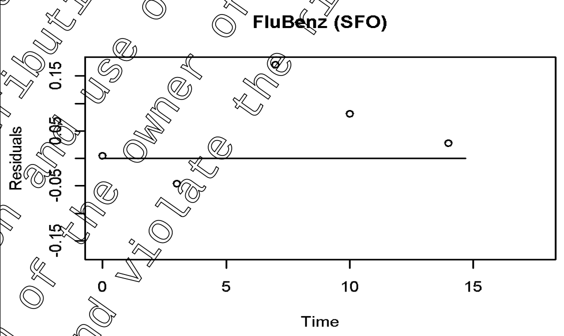
Table 8.9- 167: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial R 2007 0245/0, Agia Marina, GR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	7.0	k: 0.5703	4.1	k: <0.001	k: 0.51	k: 0.63	**1.215**	4.038
FOMC	+	7.0	α: 3.61717 β: 4.83781	0.9	-	β: 3.17	β: 6.51	1.022	4.306
DFOP	+	7.0	k1: 13.767939 k2: 0.350011 g: 0.503	0.1	k1: NA k2: 0.003	k1: NA k2: 0.34	k1: NA k2: 0.36	0.193	4.583
HS	+	7.0	k1: 0.5828289 k2: 0.3439309 tb: 3.419	0.1	k1: <0.001 k2: 0.009	k1: 0.58 k2: 0.32	k1: 0.59 k2: 0.36	1.189	4.529

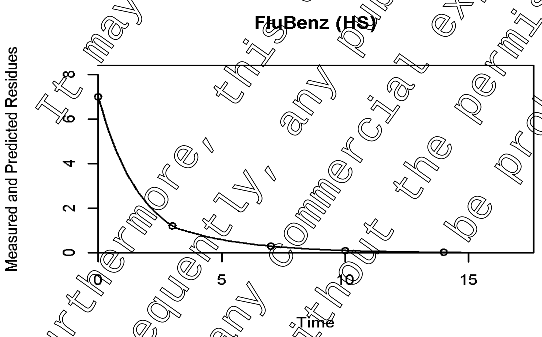
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



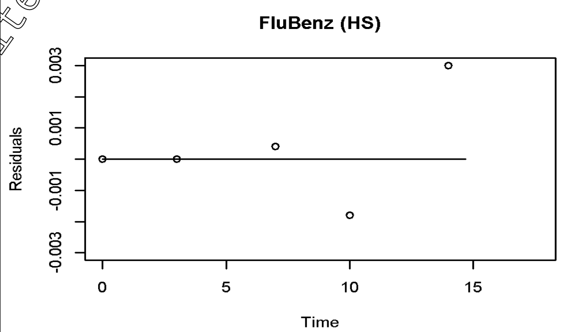
SFO



SFO



HS



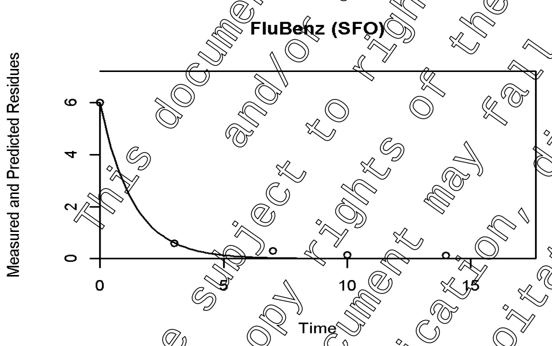
HS

R 2007 0246/9, Ouzilly, M-304278-01-1, FR, lettuce

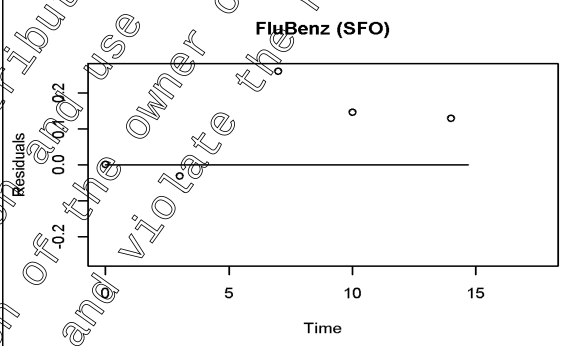
Table 8.9- 168: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial R 2007 0246/9, Ouzilly, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	6.0	k: 0.7617	8.2	k: 0.003	k: 0.56	k: 0.96	**0.910**	3.023
FOMC	+	6.0	α: 1.03958 β: 0.3568	1.3	-	β: 0.12	β: 0.60	0.338	2.912
DFOP	+	6.0	k1: 1.3189 k2: 0.13734 g: 0.880	1.5	k1: 0.124 k2: 0.126	k1: 0.26 k2: 0.02	k1: 2.38 k2: 0.25	0.618	2.907
HS	+	6.0	k1: 0.77938 k2: 0.13847 tb: 3.286	1.5	k1: 0.010 k2: 0.123	k1: 0.73 k2: 0.03	k1: 0.83 k2: 0.25	0.889	2.954

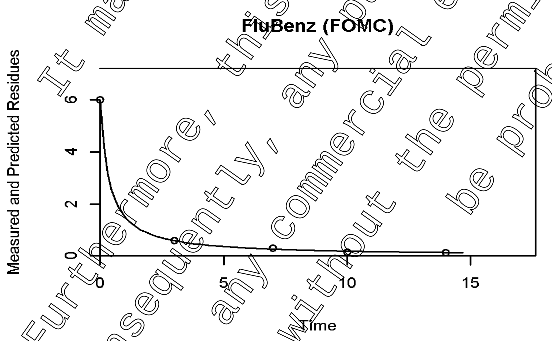
SFO fit is statistically and visually good to acceptable (χ^2 err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before 3 d), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



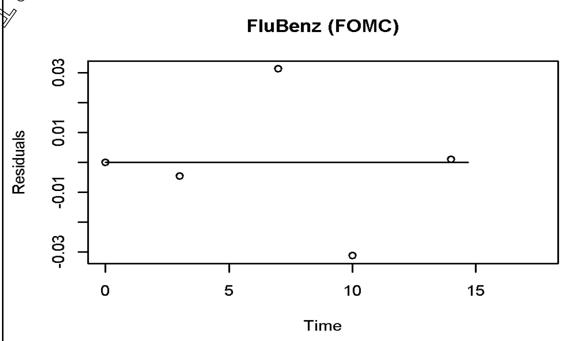
SFO



SFO



FOMC



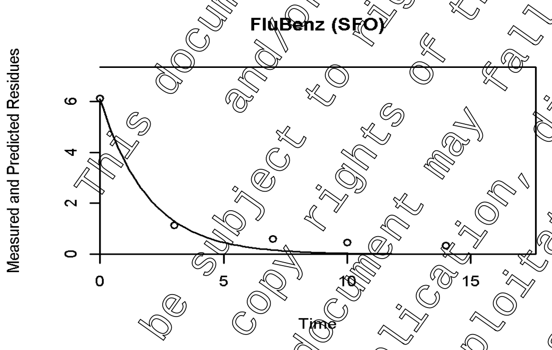
FOMC

R 2007 0537/9, Langenfeld Reusrath, M-304280-01-1, DE, lettuce

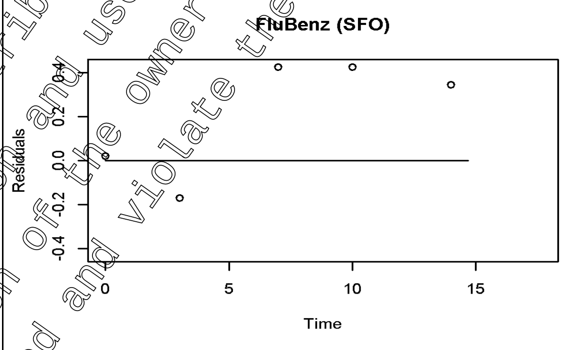
Table 8.9- 169: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial R 2007 0537/9, Langenfeld Reusrath, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	6.1	k: 0.5152	14.8	k: 0.008	k: 0.31	k: 0.72	1.346	4.47
FOMC	+	6.1	α: 0.819534 β: 0.436511	0.27	-	β: 0.39	β: 0.48	0.581	6.811
DFOP	+	6.1	k1: 0.888947 k2: 0.072576 g: 0.843	0.18	k1: 0.006 k2: 0.014	k1: 0.86 k2: 0.07	k1: 0.92 k2: 0.08	0.977	6.544
HS	+	6.1	k1: 0.563115 k2: 0.075565 tb: 3.725	0.28	k1: 0.002 k2: 0.019	k1: 0.56 k2: 0.07	k1: 0.57 k2: 0.08	1.231	6.438

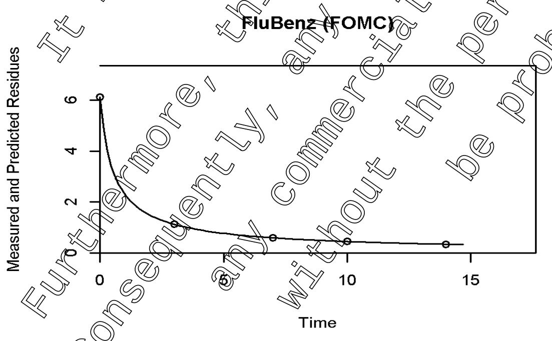
SFO fit is statistically acceptable (χ^2err <15%, t-test <0.05), but visually poor. DFOP, FOMC and HS fits were alternatively tested. DFOP fit is visually good, with lowest $\chi2$ err. Consequently, **DFOP** model is considered appropriate according to modelling purpose (FOCUS kinetics) and as best visual fit. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT50 is an adequate option.



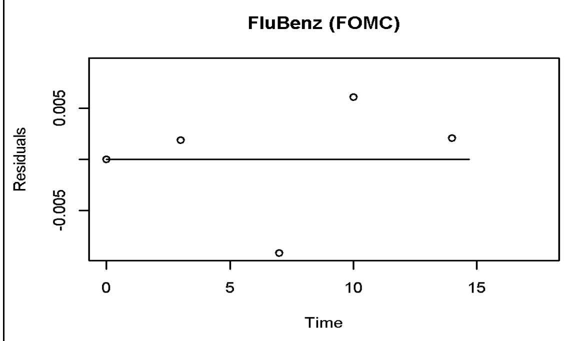
SFO



SFO



FOMC



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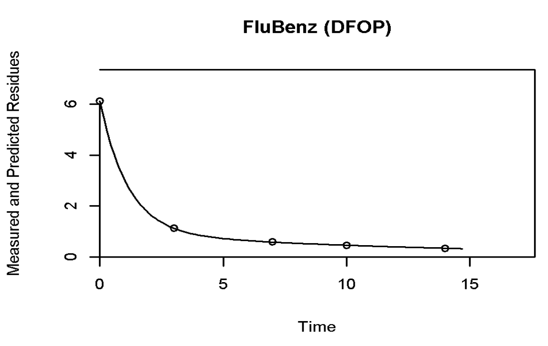
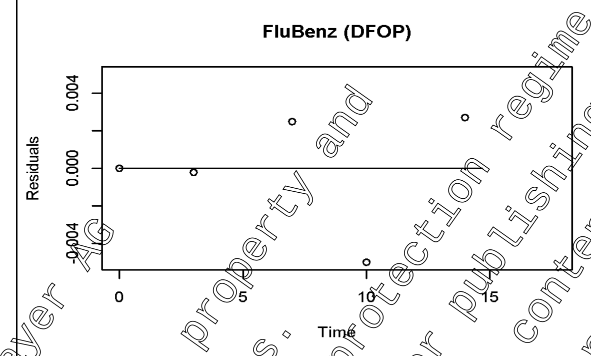
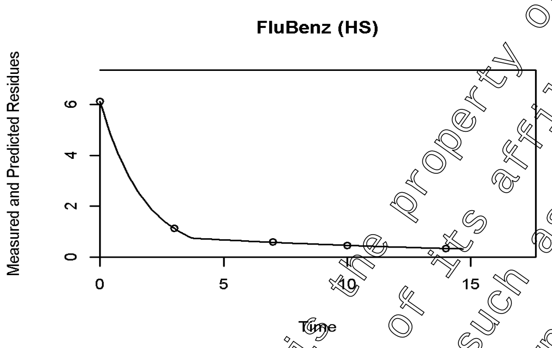


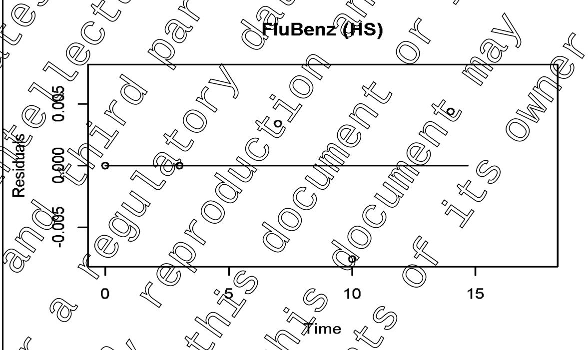
DFOP



DFOP



HS



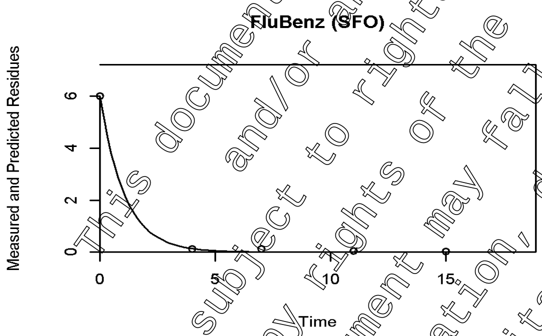
HS

R 2007 0538/7, Puzeaux, M-304280-01-1, FR, lettuce

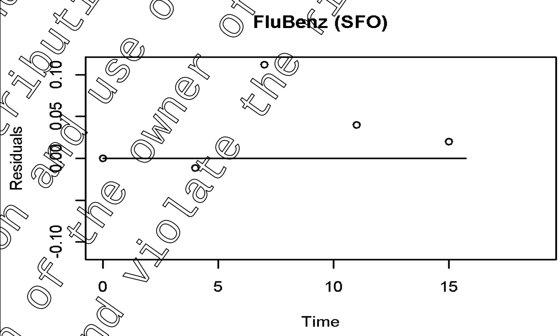
Table 8.9- 170: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial R 2007 0538/7, Puzeaux, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	6.0	k: 0.94598	3.4	k: 0.003	k: 0.70	k: 1.20	**0.733**	2.43
FOMC	o	6.0	α: 0.95011 β: 0.07633	1.5	-	β: -0.26	β: 0.41	0.082	0.79
DFOP	o	6.0	k1: 9233 k2: 0.1376 g: 0.960	1.4	k1: <0.001 k2: 0.159	k1: 9233 k2: -0.01	k1: 9232.60 k2: 0.28	7.5 E-5	3.08 E-4
HS	+	6.0	k1: 1.043872 k2: 0.13762 tb: 3.562	1.4	k1: 0.021 k2: 0.159	k1: 0.91 k2: -0.01	k1: 1.18 k2: 0.28	0.664	2.21

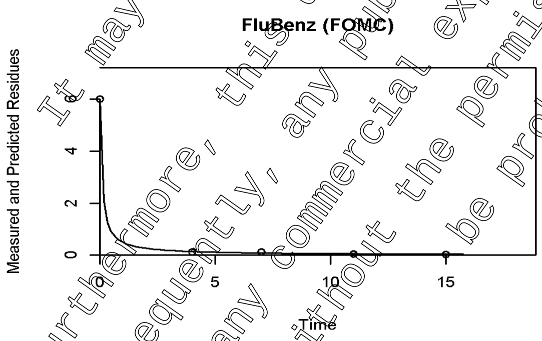
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



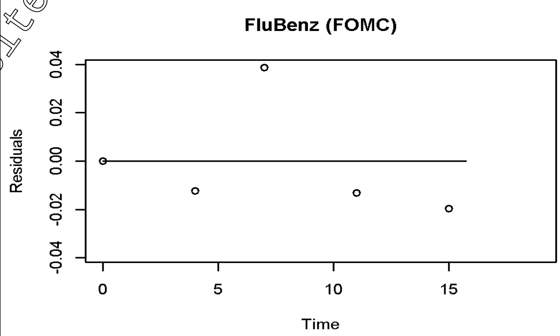
SFO



SFO



FOMC



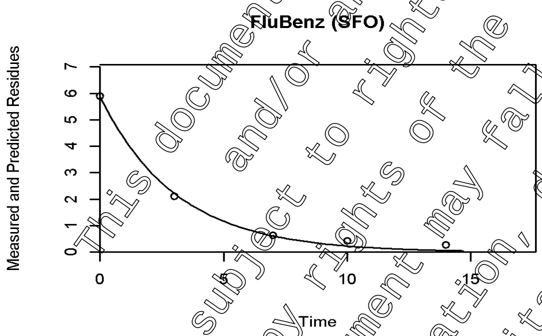
FOMC

R 2007 0539/5, Villers-Perwin, M-304280-01-1, BE, lettuce

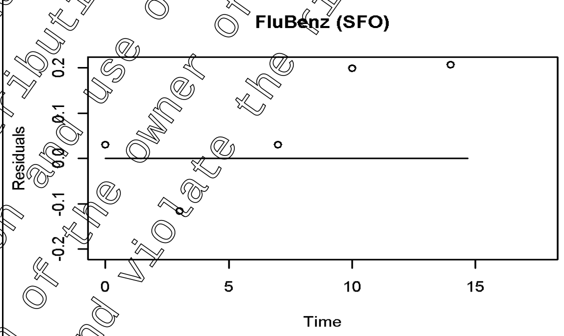
Table 8.9- 171: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial R 2007 0539/5, Villers-Perwin, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	5.9	k: 0.32355	6.0	k: <0.001	k: 0.28	k: 0.37	**2.142**	7.117
FOMC	+	5.9	α: 3.54074 β: 8.74633	2.8	-	β: 1.63	β: 15.87	1.891	8.013
DFOP	+	5.9	k1: 0.374417 k2: 0.005721 g: 0.954	1.4	k1: 0.024 k2: 0.477	k1: 0.32 k2: -0.15	k1: 0.43 k2: 0.16	1.981	7.591
HS	+	5.9	k1: 0.343037 k2: 0.125422 tb: 6.497	0.3	k1: 0.001 k2: 0.013	k1: 0.34 k2: 0.12	k1: 0.35 k2: 0.14	2.021	7.606

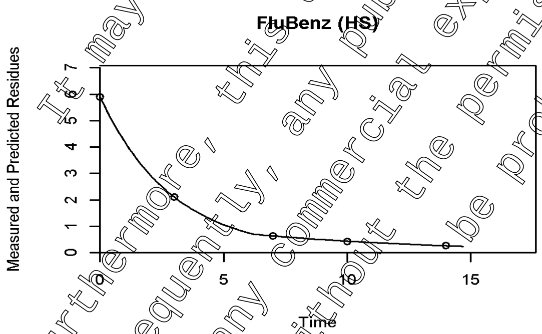
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



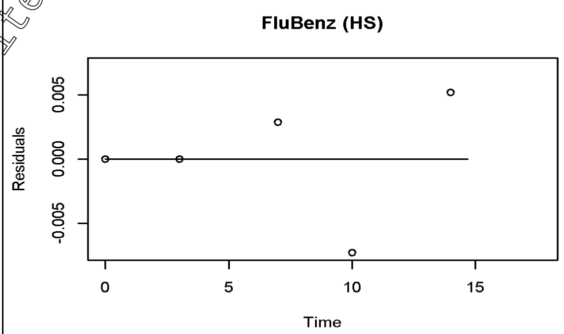
SFO



SFO



HS



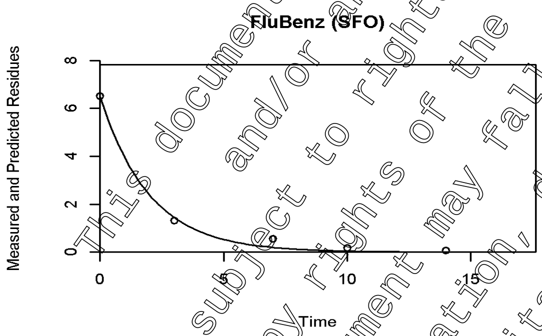
HS

R 2007 0540/9, Zwaagdijk, M-304280-01-1, NL, lettuce

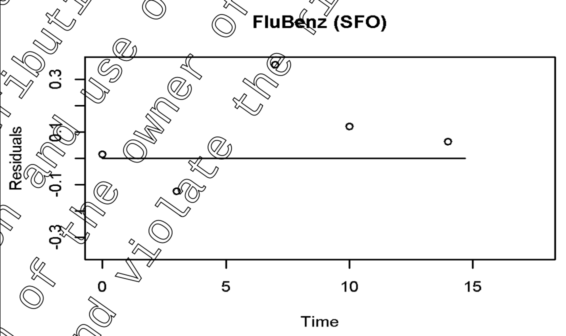
Table 8.9- 172: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial R 2007 0540/9, Zwaagdijk, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	6.5	k: 0.50143	8.3	k: 0.001	k: 0.40	k: 0.60	**1.382**	4.59
FOMC	+	6.5	α: 2.17735 β: 2.81413	3.7	-	β: -0.06	β: 5.68	1.055	5.29
DFOP	+	6.5	k1: 13.590 k2: 0.2503 g: 0.568	2.7	k1: <0.001 k2: 0.046	k1: 13.59 k2: 0.18	k1: 13.59 k2: 0.32	0.142	5.85
HS	+	6.5	k1: 0.54049 k2: 0.25031 tb: 2.890	2.7	k1: 0.014 k2: 0.046	k1: 0.49 k2: 0.18	k1: 0.59 k2: 0.32	1.282	5.85

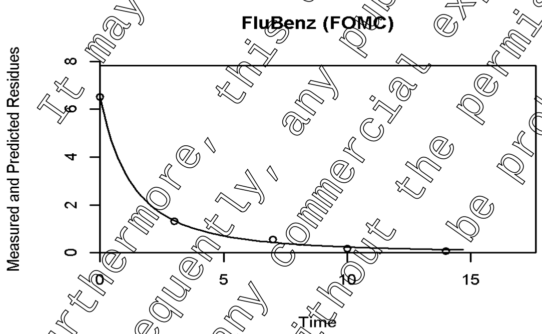
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



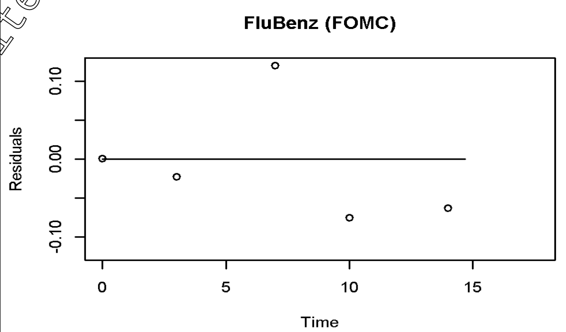
SFO



SFO



FOMC



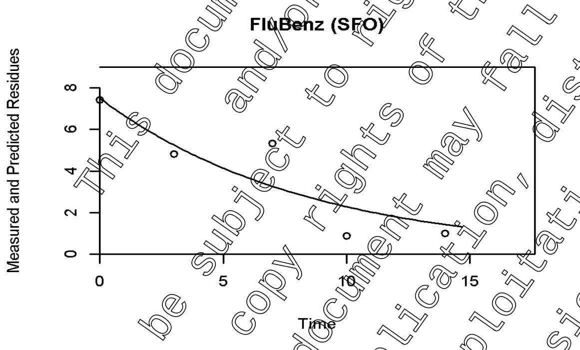
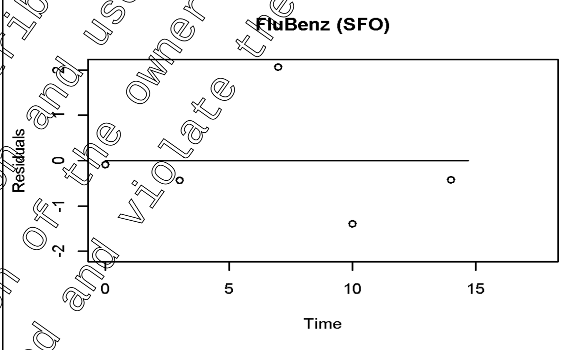
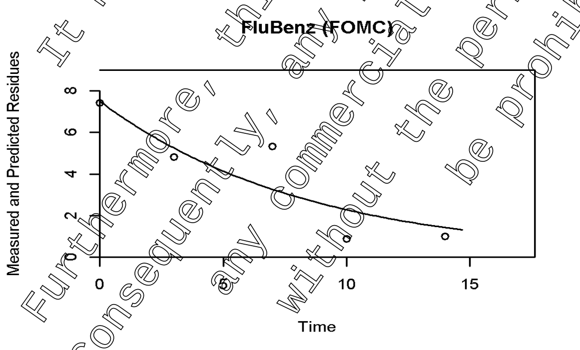
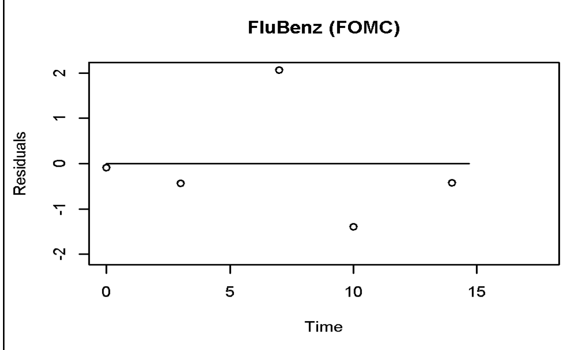
FOMC

R 2007 0541/7, Manfredonia, M-304278-01-1, IT, lettuce

Table 8.9- 173: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for lettuce of trial R 2007 0541/7, Manfredonia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.5	k: 0.11875	23.6	k: 0.037	k: 0.03	k: 0.21	**5.837**	19.39
FOMC	o	7.5	α: 15270 β: 128600	27.0	-	β: 127000	β: 130186.02	5.837	19.39
DFOP	o	7.5	k1: 0.119 k2: 0.063 g: 1.0	33.7	k1: 0.441 k2: <0.001	k1: -1.13 k2: 0.06	k1: 1.37 k2: 0.06	5.837	19.39
HS	o	7.5	k1: 0.141 k2: 0.119 tb: 4E-14	33.7	k1: NA k2: 0.254	k1: NA k2: -0.12	k1: NA k2: 0.36	5.837	19.39

SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.

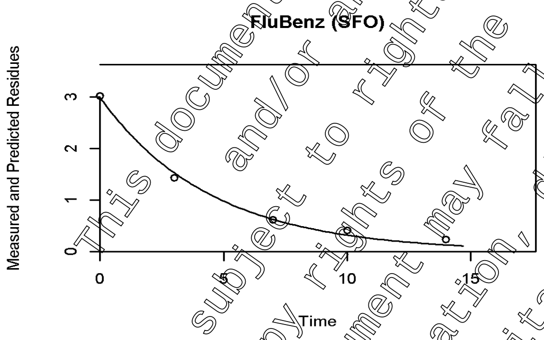
 SFO	 SFO
 FOMC	 FOMC

R 2007 0546/8, Langenfeld-Reusrath, M-297562-01-1, DE, beans

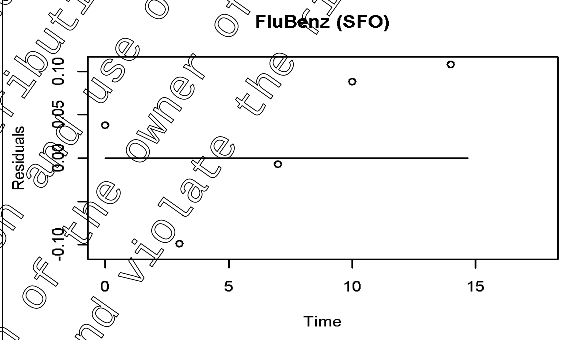
Table 8.9- 174: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2007 0546/8, Langenfeld-Reusrath, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.0	k: 0.22275	5.5	k: <0.001	k: 0.19	k: 0.25	**3.112**	10.34
FOMC	+	3.0	α: 3.13832 β: 11.02517	1.1	-	β: 7.18	β: 14.87	2.725	11.94
DFOP	+	3.0	k1: 0.31747 k2: 0.07729 g: 0.787	0.9	k1: 0.043 k2: 0.167	k1: 0.23 k2: -0.01	k1: 0.40 k2: 0.17	2.756	12.13
HS	+	3.0	k1: 0.2491941 k2: 0.1361692 tb: 5.584	0.1	k1: <0.001 k2: 0.003	k1: 0.25 k2: 0.13	k1: 0.25 k2: 0.14	2.782	12.27

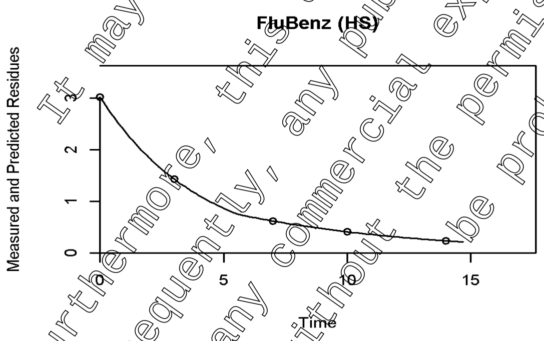
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



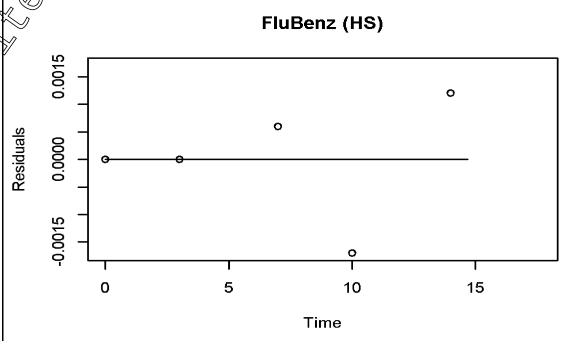
SFO



SFO



HS



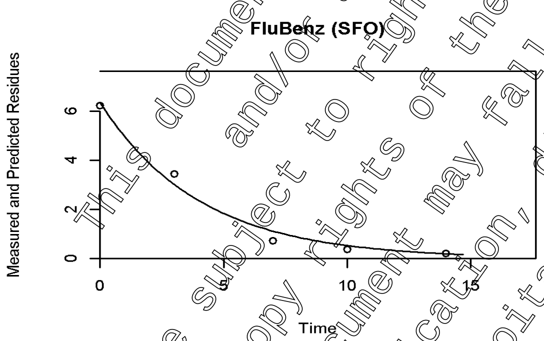
HS

R 2007 0547/6, Fresnoy les Roye, M-297562-01-1, FR, beans

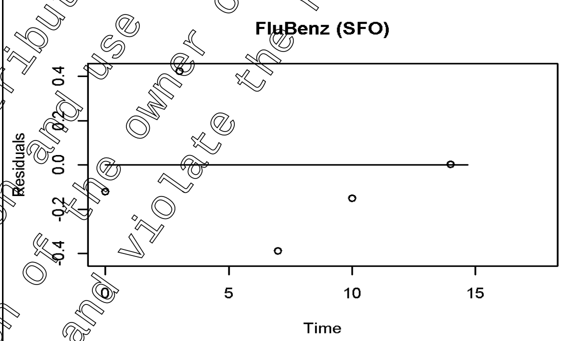
Table 8.9- 175: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2007 0547/6, Fresnoy les Roye, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	6.4	k: 0.24812	9.9	k: 0.002	k: 0.19	k: 0.30	**2.794**	9.28
FOMC	o	6.4	α: 2026000 β: 8169000	11.3	-	β: 8169000	β: 8169000	2.794	9.28
DFOP	o	6.4	k1: 0.248 k2: 2.2 E-14 g: 1.0	14.1	k1: 0.112 k2: <0.001	k1: 0.07 k2: 2,2 E-14	k1: 0.43 k2: < 0.0005	2.794	9.28
HS	o	6.4	k1: 0.248122 k2: 0.005153 tb: 15.444	14.1	k1: 0.063 k2: <0.001	k1: 0.15 k2: 0.01	k1: 0.35 k2: 0.01	2.794	9.28

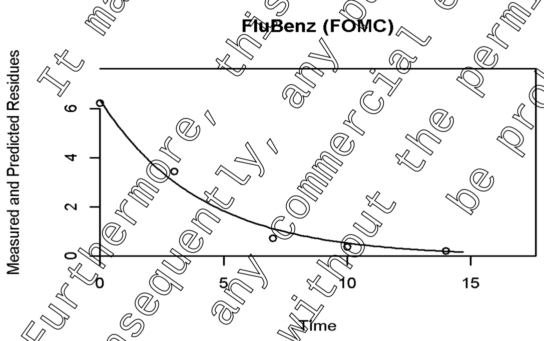
SFO fit is statistically and visually acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



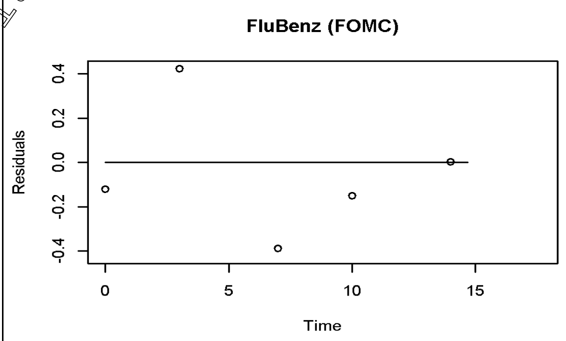
SFO



SFO



FOMC



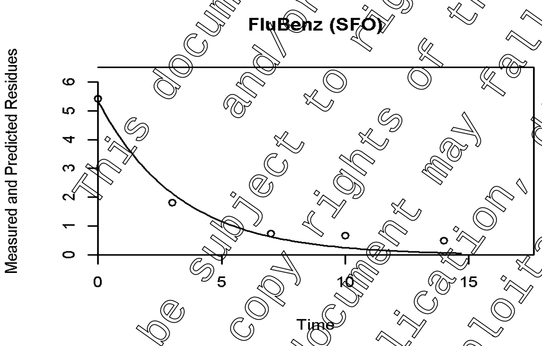
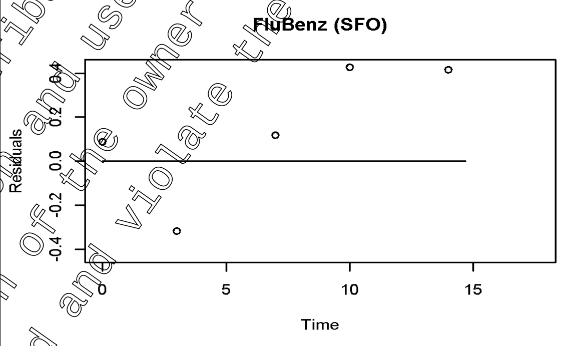
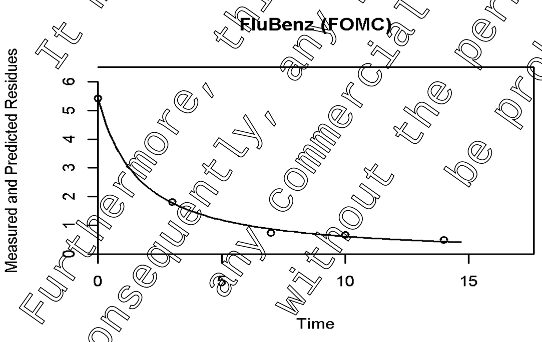
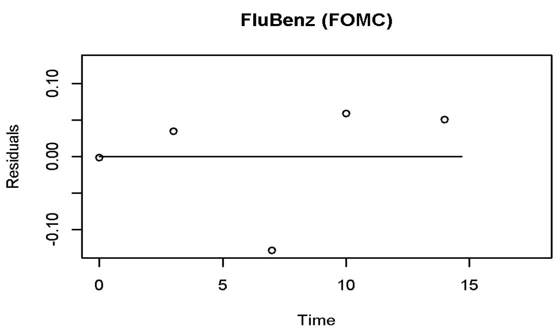
FOMC

R 2007 0548/4, Biddinghuizen, M-297562-01-1, NL, beans

Table 8.9- 176: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2007 0548/4, Biddinghuizen, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO		5.3	k: 0.30469	13.5	k: 0.005	k: 0.20	k: 0.41	2.275	7.56
FOMC		5.4	α: 1.2021 β: 1.9741	3.4	-	β: 0.46	β: 3.48	1.540	11.43
DFOP		5.4	k1: 16.28386 k2: 0.14906 g: 0.494	7.7	k1: <0.001 k2: 0.098	k1: 16.28 k2: 0.06	k1: 16.28 k2: 0.24	0.231	10.87
HS		5.4	k1: 0.363753 k2: 0.058478 tb: 5.063	1.2	k1: 0.008 k2: 0.079	k1: 0.35 k2: 0.03	k1: 0.38 k2: 0.09	1.906	12.94

SFO fit is statistically acceptable (χ^2err <15%, t-test <0.05), but visually poor to borderline. DFOP, FOMC and HS fits were alternatively tested. HS fit is statistically (χ^2err, t-test) and visually good, with lowest $\chi2$ err and most reliable degradation rates (of DFOP or HS). Consequently, **HS** model is considered appropriate according to modelling purpose (FOCUS kinetics) and as best visual fit. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT_{50} is an adequate option.

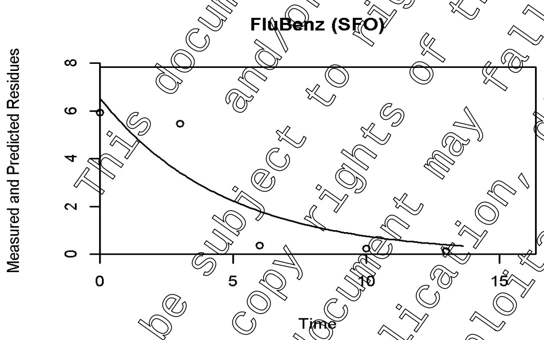
 SFO	 SFO
 FOMC	 FOMC

R 2007 0549/2, Swisttal Heimerzheim, M-297562-01-1, DE, beans

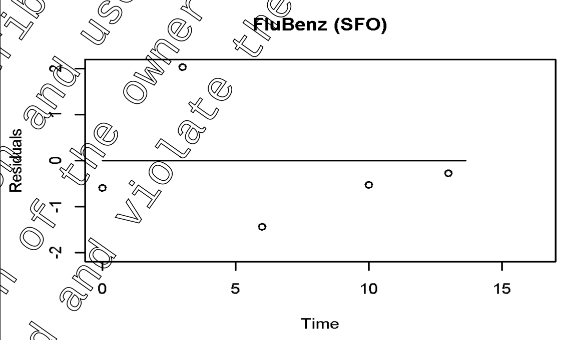
Table 8.9- 177: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2007 0549/2, Swisttal Heimerzheim, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	6.5	k: 0.21516	38.8	k: 0.058	k: 0.02	k: 0.41	**3.221**	10.70
FOMC	o	6.5	α: 36460 β: 169400	44.3	-	β: 169400	β: 169400	3.221	10.70
DFOP	o	6.5	k1: 0.215 k2: 2.2 E-14 g: 1.0	55.3	k1: 0.330 k2: <0.001	k1: -0.50 k2: 2.2 E-14	k1: 0.93 k2: < 0.0005	3.222	10.70
HS	o	6.5	k1: 0.215 k2: 2.2 E-14 tb: 17.72	55.3	k1: 0.213 k2: <0.001	k1: -0.12 k2: 2.2 E-14	k1: 0.55 k2: < 0.0005	3.222	10.70

SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



SFO



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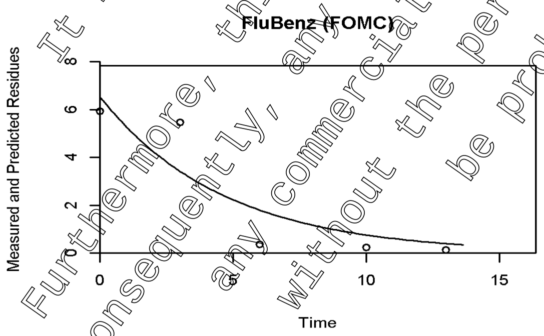
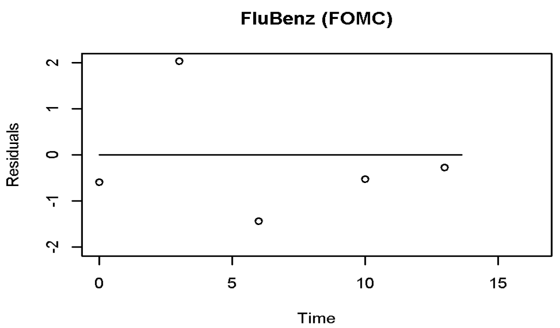


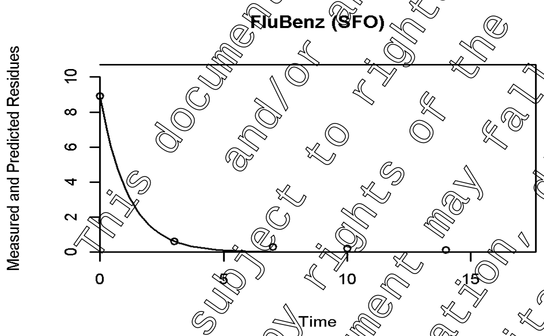
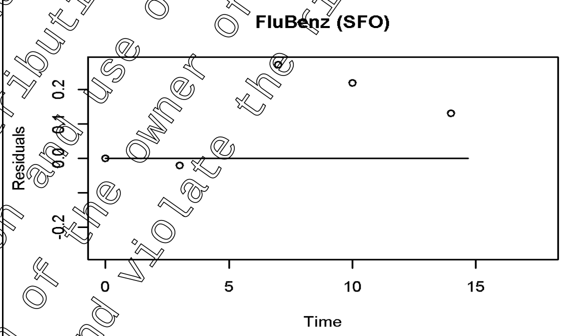
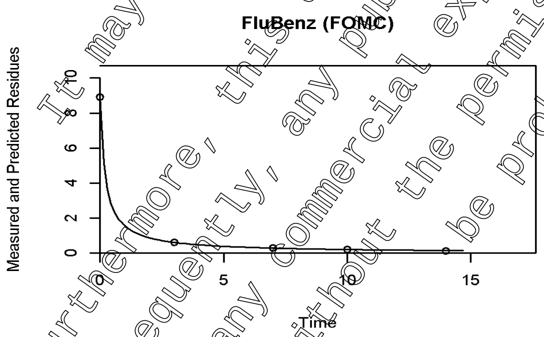
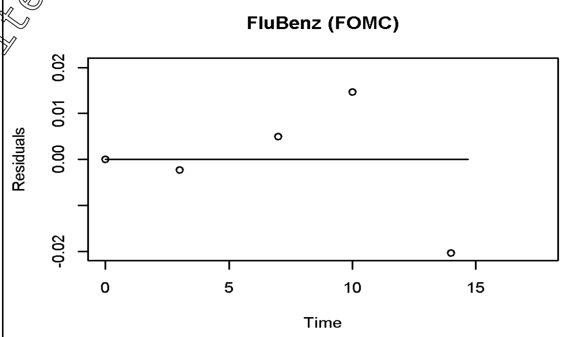
FOMC



FOMC

R 2007 0550/6, Ladispoli, M-297564-01-1, IT, beans

Table 8.9- 178: Kinetic goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2007 0550/6, Ladispoli, IT

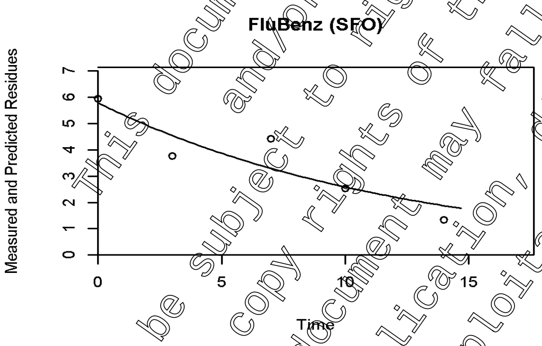
Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	8.9	k: 0.8834	6.6	k: 0.002	k: 0.66	k: 1.11	**0.785**	2.61
FOMC	+	8.9	α: 0.93981 β: 0.18411	0.5	-	β: 0.11	β: 0.26	0.201	1.95
DFOP	+	8.9	k1: 121600 k2: 0.154 g: 0.893	1.1	k1: NA k2: 0.046	k1: NA k2: 0.11	k1: NA k2: 0.20	5.7 E-6	0.416
HS	+	8.9	k1: 0.894197 k2: 0.110041 tb: 3.371	0.3	k1: 0.002 k2: 0.035	k1: 0.88 k2: 0.09	k1: 0.91 k2: 0.13	0.775	2.58
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).									
 SFO					 SFO				
 FOMC					 FOMC				

R 2007 0551/4, Alginet, M-297564-01-1, ES, beans

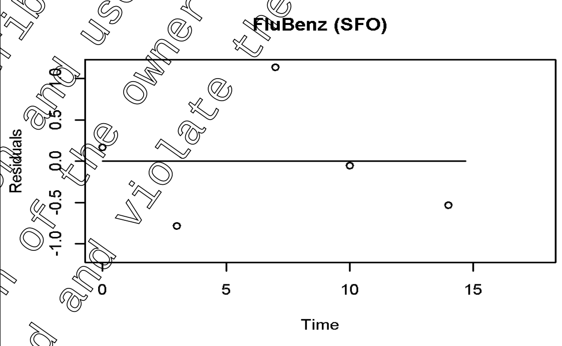
Table 8.9- 179: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2007 0551/4, Alginet, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	5.8	k: 0.08044	14.8	k: 0.024	k: 0.03	k: 0.13	**8.617**	28.63
FOMC	o	5.8	α: 5152 β: 64040	16.9	-	β: 63740	β: 64347.07	8.617	28.63
DFOP	o	5.8	k1: 0.08044 k2: 0.08044 g: 0.176	21.1	k1: 0.042 k2: 0.176	k1: 0.06 k2: -0.02	k1: 0.10 k2: 0.18	8.617	28.63
HS	o	6.0	k1: 0.14098 k2: 0.07101 tb: 1.569	20.6	k1: 0.355 k2: 0.231	k1: -0.42 k2: -0.05	k1: 0.70 k2: 0.20	8.215	30.88

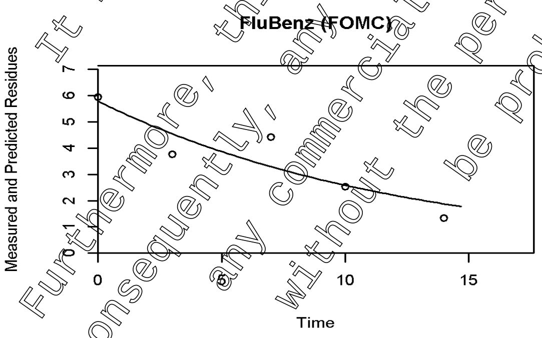
SFO fit is statistically and visually acceptable (χ^2err < 15 %. t-test <0.05). FOMC, DFOP and HS did not result in an improved fit, mainly due to the scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



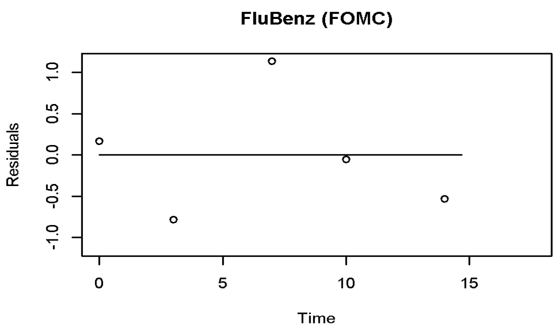
SFO



SFO



FOMC



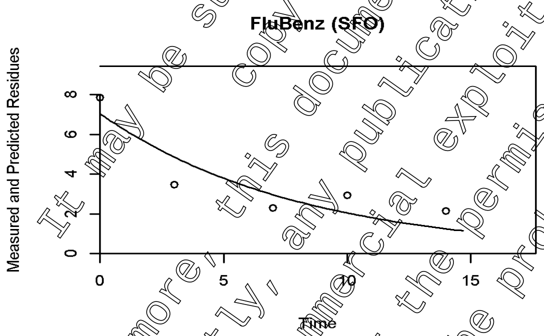
FOMC

R 2007 0552/2, Ribafria Peniche, M-297564-01-1, PT, beans

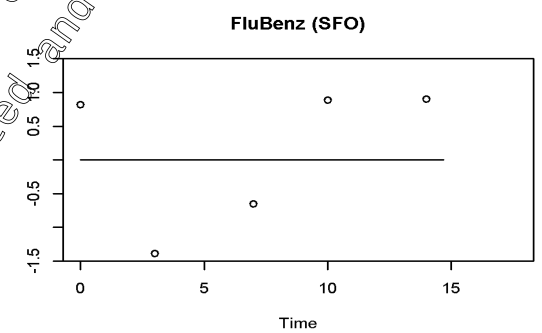
Table 8.9- 180: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for beans of trial R 2007 0552/2, Ribafria Peniche, PT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	7.0	k: 0.1236	20.6	k: 0.028	k: 0.04	k: 0.20	5.608	18.63
FOMC	+	7.9	α: 0.2671 β: 0.13456	6.8	-	β: -0.47	β: 0.73	1.668	746.10
DFOP	+	7.9	k1: 16.40 k2: 0.03701 g: 0.532	9.3	k1: <0.001 k2: 0.225	k1: 16.400 k2: -0.03	k1: 16.402 k2: 0.10	0.166	41.68
HS	+	7.9	k1: 0.27254 k2: 0.012 tb: 3.979	7.7	k1: 0.068 k2: 0.419	k1: 0.16 k2: -0.08	k1: 0.39 k2: 0.10	2.543	105.40

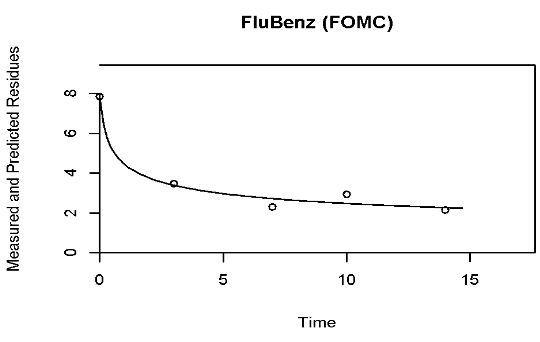
SFO fit is statistically and visually poor (χ^2err >15%, t-test <0.05). FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in $\chi2$ error and visual assessment. However, FOMC is not fully appropriate as 10% of the initial residue was not reached during study duration (decay down to 25 %), leading to an uncertain extrapolation of the DT_{90} far beyond study end. Furtheron, the t-test of DFOP and HS show a low reliability especially of the slow degradation rates k2 (t-test > 0.05). Nevertheless, a clear decay is seen and **DFOP** shows the less uncertain k rates (of HS and DFOP). Thus, the slow phase of DFOP with a $DT_{50\ slow}$ of 18.7 d could be used conservatively. However, this slow phase describes only half of the dissipation behaviour (g = 0.532, ratio of initial mass M0, which dissipates fast), and ignores the faster phase. As the DFOP DT_{90} (41.68 d) is not extrapolated far beyond the study end, a pseudo SFO DT_{50} (DT_{90} / 3.32 = 12.554 d) could be used alternatively, as the pseudo SFO curve lays always above the DFOP curve, until both curves meet at the DT_{90}. So, either **DFOP** with full parameter set, or conservatively, a pseudo SFO DT_{50} of DFOP of 12.554 d is considered appropriate. An influence of precipitation on a biphasic decay can be excluded as almost no rain occurred.



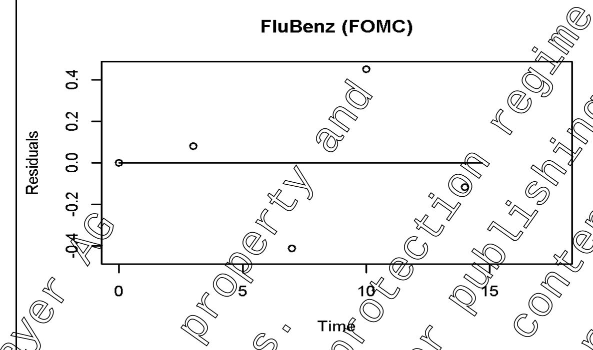
SFO



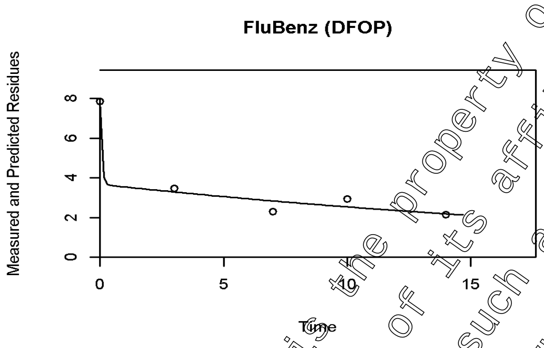
SFO



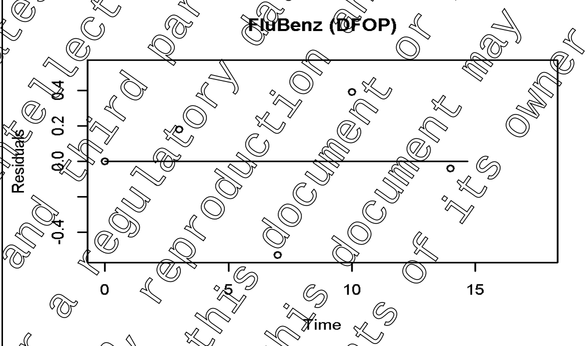
FOMC



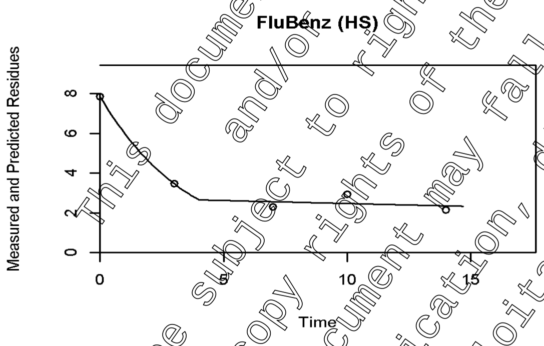
FOMC



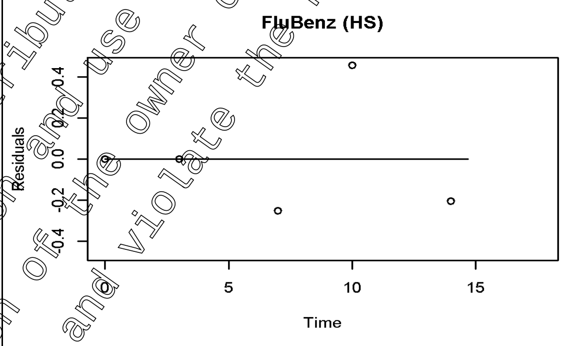
DFOP



DFOP



HS



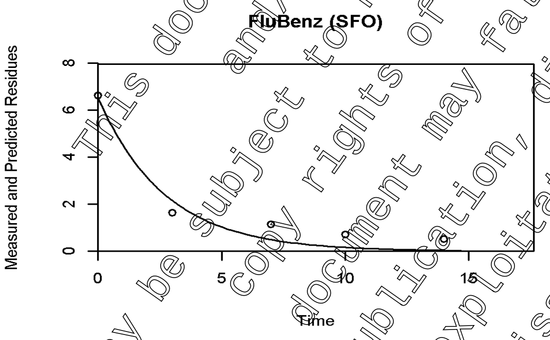
HS

R 2007 0553/0, Burscheid, M-298639-01-1, DE, pea

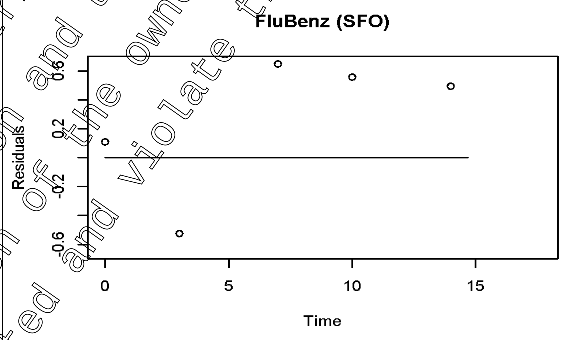
Table 8.9- 181: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for pea of trial R 2007 0553/0, Burscheid, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	6.5	k: 0.36911	18.9	k: 0.013	k: 0.19	k: 0.55	1.878	6.24
FOMC	+	6.6	α: 0.70643 β: 0.49853	3.7	-	β: -0.09	β: 1.09	0.831	12.48
DFOP	+	6.6	k1: 8.400 k2: 0.1057 g: 0.659	2.2	k1: <0.001 k2: 0.039	k1: 8.40 k2: 0.08	k1: 8.40 k2: 0.13	0.165	11.60
HS	+	6.6	k1: 0.476367 k2: 0.10567 tb: 2.905	2.2	k1: 0.013 k2: 0.039	k1: 0.44 k2: 0.08	k1: 0.51 k2: 0.13	1.455	11.60

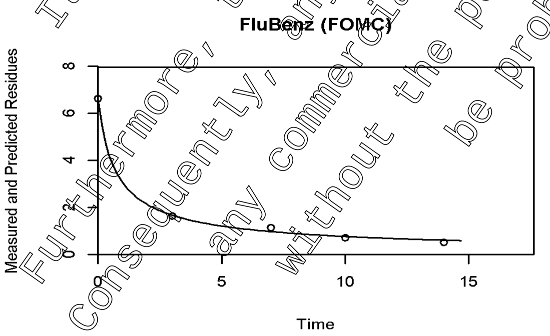
SFO fit is statistically acceptable (χ^2err <15%, t-test <0.05), but visually poor. DFOP, FOMC and HS fits were alternatively tested. HS fit is statistically (χ^2err, t-test) and visually good, with a lowest χ2 err and reliable degradation rates (of DFOP or HS). Consequently, **HS** model is considered appropriate according to modelling purpose (FOCUS kinetics) and as best visual fit. As low residues < 10% are reached at study end, a recalculation of a pseudo SFO DT_{90} is an alternative option.



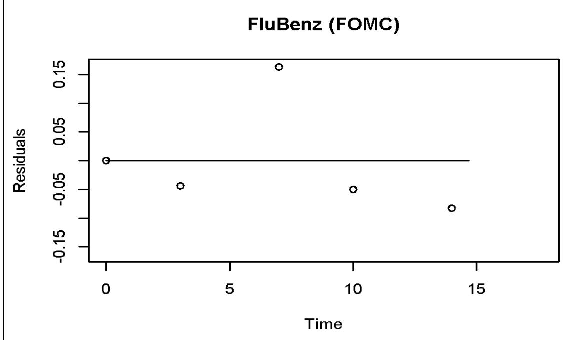
SFO



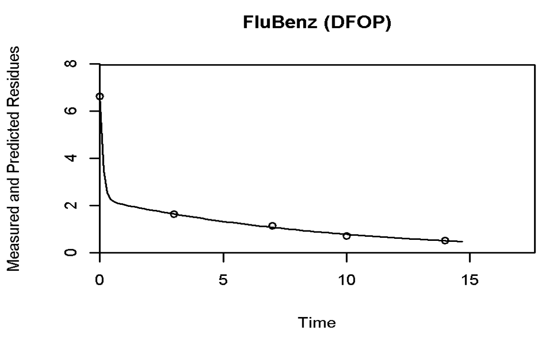
SFO



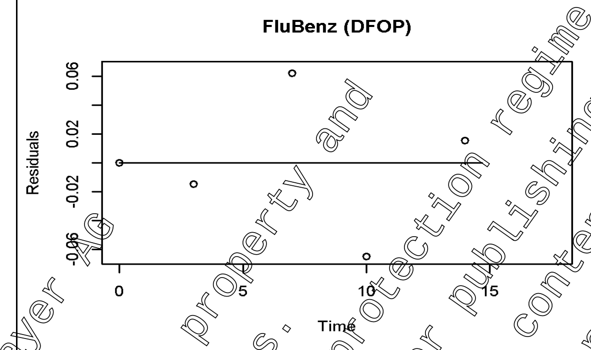
FOMC



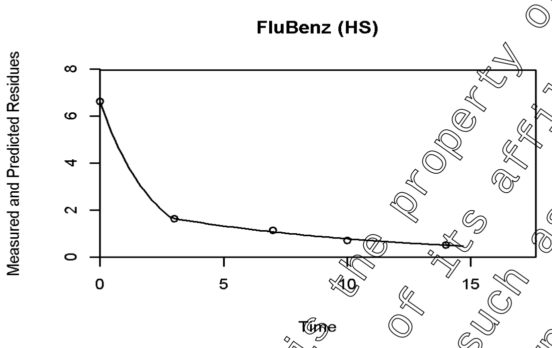
FOMC



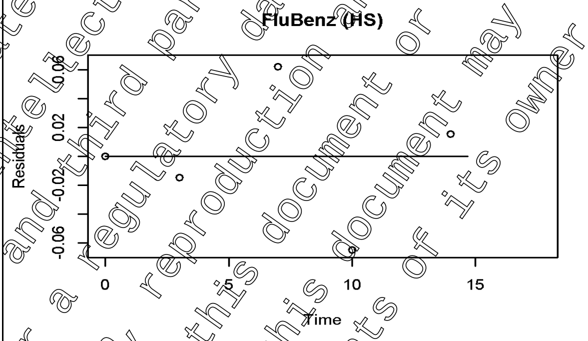
DFOP



DFOP



HS



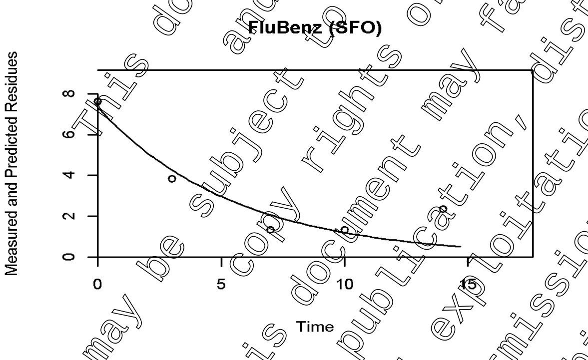
HS

R 2007 0554/9, Goyencourt, M-298639-01-1, FR, pea

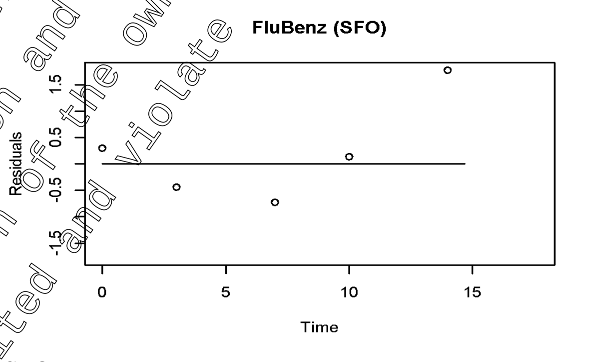
Table 8.9- 182: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for pea of trial R 2007 0554/9, Goyencourt, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	7.3	k: 0.18066	21.6	k: 0.023	k: 0.07	k: 0.29	3.837	12.75
FOMC	o	7.7	α: 0.7062 β: 1.418	17.1	-	β: -4.99	β: 7.83	2.366	35.53
DFOP	o	7.7	k1: 0.392 k2: 2.2 E-14 g: 0.793	17.2	k1: 0.299 k2: 0.50	k1: -0.66 k2: -0.50	k1: 1.44 k2: 0.50	2.545	>1000
HS	o	7.6	k1: 0.230 k2: 2.2 E-14 tb: 6.587	12.9	k1: 0.108 k2: 0.50	k1: 0.07 k2: -0.20	k1: 0.39 k2: 0.20	3.017	>1000

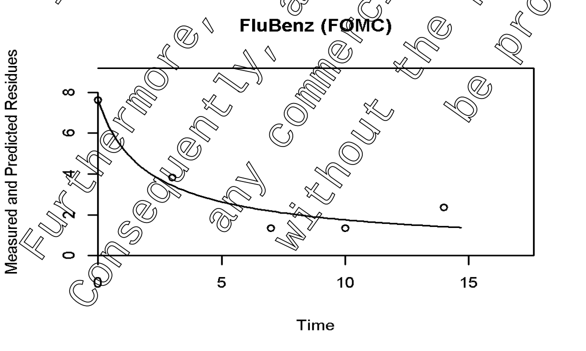
SFO fit is statistically (χ^2err >15%, t-test <0.05) and visually poor. FOMC, DFOP and HS fits were alternatively tested. The t-test of DFOP and HS show a very low reliability especially of the slow degradation rates k2 (t-test > 0.05). During study duration the lowest residues have been only slightly > 10 % (17 %) of initial mass, untypically increasing again at last data point. In addition, the FOMC DT_{90} (35.53 d) is not extrapolated far beyond the study end. Therefore, **FOMC** was considered best appropriate for modelling endpoints (FOCUS kinetics) and as well as best visual fit.



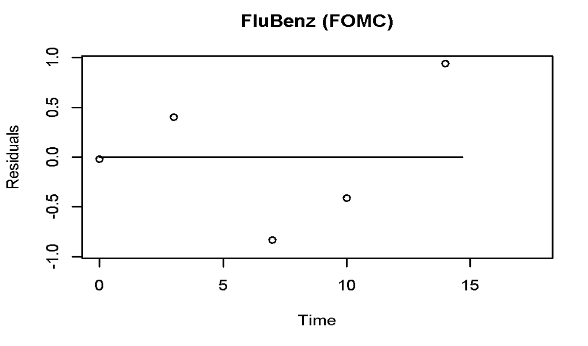
SFO



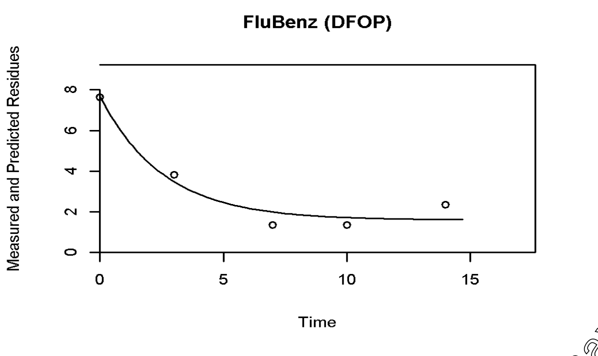
SFO



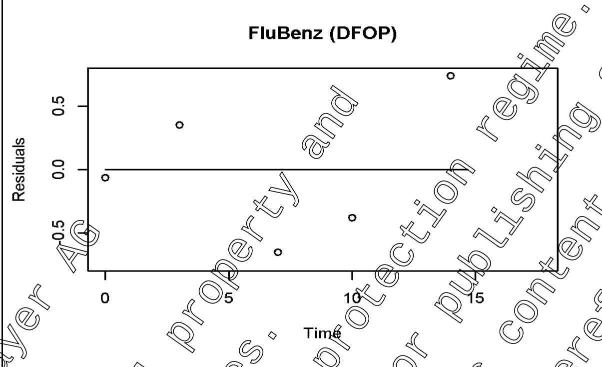
FOMC



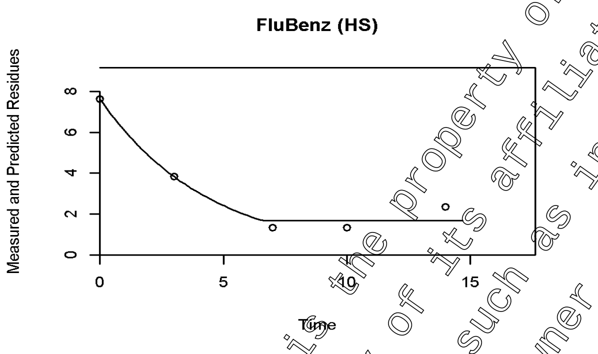
FOMC



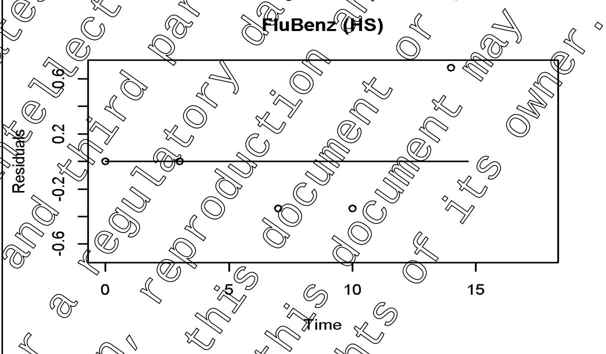
DFOP



DFOP



HS



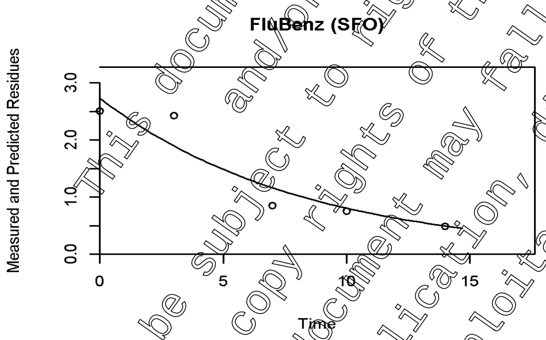
HS

R 2007 0555/7, Landenne-Sur-Meuse, M-298639-01-1, BE, pea

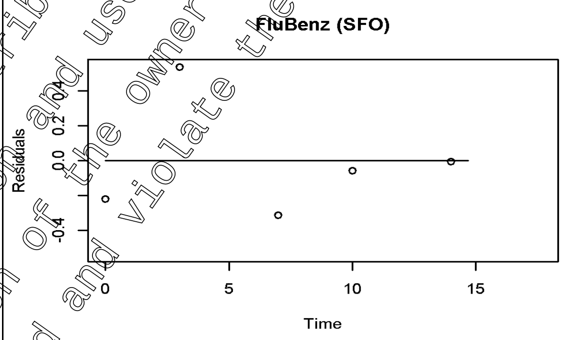
Table 8.9- 183: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for pea of trial R 2007 0555/7, Landenne-Sur-Meuse, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	2.7	k: 0.12192	16.8	k: 0.016	k: 0.06	k: 0.18	**5.685**	18.89
FOMC	o	2.7	α: 2968 β: 24340	19.2	-	β: 24120	β: 24563.25	5.685	18.89
DFOP	o	2.7	k1: 0.122 k2: 0.054 g: 1.0	24.0	k1: 0.401 k2: <0.001	k1: -0.62 k2: 0.0538	k1: 0.87 k2: 0.054	5.685	18.89
HS	o	2.7	k1: 0.122 k2: 0.084 tb: 16.394	24.0	k1: 0.135 k2: <0.001	k1: 0.01 k2: 0.084	k1: 0.23 k2: 0.084	5.685	20.00

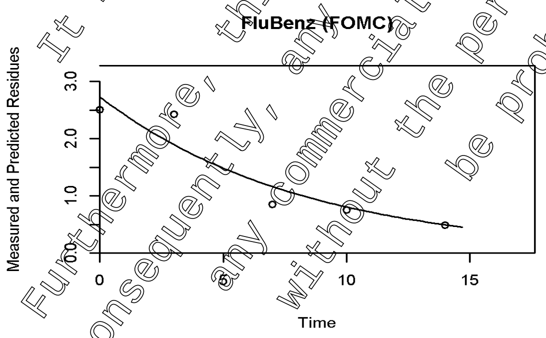
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



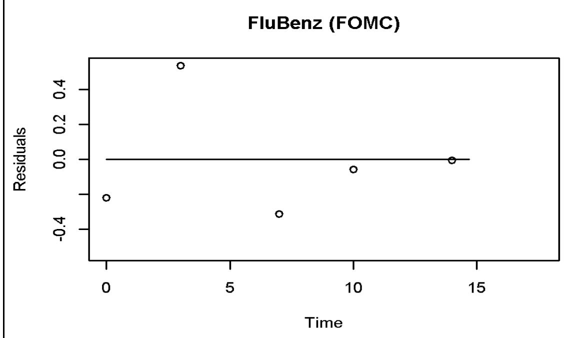
SFO



SFO



FOMC



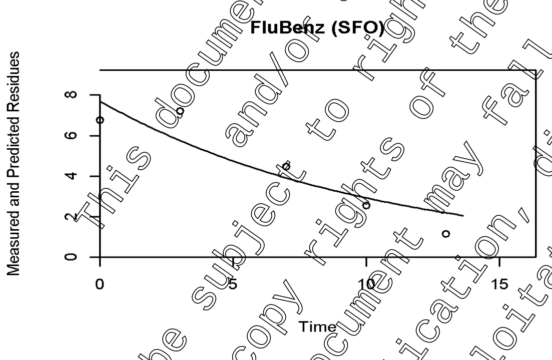
FOMC

R 2007 0556/5, Swisttal Heimerzheim, M-298639-01-1, DE, pea

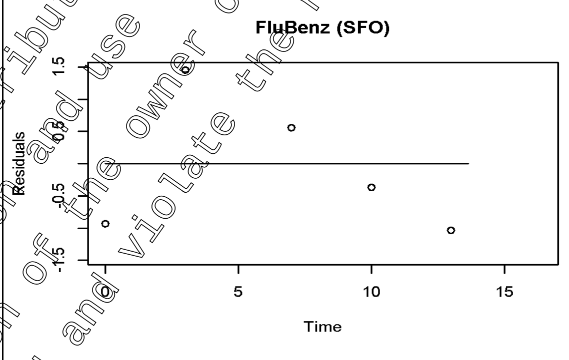
Table 8.9- 184: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for pea of trial R 2007 0556/5, Swisttal Heimerzheim, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	7.7	k: 0.09654	17.1	k: 0.024	k: 0.04	k: 0.16	**7.180**	23.85
FOMC	o	7.7	α: 7925.595 β: 82092.812	19.5	-	β: 81530	β: 82655.62	7.180	23.85
DFOP	o	7.7	k1: 0.097 k2: 0.121 g: 1.0	24.4	k1: 0.473 k2: <0.001	k1: -2.15 k2: 0.12	k1: 2.34 k2: 0.12	7.180	23.85
HS	+	7.0	k1: 2.2 E-14 k2: 0.208 tb: 4.895	4.3	k1: 0.50 k2: 0.062	k1: -0.05 k2: 0.13	k1: 0.05 k2: 0.29	8.228	15.97

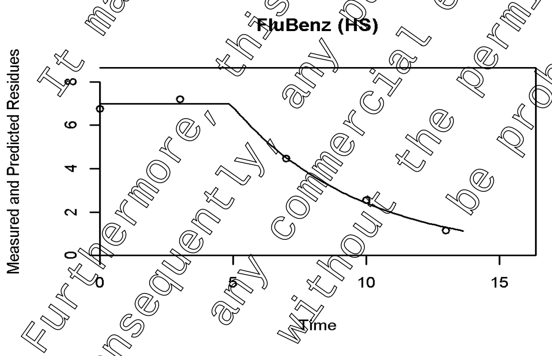
SFO fit is statistically and visually acceptable (t-test <0.05), although χ^2err is > 15 %. FOMC, DFOP and HS did not result in an improved fit, mainly due to the partly scattering data. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. The HS resulted in a lag phase, which is considered not appropriate for the intended purpose. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



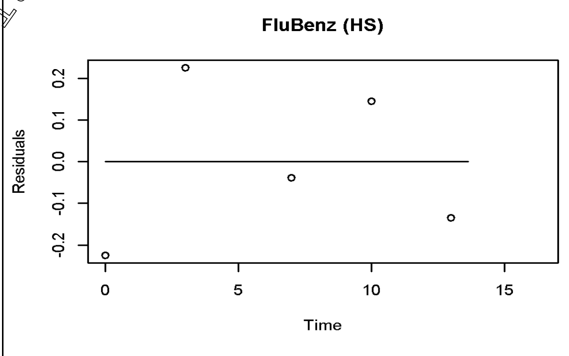
SFO



SFO



HS



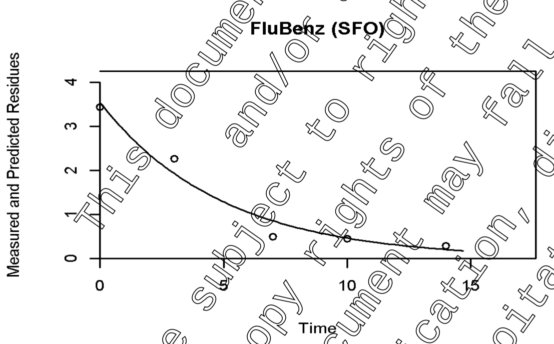
HS

R 2007 0557/3, Brenes Sevilla, M-297487-01-1, ES, pea

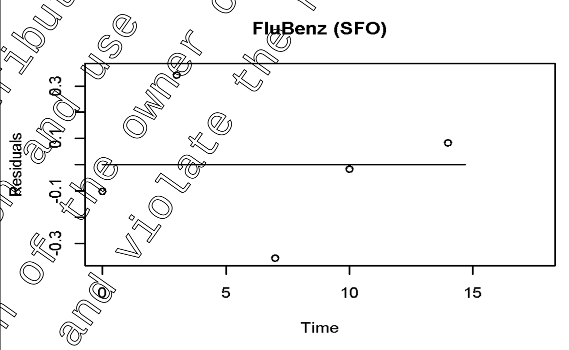
Table 8.9- 185: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for pea of trial R 2007 0557/3, Brenes Sevilla, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.5	k: 0.20275	13.2	k: 0.004	k: 0.14	k: 0.27	**3.419**	11.36
FOMC	o	3.5	α: 10980 β: 54140	15.0	-	β: 53300	β: 54982.81	3.419	11.36
DFOP	o	3.5	k1: 0.203 k2: 2.2 E-14 g: 1.0	18.8	k1: 0.179 k2: <0.001	k1: -0.05 k2: 2.2 E-14	k1: 0.45 k2: < 0.0005	3.419	11.36
HS	o	3.5	k1: 0.206 k2: 0.108 tb: 10.181	18.5	k1: 0.091 k2: 0.429	k1: 0.09 k2: -0.83	k1: 0.32 k2: 1.05	3.372	12.13

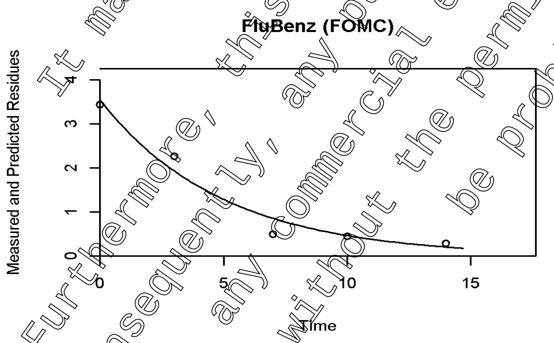
SFO fit is statistically and visually acceptable (χ^2err < 15 %, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. However, the SFO fit shows a conservative estimation, especially for the residue data at study end. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



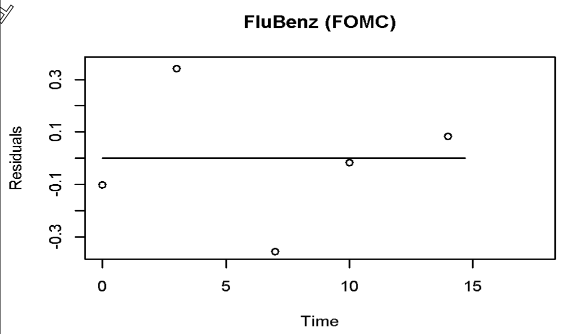
SFO



SFO



FOMC



FOMC

III. CONCLUSION

The following units are used in the following tables:

k	1/d
β, tb	d
α, g	none

Table 8.9- 186: Foliar DT_{50} parameters of fluopyram in green material of lettuce, beans and peas, after application of Luna Privilege (SC 500), based on time points after last application, for modelling purpose

Fluopyram	Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, beans, peas, Luna Privilege								
Trial	EU zone	Kinetic model	Kinetic parameters	X^2 err (%)	Prob > t	$DT_{50\ pseudo}$ (d)	$DT_{90\ actual}$ (d)	$DT_{50\ fast}$ (d)	$DT_{50\ slow}$ (d)
R 2007 0011/3, Barway, GB, M-304280-01-1	N	**SFO**	k: 0.66158	1.7	k: <0.001	**1.048**	3.482		
R 2007 0012/1, Olho Marinho, PT, M-304278-01-1	S	**SFO**	k: 0.38236	7.0	k: <0.001	**1.813**	6.02		
R 2007 0014/8 Villers-Perwin, BE, M-297562-01-1	N	**SFO**	k: 0.25363	17.7	k: 0.008	**2.733**	9.08		
R 2007 0035/0 Chazay d'Azergues, FR, M-297564-01-1	S	**SFO**	k: 0.21824	20.9	k: 0.015	**3.176**	10.55		
R 2007 0036/9 Kopstukken, NL, M-298639-01-1	N	**SFO**	k: 0.13109	13.0	k: 0.007	**5.287**	17.56		
R 2007 0037/7 Chazay d'Azergues, FR, M-297487-01-1	S	**SFO**	k: 0.20822	22.4	k: 0.017	**3.329**	11.06		
R 2007 0244/2 Meckenbeuren, DE, M-304280-01-1	N	**SFO**	k: 0.22435	14.3	k: 0.007	**3.090**	10.26		
R 2007 0245/0, Agia Marina, GR, M-304278-01-1	S	**SFO**	k: 0.57578	3.9	k: <0.001	**1.204**	3.999		
R 2007 0246/9, Ouzilly, FR, M-304278-01-1	S	**SFO**	k: 0.77429	7.7	k: 0.002	**0.8952**	2.974		
R 2007 0537/9 Langenfeld, DE, M-304280-01-1	N	**FOMC**	α: 0.847347 β: 0.457515	0.1	-	**1.949**	6.470		
R 2007 0538/7 Puzeaux, FR, M-304280-01-1	N	**SFO**	k: 0.95542	3.5	k: 0.003	**0.7255**	2.41		

Fluopyram	**Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, beans, peas, Luna Privilege**								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**$DT_{90\ actual}$ (d)**	**$DT_{50\ fast}$ (d)**	**$DT_{50\ slow}$ (d)**
R 2007 0539/5 Villers-Perwin, BE, M-304280-01-1	N	**SFO**	k: 0.32562	5.8	k: <0.001	**2.129**	7.071		
R 2007 0540/9 Zwaagdijk, NL, M-304280-01-1	N	**SFO**	k: 0.50672	8.1	k: 0.001	**1.368**	4.544		
R 2007 0541/7 Manfredonia, IT, M-304278-01-1	S	**SFO**	k: 0.11957	23.7	k: 0.037	**5.797**	19.26		
R 2007 0546/8 Langenfeld DE, M-297562-01-1	N	**SFO**	k: 0.23343	4.7	k: <0.001	**2.969**	9.864		
R 2007 0547/6 Fresnoy les Roye, FR, M-297562-01-1	N	**SFO**	k: 0.25264	10.4	k: 0.002	**2.744**	9.114		
R 2007 0548/4 Biddinghuizen, NL, M-297562-01-1	N	**HS**	k1: 0.366204 k2: 0.061325 tb: 5.123	1.3	k1: 0.008 k2: 0.080	**3.639**	12.08	1.893	11.303
R 2007 0549/2, Swisttal, DE, M-297562-01-1	N	**SFO**	k: 0.21851	39.6	k: 0.059	**3.172**	10.54		
R 2007 0550/6 Ladispoli, IT, M-297564-01-1	S	**SFO**	k: 0.9008	5.8	k: 0.002	**0.7695**	2.556		
R 2007 0551/4 Alginet, ES, M-297564-01-1	S	**SFO**	k: 0.08485	15.1	k: 0.022	**8.169**	27.14		
R 2007 0552/2 Ribafria Peniche, PT, M-297564-01-1	S	**DFOP**	k1: 11.88574 k2: 0.04164 g: 0.532	9.6	k1: <0.001 k2: 0.215	**11.166**	37.07	0.0583	16.646
R 2007 0553/0 Burscheid, DE, M-298639-01-1	N	**HS**	k1: 0.476659 k2: 0.107659 tb: 2.945	2.0	k1: 0.011 k2: 0.035	**3.401**	11.29	1.454	6.438
R 2007 0554/9 Goyencourt, FR, M-298639-01-1	N	**FOMC**	α: 0.7393 β: 1.5174	17.2	-	**9.837**	32.66		
R 2007 0555/7 Landenne-S.Meuse, BE, M-298639-01-1	N	**SFO**	k: 0.12675	17.3	k: 0.016	**5.468**	18.17		
R 2007 0556/5, Swisttal, DE, M-298639-01-1	N	**SFO**	k: 0.09858	17.0	k: 0.023	**7.032**	23.36		

Fluopyram	Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, beans, peas, Luna Privilege								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**DT_{90} actual (d)**	**DT_{50} fast (d)**	**DT_{50} slow (d)**
R 2007 0557/3 Brenes, Sevilla, ES, M-297487-01-1	S	**SFO**	k: 0.21165	13.5	k: 0.005	**3.275**	10.88		
Geomean (n=26) M						**2.845** M			

DT_{50} pseudo = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT_{90} actual time for first 90 % of residues to dissipate
DT_{50} fast = ln(2)/k1
DT_{50} slow = ln(2)/k2 (DFOP, HS)
M geomean of DT_{50} pseudo of fits for modelling purpose

Table 8.9- 187: Foliar DT_{50} parameters of fluopyram + FLU-benzamide in green material of lettuce, beans and peas, after application of Luna Privilege (SC 500), based on time points after last application, for modelling purpose

Fluopyram	Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, beans, peas, Luna Privilege								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**DT_{90} actual (d)**	**DT_{50} fast (d)**	**DT_{50} slow (d)**
R 2007 0012/1 Olho Marinho, PT, M-304278-01-1	S	**SFO**	k: 0.37945	7.2	k: <0.001	**1.827**	6.068		
R 2007 0014/8 Villers-Perwin, BE, M-297562-01-1	N	**SFO**	k: 0.25165	17.5	k: 0.008	**2.754**	9.15		
R 2007 0035/0 Chazay d'Azergues, FR, M-297564-01-1	S	**SFO**	k: 0.21313	20.6	k: 0.014	**3.252**	10.80		
R 2007 0036/9 Kopstukken, NL, M-298659-01-1	N	**SFO**	k: 0.12868	12.9	k: 0.007	**5.387**	17.89		
R 2007 0037/7 Chazay d'Azergues, FR, M-297487-01-1	S	**SFO**	k: 0.19822	21.0	k: 0.015	**3.497**	11.62		
R 2007 0244/2 Meckenbeuren, DE, M-304280-01-1	N	**SFO**	k: 0.2241	14.2	k: 0.007	**3.092**	10.27		
R 2007 0244/2 Meckenbeuren, DE, M-304280-01-1	N	**SFO**	k: 0.5703	4.1	k: <0.001	**1.215**	4.038		
R 2007 0246/9 Ouzilly, FR, M-304278-01-1	S	**SFO**	k: 0.7617	8.2	k: 0.003	**0.910**	3.023		

Fluopyram	**Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, beans, peas, Luna Privilege**								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**$DT_{90\ actual}$ (d)**	**$DT_{50\ fast}$ (d)**	**$DT_{50\ slow}$ (d)**
R 2007 0537/9 Langenfeld DE, M-304280-01-1	N	**DFOP**	k1: 0.888947 k2: 0.072576 g: 0.843	0.18	k1: 0.006 k2: 0.014	**1.971**	6.544	0.780	9.551
R 2007 0538/7 Puzeaux, FR, M-304280-01-1	N	**SFO**	k: 0.94598	3.4	k: 0.003	**0.7327**	2.43		
R 2007 0539/5 Villers-Perwin, BE, M-304280-01-1	N	**SFO**	k: 0.32355	6.0	k: <0.001	**2.142**	7.117		
R 2007 0540/9 Zwaagdijk, NL, M-304280-01-1	N	**SFO**	k: 0.50143	8.3	k: 0.001	**1.382**	4.59		
R 2007 0541/7 Manfredonia, IT, M-304278-01-1	S	**SFO**	k: 0.11875	23.6	k: 0.037	**5.837**	19.39		
R 2007 0546/8 Langenfeld DE, M-297562-01-1	N	**SFO**	k: 0.22275	5.5	k: <0.001	**3.112**	10.34		
R 2007 0547/6 Fresnoy les Roye, FR, M-297562-01-1	N	**SFO**	k: 0.24812	9.9	k: 0.002	**2.794**	9.28		
R 2007 0548/4 Biddinghuizen, NL, M-297562-01-1	N	**HS**	k1: 0.363753 k2: 0.058478 tb: 5.063	1.2	k1: 0.008 k2: 0.079	**3.898**	12.94	1.906	11.853
R 2007 0549/2 Swisttal Heimerzheim, DE, M-297562-01-1	N	**SFO**	k: 0.21516	38.8	k: 0.058	**3.221**	10.70		
R 2007 0550/6 Ladispoli, IT, M-297564-01-1	S	**SFO**	k: 0.8834	6.6	k: 0.002	**0.7846**	2.61		
R 2007 0551/4 Alginet, ES, M-297564-01-1	S	**SFO**	k: 0.08044	14.8	k: 0.024	**8.617**	28.63		
R 2007 0552/2 Ribafria Peniche, PT, M-297564-01-1	S	**DFOP**	k1: 16.40 k2: 0.03701 g: 0.532	9.3	k1: <0.001 k2: 0.225	**12.554**	41.68	0.042	18.729
R 2007 0553/0 Burscheid, DE, M-298639-01-1	N	**HS**	k1: 0.476367 k2: 0.10567 tb: 2.905	2.2	k1: 0.013 k2: 0.039	**3.494**	11.60	1.455	6.560

Fluopyram	**Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, beans, peas, Luna Privilege**								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**$DT_{90\ actual}$ (d)**	**$DT_{50\ fast}$ (d)**	**$DT_{50\ slow}$ (d)**
R 2007 0554/9 Goyencourt, FR, M-298639-01-1	N	**FOMC**	α: 0.7062 β: 1.418	17.1	-	**10.702**	35.53		
R 2007 0555/7 Landenne-Sur-Meuse, BE, M-298639-01-1	N	**SFO**	k: 0.12192	16.8	k: 0.016	**5.685**	18.89		
R 2007 0556/5 Swisttal, DE, M-298639-01-1	N	**SFO**	k: 0.09654	17.1	k: 0.024	**7.180**	23.85		
R 2007 0557/3 Brenes, Sevilla, ES, M-297487-01-1	S	**SFO**	k: 0.20275	13.2	k: 0.004	**3.419**	11.36		
Geomean, trials with FLU-benz > LOQ (n=25) [M]						3.049 [M]			
Geomean, incl. all trials (n=26) [A]						**2.926** [A]			

DT_{50} pseudo = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT_{90} actual time for first 90 % of residues to dissipate
DT_{50} fast = ln(2)/k1
DT_{50} slow = ln(2)/k2 (DFOP, HS)
M geomean DT_{50} pseudo of fits for modelling purpose, for trials with FLU-benzamide > LOQ
A geomean DT_{50} pseudo of fits for modelling purpose for trials with FLU-benzamide > LOQ and remaining trials of FLU only from table above, where FLU-benzamide was < LOQ.

Assessment and conclusion by applicant:

The study EnSa-20-0830 and its data are considered as acceptable and reliable for use in risk assessment.

The geometric mean of the DT_{50} values for fluopyram was 2.845 days (n=37).

The geometric mean DT_{50} of the combined residue was 2.926 days (~3% longer than for fluopyram alone. Thus, the contribution of the metabolite fluopyram-benzamide is negligible for risk assessment.

Data Point:	KCA 8.9/14
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolite - Kinetic evaluation of green plant residues in lettuce and peas, applying Luna Sensation (SC500, FLU+TFS)
Report No:	EnSa-20-0831
Document No:	M-763338-01-1
Guideline(s) followed in study:	not applicable
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

EXECUTIVE SUMMARY

Kinetic evaluations were conducted for the residue decline of fluopyram from foliage after application on various vegetables. All trials were evaluated with SFO and FOMC kinetics. Where the number of sampling points allowed the evaluation, 2 biphasic kinetic models were fitted additionally (DFOP and HS), with a preference for selecting SFO where the fit was considered visually and statistically acceptable. Otherwise, the best-fit of the other models was selected. To facilitate the use of the selected kinetic parameter, a surrogate SFO DT_{50} was estimated as $DT_{90}/3.32$ for the non SFO kinetics.
The geometric mean of the DT_{50} for fluopyram was 2.673 days (n=20).

Additionally, an evaluation was made of the decline kinetics of the combined residues of fluopyram and its metabolite fluopyram-benzamide (in all 26 trials the metabolite was included as analyte).
The geometric mean DT_{50} of the combined residue was 2.697 days (~1% longer than for fluopyram alone. Thus, the contribution of the metabolite fluopyram-benzamide is negligible for risk assessment.

The outcome of the evaluations is presented below.

Table 8.9- 188: Comparison of foliar DT50s of fluopyram and fluopyram + FLU-benzamide in green material of lettuce and peas

Fluopyram and FLU + FLU-benzamide	**Foliar residue dissipation in lettuce and peas**			
Trial	**EU zone**	**Kinetic model**	**$DT_{50\ mod}$ FLU (d)**	**$DT_{50\ mod}$ FLU + benzamide (d)**
14-2029-01, Villers-Perwin, B, M-534202-01-1	N	SFO	2.921	2.959
14-2029-02, Dannstadt, D, M-534202-01-1	N	SFO	2.892	2.909
14-2029-03, Zwaagdijk, NL, M-534202-01-1	N	SFO	1.682	*1.682*
14-2029-04, Lignieres de Touraine, FR, M-534202-01-1	N	SFO	2.034	2.037
14-2029-05, Leichlingen, D, M-534202-01-1	N	SFO	1.800	*1.800*

Fluopyram and FLU + FLU-benzamide	**Foliar residue dissipation in lettuce and peas**			
Trial	**EU zone**	**Kinetic model**	**$DT_{50\ mod}$ FLU (d)**	**$DT_{50\ mod}$ FLU + benzamide (d)**
14-2030-01, Alginet, ES, M-534595-01-1	S	SFO	4.804	4.852
14-2030-02, C.da Pigno, Catania, IT, M-534595-01-1	S	SFO	5.522	5.551
14-2030-03, St. Etienne du Gres, FR, M-534595-01-1	S	SFO	3.233	3.314
14-2030-04, Aronas, GR, M-534595-01-1	S	FOMC	1.918	2.028
14-2030-05, Gela, IT, M-534595-01-1	S	SFO	3.779	3.790
14-2184-01 Neuruppin, D, M-536965-01-1	N	SFO	1.095	*1.095*
14-2184-02 Hooghalen, NL, M-536965-01-1	N	SFO	4.710	4.700
14-2184-03 Nyiregyhaza, HU, M-536965-01-1	N	SFO	2.406	*2.406*
14-2184-04 Banbury, GB, M-536965-01-1	N	SFO	1.592	*1.592*
14-2185-01 Mediglia, IT, M-536963-01-1	S	SFO	1.057	1.061
14-2185-02 Pozoblanco, ES, M-536963-01-1	S	SFO	4.578	*4.578*
14-2185-03 Zafarraya, ES, M-536963-01-1	S	SFO	4.780	4.797
14-2185-04 Nea Magnisia, GR, M-536963-01-1	S	SFO	2.403	2.428
15-2030-01 Abenraa, DK, M-566823-03-1	N	SFO	3.346	3.413
15-2030-04 Mediglia, IT, M-566823-03-1	S	SFO	2.928	2.989
Geomean (n=20)			**2.673**	**2.697**

DT_{50} pseudo = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed

I. MATERIALS AND METHODS

A kinetic modelling analysis of European total crop residue decline study data of fluopyram (FLU) and fluopyram + fluopyram-benzamide (FLU-benzamide, M25) was conducted in order to derive kinetic parameters suitable for an ecotoxicological risk assessment, e.g. on birds and mammals, using the software tool KinGUI 2.1. The identification of the appropriate kinetic model followed the recommendations given by FOCUS Kinetics for modelling purpose (FOCUS kinetics, 2006, 2014) and EFSA (2019), based on a detailed statistical analysis including visual assessment, χ^2 statistic, significance t-test and correlation analysis.

In an ecotoxicological context, plant foliage residue trials are used to describe the dissipation or decline behaviour of fluopyram in potential food for birds and mammals. Dissipation curves can be used to estimate the exposure of herbivorous birds or mammals, mainly by calculating the area under the dissipation curve.

To allow for calculation of time weighted averaged residues or area under the curve, after single or multiple applications, it is most appropriate to use a full kinetic parameter set of SFO or biphasic models.

The modelling analysis is based on European crop residue data on green plant material of lettuce and peas (dicotyledons), after spray application of Luna Privilege (SC 500). All available residue data points per trial starting with the last application have been included in the evaluation. The plant metabolite fluopyram-benzamide has been analysed in the trials, but not always detected > LOQ. Foliar DT_{50} values are carried out for fluopyram, and in cases, where FLU-benzamide was detected > LOQ, also for the sum of fluopyram and FLU-benzamide.

Trials took place in both regulatory zones (N- and S-EU) with a timely variance from March - October. The BBCH growth stages at application have been 42 - 49 (lettuce) and 71 - 75 (peas).

Daily temperature and precipitation data (rain + irrigation over leaf surfaces, e.g. by sprinkler) are reported here, (e.g. based on raw data or publicly available weather station data).

In case of trials with 4 sampling points, DFOP and HS fits cannot deliver statistical information and are not appropriate, due to a too low degree of freedom (3 fitted parameters based on 4 data points). In these cases, such fits were not selected and summarised in the conclusion section. Nevertheless, reliable dissipation kinetics can be derived with 4 data points, e.g. when a clear decline can be seen, or the latest points are close to 0.

In case of trials with > 4 sampling points, all 4 model fits have been carried out, but only those graphs curves are presented in the summary which are needed for model decision..

II. RESULTS AND DISCUSSION

The following units are used in the following tables:

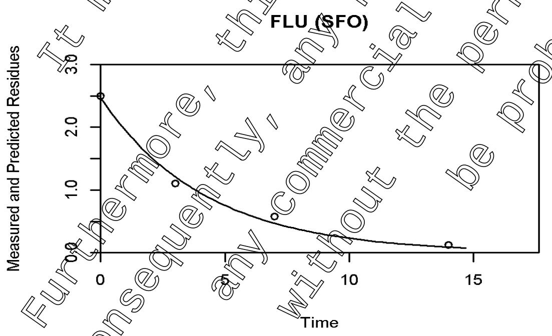
k	1/d
β, tb	d
α, g	none

Fluopyram

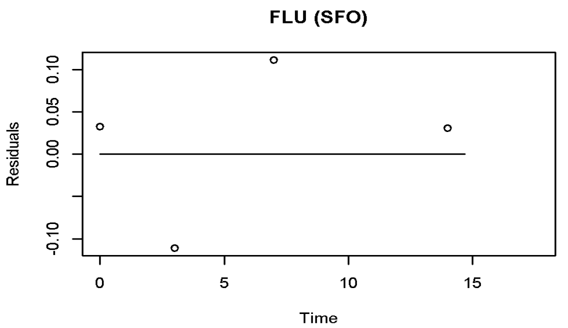
14-2029-01, Villers-Perwin, M-534202-01-1, BE, lettuce

Table 8.9- 189: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2029-01, Villers-Perwin, BE

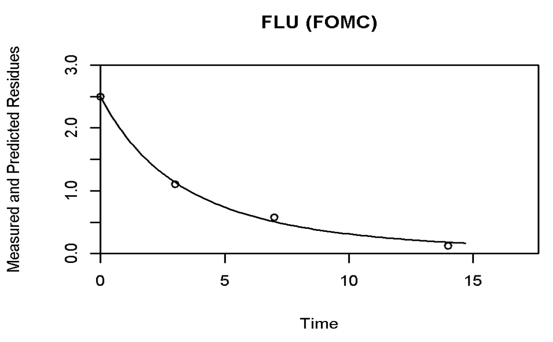
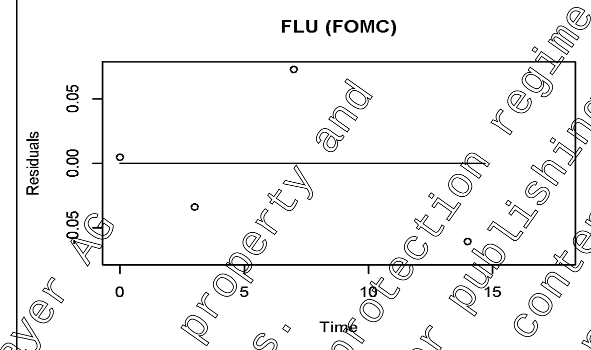
Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	2.5	k: 0.23727	6.2	k: 0.006	k: 0.19	k: 0.29	**2.921**	9.71
FOMC	+	2.5	α: 2.981 β: 9.9054	4.8	-	β: -10.68	β: 30.49	2.593	11.54
SFO fit is statistically and visually good (χ^2 err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).									



SFO



SFO

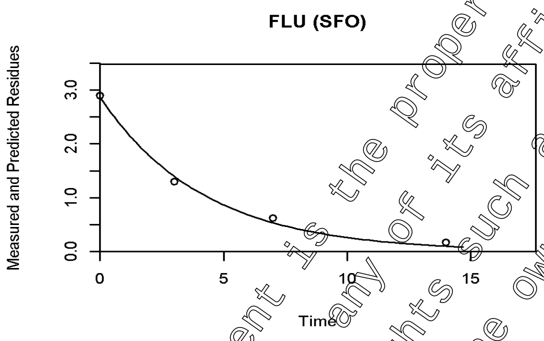
FLU (FOMC) Measured and Predicted Residues Time FOMC	FLU (FOMC) Residuals Time FOMC

14-2029-02, Dannstadt, M-534202-01-1, DE, lettuce

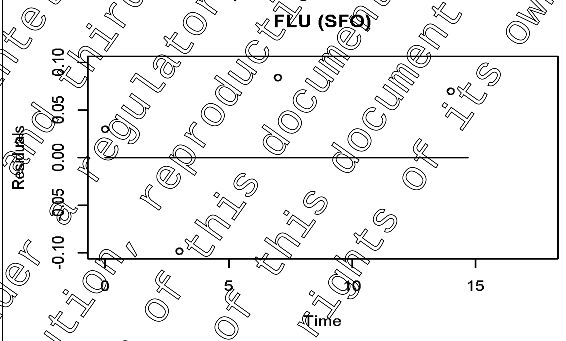
Table 8.9- 190: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2029-02, Dannstadt, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	2.9	k: 0.23968	4.9	k: 0.004	k: 0.20	k: 0.28	**2.892**	9.61
FOMC	+	2.9	α: 3.18134 β: 10.67309	2.1	-	β: 0.38	β: 20.96	2.598	11.34

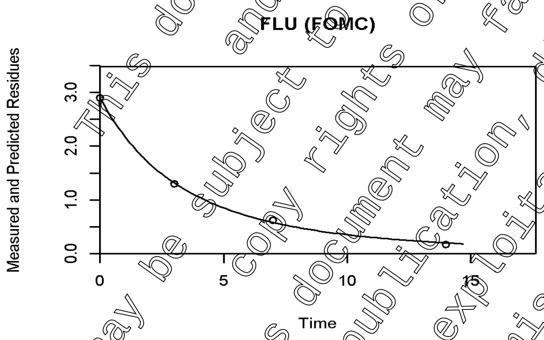
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



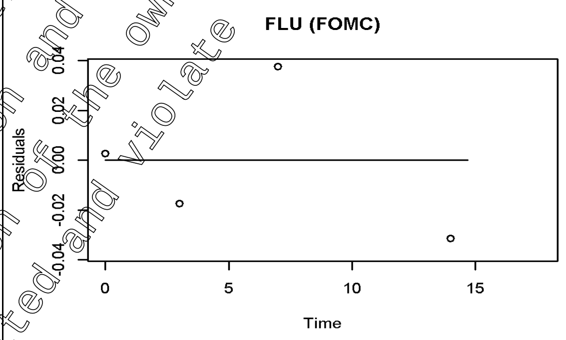
SFO



SFO



FOMC



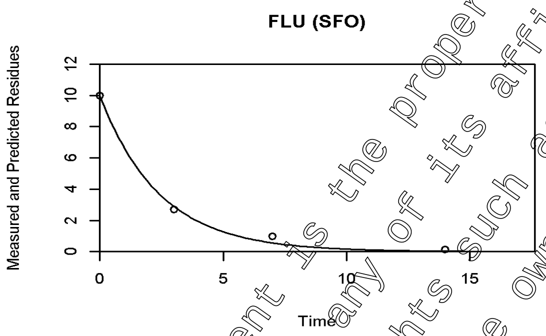
FOMC

14-2029-03, Zwaagdijk, M-534202-01-1, NL, lettuce

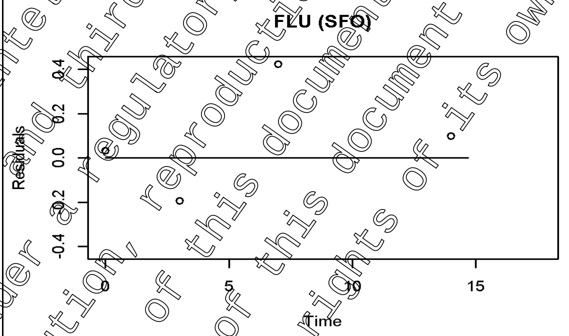
Table 8.9- 191: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2029-03, Zwaagdijk, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	10.0	k: 0.41212	5.6	k: 0.004	k: 0.34	k: 0.48	**1.682**	5.59
FOMC	+	10.0	α: 2.78396 β: 5.04377	2.3	-	β: 0.10	β: 9.99	1.426	6.49

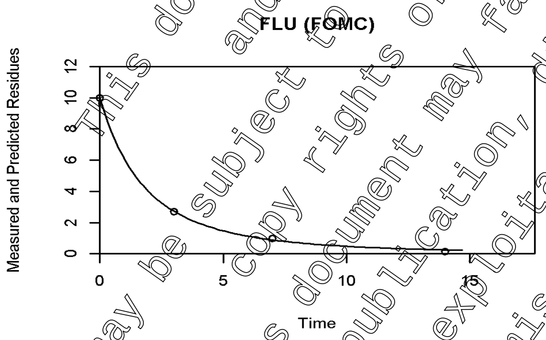
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



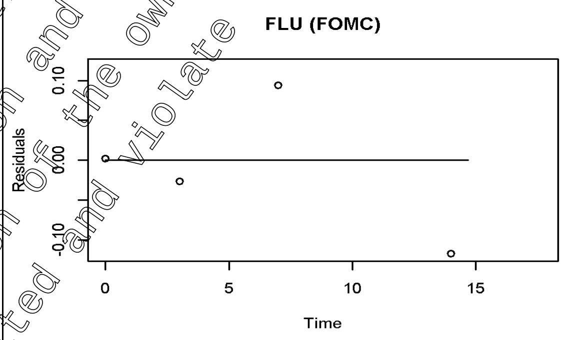
SFO



SFO



FOMC



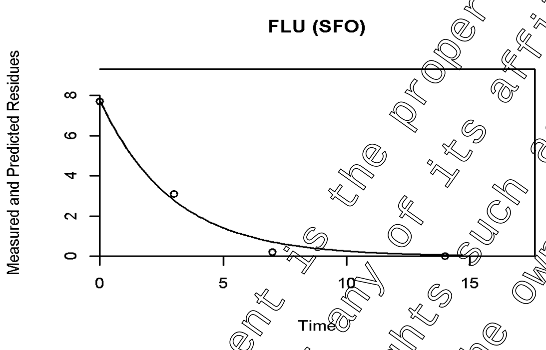
FOMC

14-2029-04, Lignieres de Touraine, M-534202-01-1, FR, lettuce

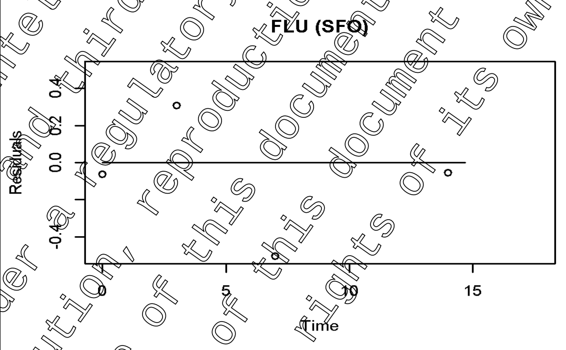
Table 8.9- 192: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2029-04, Lignieres de Touraine, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	7.8	k: 0.34079	8.8	k: 0.009	k: 0.25	k: 0.43	**2.034**	6.76
FOMC	+	7.8	α: 12320 β: 36150	11.1	-	β: 34760	β: 37550.67	2.034	6.76

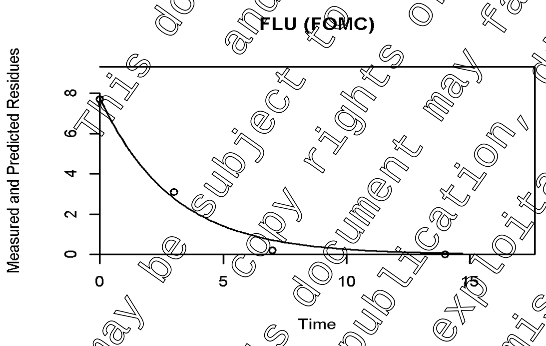
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



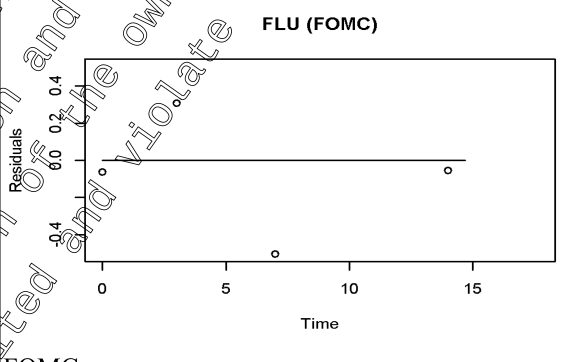
SFO



SFO



FOMC



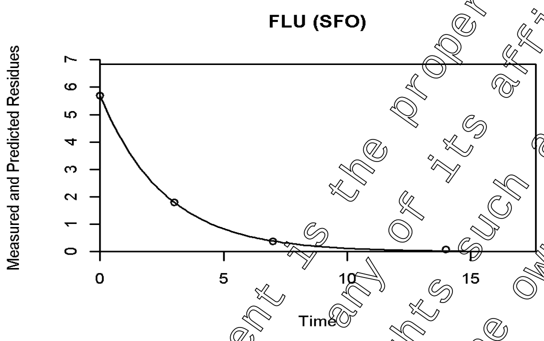
FOMC

14-2029-05, Leichlingen, M-534202-01-1, DE, lettuce

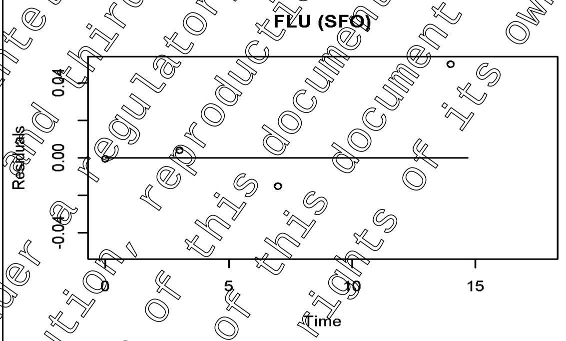
Table 8.9- 193: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2029-05, Leichlingen, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	5.7	k: 0.385019	1.1	k: <0.001	k: 0.37	k: 0.40	**1.800**	5.98
FOMC	+	5.7	α: 178.3 β: 461.3	1.3	-	β: -10630	β: 11553.49	1.796	5.99

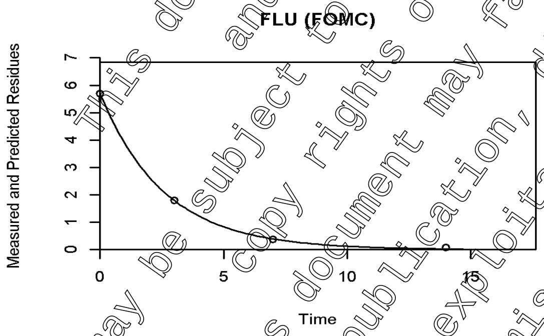
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



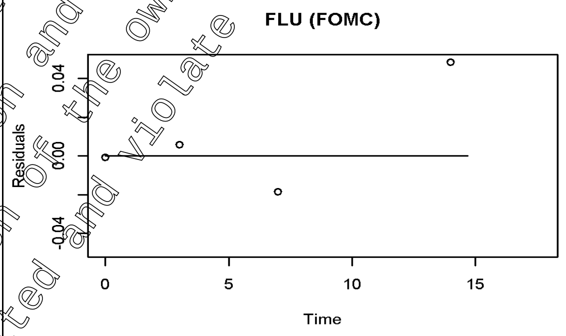
SFO



SFO



FOMC



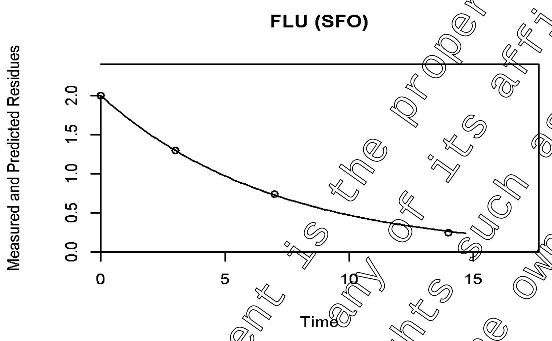
FOMC

14-2030-01, Alginet, M-534595-01-1, ES, lettuce

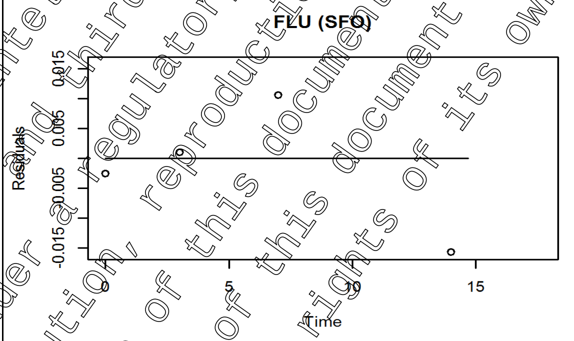
Table 8.9- 194: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2030-01, Alginet, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	2.0	k: 0.14428	0.7	k: <0.001	k: 0.14	k: 0.15	**4.804**	15.96
FOMC	+	2.0	α: 15250 β: 105700	0.9	-	β: 105700	β: 105700	4.804	15.96

SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



SFO



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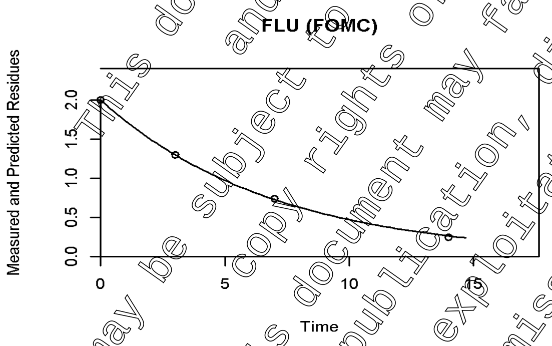
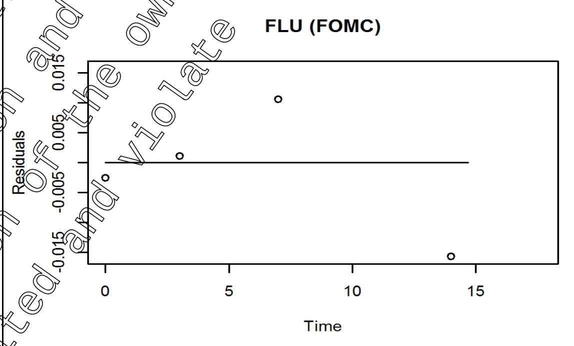


FOMC



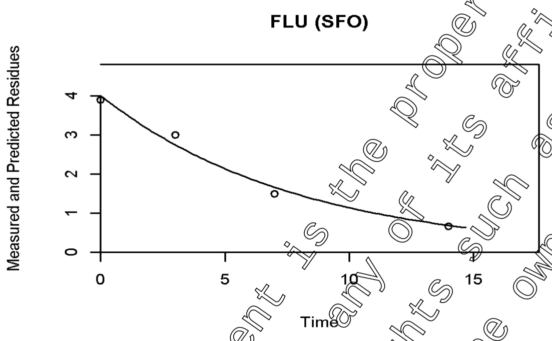
FOMC

14-2029-02, C.da Pigno, Catania, M-534595-01-1, IT, lettuce

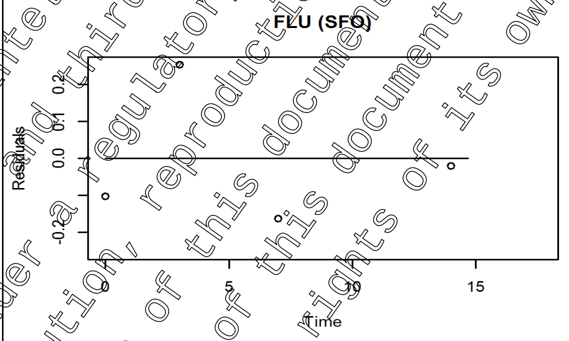
Table 8.9- 195: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2030-02, C.da Pigno, Catania, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	4.0	k: 0.12553	5.7	k: 0.008	k: 0.09	k: 0.16	**5.522**	18.34
FOMC	+	4.0	α: 6565.431 β: 52295.586	7.2	-	β: 52015.98	β: 52575.2	5.521	18.34

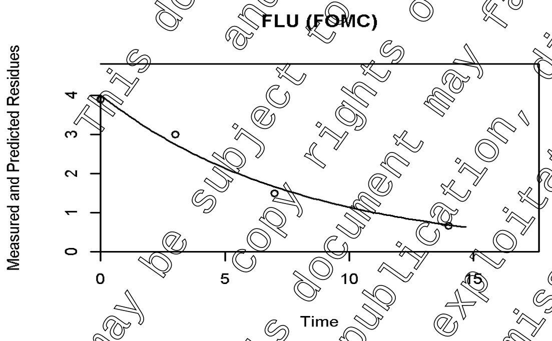
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



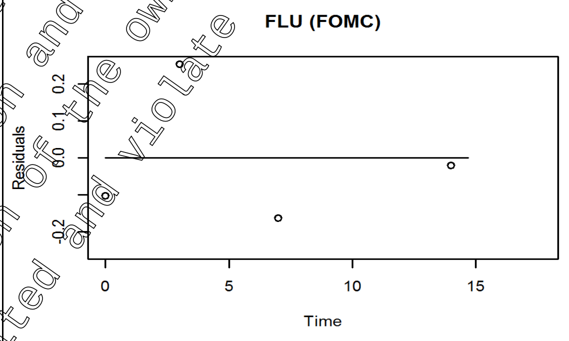
SFO



SFO



FOMC



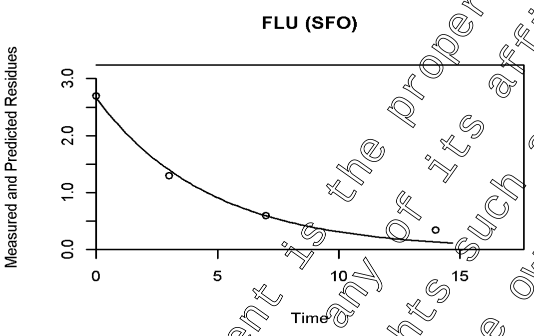
FOMC

14-2030-03, St. Etienne du Gres, M-534595-01-1, FR, lettuce

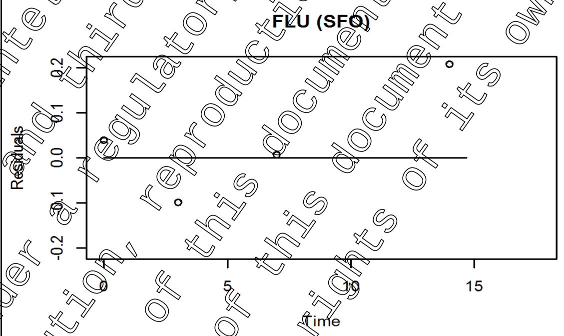
Table 8.9- 196: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2030-03, St. Etienne du Gres, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	2.7	k: 0.2144	7.7	k: 0.009	k: 0.16	k: 0.27	**3.233**	10.74
FOMC	+	2.7	α: 1.75858 β: 5.63237	2.9		β: -0.15	β: 11.42	2.721	15.23

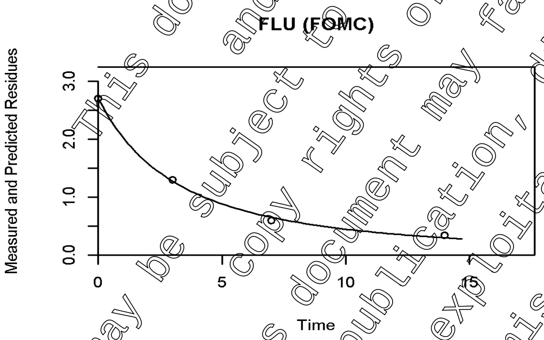
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



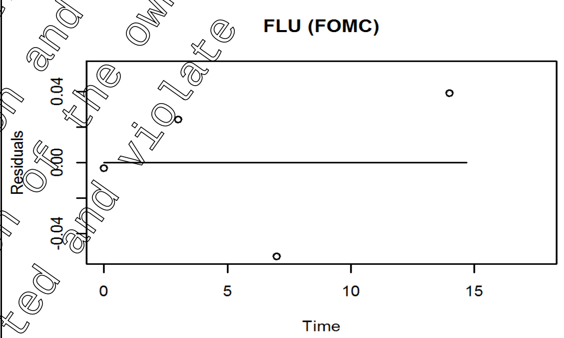
SFO



SFO



FOMC



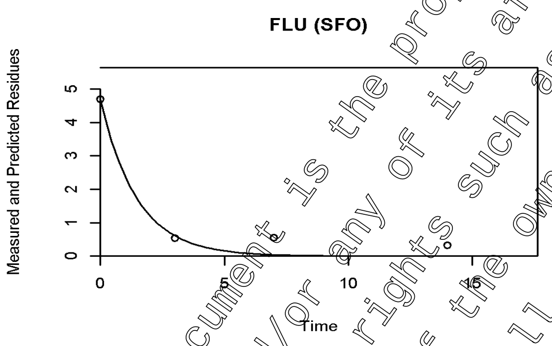
FOMC

14-2030-04, Aronas, M-534595-01-1, GR, lettuce

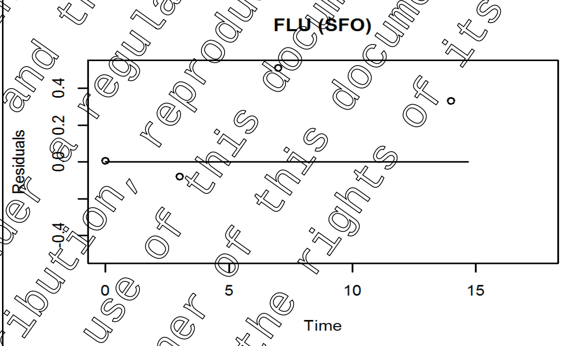
Table 8.9- 197: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2030-04, Aronas, GR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	4.7	k: 0.6807	16.4	k: 0.051	k: 0.22	k: 1.14	1.018	3.38
FOMC	+	4.7	α: 0.240553 β: 0.0004435	3.8	-	β: -0.01	β: 0.01	0.007	6.37

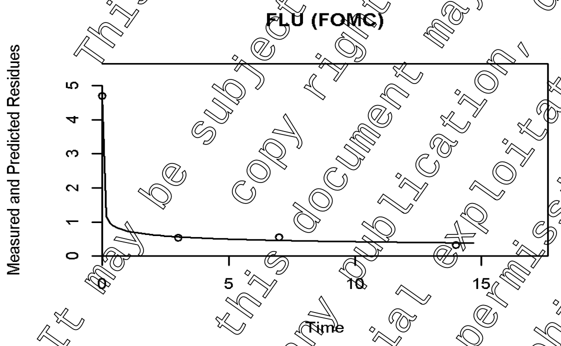
SFO fit is statistically still acceptable (χ^2err ~15%, t-test < 0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. DFOP and HS fits cannot deliver statistical information, as degrees of freedom are too low (3 fitted parameters based on 4 data points). FOMC fit is statistically (χ^2err, t-test) and visually good. Consequently, **FOMC** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



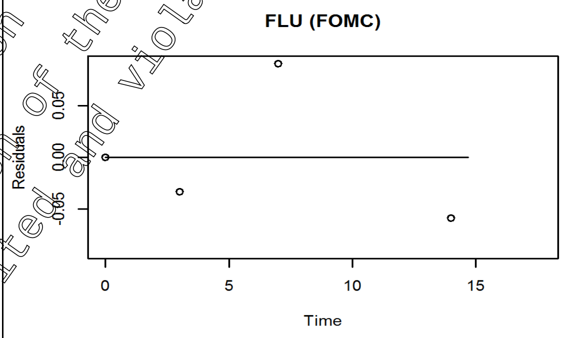
SFO



SFO



FOMC

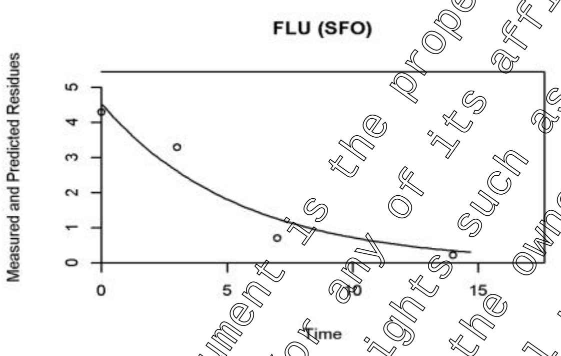
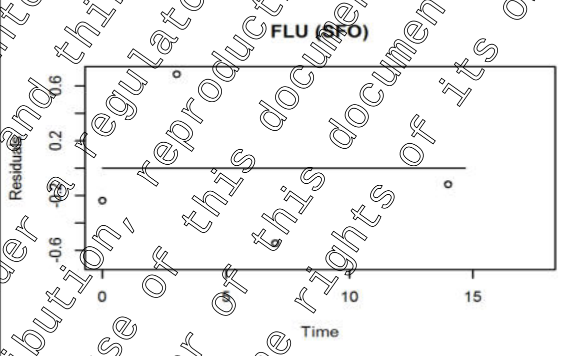
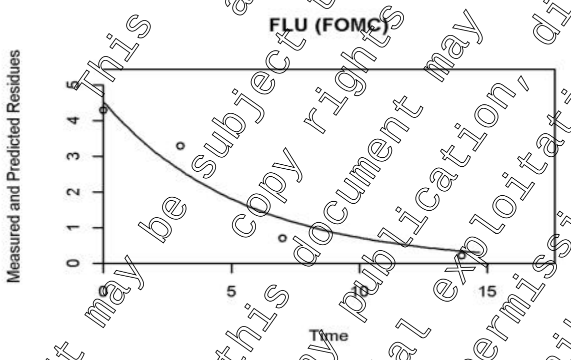
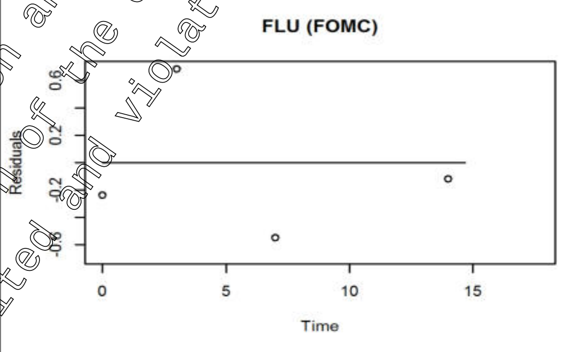


FOMC

14-2030-05, Gela, M-534595-01-1, IT, lettuce

Table 8.9- 198: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2030-05, Gela, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.5	k: 0.18343	17.5	k: 0.04344	k: 0.07	k: 0.30	**3.779**	12.55
FOMC	o	4.5	α: 7321 β: 39910	21.8	-	β: 38770	β: 41044.65	3.779	12.55
SFO fit is statistically and visually still acceptable (χ^2err ~15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.									

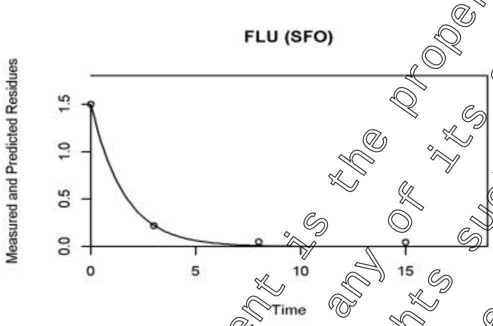
SFO	SFO
FOMC	FOMC

14-2184-01, Neuruppin, M-536965-01-1, DE, lettuce

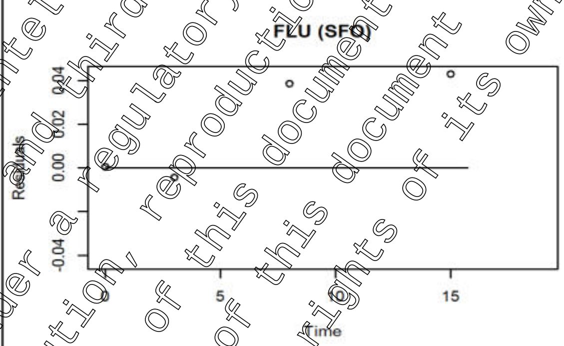
Table 8.9- 199: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2184-01, Neuruppin, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	1.5	k: 0.63311	5.2	k: 0.005	k: 0.51	k: 0.75	**1.095**	3.64
FOMC	+	1.5	α: 1.63549 β: 1.3309	2.6	-	β: -0.52	β: 3.18	0.702	4.11

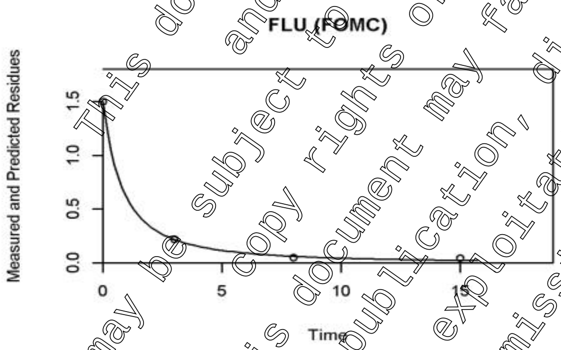
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



SFO



SFO



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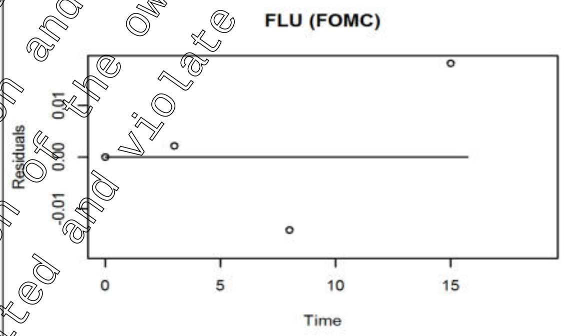


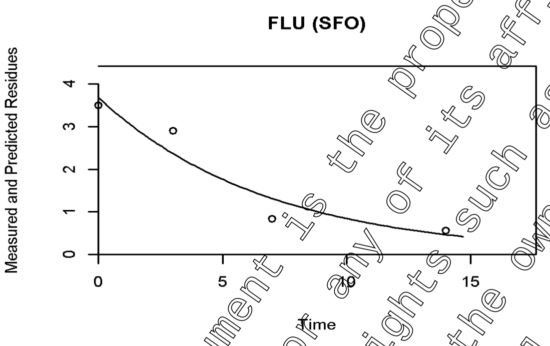
FOMC

14-2184-02, Hooghalen, M-536965-01-1, NL, lettuce

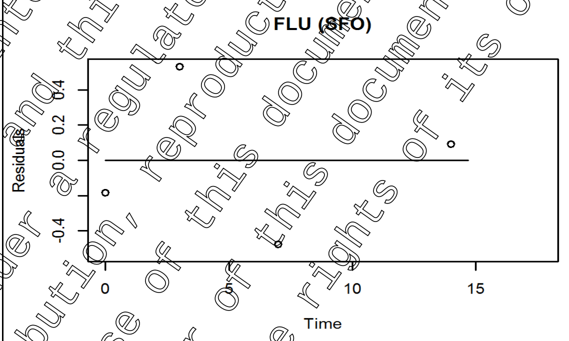
Table 8.9- 200: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2184-02, Hooghalen, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.7	k: 0.14717	15.5	k: 0.043	k: 0.06	k: 0.24	**4.710**	15.65
FOMC	o	3.7	α: 6096 β: 41420	19.4	-	β: 40660	β: 42181.65	4.710	15.65

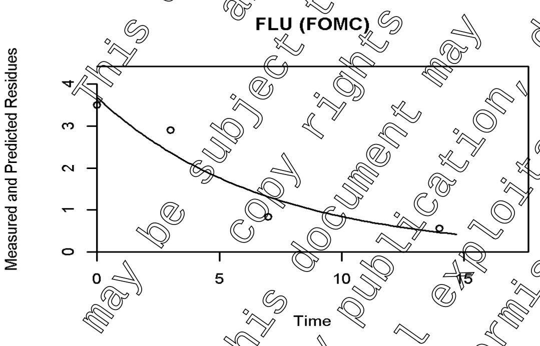
SFO fit is statistically and visually acceptable (χ^2err ~15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



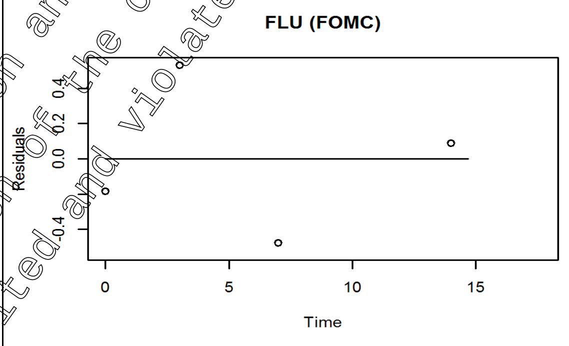
SFO



SFO



FOMC



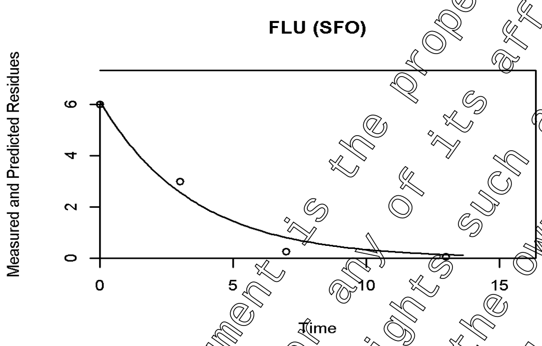
FOMC

14-2184-03, Nyiregyhaza, M-536965-01-1, HU, lettuce

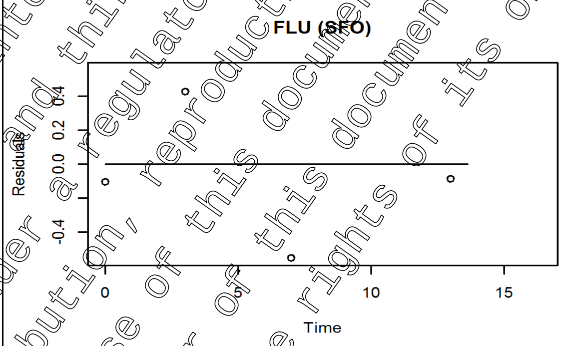
Table 8.9- 201: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2184-03, Nyiregyhaza, HU

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	6.1	k: 0.28815	12.5	k: 0.018	k: 0.18	k: 0.40	**2.406**	7.99
FOMC	+	6.1	α: 15970 β: 55420	15.6	-	β: 53150	β: 57702.32	2.405	7.99

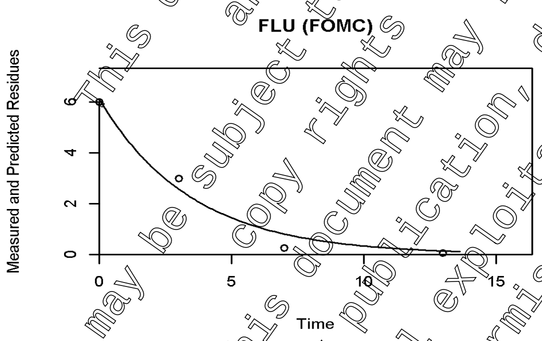
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



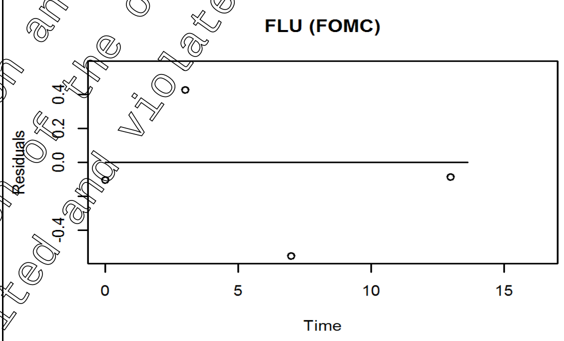
SFO



SFO



FOMC



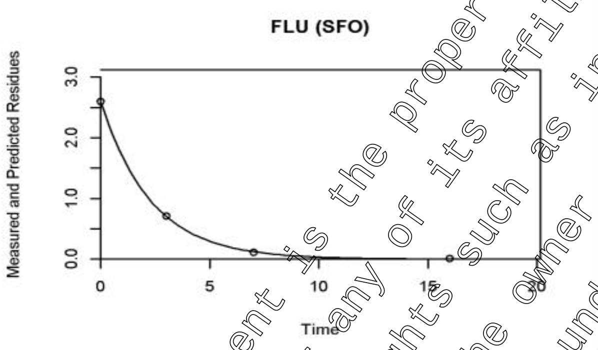
FOMC

14-2184-04, Banbury, M-536965-01-1, GB, lettuce

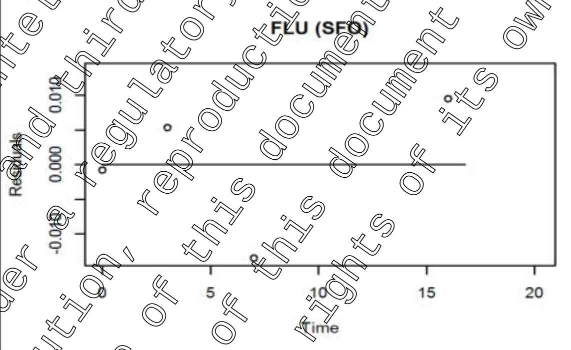
Table 8.9- 202: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2184-04, Banbury, GB

Kinetic model	Visual assessment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	2.6	k: 0.435297	0.8	k: <0.001	k: 0.42	k: 0.45	**1.592**	5.29
FOMC	+	2.6	α: 13090 β: 30080	1.0	-	β: 30080	β: 30081	1.592	5.29

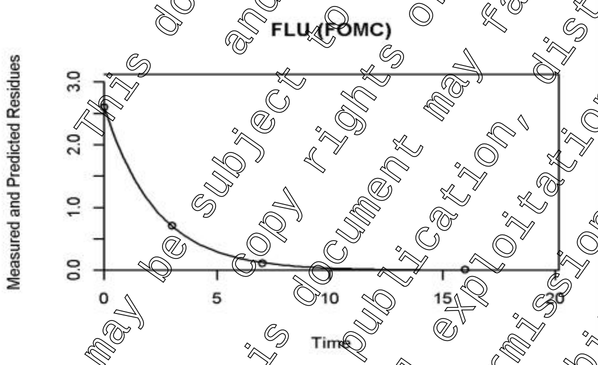
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



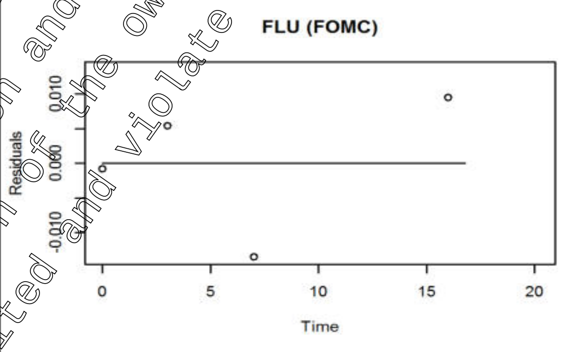
SFO



SFO



FOMC



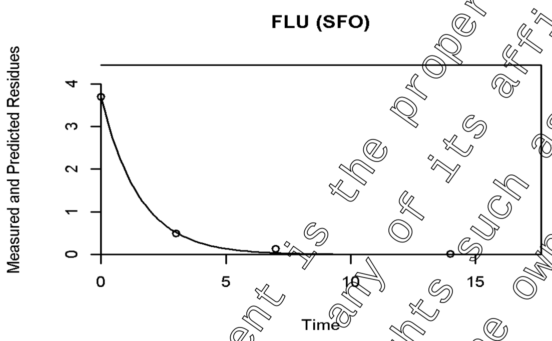
FOMC

14-2185-01, Mediglia, M-536963-01-1, IT, lettuce

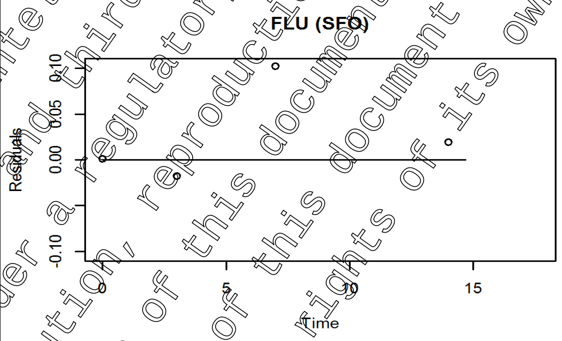
Table 8.9- 203: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2185-01, Mediglia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.7	k: 0.65562	4.0	k: 0.003	k: 0.56	k: 0.75	**1.057**	3.51
FOMC	+	3.7	α: 2.38331 β: 2.28541	0.8	-	β: 1.12	β: 3.45	0.771	3.72

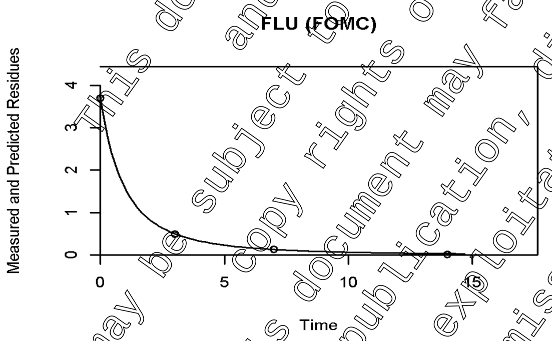
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



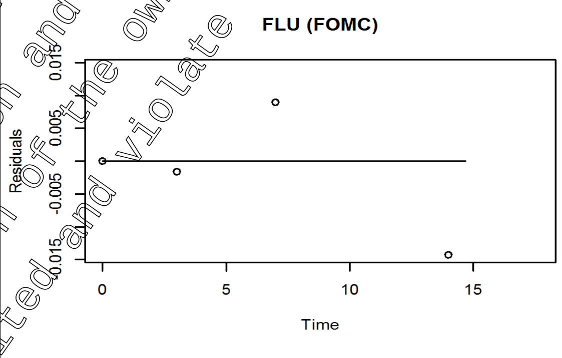
SFO



SFO



FOMC



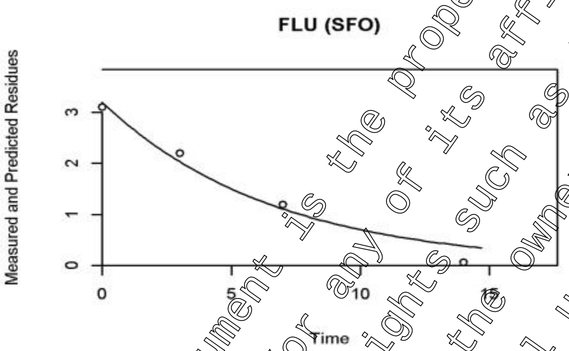
FOMC

14-2185-02, Pozoblanco, M-536963-01-1, ES, lettuce

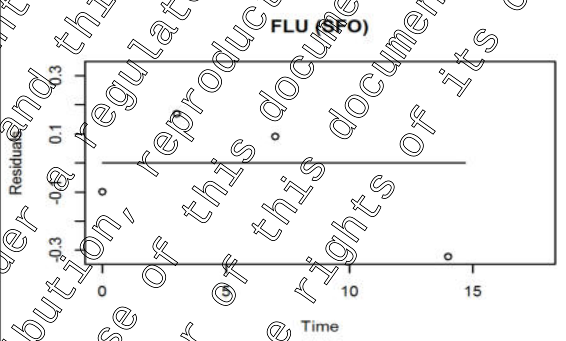
Table 8.9- 204: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2185-02, Pozoblanco, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.2	k: 0.1514	9.7	k: 0.017	k: 0.10	k: 0.21	**4.578**	15.21
FOMC	o	3.2	α: 12620 β: 83360	12.1	-	β: 83360	β: 83358.14	4.578	15.21

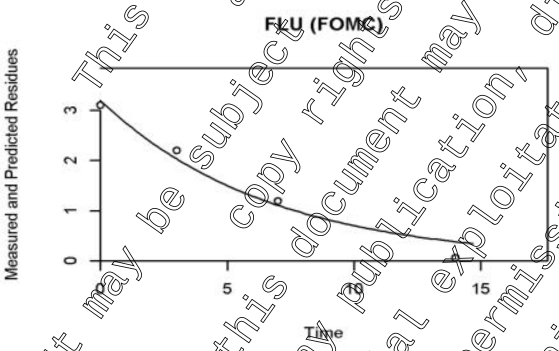
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



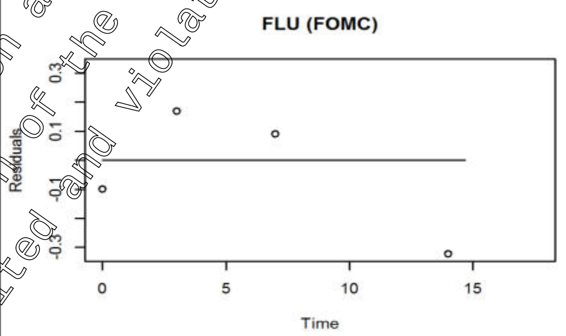
SFO



SFO



FOMC



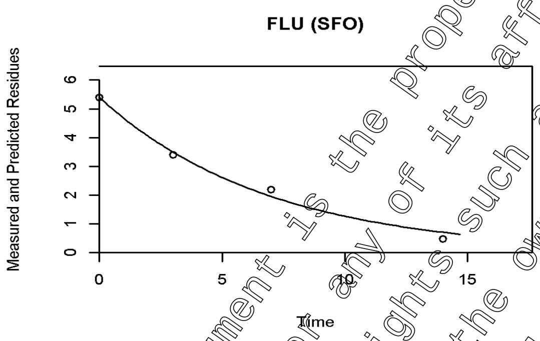
FOMC

14-2185-03, Zafarraya, M-536963-01-1, ES, lettuce

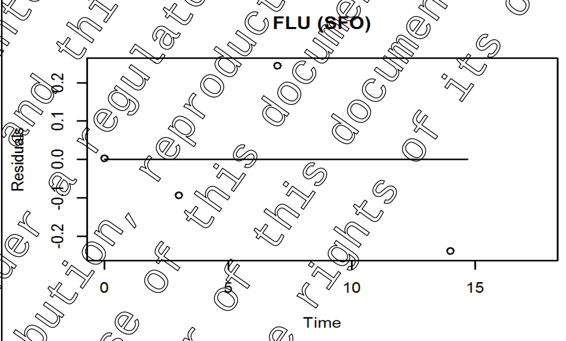
Table 8.9- 205: Kinetic models and goodness-of-fit statistics of fluopyram fits for Lettuce of trial 14-2185-03, Zafarraya, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	5.4	k: 0.14501	5.0	k: 0.005	k: 0.12	k: 0.17	**4.780**	15.88
FOMC	+	5.4	α: 13641.116 β: 94065.607	6.3	-	β: 93518.44	β: 94612.78	4.780	15.88

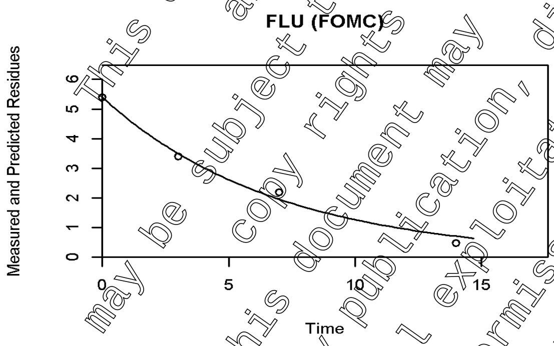
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



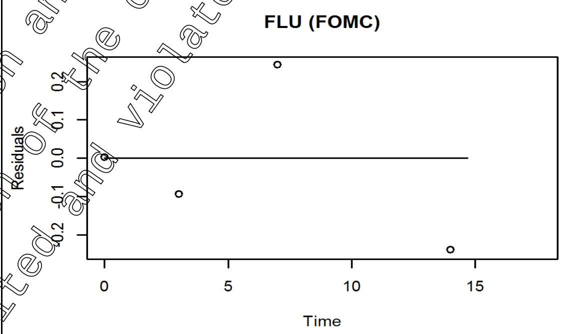
SFO



SFO



FOMC



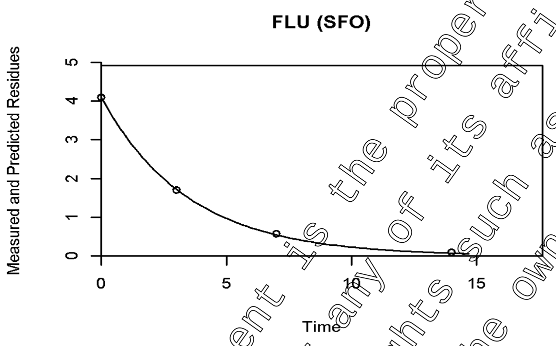
FOMC

14-2185-04, Nea Magnisia, M-536963-01-1, GR, lettuce

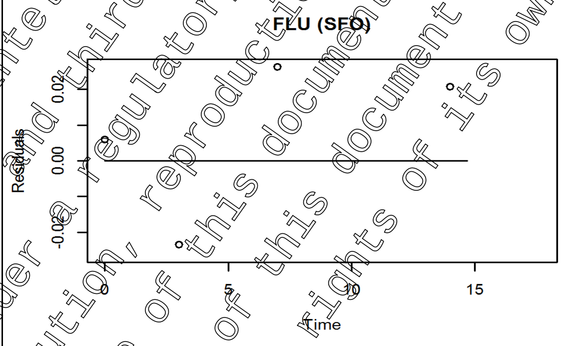
Table 8.9- 206: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 14-2185-04, Nea Magnisia, GR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	4.1	k: 0.288406	1.0	k: <0.001	k: 0.28	k: 0.30	**2.403**	7.984
FOMC	+	4.1	α: 15.65734 β: 51.93517	0.2	-	β: 35.42	β: 68.45	2.351	8.228

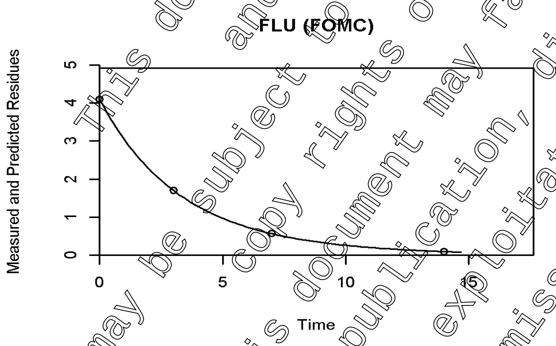
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



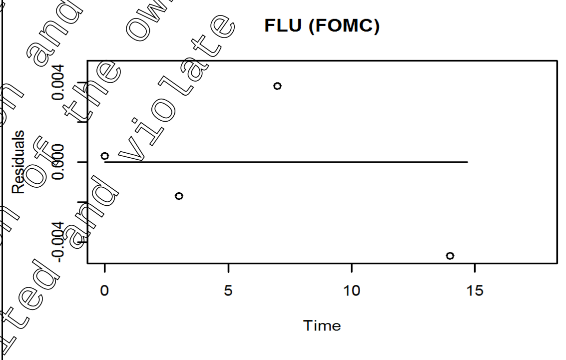
SFO



SFO



FOMC



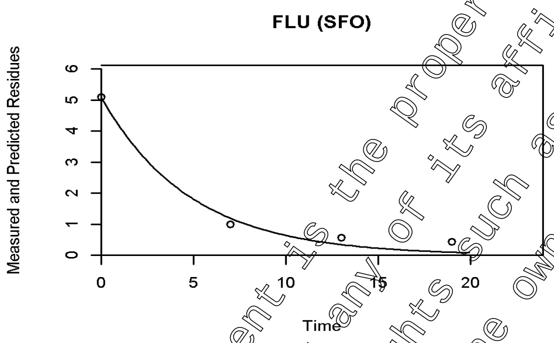
FOMC

15-2030-01 Abenraa, M-566823-03-1, DK. peas

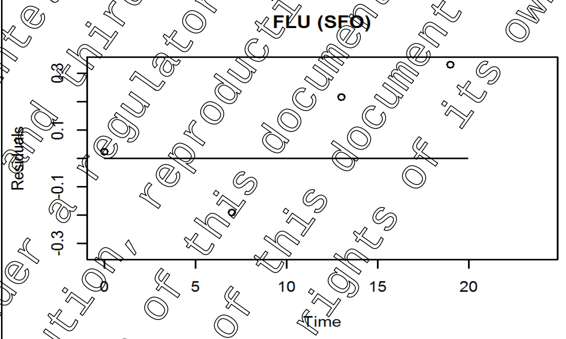
Table 8.9- 207: Kinetic models and goodness-of-fit statistics of fluopyram fits for lettuce of trial 15-2030-01, Abenraa, DK

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	5.1	k: 0.20715	10.1	k: 0.012	k: 0.14	k: 0.27	**3.346**	11.12
FOMC	+	5.1	α: 1.02347 β: 1.77546	0.9	-	β: 0.91	β: 2.64	1.719	15.07

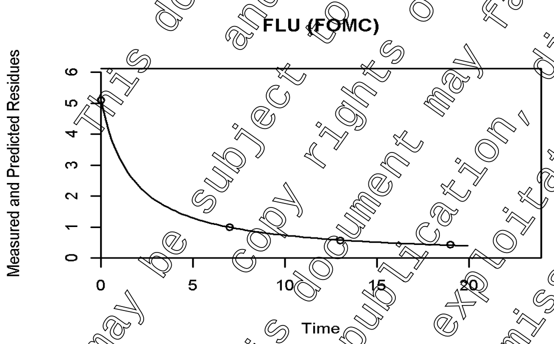
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



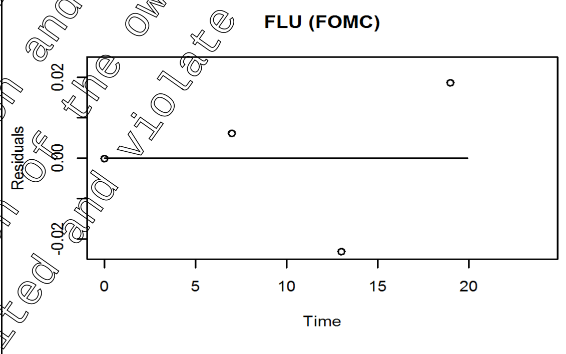
SFO



SFO



FOMC



FOMC

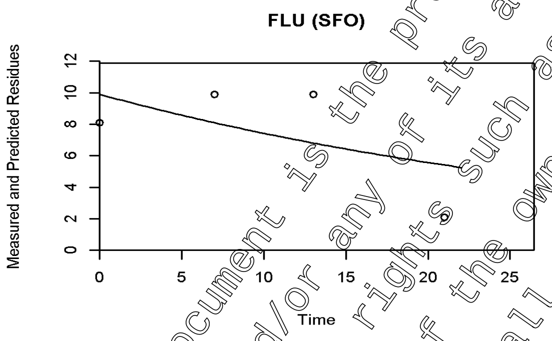
15-2030-03, Salobrena, M-566823-03-1, ES, peas

Table 8.9- 208: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial 15-2030-03, Salobrena, ES

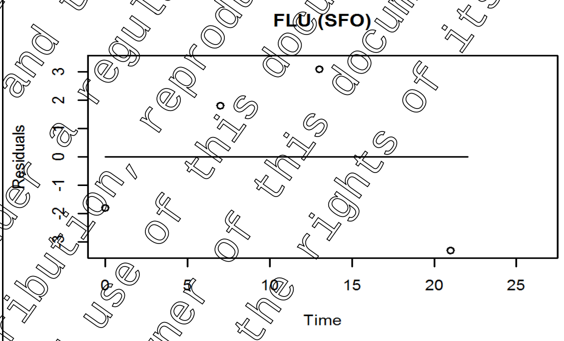
Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	9.9	k: 0.02876	28.3	k: 0.239	k: -0.04	k: 0.09	24.101	80.07
FOMC	-	9.9	α: 4182 β: 145400	35.4	-	β: 145000	β: 145798.2	24.1	80.09

SFO fit is statistically and visually poor (χ^2err >15%, t-test >0.05). FOMC, DFOP and HS did not result in an improved fit. No further explanation for the scattering and untypical residue data is given in the experimental report.

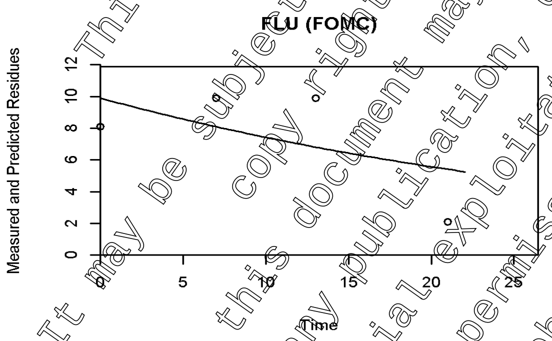
Consequently, **no statistically reliable evaluation is possible.**



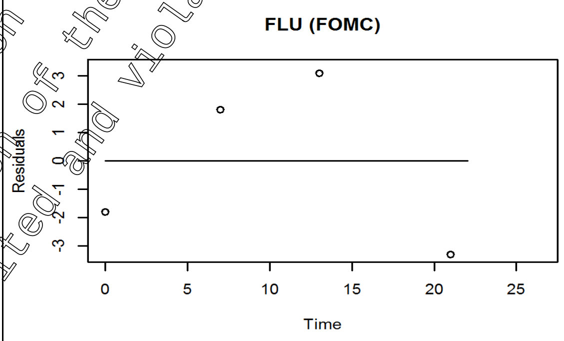
SFO



SFO



FOMC



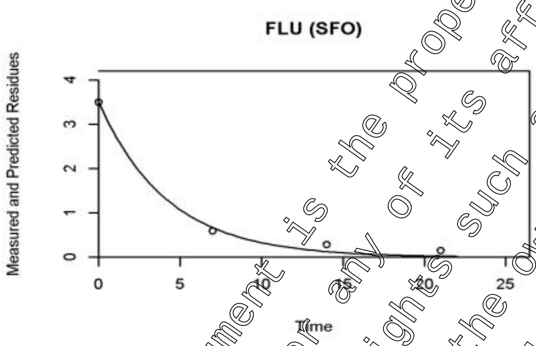
FOMC

15-2030-04 Mediglia, M-566823-03-1, IT, peas

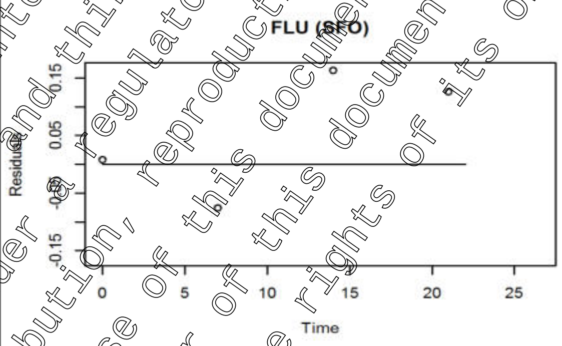
Table 8.9- 209: Kinetic models and goodness-of-fit statistics of fluopyram fits for pea of trial 15-2030-04, Mediglia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.5	k: 0.23674	7.9	k: 0.009	k: 0.17	k: 0.30	**2.928**	9.73
FOMC	+	3.5	α: 1.4539 β: 2.9312	1.0	-	β: 1.40	β: 4.47	1.790	11.35

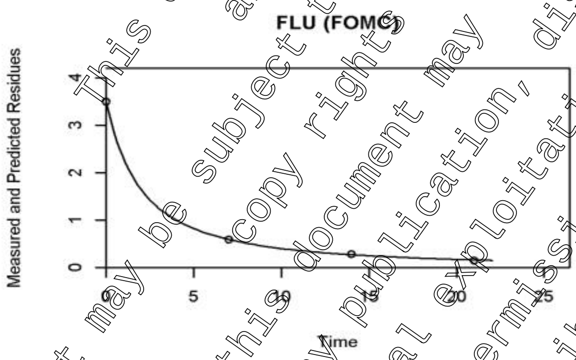
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



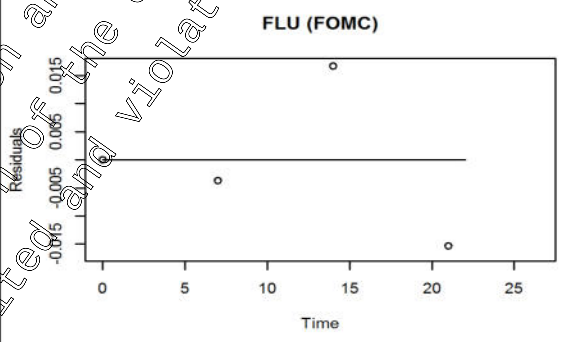
SFO



SFO



FOMC



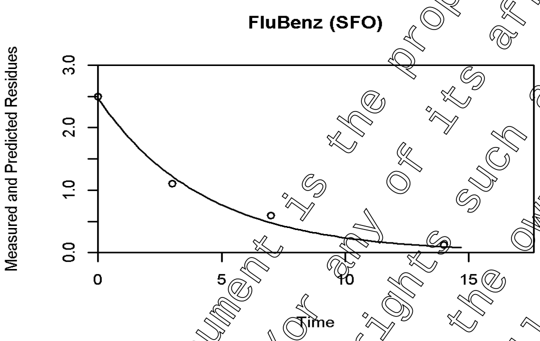
FOMC

Fluopyram + FLU-benzamide

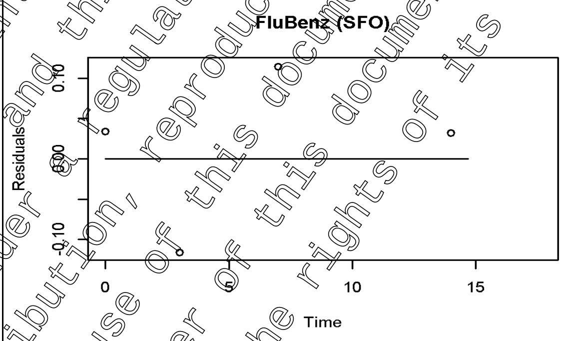
14-2029-01, Villers-Perwin, M-534202-01-1, BE, lettuce

Table 8.9- 210: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2029-01, Villers-Perwin, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	2.5	k: 0.23426	6.4	k: 0.006	k: 0.18	k: 0.29	**2.959**	9.83
FOMC	+	2.5	α: 2.8693 β: 9.5683	5.0	-	β: -10.76	β: 29.90	2.615	11.78
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).									



SFO



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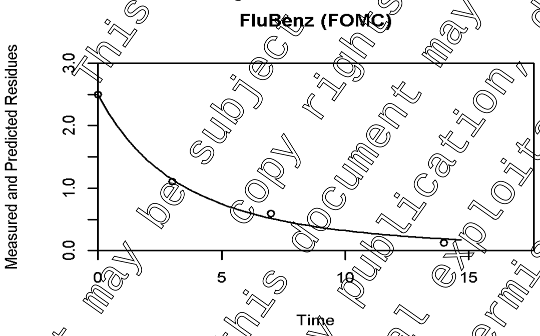
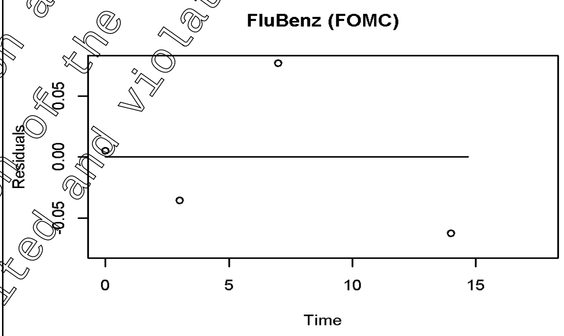


FOMC



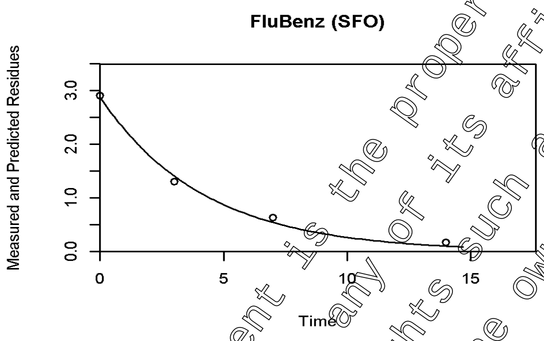
FOMC

14-2029-02, Dannstadt-Schauernheim, M-534202-01-1, DE, lettuce

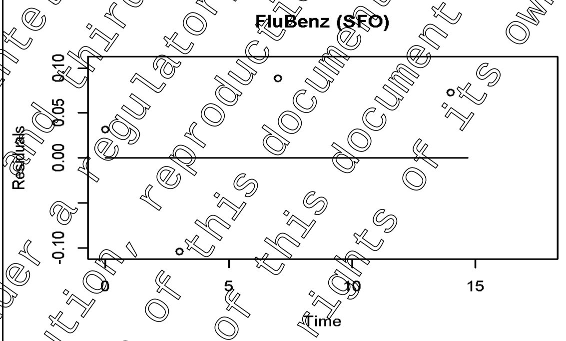
Table 8.9- 211: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2029-02, Dannstadt-Schauernheim, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	2.9	k: 0.23826	5.1	k: 0.004	k: 0.20	k: 0.28	**2.909**	9.66
FOMC	+	2.9	α: 3.03093 β: 10.11657	2.3	-	β: -0.13	β: 20.37	2.599	11.51

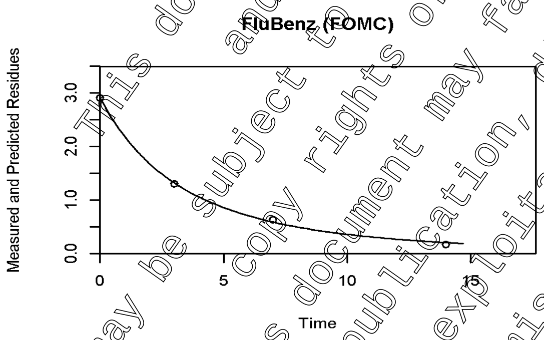
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



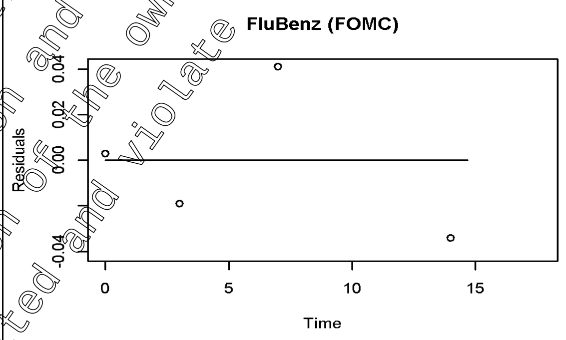
SFO



SFO



FOMC



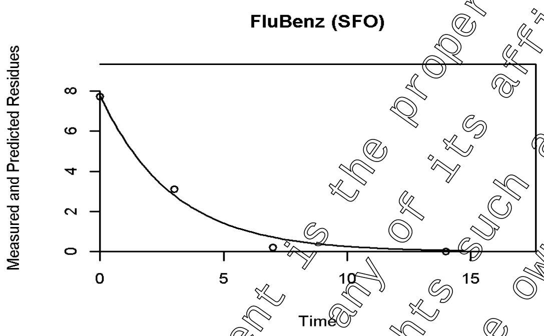
FOMC

14-2029-04, Lignieres de Touraine, M-534202-01-1, FR. lettuce

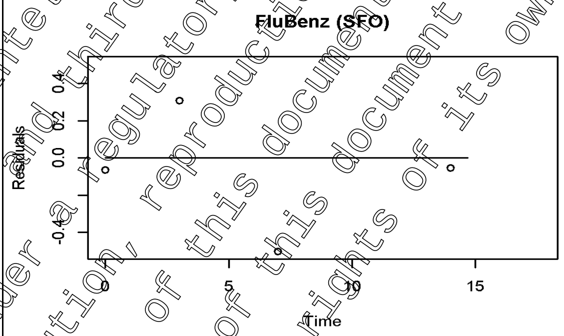
Table 8.9- 212: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2029-04, Lignieres de Touraine, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	7.8	k: 0.34022	8.8	k: 0.009	k: 0.25	k: 0.43	**2.037**	6.77
FOMC	+	7.8	α: 10350 β: 30410	11.0	-[a]	β: 29240	β: 31577.97	2.037	6.77

SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



SFO



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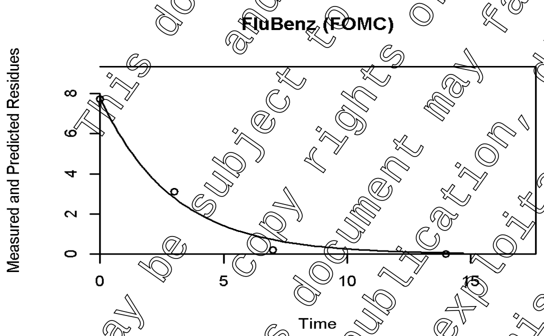
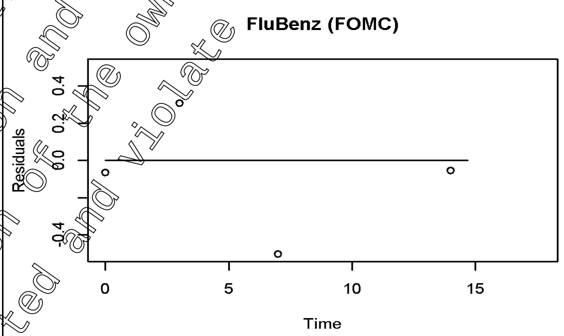


FOMC



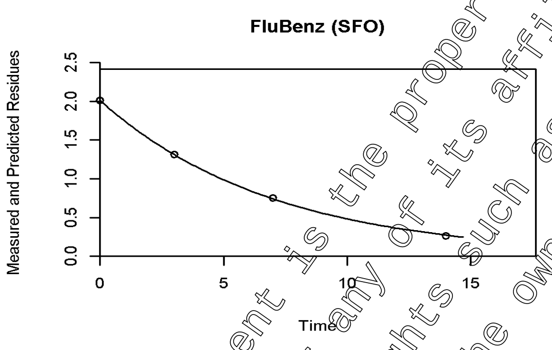
FOMC

14-2030-01, Alginet, M-534595-01-1, ES, lettuce

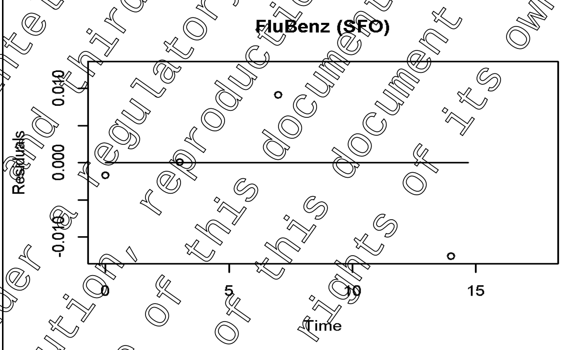
Table 8.9- 213: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2030-01, Alginet, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	2.0	k: 0.142849	0.6	k: <0.001	k: 0.14	k: 0.15	**4.852**	16.12
FOMC	+	2.0	α: 18250 β: 127800	0.7	-	β: 127800	β: 127800	4.852	16.12

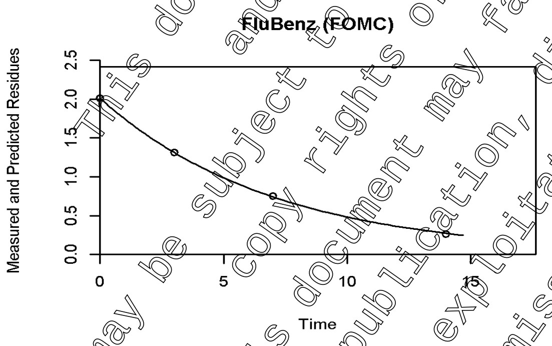
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



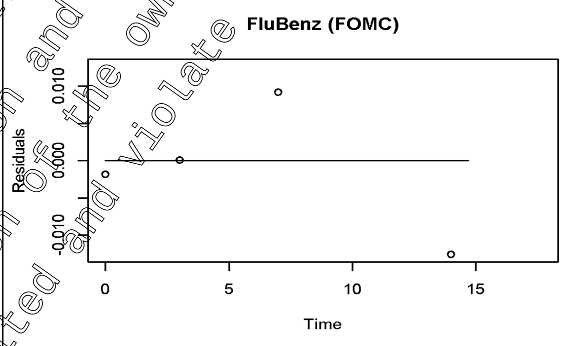
SFO



SFO



FOMC



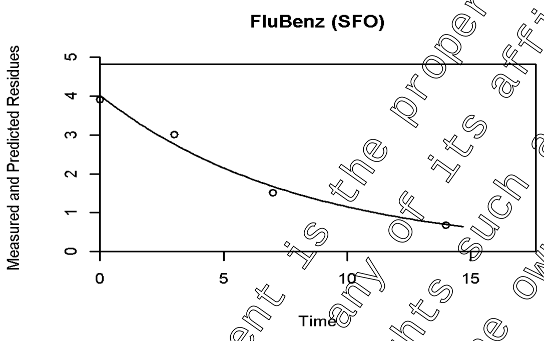
FOMC

14-2030-02, C. da Pigno, Catania, M-534595-01-1, IT, lettuce

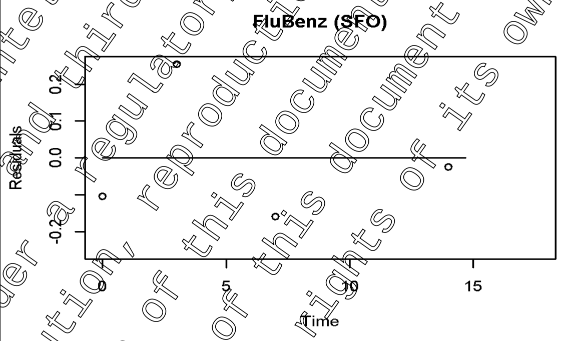
Table 8.9- 214: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2030-02, C. da Pigno, Catania, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	4.0	k: 0.12486	5.7	k: 0.008	k: 0.09	k: 0.16	**5.552**	18.44
FOMC	+	4.0	α: 35980 β: 288200	7.1	-	β: 288200.00	β: 288200.00	5.552	18.44

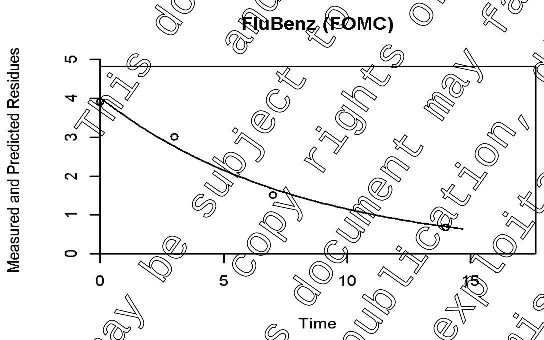
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



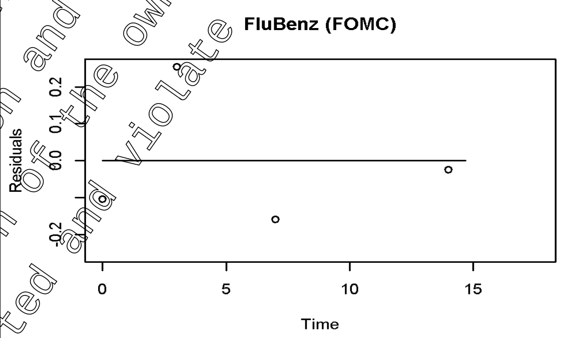
SFO



SFO



FOMC



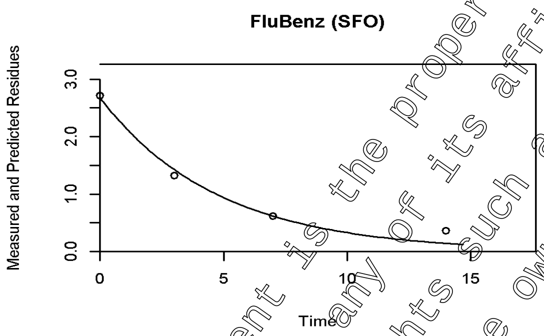
FOMC

14-2030-03,St. Etienne du Gres, M-534595-01-1, FR, lettuce

Table 8.9- 215: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2030-03,St. Etienne du Gres, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	2.7	k: 0.20913	8.1	k: 0.011	k: 0.15	k: 0.27	**3.314**	11.01
FOMC	+	2.7	α: 1.63969 β: 5.24444	3.0	-	β: -0.29	β: 10.78	2.759	16.11

SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



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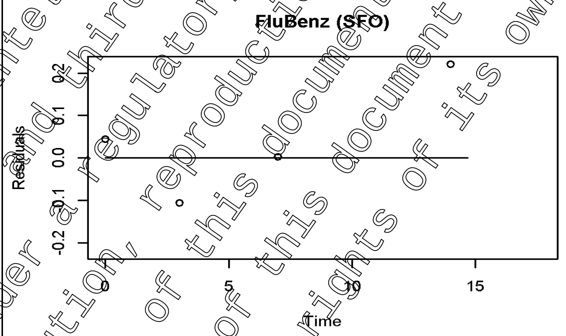

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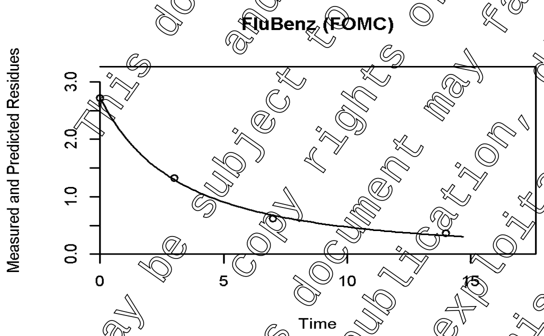
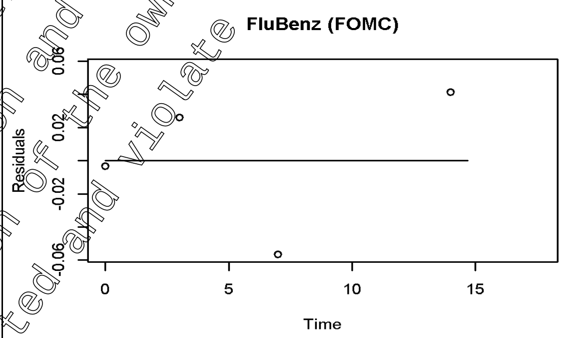


FOMC



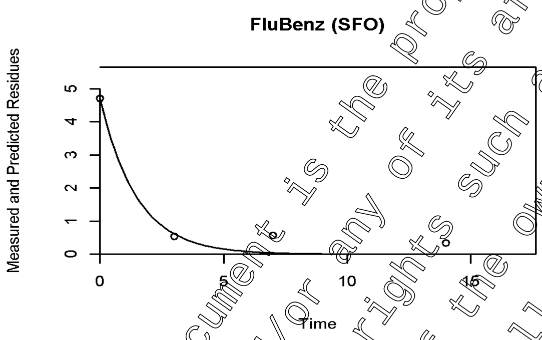
FOMC

14-2030-04, Aronas, M-534595-01-1, GR, lettuce

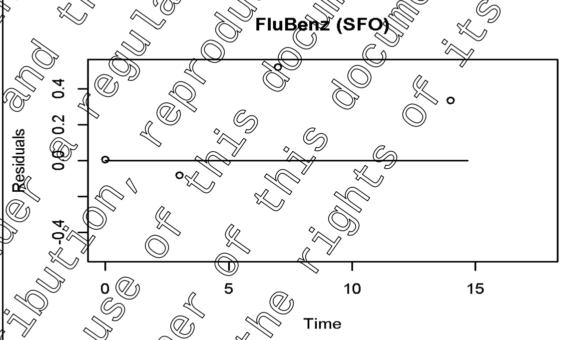
Table 8.9- 216: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2030-04, Aronas, GR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	4.7	k: 0.6773	16.6	k: 0.052	k: 0.21	k: 1.14	1.023	3.40
FOMC	+	4.7	α: 0.2355889 β: 0.0003833	3.9	-	β: -0.01	β: 0.01	0.0069	6.733

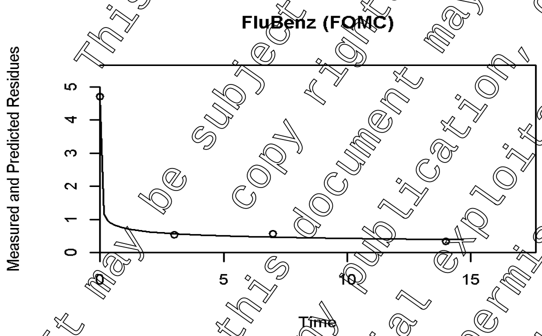
SFO fit is statistically still acceptable (χ^2err ~15%, t-test <0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. DFOP and HS fits cannot deliver statistical information, as degrees of freedom are too low (3 fitted parameters based on 4 data points). FOMC fit is statistically (χ^2err, t-test) and visually good. Consequently, **FOMC** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



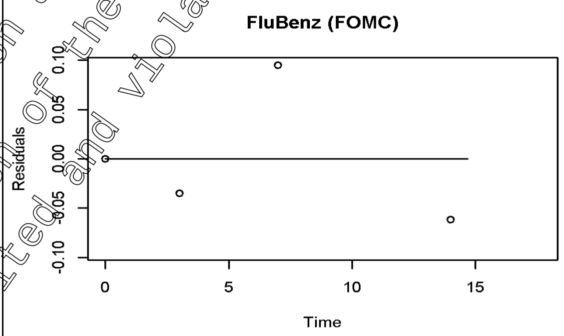
SFO



SFO



FOMC



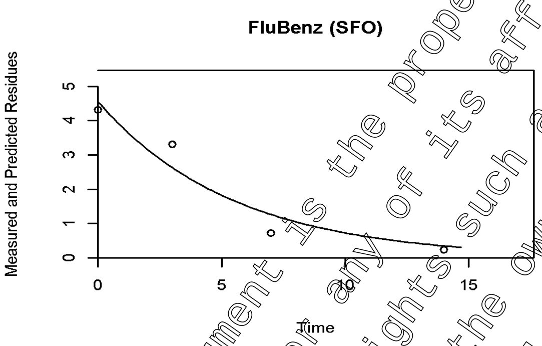
FOMC

14-2030-05, Gela, M-534595-01-1, IT, lettuce

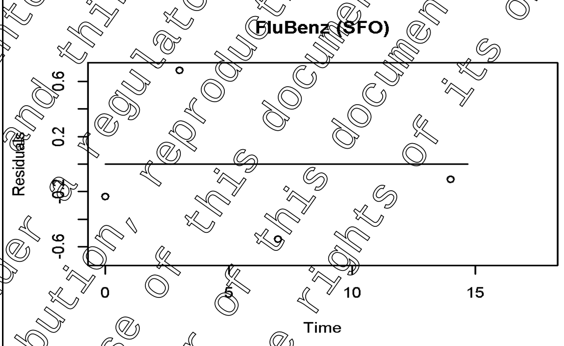
Table 8.9- 217: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2030-05, Gela, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	4.6	k: 0.1829	17.3	k: 0.043	k: 0.07	k: 0.30	**3.790**	12.59
FOMC	o	4.6	α: 9538 β: 52150	21.6	-[a]	β: 50680	β: 53613.7	3.790	12.59

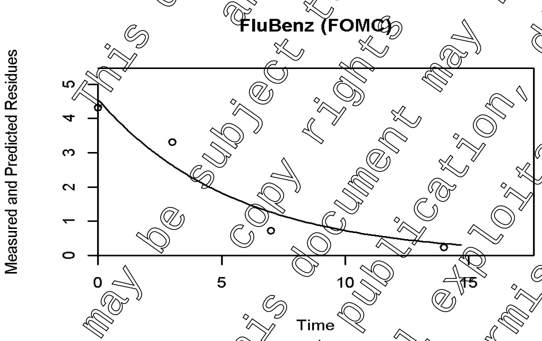
SFO fit is statistically and visually still acceptable (χ^2err ~15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



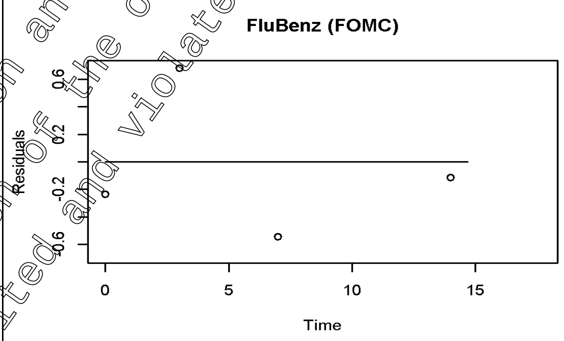
SFO



SFO



FOMC



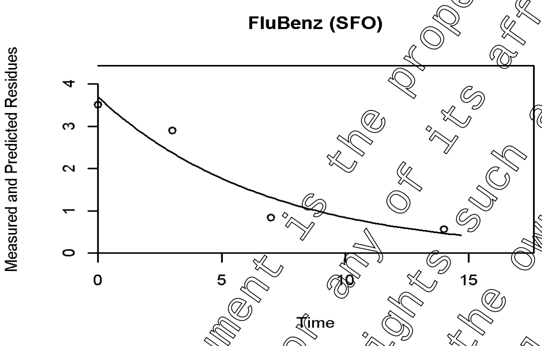
FOMC

14-2184-02, Hooghalen, M-536965-01-1, NL, lettuce

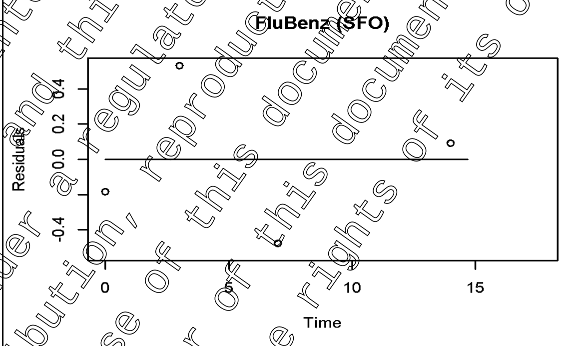
Table 8.9- 218: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2184-02, Hooghalen, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.7	k: 0.14748	15.5	k: 0.043	k: 0.06	k: 0.24	**4.700**	15.61
FOMC	o	3.7	α: 8237 β: 55850	19.4	-[a]	β: 54820	β: 56874.71	4.700	15.61

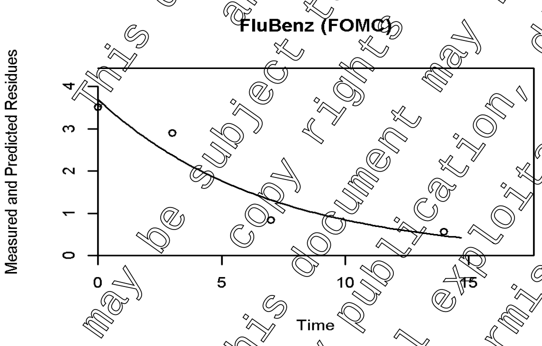
SFO fit is statistically and visually acceptable (χ^2err ~15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



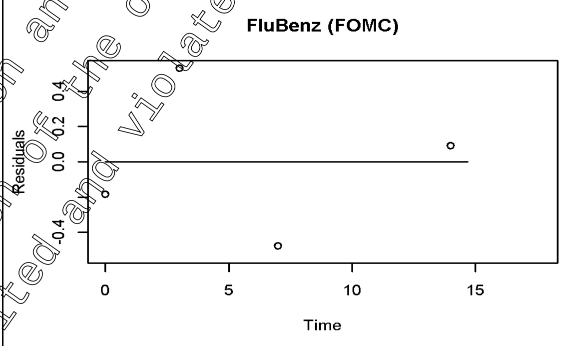
SFO



SFO



FOMC



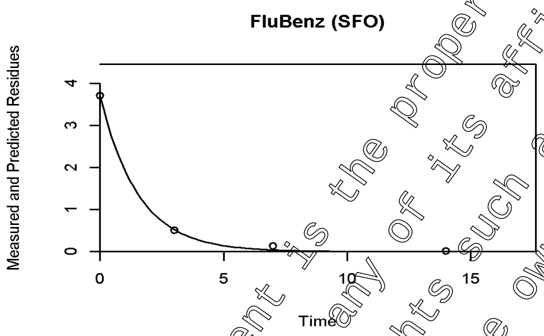
FOMC

15-2185-01, Mediglia, M-536963-01-1, IT, lettuce

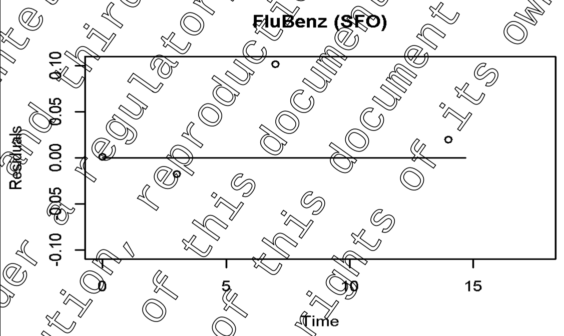
Table 8.9- 219: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2185-01, Mediglia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.7	k: 0.65338	3.9	k: 0.003	k: 0.56	k: 0.75	**1.061**	3.52
FOMC	+	3.7	α: 2.4178 β: 2.34609	0.8	-	β: 1.19	β: 3.50	0.779	3.734

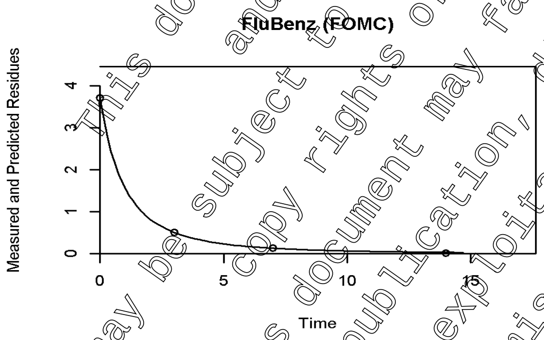
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



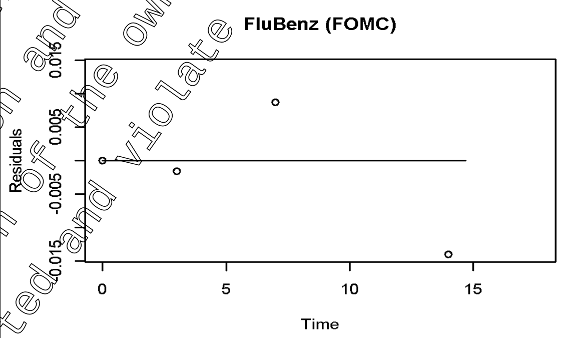
SFO



SFO



FOMC



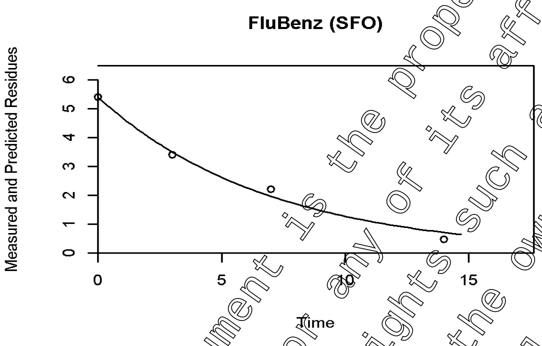
FOMC

14-2185-03, Zafarraya, M-536963-01-1, ES, lettuc

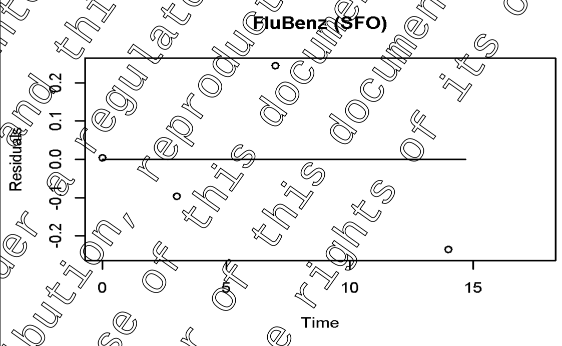
Table 8.9- 220: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2185-03, Zafarraya, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	5.4	k: 0.14449	5.0	k: 0.005	k: 0.12	k: 0.17	**4.797**	15.94
FOMC	+	5.4	α: 15450 β: 106900	6.2	-	β: 106300	β: 107514.4	4.797	15.94

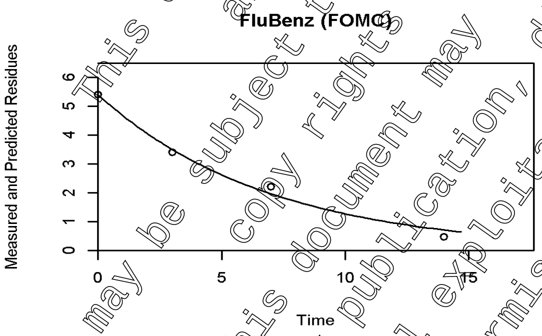
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



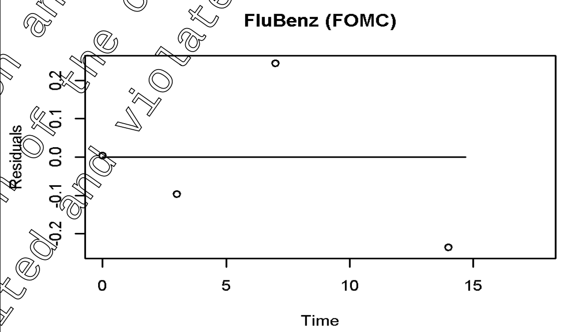
SFO



SFO



FOMC



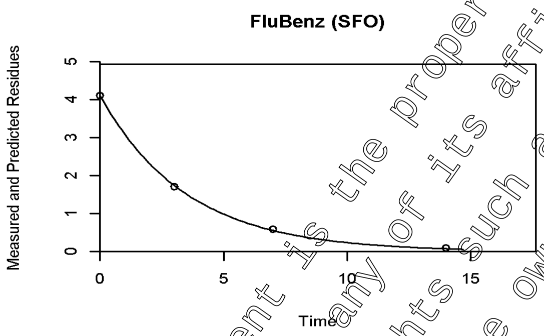
FOMC

14-2185-04, Nea Magnisia, M-536963-01-1, GR, lettuce

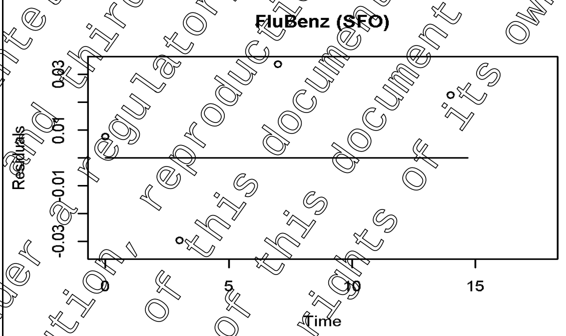
Table 8.9- 221: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for lettuce of trial 14-2185-04, Nea Magnisia, GR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	4.1	k: 0.285539	1.3	k: <0.001	k: 0.27	k: 0.30	**2.428**	8.06
FOMC	+	4.1	α: 13.0556 β: 43.35374	0.4	-	β: 21.92	β: 64.79	2.364	8.36

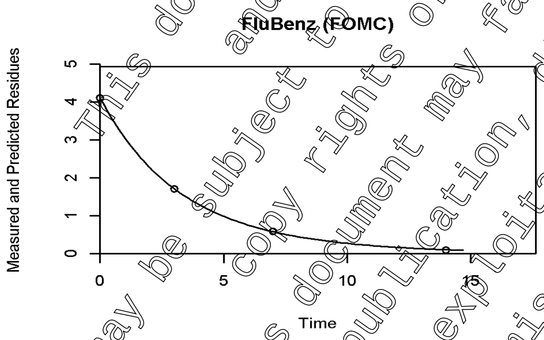
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



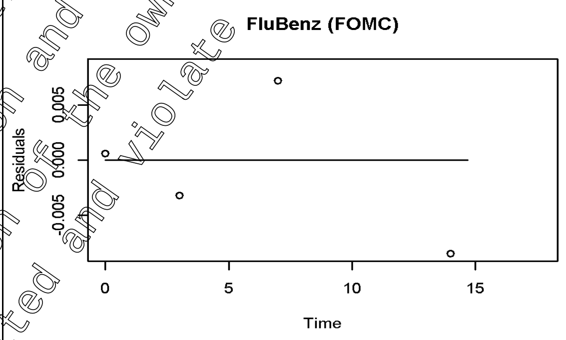
SFO



SFO



FOMC



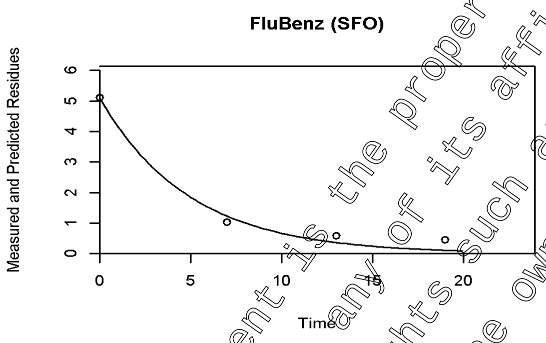
FOMC

15-2030-01, Abenraa, M-566823-03-1, DK, peas

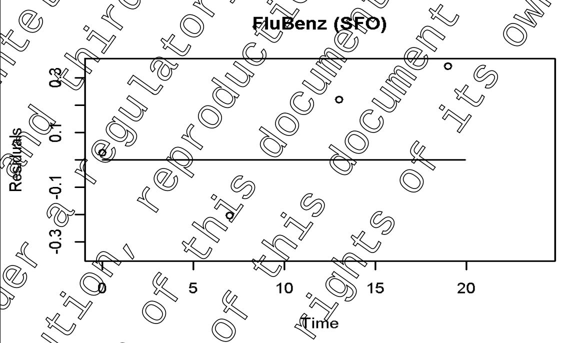
Table 8.9- 222: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for pea of trial 15-2030-01, Abenraa, DK

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	5.1	k: 0.20308	10.4	k: 0.013	k: 0.14	k: 0.27	**3.413**	11.34
FOMC	+	5.1	α: 0.99035 β: 1.7085	0.8	-	β: 0.91	β: 2.51	1.732	15.76

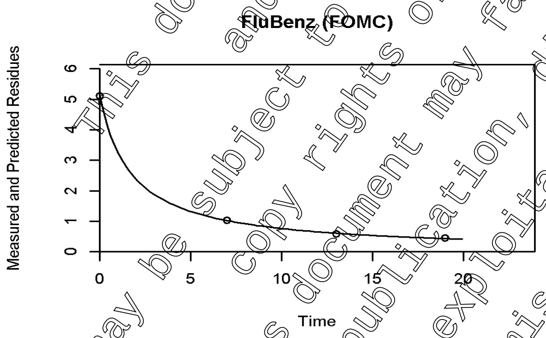
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test<0.05), and usable according modelling purpose (FOCUS kinetics).



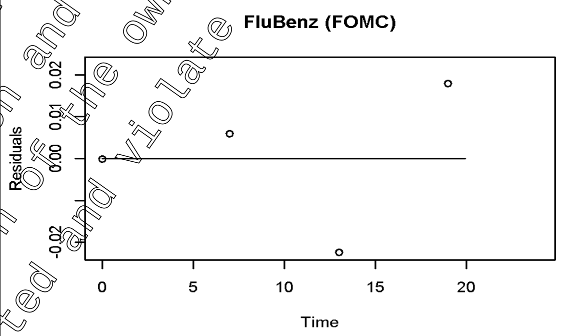
SFO



SFO



FOMC



FOMC

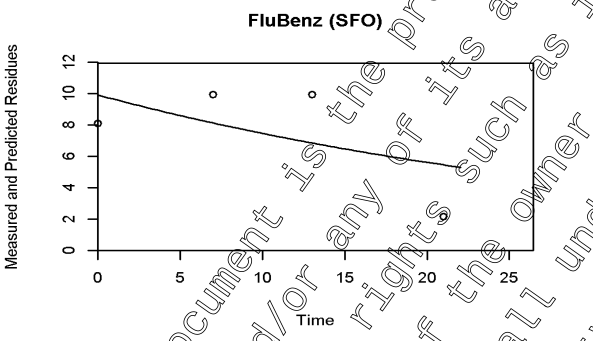
15-2030-03, Salobrena, M-566823-03-1, ES, peas

Table 8.9- 223: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for pea of trial 15-2030-03, Salobrena, ES

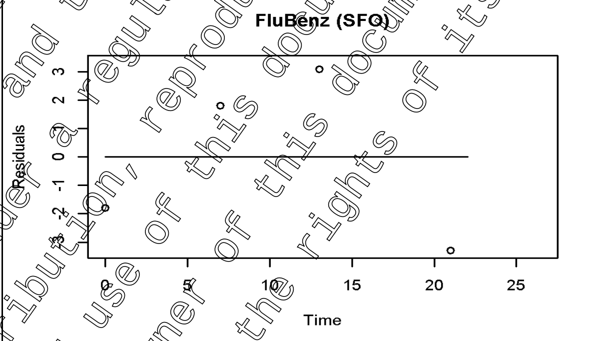
Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	9.9	k: 0.02836	28.1	k: 0.241	k: -0.04	k: 0.09	24.440	81.19
FOMC	-	9.9	α: 4268 β: 150500	35.1	-	β: 150100	β: 150881.97	24.440	81.21

SFO fit is statistically and visually poor (χ^2err >15%, t-test >0.05). FOMC, DFOP and HS did not result in an improved fit. No further explanation for the scattering and untypical residue data is given in the experimental report.

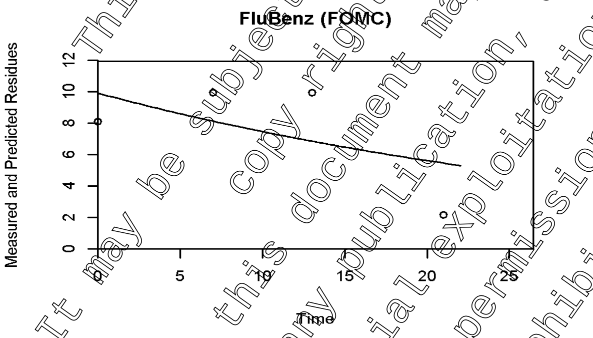
Consequently, **no statistically reliable evaluation is possible.**



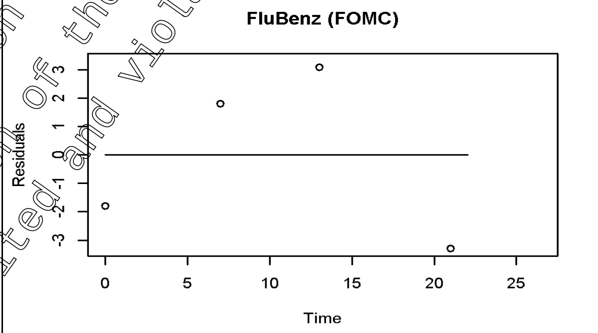
SFO



SFO



FOMC



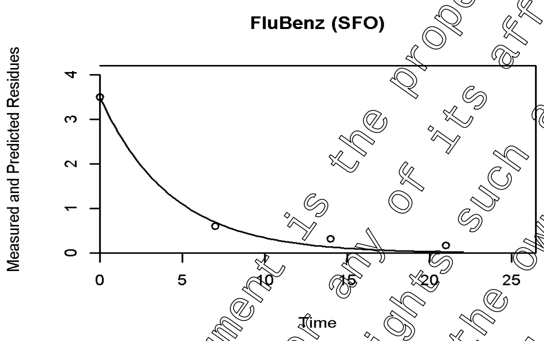
FOMC

15-2030-04, Mediglia, M-566823-03-1, IT, peas

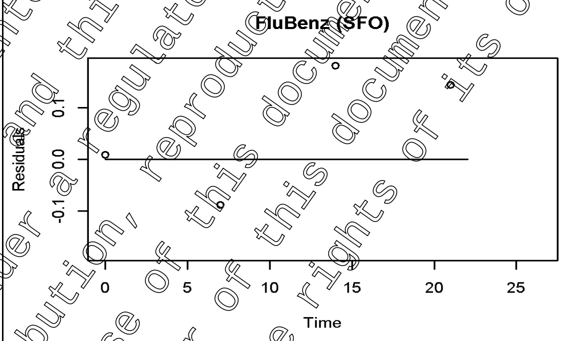
Table 8.9- 224: Kinetic models and goodness-of-fit statistics of fluopyram+benazamide fits for pea of trial 15-2030-04, Mediglia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.5	k: 0.23188	8.8	k: 0.011	k: 0.16	k: 0.30	**2.989**	9.93
FOMC	+	3.5	α: 1.27165 β: 2.35118	1.2	-	β: 0.85	β: 3.85	1.704	12.03

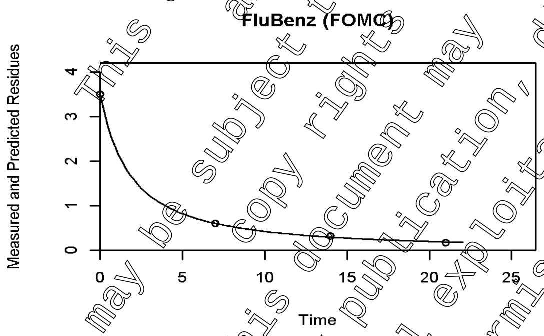
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



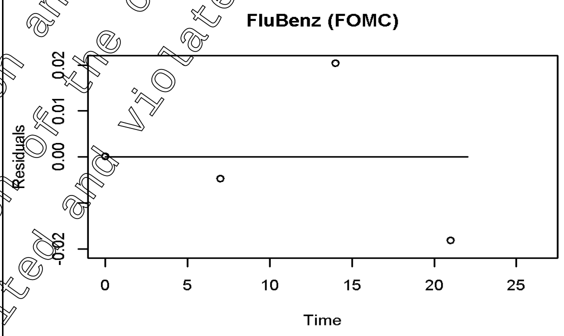
SFO



SFO



FOMC



FOMC

III. CONCLUSION

The following units are used in the following tables:

k	1/d
β, tb	d
α, g	none

Table 8.9- 225: Foliar DT_{50} parameters of fluopyram in green material of lettuce and peas, after application of Luna Privilege (SC 500), based on time points after last application, for modelling purpose

Fluopyram	**Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, peas, Luna Sensation**								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**$DT_{50\ pseudo}$ (d)**	**$DT_{90\ actual}$ (d)**	**$DT_{50\ fast}$ (d)**	**$DT_{50\ slow}$ (d)**
14-2029-01, Villers-Perwin, B, M-534202-01-1	N	**SFO**	k: 0.23727	6.2	k: 0.006	**2.921**	9.705		
14-2029-02, Dannstadt, D, M-534202-01-1	N	**SFO**	k: 0.23968	4.9	k: 0.004	**2.892**	9.607		
14-2029-03, Zwaagdijk, NL, M-534202-01-1	N	**SFO**	k: 0.41212	5.6	k: 0.004	**1.682**	5.587		
14-2029-04, Lignieres de Touraine, FR, M-534202-01-1	N	**SFO**	k: 0.34079	8.8	k: 0.009	**2.034**	6.757		
14-2029-05, Leichlingen, D, M-534202-01-1	N	**SFO**	k: 0.385019	1.1	k: <0.001	**1.800**	5.98		
14-2030-01, Alginet, ES, M-534595-01-1	S	**SFO**	k: 0.14428	0.7	k: <0.001	**4.804**	15.96		
14-2030-02, C.da Pigno, Catania, IT M-534595-01-1	S	**SFO**	k: 0.12553	5.7	k: 0.008	**5.522**	18.34		
14-2030-03, St. Etienne du Gres, FR, M-534595-01-1	S	**SFO**	k: 0.2144	7.7	k: 0.009	**3.233**	10.74		
14-2030-04, Aronas, GR, M-534595-01-1	S	**FOMC**	α: 0.240553 β: 0.0004435	3.8	-	**1.918**	6.367		
14-2030-05 Gela, IT, M-534595-01-1	S	**SFO**	k: 0.18343	17.5	k: 0.043	**3.779**	12.55		
14-2184-01 Neuruppin, D, M-536965-01-1	N	**SFO**	k: 0.63311	5.2	k: 0.005	**1.095**	3.637		

Fluopyram	**Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, peas, Luna Sensation**								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**DT_{90} actual (d)**	**DT_{50} fast (d)**	**DT_{50} slow (d)**
14-2184-02 Hooghalen, NL, M-536965-01-1	N	**SFO**	k: 0.14717	15.5	k: 0.043	**4.710**	15.65		
14-2184-03 Nyiregyhaza, HU, M-536965-01-1	N	**SFO**	k: 0.28815	12.5	k: 0.018	**2.406**	7.991		
14-2184-04 Banbury, GB, M-536965-01-1	N	**SFO**	k: 0.435297	0.8	k: <0.001	**1.592**	5.29		
14-2185-01 Mediglia, IT, M-536963-01-1	S	**SFO**	k: 0.65562	4.0	k: 0.003	**1.057**	3.512		
14-2185-02 Pozoblanco, ES, M-536963-01-1	S	**SFO**	k: 0.1514	9.7	k: 0.017	**4.578**	15.21		
14-2185-03 Zafarraya, ES, M-536963-01-1	S	**SFO**	k: 0.14501	5.0	k: 0.005	**4.780**	15.88		
14-2185-04 Nea Magnisia, GR, M-536963-01-1	S	**SFO**	k: 0.288406	1.0	k: <0.001	**2.403**	7.984		
15-2030-01 Abenraa, DK, M-566823-03-1	N	**SFO**	k: 0.20715	10.1	k: 0.012	**3.346**	11.12		
15-2030-04 Mediglia, IT, M-566823-03-1	S	**SFO**	k: 0.23674	7.9	k: 0.009	**2.928**	9.726		
Geomean (n=20) M						**2.673** M			

DT_{50} pseudo = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT_{90} actual time for first 90 % of residues to dissipate
DT_{50} fast = ln(2)/k1
DT_{50} slow = ln(2)/k2 (DFOP, HS)
M geomean of DT_{50} pseudo of fits for modelling purpose

Table 8.9- 226: Foliar DT_{50} parameters of fluopyram + FLU-benzamide in green material of lettuce and peas, after application of Luna Privilege (SC 500), based on time points after last application, for modelling purpose

Fluopyram + FLU-benzamide	**Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, peas, Luna Sensation**								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**DT_{90} actual (d)**	**DT_{50} fast (d)**	**DT_{50} slow (d)**
14-2029-01, Villers-Perwin, B, M-534202-01-1	N	**SFO**	k: 0.23426	6.4	k: 0.006	**2.959**	9.829		
14-2029-02, Dannstadt, D, M-534202-01-1	N	**SFO**	k: 0.23826	5.1	k: 0.004	**2.909**	9.664		
14-2029-04, Lignieres de T, FR, M-534202-01-1	N	**SFO**	k: 0.34022	8.8	k: 0.009	**2.037**	6.768		
14-2030-01, Alginet, ES, M-534595-01-1	S	**SFO**	k: 0.142849	0.6	k: <0.001	**4.852**	16.12		
14-2030-02, C.da Pigno, Catania, IT M-534595-01-1	S	**SFO**	k: 0.12486	5.7	k: 0.008	**5.551**	18.44		
14-2030-03, St. Etienne du Gres, FR, M-534595-01-1	S	**SFO**	k: 0.20913	8.1	k: 0.011	**3.314**	11.01		
14-2030-04, Aronas, GR, M-534595-01-1	S	**FOMC**	α: 0.2355889 β: 0.0003833	3.9	-	**2.028**	6.733		
14-2030-05 Gela, IT, M-534595-01-1	S	**SFO**	k: 0.1829	17.3	k: 0.043	**3.790**	12.59		
14-2184-02 Hooghalen, NL, M-536965-01-1	N	**SFO**	k: 0.14748	15.5	k: 0.043	**4.700**	15.61		
14-2185-01 Mediglia, IT, M-536963-01-1	S	**SFO**	k: 0.65338	3.9	k: 0.003	**1.061**	3.524		
14-2185-03 Zafarraya, ES, M-536963-01-1	S	**SFO**	k: 0.14449	5.0	k: 0.005	**4.797**	15.94		
14-2185-04 Nea Magnisia, GR, M-536963-01-1	S	**SFO**	k: 0.285539	1.3	k: <0.001	**2.428**	8.064		
15-2030-01 Abenraa, DK, M-566823-03-1	N	**SFO**	k: 0.20308	10.4	k: 0.014	**3.413**	11.34		
15-2030-04 Mediglia, IT, M-566823-03-1	S	**SFO**	k: 0.23188	8.8	k: 0.011	**2.989**	9.93		

Fluopyram + FLU-benzamide	Foliar dissipation, crop residue decline studies, in dicotyledons, lettuce, peas, Luna Sensation								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**DT_{90} actual (d)**	**DT_{50} fast (d)**	**DT_{50} slow (d)**
Geomean, trials with FLU-benz > LOQ (n=14) [M]						3.087 [M]			
Geomean, incl. all trials (n=20) [A]						**2.697** [A]			

DT_{50} pseudo	= DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT_{90} actual	time for first 90 % of residues to dissipate
DT_{50} fast	= ln(2)/k1
DT_{50} slow	= ln(2)/k2 (DFOP, HS)
M	geomean DT_{50} pseudo of fits for modelling purpose, for trials with FLU-benzamide > LOQ
A	geomean DT_{50} pseudo of fits for modelling purpose: for trials with FLU-benzamide > LOQ and remaining trials of FLU only from table above, where FLU-benzamide was < LOQ

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment.

The geometric mean of the DT_{50} for fluopyram was 2.673 days (n=20).
Additionally, an evaluation was made of the decline kinetics of the combined residues of fluopyram and its metabolite fluopyram-benzamide (in all 20 trials the metabolite was included as analyte).
The geometric mean DT_{50} of the combined residue was 2.697 days (~1% longer than for fluopyram alone. Thus, the contribution of the metabolite fluopyram-benzamide is negligible for risk assessment.

Data Point:	KCA 8.9/15
Report Author:	[redacted]
Report Year:	2021
Report Title:	Fluopyram (FLU) and metabolite - Kinetic evaluation of green plant residues in leek, onion and cabbage, applying Luna Experience (SC400, FLU+TBZ)
Report No:	EnSa-20-0832
Document No:	M-763354-02-1
Guideline(s) followed in study:	not applicable
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

EXECUTIVE SUMMARY

Kinetic evaluations were conducted for the residue decline of fluopyram from foliage after application on various vegetables. All trials were evaluated with SFO and FOMC kinetics. Where the number of sampling points allowed the evaluation, 2 biphasic kinetic models were fitted additionally (DFOP and HS), with a preference for selecting SFO where the fit was considered visually and statistically acceptable. Otherwise, the best-fit of the other models was selected. To facilitate the use of the selected kinetic parameter, a surrogate SFO DT_{50} was estimated as $DT_{90}/3.32$ for the non SFO kinetics.
The geometric mean of the DT_{50} for fluopyram was 3.921 days (n=35).

Additionally, an evaluation was made of the decline kinetics of the combined residues of fluopyram and its metabolite fluopyram-benzamide (in all 35 trials the metabolite was included as analyte).
The geometric mean DT_{50} of the combined residue was 4.144 days (~5% longer than for fluopyram alone). Thus, the contribution of the metabolite fluopyram-benzamide is negligible for risk assessment.

The outcome of the evaluations is presented below.

Table 8.9- 227: Comparison of foliar DT_{50}s of fluopyram and fluopyram + FLU-benzamide in green material of leek, onion, cabbag

Fluopyram and FLU + FLU-benzamide	**Foliar residue dissipation in leek, onion and cabbage**			
Trial	**EU zone**	**Kinetic model**	**$DT_{50\ mod}$ FLU (d)**	**$DT_{50\ mod}$ FLU + benzamide (d)**
11-2029-01, Soings en Sologne, FR, M-442996-01-1	N	SFO	2.279	*2.279*
11-2029-02, Werl-Westönnen, DE, M-442996-01-1	N	SFO	2.657	*2.657*
11-2029-03, Langenfeld, DE, M-442996-01-1	N	SFO	2.620	*2.620*

Fluopyram and FLU + FLU-benzamide	**Foliar residue dissipation in leek, onion and cabbage**			
Trial	**EU zone**	**Kinetic model**	**DT$_{50\ mod}$ FLU (d)**	**DT$_{50\ mod}$ FLU + benzamide (d)**
11-2029-04, Villers-Perwin, BE, M-442996-01-1	N	SFO	2.543	*2.543*
R 2006 0337/1, Tilloloy, FR, M-292996-01-1	N	FOMC	7.184	*7.184*
R 2006 0339/8, Saint Bonnet de Mure, FR, M-292098-01-1	S	SFO	4.448	4.590
R 2006 0343/6, Faverolles, FR, M-292101-02-1	N	SFO	8.282	*8.282*
R 2006 0344/4, Cailloux sur Fontaines, FR, M-292082-01-1	S	SFO	6.010	6.334
R 2006 0347/9, Bouafle, FR, M-292103-01-1	N	HS	4.729	*4.729*
R 2006 0348/7, Ouzilly, FR, M-293182-01-1	S	FOMC	3.693	3.717
R 2006 0465/3, Langenfeld-Reusrath, DE, M-292101-02-1	N	SFO	2.346	*2.346*
R 2006 0466/1, Chatteris, GB, M-292101-02-1	N	SFO	5.836	*5.836*
R 2006 0468/8, Bornheim - Sechtem, DE, M-292101-02-1	N	SFO	8.990	*8.990*
R 2006 0469/6, Lebrija, ES, M-292082-01-1	S	SFO	7.054	6.969
R 2006 0504/8, Burscheid, DE, M-292996-01-1	N	SFO	4.910	5.363
R 2006 0505/6, Lusia, IT, M-292098-01-1	S	SFO	3.282	3.325
R 2006 0543/9, Little Shelford, GB, M-292103-01-1	N	SFO	5.780	*5.780*
R 2006 0544/7, Andria, IT, M-293182-01-1	S	FOMC	3.148	5.858
R 2007 0043/1, Toulouse, FR, M-302325-01-1	S	FOMC	4.584	13.066
R 2007 0056/3, Schauernheim, DE, M-304288-01-1	N	DFOP	4.184	*4.184*
R 2007 0057/1, Castelsarrasin, FR, M-302775-01-1	S	FOMC	5.241	*5.241*
R 2007 0078/4, Broad Fen Drove, Wissington, GB, M-302101-01-1	N	SFO	2.062	*2.062*
R 2007 0079/2, Ouzilly, FR, M-302044-01-1	S	FMOC	4.084	*4.084*
R 2007 0249/3, Schauernheim, DE, M-304276-01-1	N	HS	3.392	*3.392*
R 2007 0250/7, Castelsarrasin, FR, M-302780-01-1	S	HS	11.434	*11.434*

Fluopyram and FLU + FLU-benzamide	**Foliar residue dissipation in leek, onion and cabbage**			
Trial	**EU zone**	**Kinetic model**	**$DT_{50\ mod}$ FLU (d)**	**$DT_{50\ mod}$ FLU + benzamide (d)**
R 2007 0567/0, Southfleet, Gravesend, GB, M-302330-01-1	N	SFO	2.992	3.062
R 2007 0568/9, Lusia, IT, M-302325-01-1	S	SFO	4.203	4.264
R 2007 0569/7, Bouafle, FR, M-304288-01-1	N	FOMC	3.551	*3.551*
R 2007 0570/0, Zwaagdijk, NL, M-304288-01-1	N	FOMC	3.675	*3.675*
R 2007 0571/9, Langenfeld-Reusrath, DE, M-304288-01-1	N	SFO	2.557	*2.557*
R 2007 0572/7, Lusia, IT, M-302775-01-1	S	SFO	1.952	1.997
R 2007 0573/5, Bouafle, FR, M-304276-01-1	N	SFO	3.321	3.378
R 2007 0574/3, Zwaagdijk, NL, M-304276-01-1	N	SFO	2.916	*2.916*
R 2007 0599/9, Meckenbeuren, DE, M-302101-01-1	N	SFO	1.979	*1.979*
R 2007 0600/6, Brenes, ES, M-302044-01-1	S	SFO	3.981	4.030
Geomean (n=35)			**3.921**	**4.1444**

DT_{50} pseudo = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed

I. MATERIALS AND METHODS

A kinetic modelling analysis of European total crop residue decline study data of fluopyram (FLU) and fluopyram + fluopyram-benzamide (FLU-benzamide, M25) was conducted in order to derive kinetic parameters suitable for an ecotoxicological risk assessment, e.g. on birds and mammals, using the software tool KinGUI 2.1. The identification of the appropriate kinetic model followed the recommendations given by FOCUS Kinetics for modelling purpose (FOCUS kinetics, 2006, 2014) and EFSA (2019), based on a detailed statistical analysis including visual assessment, χ^2 statistic, significance t-test and correlation analysis.

In an ecotoxicological context, plant foliage residue trials are used to describe the dissipation or decline behaviour of fluopyram in potential food for birds and mammals. Dissipation curves can be used to estimate the exposure of herbivorous birds or mammals, mainly by calculating the area under the dissipation curve.

To allow for calculation of time weighted averaged residues or area under the curve, after single or multiple applications, it is most appropriate to use a full kinetic parameter set of SFO or biphasic models.

The modelling analysis is based on European crop residue data on green plant material of leek, onion and cabbage, after spray application of Luna Experience (SC 400 FLU+TBZ). All available residue data points per trial starting with the last application have been included in the evaluation. The plant metabolite fluopyram-benzamide has been analysed in the trials, but not always detected > LOD. Foliar DT50 values are carried out for fluopyram, and in cases, where FLU-benzamide was detected > LOD, also for the sum of fluopyram and FLU-benzamide.

Trials took place in both regulatory residue zones (N- and S-EU) with a timely variance from May - December. The BBCH growth stages at application have been 45 - 49 (leek) and 15 - 44 - 47 (onion) and 41 - 47 (cabbage).

Daily temperature and precipitation data (rain + irrigation over leaf surfaces, e.g. by sprinkler) are reported here, (e.g. based on raw data or publicly available weather station data).

In case of trials with 4 sampling points, DFOP and HS fits cannot deliver statistical information and are not appropriate, due to a too low degree of freedom (3 fitted parameters based on 4 data points). In these cases, such fits were not selected and summarised in the conclusion section. Nevertheless, reliable dissipation kinetics can be derived with 4 data points, e.g. when a clear decline can be seen, or the latest points are close to 0.

II. RESULTS AND DISCUSSION

The following units are used in the following tables:

Confidence Interval (CI)	same unit as parameter itself
initial mass M_0	mg/kg plant
k	1/d
β, tb	d
α, g	none

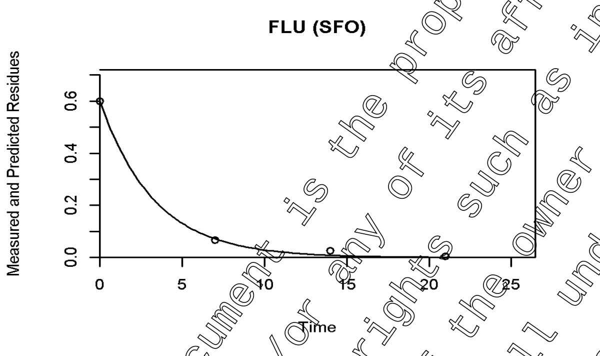
Fluopyram

11-2029-01, Soings en Sologne, M-442996-01-1, FR, leek

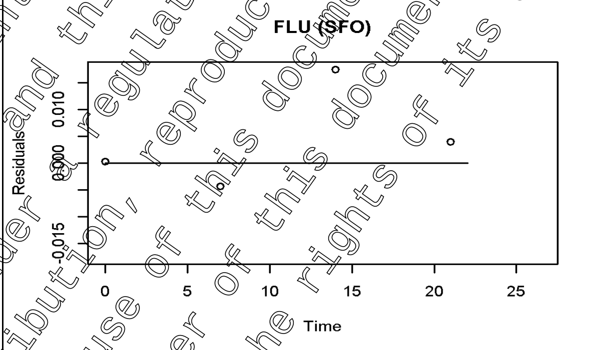
Table 8.9- 228: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial 11-2029-01, Soings en Sologne, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	0.6	k: 0.30416	4.3	k: 0.004	k: 0.25	k: 0.35	**2.279**	7.57
FOMC	+	0.6	α: 2.47045 β: 4.93669	1.9	-	β: -1.75	β: 11.63	1.599	7.601

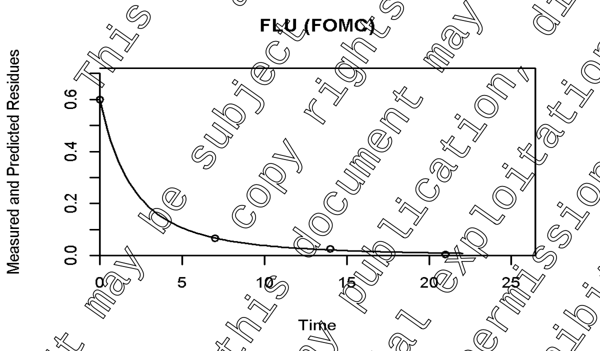
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



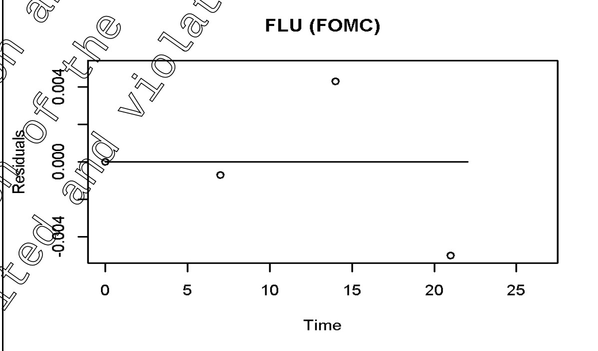
SFO



SFO



FOMC



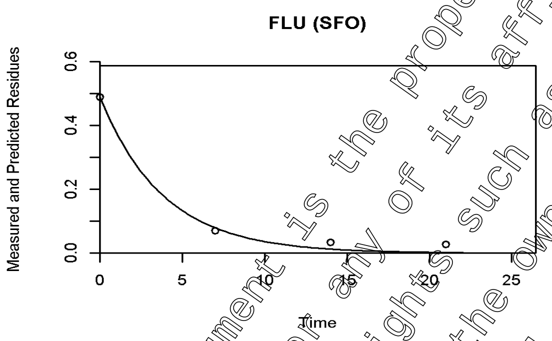
FOMC

11-2029-02, Werl-Westönnen, M-442996-01-1, DE, leek

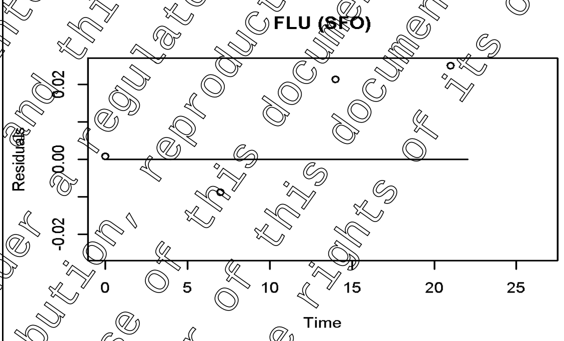
Table 8.9- 229: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial 11-2029-02, Werl-Westönnen, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	0.5	k: 0.26084	8.9	k: 0.012	k: 0.18	k: 0.34	**2.657**	8.828
FOMC	+	0.5	α: 1.04238 β: 1.26801	1.2	-	β: 0.30	β: 2.23	1.198	10.28

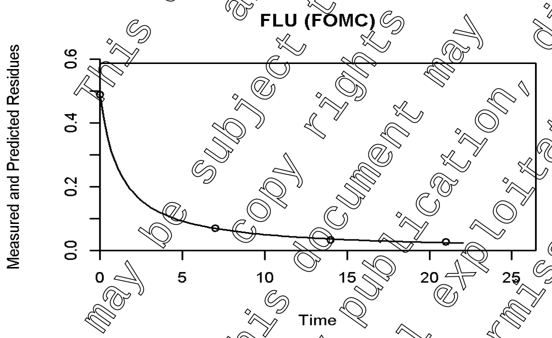
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 14), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



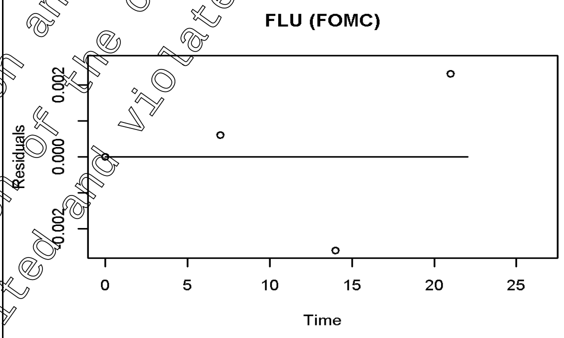
SFO



SFO



FOMC



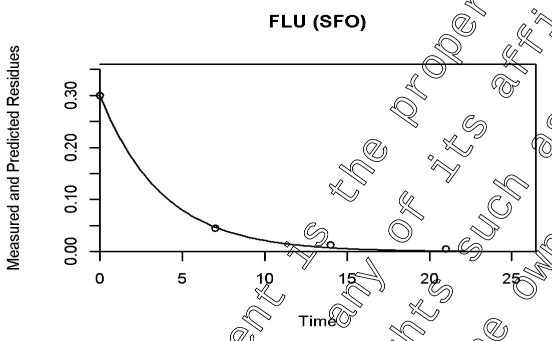
FOMC

11-2029--03, Langenfeld, M-442996-01-1, DE, leek

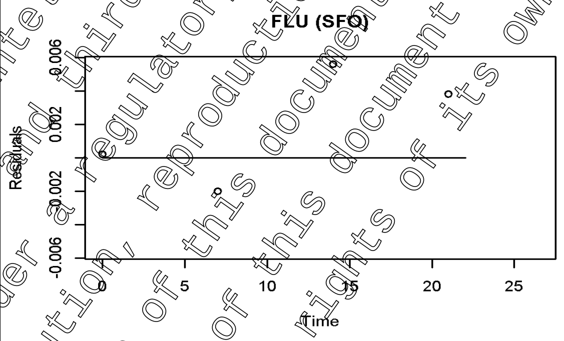
Table 8.9- 230: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial 11-2029-03, Langenfeld, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	0.3	k: 0.264583	3.2	k: 0.002	k: 0.24	k: 0.29	**2.620**	8.703
FOMC	+	0.3	α: 3.70 β: 10.45	0.1	-	β: 9.97	β: 10.94	2.154	9.023

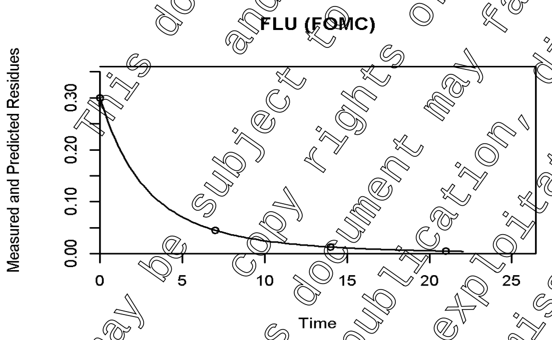
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



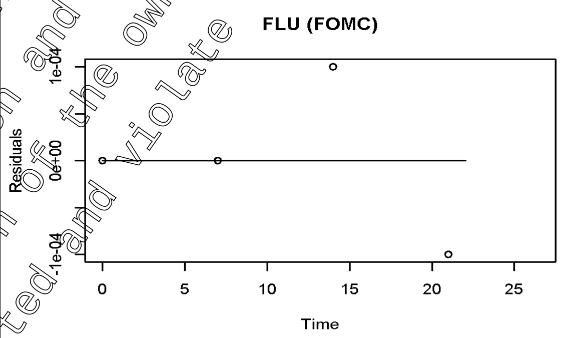
SFO



SFO



FOMC



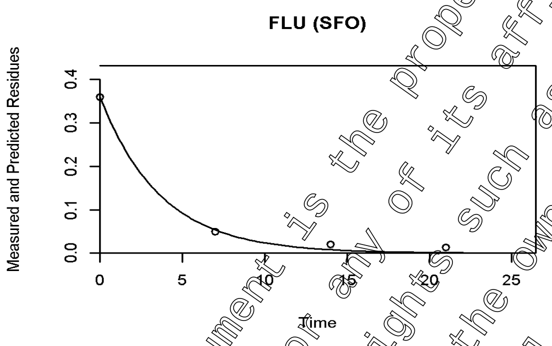
FOMC

11-2029-04, Villers-Perwin, M-442996-01-1, BE, leek

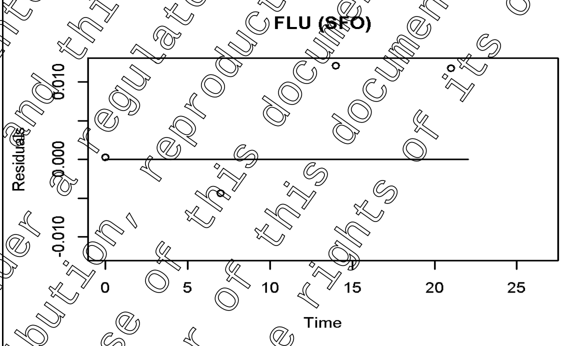
Table 8.9- 231: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial 11-2029-04, Villers-Perwin, BE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	0.4	k: 0.27257	6.5	k: 0.007	k: 0.21	k: 0.34	**2.543**	8.45
FOMC	+	0.4	α: 1.558564 β: 2.688294	0.6	-	β: 1.75	β: 3.62	1.506	9.09

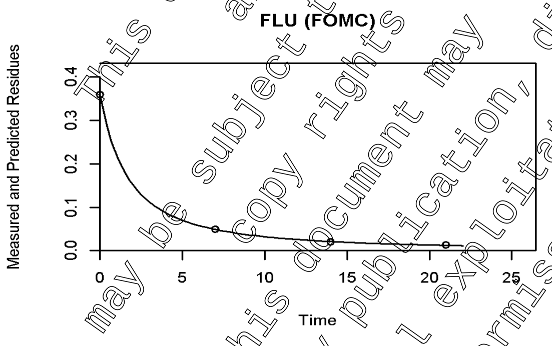
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 14), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



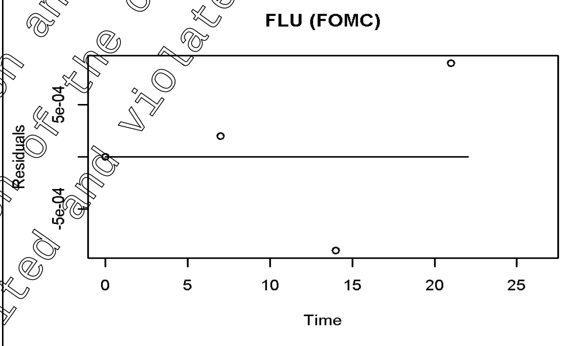
SFO



SFO



FOMC



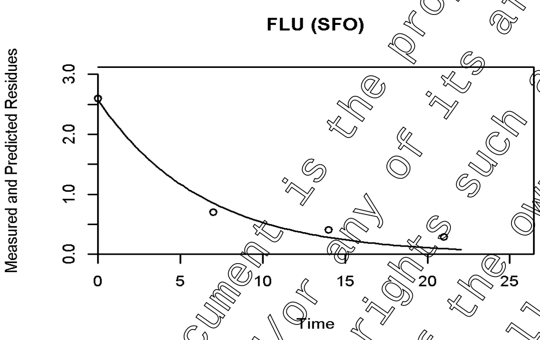
FOMC

R 2006 0337/1, Tilloloy, M-292996-01-1, FR, onion

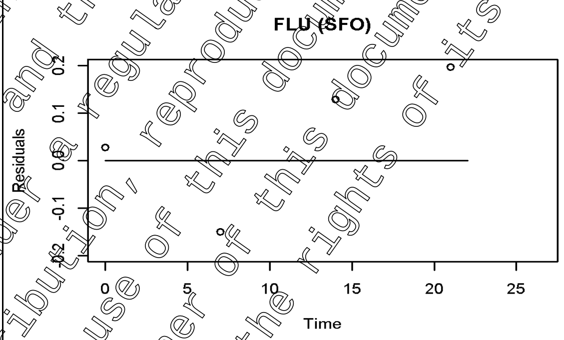
Table 8.9- 232: Kinetic models and goodness-of-fit statistics of fluopyram fits for onion of trial R 2006 0337/1, Tilloloy, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	2.6	k: 0.15816	11.5	k: 0.015	k: 0.10	k: 0.21	**4.382**	14.56
FOMC	+	2.6	α: 0.9661925 β: 2.4239851	0.04	-	β: 2.38	β: 2.47	2.543	23.85

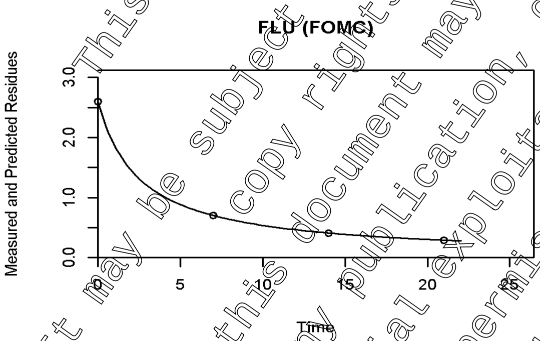
SFO fit is statistically still acceptable (χ^2err <15%, t-test <0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. DFOP and HS fits cannot deliver statistical information, as degrees of freedom are too low (3 fitted parameters based on 4 data points). FOMC fit is statistically (χ^2err, t-test) and visually good. Consequently, FOMC model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



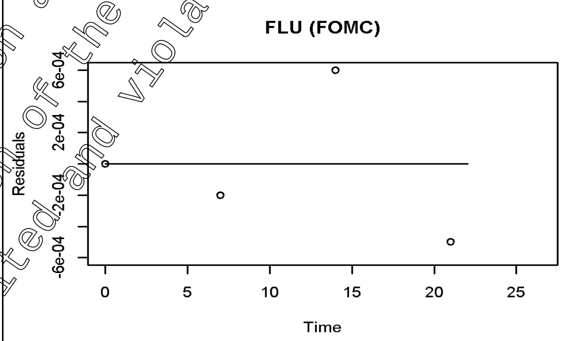
SFO



SFO



FOMC



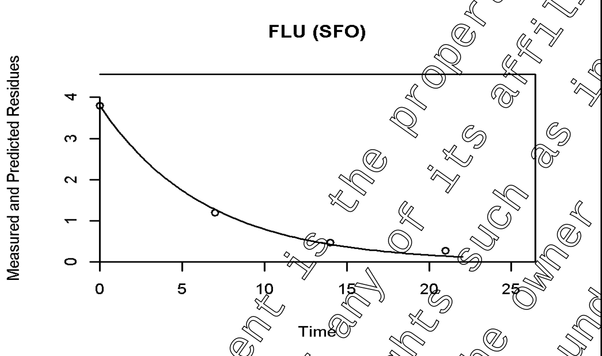
FOMC

R 2006 0339/8, Saint Bonnet de Mure, M-292098-01-1, FR, onion

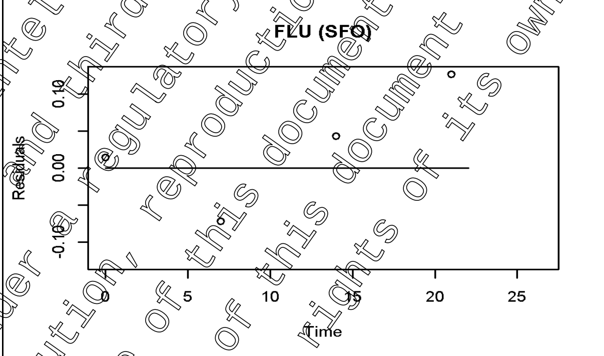
Table 8.9- 233: Kinetic models and goodness-of-fit statistics of fluopyram fits for onion of trial R 2006 0339/8, Saint Bonnet de Mure, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.8	k: 0.1558	4.3	k: 0.002	k: 0.14	k: 0.18	**4.448**	14.77
FOMC	+	3.8	α: 3.58421 β: 18.3245	1.3	-	β: 5.91	β: 30.74	3.910	16.51

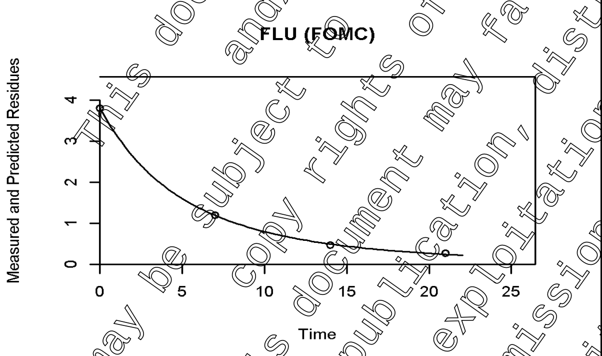
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



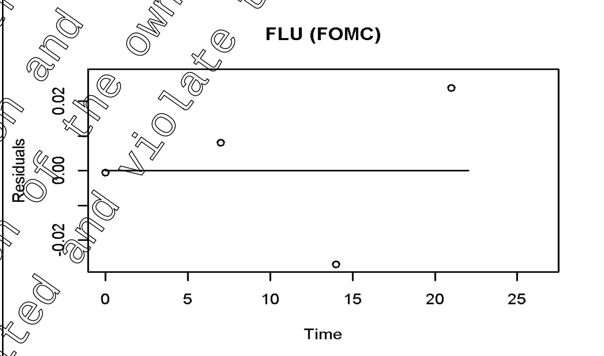
SFO



SFO



FOMC



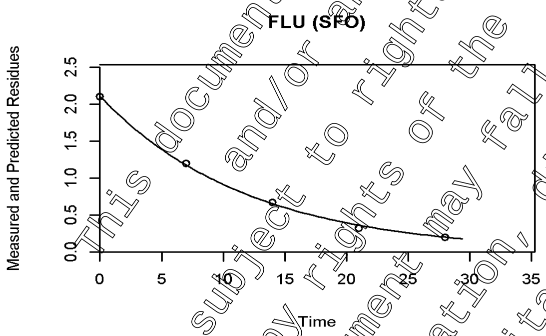
FOMC

R 2006 0343/6, Faverolles, M-292101-02-1, FR, leek

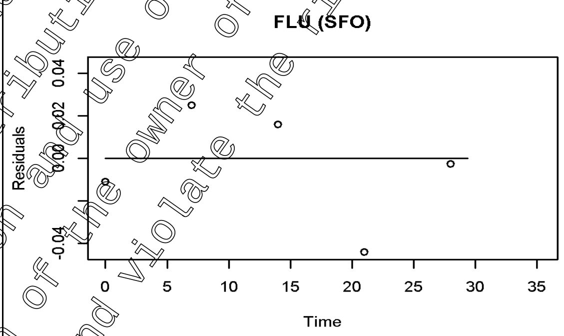
Table 8.9- 234: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2006 0343/6, Faverolles, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	2.1	k: 0.0837	2.2	k: <0.001	k: 0.08	k: 0.09	**8.282**	27.51
FOMC	+	2.1	α: 28990 β: 346400	2.5	-	β: 346400	β: 346400	8.282	27.51
DFOP	+	2.1	k1: 0.084 k2: 0.070 g: 1.00	3.1	k1: 0.227 k2: <0.001	k1: -0.06 k2: 0.07	k1: 0.23 k2: 0.07	8.282	27.51
HS	+	2.1	k1: 0.111 k2: 0.084 tb: 0	3.1	k1: <0.001 k2: 0.030	k1: 0.11 k2: 0.07	k1: 0.11 k2: 0.10	8.282	27.51

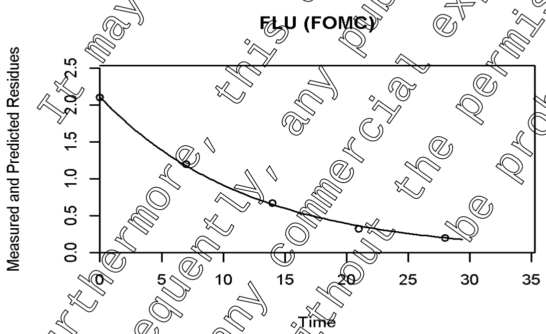
SFO fit is statistically and visually good (χ^2 err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



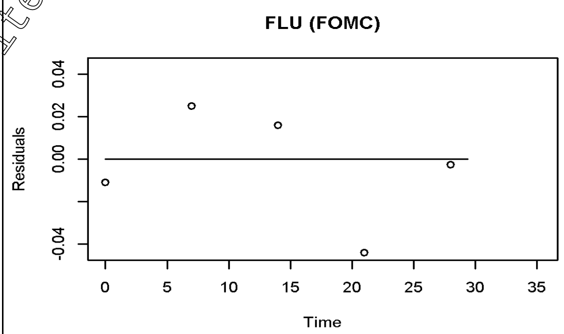
SFO



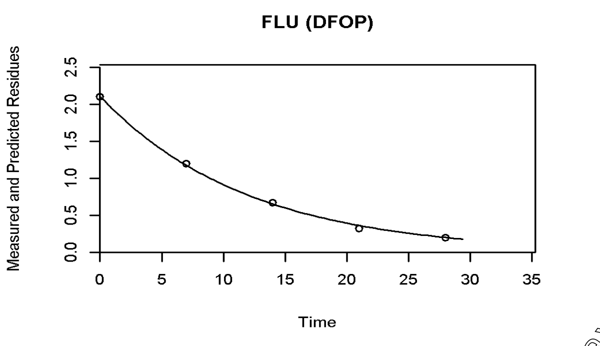
SFO



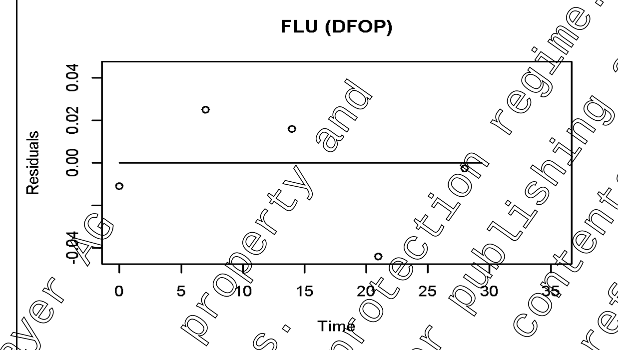
FOMC



FOMC



DFOP



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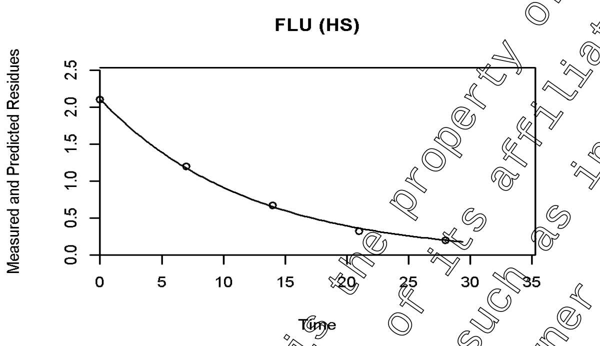
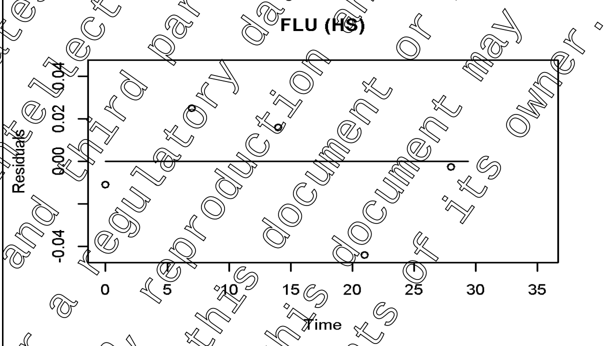


HS



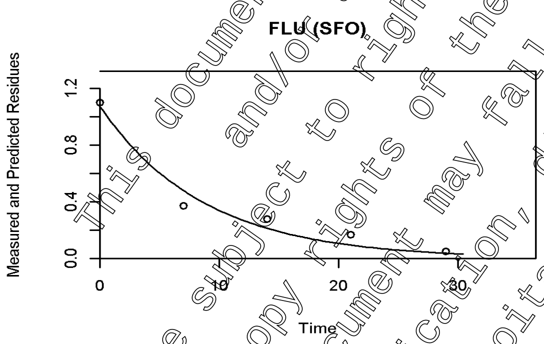
HS

R 2006 0344/4, Cailloux sur Fontaines, M-292082-01-1, FR, leek

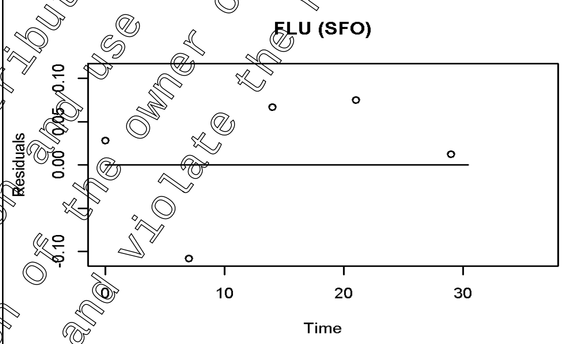
Table 8.9- 235: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2006 0344/4, Cailloux sur Fontaines, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	1.1	k: 0.11534	13.7	k: 0.004	k: 0.08	k: 0.15	**6.010**	19.96
FOMC	+	1.1	α: 1.31934 β: 6.01616	8.93	-	β: -6.73	β: 18.76	4.158	28.44
DFOP	+	1.1	k1: 4.358 k2: 0.06469 g: 0.447	7.65	k1: <0.001 k2: 0.098	k1: 4.36 k2: 0.02	k1: 4.36 k2: 0.11	1.573	26.44
HS	+	1.1	k1: 0.1699045 k2: 0.0646941 tb: 5.63	7.65	k1: 0.056 k2: 0.098	k1: 0.11 k2: 0.02	k1: 0.23 k2: 0.11	4.080	26.44

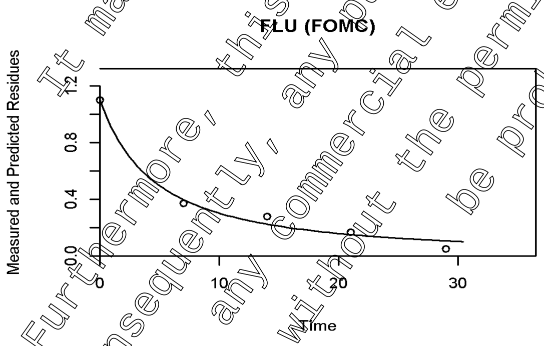
SFO fit is statistically and visually acceptable to moderate (χ^2 err <15%, t-test <0.05). However, the degradation of the compound until the last data point (< 10 % of initial residue) is described visually acceptable. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics).



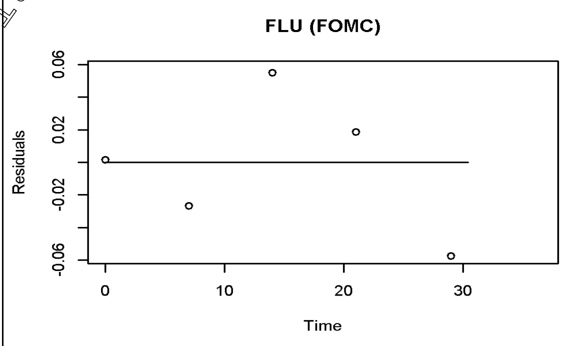
SFO



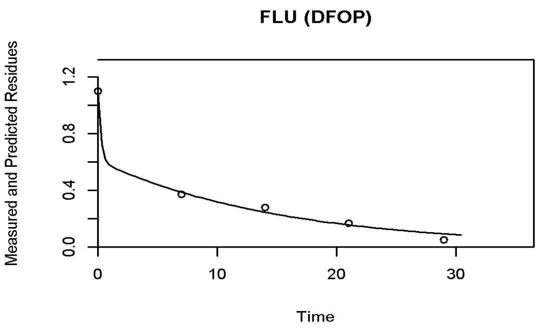
SFO



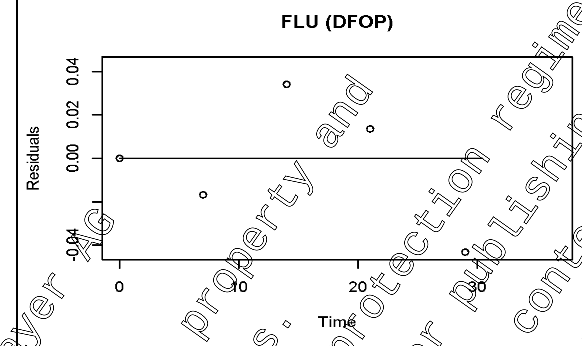
FOMC



FOMC



DFOP



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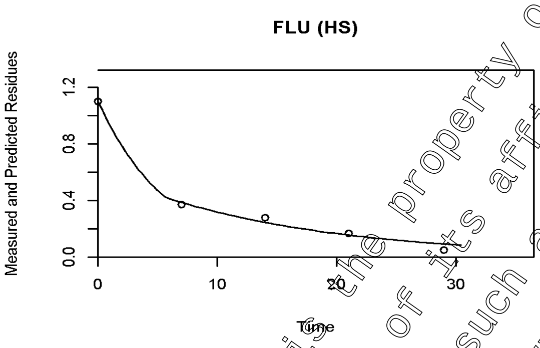
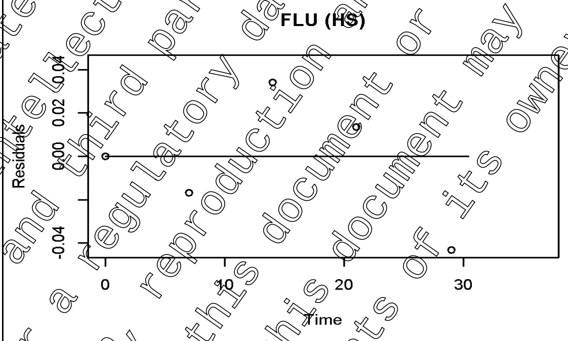


HS



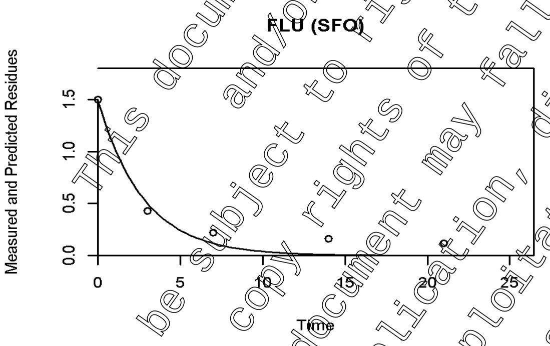
HS

R 2006 0347/9, Bouafle, M-292103-01-1, FR, cabbage

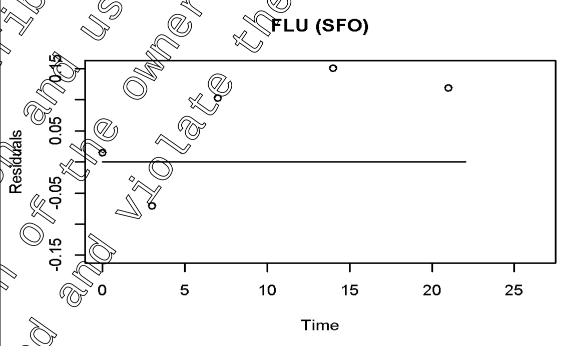
Table 8.9- 236: Kinetic models and goodness-of-fit statistics of fluopyram fits for cabbage of trial R 2006 0347/9, Bouafle, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	1.5	k: 0.36266	16.9	k: 0.011	k: 0.20	k: 0.52	1.911	6.35
FOMC	+	1.5	α: 0.74832 β: 0.67457	2.3	-	β: 0.27	β: 1.08	1.029	13.96
DFOP	+	1.5	k1: 0.620856 k2: 0.037531 g: 0.8222	0.28	k1: 0.005 k2: 0.018	k1: 0.60 k2: 0.03	k1: 0.64 k2: 0.04	1.462	15.35
HS	+	1.5	k1: 0.416478 k2: 0.04374 tb: 4.336	0.21	k1: 0.001 k2: 0.009	k1: 0.41 k2: 0.04	k1: 0.42 k2: 0.05	1.664	15.70

SFO fit is statistically still acceptable (χ^2err <15%, t-test <0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. HS fit is statistically (χ^2err, t-test) and visually good, with the lowest $\chi2$ err. Consequently, **HS** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT50 is an alternative option.



SFO



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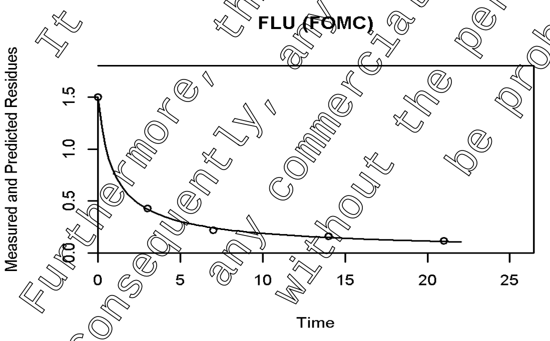
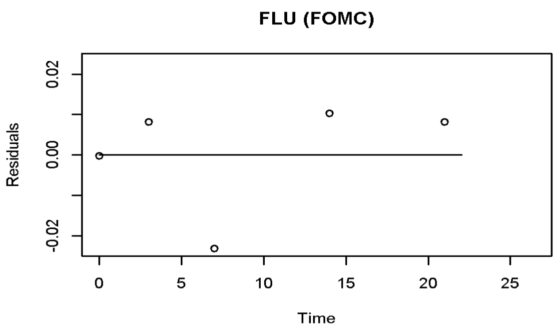
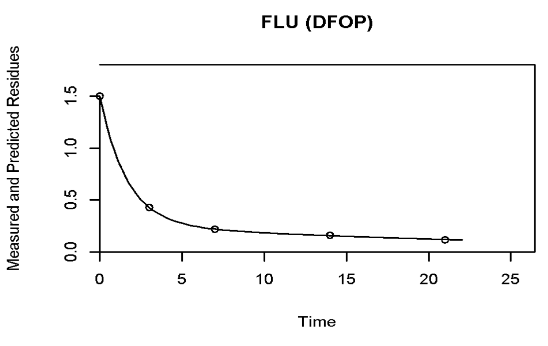


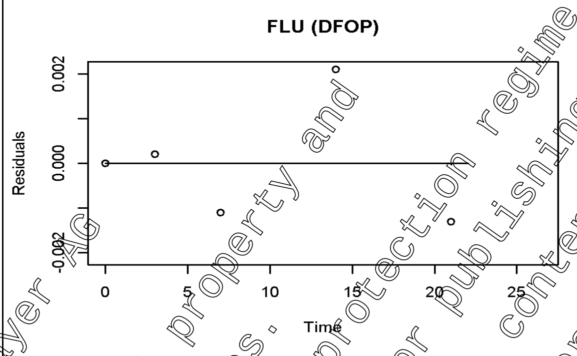
FOMC



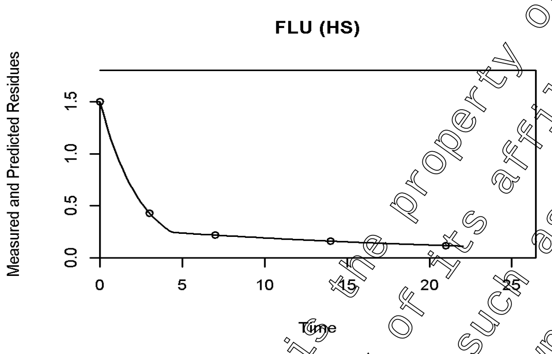
FOMC



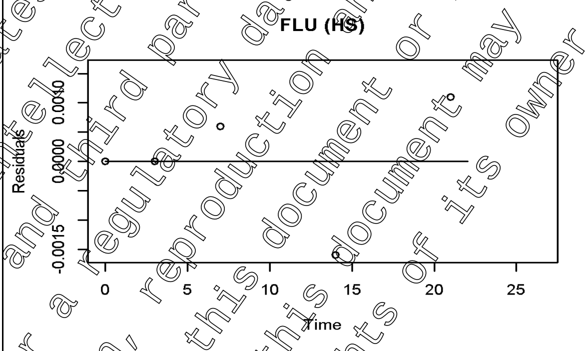
DFOP



DFOP



HS



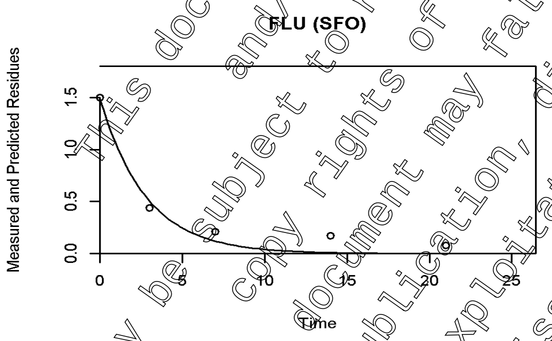
HS

R 2006 0348/7, Ouzilly, M-293182-01-1, FR, cabbage

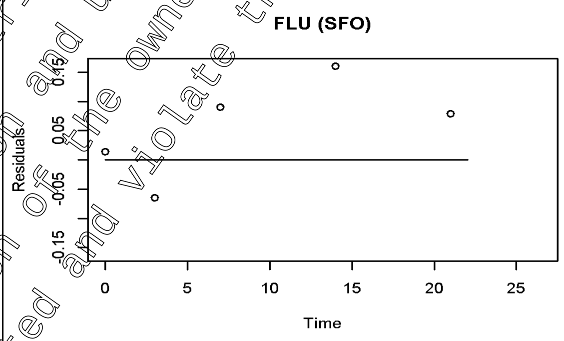
Table 8.9- 237: Kinetic models and goodness-of-fit statistics of fluopyram fits for cabbage of trial R 2006 0348/7, Ouzilly, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	1.5	k: 0.360778	15.7	k: 0.008	k: 0.21	k: 0.51	1.927	6.40
FOMC	+	1.5	α: 0.88254 β: 0.97407	4.0	-	β: 0.09	β: 1.86	1.162	12.26
DFOP	+	1.5	k1: 0.631276 k2: 0.053554 g: 0.7984	3.70	k1: 0.072 k2: 0.166	k1: 0.35 k2: -0.01	k1: 0.92 k2: 0.11	1.480	13.13
HS	+	1.5	k1: 0.40882 k2: 0.05722 tb: 4.346	3.29	k1: 0.019 k2: 0.119	k1: 0.36 k2: 0.01	k1: 0.46 k2: 0.10	1.696	13.54

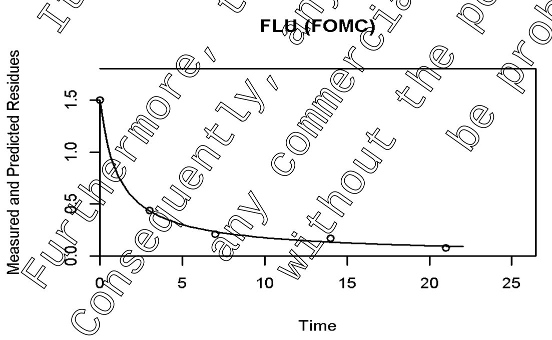
SFO fit is statistically still acceptable (χ^2err <15%, t-test <0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in χ2 error and visual assessment. However, the t-test of DFOP and HS show a low reliability especially of the slow degradation rates k2 (t-test > 0.05). Therefore, **FOMC** model is considered best appropriate for modelling endpoints (FOCUS kinetics) and as well as best visual fit.



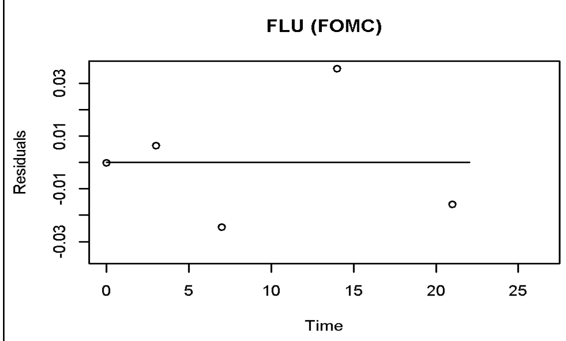
SFO



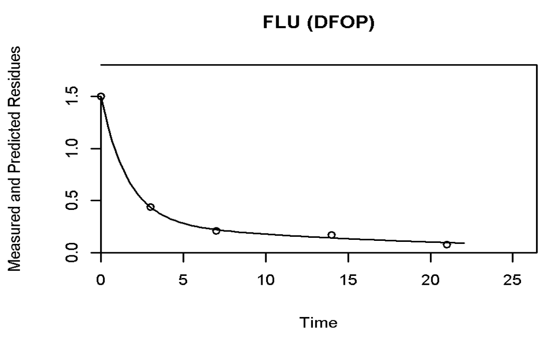
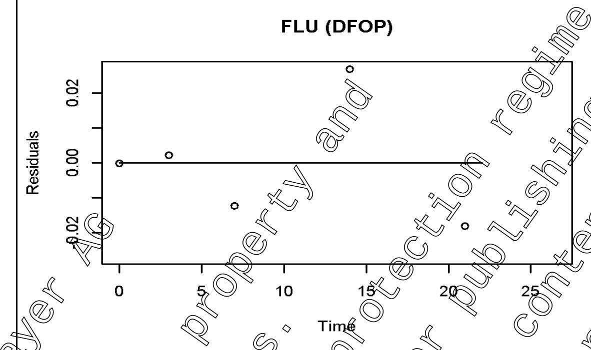
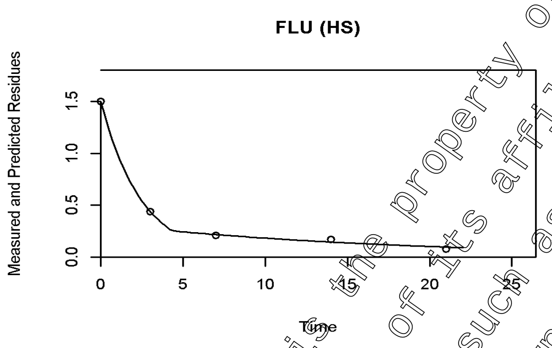
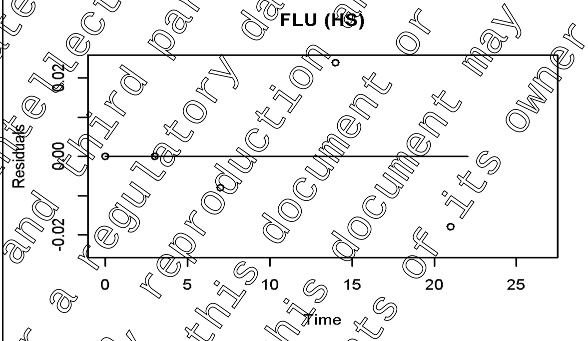
SFO



FOMC



FOMC

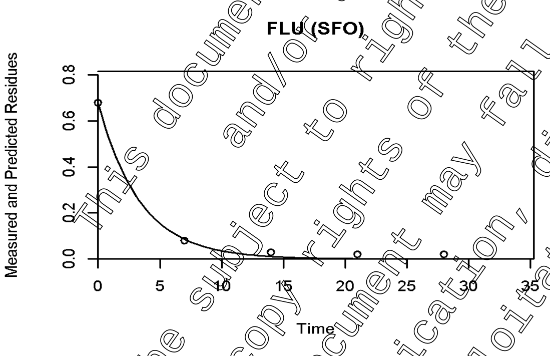
 DFOP	 DFOP
 HS	 HS

R 2006 0465/3, Langenfeld-Reusrath, M-292101-02-1, DE, leek

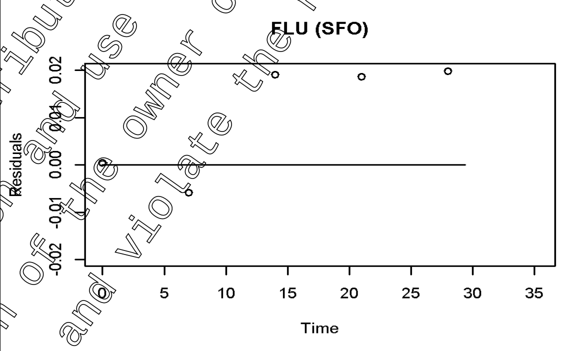
Table 8.9- 238: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2006 0465/3, Langenfeld-Reusrath, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	0.7	k: 0.29549	7.3	k: 0.001	k: 0.23	k: 0.36	**2.346**	7.79
FOMC	+	0.7	α: 1.411583 β: 1.9513	1.9	-	β: 0.43	β: 3.47	1.232	7.97
DFOP	+	0.7	k1: 0.360778 k2: 0.019164 g: 0.9524	0.8	k1: 0.015 k2: 0.204	k1: 0.33 k2: -0.01	k1: 0.39 k2: 0.05	2.052	7.71
HS	+	0.7	k1: 0.306 k2: 0.033 tb: 9.893	1.1	k1: 0.007 k2: 0.145	k1: 0.29 k2: 0.0012	k1: 0.32 k2: 0.065	2.267	7.53

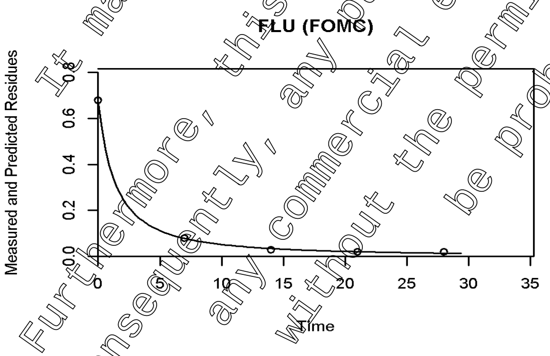
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 14), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



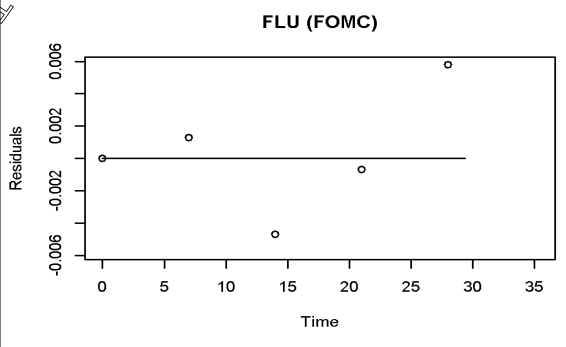
SFO



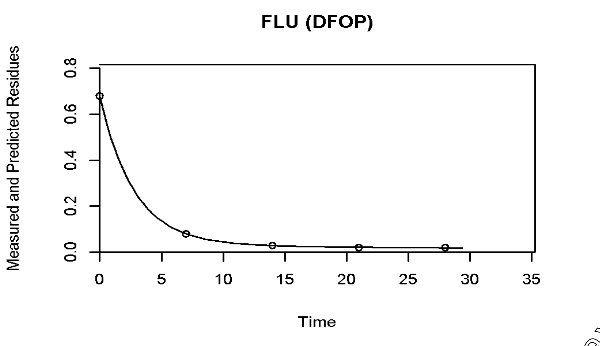
SFO



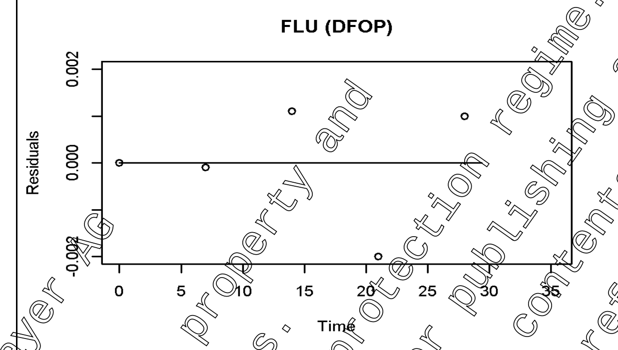
FOMC



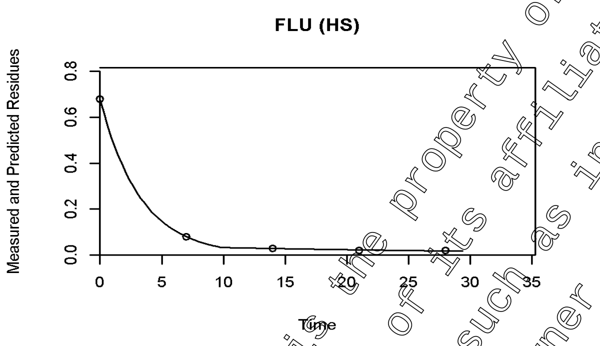
FOMC



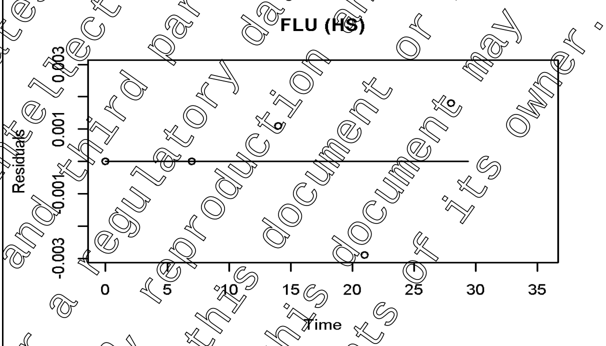
DFOP



DFOP



HS



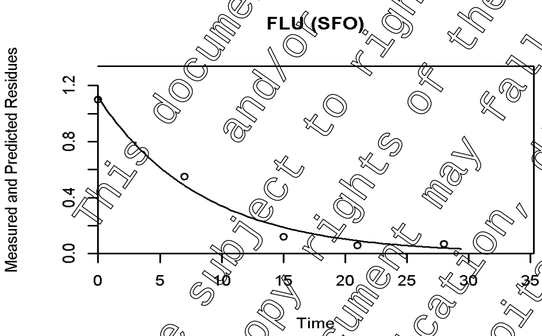
HS

R 2006 0466/1, Chatteris, M-292101-02-1, GB, leek

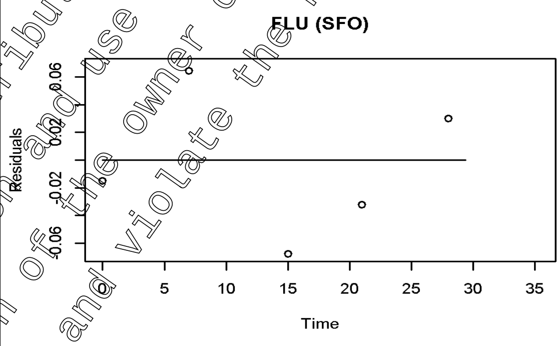
Table 8.9- 239: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2006 0466/1, Chatteris, GB

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	1.1	k: 0.11878	9.8	k: 0.001	k: 0.09	k: 0.15	**5.836**	19.39
FOMC	+	1.1	α: 14910 β: 125500	11.2	-	β: 125500	β: 125500	5.835	19.39
DFOP	+	1.1	k1: 0.119 k2: 0.009 g: 1.00	14.0	k1: 0.123 k2: <0.001	k1: 0.02 k2: 0.01	k1: 0.21 k2: 0.01	5.836	19.39
HS	+	1.1	k1: 0.188 k2: 0.119 tb: 0.0	14.0	k1: <0.001 k2: 0.132	k1: 0.19 k2: 0.02	k1: 0.19 k2: 0.22	5.836	19.39

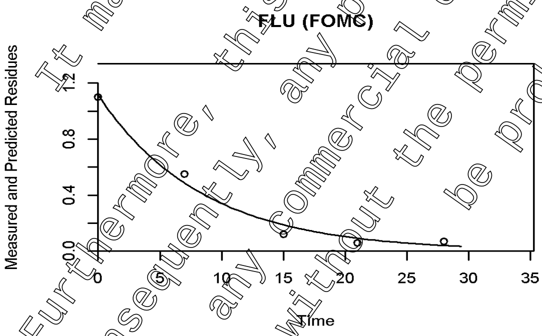
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



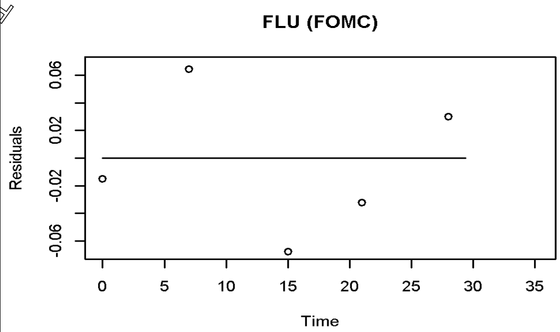
SFO



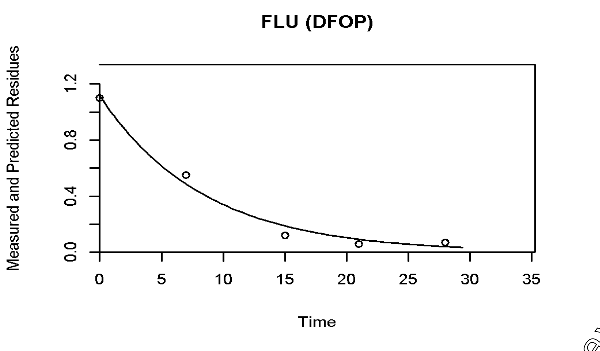
SFO



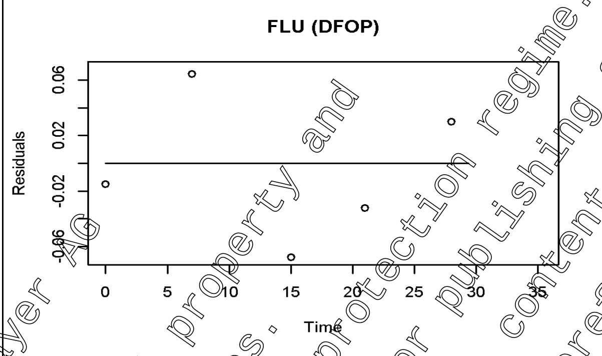
FOMC



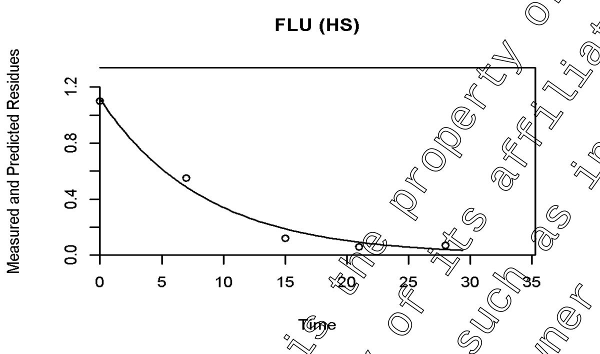
FOMC



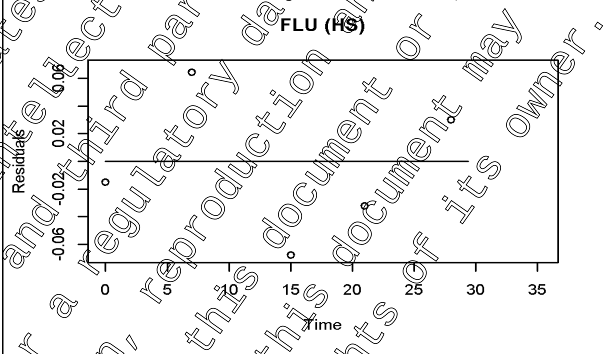
DFOP



DFOP



HS



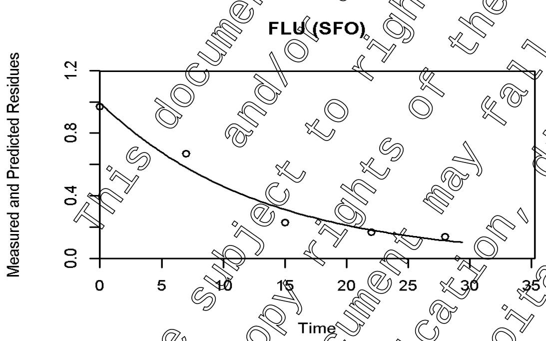
HS

R 2006 0468/8, Bornheim - Sechtem, M-292101-02-1, DE, leek

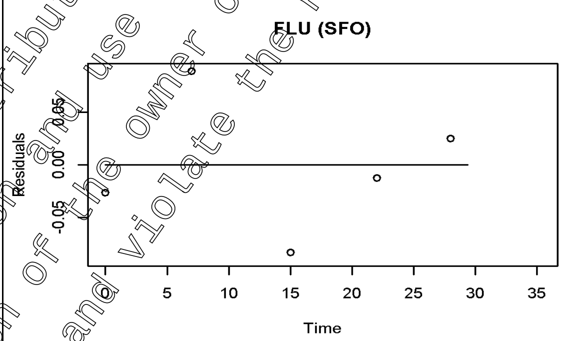
Table 8.9- 240: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2006 0468/8, Bornheim - Sechtem, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	1.0	k: 0.0771	10.5	k: 0.003	k: 0.06	k: 0.10	**8.990**	29.86
FOMC	+	1.0	α: 6404 β: 83050	12.0	-	β: 83050	β: 83049.56	8.990	29.87
DFOP	+	1.0	k1: 0.077 k2:<0.0005 g: 1.00	15.0	k1: 0.194 k2: 0.5	k1: -0.03 k2: -inf	k1: 0.18 k2: +inf	8.990	29.86
HS	+	1.0	k1: 0.079 k2: 0.016 tb: 24.155	14.6	k1: 0.079 k2: 0.480	k1: 0.04 k2: -0.49	k1: 0.12 k2: 0.52	8.802	48.46

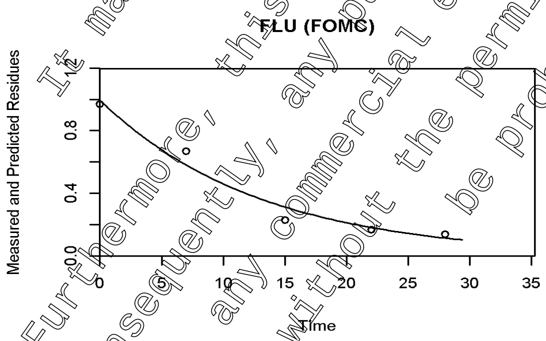
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). FOMC, DFOP and HS did not result in an improved fit. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



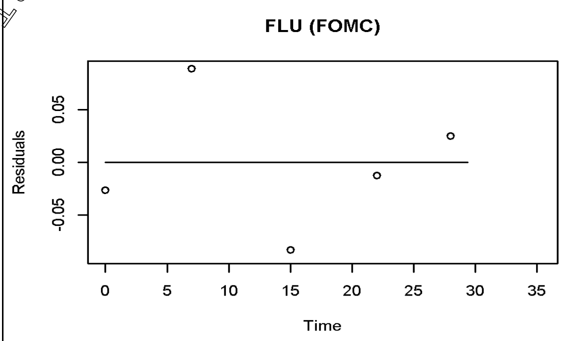
SFO



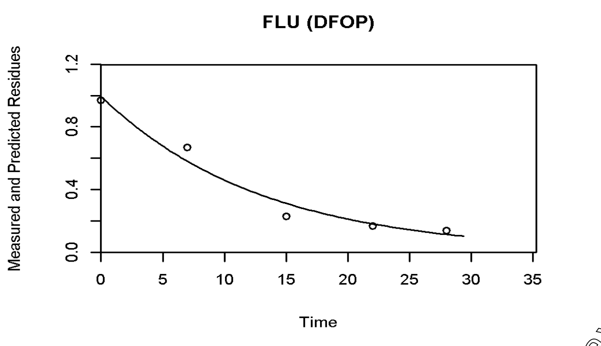
SFO



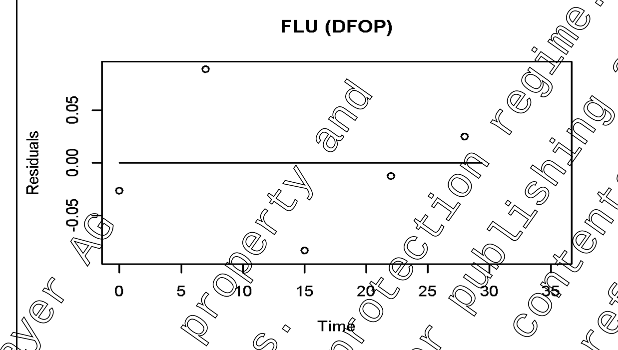
FOMC



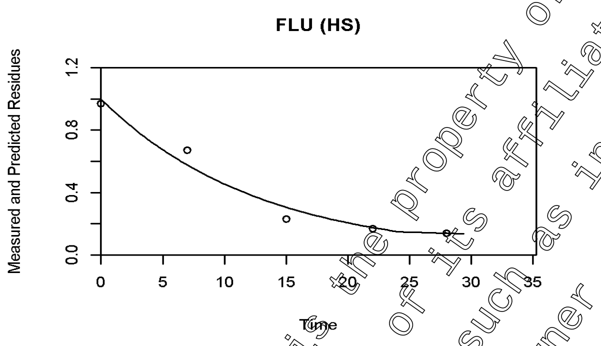
FOMC



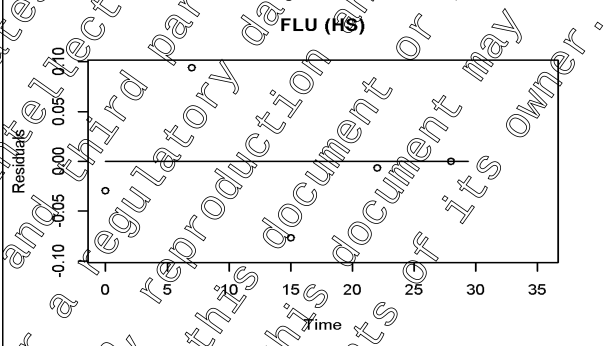
DFOP



DFOP



HS



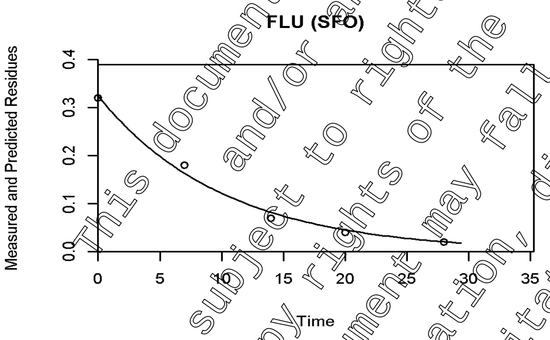
HS

R 2006 0469/6, Lebrija, M-292082-01-1, ES, leek

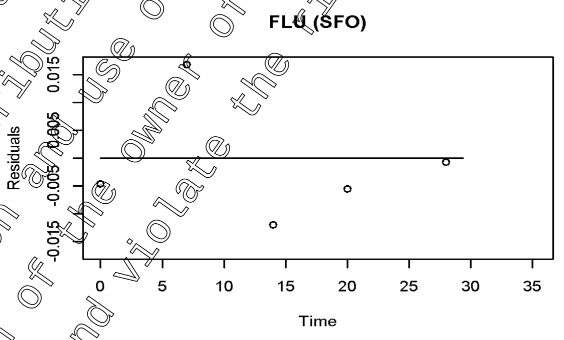
Table 8.9- 241: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2006 0469/6, Lebrija, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	$DT_{50\ actual}$ (d)	$DT_{90\ actual}$ (d)
SFO	+	0.3	k: 0.098258	6.2	k: <0.001	k: 0.08	k: 0.11	**7.054**	23.43
FOMC	+	0.3	α: 5758 β: 58590	7.1	-	β: 58590	β: 58589.24	7.054	23.44
DFOP	+	0.3	k1: 0.0982 k2: 0.037 g: 1.00	8.9	k1: 0.146 k2: <0.001	k1: 0.00316 k2: 0.0365	k1: 0.19 k2: 0.037	7.054	23.43
HS	+	0.3	k1: 0.194 k2: 0.098 tb: 4.4 E-14	8.9	k1: 0.5 k2: 0.084	k1: -inf k2: 0.05	k1: +inf k2: 0.15	7.054	23.43

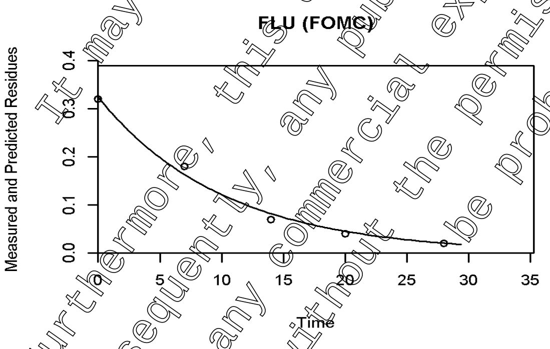
SFO fit is statistically and visually good (χ^2 err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



SFO



SFO



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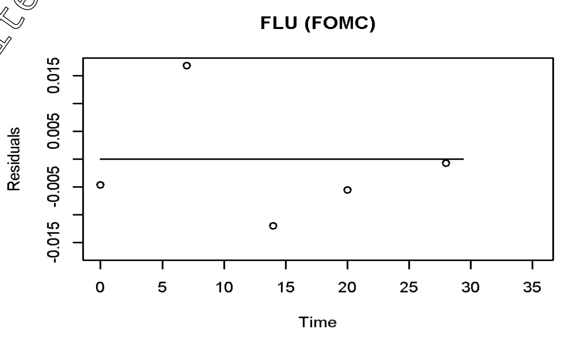
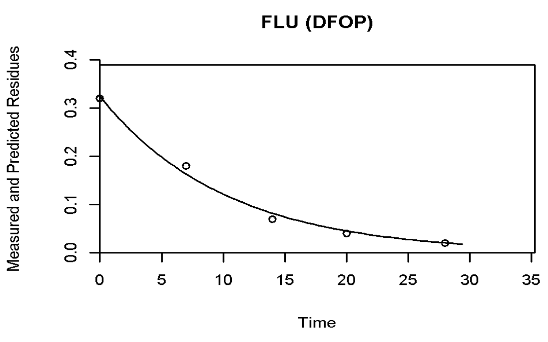
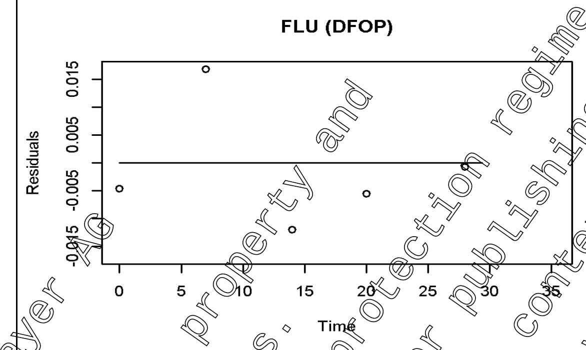
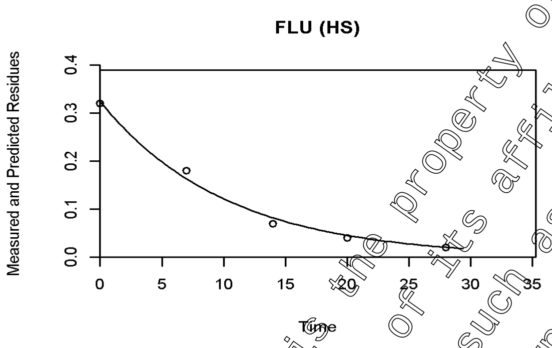
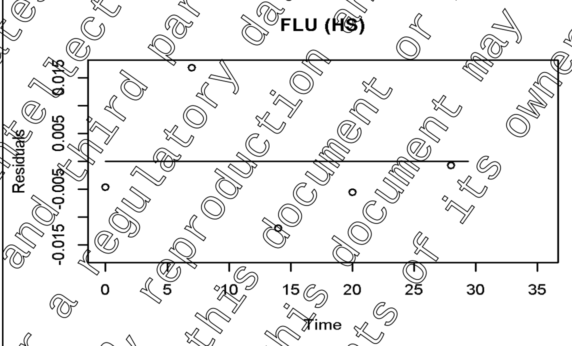


FOMC

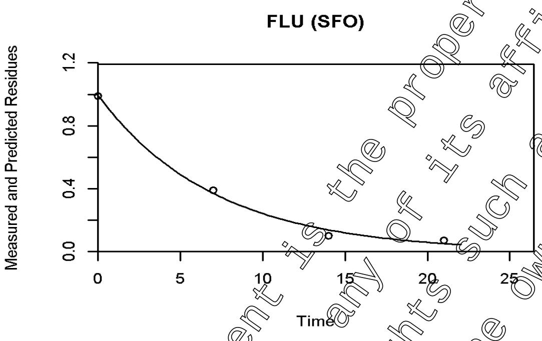
 DFOP	 DFOP
 HS	 HS

R 2006 0504/8, Burscheid, M-292996-01-1, DE, onion

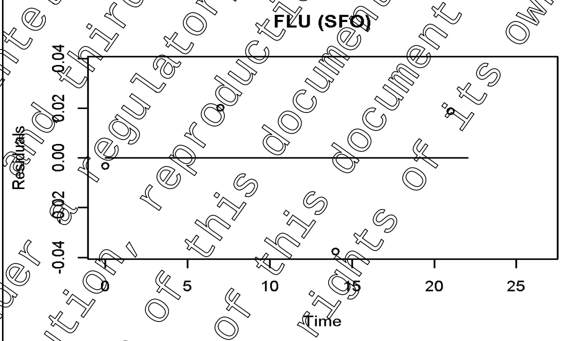
Table 8.9- 242: Kinetic models and goodness-of-fit statistics of fluopyram fits for onion of trial R 2006 0504/8, Burscheid, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	1.0	k: 0.14116	4.9	k: 0.003	k: 0.12	k: 0.16	**4.910**	16.31
FOMC	+	1.0	α: 9071 β: 64250	6.2	-	β: 64250	β: 64252.84	4.910	16.31

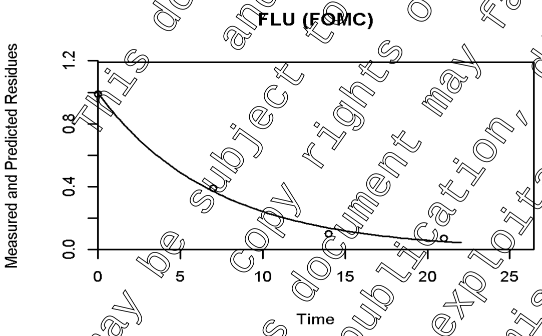
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



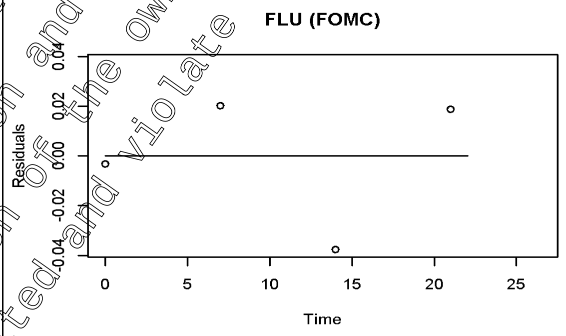
SFO



SFO



FOMC



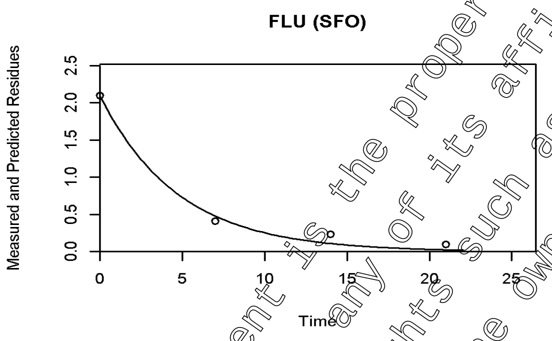
FOMC

R 2006 0505/6, Lusia, M-292098-01-1, IT, onion

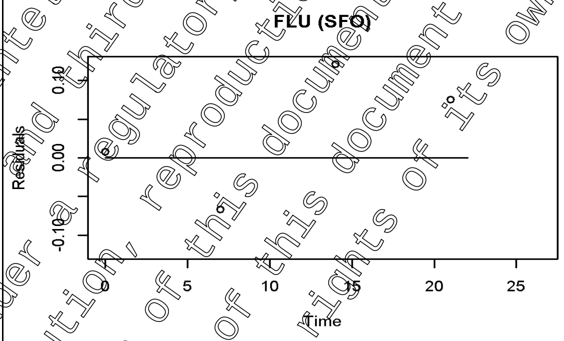
Table 8.9- 243: Kinetic models and goodness-of-fit statistics of fluopyram fits for onion of trial R 2006 0505/6, Lusia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	2.1	k: 0.21118	9.1	k: 0.010	k: 0.15	k: 0.27	**3.282**	10.90
FOMC	+	2.1	α: 1.38886 β: 3.17618	2.8	-	β: -0.94	β: 7.29	2.056	13.49

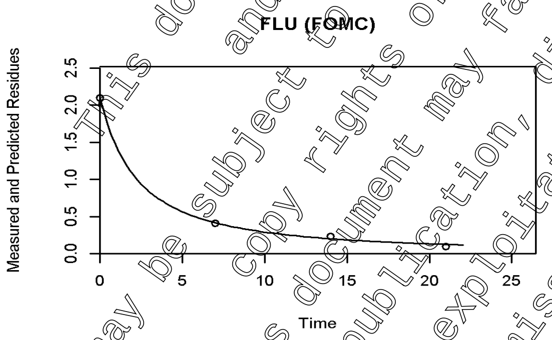
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



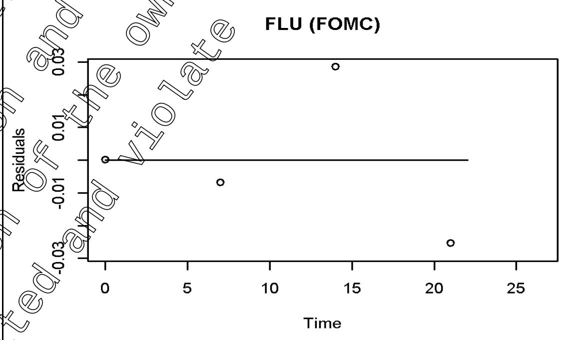
SFO



SFO



FOMC



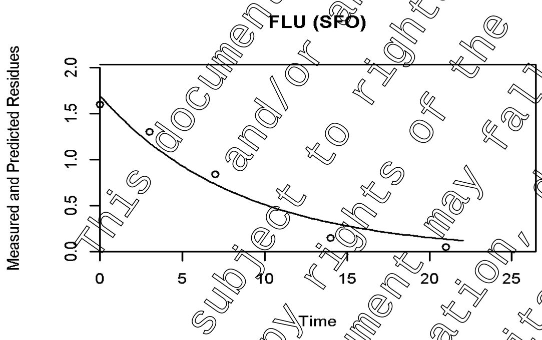
FOMC

R 2006 0543/9, Little Shelford, M-292103-01-1, GB, cabbage

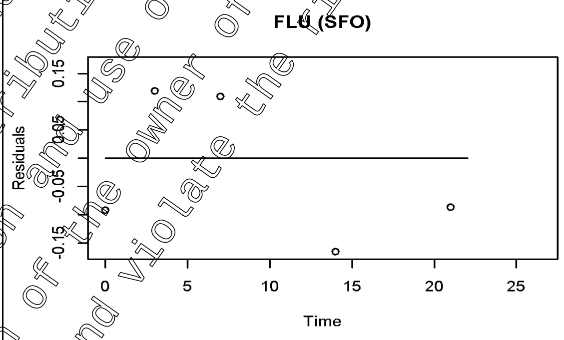
Table 8.9- 244: Kinetic models and goodness-of-fit statistics of fluopyram fits for cabbage of trial R 2006 0543/9, Little Shelford, GB

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	1.7	k: 0.11993	12.0	k: 0.006	k: 0.08	k: 0.16	**5.780**	19.20
FOMC	+	1.7	α: 24390 β: 203400	13.7	-	β: 203400	β: 203400	5.780	19.20
DFOP	+	1.7	k1: 0.120 k2: 0.053 g: 1.00	17.1	k1: 0.295 k2: <0.001	k1: -0.19 k2: 0.05	k1: 0.43 k2: 0.05	5.780	19.20
HS	+	1.7	k1: 0.120 k2: 0.148 tb: 25.079	17.1	k1: 0.099 k2: <0.001	k1: 0.04 k2: 0.15	k1: 0.20 k2: 0.15	5.780	19.20

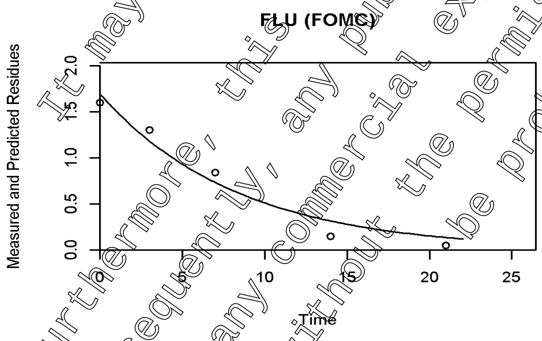
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



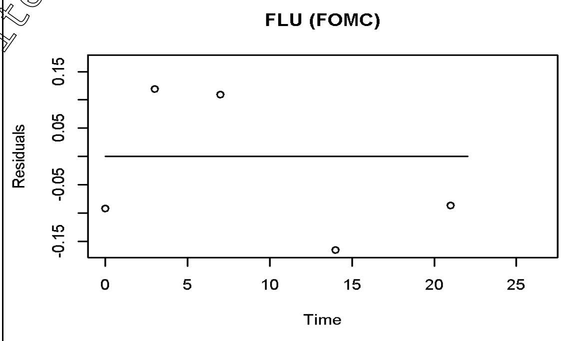
SFO



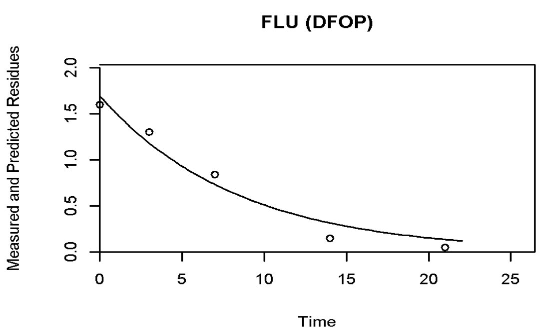
SFO



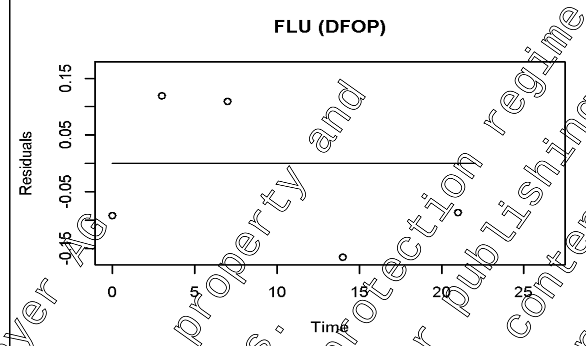
FOMC



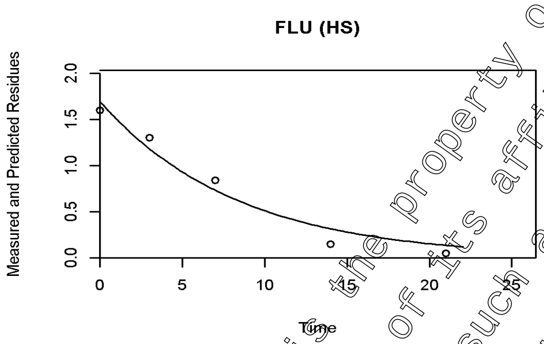
FOMC



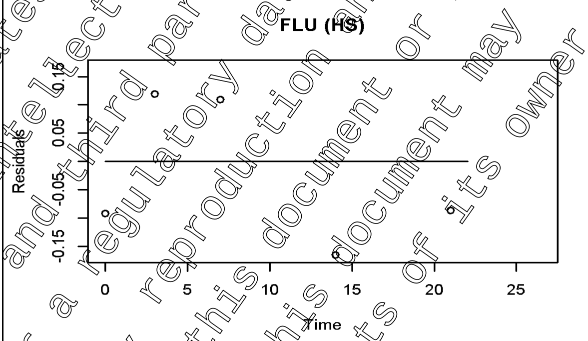
DFOP



DFOP



HS



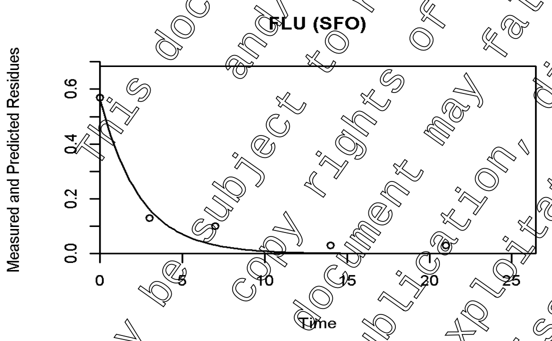
HS

R 2006 0544/7, Andria, M-293182-01-1, IT, cabbage

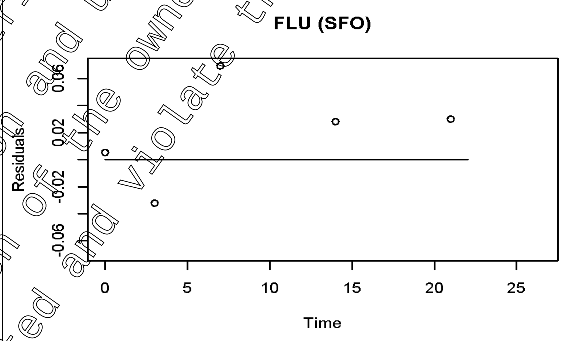
Table 8.9- 245: Kinetic models and goodness-of-fit statistics of fluopyram fits for cabbage of trial R 2006 0544/7, Andria, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	0.6	k: 0.41599	18.1	k: 0.012	k: 0.22	k: 0.61	1.666	5.54
FOMC	+	0.6	α: 0.78114 β: 0.57881	7.03	-	β: -0.54	β: 1.69	0.827	10.45
DFOP	+	0.6	k1: 8.665 k2: 0.1004 g: 0.6831	5.89	k1: <0.001 k2: 0.098	k1: 8.67 k2: 0.04	k1: 8.67 k2: 0.16	0.149	11.49
HS	+	0.6	k1: 0.496 k2: 0.100 tb: 2.904	5.89	k1: 0.031 k2: 0.098	k1: 0.40 k2: 0.04	k1: 0.59 k2: 0.16	1.397	11.49

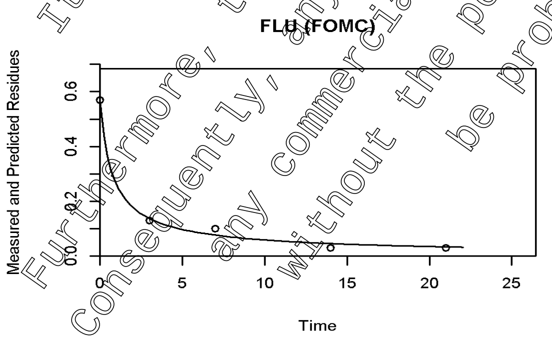
SFO fit is statistically still acceptable (χ^2err <15%, t-test <0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in $\chi 2$ error and visual assessment. However, the t-test of DFOP and HS show a low reliability especially of the slow degradation rates k2 (t-test > 0.05). Therefore, **FOMC** model is considered best appropriate for modelling endpoints (FOCUS kinetics) and as well as best visual fit.



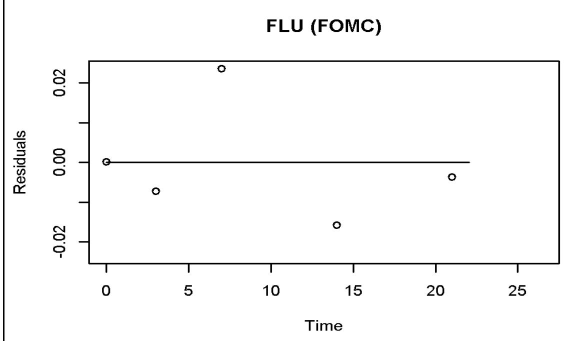
SFO



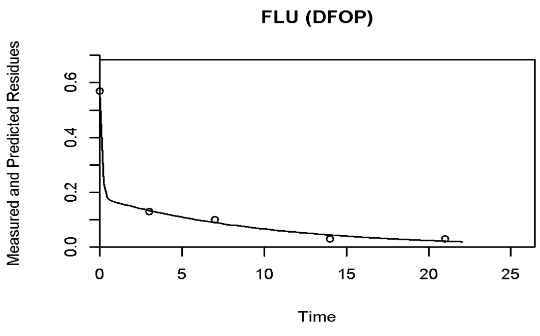
SFO



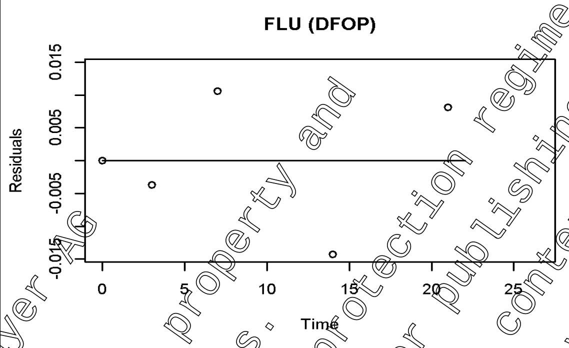
FOMC



FOMC



DFOP



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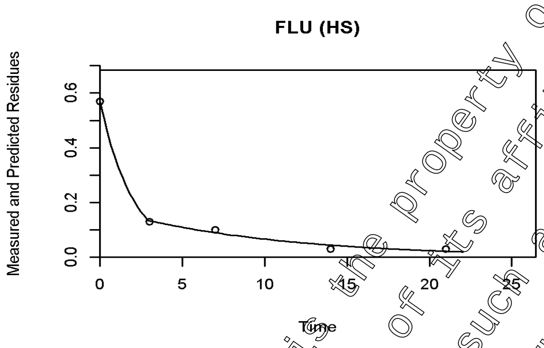
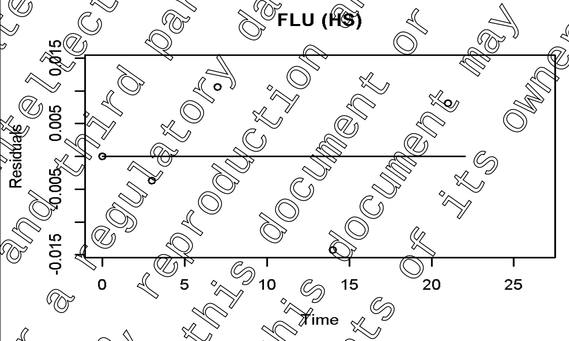


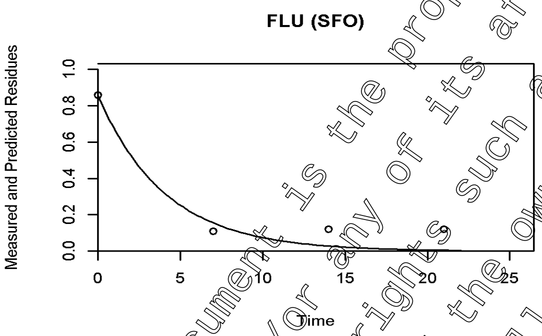
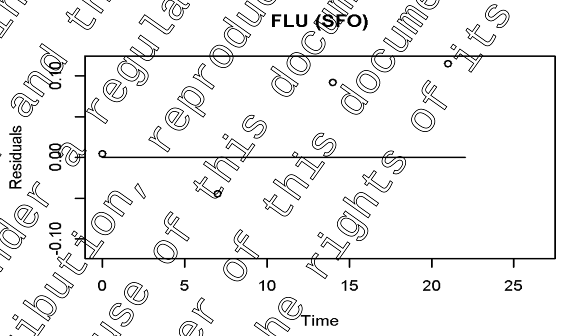
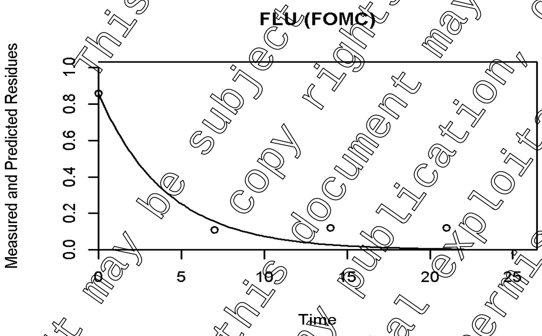
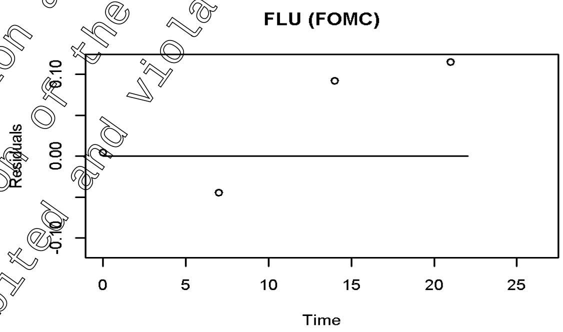
HS



HS

R 2007 0042/3, Burscheid, M-302330-01-1, DE, onion

Table 8.9- 246: Kinetic models and goodness-of-fit statistics of fluopyram fits for onion of trial R 2007 0042/3, Burscheid, DE

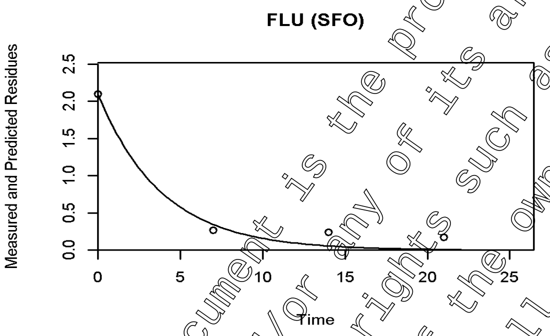
Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	$DT_{50\ actual}$ (d)	$DT_{90\ actual}$ (d)
SFO	-	0.9	k: 0.24451	20.8	k: 0.063	k: 0.06	k: 0.43	2.835	9.42
FOMC	-	0.9	α: 18230 β: 74560	26.0	-	β: 74560	β: 74559.36	2.835	9.42
SFO fit is statistically (χ2err, t-test) not acceptable and visually poor. FOMC did not result in an improved fit or in statistically very unreliable parameters, also checking for different starting values. DFOP and HS fits cannot deliver statistical information and are not appropriate, due to a too low degree of freedom (3 fitted parameters based on 4 data points). Consequently, **no statistically reliable evaluation is possible.**									
 SFO					 SFO				
 FOMC					 FOMC				

R 2007 0043/1, Toulouse, M-302325-01-1, FR, onion

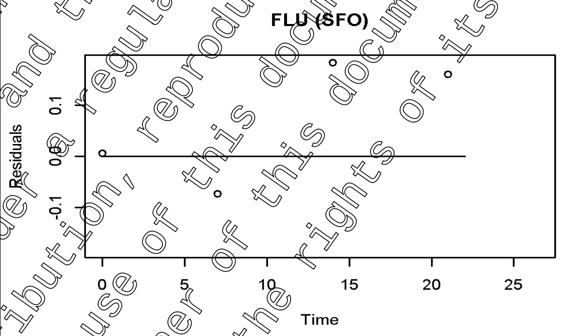
Table 8.9- 247: Kinetic models and goodness-of-fit statistics of fluopyram fits for onion of trial R 2007 0043/1, Toulouse, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	$DT_{50\ actual}$ (d)	$DT_{90\ actual}$ (d)
SFO	-	2.1	k: 0.25834	15.0	k: 0.035	k: 0.12	k: 0.40	2.683	8.91
FOMC	+	2.1	α: 0.35688 β: 0.02404	2.2	-	β: -0.11	β: 0.16	0.144	15.22

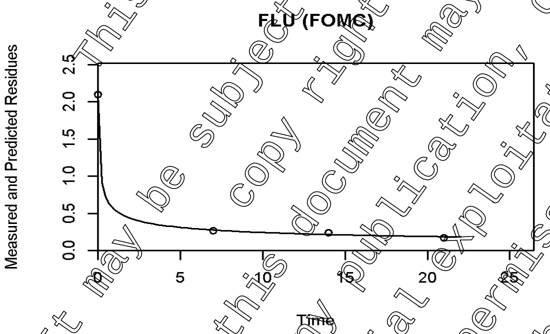
SFO fit is statistically still acceptable (χ^2err ~15%, t-test <0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. DFOP and HS fits cannot deliver statistical information, as degrees of freedom are too low (3 fitted parameters based on 4 data points). FOMC fit is statistically (χ^2err, t-test) and visually good. Consequently, **FOMC** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



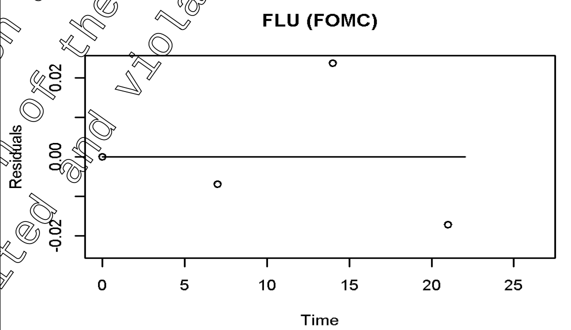
SFO



SFO



FOMC



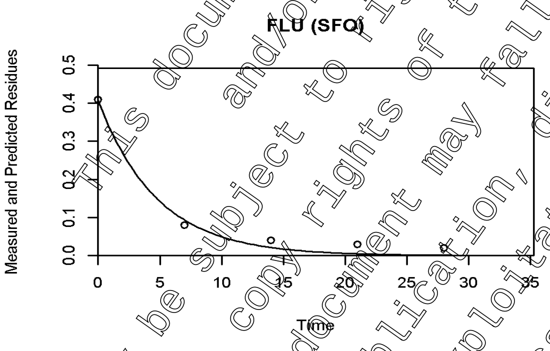
FOMC

R 2007 0056/3, Schauernheim, M-304288-01-1, DE, leek

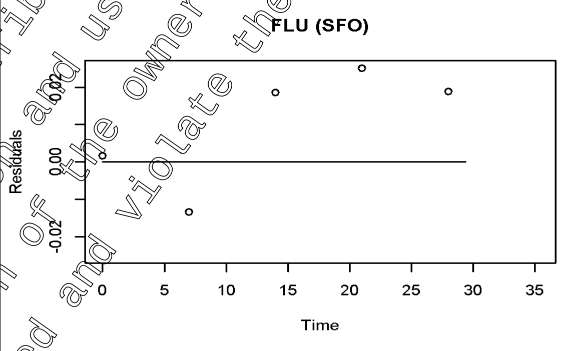
Table 8.9- 248: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2007 0056/3, Schauernheim, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	0.4	k: 0.21076	12.0	k: 0.003	k: 0.15	k: 0.27	**3.289**	10.93
FOMC	+	0.4	α: 1.133431 β: 2.155615	1.04	-	β: 1.48	β: 2.84	1.819	14.29
DFOP	+	0.4	k1: 0.357605 k2: 0.043575 g: 0.8274	0.82	k1: 0.027 k2: 0.063	k1: 0.30 k2: 0.03	k1: 0.42 k2: 0.06	2.447	13.89
HS	+	0.4	k1: 0.324 k2: 0.074 tb: 4.577	3.5	k1: 0.026 k2: 0.065	k1: 0.27 k2: 0.04	k1: 0.38 k2: 0.10	2.137	15.68

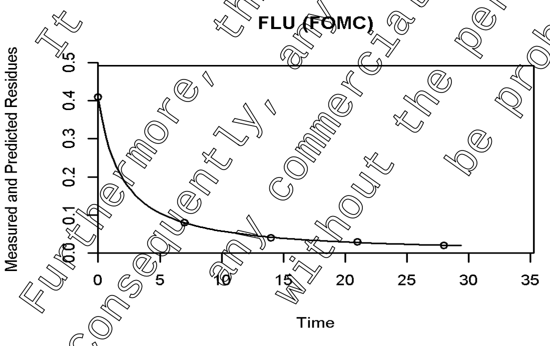
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05), but visually borderline. DFOP, FOMC and HS fits were alternatively tested. DFOP fit is statistically (χ^2err, t-test) and visually good, with the lowest $\chi 2$ err. Consequently, DFOP model is considered appropriate for modelling purpose. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT_{50} is an adequate option.



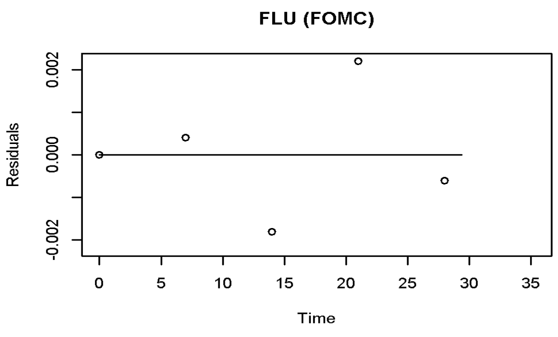
SFO



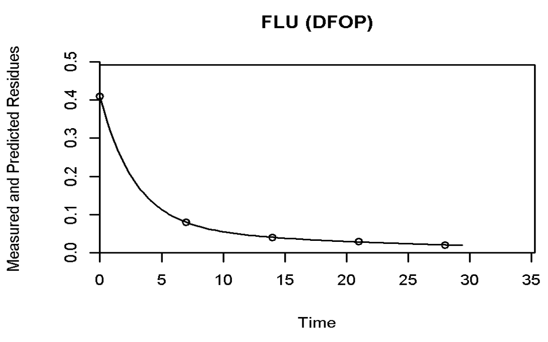
SFO



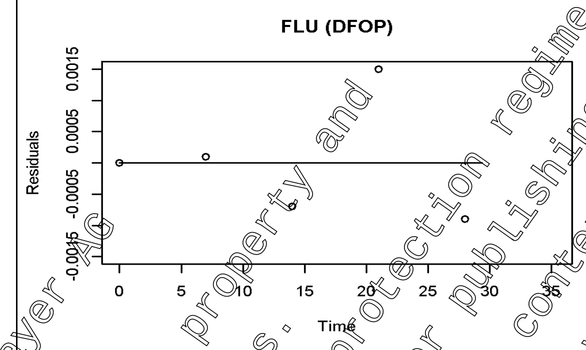
FOMC



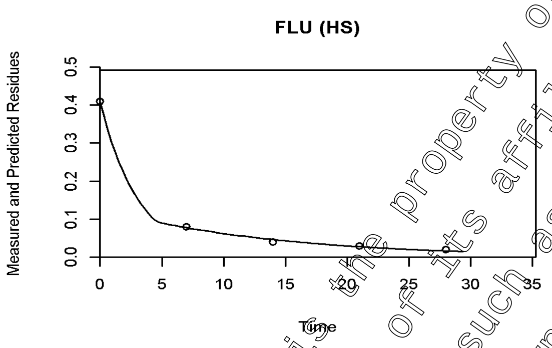
FOMC



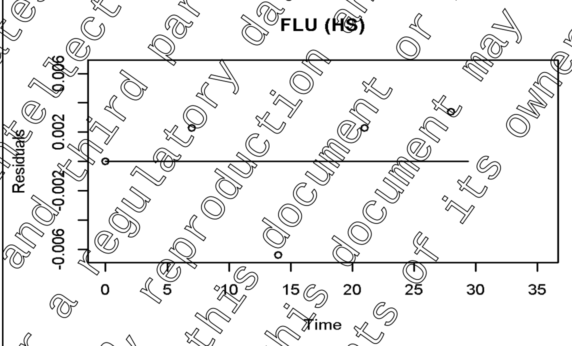
DFOP



DFOP



HS



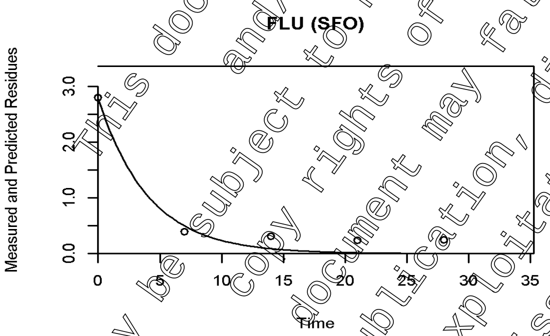
HS

R 2007 0057/1, Castelsarrasin, M-302775-01-1, FR, leek

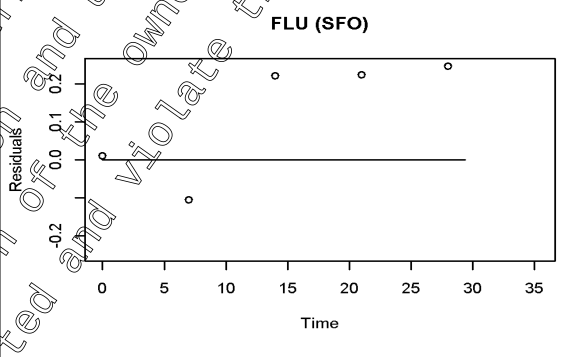
Table 8.9- 249: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2007 0057/1, Castelsarrasin, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	2.8	k: 0.24683	18.6	k: 0.017	k: 0.12	k: 0.38	2.808	9.33
FOMC	+	2.8	α: 0.36403 β: 0.03122	1.4	-	β: -0.03	β: 0.09	0.178	17.40
DFOP	+	2.8	k1: 0.533 k2: 0.016 g: 0.867	2.0	k1: 0.094 k2: 0.209	k1: 0.21 k2: -0.01	k1: 0.85 k2: 0.04	1.596	17.61
HS	+	2.8	k1: 0.372 k2: 0.025 tb: 5.255	2.5	k1: 0.017 k2: 0.108	k1: 0.33 k2: 0.01	k1: 0.41 k2: 0.04	1.862	19.13

SFO fit is statistically still acceptable (χ^2err <15%, t-test <0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in $\chi2$ error and visual assessment. However, the t-test of DFOP and HS show a low reliability especially of the slow degradation rates k2 (t-test > 0.05). Therefore, **FOMC** model is best appropriate for modelling endpoints (FOCUS kinetics) and also as best visual fit, with lowest χ^2err.



SFO



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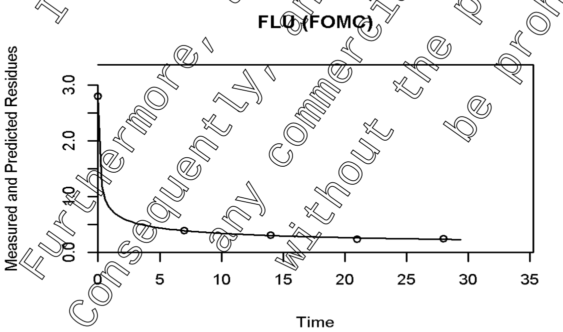
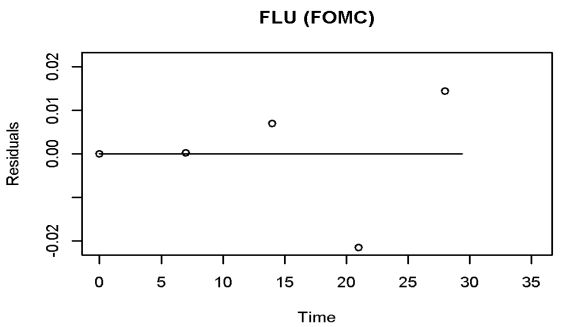


FOMC



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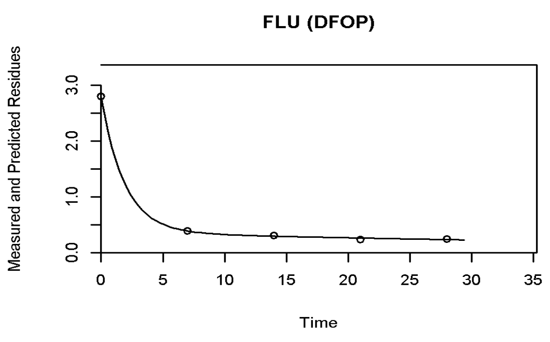
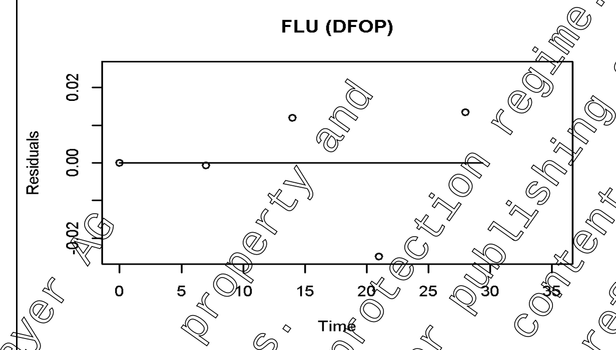


DFOP



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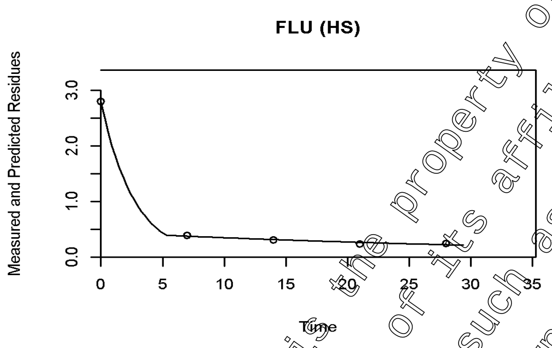
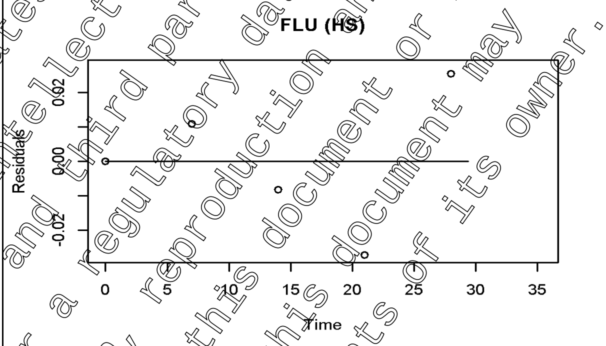


HS



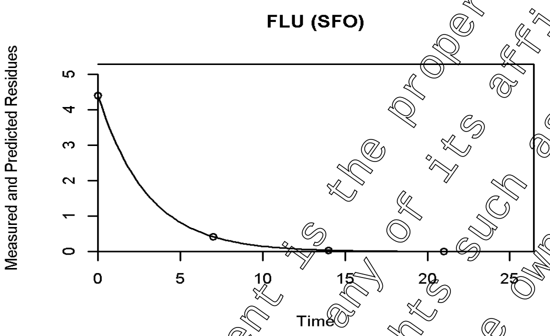
HS

R 2007 0078/4, Broad Fen Drove, Wissington, M-302101-01-1, GB, cabbage

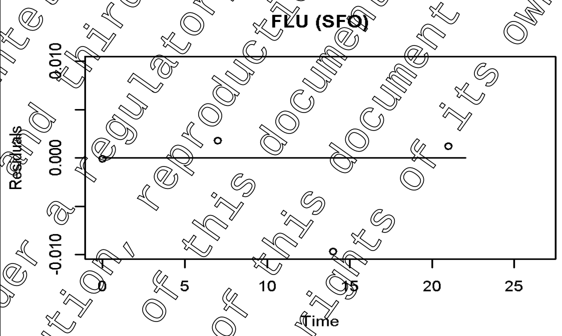
Table 8.9- 250: Kinetic models and goodness-of-fit statistics of fluopyram fits for cabbage of trial R 2007 0078/4, Broad Fen Drove, Wissington, GB

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	4.4	k: 0.336209	0.3	k: <0.001	k: 0.33	k: 0.34	**2.062**	6.849
FOMC	+	4.4	α: 22830 β: 67910	0.4	-	β: 67910	β: 67911.69	2.062	6.85

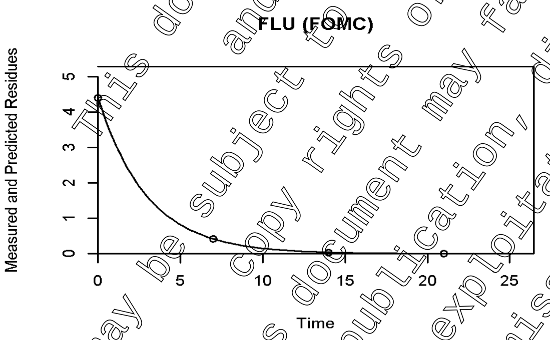
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



SFO



SFO



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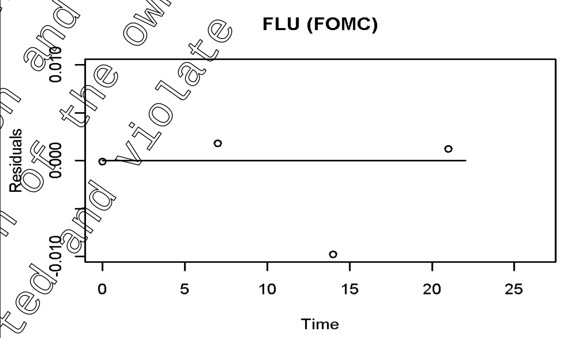


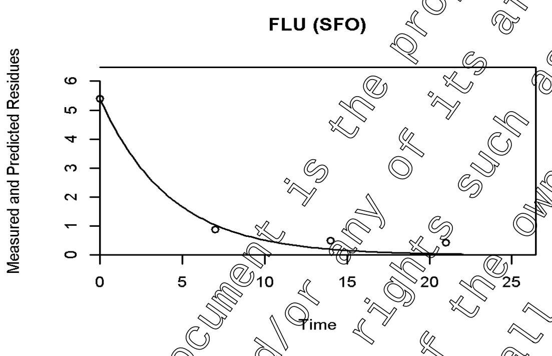
FOMC

R 2007 0079/2, Ouzilly, M-302044-01-1, FR, cabbage

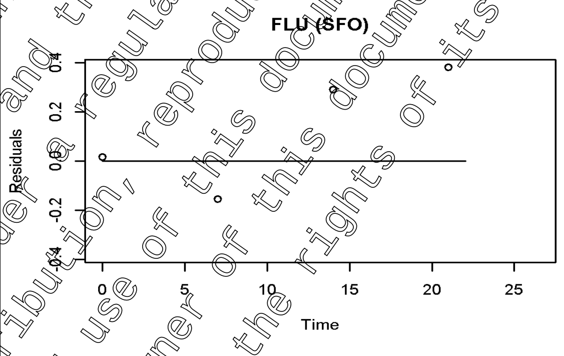
Table 8.9- 251: Kinetic models and goodness-of-fit statistics of fluopyram fits for cabbage of trial R 2007 0079/2, Ouzilly, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	$DT_{50\ actual}$ (d)	$DT_{90\ actual}$ (d)
SFO	o	5.4	k: 0.23568	11.5	k: 0.018	k: 0.14	k: 0.33	**2.941**	9.77
FOMC	+	5.4	α: 0.77916 β: 0.74459	1.4	-	β: -0.01	β: 1.50	**1.068**	13.56

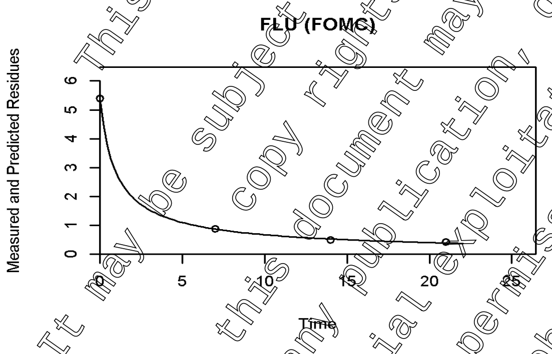
SFO fit is statistically still acceptable (χ^2err <15%, t-test <0.05) but visually borderline. FOMC, DFOP and HS fits were alternatively tested. DFOP and HS fits cannot deliver statistical information, as degrees of freedom are too low (3 fitted parameters based on 4 data points). FOMC fit is statistically (χ^2err, t-test) and visually good. Consequently, FOMC model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



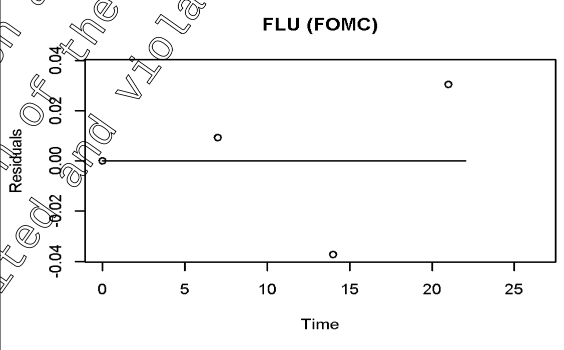
SFO



SFO



FOMC



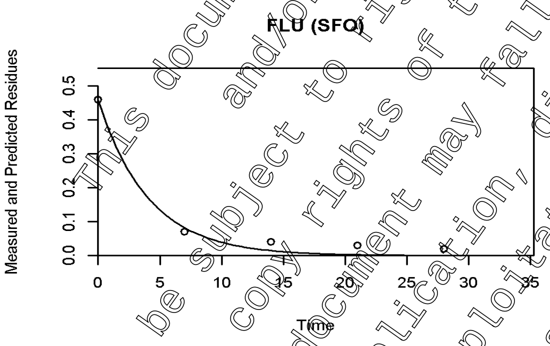
FOMC

R 2007 0249/3, Schauernheim, M-304276-01-1, DE, leek

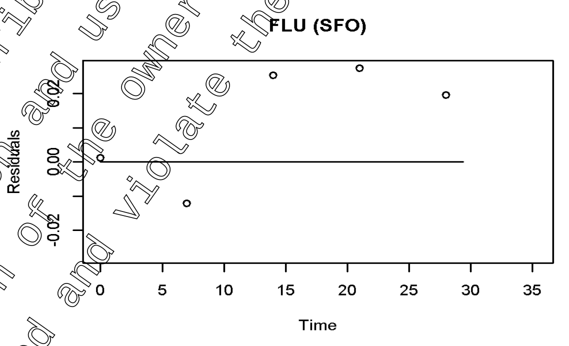
Table 8.9- 252: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2007 0249/3, Schauernheim, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	0.5	k: 0.24575	12.6	k: 0.005	k: 0.16	k: 0.33	2.821	9.37
FOMC	+	0.5	α: 0.902915 β: 0.997772	0.89	-	β: 0.63	β: 1.36	1.152	11.78
DFOP	+	0.5	k1: 0.466782 k2: 0.046679 g: 0.8331	0.61	k1: 0.029 k2: 0.041	k1: 0.38 k2: 0.03	k1: 0.55 k2: 0.06	1.876	11.73
HS	+	0.5	k1: 0.268962 k2: 0.047591 tb: 7.980	0.55	k1: 0.003 k2: 0.032	k1: 0.26 k2: 0.04	k1: 0.27 k2: 0.06	**2.577**	11.26

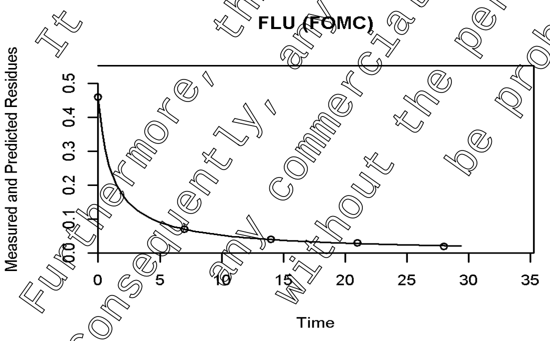
SFO fit is statistically good (χ^2err <15%, t-test <0.05), but visually borderline. DFOP, FOMC and HS fits were alternatively tested. HS fit is statistically (χ^2err, t-test) and visually good, with the lowest $\chi 2$ err. Consequently, HS model is considered appropriate for modelling purpose. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT_{50} is an adequate option.



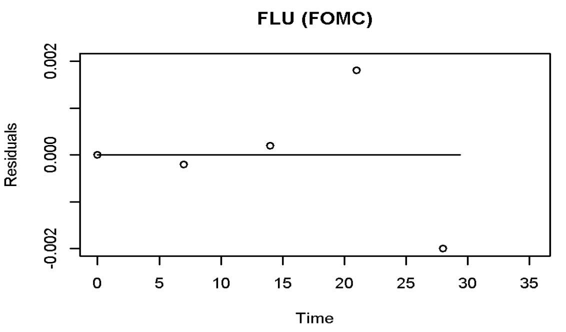
SFO



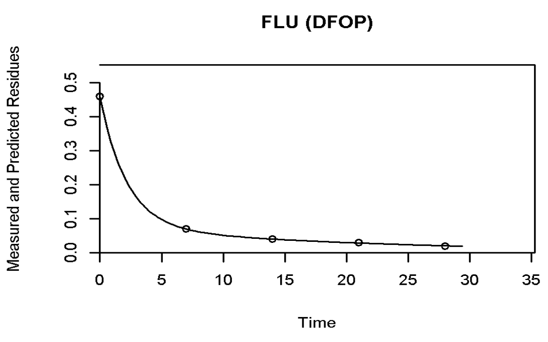
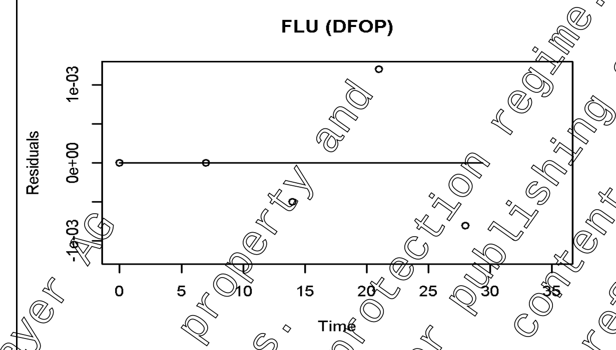
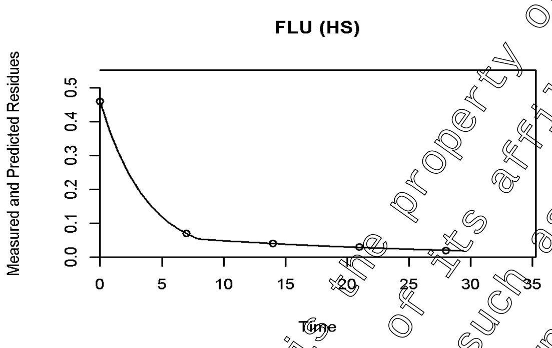
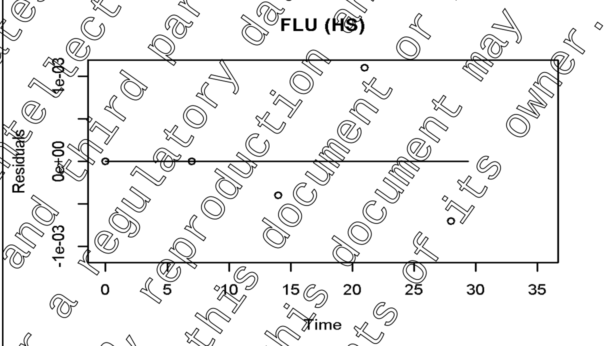
SFO



FOMC



FOMC

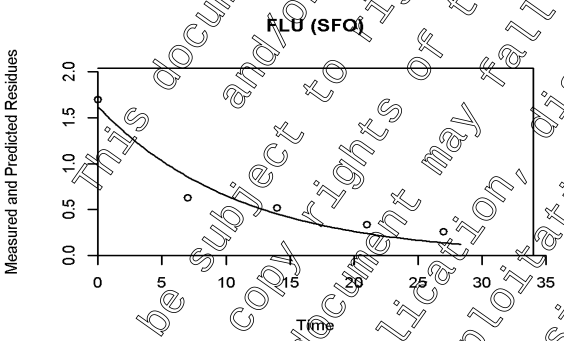
 DFOP	 DFOP
 HS	 HS

R 2007 0250/7, Castelsarrasin, M-302780-01-1, FR, leek

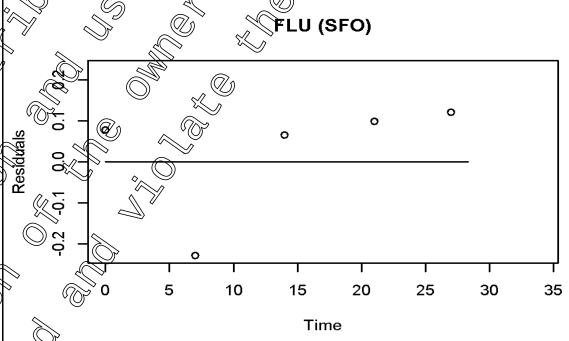
Table 8.9- 253: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2007 0250/7, Castelsarrasin, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	1.6	k: 0.09092	15.3	k: 0.007	k: 0.06	k: 0.13	7.624	25.33
FOMC	+	1.7	α: 0.695 β: 2.403	5.18	-	β: -1.27	β: 6.08	4.116	63.75
DFOP	+	1.7	k1: 5.104 k2: 0.04320 g: 0.4845	3.61	k1: <0.001 k2: 0.058	k1: 5.104 k2: 0.0277	k1: 5.104 k2: 0.059	0.916	37.96
HS	+	1.7	k1: 0.14299 k2: 0.04320 tb: 6.641	3.61	k1: 0.026 k2: 0.058	k1: 0.12 k2: 0.0277	k1: 0.17 k2: 0.059	**4.848**	37.96

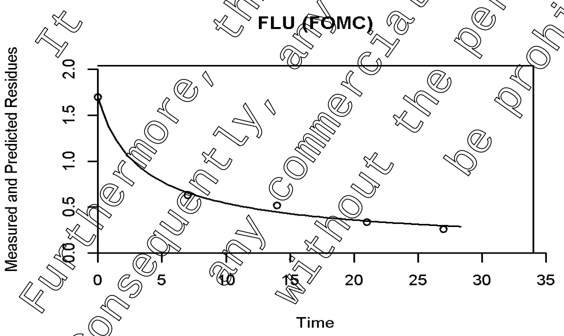
SFO fit is statistically acceptable (χ^2err ~15%, t-test <0.05), but visually borderline. DFOP, FOMC and HS fits were alternatively tested. HS fit is statistically (χ^2err, t-test) and visually good, with a lowest χ^2 err and best visual fit. Consequently, **HS** model is considered appropriate for modelling purpose. As low residues < 10 % are reached at study end, a recalculation of a pseudo SFO DT_{50} is an adequate option.



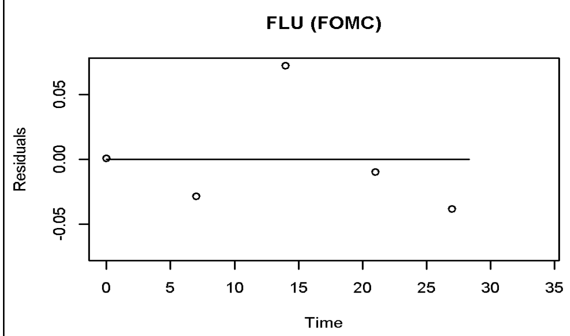
SFO



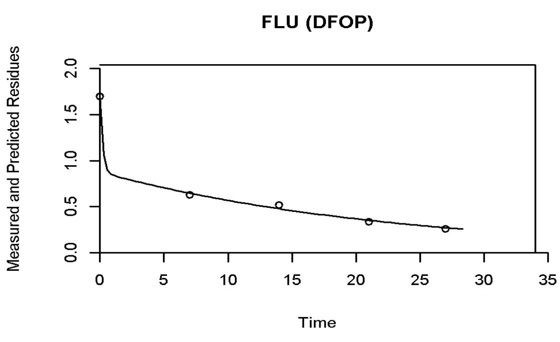
SFO



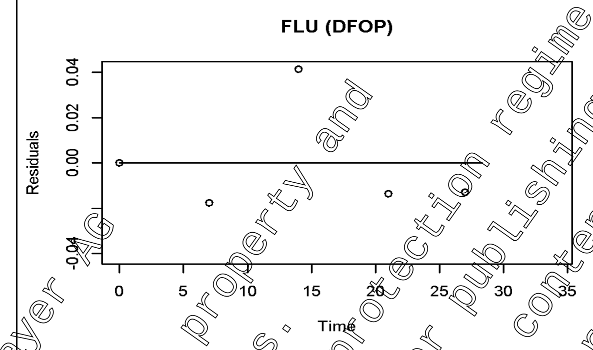
FOMC



FOMC



DFOP



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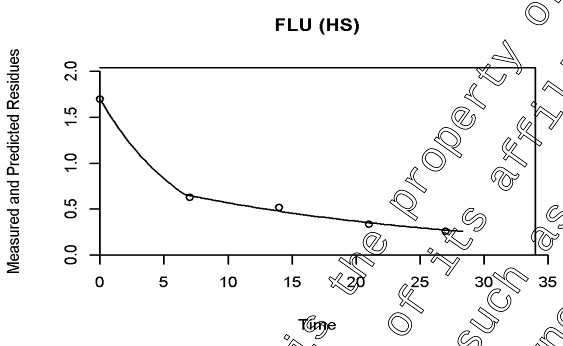
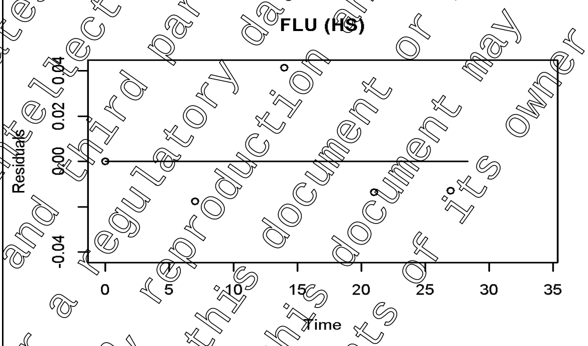


HS



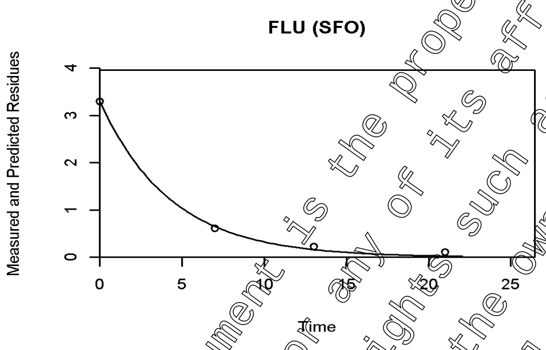
HS

R 2007 0567/0, Southfleet, Gravesend, M-302330-01-1, GB, onion

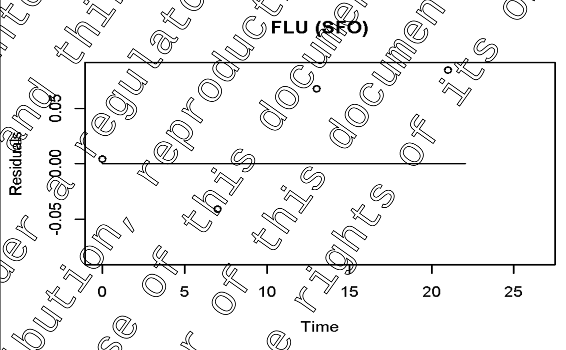
Table 8.9- 254: Kinetic models and goodness-of-fit statistics of fluopyram fits for onion of trial R 2007 0567/0, Southfleet, Gravesend, GB

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.3	k: 0.23164	4.5	k: 0.003	k: 0.20	k: 0.26	**2.992**	9.94
FOMC	+	3.3	α: 2.82659 β: 8.53296	0.8	-	β: 4.88	β: 12.18	2.371	10.74

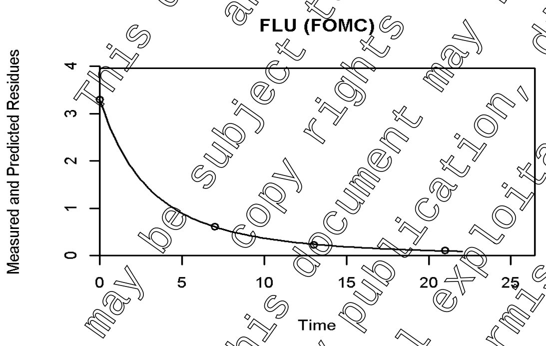
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 13), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



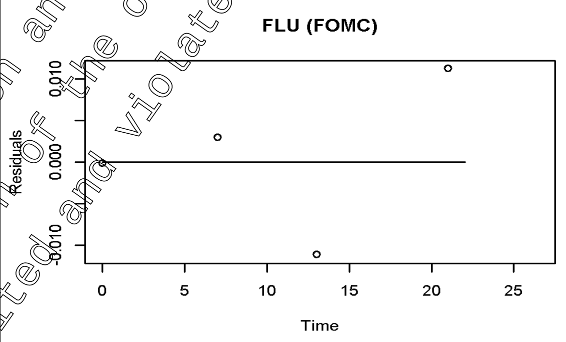
SFO



SFO



FOMC



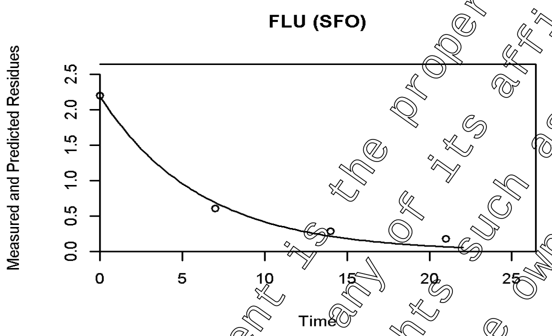
FOMC

R 2007 0568/9, Lusia, M-302325-01-1, IT, onion

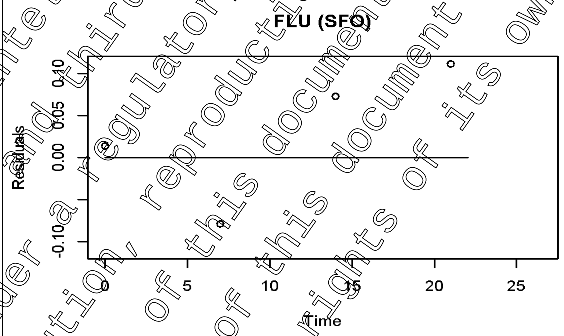
Table 8.9- 255: Kinetic models and goodness-of-fit statistics of fluopyram fits for onion of trial R 2007 0568/9, Lusia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	2.2	k: 0.1649	7.7	k: 0.007	k: 0.13	k: 0.20	**4.203**	13.96
FOMC	+	2.2	α: 1.723828 β: 6.324219	0.3	-	β: 5.46	β: 7.19	3.130	17.73

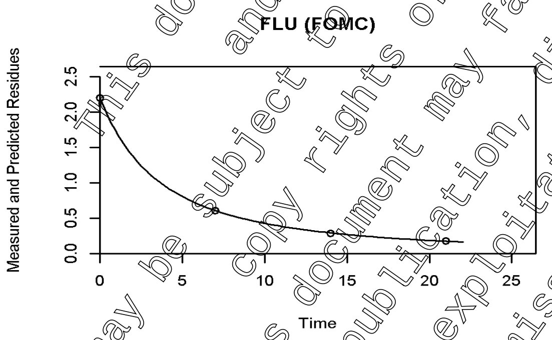
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



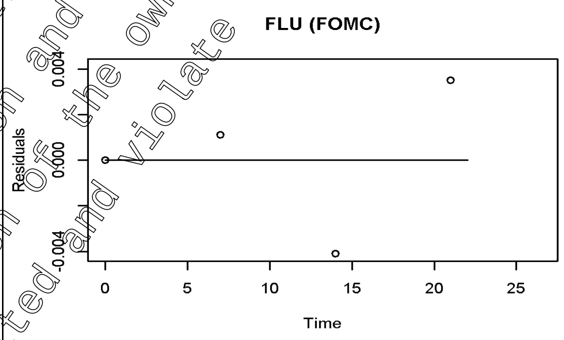
SFO



SFO



FOMC



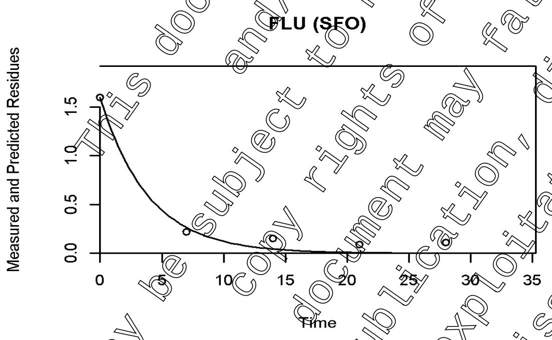
FOMC

R 2007 0569/7, Bouafle, M-304288-01-1, FR, leek

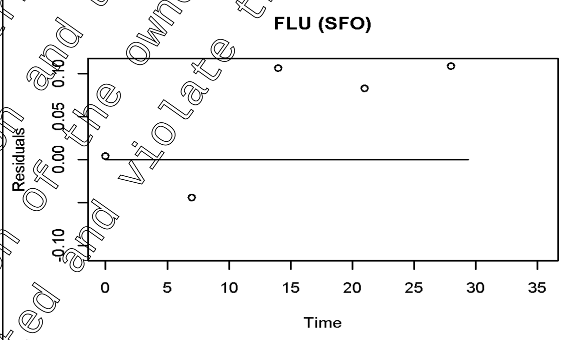
Table 8.9- 256: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2007 0569/7, Bouafle, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	1.6	k: 0.25709	14.7	k: 0.009	k: 0.15	k: 0.36	2.696	8.96
FOMC	+	1.6	α: 0.62825 β: 0.30972	2.6	-	β: -0.22	β: 0.84	0.624	11.79
DFOP	+	1.6	k1: 0.452 k2: 0.025 g: 0.880	3.6	k1: 0.118 k2: 0.282	k1: 0.11 k2: -0.03	k1: 0.79 k2: 0.08	1.828	10.52
HS	+	1.6	k1: 0.283 k2: 0.028 tb: 8.018	3.7	k1: 0.023 k2: 0.250	k1: 0.24 k2: -0.03	k1: 0.32 k2: 0.08	2.445	9.09

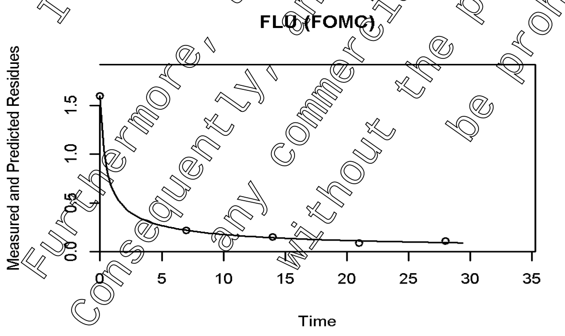
SFO fit is statistically still acceptable (χ^2err <15%, t-test <0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in $\chi2$ error and visual assessment. However, the t-test of DFOP and HS show a low reliability especially of the slow degradation rates k2 (t-test > 0.05). Therefore, **FOMC** model is best appropriate for modelling endpoints (FOCUS kinetics) and also as best visual fit, with lowest χ^2err.



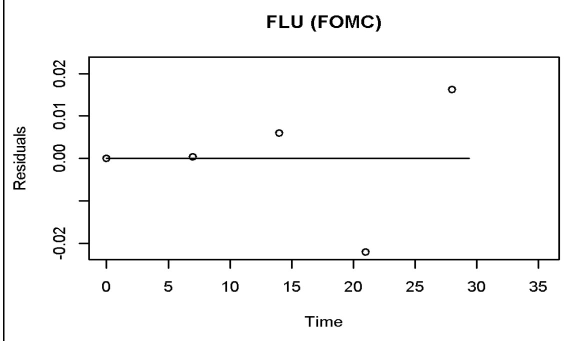
SFO



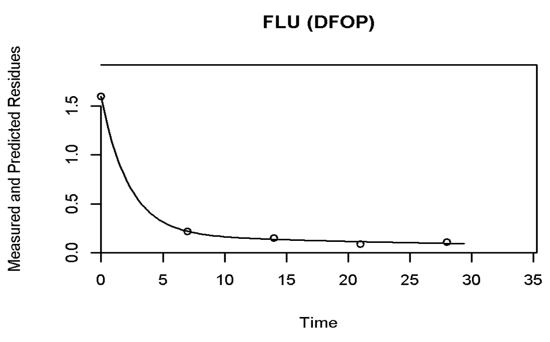
SFO



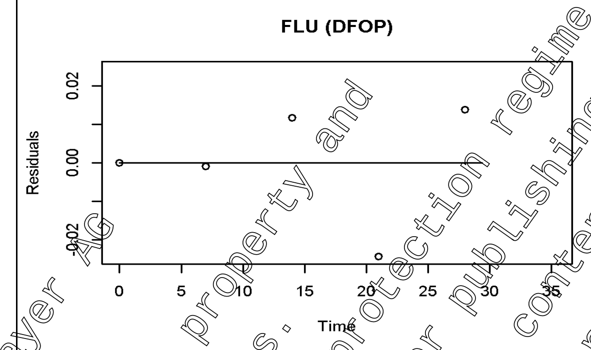
FOMC



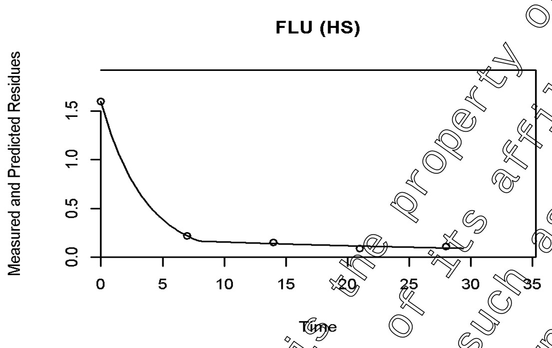
FOMC



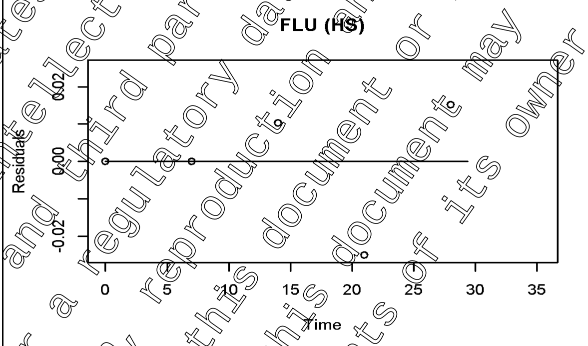
DFOP



DFOP



HS



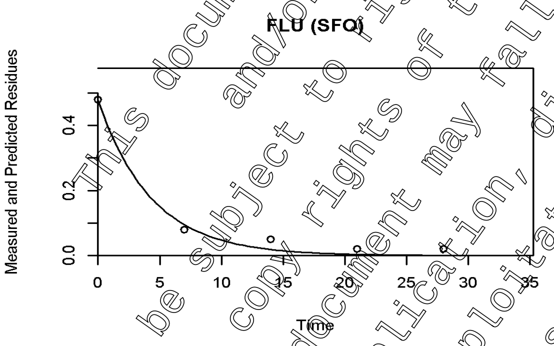
HS

R 2007 0570/0, Zwaagdijk-Oost, M-304288-01-1, NL, leek

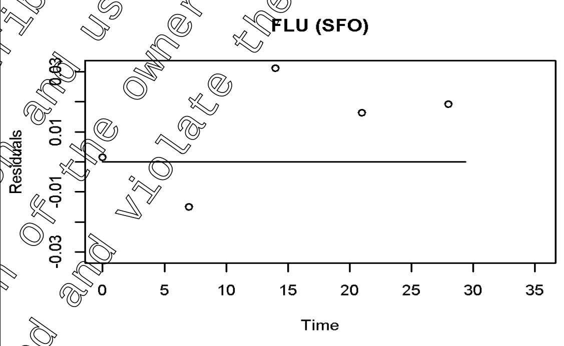
Table 8.9- 257: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2007 0570/0, Zwaagdijk, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	0.48	k: 0.23111	11.8	k: 0.004	k: 0.16	k: 0.30	2.999	9.96
FOMC	+	0.48	α: 1.17066 β: 1.983788	3.51	-	β: -0.30	β: 4.27	**1.602**	12.20
DFOP	+	0.48	k1: 3.426 k2: 0.07842 g: 0.7094	3.50	k1: <0.001 k2: 0.070	k1: 3.426 k2: 0.04	k1: 3.426 k2: 0.11	0.346	13.60
HS	+	0.48	k1: 0.257462 k2: 0.078416 tb: 6.902	3.50	k1: 0.019 k2: 0.070	k1: 0.23 k2: 0.04	k1: 0.29 k2: 0.11	2.692	13.60

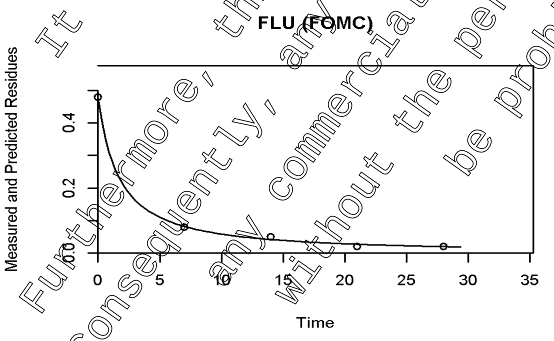
SFO fit is statistically acceptable (χ^2err < 15%, t-test <0.05), but visually poor. DFOP, FOMC and HS fits were alternatively tested. All 3 models show a similar improvement in χ error and visual assessment. However, the t-test of DFOP and HS show a reduced reliability of the slow degradation rates k2 (t-test >0.05). Therefore, **FOMC** model is best appropriate for modelling endpoints.



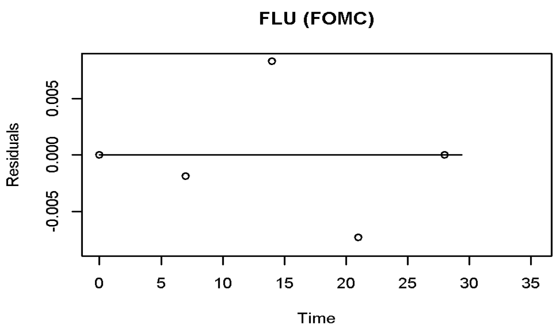
SFO



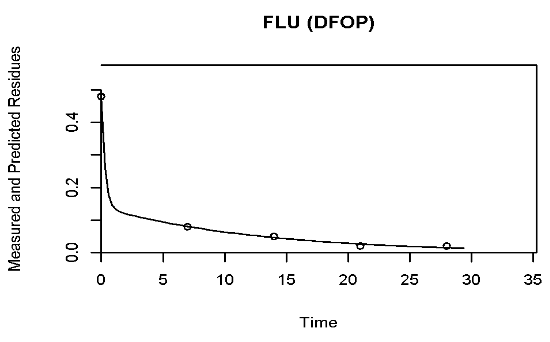
SFO



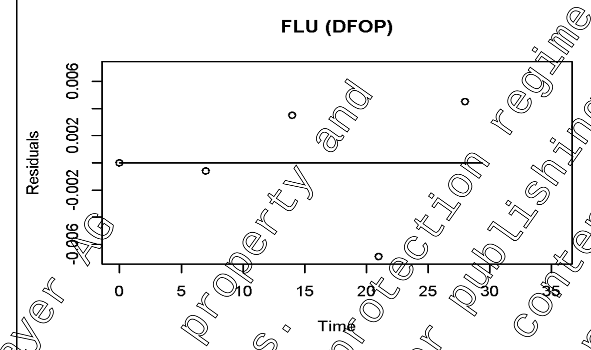
FOMC



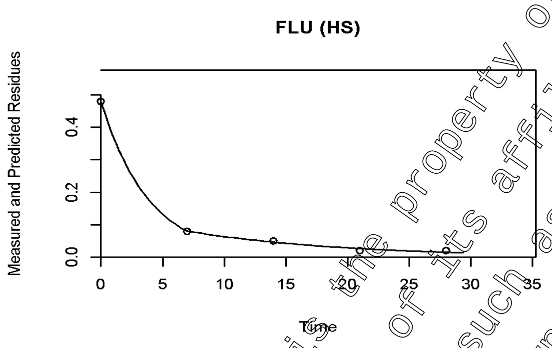
FOMC



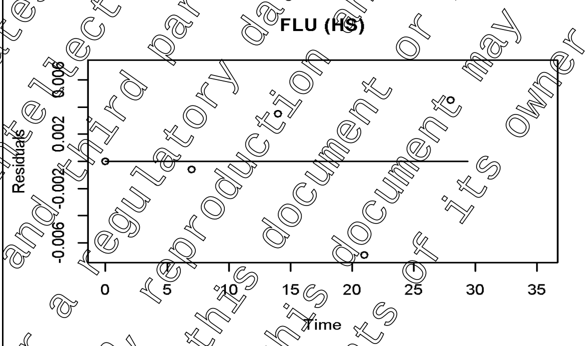
DFOP



DFOP



HS



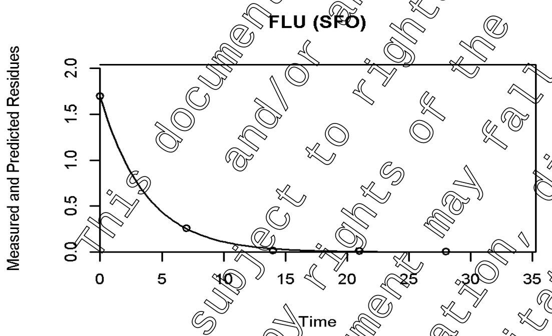
HS

R 2007 0571/9, Langenfeld-Reusrath, M-304288-01-1, DE, leek

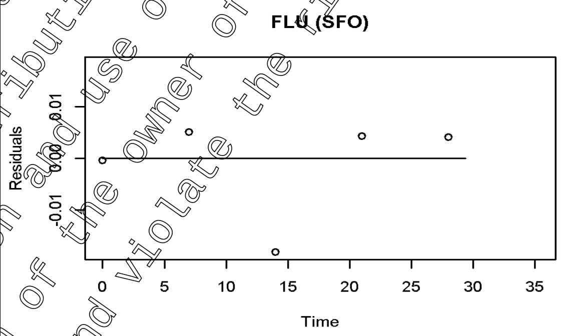
Table 8.9- 258: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2007 0571/9, Langenfeld-Reusrath, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	1.7	k: 0.271113	1.8	k: <0.001	k: 0.26	k: 0.28	**2.557**	8.49
FOMC	+	1.7	α: 25920 β: 95590	2.0	-	β: 95590	β: 95593.64	2.557	8.49
DFOP	+	1.7	k1: 0.271 k2: 0.189 g: 1.00	2.5	k1: 0.101 k2: <2e-16	k1: 0.10 k2: 0.19	k1: 0.45 k2: 0.19	2.557	8.49
HS	+	1.7	k1: 0.271 k2: 0.099 tb: 17.743	2.4	k1: 0.012 k2: 0.448	k1: 0.25 k2: -1.09	k1: 0.29 k2: 1.28	2.555	8.49

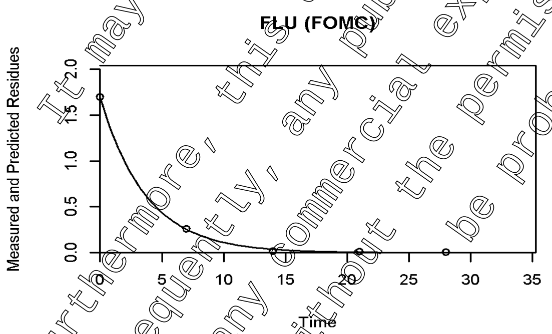
SFO fit is statistically and visually good (χ^2 err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



SFO



SFO



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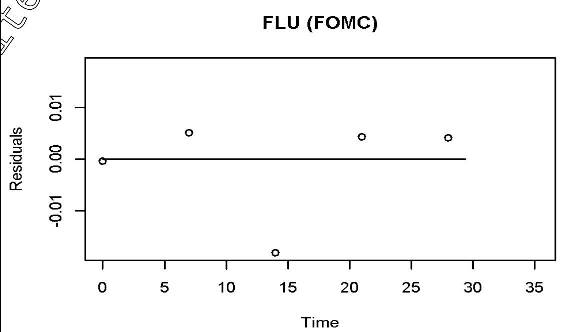
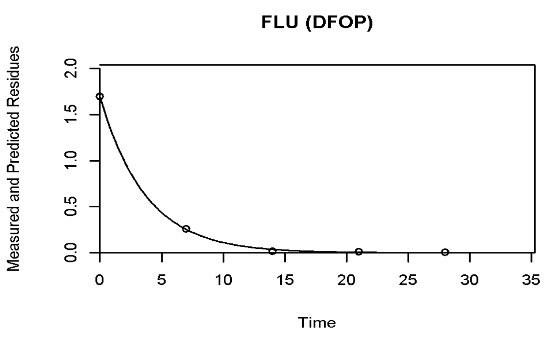
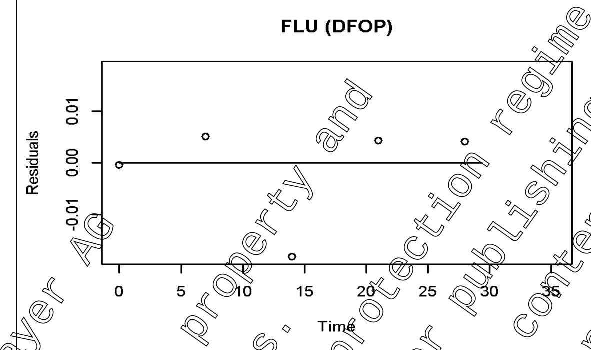


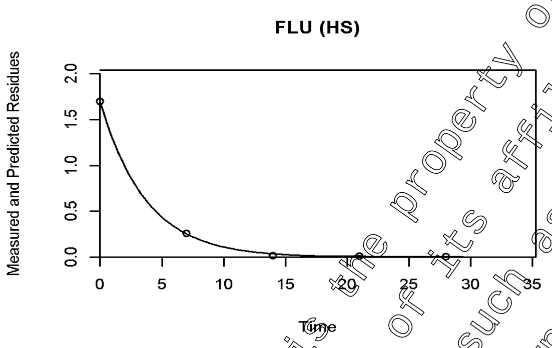
FOMC



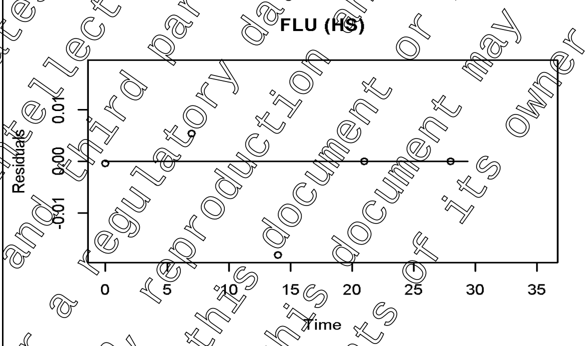
DFOP



DFOP



HS



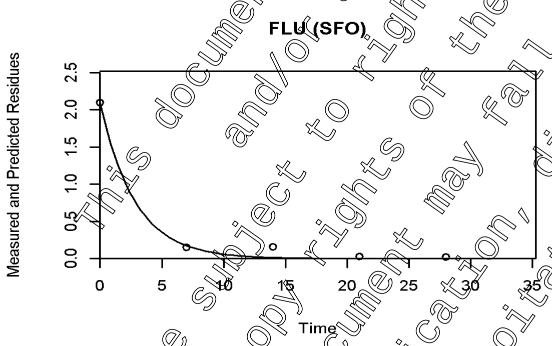
HS

R 2007 0572/7, Lusia, M-302775-01-1, IT, leek

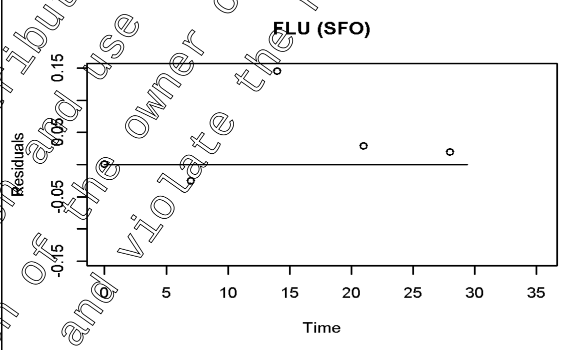
Table 8.9- 259: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2007 0572/7, Lusia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	2.1	k: 0.35501	11.0	k: 0.008	k: 0.22	k: 0.49	**1.952**	6.486
FOMC	+	2.1	α: 0.92795 β: 0.4902	6.9	-	β: -1.99	β: 2.98	0.544	5.371
DFOP	+	2.1	k1: 2327 k2: 0.072 g: 0.867	7.34	k1: <0.001 k2: 0.225	k1: 2327.00 k2: -0.05	k1: 2326.94 k2: 0.19	0.00037	4.007
HS	+	2.1	k1: 0.366 k2: 0.072 tb: 6.853	7.34	k1: 0.051 k2: 0.225	k1: 0.25 k2: -0.05	k1: 0.48 k2: 0.19	1.895	6.294

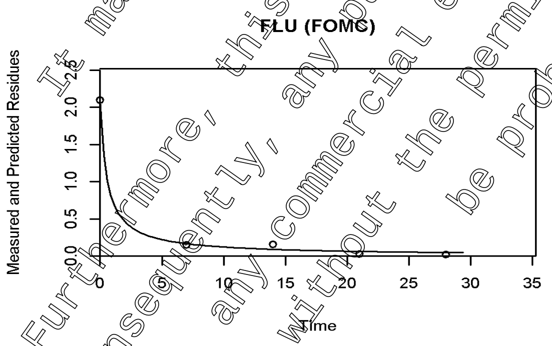
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 7), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



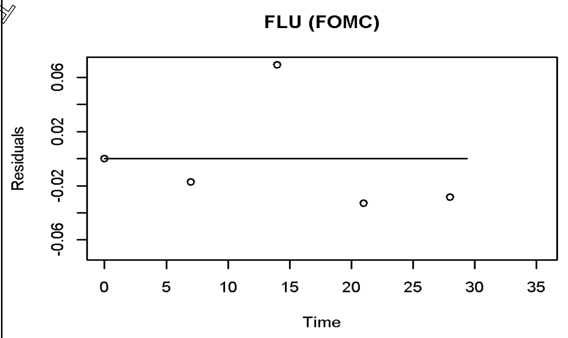
SFO



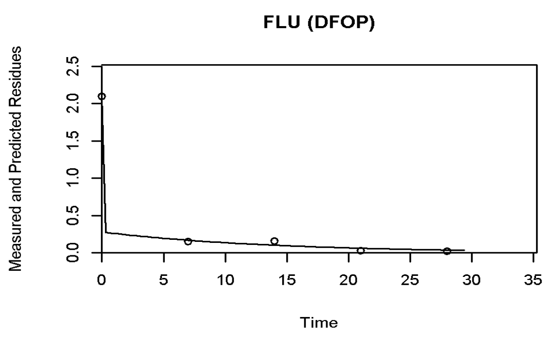
SFO



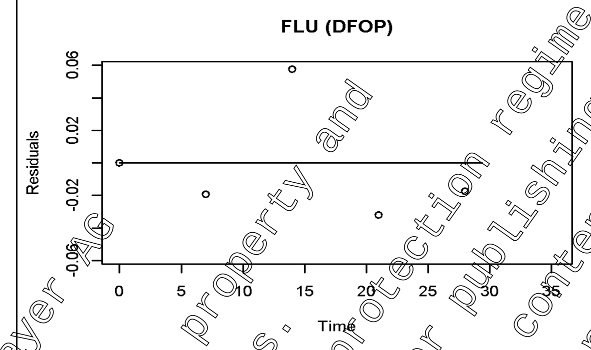
FOMC



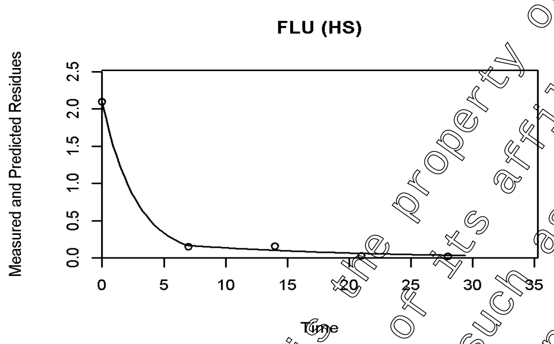
FOMC



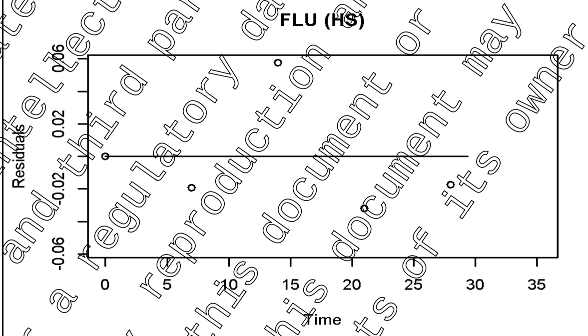
DFOP



DFOP



HS



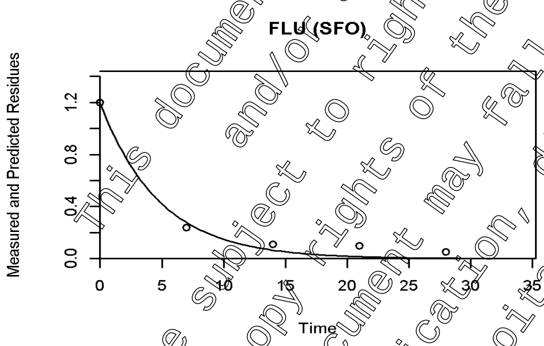
HS

R 2007 0573/5, Bouafle, M-304276-01-1, FR, leek

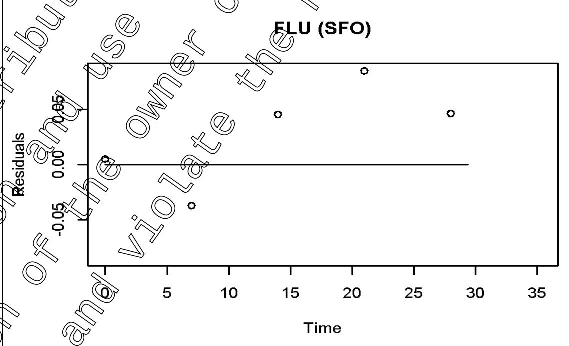
Table 8.9- 260: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2007 0573/5, Bouafle, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	1.2	k: 0.20871	12.0	k: 0.003	k: 0.15	k: 0.27	**3.321**	11.03
FOMC	+	1.2	α: 1.19125 β: 2.42083	3.02	-	β: 0.26	β: 4.58	1.911	14.31
DFOP	+	1.2	k1: 0.345 k2: 0.043 g: 0.831	3.33	k1: 0.102 k2: 0.224	k1: 0.12 k2: -0.03	k1: 0.57 k2: 0.12	2.519	13.82
HS	+	1.2	k1: 0.230 k2: 0.046 tb: 9.218	3.04	k1: 0.017 k2: 0.160	k1: 0.21 k2:<0.001	k1: 0.25 k2: 0.10	3.015	13.22

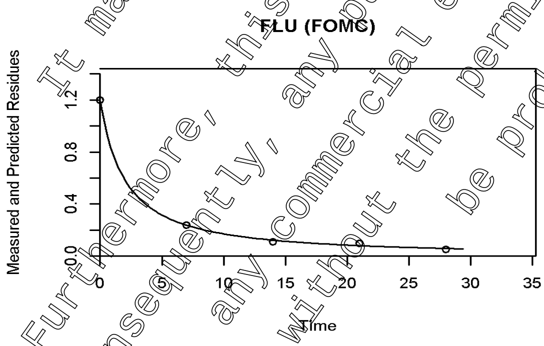
SFO fit is statistically and visually good to acceptable (χ^2 err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 14), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



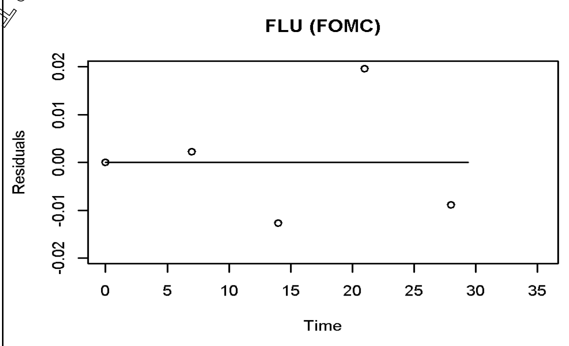
SFO



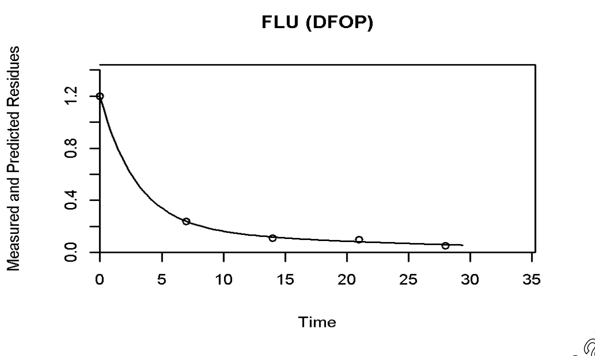
SFO



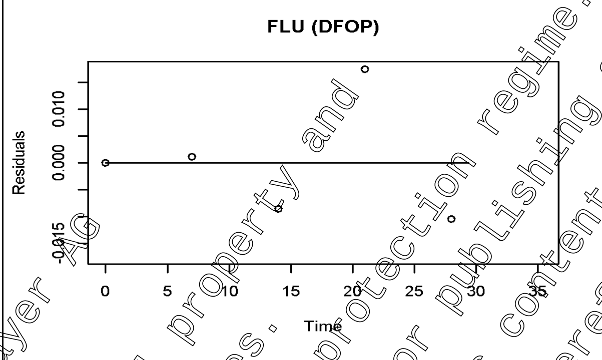
FOMC



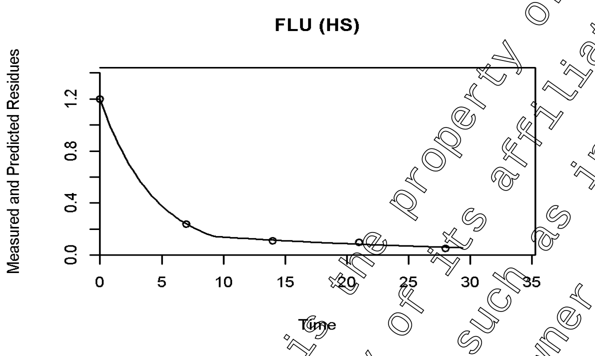
FOMC



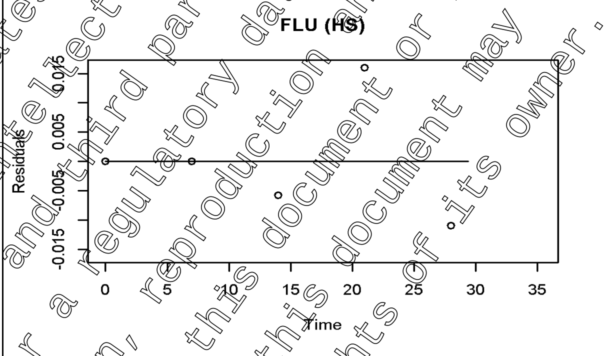
DFOP



DFOP



HS



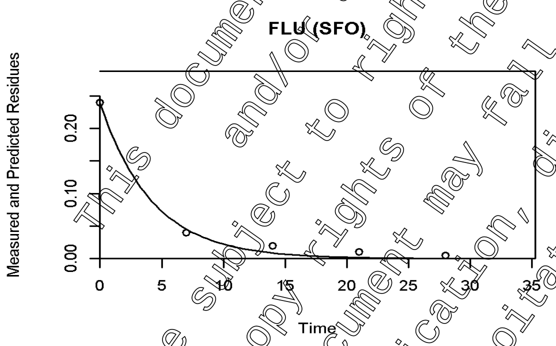
HS

R 2007 0574/3, Zwaagdijk-Oost, M-304276-01-1, NL, leek

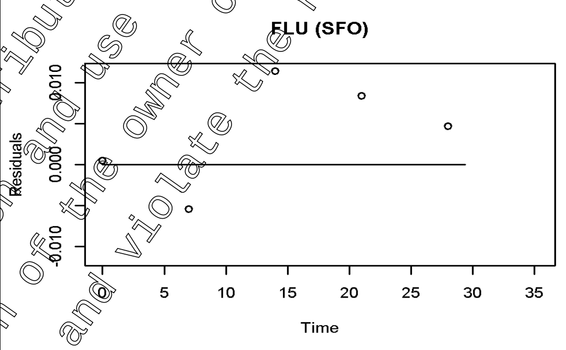
Table 8.9- 261: Kinetic models and goodness-of-fit statistics of fluopyram fits for leek of trial R 2007 0574/3, Zwaagdijk, NL

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	0.24	k: 0.237708	9.0	k: 0.002	k: 0.18	k: 0.29	**2.916**	9.687
FOMC	+	0.24	α: 1.613808 β: 3.488899	1.94	-	β: 1.40	β: 5.57	1.872	11.04
DFOP	+	0.24	k1: 3.41 k2: 0.09902 g: 0.6667	0.0009	k1: <0.001 k2: <0.001	k1: 3.41 k2: 0.10	k1: 3.41 k2: 0.10	0.385	12.16
HS	+	0.24	k1: 0.256 k2: 0.09902 tb: 7.0	0.0005	k1: <0.001 k2: <0.001	k1: 0.26 k2: 0.10	k1: 0.26 k2: 0.10	2.708	12.16

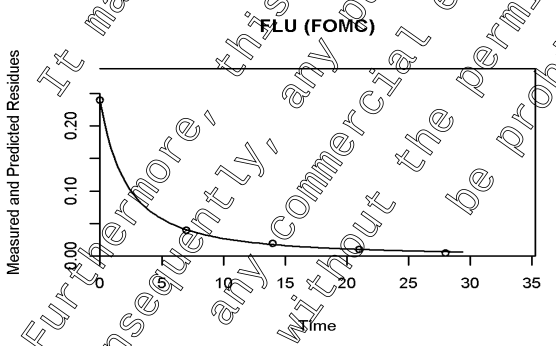
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 14), is described visually acceptable. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



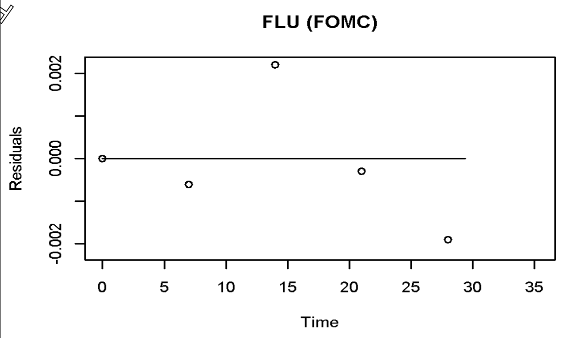
SFO



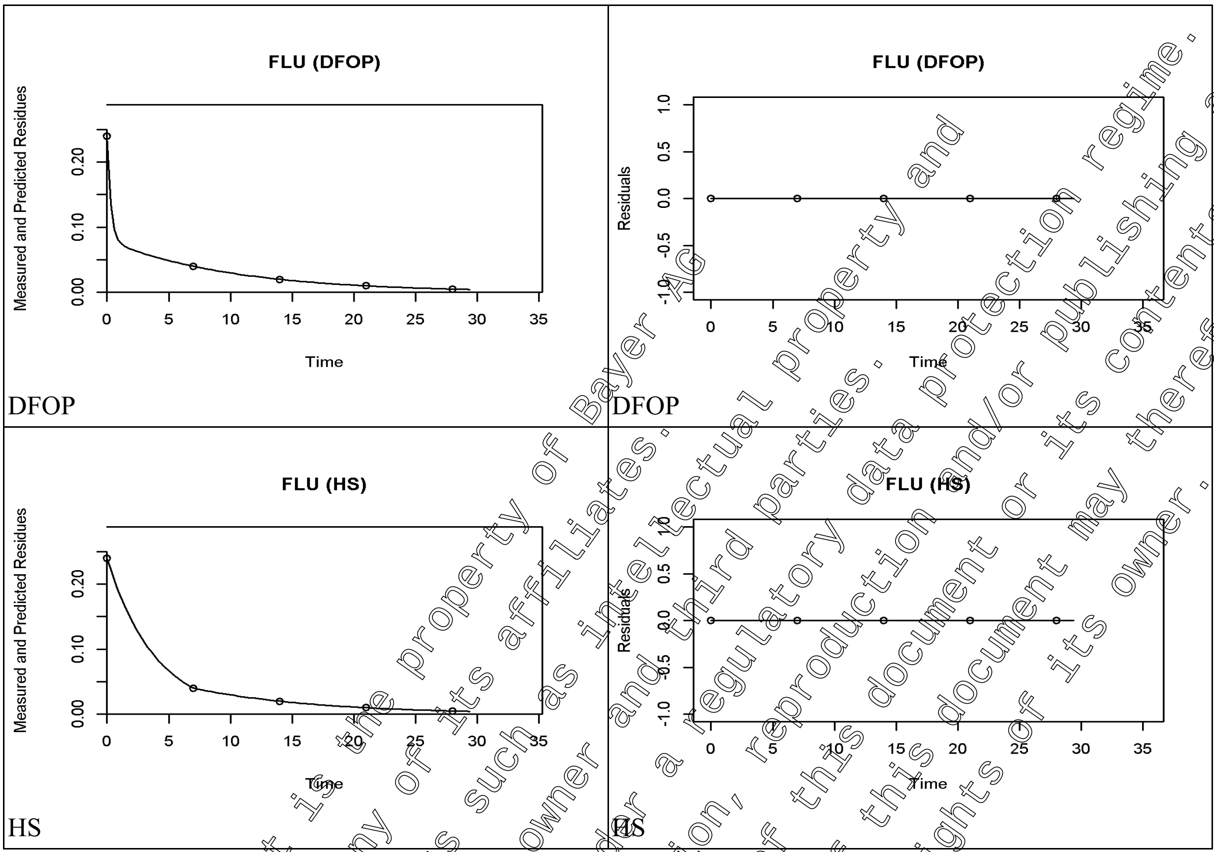
SFO



FOMC



FOMC

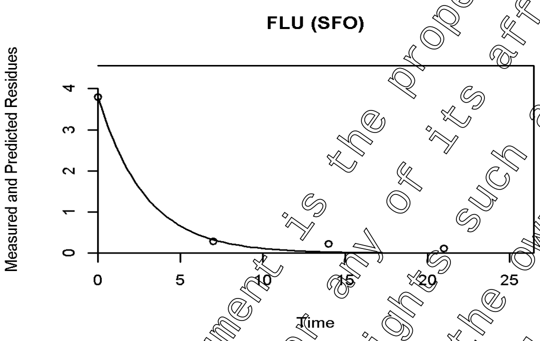

FLU (DFOP)
Measured and Predicted Residues
Time
DFOP
FLU (DFOP)
Residuals
Time
DFOP
FLU (HS)
Measured and Predicted Residues
Time
HS
FLU (HS)
Residuals
Time
HS

R 2007 0599/9, Meckenbeuren, M-302101-01-1, DE, cabbage

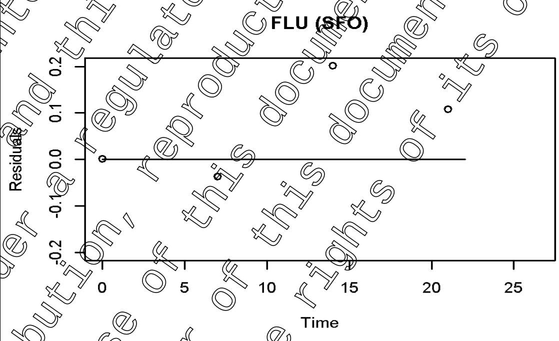
Table 8.9- 262: Kinetic models and goodness-of-fit statistics of fluopyram fits for cabbage of trial R 2007 0599/9, Meckenbeuren, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	3.8	k: 0.35027	8.5	k: 0.019	k: 0.21	k: 0.49	**1.979**	6.574
FOMC	+	3.8	α: 0.67943 β: 0.17074	2.5	-	β: -0.57	β: 0.91	0.303	4.889

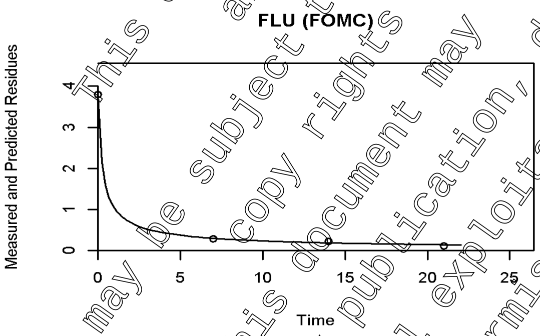
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached, is described visually good (before day 7). Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



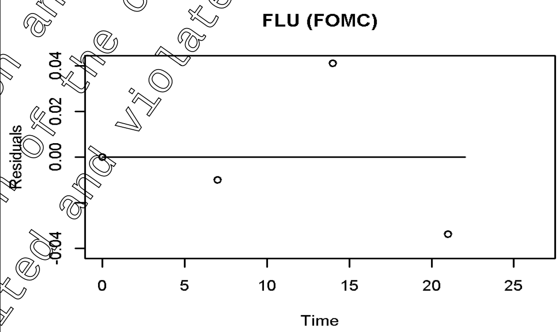
SFO



SFO



FOMC



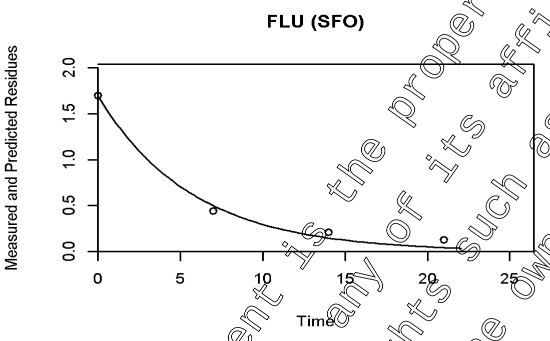
FOMC

R 2007 0600/6, Brenes, M-302044-01-1, ES, cabbage

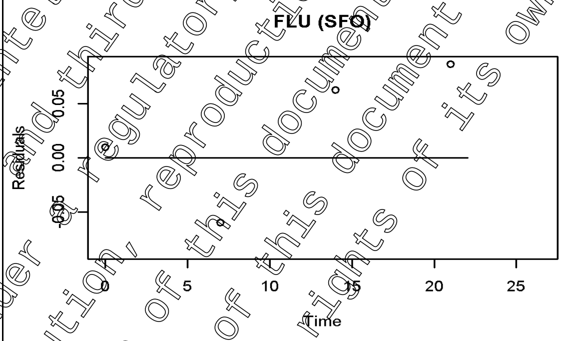
Table 8.9- 263: Kinetic models and goodness-of-fit statistics of fluopyram fits for cabbage of trial R 2007 0600/6, Brenes, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	1.7	k: 0.17413	8.1	k: 0.008	k: 0.13	k: 0.22	**3.981**	13.22
FOMC	+	1.7	α: 1.630881 β: 5.417322	0.2	-	β: 4.93	β: 5.90	2.869	16.81

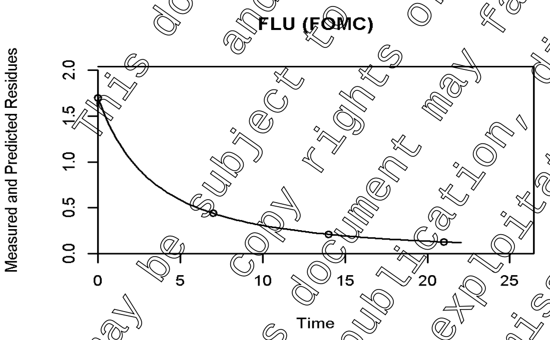
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



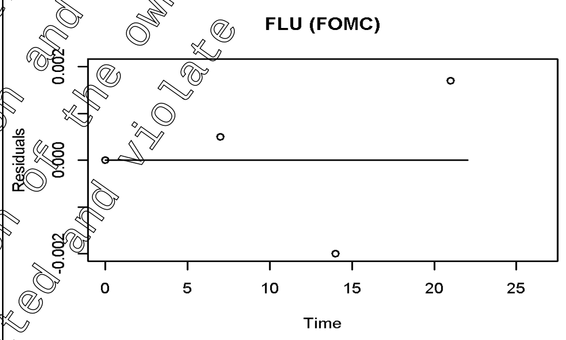
SFO



SFO



FOMC



FOMC

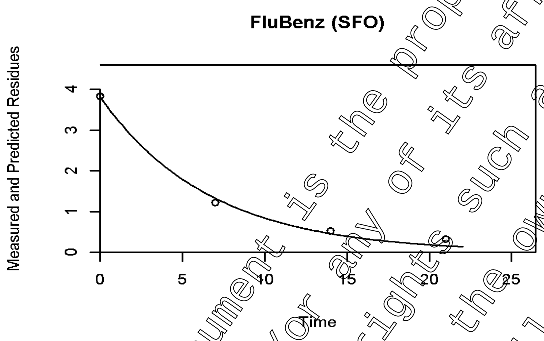
Fluopyram + FLU-benzamide

R 2006 0339/8, Saint Bonnet de Mure, M-292098-01-1, FR, onion

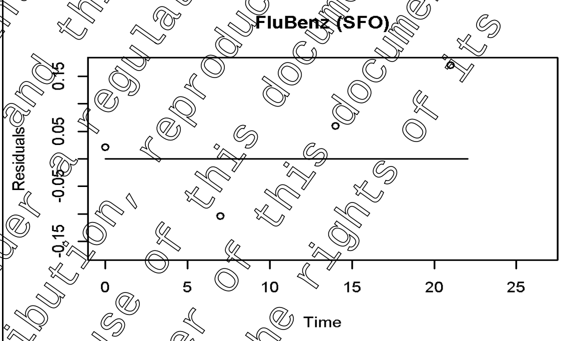
Table 8.9- 264: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for onion of trial R 2006 0339/8, Saint Bonnet de Mure, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	$DT_{50\ actual}$ (d)	$DT_{90\ actual}$ (d)
SFO	+	3.8	k: 0.151	5.8	k: 0.004	k: 0.12	k: 0.18	**4.590**	15.25
FOMC	+	3.8	α: 2.50736 β: 12.00407	1.5	-	β: 4.30	β: 19.71	3.823	18.07

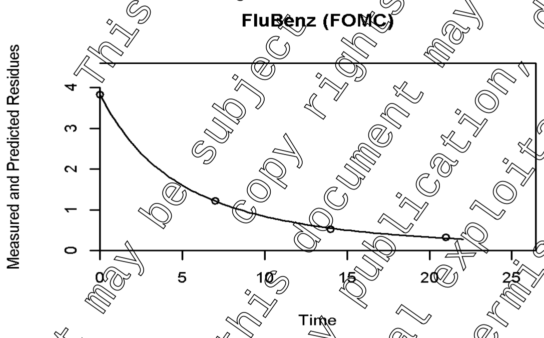
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



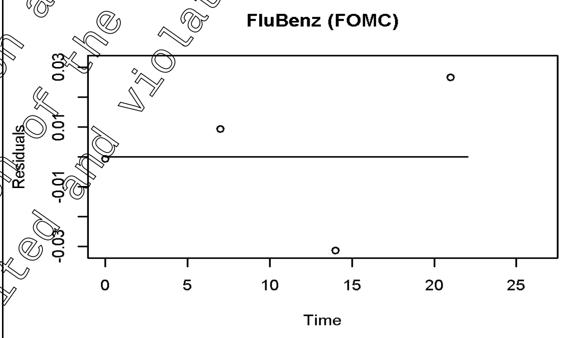
SFO



SFO



FOMC



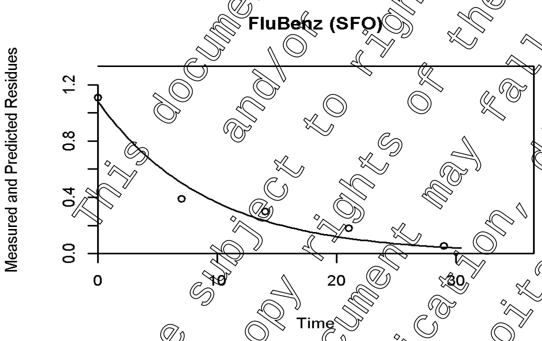
FOMC

R 2006 0344/4, Cailloux sur Fontaines, M-292082-01-1, FR, leek

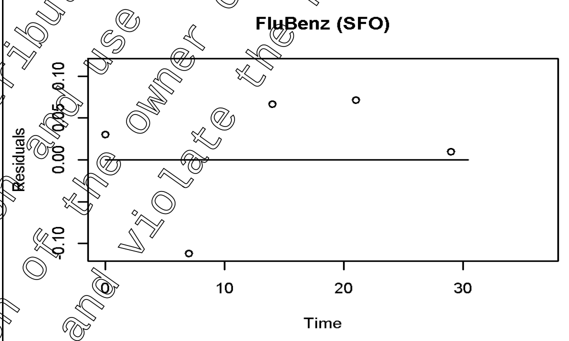
Table 8.9- 265: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for leek of trial R 2006 0344/4, Cailloux sur Fontaines, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	1.1	k: 0.10944	13.4	k: 0.004	k: 0.07	k: 0.14	**6.334**	21.04
FOMC	+	1.1	α: 1.35353 β: 6.67804	9.2	-	β: -7.96	β: 21.31	4.466	29.92
DFOP	+	1.1	k1: 4.465 k2: 0.06381 g: 0.4245	8.0	k1: <0.001 k2: 0.100	k1: 4.47 k2: 0.02	k1: 4.47 k2: 0.11	2.205	27.43
HS	+	1.1	k1: 0.164 k2: 0.064 tb: 5.501	8.0	k1: 0.062 k2: 0.100	k1: 0.10 k2: 0.02	k1: 0.23 k2: 0.11	4.220	27.43

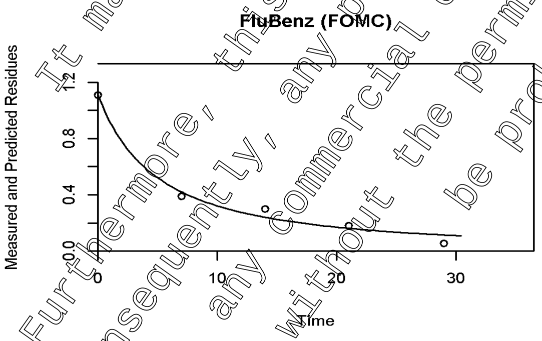
SFO fit is statistically and visually acceptable to moderate (χ^2err <15%, t-test <0.05). However, the degradation of the compound until the last data point (< 10 % of initial residue) is described visually acceptable. Consequently, **SFO** model is appropriate for modelling endpoints (FOCUS kinetics).



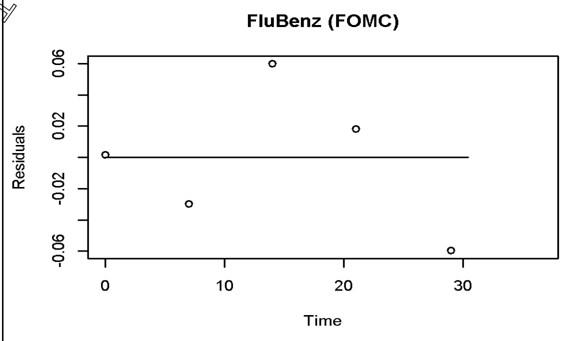
SFO



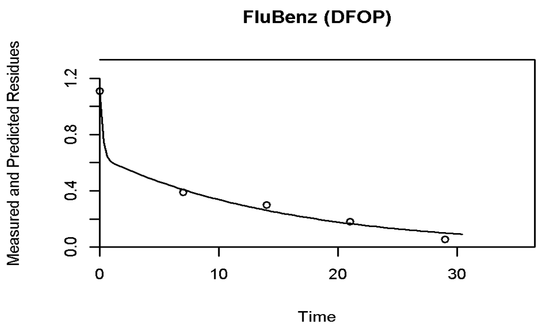
SFO



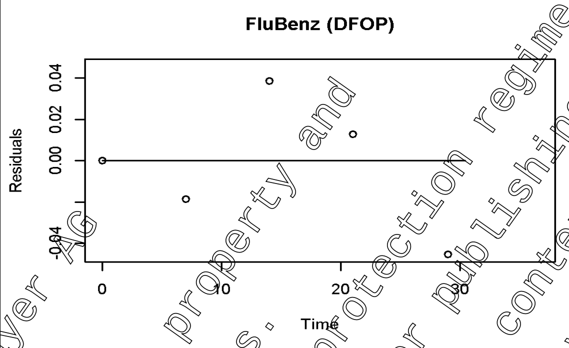
FOMC



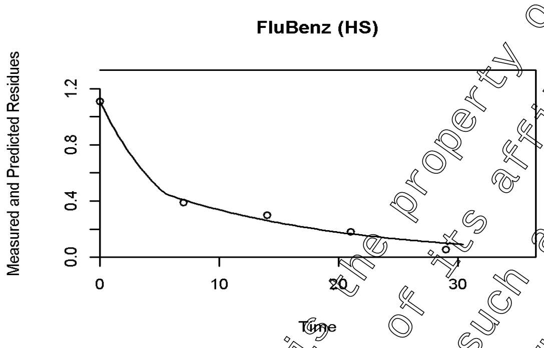
FOMC



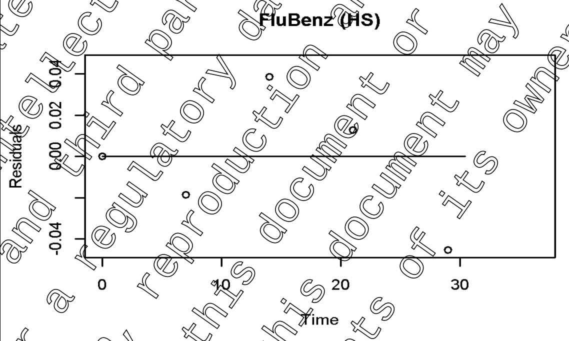
DFOP



DFOP



HS



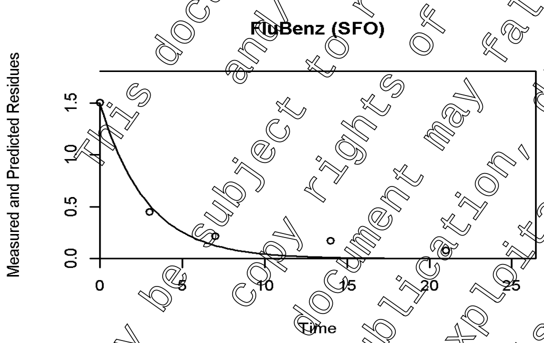
HS

R 2006 0348/7, Ouzilly, M-293182-01-1, FR, cabbage

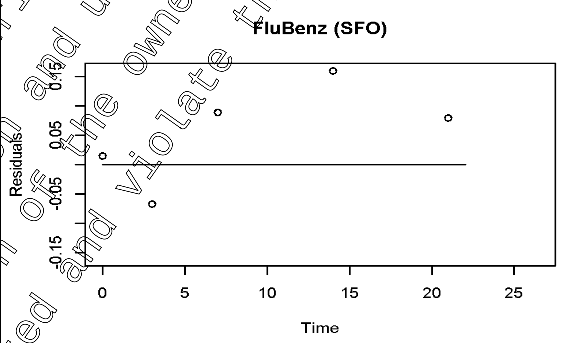
Table 8.9- 266: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for cabbage of trial R 2006 0348/7, Ouzilly, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	1.5	k: 0.35301	15.6	k: 0.008	k: 0.21	k: 0.49	1.964	6.52
FOMC	+	1.5	α: 0.90459 β: 1.0505	3.8	-	β: 0.15	β: 1.96	1.210	12.34
DFOP	+	1.5	k1: 0.623598 k2: 0.05521 g: 0.7930	3.6	k1: 0.070 k2: 0.157	k1: 0.35 k2: -0.00316	k1: 0.90 k2: 0.114	1.509	13.22
HS	+	1.5	k1: 0.40243 k2: 0.05911 tb: 4.362	3.1	k1: 0.018 k2: 0.111	k1: 0.36 k2: 0.02	k1: 0.45 k2: 0.10	1.722	13.62

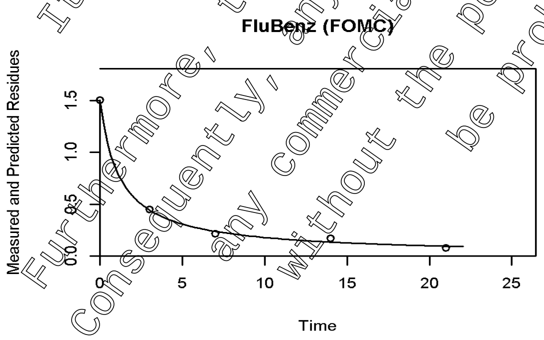
SFO fit is statistically still acceptable (χ^2err <15%, t-test <0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in $\chi 2$ error and visual assessment. However, the t-test of DFOP and HS show a low reliability especially of the slow degradation rates k2 (t-test > 0.05). Therefore, **FOMC** model is considered best appropriate for modelling endpoints (FOCUS kinetics) and as well as best visual fit.



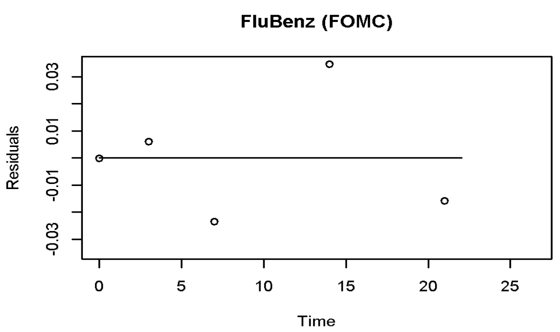
SFO



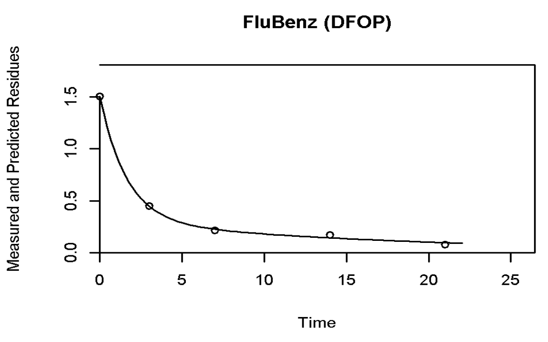
SFO



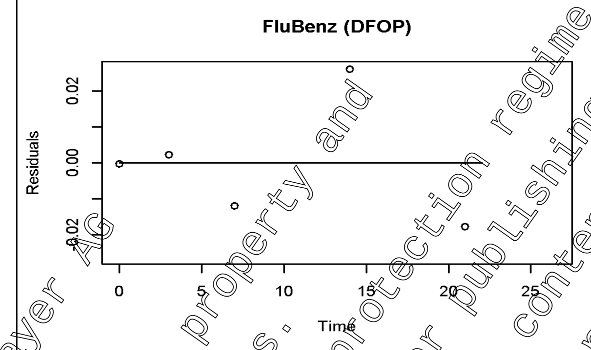
FOMC



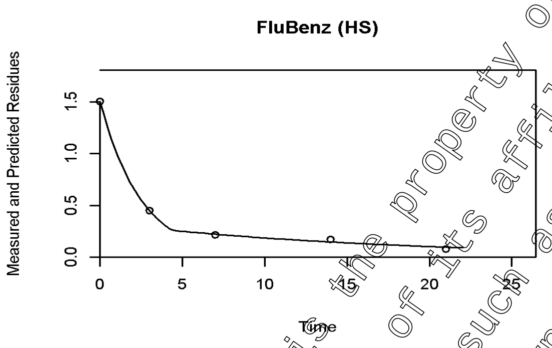
FOMC



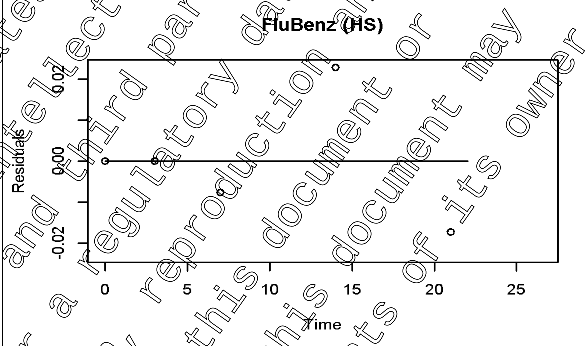
DFOP



DFOP



HS



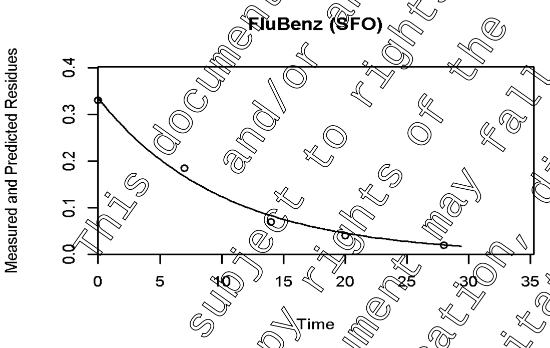
HS

R 2006 0469/6, Lebrija, M-292082-01-1, ES, leek

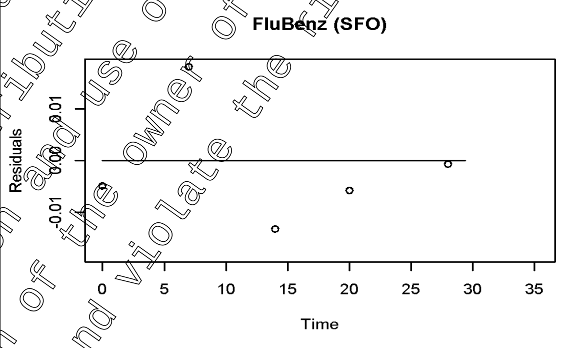
Table 8.9- 267: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for leek of trial R 2006 0469/6, Lebrija, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	0.3	k: 0.099	6.6	k: <0.001	k: 0.08	k: 0.12	**6.969**	23.15
FOMC	+	0.3	α: 13170 β: 132500	7.5	-	β: 132500	β: 132500	6.969	23.15
DFOP	+	0.3	k1: 0.099 k2: 0.033 g: 1.00	9.4	k1: 0.143 k2: <0.001	k1: 0.01 k2: 0.03	k1: 0.19 k2: 0.03	6.969	23.15
HS	+	0.3	k1: 31.880 k2: 0.099 tb: 0.0	9.4	k1: 0.5 k2: 0.089	k1: -inf k2: 0.04	k1: +inf k2: 0.16	6.969	23.15

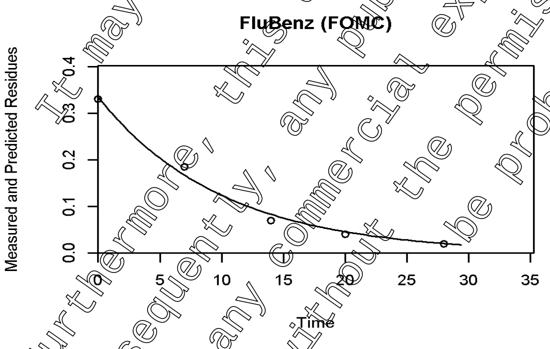
SFO fit is statistically and visually good (χ^2 err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



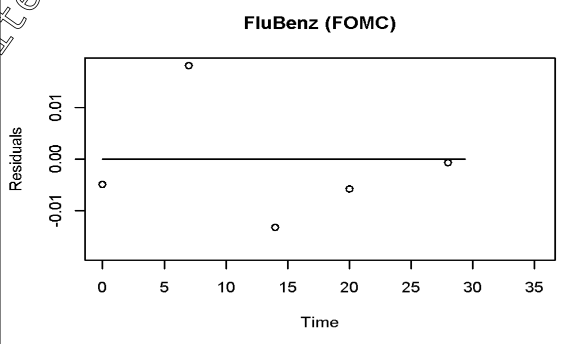
SFO



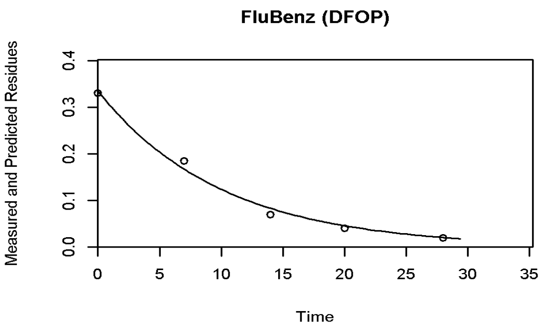
SFO



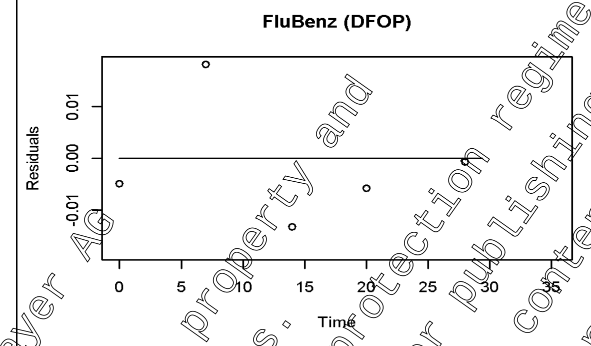
FOMC



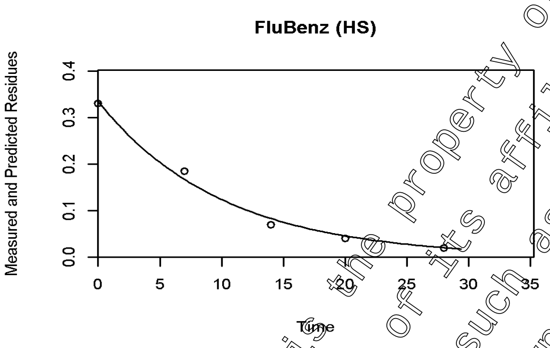
FOMC



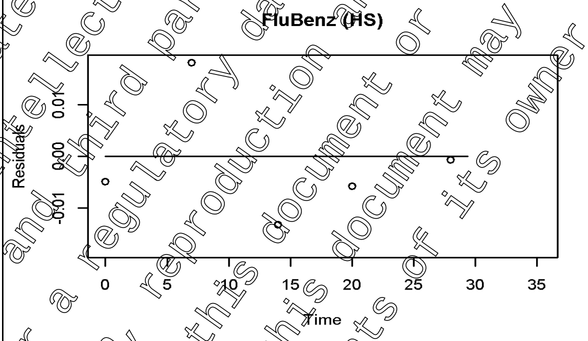
DFOP



DFOP



HS



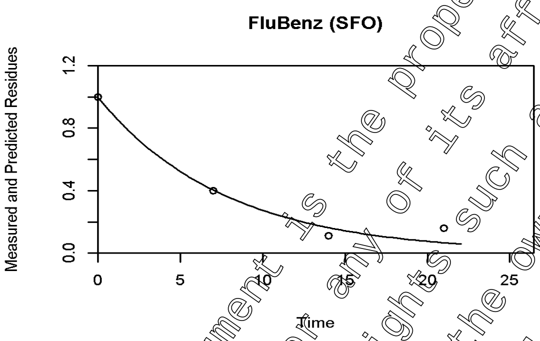
HS

R 2006 2006 0504/8, Burscheid, M-292996-01-1, DE, onion

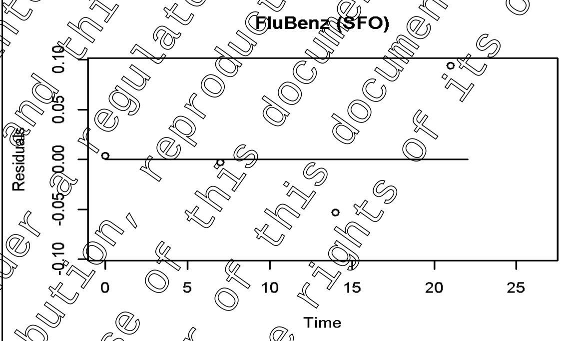
Table 8.9- 268: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for onion of trial R 2006 0504/8, Burscheid, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	1.0	k: 0.12924	10.6	k: 0.013	k: 0.09	k: 0.17	**5.363**	17.82
FOMC	+	1.0	α: 2.74795 β: 16.29621	11.7	-	β: -73.65	β: 106.24	4.675	21.37

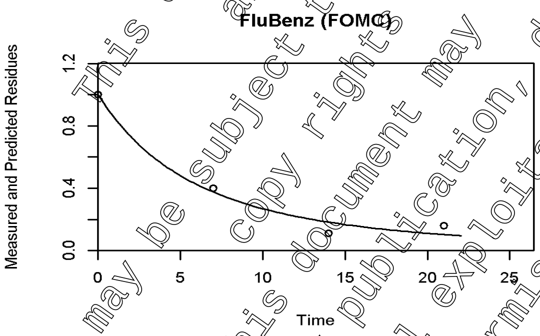
SFO fit is statistically and visually acceptable (χ^2 err <15%, t-test <0.05), and also the best visual fit (incl. all biphasic fits). No statistical improvement could be reached using biphasic models. Consequently, SFO model is appropriate for modelling purpose (FOCUS kinetics).



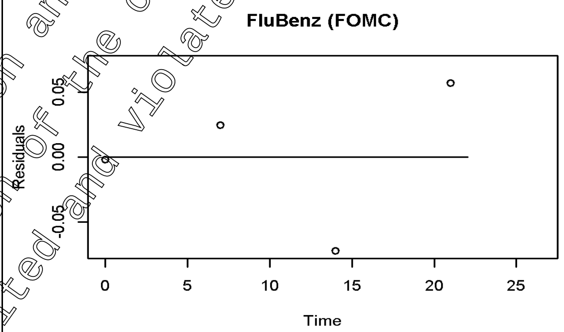
SFO



SFO



FOMC



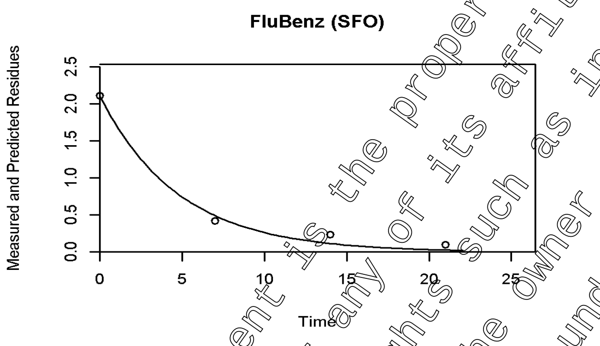
FOMC

R 2006 0505/6, Lusia, M-292098-01-1, IT, onion

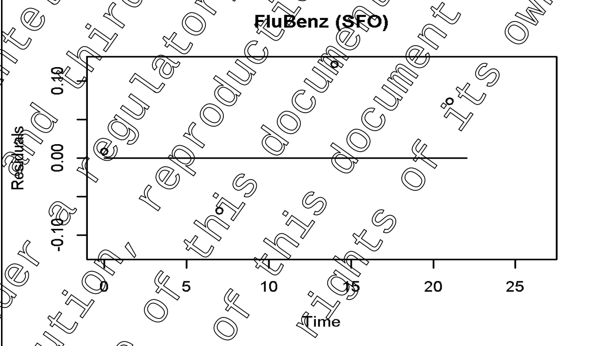
Table 8.9- 269: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for onion of trial R 2006 0505/6, Lusia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	2.1	k: 0.20847	9.0	k: 0.010	k: 0.15	k: 0.27	**3.325**	11.04
FOMC	+	2.1	α: 1.4245 β: 3.38349	2.9	-	β: -1.11	β: 7.88	2.121	13.65

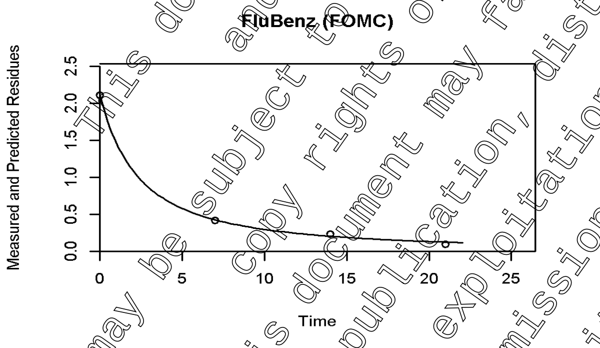
SFO fit is statistically and visually good to acceptable (χ^2 err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



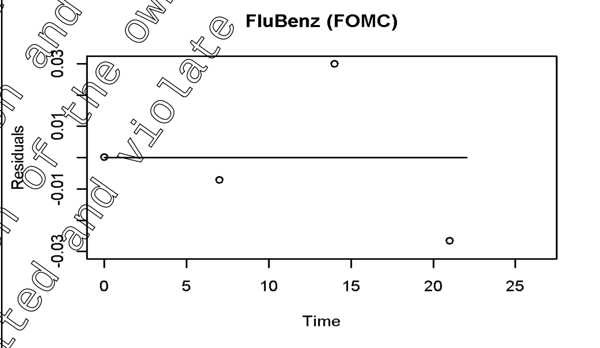
SFO



SFO



FOMC



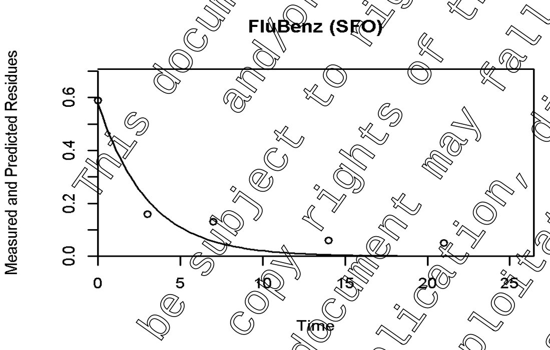
FOMC

R 2006 2006 0544/7, Andria, M-293182-01-1, IT, cabbage

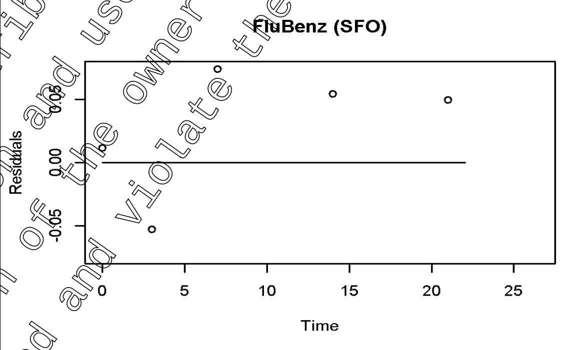
Table 8.9- 270: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for cabbage of trial R 2006 0544/7, Andria, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	0.6	k: 0.33318	21.2	k: 0.020	k: 0.15	k: 0.52	2.080	6.91
FOMC	+	0.6	α: 0.59614 β: 0.41743	5.9	-	β: -0.31	β: 1.15	0.918	19.45
DFOP	+	0.6	k1: 9.99 k2: 0.07403 g: 0.6551	4.3	k1: <0.001 k2: 0.071	k1: 9.99 k2: 0.04	k1: 9.99 k2: 0.11	0.142	16.73
HS	+	0.6	k1: 0.433816 k2: 0.07403 tb: 2.958	4.3	k1: 0.024 k2: 0.071	k1: 0.37 k2: 0.04	k1: 0.50 k2: 0.11	1.598	16.73

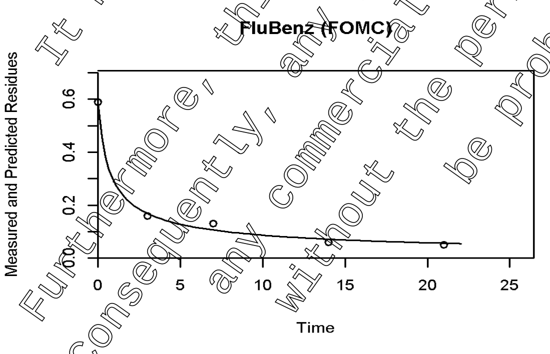
SFO fit is statistically (χ^2err >15%, t-test <0.05) and visually poor. FOMC, DFOP and HS fits were alternatively tested. All 3 models show a similar improvement in $\chi 2$ error and visual assessment. However, the t-test of DFOP and HS show a low reliability especially of the slow degradation rates k2 (t-test > 0.05). Therefore, **FOMC** model is considered best appropriate for modelling endpoints (FOCUS kinetics) and as well as best visual fit.



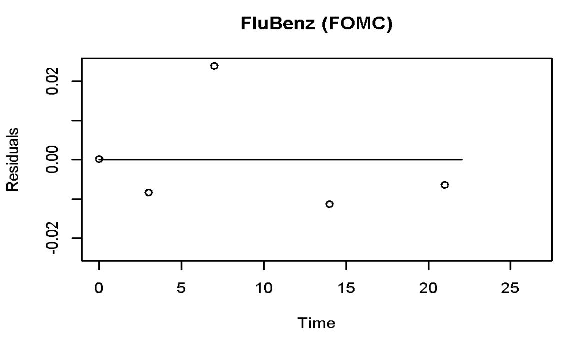
SFO



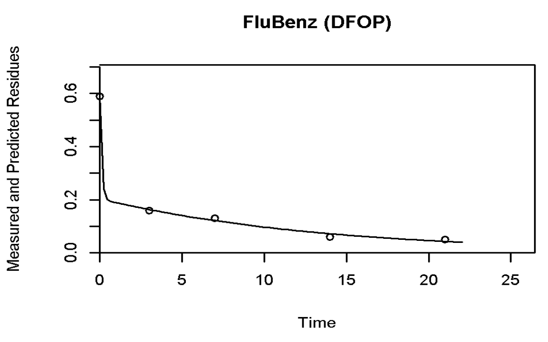
SFO



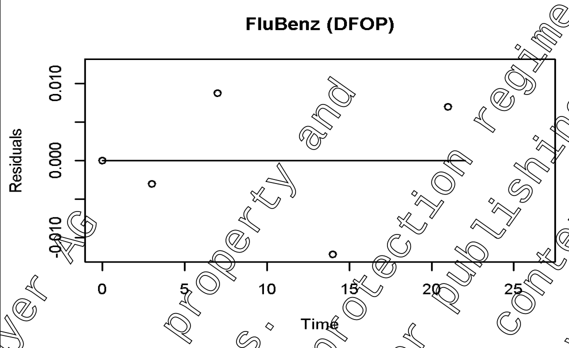
FOMC



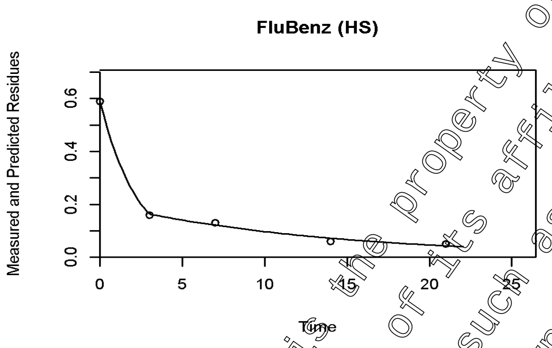
FOMC



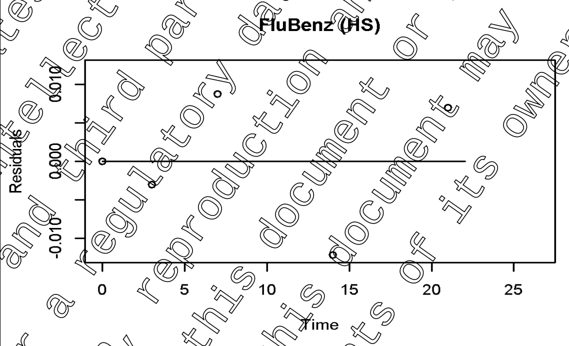
DFOP



DFOP



HS



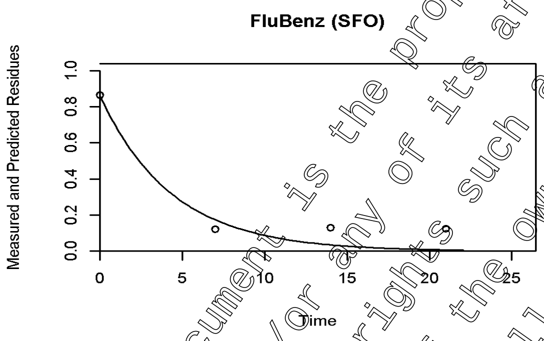
HS

R 2007 0042/3, Burscheid, M-302330-01-1, DE, onion

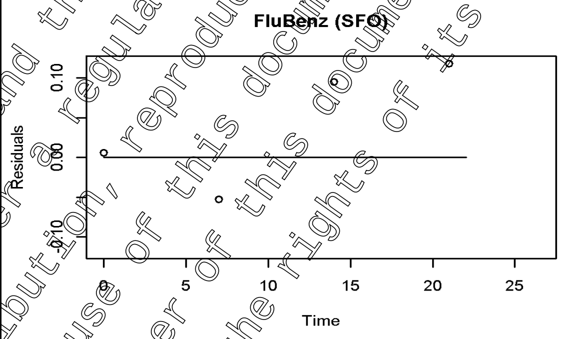
Table 8.9- 271: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for onion of trial R 2007 0042/3, Burscheid, DE

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	0.9	k: 0.22931	21.2	k: 0.061	k: 0.06	k: 0.40	3.023	10.04
FOMC	-	0.9	α: 91810 β: 400400	26.5		β: 400400	β: 400400	3.023	10.04

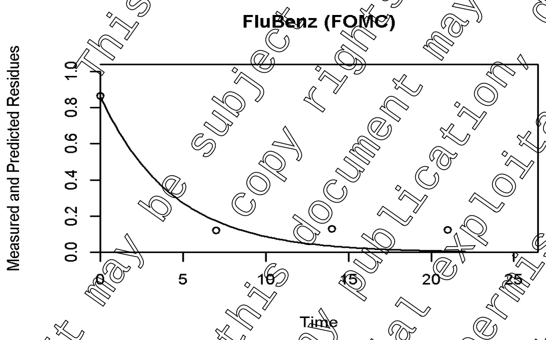
SFO fit is statistically (χ2err, t-test) not acceptable and visually poor. FOMC did not result in an improved fit or in statistically very unreliable parameters, also checking for different starting values. DFOP and HS fits cannot deliver statistical information and are not appropriate, due to a too low degree of freedom (3 fitted parameters based on 4 data points). Consequently, **no statistically reliable evaluation is possible.**



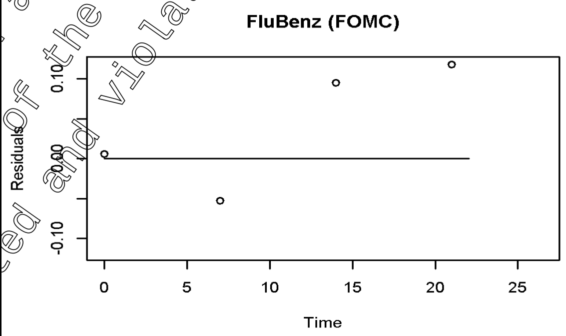
SFO



SFO



FOMC



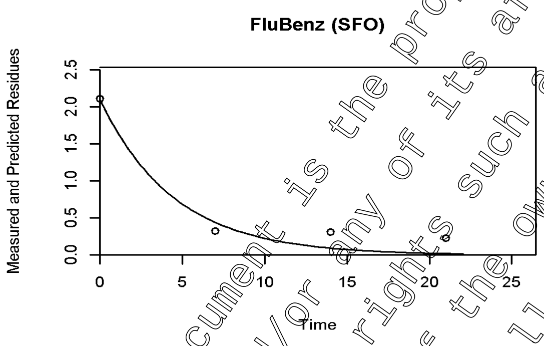
FOMC

R 2007 0043/1, Toulouse, M-302325-01-1, FR, onion

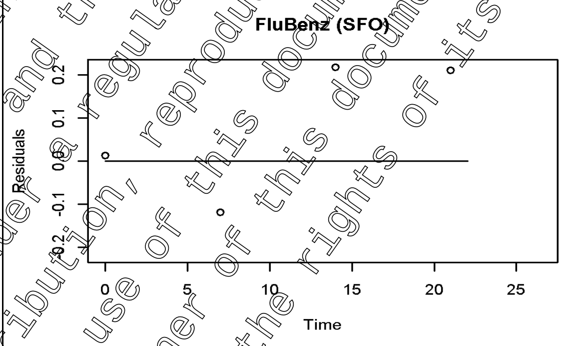
Table 8.9- 272: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for onion of trial R 2007 0043/1, Toulouse, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	-	2.1	k: 0.22335	17.9	k: 0.043	k: 0.09	k: 0.36	3.103	10.31
FOMC	+	2.1	α: 0.245024 β: 0.003598	2.7	-	β: -0.04	β: 0.04	0.057	43.38

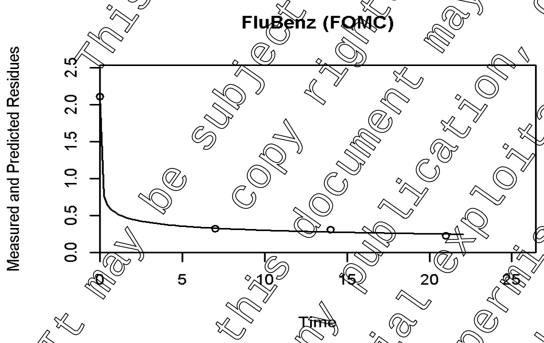
SFO fit is statistically still acceptable (χ^2err ~15%, t-test<0.05), but visually poor. FOMC, DFOP and HS fits were alternatively tested. DFOP and HS fits cannot deliver statistical information, as degrees of freedom are too low (3 fitted parameters based on 4 data points). FOMC fit is statistically (χ^2err, t-test) and visually good. Consequently, **FOMC** model is appropriate for modelling endpoints (FOCUS kinetics) and the best visual fit.



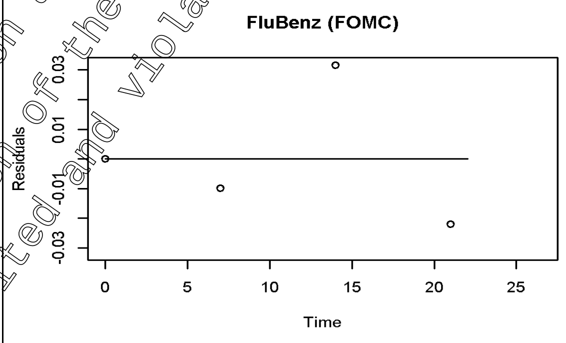
SFO



SFO



FOMC



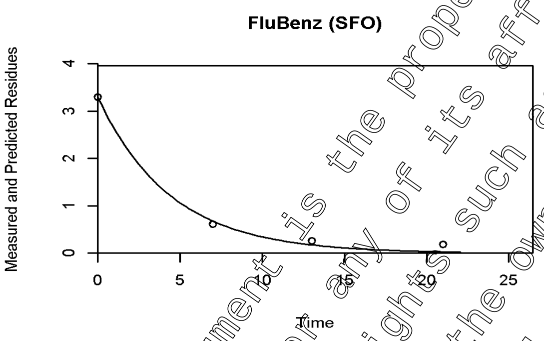
FOMC

R 2007 0567/0, Southfleet, Gravesend, M-302330-01-1, GB, onion

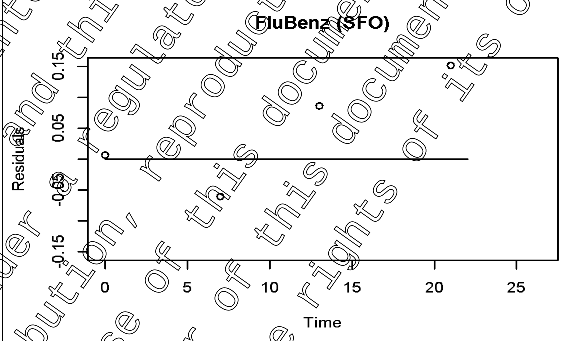
Table 8.9- 273: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for onion of trial R 2007 0567/0, Southfleet, Gravesend, GB

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	3.3	k: 0.2263	6.9	k: 0.006	k: 0.18	k: 0.28	**3.062**	10.17
FOMC	+	3.3	α: 1.68955 β: 4.05449	2.0	-	β: 0.02	β: 8.09	2.056	11.79

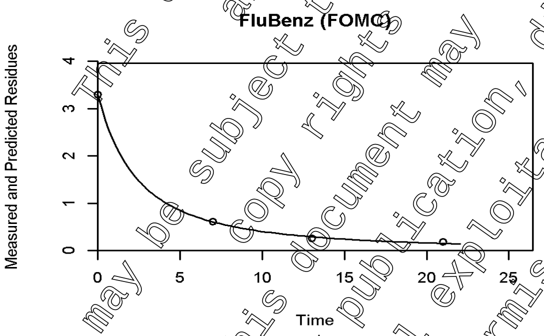
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 13), is described visually acceptable. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



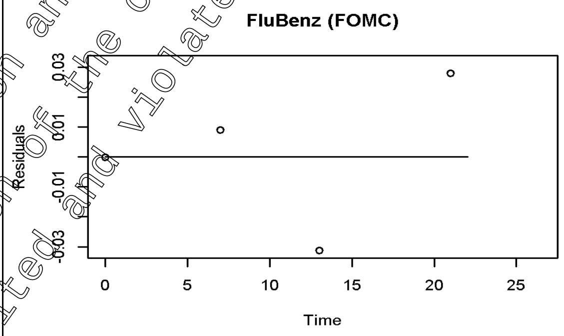
SFO



SFO



FOMC



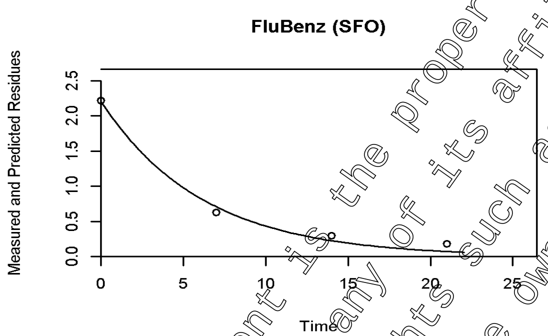
FOMC

R 2007 0568/9, Lusia, M-302325-01-1, IT, onion

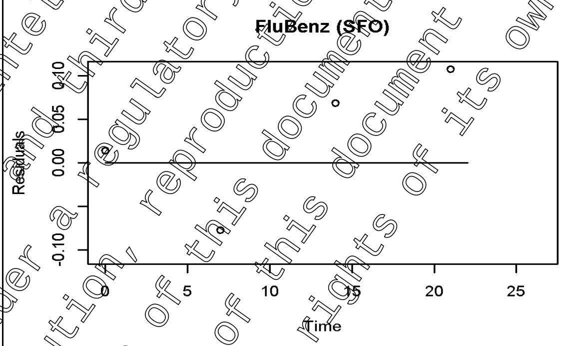
Table 8.9- 274: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for onion of trial R 2007 0568/9, Lusia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	+	2.2	k: 0.16256	7.3	k: 0.006	k: 0.13	k: 0.20	**4.264**	14.16
FOMC	+	2.2	α: 1.847811 β: 7.149256	0.3	-	β: 6.14	β: 8.16	3.254	17.71

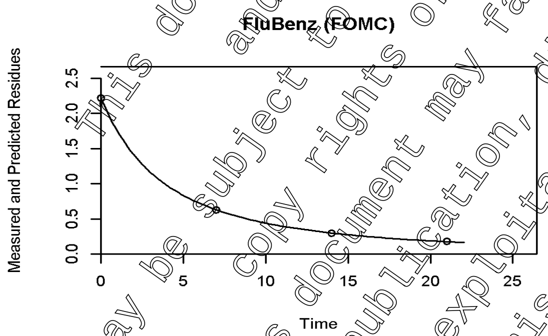
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



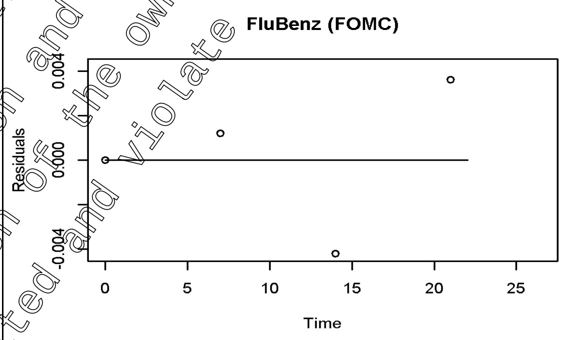
SFO



SFO



FOMC



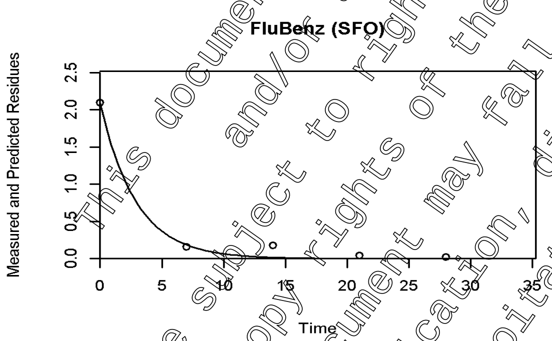
FOMC

R 2007 0572/7, Lusia, M-302775-01-1, IT, leek

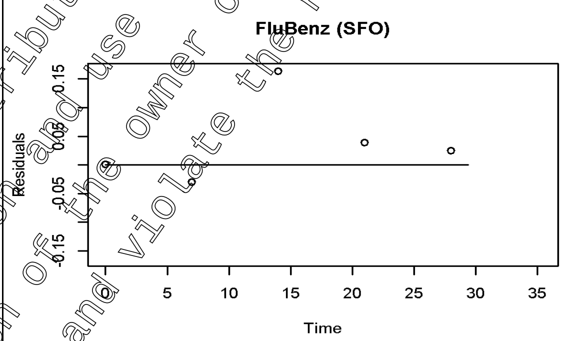
Table 8.9- 275: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for leek of trial R 2007 0572/7, Lusia, IT

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	2.1	k: 0.347	12.4	k: 0.010	k: 0.20	k: 0.50	**1.997**	6.634
FOMC	+	2.1	α: 0.8208 β: 0.3583	7.7	-	β: -1.78	β: 2.50	0.475	5.566
DFOP	+	2.1	k1: 1033.0 k2: 0.065 g: 0.866	8.2	k1: <2e-16 k2: 0.239	k1: 1033.00 k2: -0.05	k1: 1033.30 k2: 0.18	0.001	4.513
HS	+	2.1	k1: 0.379 k2: 0.065 tb: 6.395	8.2	k1: 0.058 k2: 0.239	k1: 0.24 k2: -0.05	k1: 0.52 k2: 0.18	1.828	6.074

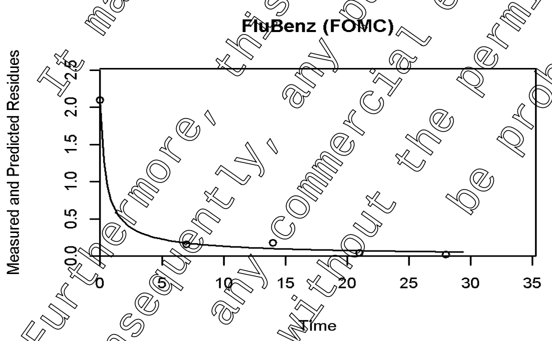
SFO fit is statistically and visually good to acceptable (χ^2 err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 7), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



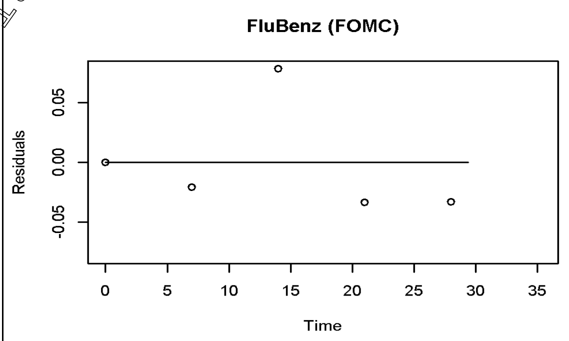
SFO



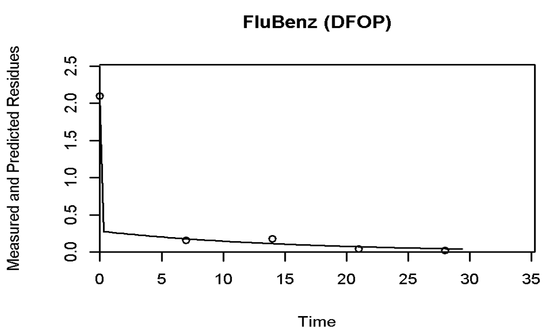
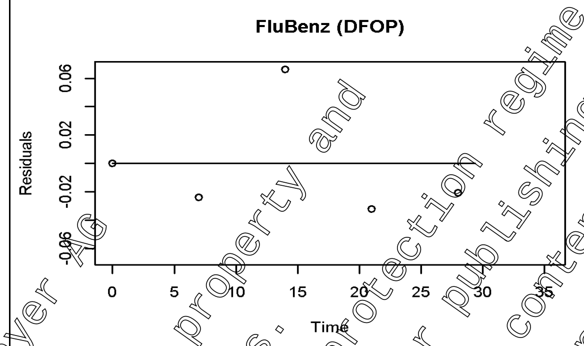
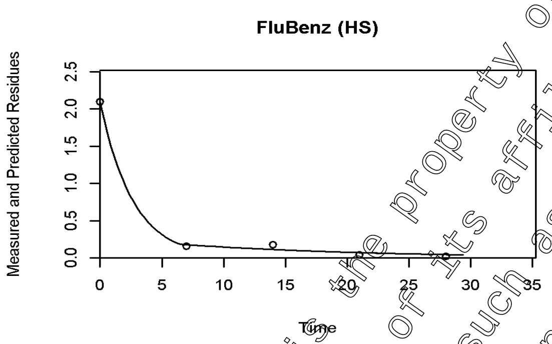
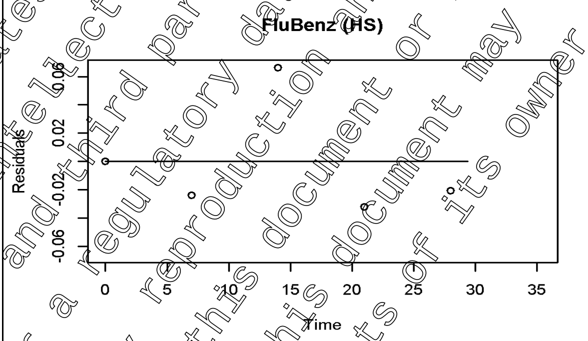
SFO



FOMC



FOMC

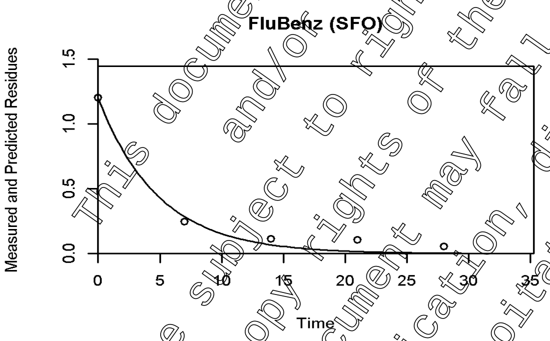
 DFOP	 DFOP
 HS	 HS

R 2007 0573/5, Bouafle, M-304276-01-1, FR, leek

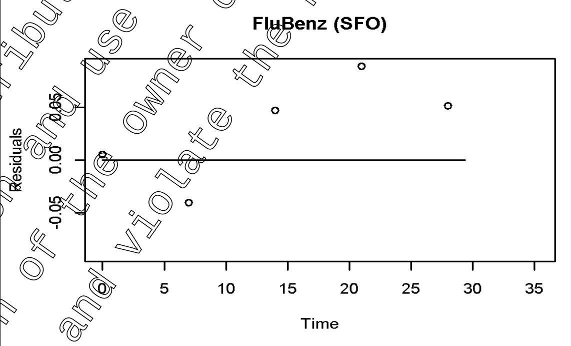
Table 8.9- 276: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for leek of trial R 2007 0573/5, Bouafle, FR

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	1.2	k: 0.20517	12.4	k: 0.004	k: 0.14	k: 0.27	**3.378**	11.22
FOMC	+	1.2	α: 1.13214 β: 2.24412	3.0	-	β: 0.25	β: 4.24	1.895	14.91
DFOP	+	1.2	k1: 0.344 k2: 0.041 g: 0.830	3.3	k1: 0.099 k2: 0.222	k1: 0.13 k2: -0.03	k1: 0.56 k2: 0.11	2.536	14.44
HS	+	1.2	k1: 0.22757 k2: 0.043477 tb: 9.4186	3.0	k1: 0.017 k2: 0.157	k1: 0.20 k2: -0.0023	k1: 0.25 k2: 0.089	3.046	14.07

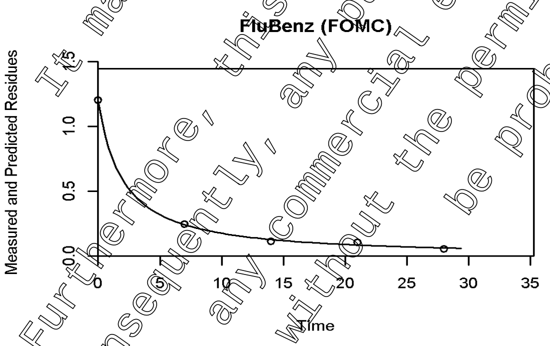
SFO fit is statistically and visually good to acceptable (χ^2err <15%, t-test <0.05). The degradation of the compound until 10 % of the residues have been reached (before day 14), is described visually good. Consequently, **SFO** model is appropriate for modelling purpose (FOCUS kinetics).



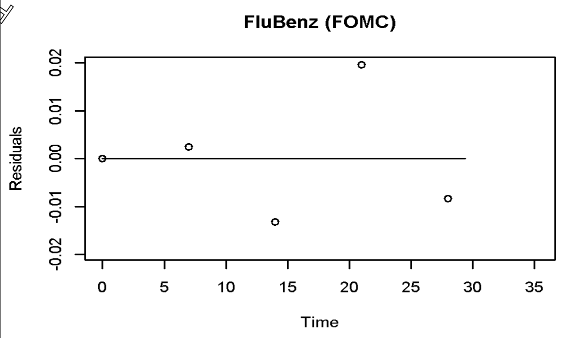
SFO



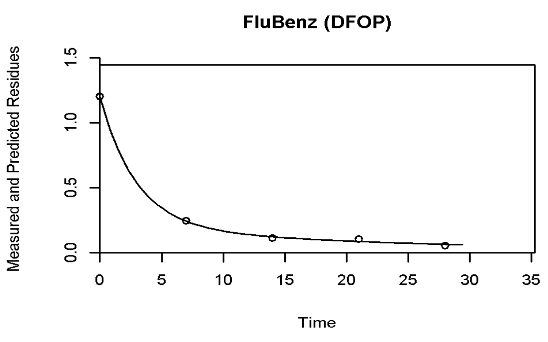
SFO



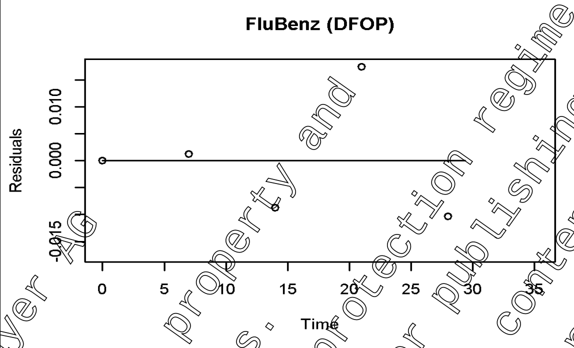
FOMC



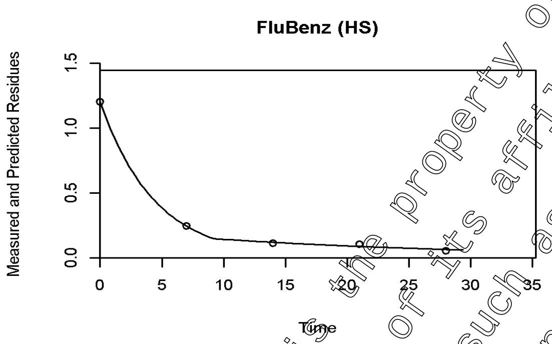
FOMC



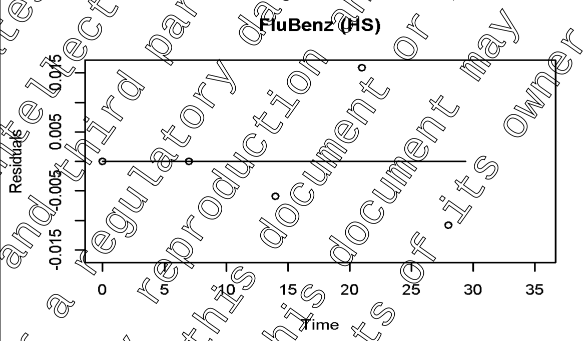
DFOP



DFOP



HS



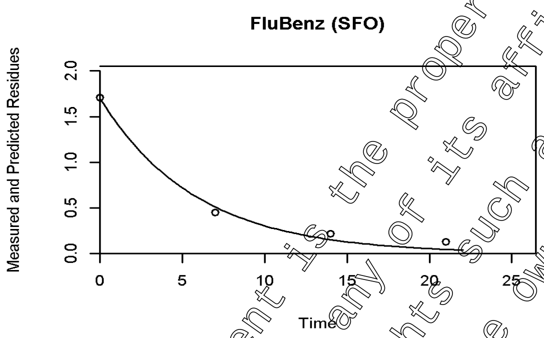
HS

R 2007 0600/6, Brenes, M-302044-01-1, ES, cabbage

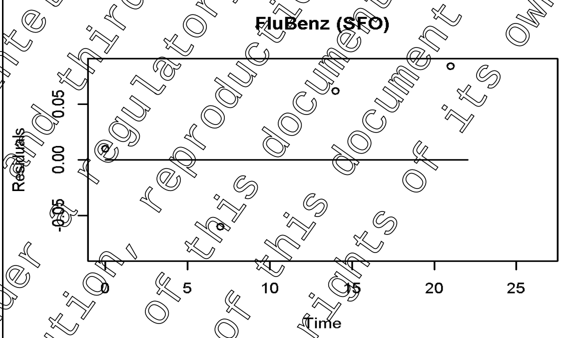
Table 8.9- 277: Kinetic models and goodness-of-fit statistics of fluopyram+benzamide fits for cabbage of trial R 2007 0600/6, Brenes, ES

Kinetic model	Visual assess-ment	M_0	Kinetic parameters	X^2 error (%)	Prob > t	Lower 95% CI	Upper 95% CI	DT_{50} actual (d)	DT_{90} actual (d)
SFO	o	1.7	k: 0.17201	7.9	k: 0.007	k: 0.13	k: 0.21	**4.030**	13.39
FOMC	+	1.7	α: 1.6841631 β: 5.7861029	0.1	-	β: 5.62	β: 5.95	2.946	16.92

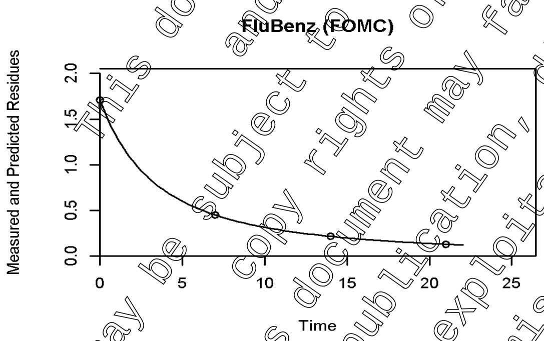
SFO fit is statistically and visually good (χ^2err <15%, t-test <0.05), and usable according modelling purpose (FOCUS kinetics).



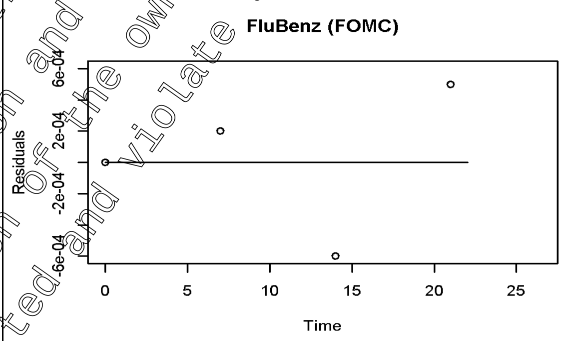
SFO



SFO



FOMC



FOMC

III. CONCLUSION

The following units are used in the following tables:

k 1/d
β, tb d
α, g none

Table 8.9- 278: Foliar DT_{50} parameters of fluopyram in green material of leek, onion and cabbage, after application of Luna Experience (SC 400 FLU+TBZ), based on time points after last application

Fluopyram	Foliar dissipation, crop residue decline studies, in dicotyledons, leek, onion, cabbage, Luna Experience								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**$DT_{90\ actual}$ (d)**	**$DT_{50\ fast}$ (d)**	**$DT_{50\ slow}$ (d)**
11-2029-01, Soings en Sologne, FR, M-442996-01-1	N	**SFO**	k: 0.30416	4.3	k: 0.004	**2.279**	7.57		
11-2029-02, Werl-Westönnen, DE, M-442996-01-1	N	**SFO**	k: 0.26084	8.9	k: 0.012	**2.657**	8.828		
11-2029-03, Langenfeld, DE, M-442996-01-1	N	**SFO**	k: 0.264583	3.2	k: 0.002	**2.620**	8.703		
11-2029-04, Villers-Perwin, BE, M-442996-01-1	N	**SFO**	k: 0.27257	6.5	k: 0.007	**2.543**	8.448		
R 2006 0337/1, Tilloloy, FR, M-292996-01-1	N	**FOMC**	α: 0.9662 β: 2.424	0.04	-	**7.184**	23.85		
R 2006 0339/8, Saint Bonnet de Mure, FR, M-292098-01-1	S	**SFO**	k: 0.1558	4.3	k: 0.002	**4.448**	14.77		
R 2006 0343/6, Faverolles, FR, M-292101-02-1	N	**SFO**	k: 0.0837	2.2	k: <0.001	**8.282**	27.51		
R 2006 0344/4, Cailloux sur Fontaines, FR, M-292082-01-1	S	**SFO**	k: 0.11534	13.7	k: 0.004	**6.010**	19.96		
R 2006 0347/9, Bouafle, FR, M-292103-01-1	N	**HS**	k1: 0.416478 k2: 0.04374 tb: 4.336	0.21	k1: 0.001 k2: 0.009	**4.729**	15.7	1.664	15.85
R 2006 0348/7, Ouzilly, FR, M-293182-01-1	S	**FOMC**	α: 0.88254 β: 0.97407	4.0	-	**3.693**	12.26		
R 2006 0465/3, Langenfeld-Reusrath, DE, M-292101-02-1	N	**SFO**	k: 0.29549	7.3	k: 0.001	**2.346**	7.792		
R 2006 0466/1, Chatteris, GB, M-292101-02-1	N	**SFO**	k: 0.11878	9.8	k: 0.001	**5.836**	19.39		

Fluopyram	Foliar dissipation, crop residue decline studies, in dicotyledons, leek, onion, cabbage, Luna Experience								
Trial	EU zone	Kinetic model	Kinetic parameters	X^2 err (%)	Prob > t	DT_{50} pseudo (d)	$DT_{90\ actual}$ (d)	$DT_{50\ fast}$ (d)	$DT_{50\ slow}$ (d)
R 2006 0468/8, Bornheim - Sechtem, DE, M-292101-02-1	N	**SFO**	k: 0.0771	10.5	k: 0.003	**8.990**	29.86		
R 2006 0469/6, Lebrija, ES, M-292082-01-1	S	**SFO**	k: 0.098258	6.2	k: <0.001	**7.054**	23.43		
R 2006 0504/8, Burscheid, DE, M-292996-01-1	N	**SFO**	k: 0.14116	4.9	k: 0.003	**4.910**	16.31		
R 2006 0505/6, Lusia, IT, M-292098-01-1	S	**SFO**	k: 0.21118	9.1	k: 0.010	**3.282**	10.9		
R 2006 0543/9, Little Shelford, GB, M-292103-01-1	N	**SFO**	k: 0.11993	12.0	k: 0.006	**5.780**	19.2		
R 2006 0544/7, Andria, IT, M-293182-01-1	S	**FOMC**	α: 0.78114 β: 0.57881	7.03	-	**3.148**	10.45		
R 2007 0043/1, Toulouse, FR, M-302325-01-1	S	**FOMC**	α: 0.35688 β: 0.02404	2.2	-	**4.584**	15.22		
R 2007 0056/3, Schauernheim, DE, M-304288-01-1	N	**DFOP**	k1: 0.357605 k2: 0.043575 g: 0.8274	0.82	k1: 0.027 k2: 0.063	**4.184**	13.89	1.938	15.91
R 2007 0057/1, Castelsarrasin, FR, M-302775-01-1	S	**FOMC**	α: 0.36403 β: 0.03122	1.4	-	**5.241**	17.4		
R 2007 0078/4, Broad Fen Drove, Wissington, GB, M-302101-01-1	N	**SFO**	k: 0.336209	0.5	k: <0.001	**2.062**	6.849		
R 2007 0079/2, Ouzilly, FR, M-302044-01-1	S	**FOMC**	α: 0.7792 β: 0.7446	1.39	-	**4.084**	13.56		
R 2007 0249/3, Schauernheim, DE, M-304276-01-1	N	**HS**	k1: 0.268962 k2: 0.047591 tb: 7.98	0.55	K1: 0.003 K2: 0.032	**3.392**	11.26	2.577	14.56
R 2007 0250/7, Castelsarrasin, FR, M-302780-01-1	S	**HS**	k1: 0.1429889 k2: 0.0432013 tb: 6.64	3.61	K1: 0.026 K2: 0.058	**11.43**	37.96	4.848	16.04

Fluopyram	Foliar dissipation, crop residue decline studies, in dicotyledons, leek, onion, cabbage, Luna Experience								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**$DT_{90\ actual}$ (d)**	**$DT_{50\ fast}$ (d)**	**$DT_{50\ slow}$ (d)**
R 2007 0567/0, Southfleet, Gravesend, GB, M-302330-01-1	N	**SFO**	k: 0.23164	4.5	k: 0.003	**2.992**	9.94		
R 2007 0568/9, Lusia, IT, M-302325-01-1	S	**SFO**	k: 0.1649	7.7	k: 0.007	**4.203**	13.96		
R 2007 0569/7, Bouafle, FR, M-304288-01-1	N	**FOMC**	α: 0.62825 β: 0.30972	2.6		**3.551**	11.79		
R 2007 0570/0, Zwaagdijk, NL, M-304288-01-1	N	**FOMC**	α: 1.1707 β: 1.9838	3.51	-	**3.675**	12.2		
R 2007 0571/9, Langenfeld-Reusrath, DE, M-304288-01-1	N	**SFO**	k: 0.271	1.8	k: <0.001	**2.557**	8.493		
R 2007 0572/7, Lusia, IT, M-302775-01-1	S	**SFO**	k: 0.35501	11.0	k: 0.008	**1.952**	6.486		
R 2007 0573/5, Bouafle, FR, M-304276-01-1	N	**SFO**	k: 0.20871	12.0	k: 0.003	**3.321**	11.03		
R 2007 0574/3, Zwaagdijk, NL, M-304276-01-1	N	**SFO**	k: 0.237708	9.0	k: 0.002	**2.916**	9.687		
R 2007 0599/9, Meckenbeuren, DE, M-302101-01-1	N	**SFO**	k: 0.35027	8.5	k: 0.019	**1.979**	6.574		
R 2007 0600/6, Brenes, ES, M-302044-01-1	S	**SFO**	k: 0.17413	8.1	k: 0.008	**3.981**	13.22		
Geomean (n=35) M						**3.921M**			

DT_{50} pseudo = DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT_{90} actual time for first 90 % of residues to dissipate
DT_{50} fast = ln(2)/k1
DT_{50} slow = ln(2)/k2 (DFOP, HS)
M geomean of DT_{50} pseudo of fits for modelling purpose

Table 8.9- 279: Foliar DT_{50} parameters of fluopyram + FLU-benzamide in green material of leek, onion and cabbage, after application of Luna Experience (SC 400 FLU+TBZ), based on time points after last application

Fluopyram + FLU-benzamide	Foliar dissipation, crop residue decline studies, in dicotyledons, leek, onion, cabbage, Luna Experience								
Trial	EU zone	Kinetic model	Kinetic parameters	X^2 err (%)	Prob > t	DT_{50} pseudo (d)	$DT_{90\ actual}$ (d)	$DT_{50\ fast}$ (d)	$DT_{50\ slow}$ (d)
R 2006 0339/8, Saint Bonnet de Mure, FR, M-292098-01-1	S	**SFO**	k: 0.151	5.8	k: 0.004	**4.590**	15.25		
R 2006 0344/4, Cailloux sur Fontaines, FR, M-292082-01-1	S	**SFO**	k: 0.10944	13.4	k: 0.004	**6.334**	21.04		
R 2006 0348/7, Ouzilly, FR, M-293182-01-1	S	**FOMC**	α: 0.90459 β: 1.0505	3.8	-	**3.717**	12.34		
R 2006 0469/6, Lebrija, ES, M-292082-01-1	S	**SFO**	k: 0.099	6.6	k: <0.001	**6.969**	23.15		
R 2006 0504/8, Burscheid, DE, M-292996-01-1	N	**SFO**	k: 0.12924	10.6	k: 0.013	**5.363**	17.82		
R 2006 0505/6, Lusia, IT, M-292098-01-1	S	**SFO**	k: 0.20847	9.0	k: 0.010	**3.325**	11.04		
R 2006 0544/7, Andria, IT, M-293182-01-1	S	**FOMC**	α: 0.59614 β: 0.41743	5.9	-	**5.858**	19.45		
R 2007 0043/1, Toulouse, FR, M-302325-01-1	S	**FOMC**	α: 0.245024 β: 0.003598	2.7	-	**13.066**	43.38		
R 2007 0567/0, Southfleet, Gravesend, GB, M-302330-01-1	N	**SFO**	k: 0.2263	6.9	k: 0.006	**3.062**	10.17		
R 2007 0568/9, Lusia, IT, M-302325-01-1	S	**SFO**	k: 0.16256	7.3	k: 0.006	**4.264**	14.16		
R 2007 0572/7, Lusia, IT, M-302775-01-1	S	**SFO**	k: 0.347	12.4	k: 0.010	**1.997**	6.634		
R 2007 0573/5, Bouafle, FR, M-304276-01-1	N	**SFO**	k: 0.205	12.4	k: 0.004	**3.378**	11.22		
R 2007 0600/6, Brenes, ES, M-302044-01-1	S	**SFO**	k: 0.17201	7.9	k: 0.007	**4.030**	13.39		

Fluopyram + FLU-benzamide	**Foliar dissipation, crop residue decline studies, in dicotyledons, leek, onion, cabbage, Luna Experience**								
Trial	**EU zone**	**Kinetic model**	**Kinetic parameters**	**X^2 err (%)**	**Prob > t**	**DT_{50} pseudo (d)**	**$DT_{90\ actual}$ (d)**	**$DT_{50\ fast}$ (d)**	**$DT_{50\ slow}$ (d)**
Geomean, trials with FLU-benz > LOD (n=13) M						4.556 M			
Geomean, incl. all trials (n=35) A						**4.144** A			

DT_{50} pseudo	= DT_{90} actual / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT_{90} actual	time for first 90 % of residues to dissipate
DT_{50} fast	= ln(2)/k1
DT_{50} slow	= ln(2)/k2 (DFOP, HS)
M	geomean DT_{50} pseudo of fits for modelling purpose, for trials with FLU-benzamide > LOD.
A	geomean DT_{50} pseudo of fits for modelling purpose: for trials with FLU-benzamide > LOD and remaining trials of FLU only from table above, where FLU-benzamide was < LOD.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment.

Pseudo-DT_{50} values for Fluopyram + Fluopyram-benzamide in dicotyledons, leek, onion, cabbage resulted in 4.144 days.

Studies relevant to address residues in/on plant material

Grass / Cereals

In the following section the residue study summaries are presented that have been analysed in the kinetic report by M-617837-01-1.

Data Point:	KCA 8.9/16
Report Author:	[redacted]
Report Year:	2013
Report Title:	Determination of the residues of AE C656948 and prothioconazole in/on barley, spring after spray application of AE C656948 & JAU 6476 SE 250 in Germany, Belgium and the Netherlands
Report No:	13-2950
Document No:	M-471216-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, EC Guidance working document 7029/VI/95 rev.5 (1997-07-22), OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial, US EPA OCSPP Guideline No. 860.1500
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in Northern Europe (2x Germany, Belgium and Netherlands) on spring barley, during the 2013 season. One application with Fluopyram & JAU 6476 SE 250 (a suspo-emulsion formulation containing 125 g/L fluopyram (AE C656948) and 125 g/L prothioconazole (JAU 6476)) was conducted. Only the parameters and results relevant to fluopyram have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram & JAU 6476 SE 250 on spring barley green material declined markedly during the sampling period.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram & JAU 6476 SE 250 (125 +125 g/L)

   Batch no.: LOT290586

   Active Ingredient: Fluopyram and prothioconazole

Storage:	Not stated in the report
Expiry date:	2014-02-20

2.	Test commodity:	Barley / spring barley
	Crop part:	Green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 13-2950 was to determine the magnitude of the relevant residues of fluopyram in/on spring barley (green material) after one spray application with Fluopyram & JAU 6476 SE 250 (125 +125 g/L)", a suspo-emulsion (SE) formulation containing 125 g/L fluopyram. This summary focuses only on the residues of fluopyram.

Field phase

The study included four supervised residue trials conducted in northern Europe (2 x Germany, Belgium and Netherlands) during the 2013 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 280: Description of the trial locations and cropping information on treated plots

Trial number	**13-2950-01**	**13-2950-02**	**13-2950-03**	**13-2950-04**
Trial location	51399 Burscheid	49377 Langförden	6221 Saint-Amand	1775 PN Middenmeer
Country	Germany	Germany	Belgium	Netherlands
Area of application	Field	Field	Field	Field
Plot size [m^2]	108	50	36	60
Type of soil	Sandy Loam	Loamy sand	Silt loam	Clay
pH-value of soil (in water)	-	-	7.3	7.5
pH-value of soil (in $CaCl_2$)	6.6	5.8	-	-
Content of organic C [%]	1.05	1.16	2.21	1.28
Test system	Barley, spring	Barley, spring	Barley, spring	Barley, spring
Variety	Conchita	Grace	Quench Untreated seeds of spring barley	Tipple
Date of sowing	2013-03-28	2013-04-09	2013-03-06	2013-04-07
Date of commercial harvest	-	-	2013-08-10 to 2013-08-21	2013-08-10 to 2013-08-20

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range.

Application was performed at an BBCH between 30-31 with an application rate of 0.125 g a.s./ha and a water rate of 300 L/ha.

Table 8.9- 281: Overview on application with Fluopyram & JAU 6476 SE 250 on spring barley

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (kg/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
13-2950-01 Germany	1	T	Fluopyram & JAU 6476 SE 250	SPI	30	-	1.0	300	JAU 6476	0.125
									Fluopyram	0.125
13-2950-02 Germany	1	T	Fluopyram & JAU 6476 SE 250	SPI	31	-	1.0	300	JAU 6476	0.125
									Fluopyram	0.125
13-2950-03 Belgium	1	T	Fluopyram & JAU 6476 SE 250	SPI	30	-	1.0	300	JAU 6476	0.125
									Fluopyram	0.125
13-2950-04 Netherlands	1	T	Fluopyram & JAU 6476 SE 250	SPI	30	-	1.0	300	JAU 6476	0.125
									Fluopyram	0.125

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of green material of spring barley. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 282: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
13-2950-01 13-2950-02 13-2950-03 13-2950-04	Spring barley	Green material	C	-0
			T	0
				1
				2
				3
				5
				7
				10

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram were, analysed within the residue trials samples according to the following method:

Table 8.9- 283: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram in barley green material)

Full details and acceptable validation data to support this method are presented within document MCA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 284: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Spring barley / green material	0.01	84; 91; 93; 99; 100; 101; 101	96	6.8	0.01
	0.10	106; 107; 108	107	0.9	
	0.80	98; 101	100	-	
	3.6	98; 98; 99	98	0.6	
	18	94; 96; 98; 102; 103	99	3.9	
		Overall recovery (n=20)	**99**	**5.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with Fluopyram, determined as Fluopyram and calculated as Fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 84 and 104 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries. For fluopyram, the residues levels in/on spring barley green material are summarised in the following table.

Table 8.9- 285: Residue summary of fluopyram in/on spring barley, green material

Trial No. Country	Sample material	BBCH	DALT	Residues [mg/kg] a.s. Fluopyram
13-2950-01 Germany	Green material	30	0	8.6
	Green material	30	1	6.8
	Green material	30	2	5.0
	Green material	30	3	2.3
	Green material	31	5	1.5
	Green material	31	7	0.53
	Green material	32	10	0.24
13-2950-02 Germany	Green material	31	0	4.5
	Green material	31	1	0.96
	Green material	31	2	0.83
	Green material	31	3	0.75
	Green material	32	5	0.61
	Green material	32	7	0.44
	Green material	32	10	0.25
13-2950-03 Belgium	Green material	30	0	7.3
	Green material	30	1	1.4
	Green material	31	2	1.2
	Green material	31	3	1.0
	Green material	31	5	0.54
	Green material	31	7	0.30
	Green material	31	10	0.20
13-2950-04 Netherlands	Green material	30	0	8.0
	Green material	30	1	6.3
	Green material	30	2	1.5
	Green material	30	3	1.4
	Green material	30	5	0.67
	Green material	30	7	0.41
	Green material	30	10	0.20

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on barley green material

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 286: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date	Time after treatment (d)	Shifted time (d)	Fluopyram residues (mg/kg)	Precipitation (mm)	Mean temp. (°C)
13-2950-01 Burscheid, D, Glaubitz, Szeley, 2013 spring barley, green material						Höfchen, Bayer station	Höfchen, Bayer station
	30	14/05/2013	0		8.6	0	10.72
	30	15/05/2013	1		6.8	0.1	13.25
	30	16/05/2013	2		5.0	5.5	13.11
	30	17/05/2013	3	0	2.3	0.4	9.24
		18/05/2013	4	1	-	0	10.83
	31	19/05/2013	5	2	1.5	0	15.23
		20/05/2013	6	3	-	8.7	11.43
	31	21/05/2013	7	4	0.53	8.5	12.03
		22/05/2013	8	5	-	1.6	8.0
		23/05/2013	9	6	-	5.3	5.83
	32	24/05/2013	10	7	0.24	0	7.53
						Sum: 30.1	Mean: 10.65

Irrigation during trial period: No irrigation done.

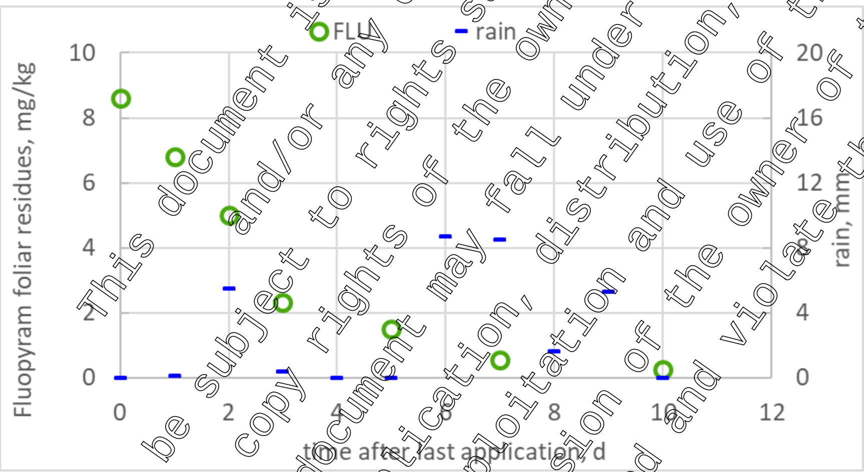


Figure 8.9- 81: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the spring barley green material

The rainfall on day 2 (5.5 mm) may have slightly influenced the residue level but does not seem to have had a marked influence on the decline curve.

Table 8.9- 287: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date	Time after treatment (d)	Shifted time (d)	Fluopyram residues (mg/kg)	Precipitation (mm)	Precipitation (mm)	Mean temp. (°C)
13-2950-02 Langförden, D,						Langförden, 1 km, report 13-2950	Mars grid 25x25km 110105	Mars grid 25x25km 110105
Glaubitz, Szeley, 2013	31	21/05/2013	0		4.5	2 (8 mm, 6-24 h after appl.)	9	13
spring barley, green material	31	22/05/2013	1	0	0.96	8	1	8.9
	31	23/05/2013	2	1	0.83	0	1	6.6
	31	24/05/2013	3	2	0.75	1	0	8.1
		25/05/2013	4	3	-	-	4	8.2
	32	26/05/2013	5	4	0.61	4	5	10.6
		27/05/2013	6	5	-	-	0.5	12
	32	28/05/2013	7	6	0.44	0	8	13.6
		29/05/2013	8	7	-	-	0.1	13.6
		30/05/2013	9	8	-	-	0	14.2
	32	31/05/2013	10	9	0.25	0	0	17.4
							Sum: 28.6	Mean: 11.5

Irrigation during trial period: No irrigation done.

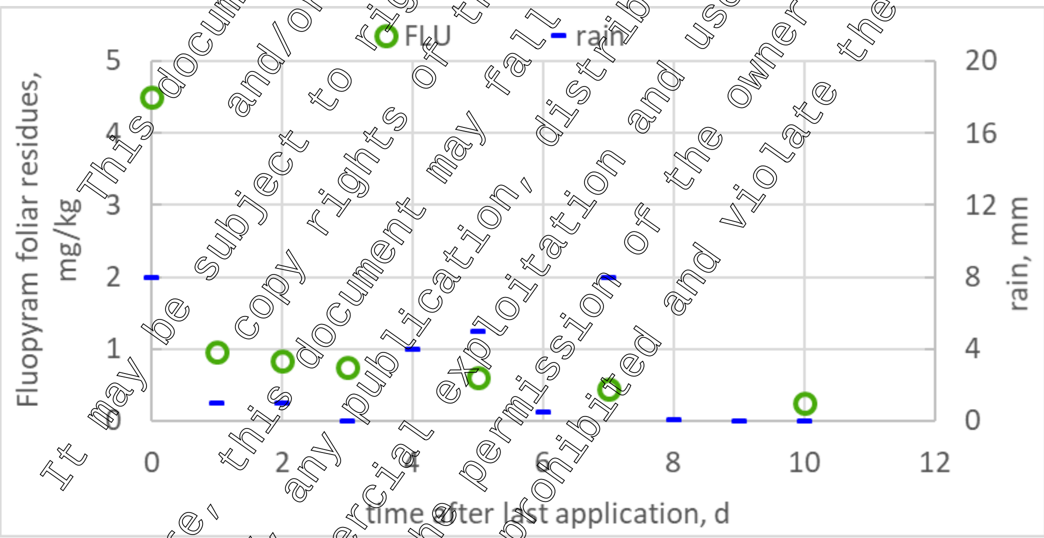


Figure 8.9- 82: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the spring barley green material

The rainfall on day 0 (8 mm) coincides with a large drop of the residue level and has probably markedly influenced the residue decline pattern.

Table 8.9- 288: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date	Time after treatment (d)	Shifted time (d)	Fluopyram residues (mg/kg)	Precipitation (mm)	Precipitation (mm)	Mean temp. (°C)
13-2950-03 Saint-Amand, B,						Redebel, 0.3 km, report 13-2950	Mars Grid 25x25 km 100094	Redebel, 0.3 km
Glaubitz, Szeley, 2013	30	15/05/2013	0		7.3	2.26 (6 mm 16-24 h after appl.)	3	12.0
spring barley, green material	30	16/05/2013	1	0	1.4	6.5	6	9.1
	31	17/05/2013	2	1	1.2	5.02	2	8.3
	31	18/05/2013	3	2	1.0	0	0	10.3
		19/05/2013	4	3	-	0	0.7	11.1
	31	20/05/2013	5	4	0.54	2.76	2.3	10.1
		21/05/2013	6	5	-	7.51	8	9.9
	31	22/05/2013	7	6	0.30	0.5	5	9.0
		23/05/2013	8	7	-	1.75	8	7.2
		24/05/2013	9	8	-	2.03	0.9	5.4
	31	25/05/2013	10	9	0.20	0.25	0	8.2
						Sum: 28.6		Mean: 9.1

Irrigation during trial period: No irrigation done.

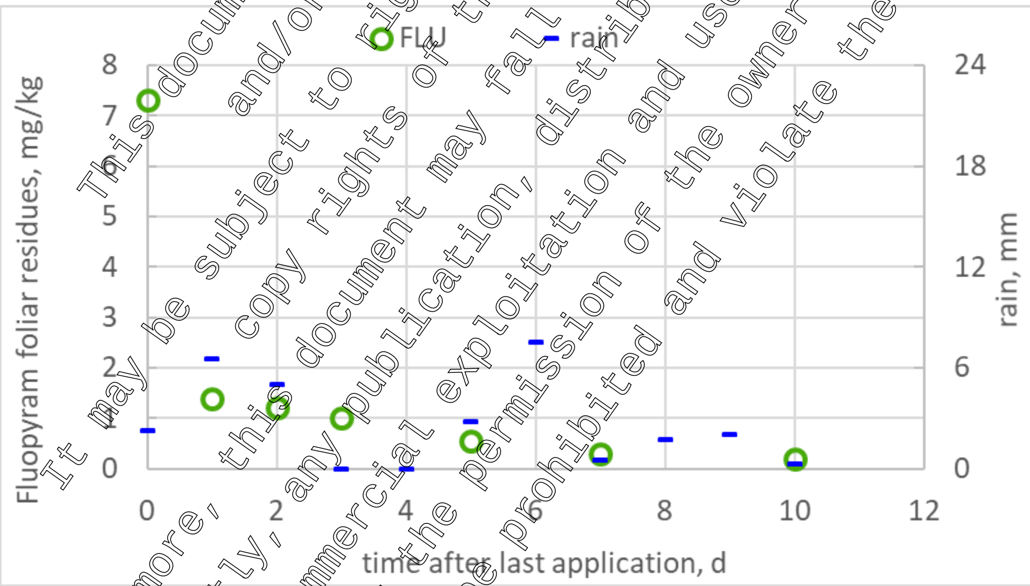


Figure 8.9- 83: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the spring barley green material

The rainfall on day 0 and day 1 coincides with a large drop of the residue level and has probably markedly influenced the residue decline pattern.

Table 8.9- 289: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date	Time after treatment (d)	Shifted time (d)	Fluopyram residues (mg/kg)	Precipitation (mm)	Precipitation (mm)	Mean temp. (°C)
13-2950-04 Midden-meer, NL,						Middenmeer, at field, raw data	Mars grid 25x25 km 110096	KNMI Berkhout, ~23 km, raw data
Glaubitz, Szeley, 2013	30	24/05/2013	0		8.0	0	3	7
	30	25/05/2013	1		6.3	6	5	8
	30	26/05/2013	2	0	1.5	0	0	9
spring barley, green material	30	27/05/2013	3	1	1.4	0	0	12
		28/05/2013	4	2	-	0	0.7	16
	30	29/05/2013	5	3	0.67	0	6	12
		30/05/2013	6	4	-	0	0	13
	30	31/05/2013	7	5	0.41	0	0	13
		01/06/2013	8	6	-	0	0	10
		02/06/2013	9	7	-	0	0	11
	30	03/06/2013	10	8	0.20	0	0	10
						Sum: 6		Mean: 11

Irrigation during trial period: No irrigation done.

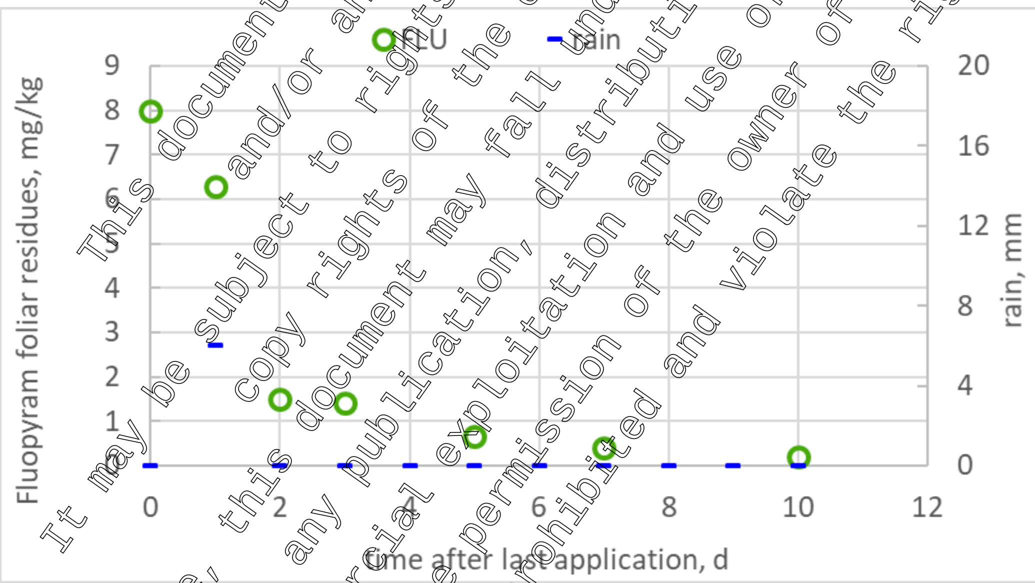


Figure 8.9- 84: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the spring barley green material

The rainfall on day 1 (6 mm) coincides with a large drop of the residue level and has probably markedly influenced the residue decline pattern.

III. CONCLUSION

After one spray application of Fluopyram & JAU 6476 SE 250 on spring barley in four residue trials conducted in Northern Europe (2x Germany, Belgium and Netherlands) during the 2013 season the residues of fluopyram in/on green material declined markedly during the sampling period.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall as observed in trials 13-2950-02, -03 and -04 appears to have influenced the decline pattern, but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Residues of fluopyram in spring barley, green material, markedly declined over the test period.

Data Point:	KCA 8.9/17
Report Author:	[redacted]
Report Year:	2016
Report Title:	Determination of the residues of AE C656948 and prothioconazole in/on wheat after spray application of AE C656948 & JAU 6476 SE 250 in the Netherlands, Belgium, Italy and Spain
Report No:	15-2952
Document No:	M-566830-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in northern Europe and southern Europe (The Netherlands, Belgium, Italy and Spain) on wheat, during the 2015 season. One application with Fluopyram & JAU 6476 SE 250 (a suspo-emulsion formulation containing 125 g/L fluopyram and 125 g/L prothioconazole (JAU 6476)) was conducted. Only the parameters and results relevant to fluopyram have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram & JAU 6476 SE 250 on wheat green material declined markedly during the sampling period.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram & JAU 6476 SE 250 (125 +125 g/L)
	Batch no.:	EM4L012612
	Active Ingredient:	Fluopyram and prothioconazole
	Storage:	Not stated in the report
	Expiry date:	2016-02-13
2.	Test commodity:	Wheat
	Crop part:	Green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 15-2952 was to determine the magnitude of the relevant residues of fluopyram in/on wheat (green material) after one spray application with “Fluopyram & JAU 6476 SE 250 (125 g/L + 125 g/L)”, a suspo-emulsion (SE) formulation containing 125 g/L fluopyram. This summary focuses only on the residues of fluopyram.

<u>Field phase</u>

The study included four supervised residue trials conducted in northern Europe and southern Europe (The Netherlands, Belgium, Italy and Spain) during the 2015 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 290: Description of the trial locations and cropping information on treated plots

Trial number	15-2952-01	15-2952-02	15-2952-03	15-2952-04
Trial location	1771 SC Wieringerwerf	5140 Vieille Maison	I-76123 Andria	41310 Brenes
Country	The Netherlands	Belgium	Italy	Spain
Area of application	Field	Field	Field	Field
Plot size [m^2]	100	60	120	67.5
Type of soil	Clay	Silt loam	Sand	Clay loam
pH-value of soil (in water)	7.8	7.2	8.4	8.5
Content of organic C [%]	4.88	1.57	1.15	0.46
Test system	Wheat	Wheat	Wheat	Wheat
Variety	Quintes Summer	Cellule Winter wheat	Saragolla	Euroduro durum
Date of sowing	2015-04-23	2014-10-12	2015-01-22	2015-02-05
Start of flowering	2015-06-25	2015-05-30	2015-05-01	2015-04-23
End of flowering	2015-07-05	2015-06-11	2015-05-10	2015-05-01
Date of commercial harvest	2015-09-01 to 2015-09-15	2015-07-25 to 2015-08-05	2015-06-30 to 2015-07-15	2015-06-01 to 2015-06-25

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. Application was performed at an BBCH between 24-29 with an application rate of 0.125 kg a.s./ha and a water rate of 300-400 L/ha.

Table 8.9- 291: Overview on application with fluopyram & JAU 6476 SE 250 on wheat

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
15-2952-01 The Netherlands	1	T	Fluopyram & JAU 6476 SE 250	SPI	29	-	1.0	400	Fluopyram	0.125
									JAU 6476	0.125
15-2952-02 Belgium	1	T	Fluopyram & JAU 6476 SE 250	SPI	24	-	1.0	300	Fluopyram	0.125
									JAU 6476	0.125
15-2952-03 Italy	1	T	Fluopyram & JAU 6476 SE 250	SPI	29	-	1.0	300	Fluopyram	0.125
									JAU 6476	0.125
15-2952-04 Spain	1	T	Fluopyram & JAU 6476 SE 250	SPI	29	-	1.0	300	Fluopyram	0.125
									JAU 6476	0.125

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of green material of wheat. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 292: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
15-2952-01 15-2952-02 15-2952-03 15-2952-04	Wheat	Green material	C	-0
			T	0
				1
				2
				3
				5
				7
				10

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram were analysed within the residue trials samples according to the following method:

Table 8.9- 293: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram in wheat green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 294: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Wheat / green material	0.01	98; 102; 102; 105; 105	102	2.8	0.01
	0.10	97; 98; 101; 103; 103	100	2.8	
	1.0	103; 103	103	-	
	10	90; 103; 104	99	7.9	
		Overall recovery (n = 15)	**101**	**3.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 202 and 496 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries. For fluopyram, the residues levels in/on wheat green material are summarised in the following table. For the analysis of the sample of trial 15-2952-02 DALT 1, the retain sample was used additionally and the result was calculated as the mean of the three individual analyses of 6.31 mg/kg and 6.43 mg/kg and 6.82 mg/kg.

Table 8.9- 295: Residue summary of fluopyram in/on wheat, green material

Trial No. Country	Sample material	BBCH	DALT	Residues [mg/kg] a.s. fluopyram
15-2952-01 The Netherlands	Green material	29	0	9.0
	Green material	30	1	7.2
	Green material	30	2	5.0
	Green material	30	3	4.1
	Green material	31	5	3.5
	Green material	32	7	2.8
	Green material	32	10	0.91
15-2952-02 Belgium	Green material	24	0	9.6
	Green material	24	1	6.5*
	Green material	24	2	8.7
	Green material	24	3	8.2
	Green material	24	5	4.6
	Green material	30	7	4.7
	Green material	31	11	3.6
15-2952-03 Italy	Green material	29	0	9.2
	Green material	29	1	6.3
	Green material	29	2	6.1
	Green material	29	3	4.4
	Green material	30	5	3.7
	Green material	31	7	0.64
	Green material	31	10	0.45
15-2952-04 Spain	Green material	29	0	7.4
	Green material	29	1	6.4
	Green material	29	2	7.0
	Green material	30	4	4.5
	Green material	31	5	3.0
	Green material	32	6	2.8
	Green material	34	11	0.64

DALT = Days after last treatment
*This value is the mean value of three individual values

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on wheat green material

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results

Table 8.9- 296: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date	Time after treatment (d)	Shifted time (d)	Fluopyram residues (mg/kg)	Precipitation (mm)	Precipitation (mm)	Mean temp. (°C)
15-2952-01 Wieringer-werf, NL,						De Kooy, Den Helder, 15 km, report 15-2952	Mars grid 25x25 km 110096	Mars grid 25x25 km 110096
Glaubitz, Hennes, 2016a	29	08/06/2015	0	0	9	0	0	11
	30	09/06/2015	1	1	7.2	0	0	11.1
	30	10/06/2015	2	2	5	0	0	13
wheat, green material	30	11/06/2015	3	3	4.1	0	0	14.6
		12/06/2015	4	4	-	-	0	18.8
	31	13/06/2015	5	5	3.5	1	0.3	17.1
		14/06/2015	6	6	-	-	0.3	13.8
	32	15/06/2015	7	7	2.8	0	0	13
		16/06/2015	8	-	-	-	8	10.9
		17/06/2015	9	-	-	-	5.1	13.5
	32	18/06/2015	10	-	0.91	0	4	13.8
							Sum: 17.7	Mean: 13.7

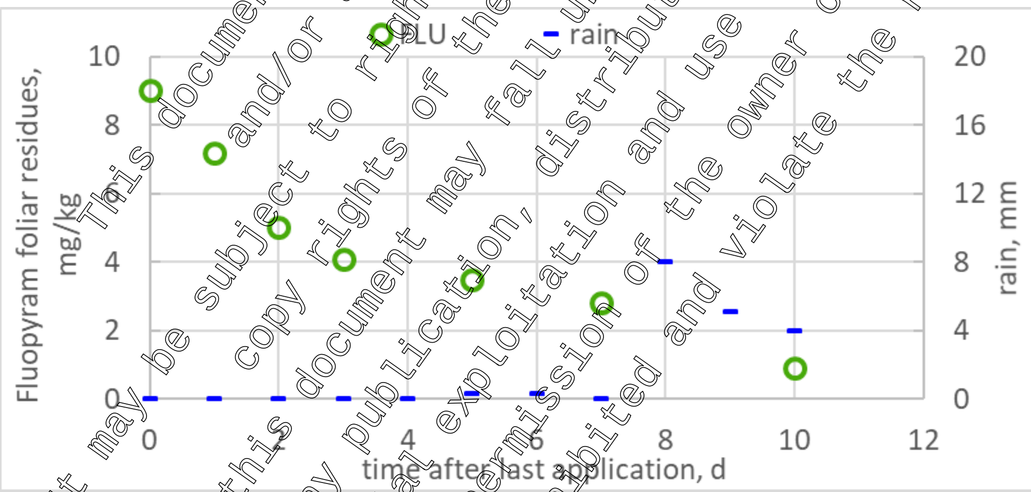


Figure 8.9- 85: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

Rainfall occurred only during the last days of the trial and does not appear to have had a marked influence on the residue decline curve.

Table 8.9- 297: Climatic conditions and residue concentration

Study trial, crop	**BBCH growth stage**	**Date**	**Time after treatment (d)**	**Shifted time (d)**	**Fluopyram residues (mg/kg)**	**Precipitation (mm)**	**Precipitation (mm)**	**Mean temp. (°C)**
15-2952-02 Vieille Maison, B,						Redebel, 8 km, report 13-2952	Mars grid 25x25 km 100094	Mars grid 25x25 km 100094
Glaubitz, Hennes, 2016a	24	05/03/2015	0		9.6	0	0	4.2
	24	06/03/2015	1		6.5 *	0	0	4.5
wheat, green material	24	07/03/2015	2		8.7	0	0	8.3
	24	08/03/2015	3		8.2	0	0.1	10.4
		09/03/2015	4		-	-	0.3	8.4
	24	10/03/2015	5		4.6	1	0.8	9.4
		11/03/2015	6		-	-	0	5
	30	12/03/2015	7		4.7	0	0	6.2
		13/03/2015	8		-	-	0	5.1
		14/03/2015	9		-	-	0	4.4
		15/03/2015	10		-	-	0.7	4.3
	31	05/03/2015	11		3.6	1	0	5.2
							Sum: 1.9	Mean: 6.3

* analysed 3 times, mean of n=3 (Glaubitz and Hennes 2016a).

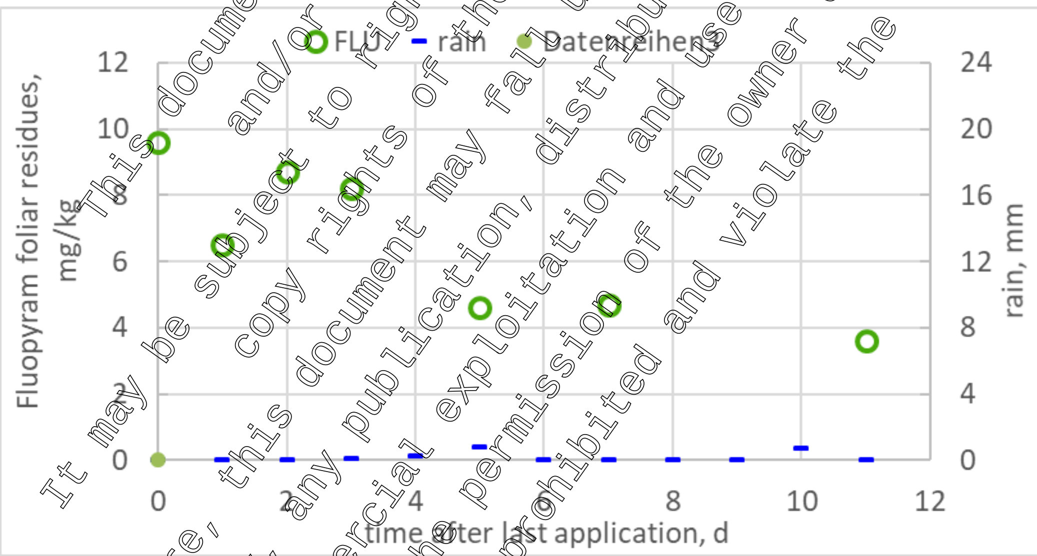


Figure 8.9- 86: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

There was nearly no rain during the trial and no influence on the residue decline.

Table 8.9- 298: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date	Time after treatment (d)	Shifted time (d)	Fluopyram residues (mg/kg)	Precipitation (mm)	Precipitation (mm)	Mean temp. (°C)
15-2952-03 Andria, I, Glaubitz, Hennes, 2016a wheat, green material						Bonifica Capitanata, Trinitapoli, 19.5 km, report 13-2952	Mars grid 25x25 km 59131	Mars grid 25x25 km 59131
	29	30/03/2015	0	0	9.2	0	0	11.1
	29	31/03/2015	1	1	6.3	0	0	14.2
	29	01/04/2015	2	2	6.1	0	0	14.3
	29	02/04/2015	3	3	4.4	0	0	11
		03/04/2015	4	4	-	-	0	9.5
	30	04/04/2015	5	5	3.7	0	5	7.5
		05/04/2015	6	-	-	-	2.2	11.8
	31	06/04/2015	7	-	0.64	0	0	7.4
		07/04/2015	8	-	-	-	0	4.2
		08/04/2015	9	-	-	-	0	6.9
	31	09/04/2015	10	-	0.45	0	0	9
							Sum: 7.2	Mean: 9.7

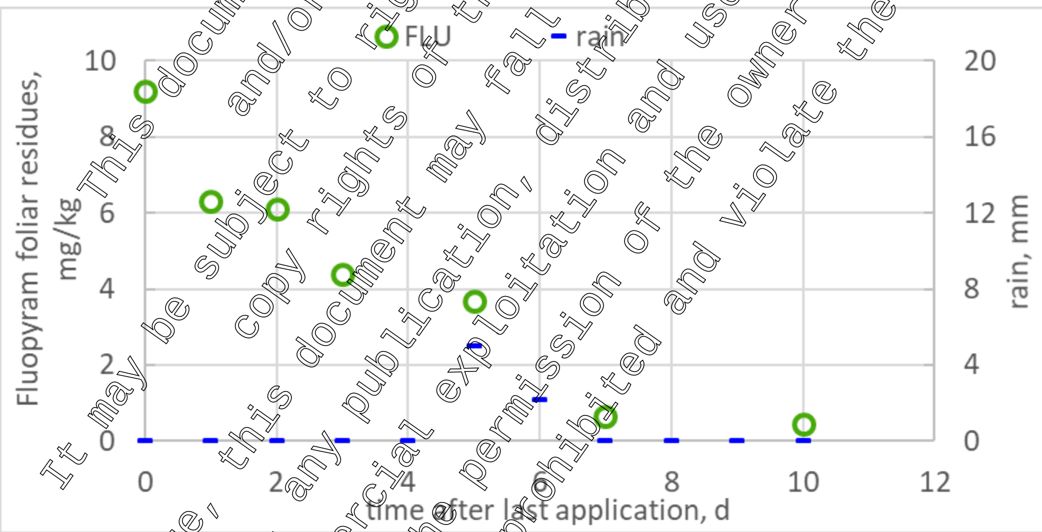


Figure 8.9- 87: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

Rainfall on days 5 and 6 does not appear to have a marked influence on the residue decline curve.

Table 8.9- 299: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date	Time after treatment (d)	Shifted time (d)	Fluopyram residues (mg/kg)	Precipitation (mm)	Precipitation (mm)	Mean temp. (°C)
15-2952-04 Brenes, Es, Glaubitz, Hennes, 2016a wheat, green material						Brenes Farm, 0.1 km, report 13-2952	ProClimate db	ProClimate db
	29	26/03/2015	0	0	7.4	0	0	12.3
	29	27/03/2015	1	1	6.4	0	0	15.9
	29	28/03/2015	2	2	7	0	0.2	18.3
		29/03/2015	3	3	-	-	0	19.0
	30	30/03/2015	4	4	4.5	0	0	19.8
	31	31/03/2015	5	5	3	0	0	20.8
	32	01/04/2015	6	6	2.8	0	0	22.4
		02/04/2015	7	-	-	-	0	20.2
		03/04/2015	8	-	-	-	0	18.8
		04/04/2015	9	-	-	-	0	19.6
		05/04/2015	10	-	-	-	0	18.7
	34	26/03/2015	11	-	0.64	9	9.2	18.4
							Sum: 9.4	Mean: 18.7

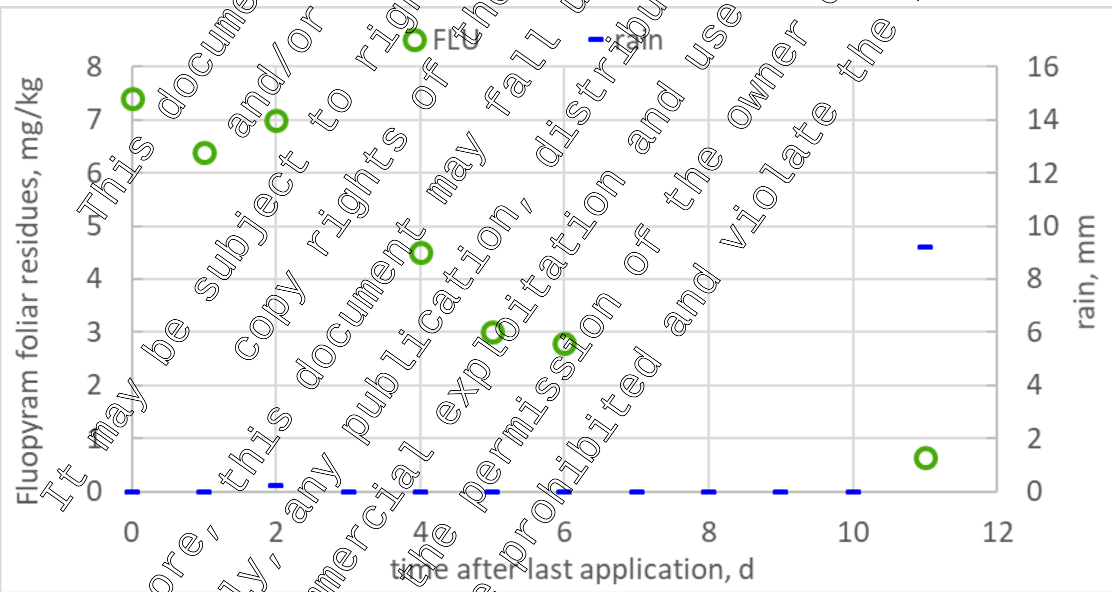


Figure 8.9- 88: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

There was nearly no rain over the trial period until day 11, which does not appear to have influenced the residue decline curve.

III. CONCLUSION

After one spray application of Fluopyram & JAU 6476 SE 250 on wheat in four residue trials conducted northern Europe and southern Europe (The Netherlands, Belgium, Italy and Spain)during the 2015 season the residues of fluopyram in/on green material declined markedly during the sampling period.

Assessment and conclusion by applicant:
The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall did not seem to have a marked influence on residue dissipation in any of the 4 trials.

Data Point:	KCA 8.9/18
Report Author:	[redacted]
Report Year:	2016
Report Title:	Determination of the residues of AE C656948 and trifloxystrobin in/on wheat after spray application of AE C656948 & CGA279202 SC 500 in the field in northern France, United Kingdom, Italy and Greece
Report No:	15-2953
Document No:	M-566828-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in northern Europe and southern Europe (northern France, United Kingdom, Italy and Greece) on wheat, during the 2015 season. One application with Fluopyram & CGA 279202 SC 500, containing 250 g/L fluopyram and 250 g/L trifloxystrobin (CGA 279202) was conducted. Only the parameters and results relevant to fluopyram have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram & CGA 279202 SC 500 on wheat green material declined markedly during the sampling period.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram & CGA 279202 SC 500 (250+250 g/L)
	Batch no.:	EV65000048
	Active Ingredient:	Fluopyram and trifloxystrobin
	Storage:	Not stated in the report
	Expiry date:	2018-02-12
2.	Test commodity:	Wheat
	Crop part:	Green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 15-2953 was to determine the magnitude of the relevant residues of fluopyram in/on wheat (green material) after one spray application with Fluopyram & CGA 279202 SC 500 (250 g/L + 250 g/L)", a suspension concentrate formulation containing 250 g/L fluopyram. This summary focuses only on the residues of fluopyram.

Field phase

The study included four supervised residue trials conducted in northern Europe and southern Europe (northern France, United Kingdom, Italy and Greece) during the 2015 season. Details on trial locations and cropping information on the treated plots are given within the following table:

Table 8.9- 300: Description of the trial locations and cropping information on treated plots

Trial number	15-2953-01	15-2953-02	15-2953-03	15-2953-04
Trial location	37310 Chambourg sur Indre	SG8 8SS Great Chishill	95100 C.da Reitana; Catania (CT)	GR - 61100 Kristoni village, Kilkis
Country	France	United Kingdom	Italy	Greece
Area of application	Field	Field	Field	Field
Plot size [m^2]	120	90	189	150
Type of soil	Clayey silt	Clay	Sandy Clay Loam	Clay loam
pH-value of soil (in water)	8.0	7.8	7.3	8.0
Content of organic C [%]	1.32	2.91	0.57	0.66
Test system	Wheat	Wheat	Wheat	Wheat
Variety	Oregrain winter wheat	Solstice Milling Wheat	Mongibello	Avorio soft wheat
Date of sowing	2014-10-29	2014-10-10	2015-01-15	2014-11-26
Start of flowering	2015-05-15	2015-06-08	2015-04-30	2015-05-24
End of flowering	2015-05-25	2015-06-22	2015-05-15	2015-06-02
Date of commercial harvest	2015-07-01 to 2015-07-10	2015-08-03 to 2015-08-24	2015-06-01 to 2015-06-30	2015-06-17 to 2015-06-17

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. Application was performed at a BBCH between 28-29 with an application rate of 0.2 kg a.s./ha and a water rate of 200-400 L/ha.

Table 8.9- 301: Overview on application with Fluopyram& CGA 279202 SC 500 on wheat

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
15-2953-01 France	1	T	Fluopyram & CGA 279202 SC 500	SPI	29	-	0.8	300	Fluopyram CGA 279202	0.2 0.2
15-2953-02 United Kingdom	1	T	Fluopyram & CGA 279202 SC 500	SPI	29	-	0.8	200	Fluopyram CGA 279202	0.2 0.2
15-2953-03 Italy	1	T	Fluopyram & CGA 279202 SC 500	SPI	29	-	0.8	400	Fluopyram CGA 279202	0.2 0.2
15-2953-04 Greece	1	T	Fluopyram & CGA 279202 SC 500	SPI	28	-	0.8	400	Fluopyram CGA 279202	0.2 0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of green material of wheat. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 302: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
15-2953-01 15-2953-02 15-2953-03 15-2953-04	Wheat	Green material	C	-0
			T	0
				1
				2
				3
				5
				7
				10

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram were analysed within the residue trials samples according to the following method:

Table 8.9- 303: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram in wheat green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 304: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Wheat / green material	0.01	104; 107	106	-	0.01
	0.10	94; 96	95	-	
	1.0	96; 99	98	-	
	10	85; 103	94	-	
	15	105; 105	105	-	
		Overall recovery (n = 10)	**99**	**6.8**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 252 and 290 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries. In trial 15-2953-04 samples were analysed 3 times to confirm the results. It can be assumed that samples were mixed up in the field.

For fluopyram, the residues levels in/on wheat green material are summarised in the following table.

Table 8.9- 305: Residue summary of fluopyram in/on wheat, green material

Trial No. Country	Sample material	BBCH	DALT	Residues [mg/kg] a.s. fluopyram
15-2953-01 France	Green material	29	0	14
	Green material	29	1	5.1
	Green material	29	2	2.0
	Green material	29	3	1.8
	Green material	29	5	0.93
	Green material	29	7	0.37
	Green material	30	10	0.24
15-2953-02 United Kingdom	Green material	29	0	8.7
	Green material	29	1	7.1
	Green material	29	2	6.4
	Green material	29	3	8.1
	Green material	29	4	5.5
	Green material	30	7	1.3
	Green material	30	10	0.98
15-2953-03 Italy	Green material	29	0	8.5
	Green material	29	1	9.2
	Green material	30	2	6.9
	Green material	31	3	4.4
	Green material	31	5	4.4
	Green material	32	8	3.7
	Green material	32	10	1.5
15-2953-04 Greece	Green material	28	0	8.1*
	Green material	28	1	8.6*
	Green material	28	2	11*
	Green material	29	3	15*
	Green material	29	5	8.0*
	Green material	30	8	8.7*
	Green material	31	10	6.0*

DALT = Days after last treatment

Analyte: Fluopyram | Final determination as: Fluopyram | Residues calculated as: Fluopyram

*These samples were analyzed 3 times

2. Climatic conditions and time course of residue concentrations in/on wheat green material

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 306: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date	Time after treatment (d)	Shifted time (d)	Fluopyram residues (mg/kg)	Precipitation (mm)	Precipitation (mm)	Mean temp. (°C)
15-2953-01 Chambourg sur Indre, F,						Reignac sur Indre, 5 km, report 15-2953	Mars grid 25x25 km 87082	Mars grid 25x25 km 87082
Glaubitz, Hennes, 2016b	29	23/03/2015	0		14	4 (6 mm 20-24 h after appl.)	4	7.3
	29	24/03/2015	1		5.1	9	8.5	5.1
wheat, green material	29	25/03/2015	2	0	2.0	0	0	5.8
	29	26/03/2015	3	1	1.8	1	0.8	4
		27/03/2015	4	2	-	-	1.8	7.3
	29	28/03/2015	5	3	0.93	0	0	11.5
		29/03/2015	6	4	-	-	7.6	11.4
	29	30/03/2015	7	5	0.37	2	1.8	13
		31/03/2015	8	6	-	-	0.4	12.8
		01/04/2015	9	7	-	-	0	8.9
	30	02/04/2015	10	8	0.24	0	0	9.1
							Sum: 24.9	Mean: 8.7

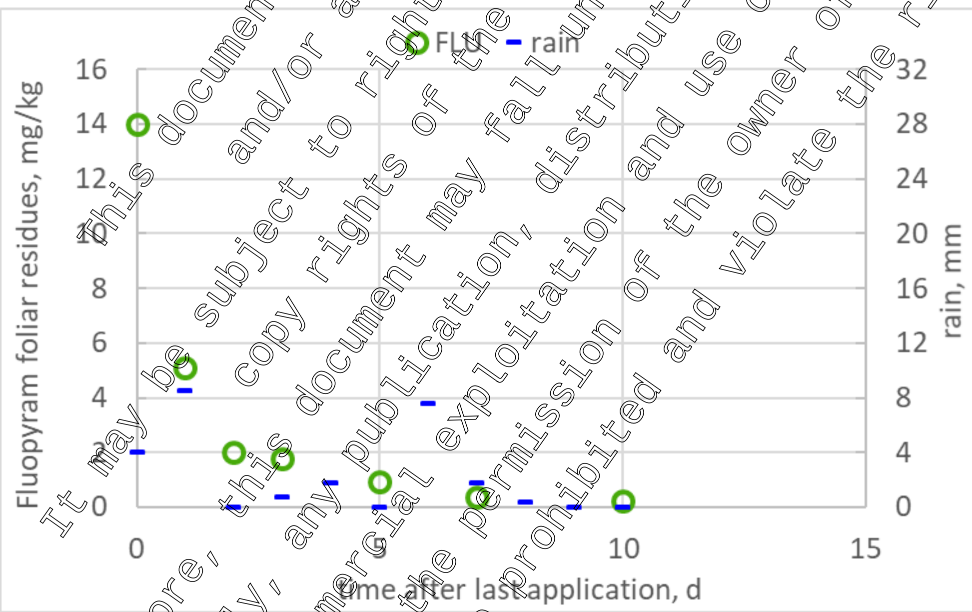


Figure 8.9- 89: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

Rainfall on the day of application and on day 1 may have influenced the steep initial residue decline.

Table 8.9- 307: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date	Time after treatment (d)	Shifted time (d)	Fluopyram residues (mg/kg)	Precipitation (mm)	Precipitation (mm)	Mean temp. (°C)
15-2953-02 Great Chishill, UK, Glaubitz, Hennes, 2016b wheat, green material						Great Chishill, 0.4 km, report 15-2953	ProClimate db	ProClimate db
	29	20/04/2015	0	0	8.7	0	0	8.1
	29	21/04/2015	1	1	7.1	0	0	9.3
	29	22/04/2015	2	2	6.4	0	0	8.4
	29	23/04/2015	3	3	8.1	0	0	8.5
	29	24/04/2015	4	4	5.5	0	0	11.7
		25/04/2015	5	-	-	-	14.8	12.5
		26/04/2015	6	-	-	-	3	7.5
	30	27/04/2015	7	-	1.3	0	0	6.8
		28/04/2015	8	-	-	-	0	7.3
		29/04/2015	9	-	-	-	4.4	8.1
	30	30/04/2015	10	-	0.98	0	0	7.7
							Sum: 22.2	Mean: 8.7

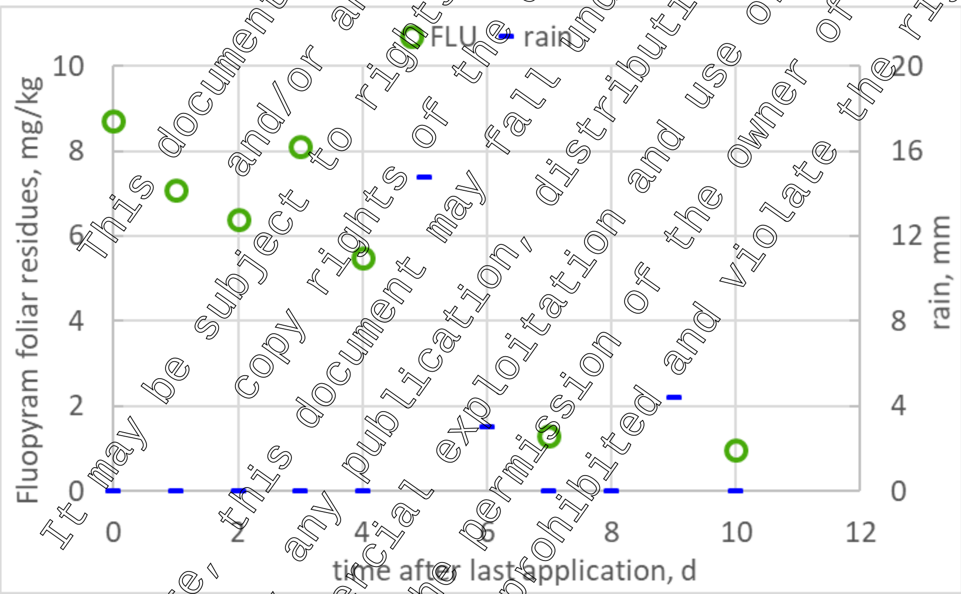


Figure 8.9- 90: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

The rainfall on day 5 coincides with a moderate drop of the residue levels and may thus have slightly altered the overall DT_{50}.

Table 8.9- 308: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date	Time after treatment (d)	Shifted time (d)	Fluopyram residues (mg/kg)	Precipitation (mm)	Precipitation (mm)	Mean temp. (°C)
15-2953-03 C. da Reitana, Catania, I, Glaubitz, Hennes, 2016b wheat, green material						SIAS Station 228, C. da San Francesco la Rena, 4 km (no irrigation), report 13-2953	Mars grid 25x25 km 43127	Mars grid 25x25 km 43127
	29	30/03/2015	0		8.5	0	0	11.8
	29	31/03/2015	1		9.2	0	0	14.9
	30	01/04/2015	2		6.9	0	0	16.3
	31	02/04/2015	3		4.4	0	0	12.6
		03/04/2015	4		-	-	0	12.5
	31	04/04/2015	5		4.4	0	0	11.1
		05/04/2015	6		-	-	0	15.7
		06/04/2015	7		-	-	0	12.6
	32	07/04/2015	8		3.7	0	0	9
		08/04/2015	9		-	-	0	9.4
	32	09/04/2015	10		1.5	0	0	9
							Sum: 0	Mean: 12.3

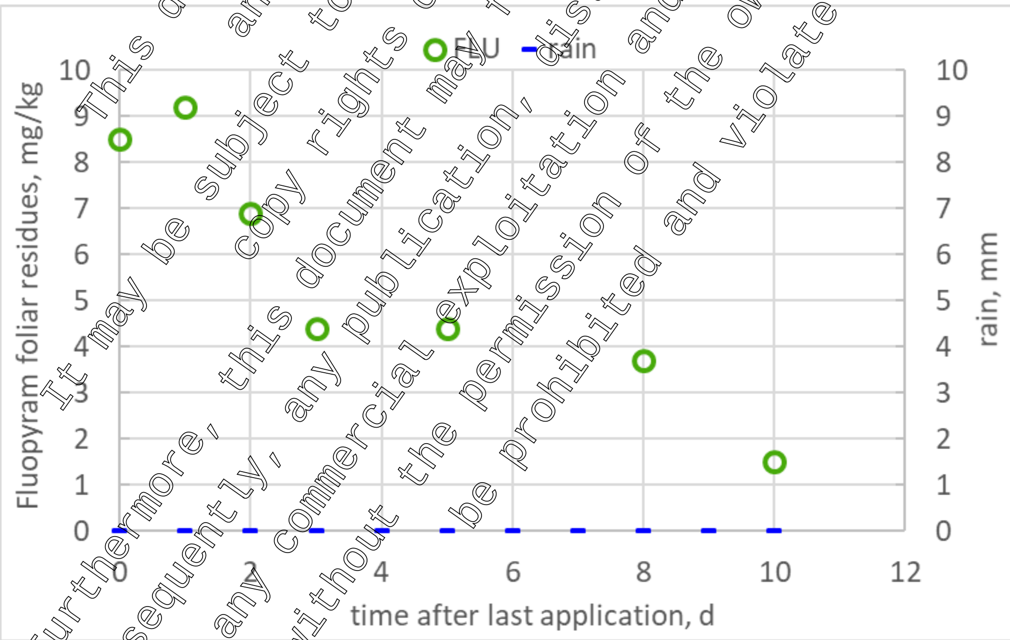


Figure 8.9- 91: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

There was no rainfall over the trial period which could have influenced the residue dissipation.

Table 8.9- 309: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date	Time after treatment (d)	Shifted time (d)	Fluopyram residues (mg/kg)	Precipitation (mm)	Precipitation (mm)	Mean temp. (°C)
15-2953-04 Kristoni village, Kilkis, Gr,						Kilkis, 7 km (no irrigation), report 13-2953	Mars grid 25x25 km 61153	Mars grid 25x25 km 61153
Glaubitz, Hennes, 2016b	28	06/04/2015	0		8.1*	13 (0 mm 24h after appl.)	4	9.6
wheat, green material	28	07/04/2015	1		8.6*	0	3	7.3
	28	08/04/2015	2		11*	0	0	7.8
	29	09/04/2015	3		15*	0	0	10.1
		10/04/2015	4		-	-	0	12.2
	29	11/04/2015	5		8.0*	0	0	11.5
		12/04/2015	6		-	-	0	13.8
		13/04/2015	7		-	-	0.1	17.1
	30	14/04/2015	8		8.7*	0	0	14.5
		15/04/2015	9		-	-	0	15.4
	31	16/04/2015	10		6.0*	0	0	14.2
							Sum: 7.1	Mean: 12.1

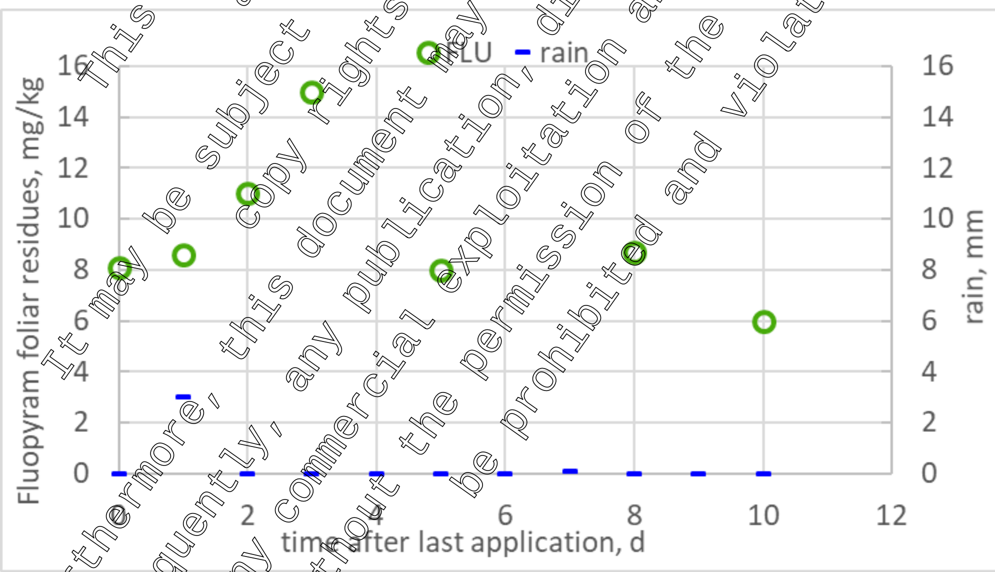


Figure 8.9-92: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

Little rainfall on day 1 does not appear the residue decline. However the residue time course is spurious and likely related to a mix-up of samples.

III. CONCLUSION

After one spray application of Fluopyram & CGA 279202 SC 500 on wheat in four residue trials conducted in northern Europe and southern Europe (northern France, United Kingdom, Italy and Greece) during the 2015 season the residues of fluopyram in/on green material declined markedly during the sampling except trial 15-2593-04 where it can be assumed that samples were mixed up in the field.

Assessment and conclusion by applicant:
Only one trial of this study is unequivocally reliable for risk assessment (15-2593-03). Trials 15-2593-01 (marked) and 15-2593-02 (slight) appear influenced by rainfall, but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments. Trial 15-2593-04 appears impacted by a sample mix-up and is unreliable.

In the following section the residue study summaries are presented that have been analysed in the kinetic report by M-763188-01-1:

Data Point:	KCA 8.9/19
Report Author:	[redacted]
Report Year:	2020
Report Title:	Determination of the residues of prothioconazole and AE C656948 in/on wheat after spraying of AE C656948 & JAU 6476 SE 250 in the field in Germany and Belgium
Report No:	18-2951
Document No:	M-678413-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with three residue trials was conducted in northern Europe (2 x Germany and Belgium) on wheat, during the 2018 season. One application with Fluopyram & JAU 6476 SE 250 (a suspo-emulsion formulation containing 125 g/L fluopyram and 125 g/L prothioconazole (JAU 6476)) was conducted. Only the parameters and results relevant to fluopyram have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram & JAU 6476 SE 250 on wheat green material declined markedly during the sampling period.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram & JAU 6476 SE 250 (125 +125 g/L)

   Batch no.: EV65000571

   Active Ingredient: Fluopyram and prothioconazole

   Storage: Not stated in the report

   Expiry date: 2020-03-10

2. Test commodity: Wheat

   Crop part: Green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 18-2951 was to determine the magnitude of the relevant residues of fluopyram in/on wheat (green material) after one spray application with Fluopyram & JAU 6476 SE 250 (125 g/L + 125 g/L), a suspo-emulsion (SE) formulation containing 125 g/L fluopyram. This summary focuses only on the residues of fluopyram.

Field phase

The study included three supervised residue trials conducted in in northern Europe (2 x Germany and Belgium) during the 2018 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 310: Description of the trial locations and cropping information on treated plots

Trial number	**18-2951-01**	**18-2951-02**	**18-2951-03**
Trial location	51399 Burscheid	63863 Eschau	6211 Mellet
Country	Germany	Germany	Belgium
Area of application	Field	Field	Field
Plot size [m^2]	144	82.5	42.5
Type of soil	Sandy Loam	Loess	Silty loam
pH-value of soil (in water)	-	-	7.1
pH-value of soil (in $CaCl_2$)	6.6	6.1	-
Content of organic C [%]	0.87	0.64	2.15
Test system	Wheat	Wheat	Wheat
Variety	Elixer	KWS Champsin	Olympus
Date of sowing	2017-09-25	2018-04-07	2017-11-02
Start of flowering	2018-05-26	2018-06-11	2018-06-04
End of flowering	2018-06-05	2018-06-14	2018-06-11
Date of commercial harvest	2018-07-15 to 2018-08-15	2018-07-25 to 2018-08-05	2018-07-19 to 2018-07-26

The soil characterisation was not conducted according to GLP

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. Application was performed at an BBCH between 29-30 with an application rate of 0.115 to 0.125 kg a.s./ha and a water rate of 231-301 L/ha. Because of bad weather conditions (wind, rainfall) the application for trial 18-2951-02 was done at crop stage BBCH 30 instead of BBCH 29. This has no impact on the study. In trial 18-2951-03 there was an underdosage of approximately 8% but this had also no impact on the study.

Table 8.9- 311: Overview on application with Fluopyram & JAU 6476 SE 250 on wheat

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
18-2951-01 Germany	1	T	Fluopyram & JAU 6476 SE 250	SPI	29	-	0.970	291	Fluopyram	0.121
									JAU 6476	0.121
18-2951-02 Germany	1	T	Fluopyram & JAU 6476 SE 250	SPI	30	-	1.022	301	Fluopyram	0.125
									JAU 6476	0.125
18-2951-03 Belgium	1	T	Fluopyram & JAU 6476 SE 250	SPI	29	-	0.922	231	Fluopyram	0.115
									JAU 6476	0.115

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of green material of wheat. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 312: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
18-2951-01 18-2951-02 18-2951-03	Wheat	Green material	C	-0
			T	0
				1
				2
				3
				5
				7
				10

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram were analysed within the residue trials samples according to the following method:

Table 8.9- 313: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram in wheat green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 314: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Wheat / green material	0.01	107; 109; 117	111	4.8	0.01
	0.50	100; 103; 105	103	2.5	
	10	95; 97; 97	96	1.2	
	15	98; 98; 100	99	1.2	
		Overall recovery (n = 12)	**102**	**6.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 350 and 415 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries. For fluopyram, the residues levels in/on wheat green material are summarised in the following table.

Table 8.9- 315: Residue summary of fluopyram in/on wheat, green material

Trial No. Country	Sample material	BBCH	DALT	Residues [mg/kg] a.s. fluopyram
18-2951-01 Germany	Green material	29	0	14
	Green material	29	1	12
	Green material	29	2	11
	Green material	29	3	9.4
	Green material	29	5	1.8
	Green material	30	7	1.4
	Green material	30	10	0.75
18-2951-02 Germany	Green material	30	0	4.3
	Green material	30	1	3.9
	Green material	30	2	3.0
	Green material	30	3	2.7
	Green material	31	5	1.5
	Green material	31	7	0.71
	Green material	37	10	0.39
18-2951-03 Belgium	Green material	29	0	6.6
	Green material	29	1	5.7
	Green material	30	2	5.1
	Green material	30	3	4.1
	Green material	30	4	3.5
	Green material	31	7	1.2
	Green material	31	10	0.56

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on wheat green material

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary; there is no negative impact on the study results.

Table 8.9- 316: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2951-01 Burscheid, DE, M-678413-01-1 wheat, green material Propulse						ProPlant DB Versuchsgut Höfchen (0 km)	no	ProPlant DB Versuchsgut Höfchen (0 km)
	29	24/03/2018	0	14	not analysed	0		6.3
	29	25/03/2018	1	12		0		7.2
	29	26/03/2018	2	11		0		7.4
	29	27/03/2018	3	9.4		5.7		5.6
		28/03/2018	4			10.8		6.9
	29	29/03/2018	5	1.8		1.4		5.2
		30/03/2018	6			2.9		8.1
	30	31/03/2018	7	1.4		4.7		7.8
		01/04/2018	8			9.1		5.3
		02/04/2018	9			1.4		7.5
	30	03/04/2018	10	0.75		7.9		11.4

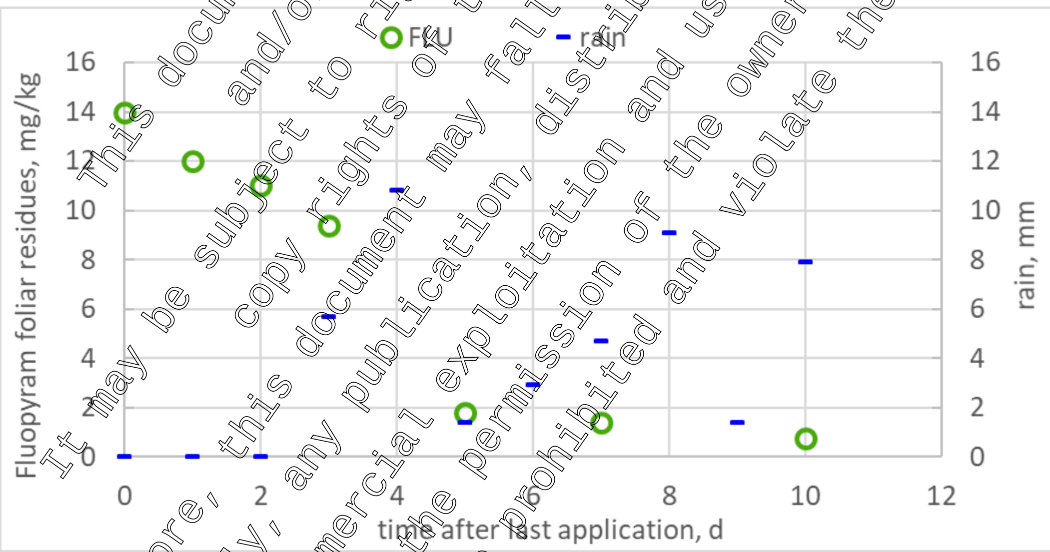


Figure 8.9- 93: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

The rainfall on day 3 (5.7 mm) and day 4 (10.3 mm) coincides with a large drop in residue levels and a corresponding change of the slope of the decline curve.

Table 8.9- 317: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2951-02 Eschau, DE,						at field[a)]	no	Großostheim (18.5 km)
M-678413-01-1	30	18/05/2018	0	4.3	not analysed	0		11
	30	19/05/2018	1	3.9		0		13
wheat, green material Propulse	30	20/05/2018	2	3.0		0.4		16
	30	21/05/2018	3	2.7		0		20
		22/05/2018	4			0		18
	31	23/05/2018	5	1.5		0		17
		24/05/2018	6			0.6 sum[b)]		17
	31	25/05/2018	7	0.71		0.6 sum[b)]		19
		26/05/2018	8			0		21
		27/05/2018	9			0		22
	37	28/05/2018	10	0.39		0		23

[a)] rain gauge was placed at the field site and was read and emptied at each sampling event
[b)] sum of rain for 2-3 days, where same value is marked, the value was used only for the first day in graph

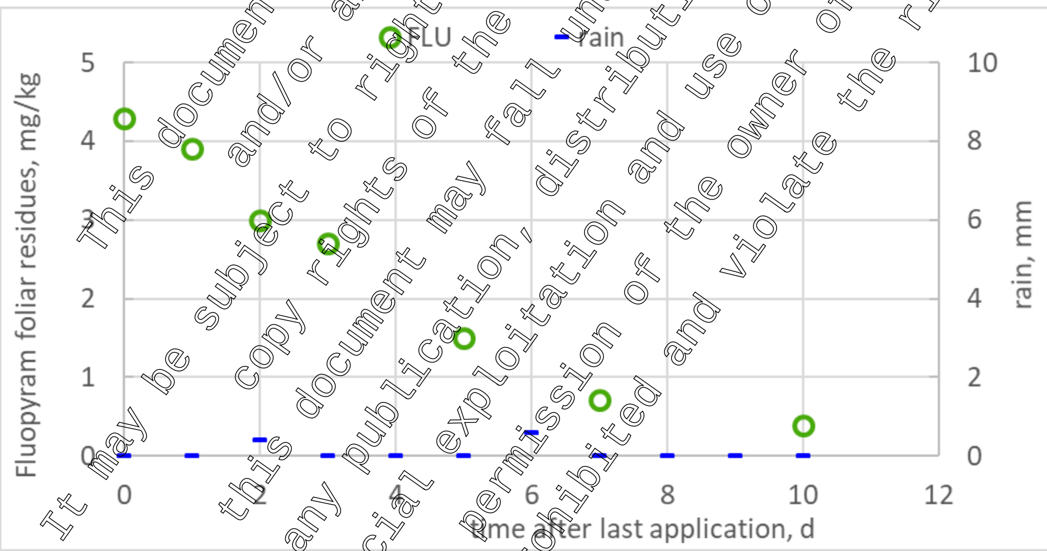


Figure 8.9- 94: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

There is no discernable relation between the slight rainfall on days 2 and 6 and the residue decline.

Table 8.9- 318: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2951-03 Mellet, BE,						at field [a]	no	Redebel (2.3 km)
M-678413-01-1	29	16/04/2018	0	6.6	not analysed	0		13
	29	17/04/2018	1	5.7		0		13
wheat, green material Propulse	30	18/04/2018	2	5.0		0		16
	30	19/04/2018	3	4.1		0		20
	30	20/04/2018	4	3.5		0		20
		21/04/2018	5			0		17
		22/04/2018	6			0		19
	31	23/04/2018	7	1.2		0		14
		24/04/2018	8			0.5 sum [b]		12
		25/04/2018	9			0.5 sum [b]		13
	31	26/04/2018	10	0.56		0.5 sum [b]		10

[a] rain gauge was placed at the field site and was read and emptied at each sampling event
[b] sum of rain for 2-3 days, where same value is marked, the value was used only for the first day in graph

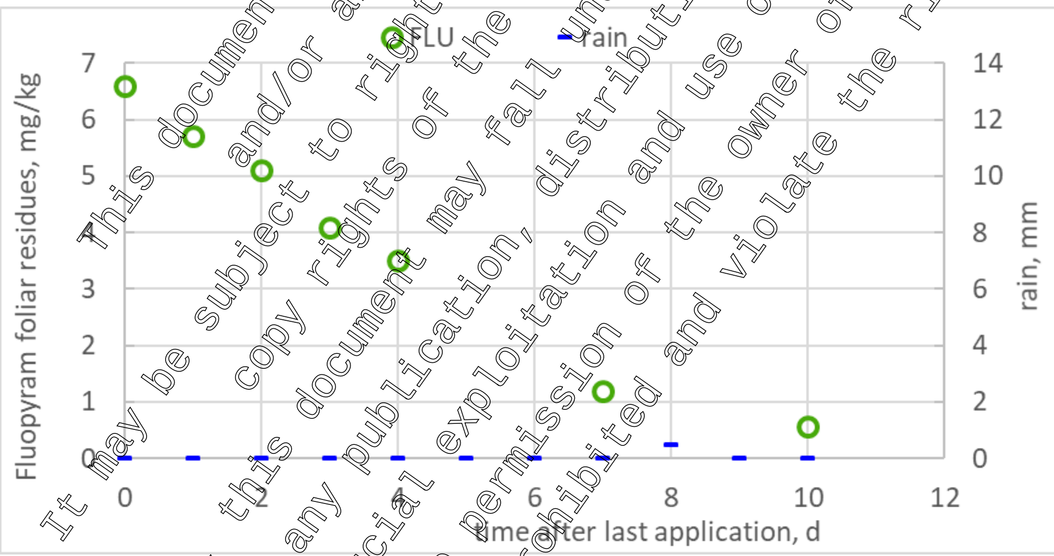


Figure 8.9- 95: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

There is no discernable relation between the rainfall and the decline curve.

III. CONCLUSION

After one spray application of Fluopyram & JAU 6476 SE 250 on wheat in three residue trials conducted in northern Europe (2 x Germany and Belgium) during the 2018 season the residues of fluopyram in/on green material declined markedly during the sampling period.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall, as observed in trial 18-2951-01 appears to have influenced the decline pattern, but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/20
Report Author:	[redacted]
Report Year:	2020
Report Title:	Amendment no. 01: Determination of the residues of prothioconazole and AE C656948 in/on wheat after spray application of AE C656948 & JAU 6476 SE 250 in Spain and Bulgaria
Report No:	18-2954
Document No:	M-675129-02-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009). US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with three supervised residue trials in the field was conducted in southern Europe (2 x Spain and Bulgaria) on wheat during the 2018 season. One application with Fluopyram & JAU 6476 SE 250 (a suspo-emulsion formulation containing 125 g/L fluopyram and 125 g/L prothioconazole (JAU 6476)) was conducted. Only the parameters and results relevant to fluopyram have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram & JAU 6476 SE 250 on wheat green material declined markedly during the sampling period.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram & JAU 6476 SE 250 (125 +125 g/L)
	Batch no.:	EV65000571
	Active Ingredient:	Fluopyram and prothioconazole
	Storage:	Not stated in the report
	Expiry date:	2020-03-10
2.	Test commodity:	Wheat
	Crop part:	Green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 18-2954 was to determine the magnitude of the relevant residues of fluopyram in/on wheat (green material) after one spray application with Fluopyram & JAU 6476 SE 250 (125 g/L + 125 g/L), a suspo-emulsion (SE) formulation containing 125 g/L fluopyram. This summary focuses only on the residues of fluopyram.

Field phase

The study included three supervised residue trials conducted in the field in southern Europe (2 x Spain and Bulgaria) during the 2018 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 319: Description of the trial locations and cropping information on treated plots

Trial number	18-2954-01	18-2954-02	18-2954-03
Trial location	44492 Fonfria	50374 Torralba de los Frailes	BG-4531 Smilets
Country	Spain	Spain	Bulgaria
Area of application	Field	Field	Field
Plot size [m^2]	300	300	360
Type of soil	Sandy Loam	Loam	Silty clay
pH-value of soil (in water)	8.3	8.5	7.6
Content of organic C [%]	1.8	1.74	0.58
Test system	Wheat	Wheat	Wheat
Variety	Alabanza	Arthur Nick	Anapurna
Date of sowing	2018-01-30	2018-01-25	2017-11-07
Start of flowering	2018-06-11	2018-06-04	2018-05-14
End of flowering	2018-06-18	2018-06-12	2018-05-22
Date of commercial harvest	2018-07-02 to 2018-07-10	2018-07-01 to 2018-07-10	2018-06-25 to 2018-07-15

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. Application was performed at an BBCH between 29-30 with an application rate of 0.119 to 0.128 kg a.s./ha and a water rate of 287-308 L/ha.

Table 8.9- 320: Overview on application with Fluopyram & JAU 6476 SE 250 on wheat

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
18-2954-01 Spain	1	T	Fluopyram & JAU 6476 SE 250	SPI	30	-	1.02	307	Fluopyram	0.127
									JAU 6476	0.127
18-2954-02 Spain	1	T	Fluopyram & JAU 6476 SE 250	SPI	30	-	0.952	287	Fluopyram	0.119
									JAU 6476	0.119
18-2954-03 Bulgaria	1	T	Fluopyram & JAU 6476 SE 250	SPI	29	-	1.03	308	Fluopyram	0.128
									JAU 6476	0.128

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of green material of wheat. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 321: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
18-2954-01 18-2954-02 18-2954-03	Wheat	Green material	C	-0
			T	0
				1
				2
				3
				5
				7
				10

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram were analysed within the residue trials samples according to the following method:

Table 8.9- 322: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram in wheat green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 323: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Wheat / green material	0.01	103; 106; 107	105	2.0	0.01
	0.50	106; 107; 109	107	1.4	
	10	100; 101; 101	101	0.6	
		Overall recovery (n = 9)	**104**	**3.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 353 and 405 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries. For fluopyram, the residues levels in/on wheat green material are summarised in the following table.

Table 8.9- 324: Residue summary of fluopyram in/on wheat, green material

Trial No. Country	Sample material	BBCH	DALT	Residues [mg/kg] a.s. fluopyram
18-2954-01 Spain	Green material	30	0	10.0
	Green material	30	1	6.6
	Green material	30	2	9.0
	Green material	31	3	8.7
	Green material	31	5	2.9
	Green material	31	7	2.5
	Green material	33	10	1.7
18-2954-02 Spain	Green material	30	0	8.1
	Green material	30	1	7.4
	Green material	30	2	8.6
	Green material	30	3	8.0
	Green material	31	5	1.8
	Green material	31	7	1.1
	Green material	37	10	0.69
18-2954-03 Bulgaria	Green material	29	0	7.0
	Green material	29	1	6.1
	Green material	30	2	5.7
	Green material	30	3	4.7
	Green material	30	5	2.4
	Green material	30	7	1.6
	Green material	31	10	0.89

DALT = Days after last treatment

Analyte: Fluopyram | Final determination as: Fluopyram | Residues calculated as: Fluopyram

2. Climatic conditions and time course of residue concentrations in/on wheat green material

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary; there is no negative impact on the study results.

Table 8.9- 325: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2954-01 Fonfria, ES,						at field [a]	no	Daroca (30 km), study raw data
M-675129-02-1	30	15/05/2018	0	10	not analysed	0		11.2
Wheat, green material Propulse	30	16/05/2018	1	6.6		0		13.3
	30	17/05/2018	2	9.0		0		14.9
	31	18/05/2018	3	8.7		0		13.2
		19/05/2018	4			20 sum [b]		14
	31	20/05/2018	5	2.9		20 sum [b]		14.3
		21/05/2018	6			0		14.1
	31	22/05/2018	7	2.5		0		16.2
		23/05/2018	8			0		16.7
		24/05/2018	9			0		19
	33	25/05/2018	10	1.7		0		16.6

[a] rain gauge was placed at the field site and was read and emptied at each sampling event
[b] sum of rain for 2-3 days, where same value is marked, the value was used only for the first day in graph

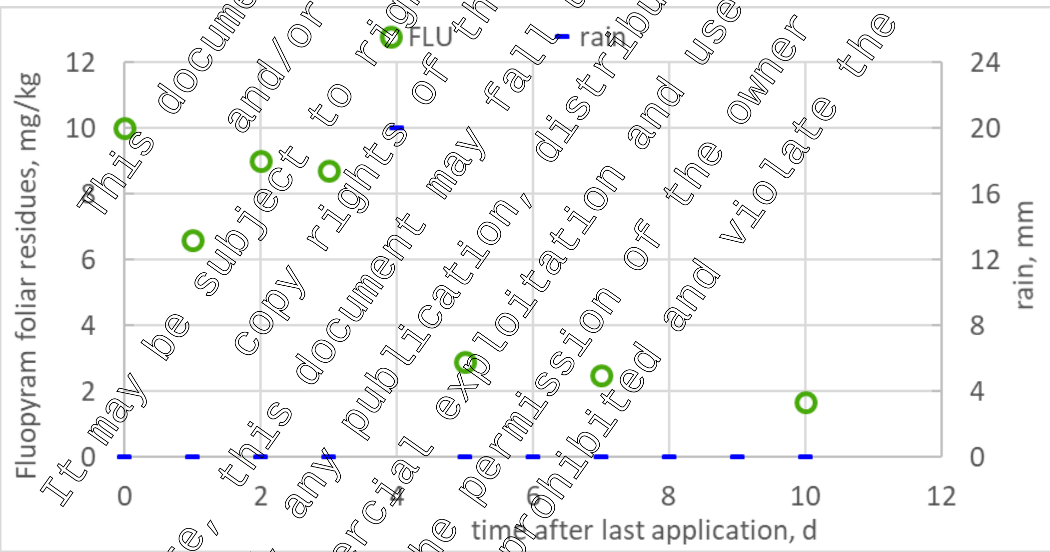


Figure 8.9- 96: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

The rainfall on day 4 (20 mm) coincides with a large drop in residue levels and a corresponding change of the slope of the decline curve.

Table 8.9- 326: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2954-02 Torralba de los Frailes, ES, M-675129-02-1 Wheat, green material Propulse						at field [a]	no	Daroca (21 km), study raw data
	30	14/05/2018	0	8.1	not analysed	0		10.5
	30	15/05/2018	1	7.4		0		11.2
	30	16/05/2018	2	8.6		0		13.3
	30	17/05/2018	3	8.0		0		14.9
		18/05/2018	4			21 sum [b]		13.2
	31	19/05/2018	5	1.8		21 sum [b]		14
		20/05/2018	6			8 sum [b]		14.3
	31	21/05/2018	7	1.1		8 sum [b]		14.1
		22/05/2018	8			4 sum [b]		16.2
		23/05/2018	9			4 sum [b]		16.7
	37	24/05/2018	10	0.69		4 sum [b]		19

[a] rain gauge was placed at the field site and was read and emptied at each sampling event
[b] sum of rain for 2-3 days, where same value is marked, the value was used only for the first day in graph

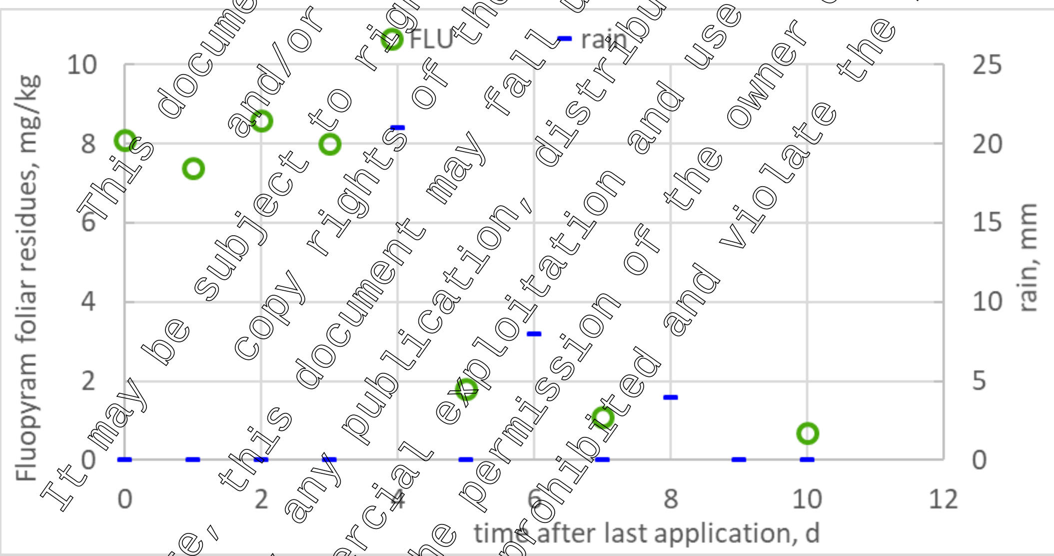


Figure 8.9- 97: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

The rainfall on day 4 (21 mm) coincides with a large drop in residue levels and a corresponding change of the slope of the decline curve.

Table 8.9- 327: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2954-03 Smilets, BG,						at field[a)]	no	Pazardzhik (19.2 km)
M-675129-02-1	29	03/04/2018	0	7.0	not analysed	0		10
Wheat, green material Propulse	29	04/04/2018	1	6.1		0		13
	30	05/04/2018	2	5.7		0		15
	30	06/04/2018	3	4.7		0		14
		07/04/2018	4			0		14
	30	08/04/2018	5	2.4		0		13
		09/04/2018	6			0		14
	30	10/04/2018	7	1.6		0		15
		11/04/2018	8			0		14
		12/04/2018	9			0		18
	31	13/04/2018	10	0.89		0		16

a) rain gauge was placed at the field site and was read and emptied at each sampling event

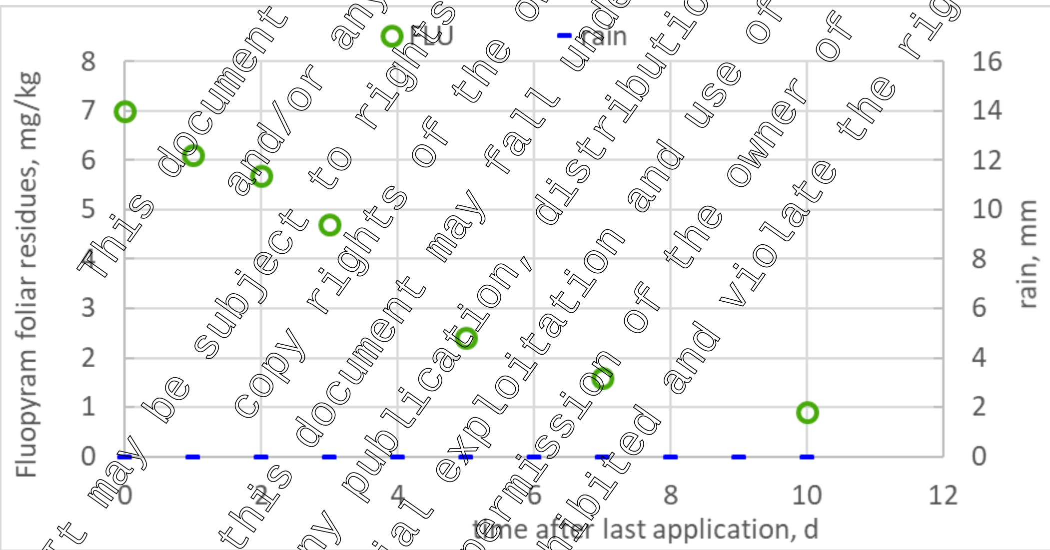


Figure 8.9- 98: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

There was no rainfall which could have unduly influenced the decline DT50.

III. CONCLUSION

After one spray application of Fluopyram & JAU 6476 SE 250 on wheat in three residue trials conducted in southern Europe (2 x Spain and Bulgaria) during the 2018 season the residues of fluopyram in/on green material declined markedly during the sampling period.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall as observed in trials 18-2954-01 and 18-2954-02 appears to have influenced the decline pattern, but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/21
Report Author:	[redacted].
Report Year:	2021
Report Title:	Determination of the residues of fosetyl-AL, prothioconazole, fluopicolide and AE C656948 in/on wheat after a spray application of FLU+PTZ SE 125+125 G U-EU and fluopicolide & Fosetyl-aluminium WG 71.1 in the field in southern France, Spain and Italy
Report No:	E19RP087
Document No:	M-758649-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four supervised residue trials in the field was conducted in southern Europe (southern France, Spain and 2 x Italy) on wheat during the 2019 season. One application with FLU+PTZ SE 125+125 G U-EU, a suspo-emulsion (SE) formulation containing 125 g/L fluopyram and 125 g/L prothioconazole, was conducted. Only the parameters and results relevant to fluopyram and fluopyram-benzamide have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram+PTZ SE 125+125 on wheat green material declined markedly during the sampling period. No residues of fluopyram-benzamide above the LOQ (0.00477 mg/kg expressed as itself) were detectable.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram & PTZ SE (125 +125 g/L)
   Batch no.: EV65000569
   Active Ingredients: Fluopyram and prothioconazole
   Storage: Not stated in the report
   Expiry date: 2022-05-23
2. Test commodity: Wheat
   Crop part: Green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study was to determine the magnitude of the relevant residues of fluopyram in/on wheat (green material) after one spray application with FLU+PTZ SE 125+125 G U-EU, a suspo-emulsion (SE) formulation containing 125 g/L fluopyram. This summary focuses only on the residues of fluopyram and its metabolite fluopyram-benzamide.

Field phase

The study included four supervised residue trials conducted in the field in southern Europe (southern France, Spain and 2 x Italy) during the 2019 season. Only the plots T1 were treated with product FLU+PTZ SE 125. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 328: Description of the trial locations and cropping information on treated plots

Trial number	E19RP087-01		E19RP087-02	
Trial location	31620 Bouloc		29200 Antequera	
Country	Southern France		Spain	
Area of application	Field (T1)	Field (T2)	Field (T1)	Field (T2)
Plot size [m^2]	75	75	33.75	33.75
Type of soil	Clayey loam	Clayey loam	Clay	Clay
pH-value of soil (in water)	8.3	8.3	7.3	7.3
Content of organic C [%]	0.7	0.7	0.66	0.66
Test system	Wheat	Wheat	Wheat	Wheat
Date of sowing	2018-10-26	2018-10-26	2019-02-08	2019-02-08
Start of flowering	2019-05-10	2019-05-10	2019-05-20	2019-05-20
End of flowering	2019-06-20	2019-06-20	2019-06-05	2019-06-05
Date of commercial harvest	2019-06-25 to 2019-07-05	2019-06-25 to 2019-07-05	2019-07-01 to 2019-07-31	2019-07-01 to 2019-07-31

Trial number	E19RP087-03		E19RP087-04	
Trial location	44042 Cento		70024 Gravina di Puglia (BA)	
Country	Italy		Italy	
Area of application	Field (T1)	Field (T2)	Field (T1)	Field (T2)
Plot size [m²]	67.5	67.5	120	120
Type of soil	Silty clay	Silty clay	Sandy Loam	Sandy Loam
pH-value of soil (in water)	7.9	7.9	7.6	7.6
Content of organic C [%]	1.05	1.05	0.99	0.99
Test system	Wheat	Wheat	Wheat	Wheat
Date of sowing	2018-11-05	2018-11-05	2018-11-20	2018-11-20
Start of flowering	2019-05-01	2019-05-01	2019-05-01	2019-05-01
End of flowering	2019-05-10	2019-05-10	2019-05-15	2019-05-15
Date of commercial harvest	2019-06-17 to 2019-06-30	2019-06-17 to 2019-06-30	2019-06-15 to 2019-07-15	2019-06-15 to 2019-07-15

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. Application was performed at BBCH stage 29 with an application rate of 0.122 to 0.126 kg a.s./ha and a water rate of 293-351 L/ha.

Table 8.9- 329: Overview on application with Fluopyram & JAU 6476 SE 250 on wheat

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
E19RP087-01 Southern France	1	T	FLU+PTZ SE 125+125 G U-EU	SPI	29	-	1.01	303	Fluopyram	0.126
									Prothio-conazole	0.126
E19RP087-02 Spain	1	T	FLU+PTZ SE 125+125 G U-EU	SPI	29	-	1.00	298	Fluopyram	0.125
									Prothio-conazole	0.125
E19RP087-03 Italy	1	T	FLU+PTZ SE 125+125 G U-EU	SPI	29	-	1.00	351	Fluopyram	0.126
									Prothio-conazole	0.126
E19RP087-04 Italy	1	T	FLU+PTZ SE 125+125 G U-EU	SPI	29	-	0.978	293	Fluopyram	0.122
									Prothio-conazole	0.122

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of green material of wheat. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 330: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
E19RP087-01 E19RP087-02 E19RP087-03 E19RP087-04	Wheat	Green material	C	-0
			T	0
				1
				2
				3
				5
				10

DALT: Days after last treatment “-0”: before the last application

2. Description of Analytical Procedures

Residues of fluopyram were analysed within the residue trials samples according to the following method:

Table 8.9- 331: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram) and 0.00477 mg/kg (for fluopyram-benzamide expressed as itself) in wheat green material

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 332: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Wheat / green material	0.01	87; 88; 91	89	2.3	0.01
	0.50	87; 88; 88	88	0.7	
	15	80; 83; 85	83	3.0	
		Overall recovery (n = 9)	**86**	**3.8**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 333: Procedural recoveries for fluopyram-benzamide

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Wheat / green material	0.005	97; 100; 104	100	3.5	0.00477
	0.20	85; 85; 89	86	2.7	
		Overall recovery (n = 6)	**93**	**8.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram-benzamide

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 300 and 324 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram and its metabolite were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries. For fluopyram, the residues levels in/on wheat green material are summarised in the following table.

Table 8.9- 334: Residue summary of fluopyram in/on wheat, green material

Trial No. Country	Sample material	BBCH	DALT	Residues [mg/kg] a.s. fluopyram	Residues [mg/kg] a.s. fluopyram-benzamide
E19RP087-01 Southern France	Green material	29	0	4.6	<0.00477
	Green material	29	1	4.8	<0.00477
	Green material	29	2	4.4	<0.00477
	Green material	30	3	4.3	<0.00477
	Green material	30	6	3.0	<0.00477
	Green material	31	10	2.5	<0.00477
E19RP087-02 Spain	Green material	29	0	5.8	<0.00477
	Green material	29	1	4.5	<0.00477
	Green material	30	2	2.8	<0.00477
	Green material	30	3	1.5	<0.00477
	Green material	31	5	0.75	<0.00477
	Green material	32	9	0.48	<0.00477
E19RP087-03 Italy	Green material	29	0	3.5	<0.00477
	Green material	29	1	3.2	<0.00477
	Green material	29	2	3.3	<0.00477
	Green material	29	3	2.6	<0.00477
	Green material	30	5	0.67	<0.00477
	Green material	31	10	0.26	<0.00477
E19RP087-04 Italy	Green material	29	0	5.7	<0.00477
	Green material	29	1	6.2	<0.00477
	Green material	29	2	5.5	<0.00477
	Green material	29	3	2.5	<0.00477
	Green material	29	5	1.3	<0.00477
	Green material	31	10	0.56	<0.00477

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram-benzamide

2. Climatic conditions and time course of residue concentrations in/on wheat green material

Climatic data recording was not conducted according to GLP. In the following, weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 335: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
E19RP087-01 Bouloc, FR, M-758649-01-1 wheat, green material Propulse						at field [a]	no	Blagnac (18 km)
	29	19/03/2019	0	4.6	FLU-benz	0		9
	29	20/03/2019	1	4.8	< LOQ	0		8
	29	21/03/2019	2	4.4		0		8
	30	22/03/2019	3	4.3		0		11
		23/03/2019	4			0		13
		24/03/2019	5			0		13
	30	25/03/2019	6	3		0		11
		26/03/2019	7			0		9
		27/03/2019	8			0		9
		28/03/2019	9			0		10
	31	29/03/2019	10	2.5		0		12

[a] rain gauge was placed at the field site and was read and emptied at each sampling event

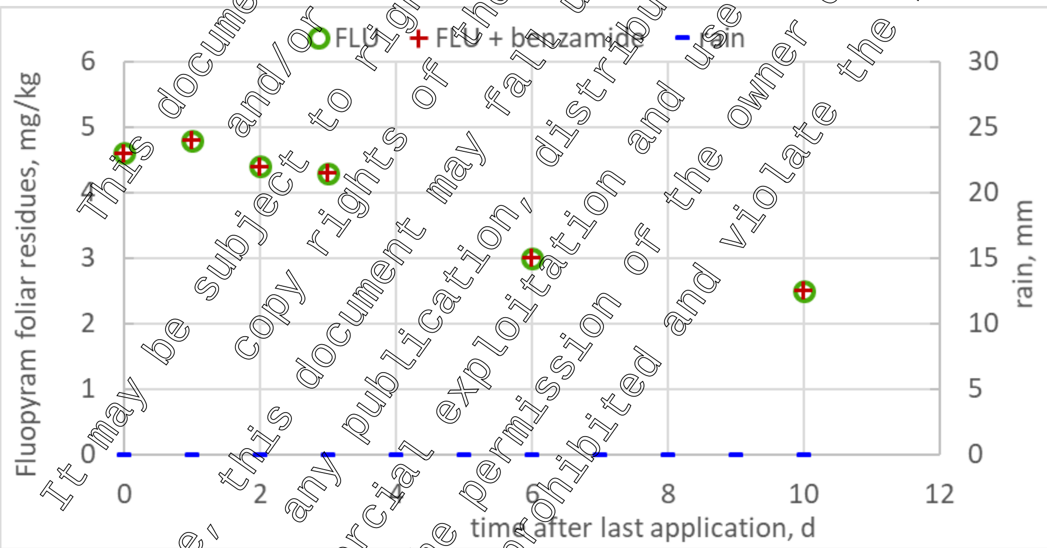


Figure 8.9- 99: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

There was no rainfall which could have unduly influenced the decline DT_{50}.

Table 8.9- 336: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
E19RP087-02 Antequera, ES,						at field [a]	no	Antequera Malaga (6 km)
	29	03/04/2019	0	5.8	FLU-benz	0		13
M-758649-01-1	29	04/04/2019	1	4.5	< LOQ	0		11
	30	05/04/2019	2	2.8		1		9
wheat,	30	06/04/2019	3	1.5		4.5		8
green material		07/04/2019	4			15 sum [b]		na
Propulse	31	08/04/2019	5	0.75		15 sum [b]		12
		09/04/2019	6			1 sum [b]		na
		10/04/2019	7			1 sum [b]		11
		11/04/2019	8			0		na
	32	12/04/2019	9	0.48		0		12

[a] rain gauge was placed at the field site and was read and emptied at each sampling event
[b] sum of rain for 2 days, where same value is marked, the value was used only for the first day in graph

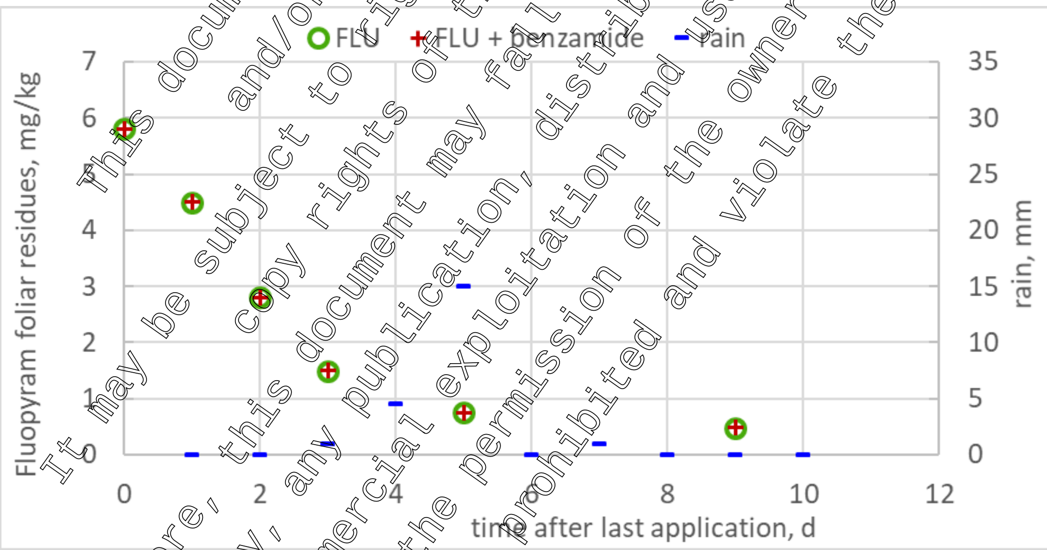


Figure 8.9- 100: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

There is no discernable relation between the rainfall on days 3, 4 and 5 and the decline curve that would unduly influence the DT_{50}.

Table 8.9- 337: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
E19RP087-03 Cento, IT, M-758649-01-1 wheat, green material Propulse						Finale Emilia Modena (15 km)	no	Finale Emilia Modena (15 km)
	29	01/04/2019	0	3.5	FLU-benz	0		14
	29	02/04/2019	1	3.2	< LOQ	0		15
	29	03/04/2019	2	3.3		1.8		14
	29	04/04/2019	3	2.6		19		12
		05/04/2019	4			2.2		10
	30	06/04/2019	5	0.67		0		11
		07/04/2019	6			1.4		12
		08/04/2019	7			0.2		12
		09/04/2019	8			0		14
		10/04/2019	9			0.6		14
	31	11/04/2019	10	0.26		5.8		12

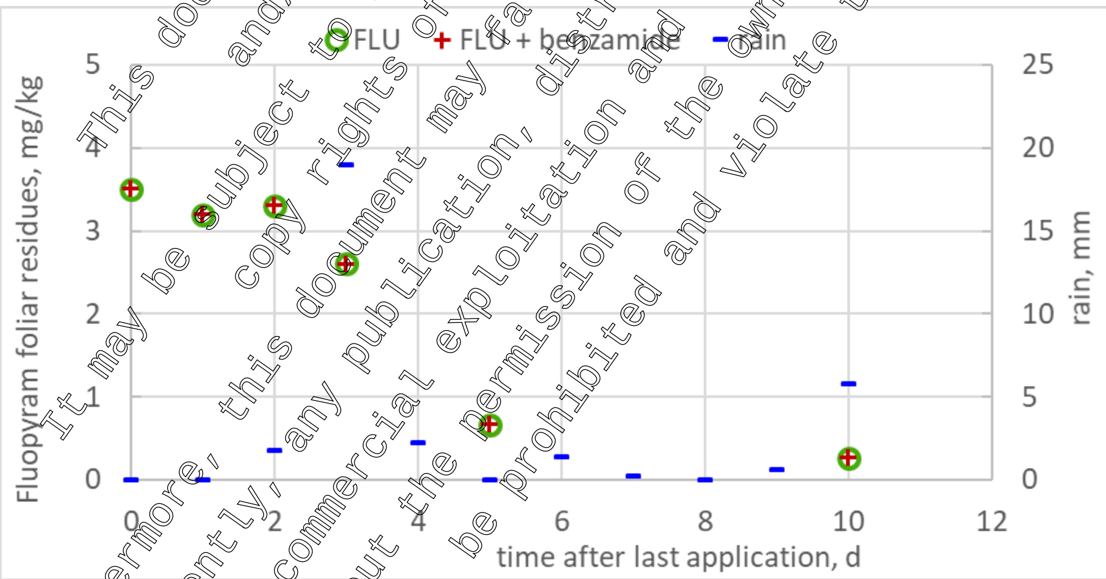


Figure 8.9- 101: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

The rainfall on day 3 (19 mm) and day 4 (2.2 mm) coincides with a large drop in residue levels and a corresponding change of the slope of the decline curve.

Table 8.9- 338: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
E19RP087-04 Gravina di Puglia, IT,						at field [a)]	no	Gioia del Colle (40 km)
	29	01/04/2019	0	5.7	FLU-benz	0		11
M-758649-01-1	29	02/04/2019	1	6.2	< LOQ	0		11
	29	03/04/2019	2	5.5		0		12
wheat, green material Propulse	29	04/04/2019	3	2.5		2		11
		05/04/2019	4			4 sum [b)]		12
	29	06/04/2019	5	1.3		4 sum [b)]		13
		07/04/2019	6			15 sum [b)]		12
		08/04/2019	7			15 sum [b)]		10
		09/04/2019	8			10 sum [b)]		10
		10/04/2019	9			10 sum [b)]		12
	31	11/04/2019	10	0.56		10 sum [b)]		9

[a)] rain gauge was placed at the field site and was read and emptied at each sampling event
[b)] sum of rain for 2-3 days, where same value is marked, the value was used only for the first day in graph

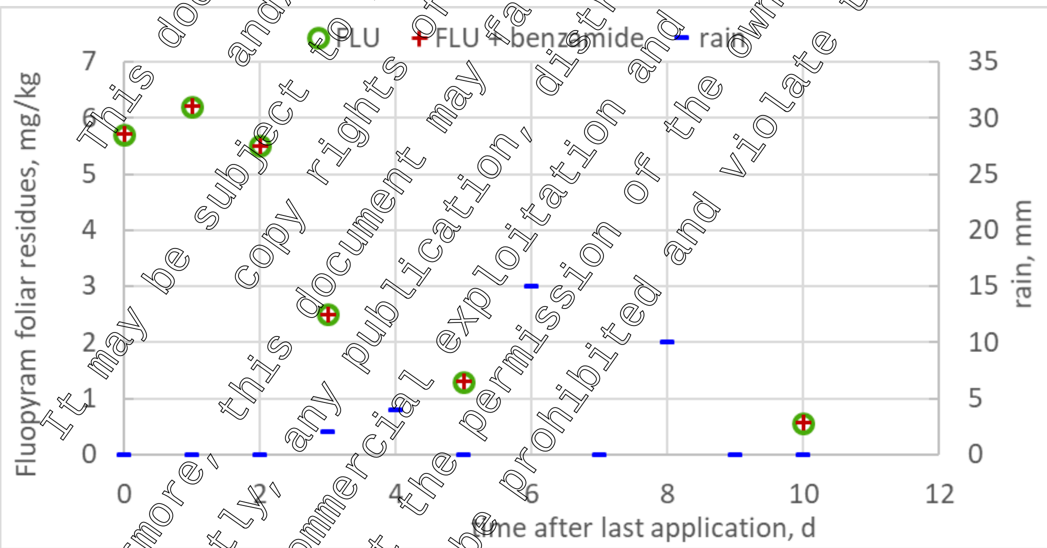


Figure 8.9-102: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

There is a possible relation between the rainfall on day 3 (2 mm) and 4 (4 mm) and the decline curve that might have influenced the DT_{50}.

III. CONCLUSION

After one spray application of FLU+PTZ SE 125+125 G U-EU on wheat in four residue trials conducted in southern Europe (southern France, Spain and 2 x Italy) during the 2019 season, the residues of fluopyram in/on green material declined markedly during the sampling period. No residues of fluopyram-benzamide above the LOQ (0.00477 mg/kg expressed as itself) were detectable.

Assessment and conclusion by applicant:
The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall as observed in trial E19RP087-03 (marked) and possibly E19RP087-04 (slight) appears to have influenced the decline pattern, but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/22
Report Author:	[redacted]
Report Year:	2020
Report Title:	Determination of the residues of fosetyl-AL, prothioconazole, fluopicolide and AE C656948 in/on wheat after a spray application of FLU+PTZ SE 125+125 G U-EU and fluopicolide & fosetyl-aluminium WG 71.1 in the field in northern France, United Kingdom and Germany
Report No:	E19RP102
Document No:	M-758824-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500 Crop Field Trial
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four supervised residue trials in the field was conducted in northern Europe (northern France, United Kingdom and 2 x Germany) on wheat during the 2019 season. One application with FLU+PTZ SE 125+125 G U-EU, a suspo-emulsion (SE) formulation containing 125 g/L fluopyram and 125 g/L prothioconazole, was conducted. Only the parameters and results relevant to fluopyram and fluopyram-benzamide have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram +PTZ SE 125+125 on wheat green material declined markedly during the sampling period. Residues of fluopyram-benzamide above the LOQ (0.00477 mg/kg expressed as itself) were detectable in one sample at DALT 10 (0.005 mg/kg).

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram & PTZ SE (125 +125 g/L) 125 G U-EU
	Batch no.:	EV65000569
	Active Ingredient:	Fluopyram and prothioconazole
	Storage:	Not stated in the report
	Expiry date:	2022-05-23
2.	Test commodity:	Wheat
	Crop part:	Green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study was to determine the magnitude of the relevant residues of fluopyram in/on wheat (green material) after one spray application with FLU+PTZ SE 125+125 G U-EU, a suspo-emulsion (SE) formulation containing 125 g/L fluopyram. This summary focuses only on the residues of fluopyram and its metabolite fluopyram-benzamide.

Field phase

The study included four supervised residue trials conducted in the field in northern Europe (northern France, United Kingdom and 2 x Germany) during the 2019 season. Only the plots T1 were treated with product FLU+PTZ SE 125. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 339: Description of the trial locations and cropping information on treated plots

Trial number	**E19RP102-01**		**E19RP102-02**	
Trial location	37270 Athée sur Cher		SG8 8SS Great Chishill, Near Royston	
Country	France		United Kingdom	
Area of application	Field (T1)	Field (T2)	Field (T1)	Field (T2)
Plot size [m²]	100	100	90	90
Type of soil	Clayey loam	Clayey loam	Clayey loam	Clayey loam
pH-value of soil (in water)	8.0	8.0	6.7	6.7
Content of organic C [%]	1.38	1.38	3.2	3.2
Test system	Wheat	Wheat	Wheat	Wheat
Variety	Filon	Filon	KWS Basset	KWS Basset
Seed rate [kg/ha]	150	150	151	151
Date of sowing	2018-10-25	2018-10-25	2018-10-23	2018-10-23
Start of flowering	2019-05-31	2019-05-31	2019-06-10	2019-06-10
End of flowering	2019-06-07	2019-06-07	2019-06-22	2019-06-22
Date of commercial harvest	2019-07-01 to 2019-07-10	2019-07-01 to 2019-07-10	2019-08-02 to 2019-08-30	2019-08-02 to 2019-08-30

Trial number	**E19RP102-03**		**E19RP102-04**	
Trial location	51399 Burscheid		63943 Röllbach	
Country	Germany		Germany	
Area of application	Field (T1)	Field (T2)	Field (T1)	Field (T2)
Plot size [m²]	144	144	25	25
Type of soil	Sandy Loam	Sandy Loam	Loess	Loess
pH-value of soil (in CaCl2)	6.8	6.8	6.1	6.1
Content of organic C [%]	1.22	1.22	1.28	1.28
Test system	Wheat	Wheat	Wheat	Wheat
Variety	Elixer	Elixer	Kerubino	Kerubino
Seed rate [kg/ha]	150	150	168	168
Date of sowing	2018-09-18	2018-09-18	2018-12-08	2018-12-08
Start of flowering	2019-05-31	2019-05-31	2019-05-20	2019-05-20
End of flowering	2019-06-04	2019-06-04	2019-06-05	2019-06-05
Date of commercial harvest	2019-08-01 to 2019-08-15	2019-08-01 to 2019-08-15	2019-07-10 to 2019-07-31	2019-07-10 to 2019-07-31

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. Application was performed at BBCH stages from 28 to 30 with an application rate of 0.127 to 0.131 kg a.s./ha and a water rate of 306-314 L/ha.

Table 8.9- 340: Overview on application with Fluopyram & JAU 6476 SE 250 on wheat

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
E19RP102-01 Northern France	1	T	FLU+PTZ SE 125+125 G U-EU	SPI	30	-	1.02	306	Fluopyram	0.128
									Prothio-conazole	0.128
E19RP102-02 United Kingdom	1	T	FLU+PTZ SE 125+125 G U-EU	SPI	28	-	1.04	311	Fluopyram	0.130
									Prothio-conazole	0.130
E19RP102-03 Germany	1	T	FLU+PTZ SE 125+125 G U-EU	SPI	29	-	1.02	307	Fluopyram	0.127
									Prothio-conazole	0.127
E19RP102-04 Germany	1	T	FLU+PTZ SE 125+125 G U-EU	SPI	29	-	1.05	314	Fluopyram	0.131
									Prothio-conazole	0.131

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of green material of wheat. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 341: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
E19RP102-01 E19RP102-02 E19RP102-03 E19RP102-04	Wheat	Green material	C	-0
			T	0
				1
				2
				3
				5
				10

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram were analysed within the residue trials samples according to the following method:

Table 8.9- 342: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram) and 0.00477 mg/kg (for fluopyram-benzamide, expressed as itself) in wheat green material

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 343: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Wheat / green material	0.01	93; 97; 98	96	2.8	0.01
	1.0	96; 96; 97	96	0.6	
	15	76; 79; 82	79	3.8	
		Overall recovery (n = 9)	**90**	**9.8**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 344: Procedural recoveries for fluopyram-benzamide

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Wheat / green material	0.005	85; 94; 96	92	6.4	0.00477
	0.50	92; 96; 102	97	5.2	
		Overall recovery (n = 6)	**94**	**5.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram-benzamide

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 288 and 322 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram and its metabolite were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries. For fluopyram, the residues levels in/on wheat green material are summarised in the following table.

Table 8.9- 345: Residue summary of fluopyram in/on wheat, green material

Trial No. Country	Sample material	BBCH	DALT	Residues [mg/kg] a.s. fluopyram	Residues [mg/kg] a.s. fluopyram-benzamide
E19RP102-01 Northern France	Green material	30	0	5.5	<0.00477
	Green material	30	1	5.3	<0.00477
	Green material	30	2	5.2	<0.00477
	Green material	31	3	4.4	<0.00477
	Green material	31	6	2.8	<0.00477
	Green material	31	10	1.9	<0.00477
E19RP102-02 United Kingdom	Green material	28	0	7.0	<0.00477
	Green material	28	1	6.6	<0.00477
	Green material	28	2	7.2	<0.00477
	Green material	28	4	5.2	<0.00477
	Green material	28	5	4.7	<0.00477
	Green material	30	10	3.0	<0.00477
E19RP102-03 Germany	Green material	29	0	6.2	<0.00477
	Green material	29	1	6.2	<0.00477
	Green material	29	2	5.6	<0.00477
	Green material	30	3	5.4	<0.00477
	Green material	30	5	3.1	<0.00477
	Green material	30	10	2.7	0.005
E19RP102-04 Germany	Green material	29	0	2.9	<0.00477
	Green material	29	1	3.2	<0.00477
	Green material	30	2	1.4	<0.00477
	Green material	30	3	1.3	<0.00477
	Green material	30	5	1.0	<0.00477
	Green material	31	10	0.71	<0.00477

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram-benzamide

2. Climatic conditions and time course of residue concentrations in/on wheat green material

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 346: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
E19RP102-01 Athée sur Cher, FR,						at field [a)]	no	Lignieres de Touraine (0 km)
M-758824-01-1	30	19/03/2019	0	5.5	FLU-benz	0		6
	30	20/03/2019	1	5.3	< LOQ	0		7
wheat, green material Propulse	30	21/03/2019	2	5.2		0		8
	31	22/03/2019	3	4.4		0		8
		23/03/2019	4			0		9
		24/03/2019	5			0		8
	31	25/03/2019	6	2.8		0		7
		26/03/2019	7			0		7
		27/03/2019	8			0		7
		28/03/2019	9			0		8
	31	29/03/2019	10	1.9		0		9

[a)] rain gauge was placed at the field site and was read and emptied at each sampling event

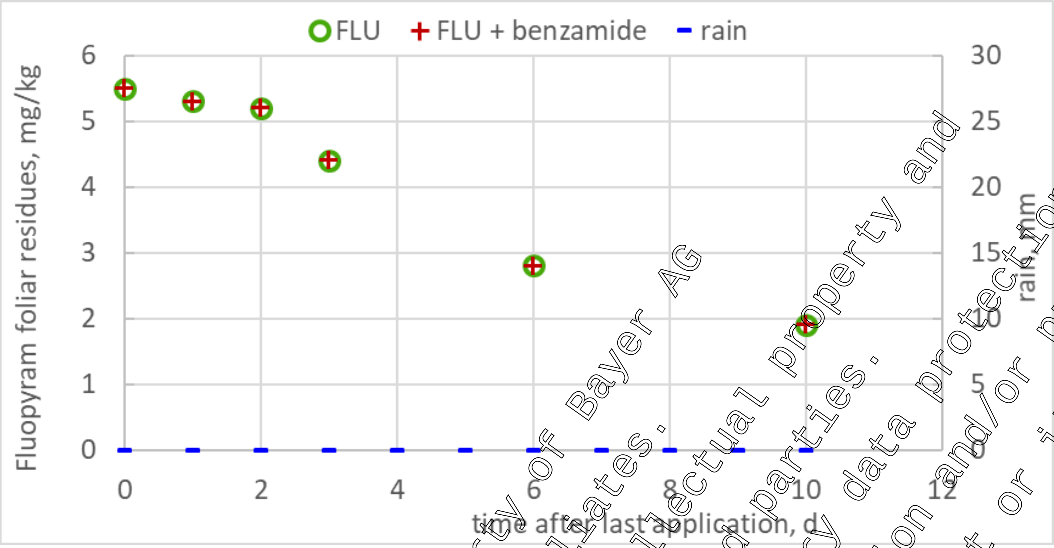


Figure 8.9- 103: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

There was no rainfall which could have unduly influenced the decline DT_{50}.

Table 8.9- 347: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
E19RP102-02 Great Chishill, Near Royston, GB, M-758824-01-1 wheat, green material Propulse						at field [a]	no	Chishill (0.4 km)
	28	11/04/2019	0	7	FLU-benz	0		5
	28	12/04/2019	1	6.6	< LOQ	0		5
	28	13/04/2019	2	7.2		0		4
		14/04/2019	3			0		4
	28	15/04/2019	4	5.2		0		7
	28	16/04/2019	5	4.7		0		12
		17/04/2019	6			0		10
		18/04/2019	7			0		13
		19/04/2019	8			0		14
		20/04/2019	9			0		13
	30	21/04/2019	10	3		0		14

[a] rain gauge was placed at the field site and was read and emptied at each sampling event

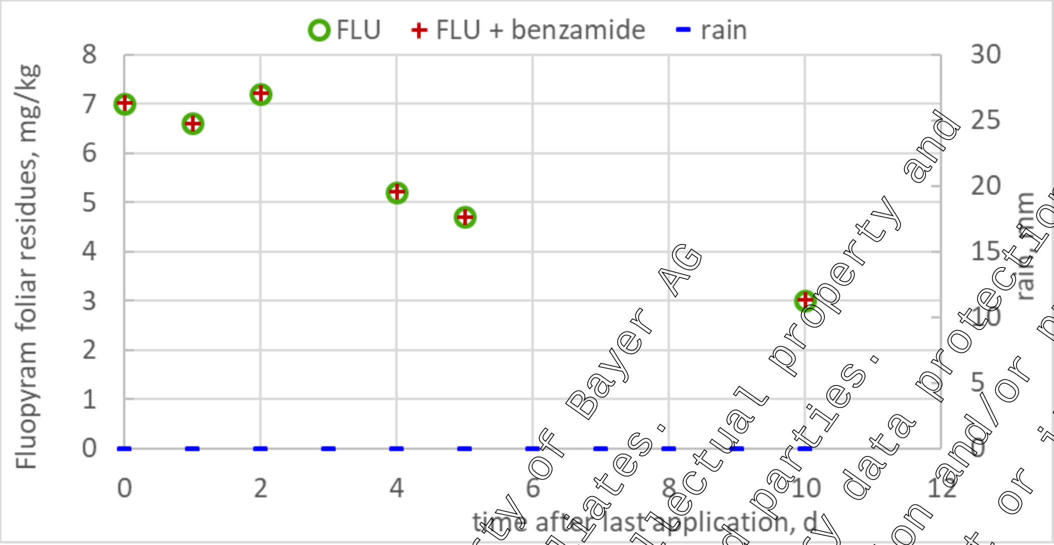


Figure 8.9- 104: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

There was no rainfall which could have unduly influenced the decline DT_{50}.

Table 8.9- 348: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
E19RP102-03 Burscheid, DE,						at field plot [c]	no	Versuchsgut Höfchen (0 km)
M-758824-01-1	29	22/03/2019	0	6.2	6.205 [a]	0		13
	29	23/03/2019	1	6.2	6.205 [a]	0		8.9
	29	24/03/2019	2	5.6	5.605 [a]	0		8.5
wheat, green material Propulse	30	25/03/2019	3	5.4	5.405 [a]	< 1 (0.2) [d]		5.7
		26/03/2019	4			2 sum (2) [e]		6.2
	30	27/03/2019	5	3.1	3.105 [a]	2 sum (0) [e]		7.4
		28/03/2019	6			0		8.2
		29/03/2019	7			0		11.2
		30/03/2019	8			0		12.1
		31/03/2019	9			0		8.7
	30	01/04/2019	10	2.7	2.710 [b]	0		9.7

[a] for FLU-benzamide 0.5 LOQ added
[b] FLU-benzamide originally not reported in mg ai. eq./kg, this was transformed here.
[c] rain gauge was placed at the field plot and was read and emptied at each sampling event
[d] at central weather station Versuchsgut Höfchen, rain: 25th March 2.2 mm, 26th March 0 mm. at plot: most likely, 26th March 2 mm, remaining 0.2 mm were linked to 25th March.
[e] sum of rain for 2 days, where same value is marked, the value was used only for the first day in graph

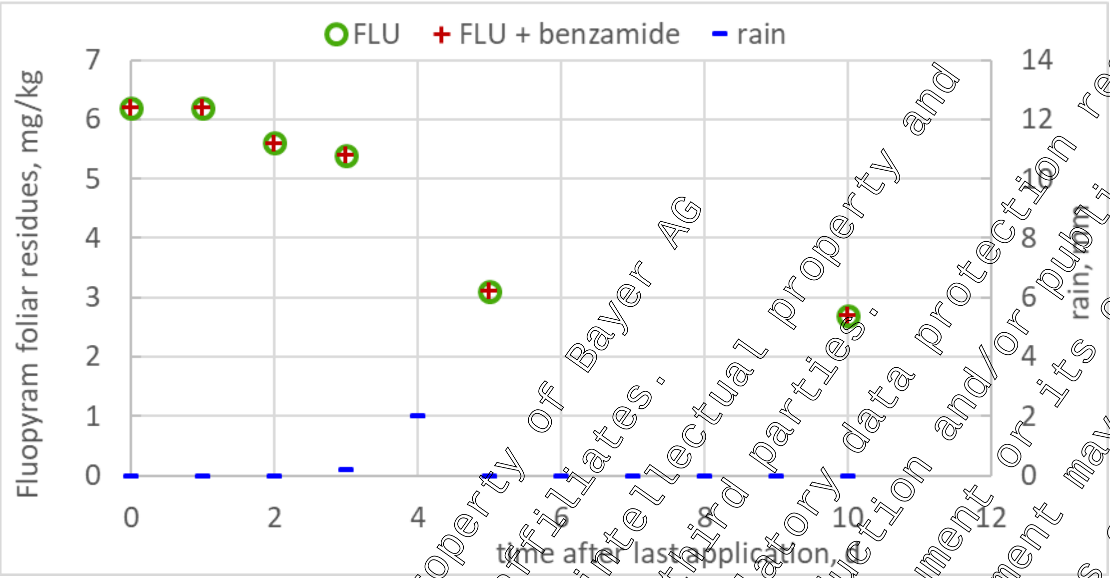


Figure 8.9- 105: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

The rainfall on day 3 (2 mm) may have slightly impacted the decline curve and influenced the DT_{50}.

Table 8.9- 349: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
E19RP102-04 Röllbach, DE,						at field [a)]	no	Röllbach (1.5 km)
M-758824-01-1	29	12/04/2019	0	2.9	FLU-benz	0		4
	29	13/04/2019	1	3.2	< LOQ	0		3
	30	14/04/2019	2	1.4		4		5
wheat, green material Propulse	30	15/04/2019	3	1.3		0		9
		16/04/2019	4			0.2 sum [b)]		12
	30	17/04/2019	5	1		0.2 sum [b)]		12
		18/04/2019	6			0		15
		19/04/2019	7			0		16
		20/04/2019	8			0		16
		21/04/2019	9			0		15
	31	22/04/2019	10	0.71		0		16

[a)] rain gauge was placed at the field site and was read and emptied at each sampling event
[b)] sum of rain for 2 days, where same value is marked, the value was used only for the first day in graph

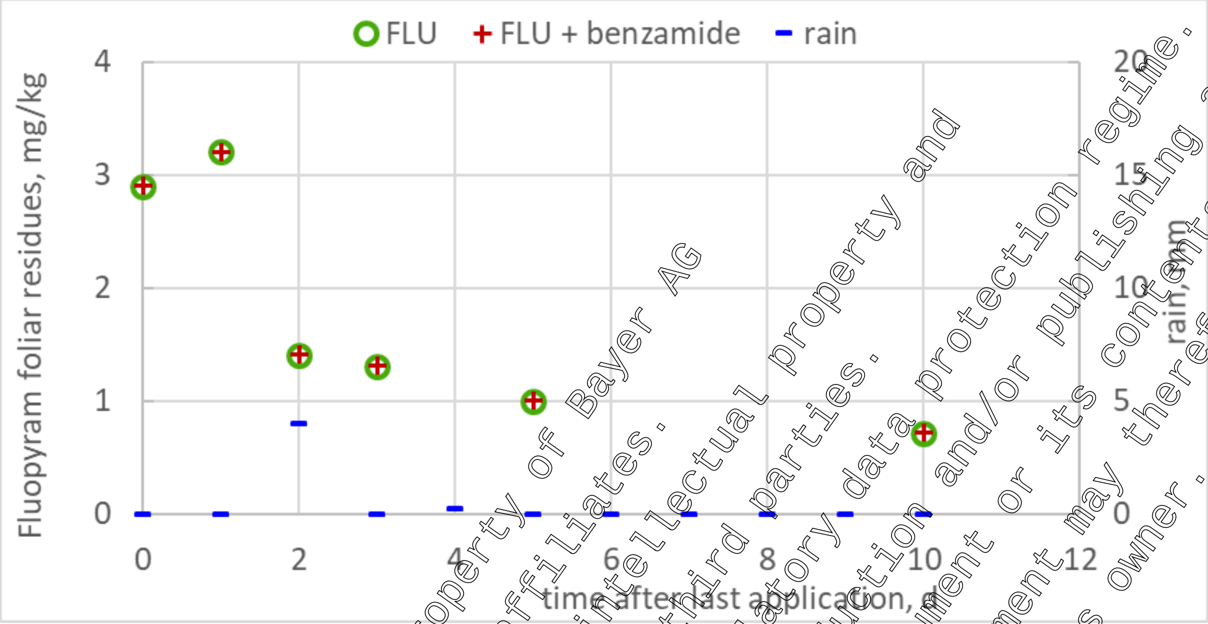


Figure 8.9- 106: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the wheat green material

The rainfall on day 1 (3 mm) may have slightly impacted the decline curve and influenced the DT_{50}.

III. CONCLUSION

After one spray application of FLU+PTZ SE 125+125 G U-EI on wheat in four residue trials conducted in northern Europe (northern France, United Kingdom and 2 x Germany) during the 2019 season, the residues of fluopyram in/on green material declined markedly during the sampling period. Residues of fluopyram-benzamide above the LOQ (0.00477 mg/kg, expressed as itself) were detectable in one sample at DALT 10 (0.005 mg/kg).

Assessment and conclusion by applicant:
The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall as observed in trials E19RP102-03 and E19RP102-04 may have slightly influenced the decline pattern, but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Non-herbs dicot plants

In the following section the residue study summaries are presented that have been analysed in the kinetic report by M-763335-01-1:

Data Point:	KCA 8.9/23
Report Author:	[redacted]
Report Year:	2010
Report Title:	Determination of the residues of AE C656948 in/on bean, kidney after spraying of fluopyram SC 500 in the field in France (North)
Report No:	08-2034
Document No:	M-365530-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in northern Europe (2 x northern France) on kidney bean during the 2008 season. Two applications with Fluopyram SC 500 containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on kidney bean, pod and green material declined markedly during the sampling period. Residues of fluopyram-benzamide, fluopyram-pyridyl-acetic acid and acid were detected above the LOQ (0.01 mg/kg) with a maximum value of 0.04 mg/kg in green material and 0.02 mg/kg in pod and 0.01 mg/kg in green material and pod, respectively. Residues of fluopyram-pyridyl-carboxylic acid were always below LOQ the LOQ in pod and green material.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram (500 SC)
	Batch no.:	2007-002115 / 2007-002559
	Active substance:	Fluopyram
	Storage:	Not stated in the report
	Expiry date:	2009-03-30 / 2009-02-06

2. Test commodity: Kidney bean

   Crop part: Pod and green material

Two different batches of the formulation were used for the application in the two trials. Batch no. 2007-002115 was used in trial 08-2034-01 and batch no. 2007-002559 was used in trial 08-2034-02.

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 08-2034 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on kidney bean (pod and green material) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

Field phase

The study included two supervised residue trials conducted in northern Europe (2 x northern France) during the 2008 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 350: Description of the trial locations and cropping information on treated plots

Trial number	08-2034-01	08-2034-02
Trial location	80700 Damery Picardie	80700 Damery Picardie
Country	France	France
Area of application	Field	Field
Plot size [m²]	60	60
Type of soil	Loam	Loam
pH-value of soil (in water)	7.5	7.5
Content of organic C [%]	1.1	1.1
Test system	Bean, kidney	Bean, kidney
Variety	Flavert	Flavert
Date of sowing	2008-05-23	2008-05-23
Start Flowering	2008-07-07	2008-07-07
End Flowering	2008-07-12	2008-07-12
Date of commercial harvest	2008-09-01 to 2008-09-08	2008-09-01 to 2008-09-08

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stage 79 and the second also at stage 79 with an application rate of 0.25 kg a.s./ha and a water rate of 500 L/ha.

Table 8.9- 351: Overview on application with Fluopyram SC 500 on kidney bean

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
08-2034-01 Northern France	1	T	Fluopyram SC 500	SPI	7	79	14	0.5	500	Fluopyram	0.25
	2					79	7*	0.5	500		0.25
08-2034-02 Northern France	1	T	Fluopyram SC 500	SPI	7	79	14	0.5	500	Fluopyram	0.25
	2					79	7*	0.5	500		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying

DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of kidney bean pod and green material. The samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 352: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
08-2034-01 08-2034-02	Kidney bean	Pod, green material	C	-0
				3
				7
				14
		Pod, green material	T	-0
				0
				3
				7
				10
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites were analysed within the residue trials samples according to the following method:

Table 8.9- 353: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in kidney bean (pod and green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The means of the concurrent recoveries were for all matrices and for all fortification levels (except 0.01 and 0.5 mg/kg for AE F148815 for which the mean recoveries were 112 and 111% respectively for the pod) within the acceptable range of 70 – 110 %. Consequently, all the results are considered as valid. The overall RSD values were below 20%. Details are given in the table below.

Table 8.9- 354: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	90		--	0.01
	0.1	94		--	
	1	96		--	
	Overall Recovery (n = 3)		93	3.3	
Kidney bean green material	0.01	85		--	0.01
	0.1	95		--	
	5	93		--	
	Overall Recovery (n = 3)		91	5.8	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 355: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	86		--	0.01
	0.1	87		--	
	1	90		--	
	Overall Recovery (n = 3)		88	2.4	
Kidney bean green material	0.01	97		--	0.01
	0.1	85		--	
	5	88		--	
	Overall Recovery (n = 3)		90	6.9	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

Table 8.9- 356: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	95		--	0.01
	0.1	87		--	
	1	88		--	
	Overall Recovery (n = 3)		90	4.8	
Kidney bean green material	0.01	77		--	0.01
	0.1	85		--	
	5	86		--	
	Overall Recovery (n = 3)		83	6.0	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram

Table 8.9- 357: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	104		--	0.01
	0.1	98		--	
	1	94		--	
	Overall recovery (n = 3)		99	5.1	
Kidney bean green material	0.01	100		--	0.01
	0.1	93		--	
	5	99		--	
	Overall recovery (n = 3)		97	3.9	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 341 and 377 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water and high protein matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on kidney bean (pod and green material) are summarised in the following table.

Table 8.9- 358: Residue summary of fluopyram in/on kidney bean

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram -pyridyl-carboxylic acid
08-2034-01 Northern France	Pod	79	-0	0.07	<0.01	<0.01	<0.01
	Green material	79	-0	0.19	<0.01	<0.01	<0.01
	Pod	79	0	0.41	<0.01	<0.01	<0.01
	Green material	79	0	3.52	0.01	<0.01	<0.01
	Pod	79	3	0.48	<0.01	<0.01	<0.01
	Green material	79	3	3.57	0.02	<0.01	<0.01
	Pod	79	7	0.17	0.01	<0.01	<0.01
	Green material	79	7	0.55	0.03	<0.01	<0.01
	Pod	81	10	0.14	0.02	<0.01	<0.01
	Green material	81	10	0.33	0.03	<0.01	<0.01
	Pod	81	14	0.16	0.02	<0.01	<0.01
	Green material	81	14	0.30	0.03	0.01	<0.01
08-2034-02 Northern France	Pod	79	-0	0.06	<0.01	<0.01	<0.01
	Green material	79	-0	0.13	<0.01	<0.01	<0.01
	Pod	79	0	0.48	<0.01	<0.01	<0.01
	Green material	79	0	3.75	0.01	<0.01	<0.01
	Pod	79	3	0.45	<0.01	<0.01	<0.01
	Green material	79	3	3.78	0.02	<0.01	<0.01
	Pod	79	7	0.17	0.01	<0.01	<0.01
	Green material	79	7	0.58	0.03	<0.01	<0.01
	Pod	81	10	0.12	0.01	<0.01	<0.01
	Green material	81	10	0.32	0.03	<0.01	<0.01
	Pod	81	14	0.14	0.02	0.01	<0.01
	Green material	81	14	0.27	0.04	0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on kidney bean

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 359: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq. /kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
08-2034-01 Damery, FR M-365530-01-1 bean, kidney, green material						Rouvroy en Santerre (6 km), study raw data	no	Rouvroy en Santerre (6 km), study raw data
	79	28/08/2008	0	3.52	3.53	0		16.4
		29/08/2008	1			0		17.3
		30/08/2008	2			0		19.6
		31/08/2008	3	3.57	3.59	2.4		19.4
		01/09/2008	4			0		16.5
		02/09/2008	5			4.2		16.1
		03/09/2008	6			0.4		13.4
		04/09/2008	7	0.55	0.58	0		14.8
		05/09/2008	8			4.2		16.2
		06/09/2008	9			0.6		16.8
		07/09/2008	10	0.33	0.36	0.2		14.8
		08/09/2008	11			0		14
		09/09/2008	12			0.4		17.1
		10/09/2008	13			0		18.4
		11/09/2008	14	0.3	0.33	14.6		18.4

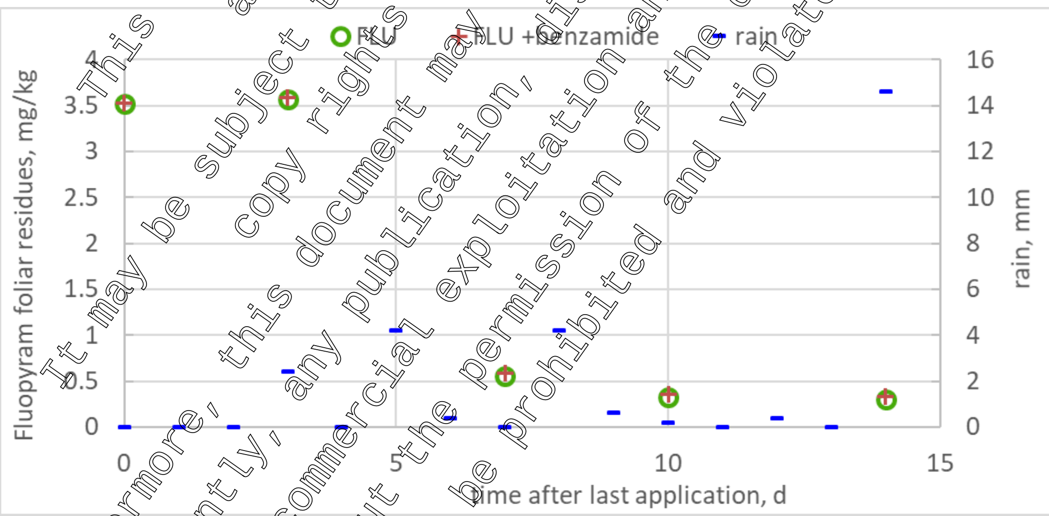


Figure 8.9- 107: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

The rainfall on day 3 (2.4 mm) and day 5 (4.2 mm) coincides with a large drop in residue levels and a corresponding change of the slope of the decline curve.

Table 8.9- 360: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg as eq./ kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
08-2034-02 Damery, FR, M-365530-01-1 bean, kidney, green material						Rouvroy en Santerre (6 km), study raw data	no	Rouvroy en Santerre (6 km), study raw data
	79	28/08/2008	0	3.75	3.76	0		16.4
		29/08/2008	1			0		17.3
		30/08/2008	2			0		19.6
		31/08/2008	3	3.78	3.8	2.4		19.4
		01/09/2008	4			0		16.5
		02/09/2008	5			4.2		16.1
		03/09/2008	6			0.4		13.4
		04/09/2008	7	0.58	0.61	0		14.8
		05/09/2008	8			4.2		16.2
		06/09/2008	9			0.6		16.8
		07/09/2008	10	0.32	0.35	0.2		14.8
		08/09/2008	11			0		14
		09/09/2008	12			0.4		17.1
		10/09/2008	13			0		18.4
		11/09/2008	14	0.27	0.31	14.6		18.4

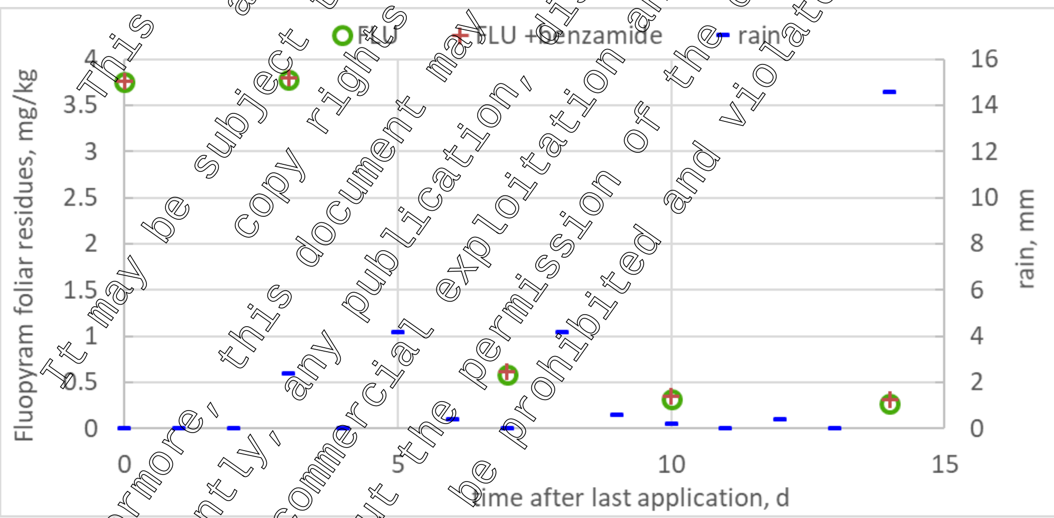


Figure 8.9- 108: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

The rainfall on day 3 (2.4 mm) and day 5 (4.2 mm) coincides with a large drop in residue levels and a corresponding change of the slope of the decline curve.

II. CONCLUSION

After two spray applications of Fluopyram SC 500 on kidney bean in two residue trials conducted in northern Europe (2 x northern France) during the 2008 season the residues of fluopyram in/on kidney bean green material declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected above the LOQ (0.01 mg/kg) in all samples with a maximum value of 0.04 mg/kg. The metabolite fluopyram-pyridyl-acetic acid was detected at the LOQ in two samples with a maximum value of 0.01 mg/kg. Residues for fluopyram-pyridyl-carboxylic acid were always below LOQ.

Residues of fluopyram in/on kidney bean pod were detected above the LOQ in all samples and declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ in almost all samples with a maximum value of 0.02 mg/kg. The metabolite fluopyram-pyridyl-acetic acid was detected slightly above the LOQ only in one sample (0.01 mg/kg). Residues for fluopyram-pyridyl-carboxylic acid were always below LOQ.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall as observed in trials 08-2034-01 and 08-2034-02 appears to have influenced the decline pattern, but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/24
Report Author:	[redacted]
Report Year:	2010
Report Title:	Determination of the residues of AE C656948 in/on bean, kidney after spraying of fluopyram SC 500 in the field in Italy
Report No:	08-2096
Document No:	M-365542-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in southern Europe (2 x Italy) on kidney bean during the 2008 season. Two applications with Fluopyram SC 500 containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on kidney bean (pod and green material) declined markedly during the sampling period. Residues of fluopyram-benzamide were detected above the LOQ (0.01 mg/kg) in almost all samples with a maximum value of 0.10 mg/kg in green material and 0.03 mg/kg in pod. Residues of fluopyram-pyridyl-acetic acid were detected with maximum values of 0.02 mg/kg in green material and pod. Residues of fluopyram-pyridyl-carboxylic acid were always below the LOQ.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram (500 SC)
	Batch no.:	2007-002115 / 2007-002559
	Active substance:	Fluopyram
	Storage:	Not stated in the report
	Expiry date:	2009-03-30 / 2009-02-06
2.	Test commodity:	Kidney bean
	Crop part:	Pod and green material

Two different batches of the formulation were used for the application in the two trials. Batch no. 2007-002115 was used in trial 08-2034-01 and batch no. 2007-002559 was used in trial 08-2034-02.

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 08-2096 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on kidney bean (pod and green material) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

Field phase

The study included two supervised residue trials conducted in southern Europe (2 x Italy) during the 2008 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 361: Description of the trial locations and cropping information on treated plots

Trial number	08-2096-01	08-2096-02
Trial location	00055 Ladispoli (RM), Lazio	00055 Ladispoli (RM), Lazio
Country	Italy	Italy
Area of application	Field	Field
Plot size [m^2]	80	80
Type of soil	Clay Sand	Clay Sand
pH-value of soil (in water)	6.9	6.9
Content of organic C [%]	0.8	0.8
Test system	Bean, kidney	Bean, kidney
Variety	Bronco	Bronco
Date of sowing	2008-05-05	2008-05-05
Start Flowering	2008-06-16	2008-06-16
End Flowering	2008-07-08	2008-07-08
Date of commercial harvest	2008-06-20 to 2008-07-31	2008-06-20 to 2008-07-31

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stage 62 and the second at 75 with an application rate of 0.25 kg a.s./ha and a water rate of 800 L/ha.

Table 8.9- 362: Overview on application with Fluopyram SC 500 on kidney bean

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
08-2034-01 Northern France	1	T	Fluopyram SC 500	SPI	7	62	14	0.5	800	Fluopyram	0.25
	2					75	7*	0.5	800		0.25
08-2034-02 Northern France	1	T	Fluopyram SC 500	SPI	7	62	14	0.5	800	Fluopyram	0.25
	2					75	7*	0.5	800		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of kidney bean pod and green material. The samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 363: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
08-2096-01 08-2096-02	Kidney bean	Pod, green material	C	-0
				3
				7
				14
		Pod, green material	T	-0
				0
				3
				7
				10
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites were analysed within the residue trials samples according to the following method:

Table 8.9- 364: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in kidney bean (pod and green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The means of the concurrent recoveries were for all matrices and for all fortification levels within the acceptable range of 70 – 110 %. Consequently, all the results are considered as valid. The overall RSD values were below 20%. Details are given in the tables below.

Table 8.9- 365: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	86	--	--	0.01
	0.1	105	--	--	
	1	110	--	--	
	Overall Recovery (n = 3)		**100**	**12.6**	
Kidney bean green material	0.01	109	--	--	0.01
	0.1	100	--	--	
	10	87	--	--	
	Overall Recovery (n = 3)		**99**	**11.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 366: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	93	--	--	0.01
	0.1	90	--	--	
	1	99	--	--	
	Overall Recovery (n = 3)		94	4.9	
Kidney bean green material	0.01	97	--	--	0.01
	0.1	97	--	--	
	10	92	--	--	
	Overall Recovery (n = 3)		95	3.0	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

Table 8.9- 367: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	89	--	--	0.01
	0.1	98	--	--	
	1	94	--	--	
	Overall Recovery (n = 3)		94	4.8	
Kidney bean green material	0.01	89	--	--	0.01
	0.1	91	--	--	
	10	89	--	--	
	Overall Recovery (n = 3)		90	1.3	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram

Table 8.9- 368: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	94	--	--	0.01
	0.1	93	--	--	
	1	97	--	--	
	Overall recovery (n = 3)		95	2.2	
Kidney bean green material	0.01	110	--	--	0.01
	0.1	94	--	--	
	10	91	--	--	
	Overall recovery (n = 3)		98	10.4	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 433 and 456 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water and high protein matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on kidney bean (pod and green material) are summarised in the following table.

Table 8.9- 369: Residue summary of fluopyram in/on kidney bean

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram -pyridyl-carboxylic acid
08-2034-01 Northern France	Pod	75	-0	0.04	<0.01	<0.01	<0.01
	Green material	75	-0	0.65	0.03	<0.01	<0.01
	Pod	75	0	0.39	<0.01	<0.01	<0.01
	Green material	75	0	7.7	0.04	<0.01	<0.01
	Pod	77	3	0.24	0.01	<0.01	<0.01
	Green material	77	3	4.6	0.06	<0.01	<0.01
	Pod	79	7	0.11	0.02	<0.01	<0.01
	Green material	79	7	0.82	0.08	0.02	<0.01
	Pod	79	10	0.09	0.02	<0.01	<0.01
	Green material	79	10	0.67	0.08	0.02	<0.01
	Pod	79	14	0.06	0.03	0.02	<0.01
	Green material	79	14	0.41	0.10	0.02	<0.01
08-2034-02 Northern France	Pod	75	-0	0.05	<0.01	<0.01	<0.01
	Green material	75	-0	0.59	0.03	<0.01	<0.01
	Pod	75	0	0.42	<0.01	<0.01	<0.01
	Green material	75	0	6.5	0.04	<0.01	<0.01
	Pod	77	3	0.32	0.01	<0.01	<0.01
	Green material	77	3	5.4	0.07	<0.01	<0.01
	Pod	79	7	0.15	0.02	<0.01	<0.01
	Green material	79	7	0.85	0.08	0.02	<0.01
	Pod	79	10	0.13	0.03	0.02	<0.01
	Green material	79	10	0.73	0.08	0.02	<0.01
	Pod	79	14	0.08	0.03	0.01	<0.01
	Green material	79	14	0.36	0.09	0.02	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on kidney bean

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 370: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
08-2096-01 Ladispoli, IT, M-365542-01-1 bean, kidney, green material						www.ilmeteo.it Ladispoli	sprinkler	www.ilmeteo.it Ladispoli
	75	01/07/2008	0	7.7	7.74	0		26
		02/07/2008	1			0		24
		03/07/2008	2			0		26
		04/07/2008	3	4.6	4.66	0		27
		05/07/2008	4			0		24
		06/07/2008	5			0	25	23
		07/07/2008	6			0		26
		08/07/2008	7	0.82	0.9	0		26
		09/07/2008	8			0		23
		10/07/2008	9			0		21
		11/07/2008	10	0.67	0.75	0		23
		12/07/2008	11			0	25	23
		13/07/2008	12			nd		26
		14/07/2008	13			0		23
		15/07/2008	14	0.41	0.51	0		22

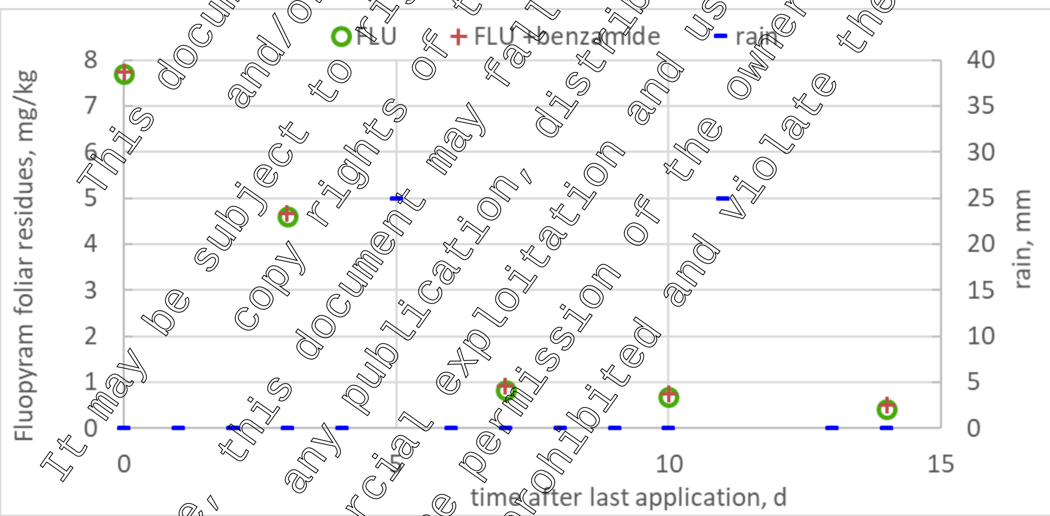


Figure 8.9- 109: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

There is no discernable relation between the irrigation on day 5 (25 mm) and day 11 (25 mm) and the decline curve that would unduly influence the DT_{50}.

Table 8.9- 371: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
08-2096-02 Ladispoli, IT, M-365542-01-1 bean, kidney, green material						www.ilmeteo.it Ladispoli	sprinkler	www.ilmeteo.it Ladispoli
	75	01/07/2008	0	6.5	6.54	0		26
		02/07/2008	1			0		24
		03/07/2008	2			0		26
		04/07/2008	3	5.4	5.47	0		27
		05/07/2008	4			0		24
		06/07/2008	5			0	25	23
		07/07/2008	6			0		26
		08/07/2008	7	0.85	0.93	0		26
		09/07/2008	8			0		23
		10/07/2008	9			0		21
		11/07/2008	10	0.73	0.81	0		23
		12/07/2008	11			0	25	23
		13/07/2008	12			nd		26
		14/07/2008	13			0		23
		15/07/2008	14	0.36	0.45	0		22

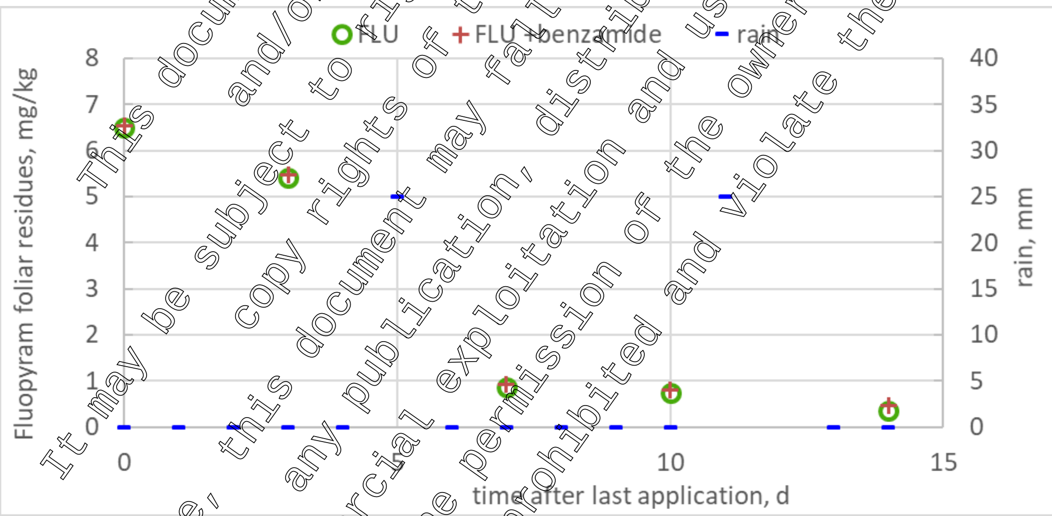


Figure 8.9- 110: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

The irrigation on day 5 (25 mm) may have impacted the decline curve and influenced the DT_{50}.

II. CONCLUSION

After two spray applications of Fluopyram SC 500 on kidney bean in two residue trials conducted in southern Europe (2 x Italy) during the 2008 season the residues of fluopyram in/on kidney bean green material declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected above the LOQ (0.01 mg/kg) in all samples with a maximum value of 0.10 mg/kg. The metabolite fluopyram-pyridyl-acetic acid was detected slightly above the LOQ in six samples with a maximum value of 0.02 mg/kg. Residues of fluopyram-pyridyl-carboxylic acid were always below the LOQ.

Residues of fluopyram in/on kidney bean pod were detected above the LOQ in all samples and declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ in almost all samples with a maximum value of 0.03 mg/kg. The metabolite fluopyram-pyridyl-acetic acid was detected slightly above the LOQ in three samples with a maximum value of 0.02 mg/kg. Residues of fluopyram-pyridyl-carboxylic acid were always below the LOQ.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Irrigation as applied in trials 08-2096-01 and 08-2096-02 appears to have influenced the decline pattern in 08-2096-02, but irrigation of vegetable fields is a typical and necessary factor during periods without rainfall, and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/25
Report Author:	[redacted]
Report Year:	2012
Report Title:	Determination of the residues of AE C656948 in/on endive (scarole) after spraying of fluopyram SC 500 in the field in the Netherlands, Germany, Belgium and northern France
Report No:	10-2099
Document No:	M-423901-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed; EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in northern Europe (Netherlands, Germany, Belgium and northern France) on endive during the 2010 season. Two applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on endive scarole head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected above the LOQ of 0.01 mg/kg in six samples. The other metabolites were always below the LOQ of 0.01 mg/kg

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram SC 500

   Batch no.: 2009-002566

   Active Ingredient: Fluopyram

   Storage: Not stated in the report

   Expiry date: 2011-06-04

2. Test commodity: Endive

   Crop part: Scarole head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 10-2099 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on endive (scarole) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

Field phase

The study included four supervised residue trials conducted in northern Europe (Netherlands, Germany, Belgium and northern France) during the 2010 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 372: Description of the trial locations and cropping information on treated plots

Trial number	10-2099-01	10-2099-02	10-2099-03	10-2099-04
Trial location	1771 RS Wieringerwerf	40764 Langenfeld-Reusrath	6210 Villers-Perwin	37230 Fondettes
Country	Netherlands	Germany	Belgium	France
Area of application	Field	Field	Field	Field
Plot size [m^2]	30	33	24	60
Type of soil	Clay	Loamy sand	Loam	Sand
pH-value of soil (in water)	7.0	7.0	5.4 in KCl	8.3
Content of organic C [%]	1.16	3.7	1.9	0.55
Test system	Endive	Endive	Endive	Endive
Variety	Seance Cos or Romaine (escarole)	Stratego escarole variety	Ramones escarole variety	Kalinka Chicoree scarole
Date of planting	2010-07-07	2010-04-28	2010-05-28	2010-04-21
Date of commercial harvest	2010-08-20 to 2010-08-24	2010-06-14 to 2010-07-27	2010-07-13 to 2010-07-23	2010-06-01 to 2010-09-01

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stages between 31-46 and the second between 44-47 with an application rate of 0.25 kg a.s./ha and a water rate of 300-500 L/ha.

Table 8.9- 373: Overview on application with Fluopyram SC 500 on endive

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
10-2099-01 Netherlands	1	T	Fluopyram SC 500	SPI	7	46	14	0.5	300	Fluopyram	0.25
	2					47	7				0.25
10-2099-02 Germany	1	T	Fluopyram SC 500	SPI	7	43	14	0.5	300	Fluopyram	0.25
	2					47	7				0.25
10-2099-03 Belgium	1	T	Fluopyram SC 500	SPI	7	31	14	0.5	500	Fluopyram	0.25
	2					44	7				0.25
10-2099-04 France	1	T	Fluopyram SC 500	SPI	7	45	14	0.5	300	Fluopyram	0.25
	2					47	7				0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of endive. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 374: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
10-2099-01 10-2099-02 10-2099-03 10-2099-04	Endive (Scarole)	Head	C	-0
				7
				21
			T	-0
				0
				3
				7
				14
				21

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites were analysed within the residue trials samples according to the following method:

Table 8.9- 375: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in endive scarole)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and its metabolites were not corrected for apparent residues in the control samples used for these recoveries. Fortification levels were calculated as fluopyram and the LOQ for all analytes was 0.01 mg/kg calculated as fluopyram. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the tables below.

Table 8.9- 376: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Endive / head	0.01	96		-	0.01
	0.10	82	-	-	
	1.0	99	-	-	
	5	91			
	10	104			
		Overall recovery (n = 5)	**94**	**8.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 377: Procedural recoveries for fluopyram-benzamide

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Endive / head	0.01	100		-	0.01
	0.10	78	-	-	
	1.0	97			
	10	89	-	-	
		Overall recovery (n = 4)	**91**	**10.8**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 378: Procedural recoveries for fluopyram-pyridyl-acetic acid

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Endive / head	0.01	75		-	0.01
	0.10	73	-	-	
	1.1	79			
	11	88			
		Overall recovery (n = 4)	**79**	**8.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 379: Procedural recoveries for fluopyram-pyridyl-carboxylic acid

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Endive / head	0.01	86			0.01
	0.10	78	-	-	
	1.0	101			
	10	101			
		Overall recovery (n = 4)	**92**	**125**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 432 and 537 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on endive scarole head are summarised in the following table.

Table 8.9- 380: Residue summary of fluopyram in/on endive, head

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
10-2099-01 The Netherlands	Head	47	-0	0.18	<0.01	<0.01	<0.01
	Head	47	0	3.6	0.01	<0.01	<0.01
	Head	48	3	1.7	<0.01	<0.01	<0.01
	Head	49	7	0.07	<0.01	<0.01	<0.01
	Head	49	14	0.01	<0.01	<0.01	<0.01
	Head	49	21	<0.01	<0.01	<0.01	<0.01
10-2099-02 Germany	Head	47	-0	0.97	<0.01	<0.01	<0.01
	Head	47	0	4.3	0.02	<0.01	<0.01
	Head	48	3	0.75	<0.01	<0.01	<0.01
	Head	49	7	0.70	0.01	<0.01	<0.01
	Head	49	14	0.34	<0.01	<0.01	<0.01
	Head	49	21	0.07	<0.01	<0.01	<0.01
10-2099-03 Belgium	Head	44	-0	1.1	0.01	<0.01	<0.01
	Head	44	0	6.9	0.02	<0.01	<0.01
	Head	46	3	1.2	0.01	<0.01	<0.01
	Head	48	7	0.40	<0.01	<0.01	<0.01
	Head	49	14	0.19	<0.01	<0.01	<0.01
	Head	49	21	0.19	<0.01	<0.01	<0.01
10-2099-04 France	Head	47	-0	0.09	<0.01	<0.01	<0.01
	Head	47	0	4.9	<0.01	<0.01	<0.01
	Head	48	3	1.2	<0.01	<0.01	<0.01
	Head	49	7	0.19	<0.01	<0.01	<0.01
	Head	49	14	0.05	<0.01	<0.01	<0.01
	Head	49	21	0.03	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on endive

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 381: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
10-2099-01 Wieringerwerf, NL, M-423901-01-1						KMNI Medemblik (8 km), study raw data	no	KMNI Medemblik (8 km), study raw data
endive, green material	47	13/08/2010	0	3.6	3.61	0.2		16
		14/08/2010	1			0		18.1
		15/08/2010	2			5.3		17.7
		16/08/2010	3	1.7	1.705 [b]	11.4		19.3
		17/08/2010	4			13.9		16.3
		18/08/2010	5			0		16.9
		19/08/2010	6			0		17.2
		20/08/2010	7	0.07	0.07	0		19.7
		21/08/2010	8			0		20
		22/08/2010	9			0		18.2
		23/08/2010	10			10.8		18.2
		24/08/2010	11			7.5		16
		25/08/2010	12			2.1		15.8
		26/08/2010	13			25.6		14.5
		27/08/2010	14	0.01	0.01	14.2		14.7
		28/08/2010	15			6.1		14.8
		29/08/2010	16			19.2		13.6
		30/08/2010	17			4.4		15
		31/08/2010	18			0		13.8
		01/09/2010	19			0		13.3
		02/09/2010	20			0.6		13.4
		03/09/2010	21	0.005 [a]	0.005	0		14.6

[a] for FLU 0.5 LOD added [b] for FLU-benzamide 0.5 LOD added

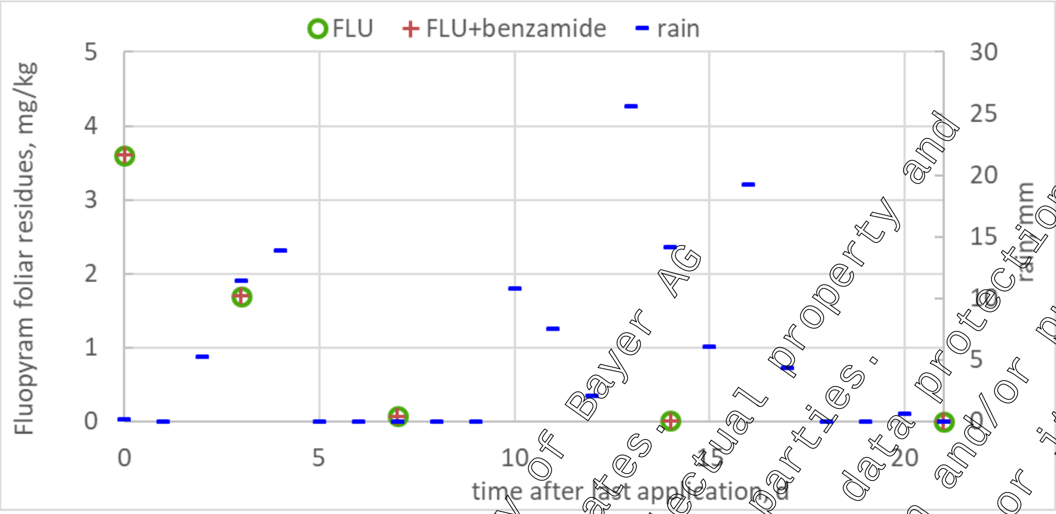


Figure 8.9- 111: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to endive

There is no discernable relation between the rainfall and the decline curve, but significant rainfall occurred already on day 2 (5.3 mm), day 3 (11.4 mm) and 4 (13.9 mm) and could have unduly influenced the DT_{50}.

Table 8.9- 382: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
10-2099-02 Langenfeld-Reusrath, DE, M-423901-01-1 endive, green material						ProPlant DB Monheim (2.5 km)	no	ProPlant DB Monheim (2.5 km)
	47	08/06/2010	0	4.3	4.32	3.4 (0) [b]		19.5
		09/06/2010	1			2.8		20.6
		10/06/2010	2			0.3		21.5
		11/06/2010	3	0.75	0.755 [a]	5.3		21.4
		12/06/2010	4			1.4		16.2
		13/06/2010	5			0		15.7
		14/06/2010	6			0		19.2
		15/06/2010	7	0.7	0.71	0		16.7
		16/06/2010	8			0		17.6
		17/06/2010	9			0		19.5
		18/06/2010	10			0		15.4
		19/06/2010	11			1.2		12.8
		20/06/2010	12			1.3		13
		21/06/2010	13			0		14.9
		22/06/2010	14	0.34	0.345 [a]	0		18.3
		23/06/2010	15			0		20
		24/06/2010	16			0		22.3
		25/06/2010	17			0		21.8
		26/06/2010	18			0		22.1
		27/06/2010	19			0		24.3
		28/06/2010	20			0		25.3
		29/06/2010	21	0.07	0.07	0.1		23.6

[a] for FLU-benzamide 0.5 LOD added
[b] no rain within 24 h after application, as in study report

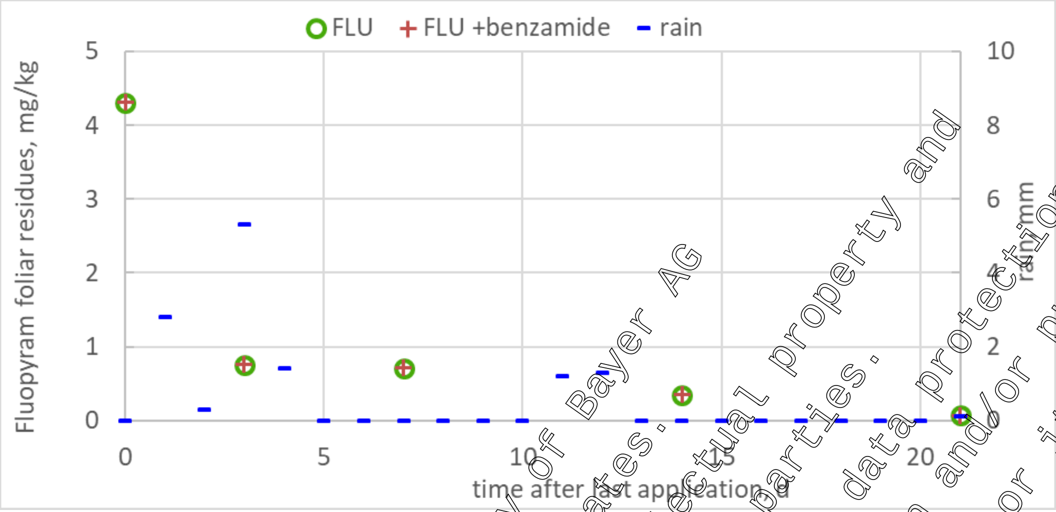


Figure 8.9- 112: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to endive.

Rainfall already on day 1 (2.8 mm) and day 3 (5.3 mm) could have unduly influenced the DT_{50}.

Table 8.9- 383: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
10-2099-03 Villers-Perwin, BE,						Redebel (2.5 km), study raw data	sprinkler	Redebel (2.5 km), study raw data
M-423901-01-1	44	02/07/2010	0	6.9	6.92	0		26.9
endive, green material		03/07/2010	1			2.5		21.8
		04/07/2010	2			0		20.2
		05/07/2010	3	1.2	1.21	0.3		17.9
		06/07/2010	4			0	1.4	17.5
		07/07/2010	5			0	1.4	19.9
		08/07/2010	6			0	1.4	24.3
		09/07/2010	7	0.4	0.405 a)	0	1.4	25.4
		10/07/2010	8			2.3	1.4	24.8
		11/07/2010	9			0.3	1.4	24.8
		12/07/2010	10			4.6		20.9
		13/07/2010	11			0		21.1
		14/07/2010	12			18.7		21.3
		15/07/2010	13			0.3		18.8
		16/07/2010	14	0.19	0.19	0		19.8
		17/07/2010	15			0		17.2
		18/07/2010	16			0		16.8
		19/07/2010	17			0		20.9
		20/07/2010	18			0		23.7
		21/07/2010	19			0		20.5
		22/07/2010	20			0		19.5
		23/07/2010	21	0.19	0.19	18.1		16.5

a) for FLU-benzamide 0.5 LOD added

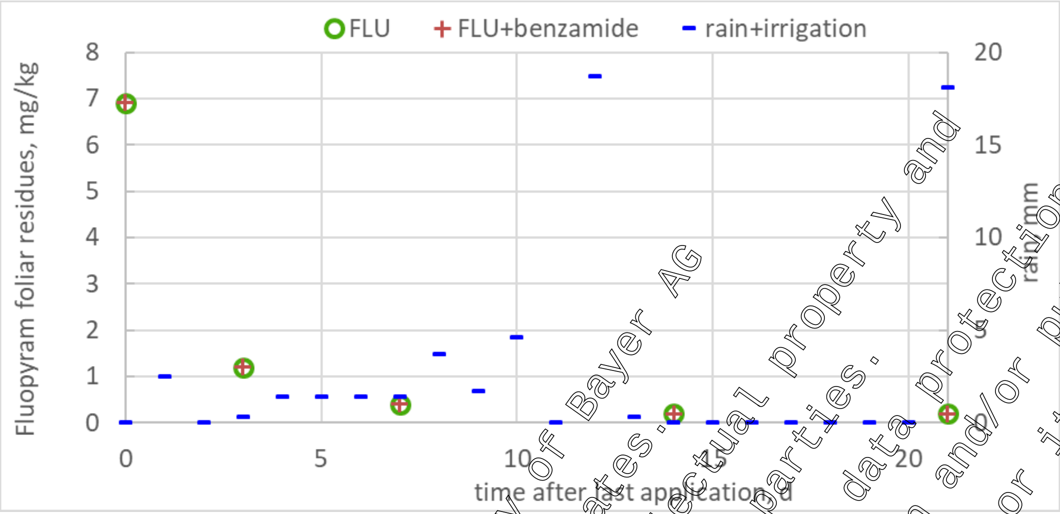


Figure 8.9- 113: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the endive.

There is no discernable relation between the rainfall and the decline curve, but small amounts of rainfall occurred already on day 1 (2.5 mm) and might have slightly influenced the DT_{50}.

Table 8.9- 384: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
10-2099-04 Fondettes, FR,						Parcay Meslay (8 km), study raw data	no	Parcay Meslay (8 km), study raw data
M-423901-01-1	47	04/06/2010	0	4.9	FLU-benz	0		21.8
		05/06/2010	1		<LOD	0.6		23.4
endive, green material		06/06/2010	2			1.8		17.7
		07/06/2010	3	1.2		0.2		16.1
		08/06/2010	4			1.8		17.7
		09/06/2010	5			5		16.8
		10/06/2010	6			16.6		18
		11/06/2010	7	0.19		12.3		18.6
		12/06/2010	8			0		18
		13/06/2010	9			0		17.2
		14/06/2010	10			1.6		15.1
		15/06/2010	11			0		16.7
		16/06/2010	12			9.5		15.4
		17/06/2010	13			1		15.8
		18/06/2010	14	0.05		0		17.1
		19/06/2010	15			0.2		13.3
		20/06/2010	16			0		12.8
		21/06/2010	17			0		13.8
		22/06/2010	18			0		18
		23/06/2010	19			0		19.7
		24/06/2010	20			0		21.8
		25/06/2010	21	0.03		0		22.3

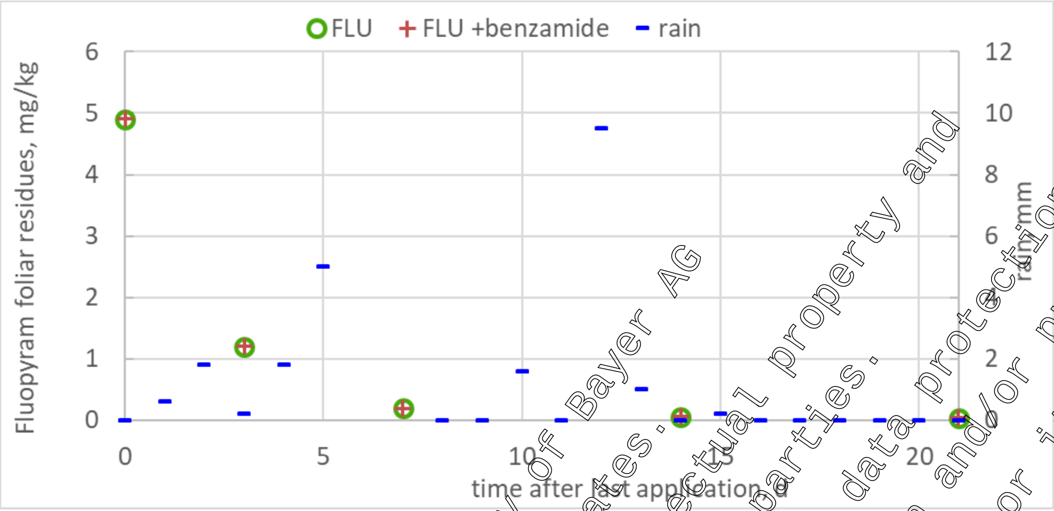


Figure 8.9- 114: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the endive.

There is no discernible relation between the rainfall and the decline curve, but a little rainfall occurred already on day 1 (0.6 mm) and day 2 (1.8 mm) and could have influenced the DT_{50}.

III. CONCLUSION

After two spray applications of Fluopyram SC 500 on endive in four residue trials conducted in northern Europe (Netherlands, Germany, Belgium and northern France) during the 2010 season the residues of fluopyram in/on endive scarole head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in 6 samples in amounts slightly above the LOQ of 0.01 mg/kg with a maximum value of 0.02 mg/kg. The residues of metabolites fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall in all trials appears to have influenced the decline pattern, but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/26
Report Author:	[redacted]
Report Year:	2019
Report Title:	Determination of the residues of AE C656948 in/on lettuce after spray application of fluopyram SC 250 or fluopyram SC 500 in Italy, Spain and Greece
Report No:	18-2086
Document No:	M-675005-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in southern Europe (2 x Italy, Spain and Greece) on lettuce during the 2018 season. Two applications with either Fluopyram SC 250 or Fluopyram SC 500 were conducted. The parameters and results relevant to fluopyram and its metabolite fluopyram-benzamide have been reported within this study summary.

The residues of fluopyram after spray application of either Fluopyram SC 250 or Fluopyram SC 500, respectively, on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in almost all samples with a maximum value of 0.19 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Items: Fluopyram 250 SC / Fluopyram 500 SC

   Batch no.: 2018-000886 / NK43GX1710

   Active Ingredient: Fluopyram

   Storage: Not stated in the report

   Expiry date: 2020-03-07 / 2020-01-05

2. Test commodity: Lettuce

   Crop part: Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 18-2086 was to determine the magnitude of the relevant residues of fluopyram and its metabolite fluopyram-benzamide in/on lettuce (head) after two spray applications with either Fluopyram SC 250 or Fluopyram SC 500, suspension concentrate formulations containing 250 g/L and 500 g/L fluopyram. This summary reports the residues of fluopyram and its metabolite fluopyram-benzamide.

<u>Field phase</u>

The study included four supervised residue trials conducted in southern Europe (2 x Italy, Spain and Greece) during the 2018 season. Each trial location consisted of two treatment plots, for each used formulation. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 385: Description of the trial locations and cropping information on treated plots

Trial number	**18-2086-01**		**18-2086-02**		**18-2086-03**		**18-2086-04**	
Trial location	00050 Palidoro Fiumicino (RM)		70038 Terlizzi		46230 Alginet		57006 Vasilika,Thessalonikis	
Country	Italy		Italy		Spain		Greece	
Area of application	Field (T1)	Field (T2)	Field (T1)	Field (T2)	Field (T1)	Field (T2)	Field (T1)	Field (T2)
Plot size [m^2]	60		40		34		25	
Type of soil	Sandy Loam		Clayey silt		Loamy sand		Loam	
pH-value of soil (in water)	7.1		7.9		8.0		7.8	
Content of organic C [%]	5.0		1.46		0.88		1.16	
Test system	Lettuce		Lettuce		Lettuce		Lettuce	
Variety	Catalogna rossa Loose leaf variety		KIPLING RZ oak leaf		Vitrai Loose leaf variety		Gracion Loose leaf variety	
Date of planting	2018-04-24		2018-07-17		2018-03-27		2018-05-22	
Date of commercial harvest	2018-05-20 to 2018-06-10		2018-09-15 to 2018-09-30		2018-05-10 to 2018-05-31		2018-06-15	

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stages between 18-47 and the second between 43-49 with an application rate of 0.24-0.262 kg a.s./ha and a water rate of 393-610 L/ha.

Table 8.9- 386: Overview on application with Fluopyram & CGA 279202 SC 250 on lettuce

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (kg a.s. /ha)
18-2086-01 Italy	1	T1	Fluopyram SC 250	SPI	7	47	14	0.973	487	Fluopyram	0.243
	2					49	7*	1.04	517		0.259
18-2086-02 Italy	1	T1	Fluopyram SC 250	SPI	7	45	14	0.959	575	Fluopyram	0.240
	2					47	7*	1.02	610		0.254
18-2086-03 Spain	1	T1	Fluopyram SC 250	SPI	7	43	14	1.04	416	Fluopyram	0.260
	2					46	7*	1.05	419		0.262
18-2086-04 Greece	1	T1	Fluopyram SC 250	SPI	7	18	14	1.01	405	Fluopyram	0.252
	2					43	7*	0.980	393		0.245

a.s.: Active substance   DBH: Days before harvest
Appl.: Application   PHI: Pre-harvest interval
SPI: Spraying   * designated as pre-harvest interval (PHI)

Table 8.9- 387: Overview on application with Fluopyram & CGA 279202 SC 500 on lettuce

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
18-2086-01 Italy	1	T2	Fluopyram SC 500	SPI	7	47	14	0.517	517	Fluopyram	0.258
	2					49	7*	0.484	487		0.242
18-2086-02 Italy	1	T2	Fluopyram SC 500	SPI	7	45	14	0.502	603	Fluopyram	0.251
	2					47	7*	0.508	610		0.254
18-2086-03 Spain	1	T2	Fluopyram SC 500	SPI	7	43	14	0.486	389	Fluopyram	0.243
	2					46	7*	0.519	416		0.259
18-2086-04 Greece	1	T2	Fluopyram SC 500	SPI	7	18	14	0.510	409	Fluopyram	0.255
	2					43	7*	0.500	401		0.250

a.s.: Active substance   DBH: Days before harvest
Appl.: Application   PHI: Pre-harvest interval
SPI: Spraying   * designated as pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of lettuce. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule presented in the following table. An exception occurred in trials 18-2086-02 and -03 where the maximum temperature during transport was above -18°C for a short period. This had no impact on the study since the scenario is considered to be covered by storage stability study M-480441-06-1, (wheat green material, 8 hours at +1°C, followed by 7, 19 & 22 days at +7°C).

Table 8.9- 388: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
18-2086-01 18-2086-02 18-2086-03 18-2086-04	Lettuce	Head	C	-0
				7
			T	-0
				0
				3
				7
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolite fluopyram-benzamide were analysed within the residue trials samples according to the following method:

Table 8.9- 389: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in lettuce head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 390: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	98; 106; 113	106	7.1	0.01
	0.10	100; 102; 105	102	2.5	
	0.50	80; 100; 104	95	13.6	
	10	90; 99; 101; 105; 111; 113	103	8.2	
		Overall recovery (n = 15)	**102**	**8.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 391: Procedural recoveries for fluopyram-benzamide

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	99; 101; 109	103	5.1	0.01
	0.10	105; 107; 108	107	1.4	
	0.50	83; 104; 109	99	14.0	
		Overall recovery (n = 9)	**103**	**8.0**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 181 and 336 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolite, the residues levels in/on lettuce head are summarised in the following table.

Table 8.9- 392: Residue summary of fluopyram in/on lettuce, head

Trial No. Country	Plot	Sample material	BBCH	DALT	Residues [mg/kg] a.s. fluopyram	Residues [mg/kg] fluopyram-benzamide
18-2086-01 Italy	T1	Head	49	-0	0.61	0.024
		Head	49	0	3.4	0.027
		Head	49	3	2.3	0.022
		Head	49	7	2.2	0.081
		Head	59	14	0.86	0.12
	T2	Head	49	-0	0.57	0.022
		Head	49	0	3.6	0.026
		Head	49	3	2.3	0.034
		Head	49	7	1.9	0.11
		Head	59	14	1.1	0.19
18-2086-02 Italy	T1	Head	47	-0	5.6	0.019
		Head	47	0	9.2	0.022
		Head	48	3	5.6	0.026
		Head	49	7	1.8	0.021
		Head	49	14	0.50	0.016
	T2	Head	47	-0	3.9	0.015
		Head	47	0	10	0.017
		Head	48	3	7.3	0.017
		Head	49	7	2.3	0.020
		Head	49	14	0.77	0.019
18-2086-03 Spain	T1	Head	46	-0	0.69	0.010
		Head	46	0	8.8	0.021
		Head	47	3	5.1	0.025
		Head	49	7	3.5	0.027
		Head	49	14	0.43	0.013
	T2	Head	46	-0	0.61	<0.01
		Head	46	0	7.8	0.013
		Head	47	3	4.9	0.029
		Head	49	7	2.8	0.032
		Head	49	14	0.44	0.011
18-2086-04 Greece	T1	Head	43	-0	0.36	0.011
		Head	43	0	10	0.023
		Head	45	3	1.7	0.015
		Head	49	7	0.31	<0.01
		Head	49	14	0.031	<0.01
	T2	Head	43	-0	0.34	0.014
		Head	43	0	9.0	0.017
		Head	45	3	1.5	0.014
		Head	49	7	0.28	<0.01
		Head	49	14	0.033	<0.01

DALT = Days after last treatment

Analyte: Final determination as: Residues calculated as:

Fluopyram Fluopyram-benzamide	Fluopyram Fluopyram-benzamide	Fluopyram Fluopyram

2. Climatic conditions and time course of residue concentrations in/on lettuce

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 393: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2086-01-T1 Palidoro Fiumicino, IT,						MARS grid 62117 (25×25 km)	drip	MARS grid 62117 (25×25 km)
M-675005-01-1	49	29/05/2018	0	3.4	3.427	0.2 (0) [b]		24.3
		30/05/2018	1			0		25.6
lettuce, green material		31/05/2018	2			0		22.8
	49	01/06/2018	3	2.3	2.322	0		22.6
		02/06/2018	4			0		23.1
		03/06/2018	5			0.2		24.3
		04/06/2018	6			0.2		22.8
	49	05/06/2018	7	2.2	2.281	0		20.6
		06/06/2018	8			0		21.5
		07/06/2018	9			0.6		22.9
		08/06/2018	10			0		22
		09/06/2018	11			0		21.9
		10/06/2018	12			0		22.6
		11/06/2018	13			0		24.6
	59	12/06/2018	14	0.86	0.98	0		22.5

[b] no rain within 24 h after application, as in study report

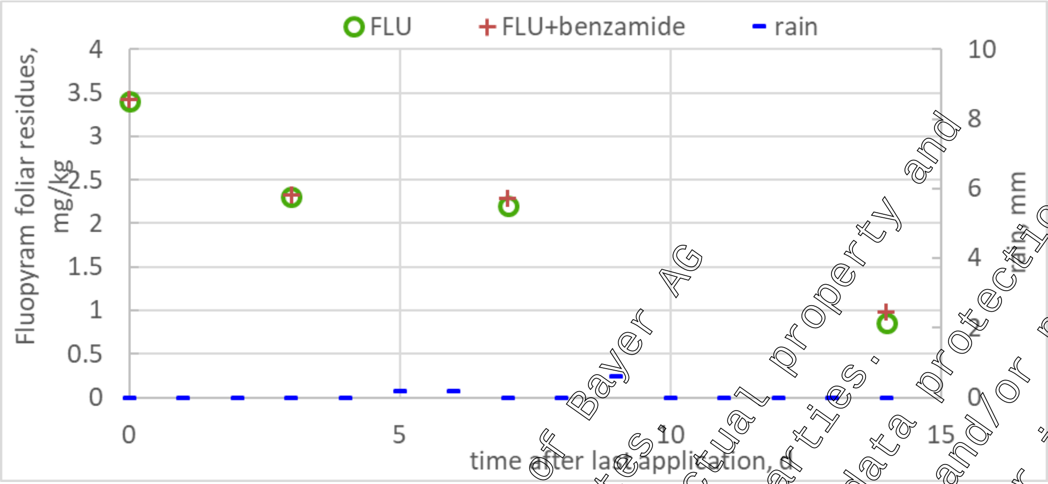


Figure 8.9- 115: Plots of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce (T1).

There was very little rainfall and no discernable influence on the residue time course.

Table 8.9- 394: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2086-01-T2 Palidoro Fiumicino, IT,						MARS grid 62117 (25×25 km)	drip	MARS grid 62117 (25×25 km)
M-675005-01-1	49	29/05/2018	0	3.6	3.626	0.2 (0) [a]		24.3
		30/05/2018	1			0		25.6
lettuce, green material		31/05/2018	2			0		22.8
	49	01/06/2018	3	2.3	2.334	0		22.6
		02/06/2018	4			0		23.1
		03/06/2018	5			0.2		24.3
		04/06/2018	6			0.2		22.8
	49	05/06/2018	7	1.9	2.01	0		20.6
		06/06/2018	8			0		21.5
		07/06/2018	9			0.6		22.9
		08/06/2018	10			0		22
		09/06/2018	11			0		21.9
		10/06/2018	12			0		22.6
		11/06/2018	13			0		24.6
	59	12/06/2018	14	1.1	1.29	0		22.5

[a] no rain 24 h after application

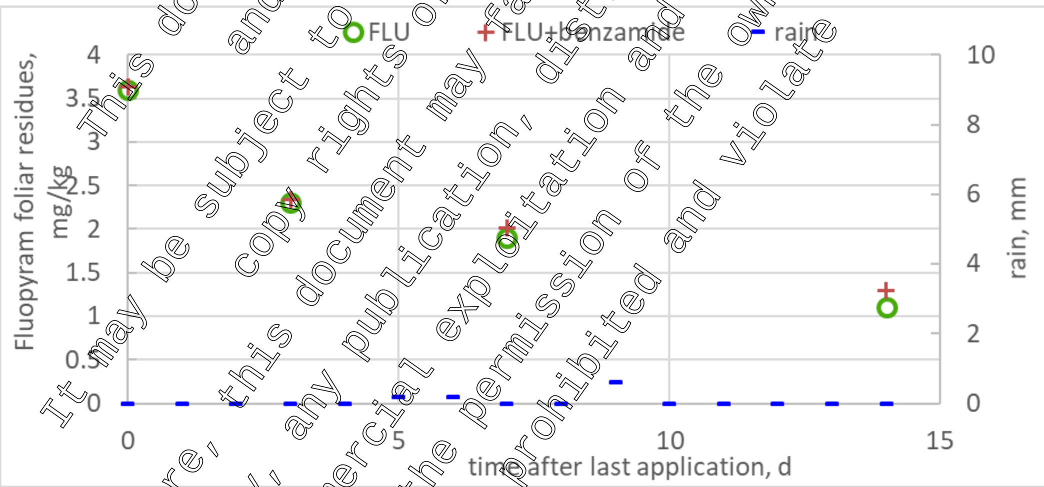


Figure 8.9- 116: Plots of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce (T2).

There was very little rainfall and no discernable influence on the residue time course.

Table 8.9- 395: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2086-02-T1 Terlizzi, IT,						Bari Palese (17 km), study raw data	drip	Bari Palese (17 km), study raw data
M-675005-01-1	47	14/09/2018	0	9.2	9.222	0		22.91
		15/09/2018	1			0		22.46
lettuce,		16/09/2018	2			0		22.53
green material	48	17/09/2018	3	5.6	5.626	0		22.74
		18/09/2018	4			0		22.91
		19/09/2018	5			0.2		23.63
		20/09/2018	6			0		22.67
	49	21/09/2018	7	1.8	1.821	0		22.46
		22/09/2018	8			0		23.07
		23/09/2018	9			0		24.98
		24/09/2018	10			0		23.92
		25/09/2018	11			0		18.54
		26/09/2018	12			0		17.95
		27/09/2018	13			0		17.85
	49	28/09/2018	14	0.5	0.516	0		17.96

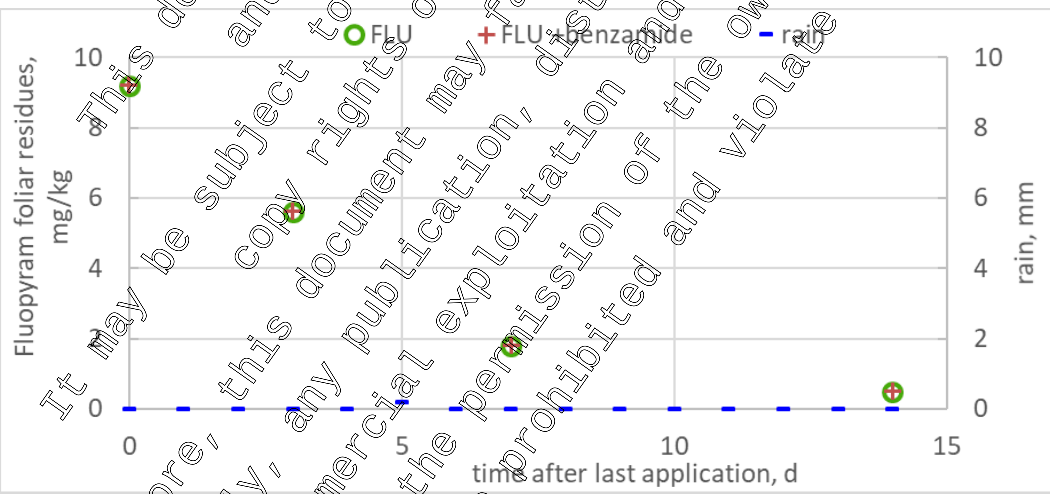


Figure 8.9- 117: Plots of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce (T1).

There was very little rainfall and no discernable influence on the residue time course.

Table 8.9- 396: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2086-02-T2 Terlizzi, IT,						Bari Palese (17 km), study raw data	drip	Bari Palese (17 km), study raw data
M-675005-01-1	47	14/09/2018	0	10	10.017	0		22.91
		15/09/2018	1			0		22.46
lettuce, green material		16/09/2018	2			0		22.53
	48	17/09/2018	3	7.3	7.317	0		22.74
		18/09/2018	4			0		22.91
		19/09/2018	5			0.2		23.63
		20/09/2018	6			0		22.67
	49	21/09/2018	7	2.3	2.32	0		22.46
		22/09/2018	8			0		23.07
		23/09/2018	9			0		24.98
		24/09/2018	10			0		23.92
		25/09/2018	11			0		18.54
		26/09/2018	12			0		17.95
		27/09/2018	13			0		17.85
	49	28/09/2018	14	0.77	0.789	0		17.96

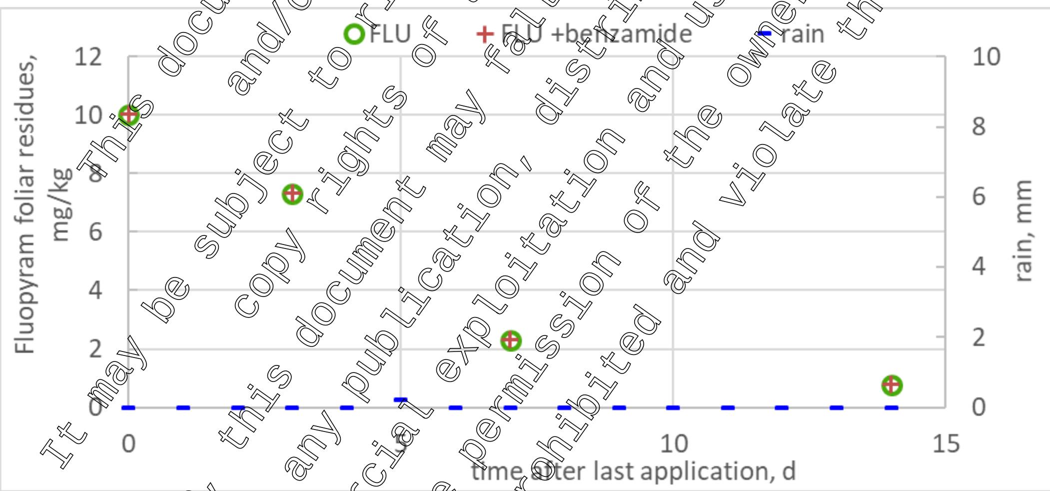


Figure 8.9- 118: Plots of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce (T2).

There was very little rainfall and no discernable influence on the residue time course.

Table 8.9- 397: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2086-03-T1 Alginet, ES, M-675005-01-1 lettuce, green material						Algemesi (5.2 km), study raw data	drip	Algemesi (5.2 km), study raw data
	46	30/04/2018	0	8.8	8.821	0		15.15
		01/05/2018	1			0		13.67
		02/05/2018	2			0		17.04
	47	03/05/2018	3	5.1	5.125	0		18.67
		04/05/2018	4			0		15.99
		05/05/2018	5			0		17.42
		06/05/2018	6			0		17.9
	49	07/05/2018	7	3.5	3.527	0		17.45
		08/05/2018	8			0		18.83
		09/05/2018	9			0		19.22
		10/05/2018	10			0		18.75
		11/05/2018	11			0		19.58
		12/05/2018	12			0		21.74
		13/05/2018	13			0		17.18
	49	14/05/2018	14	0.43	0.443	0		17.23

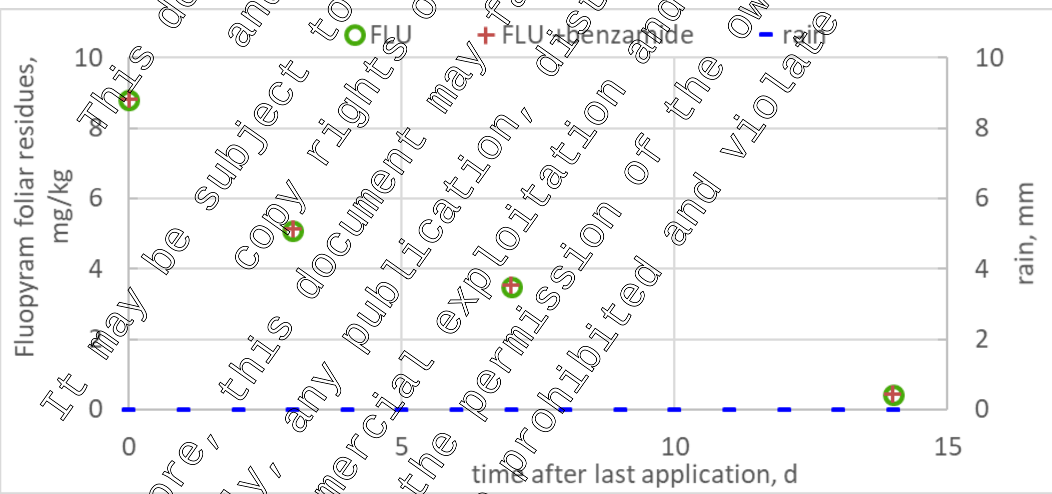


Figure 8.9- 119: Plots of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce (T1).

There was very little rainfall and no discernable influence on the residue time course.

Table 8.9- 398: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2086-03-T2 Alginet, ES,						Algemesi (5.2 km), study raw data	drip	Algemesi (5.2 km), study raw data
M-675005-01-1	46	30/04/2018	0	7.8	7.813	0		15.15
		01/05/2018	1			0		13.67
lettuce,		02/05/2018	2			0		17.04
green material	47	03/05/2018	3	4.9	4.929	0		18.67
		04/05/2018	4			0		15.99
		05/05/2018	5			0		17.42
		06/05/2018	6			0		17.9
	49	07/05/2018	7	2.8	2.832	0		17.45
		08/05/2018	8			0		18.83
		09/05/2018	9			0		19.22
		10/05/2018	10			0		18.75
		11/05/2018	11			0		19.58
		12/05/2018	12			0		21.74
		13/05/2018	13			0		17.18
	49	14/05/2018	14	0.44	0.451	0		17.23

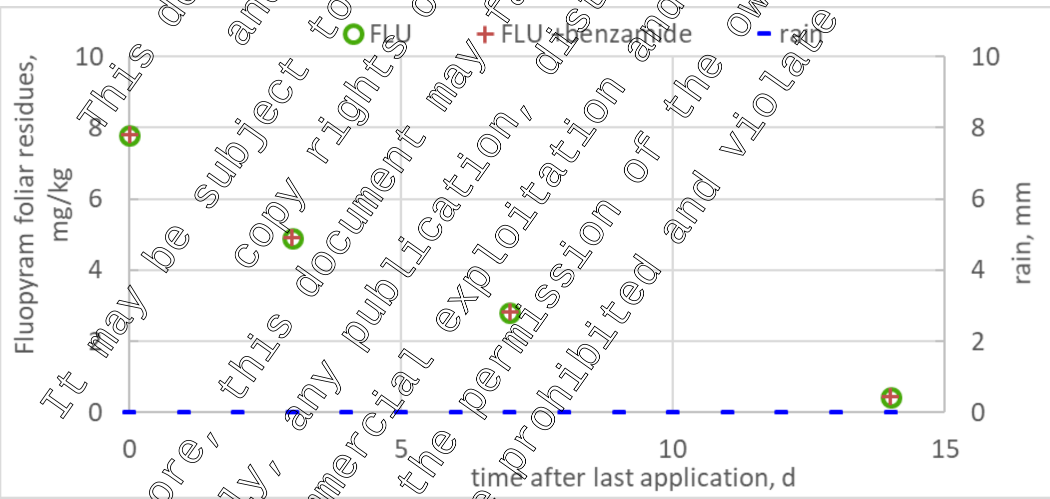


Figure 8.9-120: Plots of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce (T2).

There was no rainfall and thus no discernable influence on the residue time course.

Table 8.9- 399: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2086-04-T1 Vasilika,Thessalonikis, GR, M-675005-01-1						MARS grid 59154 (25×25km)	drip	MARS grid 59154 (25×25km)
lettuce, green material	43	08/06/2018	0	10	10.023	0		24.4
		09/06/2018	1			1		25.2
		10/06/2018	2			0.8		25
	45	11/06/2018	3	1.7	1.715	0		24.8
		12/06/2018	4			0		25
		13/06/2018	5			0		25.9
		14/06/2018	6			0.6		24.5
	49	15/06/2018	7	0.31	0.315 [a]	13.2		21.5
		16/06/2018	8			1		21.5
		17/06/2018	9			2		22.1
		18/06/2018	10			0.1		22.6
		19/06/2018	11			10		23.1
		20/06/2018	12			0		24.2
		21/06/2018	13			0		25.2
	49	22/06/2018	14	0.031	0.031	0.2		24.5

[a] for FLU-benzamide 0.5 LOD added

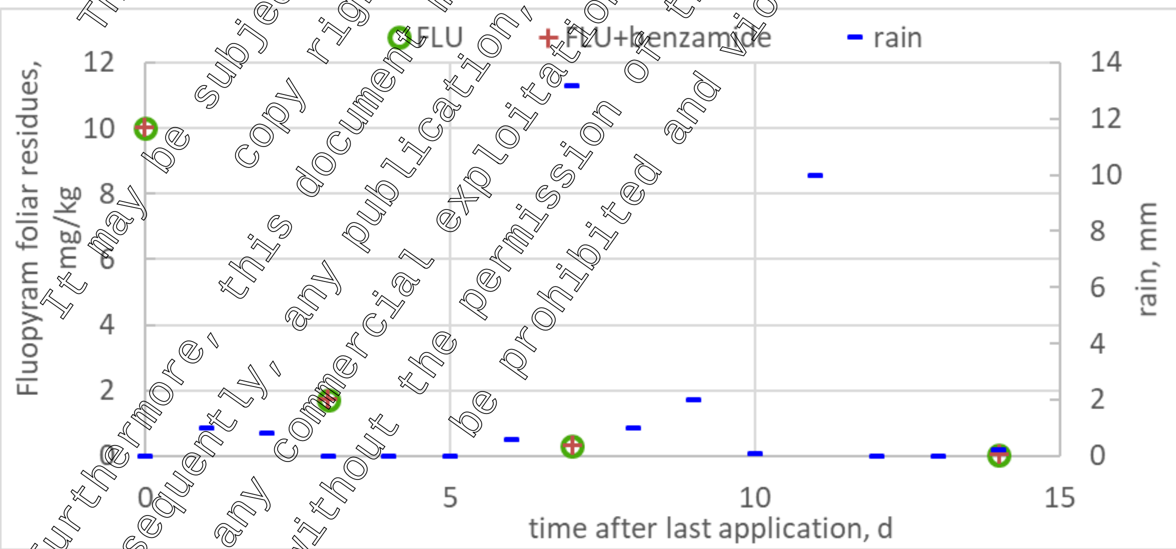


Figure 8.9- 121: Plots of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce (T1).

There was very little rainfall until day 7 which could have influenced the residue decline.

Table 8.9- 400: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
18-2086-04-T2 Vasilika,Thessalonikis, GR, M-675005-01-1 lettuce, green material						MARS grid 59154 (25×25km)	drip	MARS grid 59154 (25×25km)
	43	08/06/2018	0	9	9.017	0		24.4
		09/06/2018	1			1		25.2
		10/06/2018	2			0.8		25
	45	11/06/2018	3	1.5	1.514	0		24.8
		12/06/2018	4			0		25
		13/06/2018	5			0		25.9
		14/06/2018	6			0.6		24.5
	49	15/06/2018	7	0.28	0.285 [a)]	13.2		21.5
		16/06/2018	8			1		21.5
		17/06/2018	9			1.2		22.1
		18/06/2018	10			0.1		22.6
		19/06/2018	11			10		23.1
		20/06/2018	12			0		24.2
		21/06/2018	13			0		25.2
	49	22/06/2018	14	0.033	0.033	0.2		24.5

a) for FLU-benzamide 0.5 LOD added

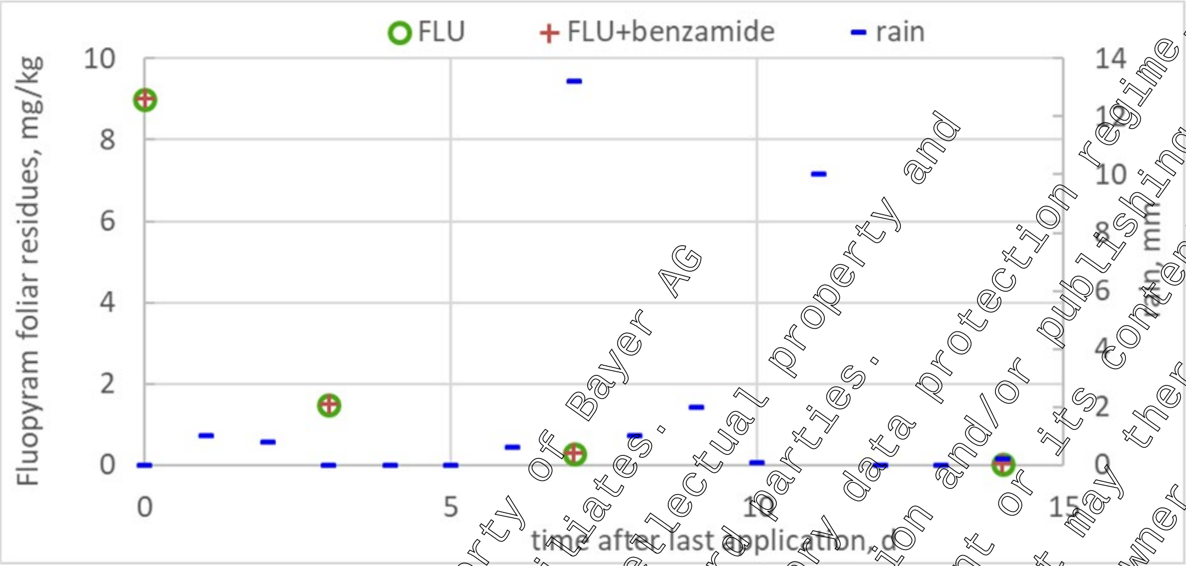


Figure 8.9- 122: Plots of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce (T2).

There was very little rainfall until day 7 which could have influenced the residue decline.

III. CONCLUSION

After two spray applications of either Fluopyram SC 250 or Fluopyram SC 500, respectively, on lettuce in four residue trials conducted in southern Europe (2 x Italy, Spain and Greece) during the 2018 season, the residues of fluopyram in/on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in almost all samples with a maximum value of 0.19 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. There was practically no rainfall which could have influenced residue decline.

Data Point:	KCA 8.9/27
Report Author:	[redacted]
Report Year:	2007
Report Title:	Determination of the residues of AE C656948 in/on head lettuce after spraying of AE C656948 (500 SC) in the field in (the) Northern France, Germany, Netherlands and United Kingdom
Report No:	RA-2592/06
Document No:	M-292048-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 - Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with five residue trials was conducted in the field in northern Europe (northern France, Germany, The Netherlands and United Kingdom) on lettuce during the 2006 season. Two applications with Fluopyram SC 500, a SC formulation containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected slightly above the LOQ (0.01 mg/kg) in almost all samples with a maximum value of 0.030 mg/kg. The residues of metabolites fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram (500 SC)

   Batch no.: 2005-004952

   Active Ingredient: Fluopyram

   Storage: Not stated in the report

   Expiry date: 2008-01-12

2. Test commodity: Lettuce

   Crop part: Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2592/06 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on lettuce (head) after two spray applications with Fluopyram SC 500 a suspension concentrate formulation containing 500 g/L fluopyram.

Field phase

The study included five supervised residue trials conducted in northern Europe (northern France, Germany, The Netherlands and United Kingdom) during the 2006 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 401: Description of the trial locations and cropping information on treated plots

Trial number	R 2006 0375/4	R 2006 0604/4	R 2006 0605/2	R 2006 0606/0	R 2006 0607/9
Trial location	F-95000 Cergy (Ile-de-France)	D-88074 Meckenbeuren (Baden-Württemberg)	D-40764 Langenfeld-Reusrath (Nordrhein-Westfalen)	NL-1681 ND Zwaagdijk-Oost (Noord-Holland)	GB-CB NR ELY (Cambridgeshire)
Country	Northern France	Germany	Germany	The Netherlands	United Kingdom
Area of application	Field	Field	Field	Field	Field
Plot size [m^2]	40	30	33	22	30
Type of soil	Clay sand	Loamy sand	Loamy sand	Clay	Bog soil
pH-value of soil (in water)	8.3	7.1	5.9	7.0	6.2
Content of organic C [%]	1.0	1.4	1.4	3.0	13.7
Test system	Head lettuce	Head lettuce	Head lettuce	Head lettuce	Head lettuce
Variety	Estelle	Jiska	Gisela	Namia	Iceburg
Date of planting/sowing	2006-05-18 / -	2006-08-18 / 2006-07-31	2006-04-22 / -	2006-06-28 / -	- / 2006-06-03
Date of commercial harvest	2006-06-27 to 2006-07-07	2006-09-23 to 2006-10-07	2006-06-05 to 2006-06-13	2006-07-28 to 2006-08-12	2006-07-11 to 2006-07-14

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range except for a deviation happened in trial R 2006 0606/0 when it rained hard one hour after the second application and sampling was done after the rainfall when the plants were dry again. This can perhaps have an impact on the residue values. The first application was performed at BBCH stages between 18-44 and the second between 43-47 with an application rate of 0.25-0.27 kg a.s./ha and a water rate of 200-800 L/ha.

Table 8.9- 402: Overview on application with Fluopyram SC 500 on lettuce

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2006 0375/4 Northern France	1	T	Fluopyram SC 500	SPI	7	44	14	0.5	500	Fluopyram	0.25
	2					47	7*	0.5	500		0.25
R 2006 0604/4 Germany	1	T	Fluopyram SC 500	SPI	7	43	14	0.5	500	Fluopyram	0.25
	2					46	7*	0.5	500		0.25
R 2006 0605/2 Germany	1	T	Fluopyram SC 500	SPI	7	43	14	0.5	600	Fluopyram	0.25
	2					47	7*	0.5	600		0.25
R 2006 0606/0 The Netherlands	1	T	Fluopyram SC 500	SPI	7	41	14	0.5	800	Fluopyram	0.25
	2					46	7*	0.5	800		0.25
R 2006 0607/9 United Kingdom	1	T	Fluopyram SC 500	SPI	7	18	14	0.5	200	Fluopyram	0.25
	2					43	7*	0.5	216		0.27

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of lettuce. For trial R 2006 0245/0 there was a deviation concerning storage as the temperature was not appropriate for a period of 3.5 hours. This had no impact on the study. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 403: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2006 0375/4 R 2006 0604/4 R 2006 0605/2 R 2006 0606/0 R 2006 0607/9	Lettuce	Head	C	-0
				3
				7
				10
			T	-0
				0
				3
				7
				10
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 404: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in lettuce head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 405: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	89; 78	84	-	0.01
	1	105; 104	105	-	
	5	81; 67	74		
	10	102	102		
	Overall recovery (n = 7)		**89**	**16.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 406: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	93; 92	93	-	0.01
	1	102	102	-	
	5	77; 68	73		
	10	94	94	-	
	Overall Recovery (n = 6)		**88**	**14.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

Table 8.9- 407: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	97; 82	90	-	0.01
	1	101	101	-	
	5	81; 60	71	-	
	10	94	94		
	Overall Recovery (n = 6)		**86**	**17.5**	

Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram

Table 8.9- 408: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	89; 67	78	-	0.01
	1	91	91	-	
	5	105; 73	89	-	
	10	97	97		
	Overall recovery (n = 6)		**87**	**16.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 158 and 267 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on lettuce head are summarised in the following table.

Table 8.9- 409: Residue summary of fluopyram in/on lettuce, head

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0375/4 Northern France	Head	47	-0	1.9	0.02	<0.01	<0.01
	Head	47	0	5.9	0.03	<0.01	<0.01
	Head	49	3	0.87	0.02	<0.01	<0.01
	Head	51	7	0.62	0.03	<0.01	<0.01
	Head	51	10	0.46	0.02	<0.01	<0.01
	Head	53	13	0.34	0.02	<0.01	<0.01
R 2006 0604/4 Germany	Head	46	-0	0.08	<0.01	<0.01	<0.01
	Head	46	0	8.2	0.01	<0.01	<0.01
	Head	47	3	1.9	0.01	<0.01	<0.01
	Head	49	7	0.18	<0.01	<0.01	<0.01
	Head	49	11	0.05	<0.01	<0.01	<0.01
	Head	49	14	0.01	<0.01	<0.01	<0.01
R 2006 0605/2 Germany	Head	47	-0	0.20	<0.01	<0.01	<0.01
	Head	47	0	4.3	0.01	<0.01	<0.01
	Head	47	3	1.3	0.01	<0.01	<0.01
	Head	49	7	0.93	0.03	<0.01	<0.01
	Head	49	10	0.47	0.02	<0.01	<0.01
	Head	49	14	0.30	0.02	<0.01	<0.01
R 2006 0606/0 The Netherlands	Head	46	-0	0.37	0.01	<0.01	<0.01
	Head	46	0	1.7	0.01	<0.01	<0.01
	Head	47	3	0.71	0.01	<0.01	<0.01
	Head	49	7	0.26	<0.01	<0.01	<0.01
	Head	49	10	0.10	<0.01	<0.01	<0.01
	Head	49	14	0.02	<0.01	<0.01	<0.01
R 2006 0607/9 United Kingdom	Head	43	-0	0.75	<0.01	<0.01	<0.01
	Head	43	0	7.6	0.01	<0.01	<0.01
	Head	44	3	1.2	<0.01	<0.01	<0.01
	Head	47	7	0.13	<0.01	<0.01	<0.01
	Head	48	10	0.02	<0.01	<0.01	<0.01
	Head	49	14	<0.01	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on lettuce

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 410: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0375/4 Cergy, FR, M-292048-01-1 lettuce, head, green material						Meteo France Pontoise (5 km), study raw data	sprinkler	Meteo France Pontoise (5 km), study raw data
	47	05/07/2006	0	5.9	5.93	0		21.4
		06/07/2006	1			0.4		19.5
		07/07/2006	2			3.8		18.4
		08/07/2006	3	0.87	0.89	7.2	15	18.6
		09/07/2006	4			0.4		20.2
		10/07/2006	5			0.2		21.6
		11/07/2006	6			0		19.6
		12/07/2006	7	0.62	0.65	0		19.8
		13/07/2006	8			0		20.5
		14/07/2006	9			0		20.4
		15/07/2006	10	0.46	0.48	0		22
		16/07/2006	11			0	10	22.7
		17/07/2006	12			0		23.6
		18/07/2006	13	0.34	0.36	0		25.2

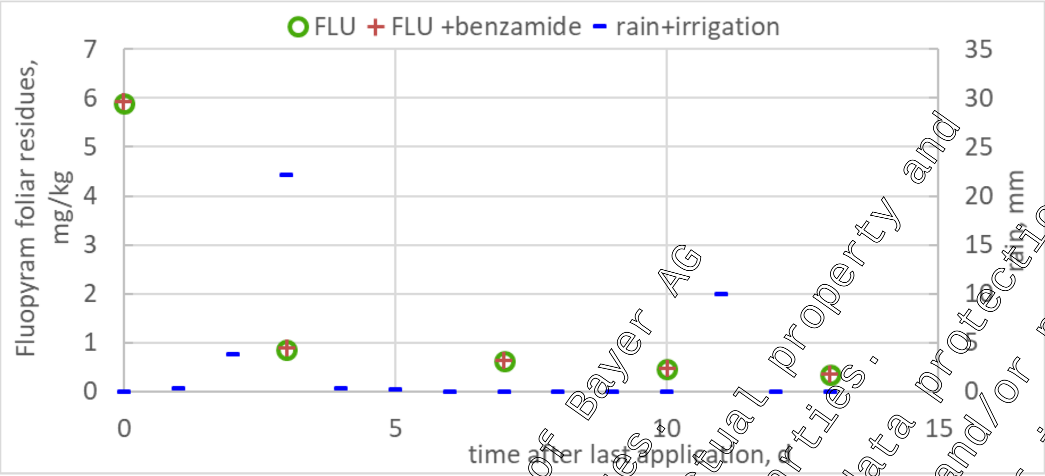


Figure 8.9- 123: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce

Rainfall and sprinkler irrigation on day 2 coincided with a marked decline of residue concentrations

Table 8.9- 411: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0604/4 Meckenbeuren, DE, M-292048-01-1 lettuce, head, green material						DWD Konstanz (25 km) a)	no	DWD Konstanz (25 km) a)
	46	21/09/2006	0	8.2	8.21	0		17.1
		22/09/2006	1			0		17.6
		23/09/2006	2			0		16.3
		24/09/2006	3	1.9	1.91	0		17.5
		25/09/2006	4			26.1		15.2
		26/09/2006	5			2.3		13.6
		27/09/2006	6			0		15.5
		28/09/2006	7	0.18	0.185 b)	0		14.3
		29/09/2006	8			0.2		15.4
		30/09/2006	9			18.6		16.7
		01/10/2006	10			12.2		15.7
		02/10/2006	11	0.05	0.05	0		17.7
		03/10/2006	12			5.3		15.9
		04/10/2006	13			0.5		11.5
		05/10/2006	14	0.01	0.01	0		11.6

a) https://opendata.dwd.de/climate_environment/CDC/
b) for FLU-benzamide 0.5 LOD added

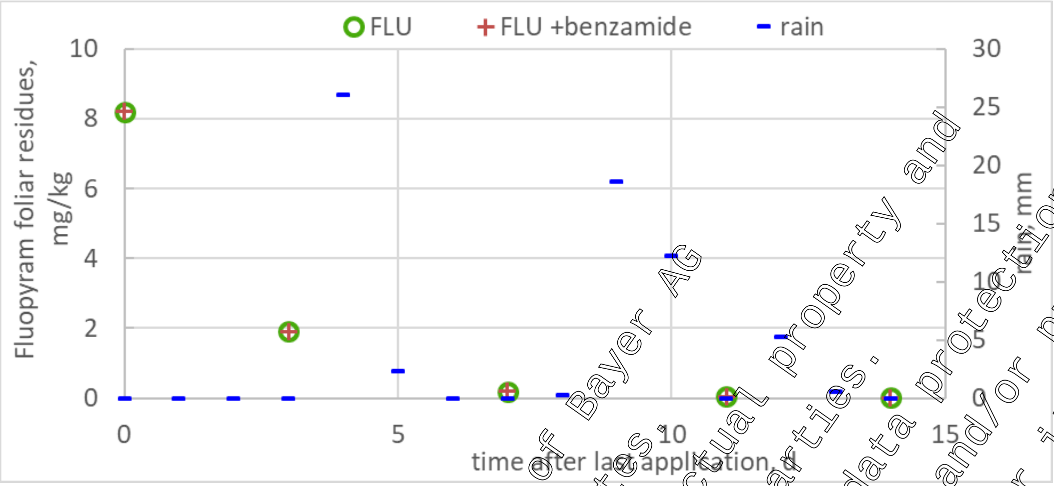


Figure 8.9- 124: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce.

Rainfall after the second sampling (day 3) had no marked influence on the residue dissipation (75% of the initial residues had already declined before the rainfall).

Table 8.9- 412: Climatic conditions and residue concentration

Study trial, crop	**BBCH growth stage**	**Date dd/mm/yyyy**	**Time after treatment (d)**	**FLU (mg/kg)**	**FLU + FLU-benzamide (mg ai eq./kg)**	**Precipitation (rain) (mm)**	**Irrigation over leafs (mm)**	**Mean temp. (°C)**
R 2006 0605/2 Langenfeld-Reusrath, DE, M-292048-01-1 lettuce, head, green material						ProPlant DB Monheim (2.5 km)	no	ProPlant DB Monheim (2.5 km)
	47	30/05/2006	0	4.3	4.31	4.8 (0) [a]		8.3
		31/05/2006	1			0.2		8.7
		01/06/2006	2			0.9		9.6
		02/06/2006	3	1.3	1.31	0		12
		03/06/2006	4			0.9		13.4
		04/06/2006	5			0		13.2
		05/06/2006	6			0		12.5
		06/06/2006	7	0.93	0.96	0		13.4
		07/06/2006	8			0		15.6
		08/06/2006	9			0		17.3
		09/06/2006	10	0.47	0.49	0		19.5
		10/06/2006	11			0		21.5
		11/06/2006	12			0		22.5
		12/06/2006	13			0		22.7
		13/06/2006	14	0.3	0.32	0		24.7

[a] no rain within 24 h after application, in study report. After spraying, the plot was covered with a tarpaulin for 24 h.

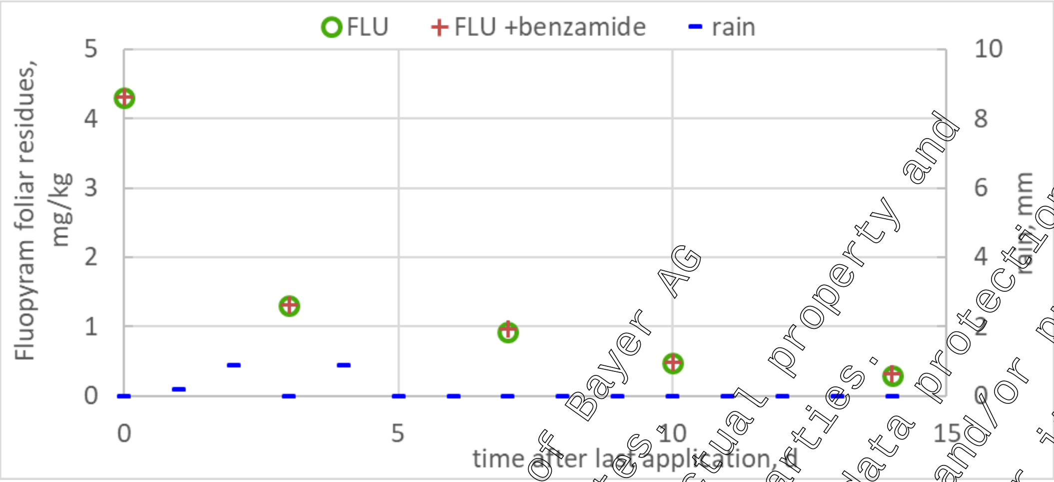


Figure 8.9- 125: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

There was very little rainfall and no discernable influence on the residue dissipation.

Table 8.9- 413: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0606/0 Zwaagdijk, NL,						KMNI De Kooy, Den Helder (35 km) a)	no	KMNI De Kooy, Den Helder (35 km) a)
M-292048-01-1	46	28/07/2006	0	1.7	1.71	<0.05 (0) b)		22
		29/07/2006	1			0		20.1
		30/07/2006	2			<0.05		20
lettuce, head, green material		31/07/2006	3	0.71	0.72	0		19.6
		01/08/2006	4			13.5		17.4
		02/08/2006	5			2		16.2
		03/08/2006	6			34.8		17.3
		04/08/2006	7	0.26	0.265 c)	1.5		18.5
		05/08/2006	8			<0.05		19.7
		06/08/2006	9			0		18.7
		07/08/2006	10	0.1	0.1	1.1		18.4
		08/08/2006	11			<0.05		17.1
		09/08/2006	12			1.1		16.7
		10/08/2006	13			13.1		14.9
		11/08/2006	14	0.02	0.02	20.2		14.5

a) http://projects.knmi.nl/klimatologie/daggegevens/selectie.cgi
b) 2.5 mm rain within 24 h after 2nd application. Rain started 1 h after appl. (appl. 13:50), hard rain for 10 min. For the rest of 24 h there was no rain. *Sampling* after 2nd application was done *after the rainfall*. The plants were dry again (study report).
c) for FLU-benzamide 0.5 LOD added

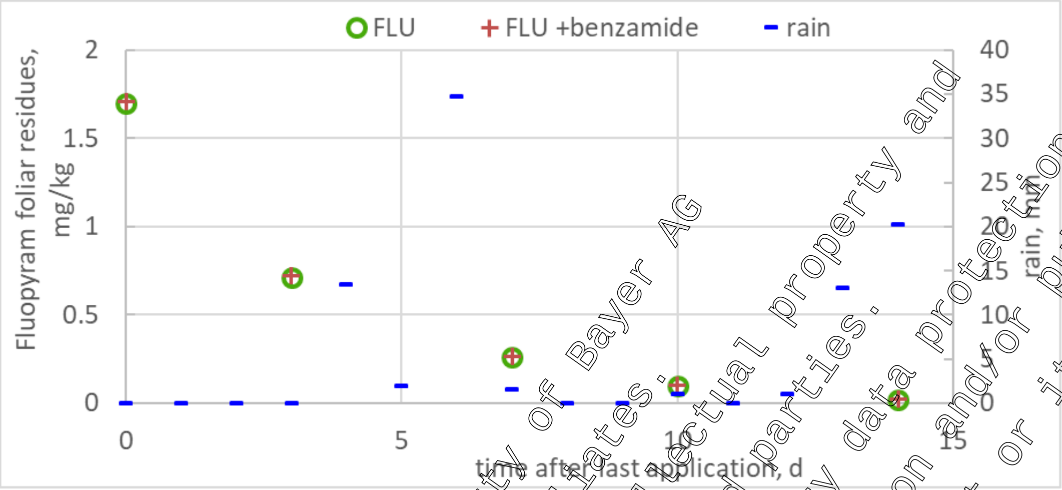


Figure 8.9- 126: of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Rainfall after the second sampling (day 3) had no marked influence on the residue dissipation (much of the initial residues had already declined before the rainfall).

Table 8.9- 414: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0607/9 Ely, GB,						Brooms Barn (40 km), Bayer raw data	sprinkler	Brooms Barn (40 km), Bayer raw data
M-292048-01-1	43	27/06/2006	0	7.6	7.61	0		14.2
		28/06/2006	1			0		14.1
lettuce, head, green material		29/06/2006	2			0	20	15.6
		30/06/2006	3	1.2	1.205 [b)]	0		17.8
		01/07/2006	4			0		19.25
		02/07/2006	5			0		22
		03/07/2006	6			0		21.6
		04/07/2006	7	0.13	0.13	0.9		20.4
		05/07/2006	8			0.4		19.85
		06/07/2006	9			0		20.3
		07/07/2006	10	0.02	0.02	0.5	25	18.5
		08/07/2006	11			2.2		16.65
		09/07/2006	12			0		18
		10/07/2006	13			0.9		17.45
		11/07/2006	14	0.005 [a)]	0.005	0		20.3

a) for FLU 0.5 LOD added
b) for FLU-benzamide 0.5 LOD added

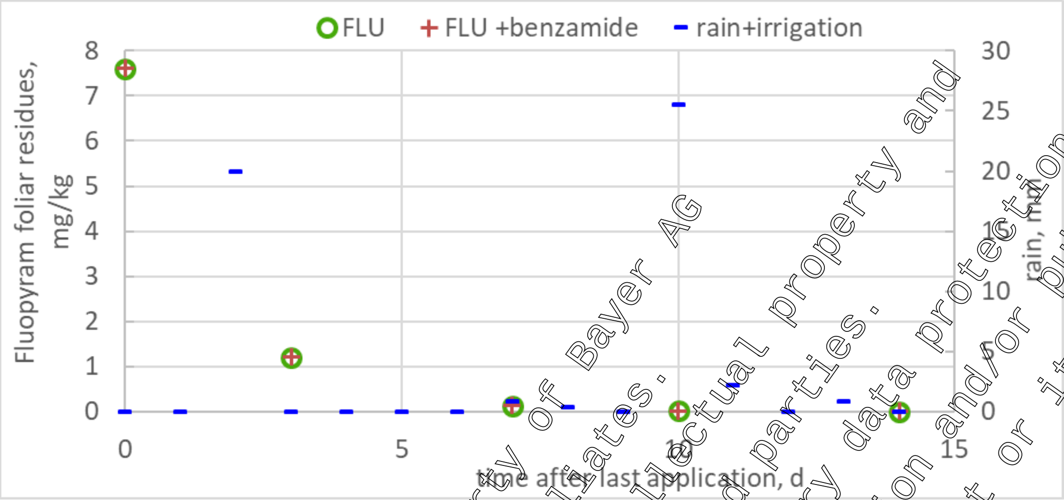


Figure 8.9- 127: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Sprinkler irrigation on day 3 coincided with a marked drop of residue levels.

III. CONCLUSION

After two spray applications of Fluopyram SC 500 on lettuce in five residue trials conducted in northern Europe (northern France, 2 x Germany, The Netherlands and United Kingdom) during the 2006 season the residues of fluopyram in/on head lettuce declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ of (0.01 mg/kg) in almost all samples with a maximum value of 0.03 mg/kg. The residues of metabolites fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ.

<u>Assessment and conclusion by applicant:</u>

The study and its data are considered as acceptable and reliable for use in risk assessment. Rain and sprinkler irrigation appear to have influenced the residue dissipation in two of the 5 trials (R 2006 0375/4 and R 2006 0607/9 but rain is a natural and irrigation a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/28
Report Author:	[redacted]
Report Year:	2007
Report Title:	Determination of the residues of AE C656948 in/on head lettuce after spraying of AE C656948 (500 SC) in the field in Southern France, Spain, Italy and Greece
Report No:	RA-2593/06
Document No:	M-292050-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 - Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with five residue trials was conducted in the field in southern Europe (southern France, Spain, 2 x Italy and Greece) on lettuce during the 2006 season. Two applications with Fluopyram SC 500 containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected slightly above the LOQ (0.01 mg/kg) in almost all samples with a maximum value of 0.05 mg/kg. The residues of metabolites fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram (500 SC)
	Batch no.:	2005-004952
	Active substance:	Fluopyram
	Storage:	Not stated in the report
	Expiry date:	2008-01-12
2.	Test commodity:	Lettuce
	Crop part:	Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2593/06 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on lettuce (head) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

Field phase

The study included five supervised residue trials conducted in southern Europe (southern France, Spain, Italy and Greece) during the 2006 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 415: Description of the trial locations and cropping information on treated plots

Trial number	R 2006 0376/2	R 2006 0608/7	R 2006 0609/5	R 2006 0610/9	R 2006 0611/7
Trial location	F-31790 St Jory (Midi-Pyrenees)	E-08410 Vilanova del Vallés (Cataluña)	I-70031 Andria (Bari) (Puglia)	I-95100 Catania (Sicilia)	GR-60100 Katerini/Paralia (Northern Greece - Macedonia)
Country	Southern France	Spain	Italy	Italy	Greece
Area of application	Field	Field	Field	Field	Field
Plot size [m^2]	45	72	60	42	20
Type of soil	Clay silt	Loamy sand	Sand	Sandy clay	No data
pH-value of soil (in water)	7.8	8.1	8.3	8.3	No data
Content of organic C [%]	1.3	1.5	3.1	1.0	No data
Test system	Head lettuce	Head lettuce	Head lettuce	Head lettuce	Head lettuce
Variety	Toucan	Rumina	Brest	Trocadero	White Boston
Date of planting/sowing	2006-03-15 / -	2006-06-10 / -	2006-02-23 / -	2006-01-20 / -	2006-06-27 / -
Date of commercial harvest	2006-05-25 to 2006-05-30	2006-06-30 to 2006-07-17	2006-05-10 to 2006-06-30	2006-04-20 to 2006-05-10	2006-07-25 to 2006-08-04

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stages between 19-48 and the second between 41-49 with an application rate of 0.25 kg a.s./ha and a water rate of 400-700 L/ha.

Table 8.9- 416: Overview on application with Fluopyram SC 500 on lettuce

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2006 0376/2 Southern France	1	T	Fluopyram SC 500	SPI	7	42	14	0.5	600	Fluopyram	0.25
	2					46	7*	0.5	600		0.25
R 2006 0608/7 Spain	1	T	Fluopyram SC 500	SPI	7	41	14	0.5	400	Fluopyram	0.25
	2					42	7*	0.5	600		0.25
R 2006 0609/5 Italy	1	T	Fluopyram SC 500	SPI	7	48	14	0.5	700	Fluopyram	0.25
	2					49	7*	0.5	700		0.25
R 2006 0610/9 Italy	1	T	Fluopyram SC 500	SPI	7	47	14	0.5	600	Fluopyram	0.25
	2					48	7*	0.5	600		0.25
R 2006 0611/7 Greece	1	T	Fluopyram SC 500	SPI	7	19	14	0.5	500	Fluopyram	0.25
	2					41	7*	0.5	500		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of lettuce. The samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 417: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2006 0376/2 R 2006 0608/7 R 2006 0609/5 R 2006 0610/9 R 2006 0611/7	Lettuce	Head	C	-0
				3
				7
				10
			T	-0
				0
				3
				7
				10
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites were analysed within the residue trials samples according to the following method:

Table 8.9- 418: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in lettuce head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 419: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	87	87	--	0.01
	5	94; 75; 86; 84; 89	86	8.2	
	10	100	100	--	
	Overall recovery (n = 7)		**88**	**8.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram

Table 8.9- 420: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	88	88	--	0.01
	5	85; 69; 82; 84; 92	82	10.2	
	10	93	93	--	
	Overall Recovery (n = 7)		**85**	**9.5**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

Table 8.9- 421: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce head	0.01	74	74	--	0.01
	5	82; 66; 69; 81; 87	77	11.7	
	10	96	96	--	
	Overall Recovery (n = 7)		**79**	**13.2**	

Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram

Table 8.9- 422: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce head	0.01	64	64	-	0.01
	5	92; 110; 98; 98; 93	98	7.3	
	Overall recovery (n = 6)		**93**	**16.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 181 and 282 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on lettuce head are summarised in the following table.

For the trial R2006 0611/7, due to high temperatures, plant development was slower. Consequently, the sample weights were smaller than those from the other trials (average weight per unit ranged from 0.019 to 0.114 kg for trial R2006 0611/7, and from 0.114 to 0.917 kg for the other trials). This could explain the higher level of residues found for the samples coming from the R 2006 0611/7 trial.

Table 8.9- 423: Residue summary of fluopyram in/on lettuce, head

Trial No, Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0376/2 Southern France	Head	46	-0	0.47	0.02	<0.01	<0.01
	Head	46	0	2.7	0.03	<0.01	<0.01
	Head	47	3	0.61	0.02	<0.01	<0.01
	Head	49	7	0.25	0.02	<0.01	<0.01
	Head	49	10	0.17	0.02	<0.01	<0.01
	Head	49	14	0.09	0.01	<0.01	<0.01
R 2006 0608/7 Spain	Head	42	-0	0.27	<0.01	<0.01	<0.01
	Head	42	0	3.5	0.01	<0.01	<0.01
	Head	45	4	1.5	0.02	<0.01	<0.01
	Head	47	7	0.29	0.01	<0.01	<0.01
	Head	48	10	0.07	<0.01	<0.01	<0.01
	Head	49	14	0.01	<0.01	<0.01	<0.01
R 2006 0609/5 Italy	Head	49	-0	0.09	<0.01	<0.01	<0.01
	Head	49	0	0.62	<0.01	<0.01	<0.01
	Head	49	4	0.02	<0.01	<0.01	<0.01

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
	Head	49	7	0.02	<0.01	<0.01	<0.01
	Head	49	10	0.03	<0.01	<0.01	<0.01
	Head	49	14	0.02	<0.01	<0.01	<0.01
R 2006 0610/9 Italy	Head	48	-0	0.59	0.01	<0.01	<0.01
	Head	48	0	1.8	0.01	<0.01	<0.01
	Head	48	3	0.92	0.01	<0.01	<0.01
	Head	49	8	0.46	0.01	<0.01	<0.01
	Head	49	10	0.23	<0.01	<0.01	<0.01
	Head	49	14	0.10	<0.01	<0.01	<0.01
R 2006 0611/7 Greece	Head	41	-0	2.1	0.03	<0.01	<0.01
	Head	41	0	11	0.04	<0.01	<0.01
	Head	46	3	6.4	0.05	<0.01	<0.01
	Head	49	8	1.7	0.04	<0.01	<0.01
	Head	49	10	0.39	0.02	<0.01	<0.01
	Head	51	14	0.02	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on lettuce

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 424: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0376/2 St. Jory, FR, M-292050-01-1						Meteo France Blagnac (14 km), study raw data	sprinkler	Meteo France Blagnac (14 km), study raw data
lettuce, head, green material	46	19/05/2006	0	2.7	2.73	0		17.3
		20/05/2006	1			0.2		17.1
		21/05/2006	2			0		19.4
		22/05/2006	3	0.61	0.63	1.6		18
		23/05/2006	4			1.6		14.4
		24/05/2006	5			0		13.4
		25/05/2006	6			0	8	15.4
		26/05/2006	7	0.25	0.27	0		19.2
		27/05/2006	8			0		20.6
		28/05/2006	9			0		21.6
		29/05/2006	10	0.17	0.19	0		20.1
		30/05/2006	11			0	10	15.4
		31/05/2006	12			0		12.7
		01/06/2006	13			0		13.6
		02/06/2006	14	0.09	0.1	0		16.2

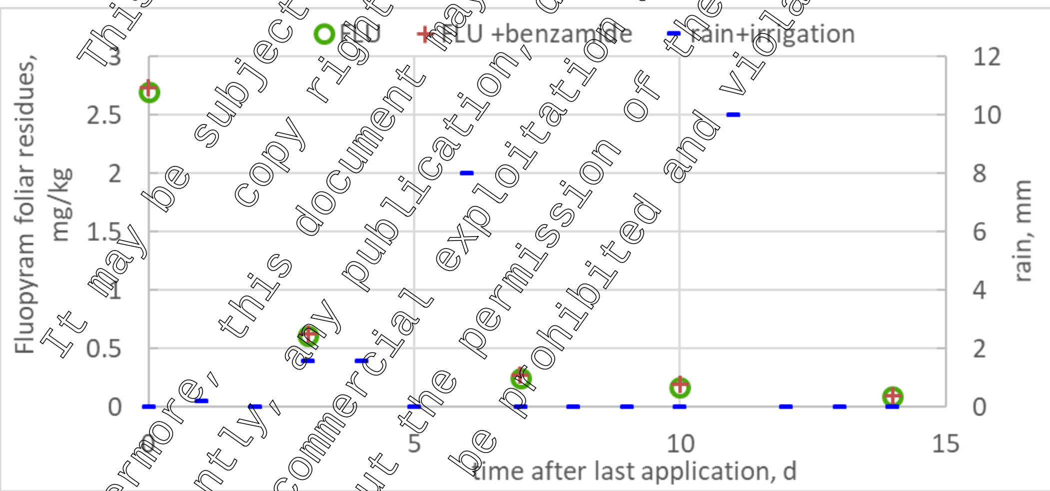


Figure 8.9- 128: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce

There was very little rain until irrigation on day 6, which did not appear to have an ifluence on the residue dissipation (> 75% already declined by day 3).

Table 8.9- 425: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0608/7 Vilanova del Vallés, ES,						Catalan Meteo, Vilanova del Vallés (3 km)	no	Catalan Meteo, Vilanova del Vallés (3 km)
M-292050-01-1	42	30/06/2006	0	3.5	3.51	0		25.5
		01/07/2006	1			0		26.4
lettuce, head, green material		02/07/2006	2			0		25.8
		03/07/2006	3			0		24.4
		04/07/2006	4	1.5	1.52	0		24.8
		05/07/2006	5			1.8		24.9
		06/07/2006	6			0.2		24
		07/07/2006	7	0.29	0.3	0.8		23.5
		08/07/2006	8			0.2		23.9
		09/07/2006	9			0		25.5
		10/07/2006	10	0.07	0.075 a)	0		26.9
		11/07/2006	11			0		26.7
		12/07/2006	12			0		27.5
		13/07/2006	13			0		26
		14/07/2006	14	0.01	0.01	1.2		24.4

a) for FLU-benzamide 0.5 LOD added

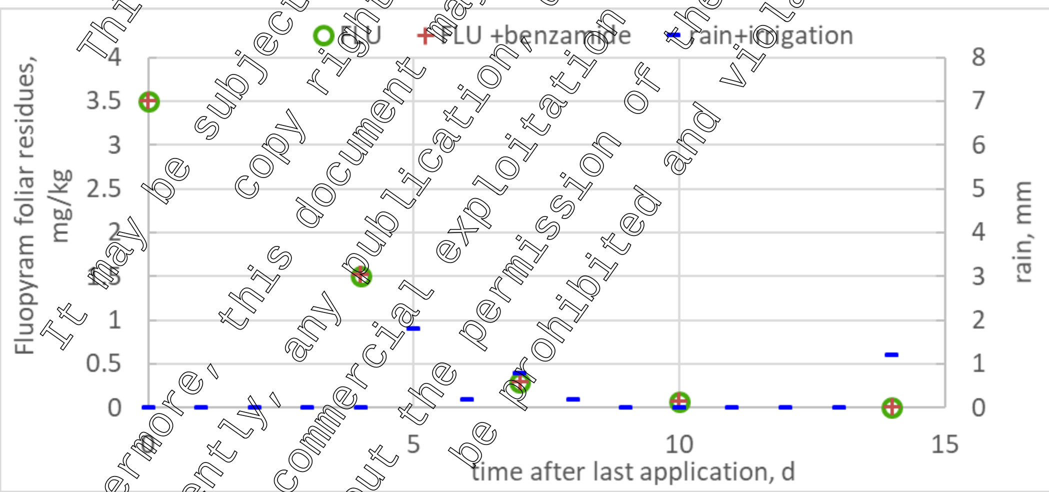


Figure 8.9- 129: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce.

There was very little rain and no discernable influence on residue dissipation.

Table 8.9- 426: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0609/5 Andria, IT, M-292050-01-1 lettuce, head, green material						Bonifica di Capitinata, Trinitapoli (23 km), raw data	sprinkler	Bonifica di Capitinata, Trinitapoli (23 km), raw data
	49	08/05/2006	0	0.62	FLU-benz	0		16.2
		09/05/2006	1		<LOD	0.4		17.56
		10/05/2006	2			0.4		14.59
		11/05/2006	3			3		14.65
		12/05/2006	4	0.02		0		16.1
		13/05/2006	5			0		18.11
		14/05/2006	6			0		19.49
		15/05/2006	7	0.02		0		18.5
		16/05/2006	8			0		19.29
		17/05/2006	9			0	15	21.32
		18/05/2006	10	0.03		0		22.88
		19/05/2006	11			0		25.57
		20/05/2006	12			0		24.89
		21/05/2006	13			0		23.79
		22/05/2006	14	0.02		0		22.26

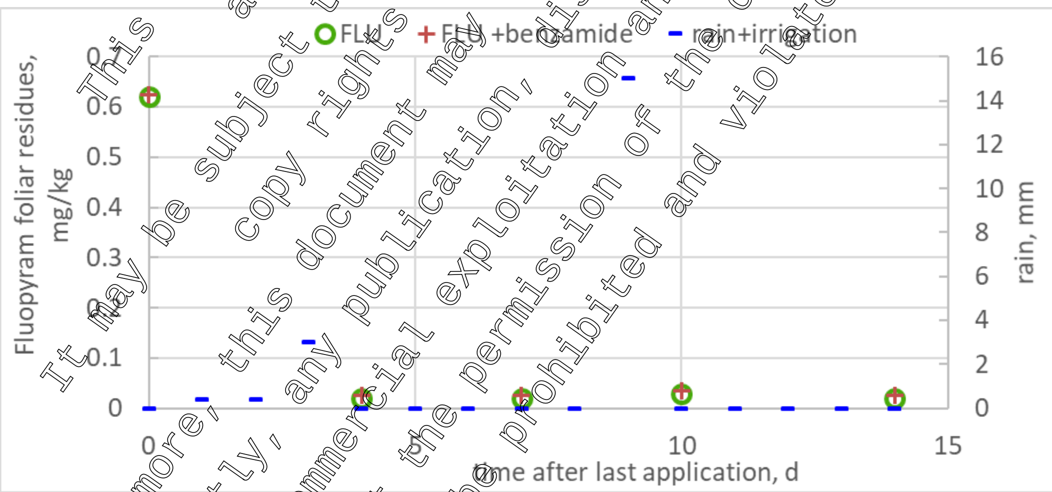


Figure 8.9- 130: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

There was little rain on the first 3 days of the trial. An influence on residue dissipation cannot be excluded.

Table 8.9- 427: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0610/9 Catania, IT,						MARS grid 43127 (25×25 km)	drip	MARS grid 43127 (25×25 km)
M-292050-01-1	48	18/04/2006	0	1.8	1.81	0		16.8
		19/04/2006	1			0		19
lettuce, head, green material		20/04/2006	2			0		15.8
		21/04/2006	3	0.92	0.93	0		14
		22/04/2006	4			0		14.5
		23/04/2006	5			0		14.9
		24/04/2006	6			0		14.9
		25/04/2006	7			0		14.1
		26/04/2006	8	0.46	0.47	0		17.2
		27/04/2006	9			0.2		16
		28/04/2006	10	0.23	0.235 [a]	37 (0) [b]		16.6
		29/04/2006	11			5		14.5
		30/04/2006	12			4		15.6
		01/05/2006	13			0		15.3
		02/05/2006	14	0.1	0.1	0		15.2

[a] for FLU-benzamide 0.5 LOD added
[b] 0 mm rain at this date in study report

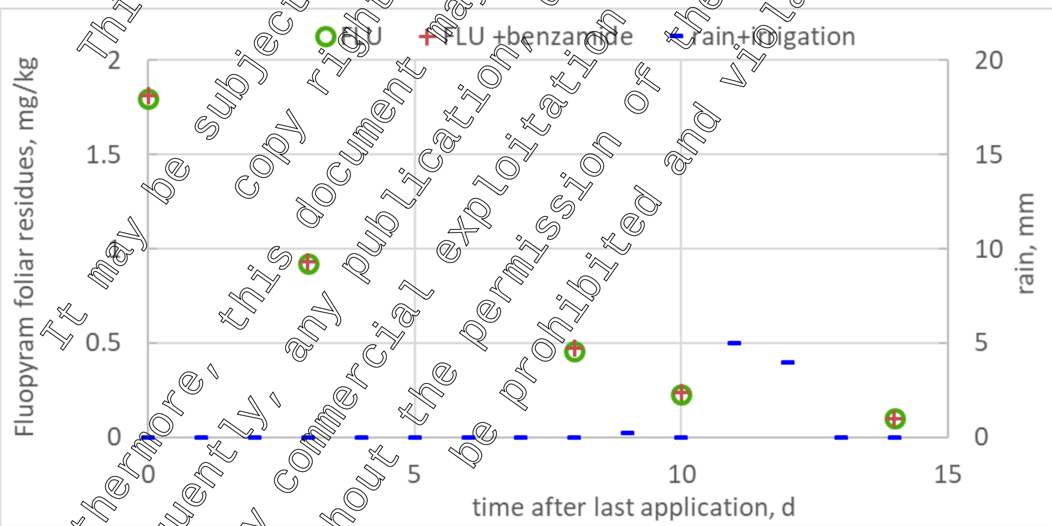


Figure 8.9- 131: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

There was no rain until very late into the trial, and no discernible influence on residue dissipation

Table 8.9- 428: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0611/7 Katerini/ Paralia, GR, M-292050-01-1 lettuce, head, green material						MARS grid 58152 (25×25 km)	drip	MARS grid 58152 (25×25 km)
	41	19/07/2006	0	11	11.04	0		24.8
		20/07/2006	1			0		24.8
		21/07/2006	2			0		27.1
		22/07/2006	3	6.4	6.45	0		25
		23/07/2006	4			0		25
		24/07/2006	5			0		26.5
		25/07/2006	6			4		27.1
		26/07/2006	7			0		26.9
		27/07/2006	8	1.7	1.74	0		28.1
		28/07/2006	9			0		27.6
		29/07/2006	10	0.39	0.41	0		27.5
		30/07/2006	11			1.4		27.3
		31/07/2006	12			0		26.6
		01/08/2006	13			0		28.6
		02/08/2006	14	0.02	0.025 [a)]	0		27.9

[a)] for FLU-benzamide 0.5 LOD added

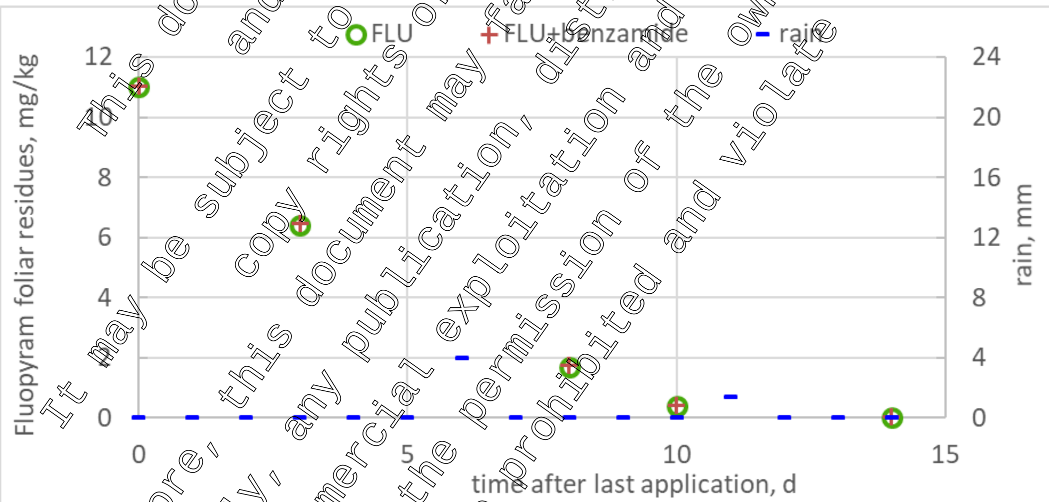


Figure 8.9- 132: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

There was no rain until day 6, with no discernible influence on residue dissipation.

III. CONCLUSION

After two spray applications of Fluopyram SC 500 on lettuce in five residue trials conducted in southern Europe (southern France, Spain, 2 x Italy and Greece) during the 2006 season the residues of fluopyram in/on lettuce head declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ of (0.01 mg/kg) with a maximum value of 0.05 mg/kg in almost all samples besides those of trial R 2006 0609/5, where residues were below the LOQ. The residues of metabolites fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ.

Assessment and conclusion by applicant: The study and its data are considered as acceptable and reliable for use in risk assessment. There was a possible influence of rain in one of the five trials (R 2006 0609/5), but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/29
Report Author:	[redacted]
Report Year:	2007
Report Title:	Determination of the residues of AE C656948 in/on kidney bean after spraying of AE C656948 (500 SC) in the field in (the) Germany, the Netherlands and Belgium
Report No:	RA-2594/06
Document No:	M-290825-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in northern Europe (2 x Germany, The Netherlands and Belgium) on kidney bean during the 2006 season. Two applications with Fluopyram SC 500 containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on kidney bean (pod and green material) declined markedly during the sampling period. Residues of fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were detected above the LOQ (0.01 mg/kg) in almost all samples with maximum values of 0.08 mg/kg in green material and 0.05 mg/kg in pod, 0.02 mg/kg in green material and pod and 0.01 mg/kg in green material and pod, respectively.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram (500 SC)
	Batch no.:	2005-004952
	Active substance	Fluopyram
	Storage:	Not stated in the report
	Expiry date:	2008-01-12
2.	Test commodity:	Kidney bean
	Crop part:	Pod and green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2594/06 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on kidney bean (pod and green material) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

<u>Field phase</u>

The study included four supervised residue trials conducted in northern Europe (2 x Germany, The Netherlands and Belgium) during the 2006 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 429: Description of the trial locations and cropping information on treated plots

Trial number	R 2006 0377/0	R 2006 0654/0	R 2006 0655/9	R 2006 0656/7
Trial location	D-68623 Lampertheim	D-40764 Langenfeld-Reusrath (Nordrhein-Westfalen)	NL-1681 ND Zwaagdijk-Oost (Noord-Holland)	B-6210 Villers - Perwin (Hainaut)
Country	Germany	Germany	Netherlands	Belgium
Area of application	Field	Field	Field	Field
Plot size [m²]	60	66	48	24
Type of soil	Clay loam	Sandy loam	Clay	Silty loam
pH-value of soil (in water)	7.5	6.9	7.0	5.5
Content of organic C [%]	2.3	1.7	3.1	2.4
Test system	Kidney bean	Kidney bean	Kidney bean	Kidney bean
Variety	Albani	Classic	-	Polder
Date of planting/sowing	2006-05-15 / -	- / 2006-06-17	- / 2006-05-18	- / 2006-05-11
Start Flowering	2006-07-03	2006-07-17	2006-07-21	2006-07-01
End Flowering	2006-07-20	2006-07-27	2006-08-28	2006-07-10
Date of commercial harvest	2006-07-24 to 2006-08-15	2006-08-01 to 2006-08-30	2006-08-04 to 2006-08-28	2006-08-01 to 2006-08-08

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. Deviations occurred within trial R 2006 0655/9 as the second application was underdosed about 8%. This is considered acceptable following the current European guideline. Furthermore, 15 minutes after the first application it rained hard for 10 minutes. This is considered as to have no major impact on the study as it is the second application which mainly determines the level of residues. The first application was performed at BBCH stages between 67-73 and the second between 74-77 with an application rate of 0.23-0.25 kg a.s./ha and a water rate of 300-650 L/ha.

Table 8.9- 430: Overview on application with Fluopyram SC 500 on kidney bean

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2006 0377/0 Germany	1	T	Fluopyram SC 500	SPI	7	67	14	0.5	500	Fluopyram	0.25
	2					77	7*	0.5	500		0.25
R 2006 0654/0 Germany	1	T	Fluopyram SC 500	SPI	7	71	14	0.5	300	Fluopyram	0.25
	2					74	7*	0.5	300		0.25

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2006 0655/9 The Netherlands	1	T	Fluopyram SC 500	SPI	7	72	14	0.5	500	Fluopyram	0.25
	2					75	7*	0.46	460		0.23
R 2006 0656/7 Belgium	1	T	Fluopyram SC 500	SPI	7	73	14	0.5	650	Fluopyram	0.25
	2	T				77	7*	0.5	650		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of kidney bean pod and green material. The samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 431: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2006 0377/0 R 2006 0654/0 R 2006 0655/9 R 2006 0656/7	Kidney bean	Pod, green material	C	-0
				3
				7
				14
		Pod, green material	T	-0
				0
				3
				7
				10
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites were analysed within the residue trials samples according to the following method:

Table 8.9- 432: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in kidney bean (pod and green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the overall RSD values were below 20%. Details are given in the table below.

Table 8.9- 433: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	88; 90; 84; 100; 98	92	7.4	0.01
	0.1	103; 104; 101; 96	101	3.5	
	0.5	95; 102	99	--	
	Overall Recovery (n = 11)		**96**	**6.9**	
Kidney bean green material	0.01	93; 77; 75; 89; 71	81	11.7	0.01
	0.1	84; 86; 90; 86	87	2.9	
	5	94; 90	92	--	
	10	68; 103	86	--	
	Overall Recovery (n = 13)		**85**	**11.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 434: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	100; 102; 101; 85; 98	97	7.2	0.01
	0.1	96; 93; 96; 89	94	3.5	
	0.5	96; 102	99	--	
	Overall Recovery (n = 11)		**96**	**5.7**	
Kidney bean green material	0.01	101; 90; 81; 88; 84	89	8.6	0.01
	0.1	86; 85; 88; 85	86	1.6	
	5	87; 82	85	--	
	Overall Recovery (n = 11)		**87**	**6.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

Table 8.9- 435: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	97; 114; 100; 101; 96	102	7.1	0.01
	0.1	95; 92; 93; 88	92	3.2	
	0.5	92; 101	97	--	
	Overall Recovery (n = 11)		**97**	**7.1**	
Kidney bean green material	0.01	84; 72; 74; 76; 72	76	6.6	0.01
	0.1	82; 80; 89; 83	84	4.6	
	5	87; 85	86	--	
	Overall Recovery (n = 11)		**80**	**7.5**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram

Table 8.9- 436: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	80; 74; 91; 94; 104	89	13.3	0.01
	0.1	80; 84; 83; 90	84	5.0	
	0.5	96; 93	95	--	
	Overall recovery (n = 11)		**88**	**9.9**	
Kidney bean green material	0.01	74; 80; 74; 72; 103	81	16.0	0.01
	0.1	89; 90; 82; 75	84	8.3	
	5	90; 91	91	--	
	Overall recovery (n = 11)		**84**	**11.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 147 and 202 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water and high protein matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on kidney bean (pod and green material) are summarised in the following table.

Table 8.9- 437: Residue summary of fluopyram in/on kidney bean

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram -pyridyl-carboxylic acid
R 2006 0377/0 Germany	Pod	77	-0	0.09	<0.01	<0.01	<0.01
	Pod	77	0	0.57	<0.01	<0.01	<0.01
	Pod	78	3	0.53	0.02	<0.01	<0.01
	Pod	82	7	0.24	0.03	<0.01	0.01
	Pod	83	10	0.18	0.04	0.01	0.02
	Pod	89	14	0.15	0.05	0.01	0.02
	Green material	77	-0	0.24	0.02	<0.01	<0.01
	Green material	77	0	3.2	0.03	<0.01	0.02
	Green material	78	3	4.1	0.05	<0.01	0.01
	Green material	82	7	0.71	0.06	<0.01	0.01
	Green material	83	10	0.40	0.06	<0.01	0.01
	Green material	89	14	0.26	0.06	<0.01	0.01
R 2006 0654/0 Germany	Pod	74	-0	0.05	<0.01	<0.01	<0.01
	Pod	74	0	0.20	<0.01	<0.01	<0.01
	Pod	75	3	0.10	<0.01	<0.01	<0.01
	Pod	77	7	0.07	<0.01	<0.01	<0.01
	Pod	77	10	0.06	<0.01	<0.01	<0.01
	Pod	89	14	0.06	<0.01	<0.01	<0.01
	Green material	74	-0	0.25	0.02	<0.01	<0.01
	Green material	74	0	7.8	0.02	<0.01	<0.01
	Green material	75	3	0.42	0.03	<0.01	<0.01
	Green material	77	7	0.24	0.03	<0.01	<0.01
	Green material	77	10	0.17	0.03	<0.01	<0.01
	Green material	89	14	0.08	0.02	<0.01	<0.01
R 2006 0655/9 The Netherlands	Pod	75	-0	0.05	<0.01	<0.01	<0.01
	Pod	75	0	0.22	<0.01	<0.01	<0.01
	Pod	76	3	0.21	<0.01	<0.01	<0.01
	Pod	76	7	0.20	0.01	<0.01	<0.01
	Pod	76	10	0.19	0.02	<0.01	<0.01
	Pod	77	14	0.13	0.02	0.01	<0.01
	Green material	75	-0	0.33	0.03	<0.01	<0.01
	Green material	75	0	5.7	0.03	<0.01	<0.01
	Green material	76	3	2.6	0.06	<0.01	<0.01
	Green material	76	7	0.88	0.08	<0.01	<0.01
	Green material	76	10	0.55	0.08	<0.01	<0.01
	Green material	77	14	0.37	0.08	<0.01	<0.01

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram - benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0656/7 Belgium	Pod	77	-0	0.14	0.01	<0.01	<0.01
	Pod	77	0	0.47	<0.01	<0.01	<0.01
	Pod	78	3	0.41	0.02	<0.01	<0.01
	Pod	79	7	0.21	0.03	<0.01	<0.01
	Pod	79	10	0.18	0.03	<0.01	<0.01
	Pod	81	14	0.12	0.03	<0.01	0.01
	Green material	77	-0	0.98	0.02	<0.01	<0.01
	Green material	77	0	14	0.03	<0.01	<0.01
	Green material	78	3	8.0	0.05	<0.01	0.01
	Green material	79	7	1.3	0.03	<0.01	<0.01
	Green material	79	10	0.99	0.02	<0.01	<0.01
	Green material	81	14	0.99	0.03	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on kidney bean

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 438: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0377/0 Lampertheim, DE, M-290825-01-1 bean, kidney, green material						DWD Worms (8 km) [a]	trickle	DWD Worms (8 km) [a]
	77	27/07/2006	0	3.2	3.23	0		25.2
		28/07/2006	1			0		23.6
		29/07/2006	2			0		23.2
		30/07/2006	3	4.1	4.15	0.2		23.4
		31/07/2006	4			0.4		21.8
		01/08/2006	5			5.9		18.5
		02/08/2006	6			3.2		17.7
		03/08/2006	7	0.71	0.77	3.1		16.7
		04/08/2006	8			4.1		18.1
		05/08/2006	9			8.2		18.6
		06/08/2006	10	0.4	0.46	0.1		19.9
		07/08/2006	11			29		21.4
		08/08/2006	12			9.3		18.8
		09/08/2006	13			3.9		18.9
		10/08/2006	14	0.26	0.32	4.7		16

[a] https://opendata.dwd.de/climate_environment/CDC/

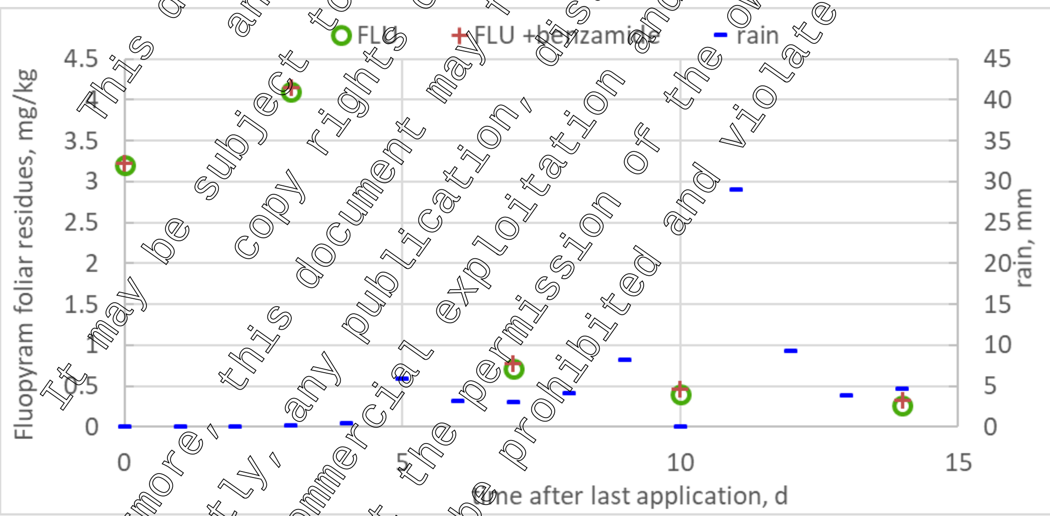


Figure 8.9-133: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

There was no rain until day 5 but it coincides with a drop of residue levels, so an influence cannot be excluded.

Table 8.9- 439: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0654/0 Langenfeld-Reusrath, DE,						ProPlant DB Laacher Hof, Monheim (~4 km) [b]	no	ProPlant DB Laacher Hof, Monheim (~4 km) [b]
M-290825-01-1	74	14/08/2006	0	7.8	7.82	4.1 (0) [a]		13.5
		15/08/2006	1			16.9		15.3
bean, kidney, green material		16/08/2006	2			0		17.1
		17/08/2006	3	0.42	0.45	1.5		18.8
		18/08/2006	4			30.2		18.4
		19/08/2006	5			4.5		17.4
		20/08/2006	6			2.6		16.2
		21/08/2006	7	0.24	0.27	9.8		15.6
		22/08/2006	8			2.1		15.8
		23/08/2006	9			0		16.3
		24/08/2006	10	0.17	0.2	4.7		15.8
		25/08/2006	11			1.9		15.1
		26/08/2006	12			3		15.4
		27/08/2006	13			1.8		15.5
		28/08/2006	14	0.08	0.1	26.8		12.8

[a] no rain within 24 h after application, in study report
[b] weather station Versuchsgut Höfchen is mentioned in study report. It is assumed to be a typo, as station Laacher Hof, Monheim is closer.

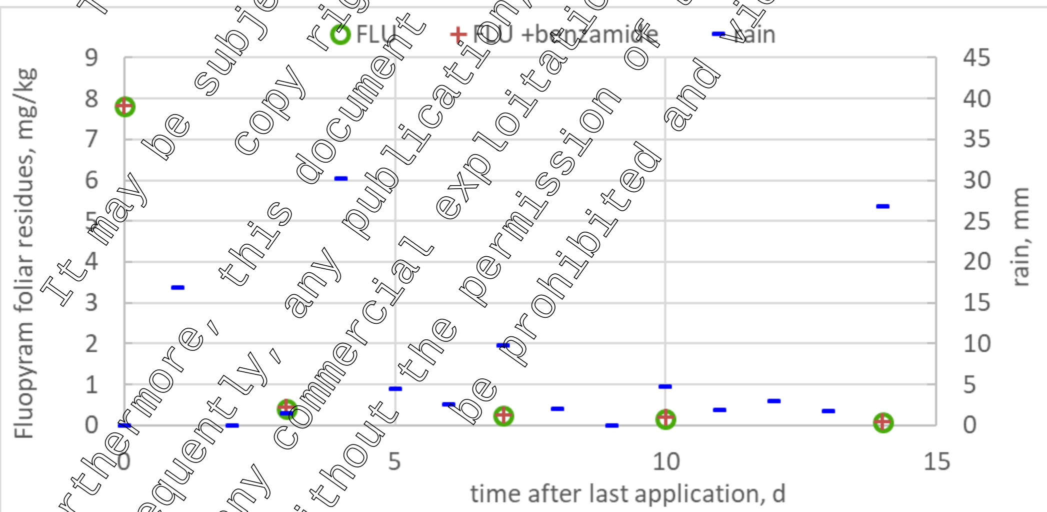


Figure 8.9- 134: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

Rainfall on day 1 (16.1 mm) coincided with a marked drop in residue concentrations, so an influence is likely

Table 8.9- 440: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0655/9 Zwaagdijk, NL,						KMNI De Kooy, Den Helder (35 km) [b]	no	KMNI De Kooy, Den Helder (35 km) [b]
M-290825-01-1	75	04/08/2006	0	5.7	5.73	1.5 (0) [a]		18.5
		05/08/2006	1			<0.05		19.7
		06/08/2006	2			0		18.7
bean, kidney, green material		07/08/2006	3	2.6	2.66	1.1		18.4
		08/08/2006	4			<0.05		17.1
		09/08/2006	5			1.1		16.7
		10/08/2006	6			13.1		14.9
		11/08/2006	7	0.88	0.96	20.2		14.5
		12/08/2006	8			2.1		15.4
		13/08/2006	9			0		16.6
		14/08/2006	10	0.55	0.63	35.1		17.6
		15/08/2006	11			1.6		16.4
		16/08/2006	12			1.4		17.8
		17/08/2006	13			<0.05		19.4
		18/08/2006	14	0.37	0.45	4.1		18.9

[a] no rain within 24 h after application, in study report
[b] http://projects.knmi.nl/klimatologie/daggegevens/selectie.cgi

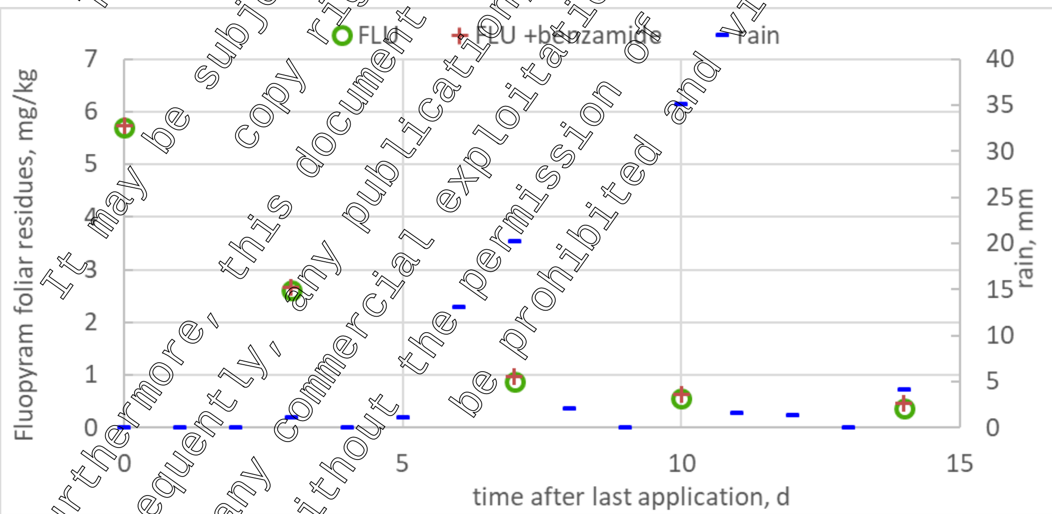


Figure 8.9- 135: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the kidney bean

Rainfall on days 6 and 7 does not appear to have influenced the residue dissipation.

Table 8.9- 441: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0656/7 Villers-Perwin, BE, M-290825-01-1 bean, kidney, green material						Redebel (3 km), study raw data	no	Redebel (3 km), study raw data
	77	25/07/2006	0	14	14.03	0		24.8
		26/07/2006	1			0		25.5
		27/07/2006	2			0		24
		28/07/2006	3	8	8.05	2.8		22.5
		29/07/2006	4			0		22.4
		30/07/2006	5			10.9		21.4
		31/07/2006	6			0		19.5
		01/08/2006	7	1.3	1.33	6.3		18.3
		02/08/2006	8			3.6		17.6
		03/08/2006	9			16.2		17
		04/08/2006	10	0.99	1.01	7.8		17.9
		05/08/2006	11			1.5		19.3
		06/08/2006	12			0		20
		07/08/2006	13			0		18.3
		08/08/2006	14	0.99	1.02	0.3		16.4

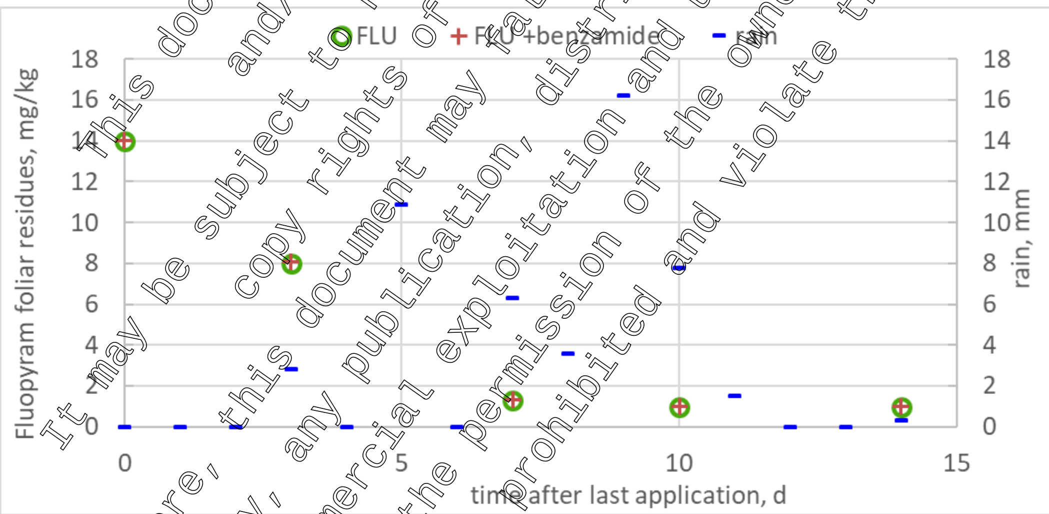


Figure 8.9- 136: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the kidney bean

Rainfall on day 3 (2.8 mm), day 5 (10.9 mm) and day 7 (6.3 mm) does not coincide with marked drops in the residue level but may have slightly influenced the residue dissipation.

II. CONCLUSION

After two spray applications of Fluopyram SC 500 on kidney bean in four residue trials conducted in northern Europe (2 x Germany, The Netherlands and Belgium) during the 2006 season the residues of fluopyram in/on kidney bean green material declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected above the LOQ of (0.01 mg/kg) in all samples with a maximum value of 0.08 mg/kg. The metabolite fluopyram-pyridyl-carboxylic acid was detected slightly above the LOQ in six samples with a maximum value of 0.02 mg/kg. The metabolite fluopyram-pyridyl-acetic acid was never detected above the LOQ.

Residues of fluopyram in/on kidney bean pod were detected above the LOQ in all samples and declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ in almost all samples with a maximum value of 0.05 mg/kg except for trial R 2006 0654/0where residues were below the LOQ. The metabolites fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were detected at the LOQ or slightly above the LOQ in four, respectively three, samples with maximum values of 0.02 and 0.01 mg/kg.

Assessment and conclusion by applicant:

Rainfall occurred in all 4 trials. No influence was visible in trial R 2006 0655/9, marked influence is likely in trial R 2006 0654/0, and slight influence may have occurred in trials R 2006 0377/0 and R 2006 0656/7.

Data Point:	KCA 8.9/30
Report Author:	[redacted]
Report Year:	2007
Report Title:	Determination of the residues of AE C656948 in/on kidney bean after spraying of AE C656948 (500 SC) in the field in (the) Spain and Italy
Report No:	RA 2595/06
Document No:	M-290827-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in Southern Europe (2 x Italy, 2 x Spain) on kidney bean during the 2006 season. Two applications with Fluopyram SC 500 containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on kidney bean (pod and green material) declined markedly during the sampling period. Residues of fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were detected above the LOQ (0.01 mg/kg) in almost all samples with a maximum value of 0.13 mg/kg in green material and

0.06 mg/kg in pod, 0.02 mg/kg in green material and pod and 0.03 mg/kg in green material and 0.04 mg/kg in pod, respectively.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram (500 SC)
	Batch no.:	2005-004952
	Active substance:	Fluopyram
	Storage:	Not stated in the report
	Expiry date:	2008-01-12
2.	Test commodity:	Kidney bean
	Crop part:	Pod and green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2595/06 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on kidney bean (pod and green material) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

Field phase

The study included four supervised residue trials conducted in southern Europe (2 x Italy, 2 x Spain) during the 2006 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 442: Description of the trial locations and cropping information on treated plots

Trial number	**R 2006 0378/9**	**R 2006 0620/6**	**R 2006 0657/5**	**R 2006 0658/3**
Trial location	E-46230 Alginet (Comunidad Valenciana)	I-37060 Pradelle di Nogarole Rocca (VR) (Veneto)	E-08380 Malgrat de Mar (Barcelona) (Cataluña)	I-00055 Ladispoli (RM) (Lazio)
Country	Spain	Italy	Spain	Italy
Area of application	Field	Field	Field	Field
Plot size [m²]	67.5	90	50	80
Type of soil	Silty clay	Sandy loam	Sandy loam	Clay sand
pH-value of soil (in water)	8.0	7.3	8.0	6.9
Content of organic C [%]	1.1	1.7	1.0	0.8
Test system	Kidney bean	Kidney bean	Kidney bean	Kidney bean
Variety	Cleo	Jamaica	Nasao	Bronco
Date of sowing	2006-05-16	2006-07-20	2006-05-02	2006-05-23
Start Flowering	2006-06-05	2006-08-28	2006-06-10	2006-06-19
End Flowering	2006-07-07	2006-09-05	2006-07-15	2006-07-25
Date of commercial harvest	2006-06-10 to 2006-07-30	2006-09-15 to 2006-10-10	2006-06-20 to 2006-07-15	2006-05-20 to 2006-10-31

The actual application data are presented in the following table. This data reflects the intended application scheme or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stages between 65-72 and the second between 71-85 with an application rate of 0.25 kg a.s./ha and a water rate of 500-800 L/ha.

Table 8.9- 443: Overview on application with Fluopyram SC 500 on kidney bean

Trial no. Country	**Appl. No.**	**Plot**	**Formu-lation**	**Appl. mode**	**Interval (days)**	**Growth stage (BBCH code)**	**DBH PHI (days)**	**Test item rate (L/ha)**	**Water rate (L/ha)**	**a.s.**	**Appl. rate (g a.s. /ha)**
R 2006 0378/9 Spain	1	T	Fluopyram SC 500	SPI	7	69	14	0.5	600	Fluopyram	0.25
	2					73	7*	0.5	600		0.25
R 2006 0620/6 Italy	1	T	Fluopyram SC 500	SPI	7	72	14	0.5	500	Fluopyram	0.25
	2					75	7*	0.5	500		0.25
R 2006 0657/5 Spain	1	T	Fluopyram SC 500	SPI	7	66	14	0.5	500	Fluopyram	0.25
	2					85	7*	0.5	600		0.25
	1	T		SPI	7	65	14	0.5	800	Fluopyram	0.25

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2006 0658/3 Italy	2		Fluopyram SC 500			71	7*	0.5	800		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of kidney bean pod and green material. The samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 444: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2006 0378/9 R 2006 0620/6 R 2006 0657/5 R 2006 0658/3	Kidney bean	Pod, green material	C	-0 3 7 14
		Pod, green material	T	-0 0 3 7 10 14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites were analysed within the residue trials samples according to the following method:

Table 8.9- 445: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in kidney bean (pod and green material))

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The means of the concurrent recoveries were for all matrices and for all fortification levels (except 0.01 and 0.5 mg/kg for fluopyram-benzamide for which the mean recoveries were 112 and 111% respectively for the pod) within the acceptable range of 70 – 110 %. Consequently, all the results are considered as valid. The overall RSD values were below 20%. Details are given in the table below.

Table 8.9- 446: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	87		--	0.01
	0.5	97; 98	98	--	
	1	93; 100	97	--	
	Overall Recovery (n = 5)		**95**	**5.4**	
Kidney bean green material	0.01	111; 89; 103	101	**11.1**	0.01
	0.5	100		--	
	5	107		--	
	10	88		--	
	Overall Recovery (n = 6)		**100**	**9.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 447: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	112		--	0.01
	0.5	112; 110	111	--	
	1	109; 104	107	--	
	Overall Recovery (n = 5)		**109**	**3.0**	
Kidney bean green material	0.01	110; 100; 101	104	6.0	0.01
	0.5	110		--	
	5	108		--	
	10	86		--	
	Overall Recovery (n = 6)		**103**	**9.0**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

Table 8.9- 448: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	86		--	0.01
	0.5	95; 98	97	--	
	1	93; 94	94	--	
	Overall Recovery (n = 5)		**93**	**4.8**	
Kidney bean green material	0.01	95; 77; 84	85	10.6	0.01
	0.5	104		--	
	5	92		--	
	10	80		--	
	Overall Recovery (n = 6)		**88**	**10.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as Fluopyram

Table 8.9- 449: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	90		--	0.01
	0.5	104; 96	100	--	
	1	88; 91	90	--	
	Overall recovery (n = 5)		**94**	**6.8**	
Kidney bean green material	0.01	120; 78; 112	103	21.1	0.01
	0.5	101		--	
	5	95		--	
	10	85		--	
	Overall recovery (n = 6)		**99**	**16.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification. Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 172 and 301 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water and high protein matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on kidney bean (pod and green material) are summarised in the following table.

Table 8.9- 450: Residue summary of fluopyram in/on kidney bean

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0378/9 Spain	Pod	73	-0	0.03	<0.01	<0.01	<0.01
	Pod	73	0	0.40	<0.01	<0.01	<0.01
	Pod	75	3	0.17	0.01	<0.01	<0.01
	Pod	77	7	0.24	0.03	<0.01	0.01
	Pod	78	10	0.13	0.03	0.01	0.03
	Pod	81	14	0.14	0.06	0.02	0.04
	Green material	73	-0	0.25	0.01	<0.01	<0.01
	Green material	73	0	3.0	0.02	<0.01	<0.01
	Green material	75	3	2.9	0.05	<0.01	0.01
	Green material	77	7	1.6	0.07	<0.01	0.01
	Green material	78	10	1.3	0.09	<0.01	0.02
	Green material	81	14	1.2	0.13	0.02	0.03
R 2006 0620/6 Italy	Pod	75	-0	0.08	<0.01	<0.01	<0.01
	Pod	75	0	0.60	<0.01	<0.01	<0.01
	Pod	77	3	0.15	<0.01	<0.01	<0.01
	Pod	79	7	0.10	<0.01	<0.01	<0.01
	Pod	79	10	0.08	<0.01	<0.01	<0.01
	Pod	79	14	0.06	<0.01	<0.01	<0.01
	Green material	75	-0	0.22	0.02	<0.01	<0.01
	Green material	75	0	7.7	0.02	<0.01	<0.01
	Green material	77	3	0.42	0.03	<0.01	<0.01
	Green material	79	7	0.34	0.03	<0.01	<0.01
	Green material	79	10	0.26	0.03	<0.01	<0.01
	Green material	79	14	0.20	0.03	<0.01	<0.01
R 2006 0657/5 Spain	Pod	89	-0	0.03	<0.01	<0.01	<0.01
	Pod	89	0	0.42	<0.01	<0.01	<0.01
	Pod	89	2	0.10	<0.01	<0.01	<0.01
	Pod	89	7	0.05	0.02	0.01	0.01
	Pod	89	10	0.05	0.03	0.02	0.02
	Pod	89	14	0.03	0.03	0.02	0.01
	Green material	85	-0	0.18	0.03	<0.01	<0.01
	Green material	85	0	3.9	0.03	<0.01	<0.01
	Green material	85	2	0.81	0.05	<0.01	<0.01
	Green material	87	7	0.25	0.06	0.01	<0.01
	Green material	88	10	0.19	0.08	0.01	<0.01
	Green material	89	14	0.13	0.10	0.02	0.01

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram - benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0658/3 Italy	Pod	71	-0	0.06	<0.01	<0.01	<0.01
	Pod	71	0	0.33	<0.01	<0.01	<0.01
	Pod	73	3	0.18	<0.01	<0.01	<0.01
	Pod	74	7	0.11	0.02	<0.01	<0.01
	Pod	76	10	0.08	0.02	<0.01	<0.01
	Pod	77	14	0.10	0.04	<0.01	<0.01
	Green material	71	-0	0.51	0.03	<0.01	<0.01
	Green material	71	0	5.8	0.04	<0.01	<0.01
	Green material	73	3	4.1	0.06	<0.01	<0.01
	Green material	74	7	0.84	0.08	<0.01	<0.01
	Green material	76	10	0.86	0.09	<0.01	<0.01
	Green material	77	14	0.39	0.09	0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on kidney bean

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 451: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0378/9 Alginet, ES,						Benifaio (5 km), study raw data	flooding	Benifaio (5 km), study raw data
M-290827-01-1	73	23/06/2006	0	3	3.02	0		23.81
		24/06/2006	1			0.2		24.82
bean, kidney, green material		25/06/2006	2			0		24.95
		26/06/2006	3	2.9	2.95	0		23.93
		27/06/2006	4			0		23.8
		28/06/2006	5			0		24.44
		29/06/2006	6			0		25.45
		30/06/2006	7	1.6	1.67	0		25.13
		01/07/2006	8			0		26.09
		02/07/2006	9			0		25.08
		03/07/2006	10	1.3	1.39	0		27.18
		04/07/2006	11			0		24.69
		05/07/2006	12			0		25.28
		06/07/2006	13			0.2		24.88
		07/07/2006	14	1.2	1.33	0		25.19

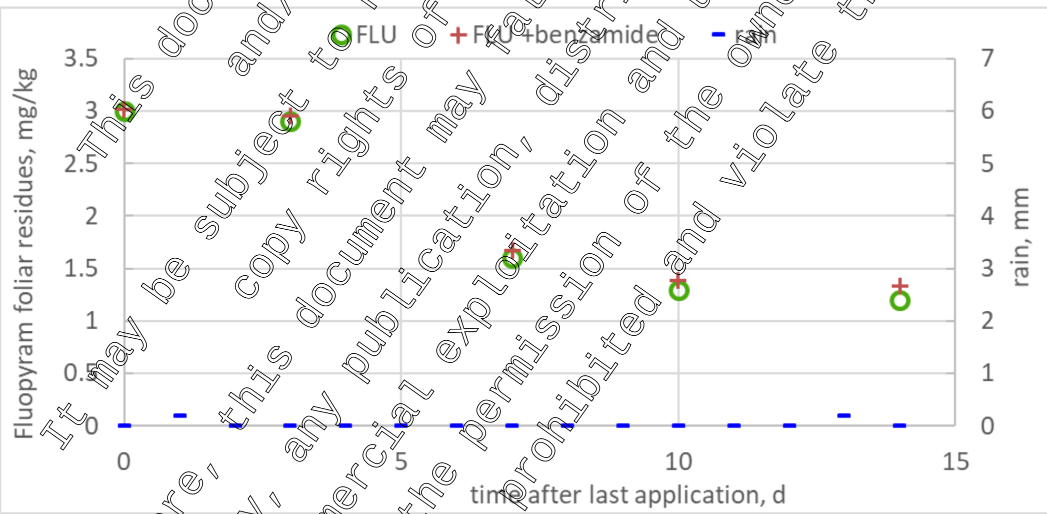


Figure 8.9- 137: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

There was practically no rainfall and no influence on residue dissipation.

Table 8.9- 452: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0620/6 Pradelle di Nogarole Rocca, IT,						www-ilmeteo.it Verona Villafranca (~ 8 km)	no	www-ilmeteo.it Verona Villafranca (~ 8 km)
M-290827-01-1	75	15/09/2006	0	7.7	7.72	48 (0) [a]		21.3
		16/09/2006	1			10.9		20.3
		17/09/2006	2			14		18.8
bean, kidney, green material		18/09/2006	3	0.42	0.45	0		20.5
		19/09/2006	4			0		21.2
		20/09/2006	5			0		21.3
		21/09/2006	6			0		21.4
		22/09/2006	7	0.34	0.37	0		22.1
		23/09/2006	8			0		20.7
		24/09/2006	9			0		18.9
		25/09/2006	10	0.26	0.29	5.1		18.4
		26/09/2006	11			1		20.3
		27/09/2006	12			0		21.3
		28/09/2006	13			0		20.6
		29/09/2006	14	0.2[illegible]	0.23	0		19.8

[a] no rain within 24 h after application, in study report

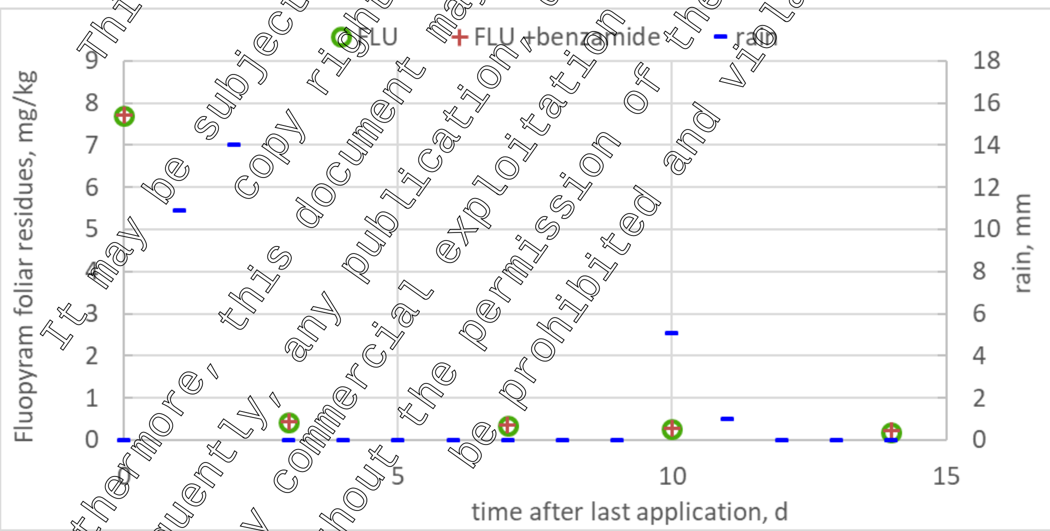


Figure 8.9- 138: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

Rainfall in the first days coincide with a marked drop in residue levels, an influence on residue dissipation is likely.

Table 8.9- 453: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0657/5 Malgrat de Mar, ES,						Catalan Meteo Malgrat de Mar (1 km)	no	Catalan Meteo Malgrat de Mar (1 km)
M-290827-01-1	85	27/06/2006	0	3.9	3.93	0		22.9
		28/06/2006	1			0		23.6
bean, kidney, green material		29/06/2006	2	0.81	0.86	0		24.4
		30/06/2006	3			0		24.1
		01/07/2006	4			0		24
		02/07/2006	5			0		24.1
		03/07/2006	6			0		24.2
		04/07/2006	7	0.25	0.31	0		24.6
		05/07/2006	8			0		25.2
		06/07/2006	9			0.2		23.1
		07/07/2006	10	0.19	0.27	0.1		23.1
		08/07/2006	11			0		23.9
		09/07/2006	12			0		24.5
		10/07/2006	13			0		25.6
		11/07/2006	14	0.13	0.23	0		24.7

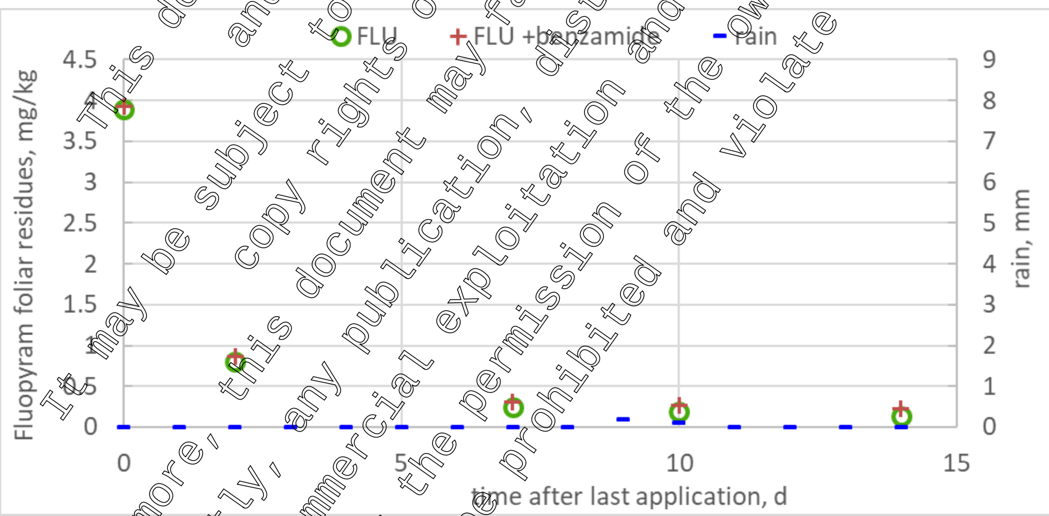


Figure 8.9- 139: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the kidney bean

There was practically no rain and no influence on residue dissipation.

Table 8.9- 454: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0658/3 Ladispoli, IT, M-290827-01-1 bean, kidney, green material						www.ilmeteo.it Ladispoli	sprinkler	www.ilmeteo.it Ladispoli
	71	11/07/2006	0	5.8	5.84	0		26.4
		12/07/2006	1			0		26.3
		13/07/2006	2			0		25.9
		14/07/2006	3	4.1	4.16	0		25.7
		15/07/2006	4			0		26.3
		16/07/2006	5			0		26.2
		17/07/2006	6			0		25.1
		18/07/2006	7	0.84	0.92	0		24.2
		19/07/2006	8			0		24.3
		20/07/2006	9			0		25.3
		21/07/2006	10	0.86	0.95	0	22	26
		22/07/2006	11			0		26.1
		23/07/2006	12			0		26.4
		24/07/2006	13			0		26.8
		25/07/2006	14	0.39	0.48	0		26.6

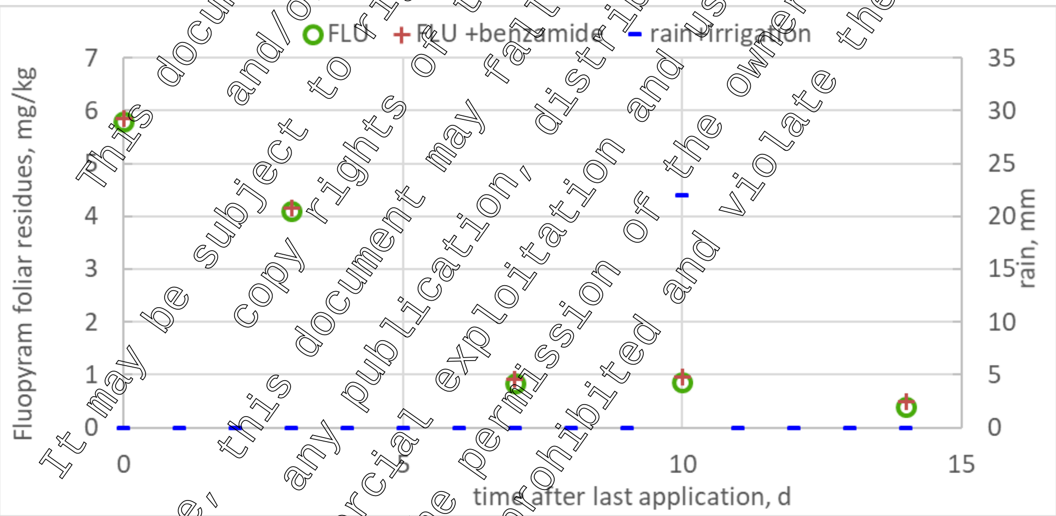


Figure 8.9- 140: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the kidney bean

There was no rain and irrigation only after 10 days; no influence on residue dissipation.

II. CONCLUSION

After two spray applications of Fluopyram SC 500 on kidney bean in four residue trials conducted in southern Europe (2 x Italy, 2 x Spain) during the 2006 season the residues of fluopyram in/on kidney bean green material declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected above the LOQ (0.01 mg/kg) in all samples with a maximum value of 0.13 mg/kg. The metabolite fluopyram-pyridyl-carboxylic acid was detected slightly above the LOQ in five samples with a maximum value of 0.03 mg/kg. The metabolite fluopyram-pyridyl-acetic acid was detected slightly above the LOQ in five samples with a maximum value of 0.03 mg/kg

Residues of fluopyram in/on kidney bean pod were detected above the LOQ in all samples and declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ in almost all samples with a maximum value of 0.06 mg/kg except for trial R 2006 0620/6where residues were below the LOQ. The metabolites fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were detected slightly above the LOQ only in trials R 2007 0657/5 and R 2006 0378/9 with maximum values of 0.04 and 0.02 mg/kg, respectively.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall in one of the 4 trials (R 2006 0620/6) has probably influenced the residue levels, but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/31
Report Author:	[redacted].
Report Year:	2007
Report Title:	Determination of the residues of AE C656948 in/on garden pea after spraying of AE C656948 (500 SC) in the field in (the) Germany and United Kingdom
Report No:	RA-2597/06
Document No:	M-291180-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 - Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with three residue trials was conducted in the field in northern Europe (2 x Germany and United Kingdom) on garden pea during the 2006 season. Two applications with Fluopyram SC 500 containing 500 g/L fl13-2950uopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on garden pea (green material) declined markedly during the sampling period. Residues of fluopyram in pod and green seed were detected above the LOQ with maximum values of 0.57 and 0.05 mg/kg, respectively.

Residues of fluopyram-benzamide were detected slightly above the LOQ (0.01 mg/kg) in almost all samples with a maximum value of 0.05 mg/kg. Residues of fluopyram-pyridyl-carboxylic acid were detected in three samples of garden pea (green seed) with a maximum value of 0.02 mg/kg and residues of fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

No residues of the metabolites above the LOQ were detected in garden pea (pod).

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram (500 SC)

   Batch no.: 2005-004952

   Active substance: Fluopyram

   Storage: Not stated in the report

   Expiry date: 2008-01-12

2. Test commodity: Garden pea

   Crop part: Green seed, pod and green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2597/06 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on garden pea (seed green, pod and green material) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

Field phase

The study included three supervised residue trials conducted in northern Europe (2 x Germany, United Kingdom) during the 2006 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 455: Description of the trial locations and cropping information on treated plots

Trial number	R 2006 0380/0	R 2006 0722/9	R 2006 0723/7
Trial location	D-04827 Machern (Sachsen)	GB-IP20 9LF Needham (Norfolk)	D-88074 Meckenbeuren (Baden-Württemberg)
Country	Germany	United Kingdom	Germany
Area of application	Field	Field	Field
Plot size [m^2]	40	50	90
Type of soil	Clay sand	Silty loam	Loamy sand
pH-value of soil (in water)	5.8	8.0	7.1
Content of organic C [%]	1.1	0.7	1.4
Test system	Garden pea	Garden pea	Garden pea
Variety	Harnaß	Hawk	Rondo
Date of planting/sowing	- / 2006-04-23	- / 2006-04-18	- / 2006-05-11
Start Flowering	2006-06-15	2006-06-12	2006-07-01
End Flowering	2006-06-30	2006-06-24	2006-07-08
Date of commercial harvest	2006-07-10 to 2006-07-20	2006-07-06 to 2006-07-11	2006-07-21 to 2006-08-04

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stages between 59-67 and the second between 71-79 with an application rate of 0.25 kg a.s./ha and a water rate of 300-336 L/ha.

Table 8.9- 456: Overview on application with Fluopyram SC 500 on garden pea

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
R 2006 0380/0 Germany	1	T	Fluopyram SC 500	SPI	7	62	14	0.5	317	Fluopyram	0.25
	2					71	7*	0.5	336		0.25
R 2006 0722/9 United Kingdom	1	T	Fluopyram SC 500	SPI	7	67	15	0.5	300	Fluopyram	0.25
	2					79	7*	0.5	300		0.25
R 2006 0723/7 Germany	1	T	Fluopyram SC 500	SPI	7	59	15	0.5	300	Fluopyram	0.25
	2					73	7*	0.5	300		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of garden pea (seed green, pod and green material). The samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 457: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2006 0380/0 R 2006 0722/9 R 2006 0723/7	Garden pea	Green material	C	-0
				7
		Seed green	C	7
		Green material	T	-0
				0
		Green material, pod	T	3
		Green material, seed green	T	7
				10
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites were analysed within the residue trials samples according to the following method:

Table 8.9- 458: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in garden pea (seed green, pod and green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 459: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	92; 120	106	-	0.01
	0.1	98	98	-	
	5	93; 99	96	-	
	Overall Recovery (n = 5)		**100**	**11.3**	
Garden pea, seed green	0.01	103; 91; 93	96	6.7	0.01
	0.1	104; 106	105	--	
	Overall Recovery (n = 5)		**99**	**6.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 460: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	97	97	-	0.01
	5	90; 91	91	-	
	Overall Recovery (n = 3)		**93**	**4.1**	
Garden pea, seed green	0.01	122; 106; 111	113	7.2	0.01
	0.1	101; 103	102	--	
	Overall Recovery (n = 5)		**109**	**7.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

Table 8.9- 461: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	73;	73	-	0.01
	0.5	92; 91	92		
	Overall Recovery (n = 3)		**85**	**12.5**	
Garden pea, seed green	0.01	95; 111; 107	104	8.0	0.01
	0.1	99; 100	100	--	
	Overall Recovery (n = 5)		**102**	**6.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram

Table 8.9- 462: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	84	--	--	0.01
	5	97; 100	99		
	Overall recovery (n = 3)		**94**	**9.1**	
Garden pea, seed green	0.01	111; 95; 105	104	7.8	0.01
	0.1	85; 79	82	--	
	5	100	**--**	--	
	Overall recovery (n = 6)		**96**	**12.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 228 and 329 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water and high protein matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on garden pea (seed green, pod and green material) are summarised in the following table.

Table 8.9- 463: Residue summary of fluopyram in/on garden pea

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0380/0 Germany	Green material	71	-0	1.2	0.02	<0.01	<0.01
	Green material	71	0	3.4	0.02	<0.01	<0.01
	Green material	73	3	3.4	0.03	<0.01	<0.01
	Pod	73	3	0.20	0.01	<0.01	<0.01
	Green material	76	7	3.5[(a)]	0.05	<0.01	<0.01
	Seed, green	76	7	0.03	<0.01	<0.01	<0.01
	Green material	77	10	1.8[(b)]	0.04	<0.01	<0.01
	Seed, green	77	10	0.02	<0.01	<0.01	0.01
	Green material	81	14	2.2[(c)]	0.06	<0.01	<0.01
	Seed, green	81	14	0.03	0.01	<0.01	0.02
R 2006 0722/9 United Kingdom	Green material	79	-0	0.91	0.01	<0.01	<0.01
	Green material	79	0	3.9	0.02	<0.01	<0.01
	Green material	79	3	4.1	0.03	<0.01	<0.01
	Pod	79	3	0.57	<0.01	<0.01	<0.01
	Green material	79	7	3.3	0.04	<0.01	<0.01
	Seed, green	79	7	0.05	<0.01	<0.01	<0.01
	Green material	79	10	2.7	0.06	<0.01	<0.01
	Seed, green	79	10	0.03	0.01	<0.01	<0.01

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
	Green material	79	14	1.7	0.07	<0.01	<0.01
	Seed, green	79	14	0.04	0.02	<0.01	<0.01
R 2006 0723/7 Germany	Green material	73	-0	0.05	<0.01	<0.01	<0.01
	Green material	73	0	4.2	0.02	<0.01	<0.01
	Green material	75	3	3.8	0.04	<0.01	<0.01
	Pod	75	3	0.40	<0.01	<0.01	<0.01
	Green material	75	7	0.46	0.04	<0.01	<0.01
	Seed, green	75	7	0.01	<0.01	<0.01	<0.01
	Green material	76	10	0.37	0.04	<0.01	<0.01
	Seed, green	76	10	<0.01	<0.01	<0.01	<0.01
	Green material	77	13	0.24	0.04	<0.01	<0.01
	Seed, green	77	13	<0.01	<0.01	<0.01	0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

(a): This result corresponds to the mean of 2 single values (3.24 and 3.72 mg/kg).
(b): This result corresponds to the mean of 2 single values (1.83 and 1.78 mg/kg).
(c): This result corresponds to the mean of 2 single values (2.64 and 1.71 mg/kg).

2. Climatic conditions and time course of residue concentrations in/on garden pea

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 464: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0380/0 Machern, DE, M-291180-01-1 pea, garden, green material						DWD Leipzig-Holzhausen (~12 km) [a)]	no	DWD Leipzig-Holzhausen (~12 km) [a)]
	71	30/06/2006	0	3.4	3.42	0		16.9
		01/07/2006	1			0		19.4
		02/07/2006	2			0		20.9
		03/07/2006	3	3.4	3.43	0		21.2
		04/07/2006	4			0		22.6
		05/07/2006	5			0		24.2
		06/07/2006	6			0		24
		07/07/2006	7	3.5	3.55	9.9		22.6
		08/07/2006	8			1.8		20.2
		09/07/2006	9			0		22.5
		10/07/2006	10	1.8	1.84	0		23.6
		11/07/2006	11			0		24.9
		12/07/2006	12			0		23.8
		13/07/2006	13			2.1		24.1
		14/07/2006	14	2.1	2.16	0		20
a) https://opendata.dwd.de/climate_environment/CDC/								

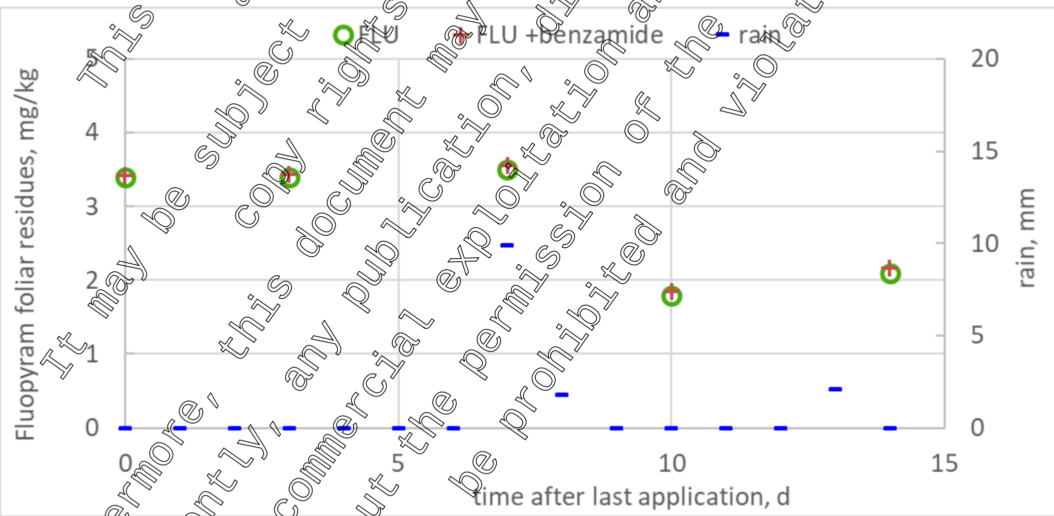


Figure 8.9- 141: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to garden pea

The rainfall on day 7 coincides with a drop in residue levels, so an influence is likely.

Table 8.9- 465: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0722/9 Needham, GB,						Brooms Barn (58 km), Bayer raw data	no	Brooms Barn (58 km), Bayer raw data
M-291180-01-1	79	27/06/2006	0	3.9	3.92	0		14.2
		28/06/2006	1			0		14.1
pea, garden, green material		29/06/2006	2			0		15.6
		30/06/2006	3	4.1	4.13	0		17.8
		01/07/2006	4			0		19.25
		02/07/2006	5			0		22
		03/07/2006	6			0		21.6
		04/07/2006	7	3.3	3.34	0.9		20.4
		05/07/2006	8			0.4		19.85
		06/07/2006	9			0		20.3
		07/07/2006	10	2.7	2.76	0.5		18.5
		08/07/2006	11			2.2		16.65
		09/07/2006	12			0		18
		10/07/2006	13			0.9		17.45
		11/07/2006	14	1.7	1.77	0		20.3

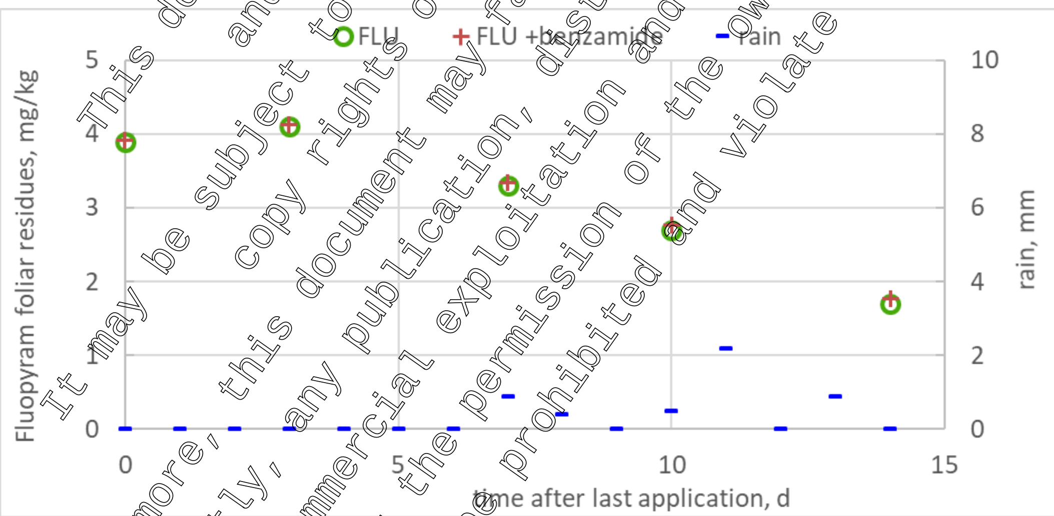


Figure 8.9- 142: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to garden pea

There was basically no rain and no influence on residue levels.

Table 8.9- 466: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0723/7 Meckenbeuren, DE, M-291180-01-1 pea, garden, green material						DWD Konstanz (25 km) [a]	no	DWD Konstanz (25 km) [a]
	73	14/07/2006	0	4.2	4.22	0		24
		15/07/2006	1			0		23.4
		16/07/2006	2			0		23.3
		17/07/2006	3	3.8	3.84	0		22.9
		18/07/2006	4			0		23.9
		19/07/2006	5			0		25.2
		20/07/2006	6			0		26.5
		21/07/2006	7	0.46	0.5	0		26.5
		22/07/2006	8			5.5		25.1
		23/07/2006	9			0.2		24.4
		24/07/2006	10	0.37	0.41	0		26.6
		25/07/2006	11			0		26.8
		26/07/2006	12			0		26.1
		27/07/2006	13	0.24	0.28	0.2		26.5

[a] https://opendata.dwd.de/climate_environment/CDC/

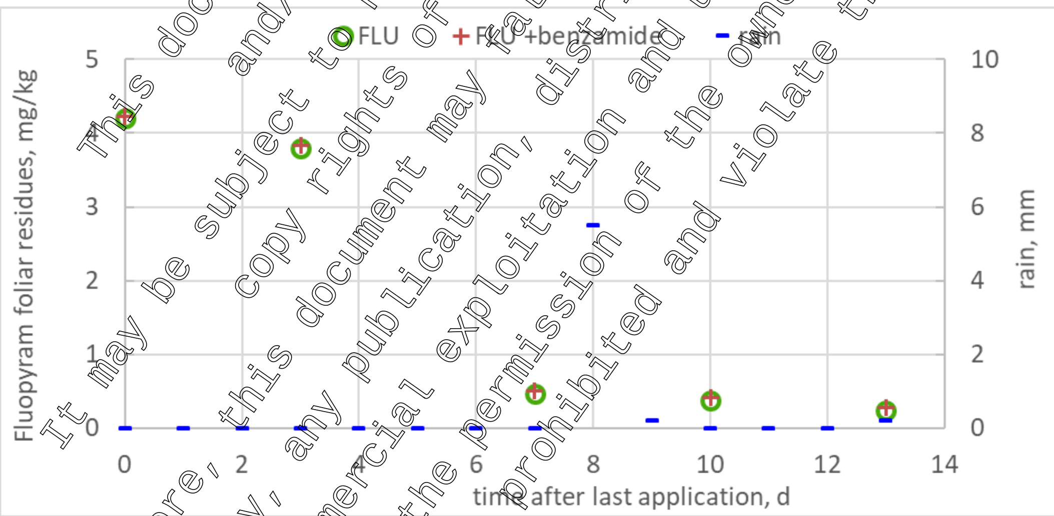


Figure 8.9- 143: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the garden pea

There was no rain until day 8 and no discernible influence on residue levels.

III. CONCLUSION

After two spray applications of Fluopyram SC 500 on garden pea in three residue trials conducted in northern Europe (2 x Germany, United Kingdom) during the 2006 season the residues of fluopyram in/on garden pea (green material) declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ of (0.01 mg/kg) in all samples with a maximum value of 0.07 mg/kg. The metabolites fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ.

Residues of fluopyram in/on garden pea (seed green) were detectable slightly above the LOQ in all samples with a maximum value of 0.05 mg/kg. The metabolite fluopyram-benzamide was detected slightly above the LOQ in three samples (2 x 0.01 and 0.02 mg/kg). The metabolite fluopyram-pyridyl-carboxylic acid was detected above the LOQ in three samples with a maximum value of 0.02 mg/kg and metabolite fluopyram-pyridyl-acetic acid was always below the LOQ.

Residues of fluopyram in garden pea (pod) were detected in all samples with a maximum value of 0.57 mg/kg. No residues of the metabolites above the LOQ were detected in garden pea (pod).

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall in one of the three trials (R 2006 0380/0) appears to have influenced the residue levels but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

In the following section the residue study summaries are presented that have been analysed in the kinetic report in M-763337-01-1:

Data Point:	KCA 8.9/32
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 in/on head lettuce and lettuce after spraying of AE C656948 (500 SC) in the field in United Kingdom, Germany, Northern France, Belgium and Netherlands
Report No:	RA-2509/07
Document No:	M-304280-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 - Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with six residue trials was conducted in the field in northern Europe (United Kingdom, Belgium, 2 x Germany, northern France, and The Netherlands) on lettuce during the 2007 season. Two applications with Fluopyram SC 500 containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected slightly above the LOQ (0.01 mg/kg) in almost all samples with a maximum value of 0.03 mg/kg. The residues of metabolites fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram (500 SC)

   Batch no.: 2006-010316

   Active Ingredient: Fluopyram

   Storage: Not stated in the report

   Expiry date: 2009-01-09

2. Test commodity: Lettuce

   Crop part: Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2509/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on lettuce (head) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

Field phase

The study included six supervised residue trials conducted in northern Europe (United Kingdom, Belgium, 2 x Germany, northern France, and The Netherlands) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 467: Description of the trial locations and cropping information on treated plots

Trial number	**R 2007 0011/3**	**R 2007 0244/2**	**R 2007 0537/9**	**R 2007 0538/7**	**R 2007 0539/5**	**R 2007 0540/9**
Trial location	GB-CB Barway/ Near Ely (Cambridge-shire)	D-88074 Meckenbeu-ren (Baden-Württemberg)	D-40764 Langenfeld-Reusrath (Nordrhein-Westfalen)	F-80320 Puzeaux (Picardie)	B-6210 Villers-Perwin (Hainaut)	NL-1681 ND Zwaagdijk-Oost (Noord-Holland)
Country	United Kingdom	Germany	Germany	Northern France	Belgium	The Netherlands
Area of application	Field	Field	Field	Field	Field	Field
Plot size [m^2]	36	30	33	60	24	32
Type of soil	Clay loam	Sandy loam	Loamy sand	Loam	Silty loam	Clay
pH-value of soil (in water)	7.3	6.5	6.9	8.3	5.7	7.0
Content of organic C [%]	13.4	2.6	1.7	0.9	2.6	3.1
Test system	Head lettuce	Head lettuce	Head lettuce	Lettuce	Lettuce	Lettuce
Variety	Elenaro	Nobilan	Torpedo	Madras	Appia	Lolo Rosso
Date of planting/ sowing	2007-04-30/-	2007-08-15/-	2007-04-05/-	-/2007-05-01	2007-04-26 / 2007-04-03	2007-06-26/-
Date of commercial harvest	2007-06-18 to 2007-06-20	2007-09-28 to 2007-10-07	2007-05-15 to 2007-05-25	2007-06-12 to 2007-06-16	2007-06-01 to 2007-06-10	2007-08-09 to 2007-08-16

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range.

The first application was performed at BBCH stages between 19-46 and the second between 42-49 with an application rate of 0.25-0.268 kg a.s./ha and a water rate of 300-750 L/ha.

Table 8.9- 468: Overview on application with Fluopyram SC 500 on lettuce

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2007 0011/3 United Kingdom	1	T	Fluopyram SC 500	SPI	7	41	14	0.5	300	Fluopyram	0.25
	2					42	7*	0.5	300		0.25
R 2007 0244/2 Germany	1	T	Fluopyram SC 500	SPI	7	44	14	0.535	321	Fluopyram	0.268
	2					44	7*	0.5	300		0.25
R 2007 0537/9 Germany	1	T	Fluopyram SC 500	SPI	7	46	14	0.5	600	Fluopyram	0.25
	2					46	7*	0.5	600		0.25
R 2007 0538/7 France	1	T	Fluopyram SC 500	SPI	7	43	14	0.5	300	Fluopyram	0.25
	2					46	7*	0.5	300		0.25
R 2007 0539/5 Belgium	1	T	Fluopyram SC 500	SPI	7	19	14	0.5	400	Fluopyram	0.25
	2					43	7*	0.5	400		0.25
R 2007 0540/9 The Netherlands	1	T	Fluopyram SC 500	SPI	7	46	14	0.5	750	Fluopyram	0.25
	2					49	7*	0.5	750		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of lettuce. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 469: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0011/3 R 2007 0244/2 R 2007 0537/9 R 2007 0538/7 R 2007 0539/5 R 2007 0540/9	Lettuce	Head	C	-0
				3
				7
				10
			T	-0
				0
				3
				7
				10
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 470: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in lettuce head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were within the acceptable range of 70 – 110% except for fluopyram-pyridyl-carboxylic acid at 10 mg/kg fortification level with only 67% recovery rate. The RSD values were below 20%. Details are given in the table below.

Table 8.9- 471: Procedural recoveries for fluopyram

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / Head lettuce (head)	0.01	63; 84	74	-	0.01
	0.1	94; 93	94	-	
	1	83	83	-	
	10	**94**	94	-	
	Overall Recovery (n = 6)		**85**	**14.0**	

Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.
Bold single values: Recoveries performed on head lettuce

Table 8.9- 472: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / Head lettuce (head)	0.01	64; 102	83	-	0.01
	0.10	94; 99	97	-	
	1.0	84	84	-	
	10	**101**	101	-	
	Overall Recovery (n = 6)		**91**	**16.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.
Bold single values: Recoveries performed on head lettuce

Table 8.9- 473: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / Head lettuce (head)	0.01	64; 93	79	-	0.01
	0.10	109; 104	107	-	
	1.0	88	88	-	
	10	**98**	98	-	
	Overall recovery (n = 6)		**93**	**17.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram. Bold single values: Recoveries performed on head lettuce

Table 8.9- 474: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / Head lettuce (head)	0.01	101; 110	106	-	0.01
	0.1	81; 101	91	-	
	1	84	84	-	
	10	**67**	67	-	
	Overall recovery (n = 6)		**91**	**17.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram. Bold single values: Recoveries performed on head lettuce

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 57 and 138 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on lettuce head are summarised in the following table.

Table 8.9- 475: Residue summary of fluopyram and metabolites in/on lettuce, head

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0011/3 United Kingdom	Head	42	-0	0.36	<0.01	<0.01	<0.01
	Head	42	0	6.1	<0.01	<0.01	<0.01
	Head	43	3	0.82	<0.01	<0.01	<0.01
	Head	46	6	0.18	<0.01	<0.01	<0.01
	Head	47	9	0.02	<0.01	<0.01	<0.01
	Head	49	13	<0.01	<0.01	<0.01	<0.01
R 2007 0244/2 Germany	Head	44	-0	0.41	<0.01	<0.01	<0.01
	Head	44	0	4.5	0.01	<0.01	<0.01
	Head	45	2	3.6	0.01	<0.01	<0.01
	Head	47	7	0.61	<0.01	<0.01	<0.01
	Head	48	10	0.44	<0.01	<0.01	<0.01
	Head	49	13	0.13	<0.01	<0.01	<0.01
R 2007 0537/9 Germany	Head	46	-0	0.85	0.02	<0.01	<0.01
	Head	46	0	6.1	0.02	<0.01	<0.01
	Head	48	3	1.1	0.03	<0.01	<0.01
	Head	49	7	0.57	0.02	<0.01	<0.01
	Head	49	10	0.43	0.03	<0.01	<0.01
	Head	49	14	0.33	0.02	<0.01	<0.01
R 2007 0538/7 Northern France	Head	46	-0	<0.01	<0.01	<0.01	<0.01
	Head	46	0	6.0	0.01	<0.01	<0.01
	Head	46	4	0.12	<0.01	<0.01	<0.01
	Head	49	7	0.12	<0.01	<0.01	<0.01
	Head	49	11	0.04	<0.01	<0.01	<0.01
	Head	51	15	0.02	<0.01	<0.01	<0.01
R 2007 0539/5 Belgium	Head	43	-0	0.09	<0.01	<0.01	<0.01
	Head	43	0	5.9	<0.01	<0.01	<0.01
	Head	45	3	2.1	0.01	<0.01	<0.01
	Head	49	7	0.63	0.01	<0.01	<0.01
	Head	49	10	0.42	0.01	<0.01	<0.01
	Head	49	14	0.26	0.01	<0.01	<0.01
R 2007 540/9 Netherlands	Head	48	-0	0.48	0.02	<0.01	<0.01
	Head	48	0	6.5	0.02	<0.01	<0.01
	Head	48	3	1.3	0.02	<0.01	<0.01
	Head	49	7	0.53	0.02	<0.01	<0.01
	Head	49	10	0.16	<0.01	<0.01	<0.01
	Head	49	14	0.07	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram

Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on lettuce

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 476: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0011/3 Barway, GB,						Brooms Barn (25 km), Bayer raw data	no	Brooms Barn (25 km), Bayer raw data
M-304280-01-1	42	06/06/2007	0	6.1	FLU-benz	0.4 (0) [b]		11.7
		07/06/2007	1		<LOD	3.3		15.25
lettuce, head, green material		08/06/2007	2			2		14.65
		09/06/2007	3	0.82		0.2		17.4
		10/06/2007	4			0		15
		11/06/2007	5			0		14.85
		12/06/2007	6	0.18		0		17.1
		13/06/2007	7			11.5		17.9
		14/06/2007	8			32.2		16.5
		15/06/2007	9	0.02		0.2		17.85
		16/06/2007	10			4.8		15.05
		17/06/2007	11			0.7		16.1
		18/06/2007	12			7.8		15.7
		19/06/2007	13	0.005 [a]		5.2		16.5

[a] for FLU 0.5 LOD added
[b] no rain in 24 h after application, as in study report

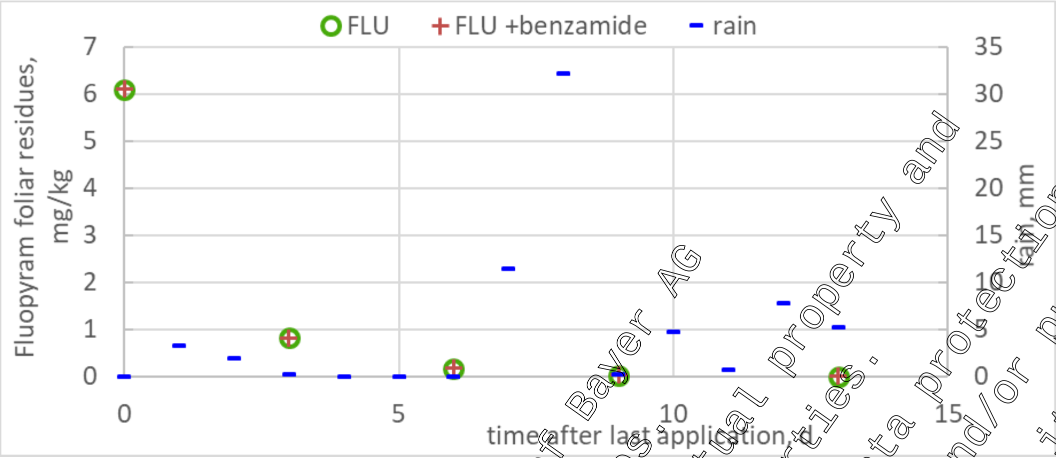


Figure 8.9- 144: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce

Rainfall on day 1 and day 2 coincides with a drop of residue levels, an influence cannot be excluded.

Table 8.9- 477: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0244/2 Meckenbeuren, DE,						DWD Konstanz [b] (32 km)	no	DWD Konstanz [b] (32 km)
M-304280-01-1	44	19/09/2007	0	4.5	4.51	0		10.8
		20/09/2007	1			0		11.1
lettuce, head, green material		21/09/2007	2	3.6	3.61	0		13.1
		22/09/2007	3			0		14.8
		23/09/2007	4			0		16.2
		24/09/2007	5			2.2		16.7
		25/09/2007	6			4.2		11.5
		26/09/2007	7	0.61	0.615 [a]	13.3		9
		27/09/2007	8			0.8		9.1
		28/09/2007	9			0.6		9.6
		29/09/2007	10	0.44	0.44	0.3		13.3
		30/09/2007	11			0		14
		01/10/2007	12			0		15
		02/10/2007	13	0.13	0.13	0		15.2

[a] for FLU-benzamide 0.5 LOD added
[b] https://opendata.dwd.de/climate_environment/CDC/

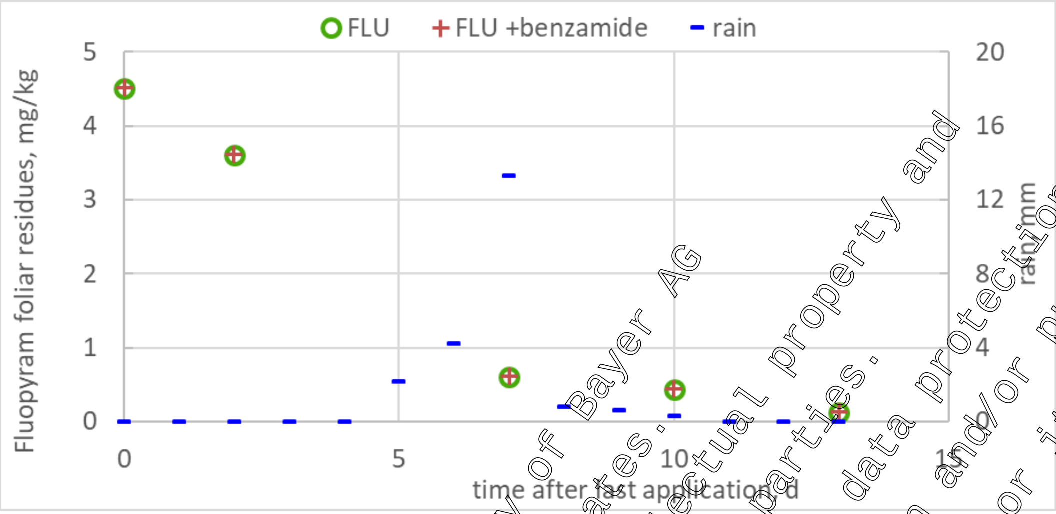


Figure 8.9- 145: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce.

Rainfall on days 5, 6 and 7 does not seem to have markedly influenced the residue levels.

Table 8.9- 478: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0537/9 Langenfeld-Reusrath, DE, M-304280-01-1 lettuce, head, green material						ProPlant db LWZ Monheim (2.5 km)	no	ProPlant db LWZ Monheim (2.5 km)
	46	11/05/2007	0	6.1	6.12	1 (0) [a]		13.1
		12/05/2007	1			4.9		13.3
		13/05/2007	2			4		16
		14/05/2007	3	1.1	1.13	1.1		15.1
		15/05/2007	4			17.4		12
		16/05/2007	5			10		11.4
		17/05/2007	6			3.3		10.2
		18/05/2007	7	0.57	0.59	0		14.9
		19/05/2007	8			4.3		16.3
		20/05/2007	9			0.2		18.8
		21/05/2007	10	0.43	0.46	0		18.7
		22/05/2007	11			14.4		18.8
		23/05/2007	12			0		19.5
		24/05/2007	13			0		21.5
		25/05/2007	14	0.33	0.35	0 [b]		21 [b]

[a] no rain 24 h after application, in study report
[b] data missing in ProPlant database, data from report was taken

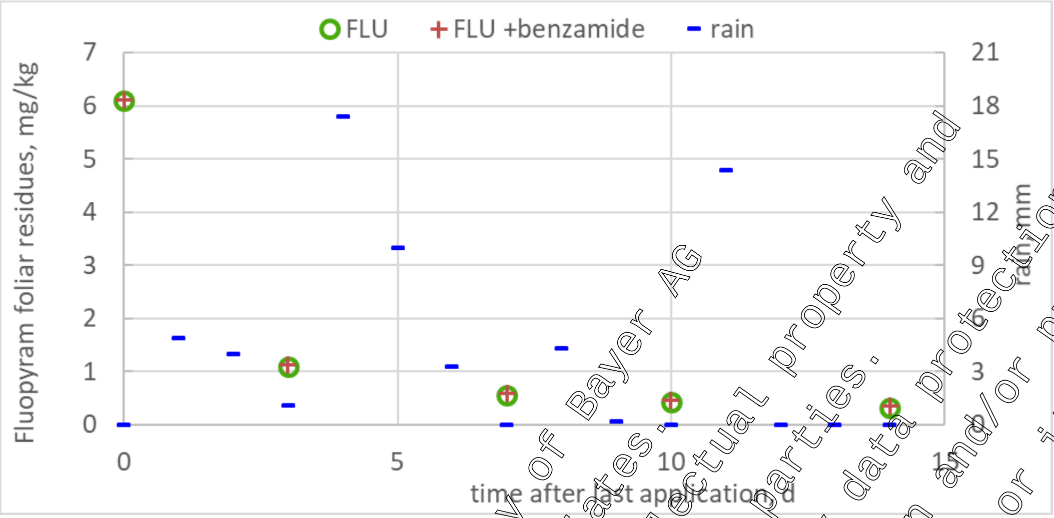


Figure 8.9- 146: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce

Frequent and early rainfall in this study may have influenced the residue dissipation.

Table 8.9- 479: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0538/7 Puzeaux, FR, M-304280-01-1						Meteo France Rouvroy en Santerre (10 km), study raw data	sprinkler	Meteo France Rouvroy en Santerre (10 km), study raw data
lettuce, green material	46	07/06/2007	0	6.0	6.01	63 (45) b)		17.9
		08/06/2007	1			0		17.6
		09/06/2007	2			0		17.2
		10/06/2007	3			0		16.8
		11/06/2007	4	0.12	0.125 a)	0		16.3
		12/06/2007	5			0	10	16.5
		13/06/2007	6			0		17.8
		14/06/2007	7	0.12	0.12	10.4		17.6
		15/06/2007	8			1.6		16.7
		16/06/2007	9			14.7		14.5
		17/06/2007	10			8.2		16.6
		18/06/2007	11	0.04	0.04	0.4		17.5
		19/06/2007	12			13.1		20.3
		20/06/2007	13			0.8		18.9
		21/06/2007	14			5.2		16.8
		22/06/2007	15	0.02	0.02	8.4		14.8

a) for FLU-benzamide 0.5 LOD added
b) 45 mm rain within 24 h after application, in study report

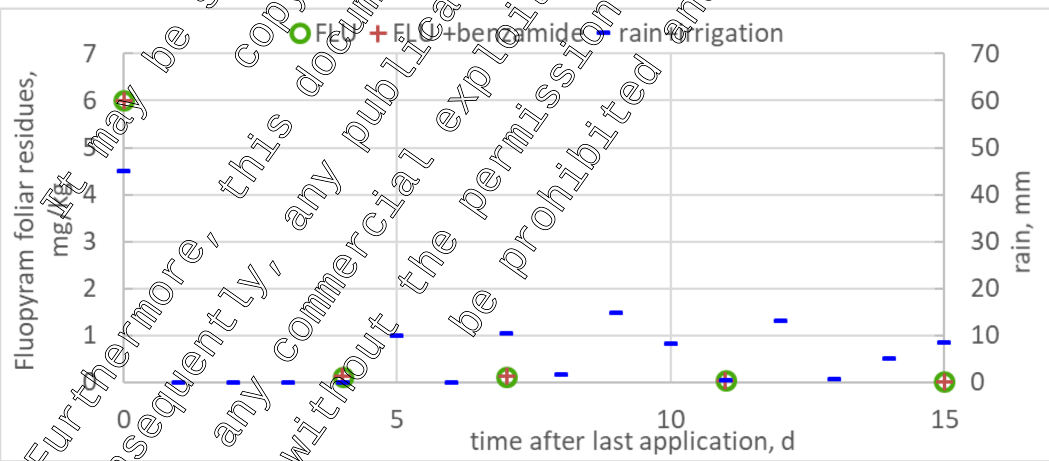


Figure 8.9- 147: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Strong rainfall after application has likely reduced residue levels to a marked extent.

Table 8.9- 480: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0539/5 Villers-Perwin, BE,						Redebel (3 km), study raw data	sprinkler	Redebel (3 km), study raw data
	43	25/05/2007	0	5.9	5.905 [a]	0 (6) [b]	-	20.2
M-304280-01-1		26/05/2007	1			0		17.2
		27/05/2007	2			0		13.4
lettuce, green material		28/05/2007	3	2.1	2.11	0		12.1
		29/05/2007	4			0		11.3
		30/05/2007	5			0		10.2
		31/05/2007	6			0		15.8
		01/06/2007	7	0.63	0.64	0.2		14.5
		02/06/2007	8			0		19.7
		03/06/2007	9			0		17.7
		04/06/2007	10	0.42	0.43	0		17.7
		05/06/2007	11			0		18
		06/06/2007	12			0		18.7
		07/06/2007	13			0		20.8
		08/06/2007	14	0.26	0.27	0		19

[a] for FLU-benzamide 0.5 LOD added
[b] 6 mm rain within 24 h, starting 12.3 h after application, in study report

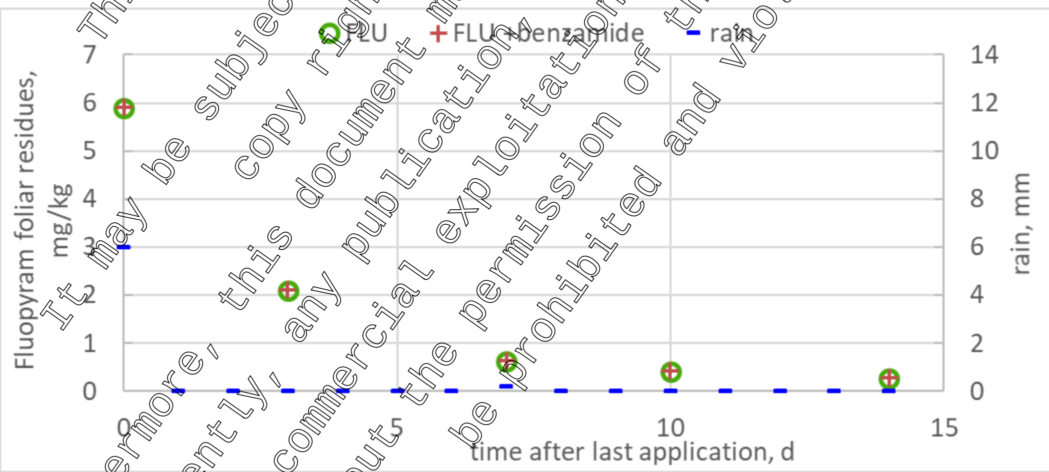


Figure 8.9- 148: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Rainfall on the day of application may have influenced residue levels, although no marked influence is visible in the residue decline pattern.

Table 8.9- 481: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0540/9 Zwaagdijk, NL, M-304280-01-1 lettuce, green material						KMNI De Kooy, Den Helder (35 km) [c]	sprinkler	KMNI De Kooy, Den Helder (35 km) [c]
	49	06/08/2007	0	6.5	6.52	1.1 (0) [b]	-	19.5
		07/08/2007	1			0		17.6
		08/08/2007	2			0		16.6
		09/08/2007	3	1.3	1.32	0		16.3
		10/08/2007	4			0		16.2
		11/08/2007	5			0		16
		12/08/2007	6			0		16.8
		13/08/2007	7	0.53	0.55	0.2		17.5
		14/08/2007	8			4.1		18
		15/08/2007	9			3.3		19.2
		16/08/2007	10	0.16	0.165 [a]	2.5		16
		17/08/2007	11			7.8		15.5
		18/08/2007	12			<0.05		16.1
		19/08/2007	13			<0.05		18.2
		20/08/2007	14	0.07	0.07	4.3		17.3

[a] for FLU-benzamide 0.5 LOD added
[b] no rain within 24 h after application; in study report
[c] http://projects.knmi.nl/klimatologie/daggegevens/selectie.cgi

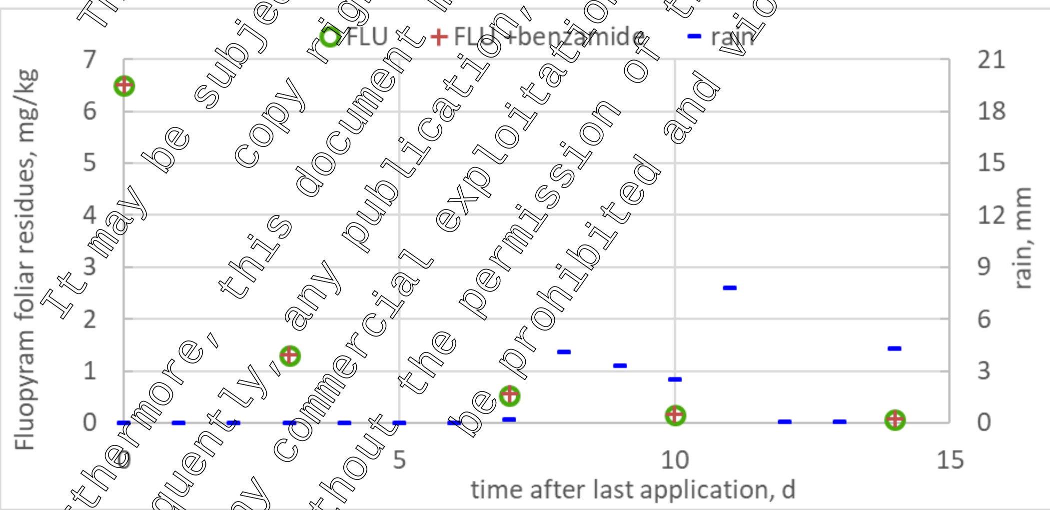


Figure 8.9-149: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

There was no rain until day 8, influence unlikely .

III. CONCLUSION

After two spray applications of Fluopyram SC 500 on lettuce in six residue trials conducted in s northern Europe (United Kingdom, Belgium, 2 x Germany, northern France and The Netherlands) during the 2007 season the residues of fluopyram in/on head declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ of (0.01 mg/kg) in almost all samples besides those of trial R 2007 0011/3 with a maximum value of 0.03 mg/kg. The residues of metabolites fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall has probably had a marked influence in one trial (R 2007 0538/7), a possible influence in three trials (R 2007 0011/3, R 2007 0537/9, R 2007 0539/5), and no influence in the remaining two trials (R 2007 0244/2, R 2007 0540/9).

However, rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/33
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 in/on head lettuce and lettuce after spraying of AE C656948 (500 SC) in the field in Portugal, Greece, Southern France and Italy
Report No:	RA-2510/07
Document No:	M-304278-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 - Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in southern Europe (Portugal, Greece, southern France and Italy) on lettuce during the 2007 season. Two applications with Fluopyram SC 500 containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected slightly above

the LOQ (0.01 mg/kg) in almost all samples with a maximum value of 0.03 mg/kg. The residues of metabolites fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram 500 SC
	Batch no.:	2006-010316
	Active Ingredient:	Fluopyram
	Storage:	Not stated in the report
	Expiry date:	2009-01-09
2.	Test commodity:	Lettuce
	Crop part:	Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2510/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on lettuce (head) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L.

<u>Field phase</u>

The study included four supervised residue trials conducted in southern Europe (Portugal, Greece, southern France and Italy) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 482: Description of the trial locations and cropping information on treated plots

Trial number	R 2007 0012/1	R 2007 0245/0	R 2007 0246/9	R 2007 0541/7
Trial location	P-2510-515 Olho Marinho (Ribatejo e Oeste)	GR-59100 Agia Marina (Northern Greece - Macedonia)	F-86380 Ouzilly (Poitou-Charentes)	I-71043 Manfredonia (Foggia) (Puglia)
Country	Portugal	Greece	Southern France	Italy
Area of application	Field	Field	field	Field
Plot size [m^2]	30	50	37.5	105
Type of soil	Sand	-	Loamy sand	Sand
pH-value of soil (in water)	6.5	-	8.1	8.1
Content of organic C [%]	1.5	-	1.0	0.3
Test system	Head lettuce (butterhead variety)	Lettuce (loose leaf variety)	Head lettuce (butterhead variety)	Lettuce (loose leaf variety)
Variety	Faustinas	Atraction	Santoro	Antony
Date of planting / sowing	2007-05-19 / -	2007-04-05 / -	- / 2007-06-07	2007-09-21 / -
Date of commercial harvest	2007-07-05 to 2007-07-07	2007-05-13 to 2007-05-20	2007-07-13 to 2007-07-27	2007-12-01 to 2007-12-31

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stages between 16-47 and the second between 45-48 with an application rate of 0.25 kg a.s./ha and a water rate of 400-700 L/ha.

Table 8.9- 483: Overview on application with Fluopyram SC 500 on lettuce

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
Portugal R 2007 0012/1	1	T	Fluopyram SC 500	SPI	7	42	14	0.5	400	Fluopyram	0.25
	2					46	7*	0.5	400		0.25
Greece R 2007 0245/0	1	T	Fluopyram SC 500	SPI	7	16	14	0.5	400	Fluopyram	0.25
	2					48	7*	0.5	400		0.25
Southern France R 2007 0246/9	1	T	Fluopyram SC 500	SPI	7	41	14	0.5	600	Fluopyram	0.25
	2					45	7*	0.5	600		0.25
Italy R 2007 0541/7	1	T	Fluopyram SC 500	SPI	7	47	14	0.5	700	Fluopyram	0.25
	2					48	7*	0.5	700		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of lettuce. For trial R 2007 0245/0 there was a deviation concerning storage as the temperature was not appropriate for a period of 4.5 hours. This had no impact on the study since the scenario is considered to be covered by storage stability study M-480441-06-1 (wheat green material, 8 hours at +1°C, followed by 7, 19 & 22 days at 7°C).

Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 484: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0012/1 R 2007 0245/0 R 2007 0246/9 R 2007 0541/7	Lettuce	Head	C	-0
				3
				7
				10
			T	-0
				0
				3
				7
				10
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 485: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in lettuce head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and its metabolites were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 486: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Head lettuce and lettuce (head)	0.01	96	96	-	0.01
	0.1	100; 109	105	-	
	10	104	104	-	
	Overall recovery (n = 4)		**102**	**5.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 487: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Head lettuce and lettuce (head)	0.01	83	83	-	0.01
	0.1	94; 94	94	-	
	10	93	93	-	
	Overall Recovery (n = 4)		**91**	**5.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 488: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Head lettuce and lettuce (head)	0.01	90	90	-	0.01
	0.1	91; 87	89	-	
	10	95	95	-	
	Overall Recovery (n = 4)		**91**	**3.6**	

Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram

Table 8.9- 489: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Head lettuce and lettuce (head)	0.01	91	91	-	0.01
	0.1	97; 94	96	-	
	10	99	99	-	
	Overall recovery (n = 4)		**95**	**3.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 93 and 342 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on lettuce head are summarised in the following table.

Table 8.9- 490: Residue summary of fluopyram and metabolites in/on lettuce, head

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0012/1 Portugal	Head	46	-0	0.31	<0.01	<0.01	<0.01
	Head	46	0	4.5	0.01	<0.01	<0.01
	Head	47	3	1.3	0.01	<0.01	<0.01
	Head	48	7	0.48	0.01	<0.01	<0.01
	Head	49	10	0.24	0.01	<0.01	<0.01
	Head	49	14	0.05	<0.01	<0.01	<0.01
R 2007 0245/0 Greece	Head	48	-0	0.11	<0.01	<0.01	<0.01
	Head	48	0	7.0	0.01	<0.01	<0.01
	Head	49	3	1.2	0.02	<0.01	<0.01
	Head	49	7	0.29	0.01	<0.01	<0.01
	Head	49	10	0.10	<0.01	<0.01	<0.01
	Head	49	14	0.03	<0.01	<0.01	<0.01
R 2007 0246/9 Southern France	Head	45	-0	0.17	<0.01	<0.01	<0.01
	Head	45	0	6.0	0.01	<0.01	<0.01
	Head	47	3	0.56	0.02	<0.01	<0.01
	Head	49	7	0.27	0.02	<0.01	<0.01
	Head	49	10	0.14	0.01	<0.01	<0.01
	Head	49	14	0.12	0.01	<0.01	<0.01
R 2007 0541/7 Italy	Head	48	-0	0.80	0.01	<0.01	<0.01
	Head	48	0	7.4	0.01	<0.01	<0.01
	Head	48	3	4.8	0.02	<0.01	<0.01
	Head	49	7	5.3	0.03	<0.01	<0.01
	Head	49	10	0.87	0.02	<0.01	<0.01
	Head	49	14	0.98	0.02	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on lettuce

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 491: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0012/1 Olho Marinho, PT,						Peniche, St. Isidoro (40 km), study raw data	sprinkler	Peniche, St. Isidoro (40 km), study raw data
M-304278-01-1	46	19/06/2007	0	4.5	4.51	0.2 (0) [b]	14	18.0
		20/06/2007	1			0	14	17.6
lettuce, head, green material		21/06/2007	2			0	14	16.9
		22/06/2007	3	1.3	1.31	0	14	17.1
		23/06/2007	4			0	14	18.4
		24/06/2007	5			0	14	19.1
		25/06/2007	6			0.3	14	18.2
		26/06/2007	7	0.48	0.49	0	14	17.8
		27/06/2007	8			0	14	18.0
		28/06/2007	9			0	14	18.1
		29/06/2007	10	0.24	0.25	0	14	19.1
		30/06/2007	11			0.1	14	20.0
		01/07/2007	12			0	14	19.5
		02/07/2007	13			0 [c]	14	19.5 [c]
		03/07/2007	14	0.05	0.055 [a]	0.1 [c]	14	19.4 [c]

[a] for FLU-benzamide 0.5 LOD added
[b] no rain within 24 h after application
[c] data from weather station Peniche, Salir do Porto, as other data were missing.

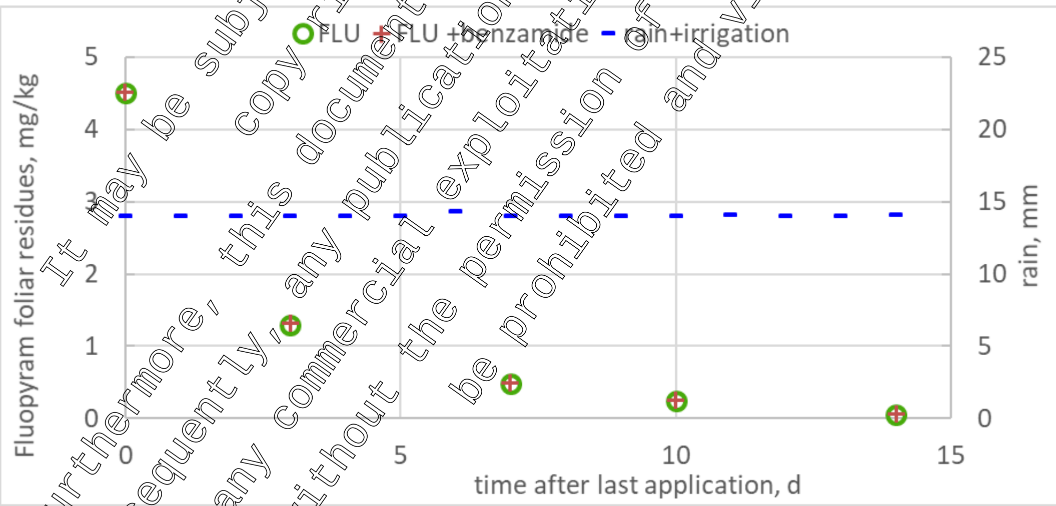


Figure 8.9-150: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce

There was very little rain but daily sprinkler irrigation which may have influenced the residue levels but not necessarily the DT_{50}.

Table 8.9- 492: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0245/0 Agia Marina, GR,						MARS grid 59151 (25×25 km)	sprinkler	MARS grid 59151 (25×25 km)
M-304278-01-1 lettuce, green material	48	02/05/2007	0	7.0	7.01	0	-	17.3
		03/05/2007	1			0 (2) [b]		17.1
		04/05/2007	2			0.3		14.9
		05/05/2007	3	1.2	1.22	0		16.9
		06/05/2007	4			0		18.9
		07/05/2007	5			0		20.2
		08/05/2007	6			0		20.6
		09/05/2007	7	0.29	0.3	0		21.5
		10/05/2007	8			0		22.1
		11/05/2007	9			0		21.2
		12/05/2007	10	0.1	0.105 [a]	0		21
		13/05/2007	11			0		23.4
		14/05/2007	12			0		23.6
		15/05/2007	13			0		20.6
		16/05/2007	14	0.03	0.03	0		20.8

[a] for FLU-benzamide 0.5 LOD added
[b] 2 mm rain, starting 18 h after application, as in study report.

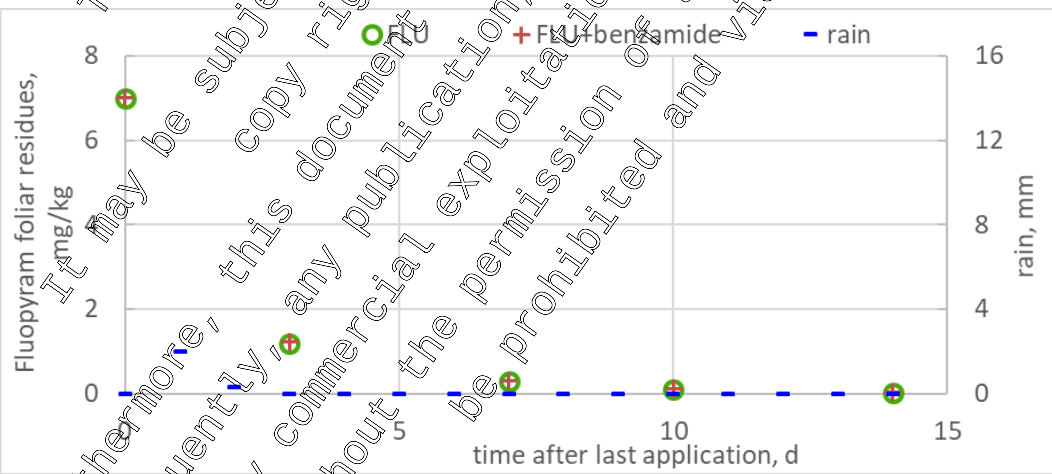


Figure 8.9- 151: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce.

Rainfall (2 mm) within 18h after application may have influenced the residue dissipation.

Table 8.9- 493: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0246/9 Ouzilly, FR, M-304278-01-1						Meteo France Poitiers Biard (21 km), study raw data	sprinkler	Meteo France Poitiers Biard (21 km), study raw data
lettuce, head, green material	45	06/07/2007	0	6.0	6.01	1.6 (0) [a]		17.9
		07/07/2007	1			0		18.5
		08/07/2007	2			0.6	16	16.9
		09/07/2007	3	0.56	0.58	8.8		13.5
		10/07/2007	4			2.2		15.1
		11/07/2007	5			0	16	15.5
		12/07/2007	6			0		17
		13/07/2007	7	0.27	0.29	0		21.5
		14/07/2007	8			0		22.6
		15/07/2007	9			0.6		24.8
		16/07/2007	10	0.14	0.15	1.8		18.3
		17/07/2007	11			0		18.2
		18/07/2007	12			0		18.9
		19/07/2007	13			0.4		19.8
		20/07/2007	14	0.12	0.13	0		17.2

[a] no rain within 24 h after application, in study report

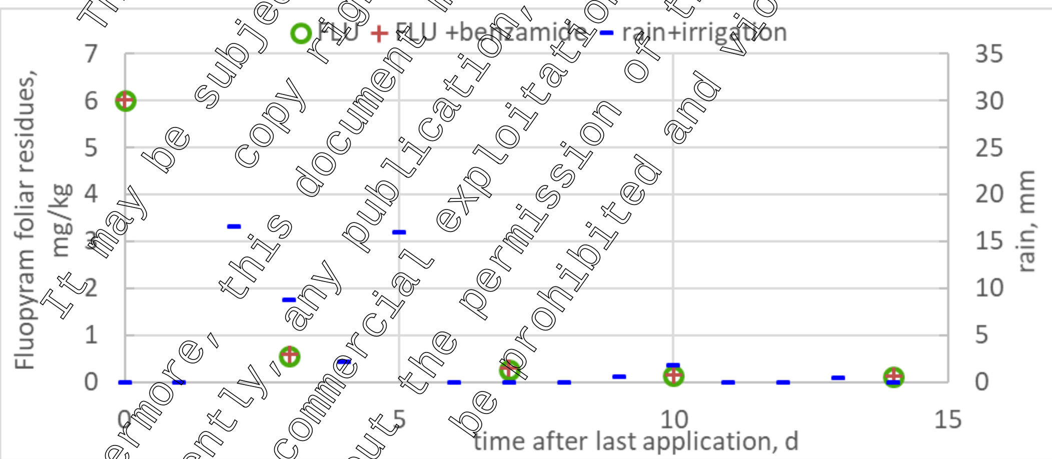


Figure 8.9- 152: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Early rainfall and irrigation have likely influenced residue dissipation.

Table 8.9- 494: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0541/7 Manfredonia, IT, M-304278-01-1 lettuce, green material						Bonifica di Capitanata, Trinitapoli (15 km), study raw data	no	Bonifica di Capitanata, Trinitapoli (15 km), study raw data
	48	01/12/2007	0	7.4	7.41	0		9.35
		02/12/2007	1			0.2		8.53
		03/12/2007	2			2		10.95
		04/12/2007	3	4.8	4.82	0.2		8.69
		05/12/2007	4			1.6		8.37
		06/12/2007	5			0		7.02
		07/12/2007	6			0		9.19
		08/12/2007	7	5.3	5.33	1.4		9.54
		09/12/2007	8			4		9.97
		10/12/2007	9			0		10.51
		11/12/2007	10	0.87	0.89	5.6		7.75
		12/12/2007	11			3.2		6.76
		13/12/2007	12			0		6.65
		14/12/2007	13			1		3.83
		15/12/2007	14	0.98	1	2.2		-0 56

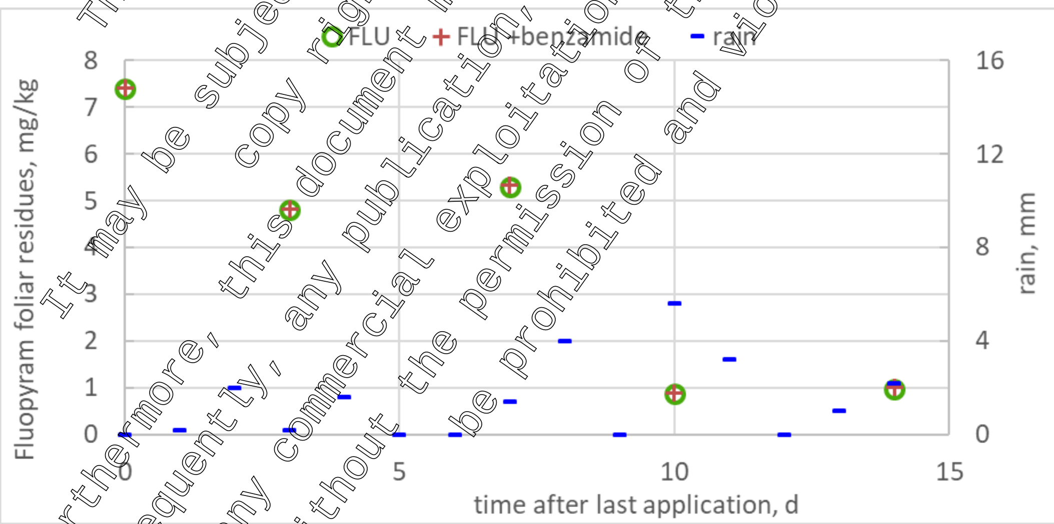


Figure 8.9- 153: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

There was frequent but little rainfall, an influence is possible.

III. CONCLUSION

After two spray applications of Fluopyram SC 500 on lettuce in four residue trials conducted in southern Europe (Portugal, Greece, southern France and Italy) during the 2007 season the residues of fluopyram in/on head lettuce declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ of (0.01 mg/kg) in almost all samples with a maximum value of 0.03 mg/kg. The residues of metabolites fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall occurred in all trials, however a marked influence is not observed. Thus, a moderate influence is possible, but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/34
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 in/on kidney bean after spraying of AE C656948 (500 SC) in the field in Belgium, Germany, Northern France and the Netherlands
Report No:	RA-2511/07
Document No:	M-297562-01-1
Guideline(s) followed in study:	EU 91/414/EEC Annex II, part A, section 6 and Annex III, part A, section 8, EC Guidance Working Document 7029/VI/95 rev. 5 (1997-07-22)
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with five residue trials was conducted in the field in Northern Europe (The Netherlands, 2 x Germany, northern France and Belgium) on kidney bean during the 2007 season. Two applications with Fluopyram SC 500 containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on kidney bean pod and green material declined markedly during the sampling period. Residues of fluopyram-benzamide and fluopyram-pyridyl-acetic acid were detected above the LOQ (0.01 mg/kg) with a maximum value of 0.06 mg/kg in green material and 0.02 mg/kg in pod and 0.02 mg/kg in green material and pod, respectively. The metabolite fluopyram-pyridyl-carboxylic acid was always below the LOQ.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram (500 SC)
	Batch no.:	2006-010316
	Active substance:	Fluopyram
	Storage:	Not stated in the report
	Expiry date:	2009-01-09
2.	Test commodity:	Kidney bean
	Crop part:	Pod and green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2511/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on kidney bean (pod and green material) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

<u>Field phase</u>

The study included five supervised residue trials conducted in northern Europe (The Netherlands, 2 x Germany, northern France and Belgium) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 495: Description of the trial locations and cropping information on treated plots

Trial number	R 2007 0014/8	R 2007 0546/8	R 2007 0547/6	R 2007 0548/4	R 2007 0549/2
Trial location	B-6210 Villers-Perwin (Hainaut)	D-40764 Langenfeld-Reusrath (Nordrhein-Westfalen)	F-80700 Fresnoy les Roye (Picardie)	NL-8256 Biddinghuizen (Flevoland)	D-53913 Swisttal – Heimerzheim (Nordrhein-Westfalen)
Country	Belgium	Germany	Northern France	The Netherlands	Germany
Area of application	Field	Field	Field	Field	Field
Plot size [m^2]	24	66	60	44	52.5
Type of soil	Silty loam	Loamy sand	Loam	Clay	Sandy loam
pH-value of soil (in water)	5.7	6.9	7.8	6.7	6.8
Content of organic C [%]	2.6	1.7	1.0	2.6	1.0
Test system	Kidney bean	Kidney bean	Kidney bean	Kidney bean	Kidney bean
Variety	Cadillac	Classic	Lugos	Cadillac	Sonesta
Date of sowing	2007-05-24	2007-03-28	2007-06-06	2007-06-28	2007-06-09
Start Flowering	2007-07-09	2007-05-31	2007-07-20	2007-08-10	2007-07-20
End Flowering	2007-07-17	2007-06-30	2007-08-13	2007-09-10	2007-08-17
Date of commercial harvest	2007-07-31 to 2007-08-10	2007-06-22 to 2007-07-30	2007-08-16 to 2007-08-20	2007-09-04 to 2007-09-18	2007-08-24 to 2007-08-29

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stages between 65-77 and the second between 72-78 with an application rate of 0.25 kg a.s./ha and a water rate of 500-1000 L/ha.

Table 8.9- 496: Overview on application with Fluopyram SC 500 on kidney bean

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2007 0014/8 Belgium	1	T	Fluopyram SC 500	SPI	7	69	14	0.5	1000	Fluopyram	0.25
	2					76	7*	0.5	1000		0.25
R 2007 0546/8 Germany	1	T	Fluopyram SC 500	SPI	7	71	14	0.5	600	Fluopyram	0.25
	2					75	7*	0.5	600		0.25
R 2007 0547/6 Northern France	1	T	Fluopyram SC 500	SPI	7	65	14	0.5	500	Fluopyram	0.25
	2					77	7*	0.5	500		0.25
R 2007 0548/4 The Netherlands	1	T	Fluopyram SC 500	SPI	7	77	14	0.5	500	Fluopyram	0.25
	2	T				78	7*	0.5	500		0.25
R 2007 0549/2 Germany	1	T	Fluopyram SC 500	SPI	8	69	15	0.5	600	Fluopyram	0.25
	2	T				72	7*	0.5	600		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying

DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 600 g of kidney bean pod and green material. The samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 497: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0014/8 R 2007 0546/8 R 2007 0547/6 R 2007 0548/4 R 2007 0549/2	Kidney bean	Green material Pod	C	-0 3 7 14
		Green material Pod	T	-0 0 3 7 10 14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites were analysed within the residue trials samples according to the following method:

Table 8.9- 498: Summary of the analytical method

Method	00984/M001
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in kidney bean (pod and green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study together with samples of study RA-2512/07. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the overall RSD values were below 20%. Details are given in the table below.

Table 8.9- 499: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean, pod	0.01	95; 103	99	--	0.01
	0.1	98; 95; 94; 94; 101; 98; 99; 98; 104;105	99	3.9	
	1.0	90		--	
	Overall Recovery (n = 13)		**98**	**4.5**	
Kidney bean, Green material	0.01	92; 96; 106	98	7.4	0.01
	0.1	107; 94; 109; 100; 103; 105; 101	103	4.9	
	1.0	89; 105	97	--	
	10	83		--	
	Overall Recovery (n = 13)		**99**	**7.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 500: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean, pod	0.01	73; 95; 110	93	20.1	0.01
	0.1	66; 95; 98; 100; 97; 84; 76; 91; 79; 74	86	13.8	
	1.0	80		--	
	Overall Recovery (n = 14)		**87**	**14.7**	
Kidney bean, green material	0.01	102; 88; 113; 100	101	10.2	0.01
	0.1	73; 74; 79; 77; 82; 80; 82	78	4.6	
	1.0	81; 90	86	--	
	10	78		--	
	Overall Recovery (n = 14)		**86**	**13.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

Table 8.9- 501: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean, pod	0.01	92; 92; 97	94	3.1	0.01
	0.1	92; 94; 95; 97; 98; 93; 91; 93; 94; 93	94	2.3	
	1.0	81		--	
	Overall Recovery (n = 14)		**93**	**4.4**	
Kidney bean, green material	0.01	93; 88; 95; 89	91	3.6	0.01
	0.1	95; 102; 99; 92; 94; 92; 96	96	3.8	
	1.0	86; 96	91	--	
	10	83		--	
	Overall Recovery (n = 14)		**93**	**5.5**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as Fluopyram

Table 8.9- 502: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean, pod	0.01	94; 102; 73	90	16.7	0.01
	0.1	114; 96; 109; 87; 92; 88; 75; 97; 83; 94	94	12.4	
	1.0	84		--	
	Overall recovery (n = 14)		**92**	**12.6**	
Kidney bean, green material	0.01	97; 96; 91; 106	98	6.4	0.01
	0.1	111; 103; 101; 92; 86; 104	100	9.1	
	1.0	81; 96	89	--	
	10	73		--	
	Overall recovery (n = 13)		**95**	**11.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 25 and 98 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water and high protein matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on kidney bean (pod and green material) are summarised in the following table:

Table 8.9- 503: Residue summary of fluopyram in/on kidney bean

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram -pyridyl-acetic acid	Residue [mg/kg] fluopyram -pyridyl-carboxylic acid
R 2007 0014/8 Belgium	Pod	76	-0	0.06	<0.01	<0.01	<0.01
	Green material	76	-0	0.37	0.02	<0.01	<0.01
	Pod	76	0	0.34	<0.01	<0.01	<0.01
	Green material	76	0	7.0	0.02	<0.01	<0.01
	Pod	77	3	0.30	<0.01	<0.01	<0.01
	Green material	77	3	4.2	0.03	<0.01	<0.01
	Pod	79	7	0.12	<0.01	<0.01	<0.01
	Green material	79	7	0.42	0.02	<0.01	<0.01
	Pod	79	10	0.09	<0.01	<0.01	<0.01
	Green material	79	10	0.33	0.02	<0.01	<0.01
	Pod	79	14	0.08	<0.01	<0.01	<0.01
	Green material	79	14	0.19	0.02	<0.01	<0.01
R 2007 0546/8 Germany	Pod	75	-0	0.09	<0.01	<0.01	<0.01
	Green material	75	-0	0.14	0.02	<0.01	<0.01
	Pod	75	0	0.39	<0.01	<0.01	<0.01
	Green material	75	0	3.0	0.02	<0.01	<0.01
	Pod	75	3	0.23	<0.01	<0.01	<0.01
	Green material	75	3	1.4	0.03	<0.01	<0.01
	Pod	79	7	0.18	0.01	<0.01	<0.01
	Green material	79	7	0.57	0.05	0.01	<0.01
	Pod	79	10	0.14	0.01	<0.01	<0.01
	Green material	79	10	0.37	0.04	0.01	<0.01
	Pod	79	14	0.13	0.02	<0.01	<0.01
	Green material	79	14	0.20	0.04	0.02	<0.01

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg]	Residue [mg/kg]	Residue [mg/kg]	Residue [mg/kg]

				a.s. fluopyram	fluopyram-benzamide	fluopyram -pyridyl-acetic acid	fluopyram-pyridyl-carboxylic acid
R 2007 0547/6 Northern France	Pod	77	-0	0.13	<0.01	<0.01	<0.01
	Green material	77	-0	0.37	0.02	<0.01	<0.01
	Pod	77	0	0.45	0.01	<0.01	<0.01
	Green material	77	0	6.2	0.03	<0.01	<0.01
	Pod	78	3	0.39	0.01	<0.01	<0.01
	Green material	78	3	3.4	0.04	<0.01	<0.01
	Pod	78	7	0.26	0.02	<0.01	<0.01
	Green material	78	7	0.68	0.05	<0.01	<0.01
	Pod	79	10	0.18	0.02	<0.01	<0.01
	Green material	79	10	0.34	0.04	<0.01	<0.01
	Pod	79	14	0.13	0.02	<0.01	<0.01
	Green material	79	14	0.17	0.03	<0.01	<0.01
R 2007 0548/4 The Netherlands	Pod	78	-0	0.07	<0.01	<0.01	<0.01
	Green material	78	-0	0.56	0.01	<0.01	<0.01
	Pod	78	0	0.27	<0.01	<0.01	<0.01
	Green material	78	0	5.4	0.02	<0.01	<0.01
	Pod	79	3	0.19	<0.01	<0.01	<0.01
	Green material	79	3	1.8	0.02	<0.01	<0.01
	Pod	79	7	0.19	<0.01	<0.01	<0.01
	Green material	79	7	0.72	0.03	<0.01	<0.01
	Pod	79	10	0.17	0.01	<0.01	<0.01
	Green material	79	10	0.65	0.03	<0.01	<0.01
	Pod	79	14	0.15	0.01	<0.01	<0.01
	Green material	79	14	0.46	0.03	<0.01	<0.01
R 2007 0549/2 Germany	Pod	72	-0	0.08	<0.01	<0.01	<0.01
	Green material	72	-0	0.20	0.04	0.01	<0.01
	Pod	72	0	0.41	<0.01	<0.01	<0.01
	Green material	72	0	5.9	0.04	0.01	<0.01
	Pod	75	3	0.35	0.01	0.01	<0.01
	Green material	75	3	5.4	0.06	0.02	<0.01
	Pod	77	7	0.17	0.01	0.02	<0.01
	Green material	77	7	0.31	0.05	0.02	<0.01
	Pod	78	10	0.10	0.01	0.02	<0.01
	Green material	79	10	0.18	0.05	0.02	<0.01
	Pod	79	14	0.08	0.01	0.02	<0.01
	Green material	79	14	0.09	0.04	0.02	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on kidney bean

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 504: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0014/8 Villers-Perwin, BE, M-297562-01-1 bean, kidney, green material						Redebel (3 km), study raw data	no	Redebel (3 km), study raw data
	76	24/07/2007	0	7.0	7.02	5.6 (0) [a]		17.6
		25/07/2007	1			0		18.1
		26/07/2007	2			1.5		18.9
		27/07/2007	3	4.2	4.23	0.3		18.4
		28/07/2007	4			4.8		18.2
		29/07/2007	5			1.3		14.8
		30/07/2007	6			0		13.9
		31/07/2007	7	0.42	0.44	0		13.6
		01/08/2007	8			0		16.6
		02/08/2007	9			9.4		17.9
		03/08/2007	10	0.33	0.35	0		18
		04/08/2007	11			0		19.9
		05/08/2007	12			0		22.5
		06/08/2007	13			2.5		21.6
		07/08/2007	14	0.19	0.21	0		17.8

[a] no rain within 24 h after application, in study report

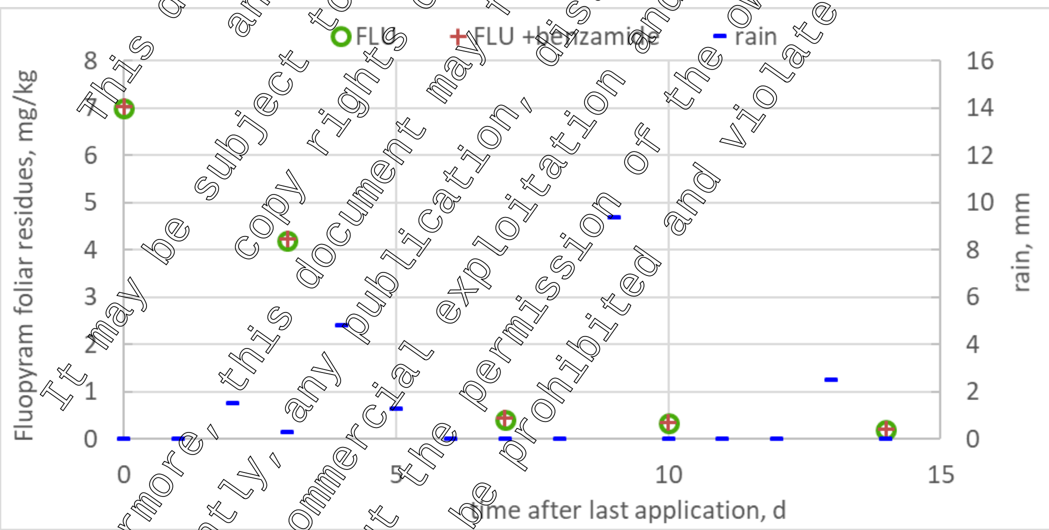


Figure 8.9- 154: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

Rainfall on days 2, 4 and 5 may have influenced residue dissipation.

Table 8.9- 505: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0546/8 Langenfeld-Reusrath, DE, M-297562-01-1 bean, kidney, green material						ProPlant DB LWZ Monheim (2.5 km)	no	ProPlant DB LWZ Monheim (2.5 km)
	75	25/06/2007	0	3.0	3.02	9.6 (0) [a]		16.3
		26/06/2007	1			3		13.2
		27/06/2007	2			0		13.1
		28/06/2007	3	1.4	1.43	0.8		15
		29/06/2007	4			1.3		14.8
		30/06/2007	5			0		16.6
		01/07/2007	6			1.7		20.1
		02/07/2007	7	0.57	0.62	6.3		17.4
		03/07/2007	8			4.1		14.8
		04/07/2007	9			18.1		13.2
		05/07/2007	10	0.37	0.41	3		14.6
		06/07/2007	11			1.9		15.4
		07/07/2007	12			0		16.6
		08/07/2007	13			1.4		17.6
		09/07/2007	14	0.2	0.24	0.4		15.1

[a] no rain within 24 h after application, in study report

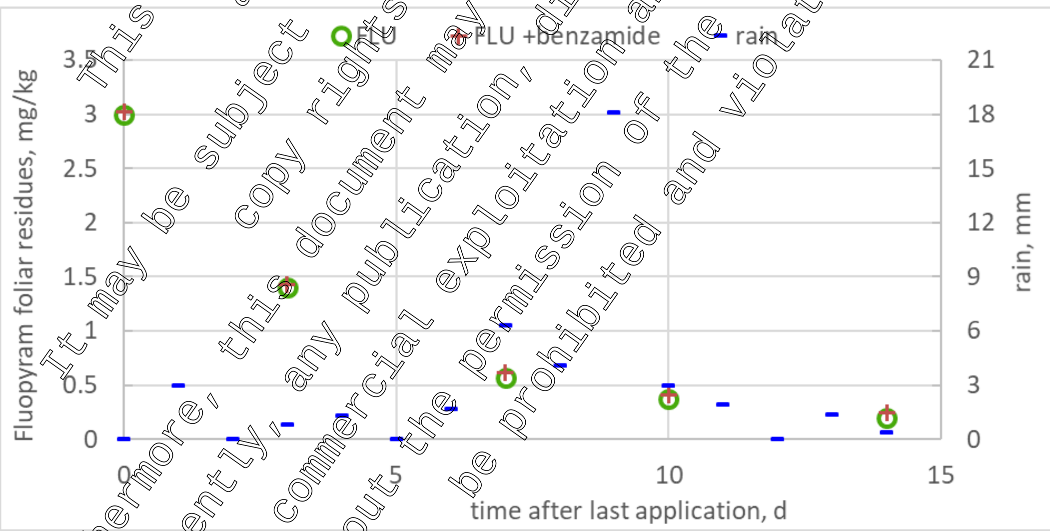


Figure 8.9- 155: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

Frequent but little rainfall may have slightly influenced residue dissipation.

Table 8.9- 506: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0547/6 Fresnoy les Roye, FR, M-297562-01-1 bean, kidney, green material						Meteo France Rouvroy en Santerre (5 km), study raw data	sprinkler	Meteo France Rouvroy en Santerre (5 km) study raw data
	77	10/08/2007	0	6.2	6.23	0		15.9
		11/08/2007	1			0		17
		12/08/2007	2			0		17
		13/08/2007	3	3.4	3.44	0		15.8
		14/08/2007	4			1.4		18.5
		15/08/2007	5			1.4		20.2
		16/08/2007	6			0		15.7
		17/08/2007	7	0.68	0.73	0.2	20	13.6
		18/08/2007	8			3.2		16.2
		19/08/2007	9			17.8		15.6
		20/08/2007	10	0.34	0.38	9		14.3
		21/08/2007	11			11		16.9
		22/08/2007	12			4.2		16.7
		23/08/2007	13			9.6		16.2
		24/08/2007	14	0.17	0.2	0.2		17.7

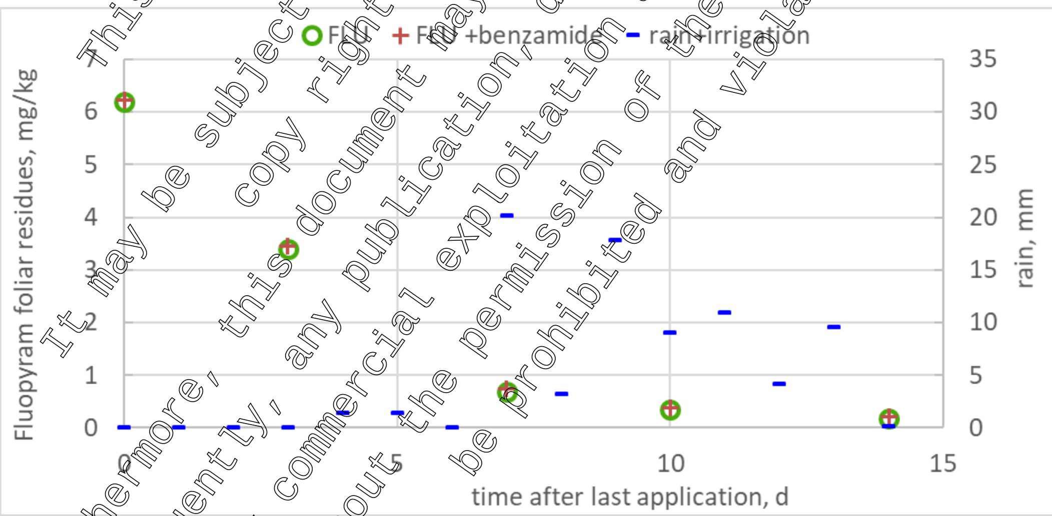


Figure 8.9- 156: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

Late irrigation and rainfall do not appear to have influenced residue dissipation.

Table 8.9- 507: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0548/4 Biddinghuizen, NL,						KMNI De Bilt (40 km) [a)]	no	KMNI De Bilt (40 km) [a)]
M-297562-01-1	78	04/09/2007	0	5.4	5.42	2		11.7
		05/09/2007	1			1.7		11.7
bean, kidney, green material		06/09/2007	2			<0.05		16.7
		07/09/2007	3	1.8	1.82	<0.05		16.1
		08/09/2007	4			1.1		16.3
		09/09/2007	5			<0.05		14.6
		10/09/2007	6			18.7		14.5
		11/09/2007	7	0.72	0.75	0.3		14
		12/09/2007	8			0		13.4
		13/09/2007	9			0		12.6
		14/09/2007	10	0.65	0.68	0.2		12.9
		15/09/2007	11			0		12.3
		16/09/2007	12			0		15.6
		17/09/2007	13			10.3		14
		18/09/2007	14	0.46	0.49	3.6		10.8

a) http://projects.knmi.nl/klimatologie/daggegevens/selectie.cgi

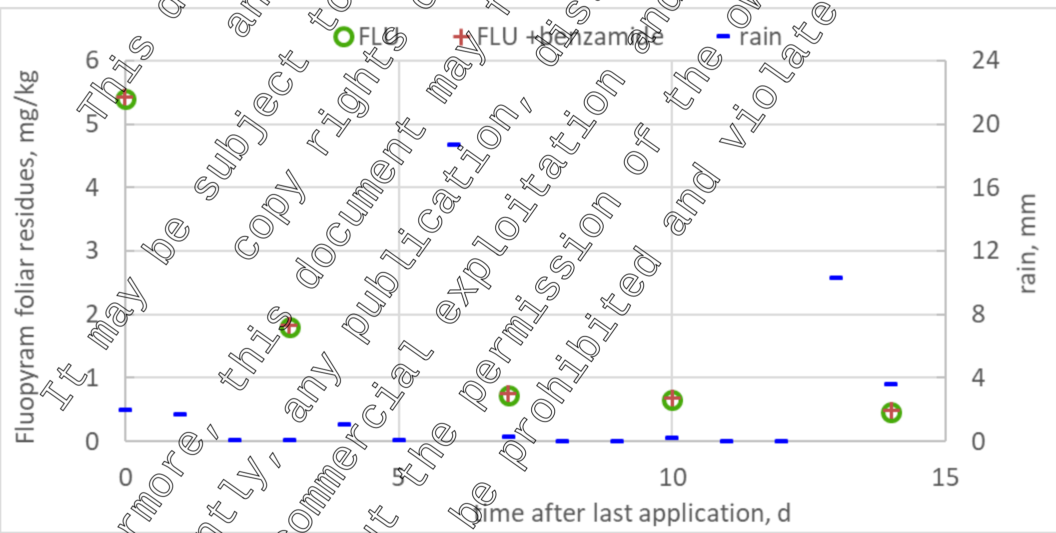


Figure 8.9- 157: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Kidney bean

Little rainfall early after application, and larger rainfall on day 6, do not appear to have markedly influenced residue dissipation.

Table 8.9- 508: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0549/2 Swisttal Heimerzheim, DE, M-297562-01-1 bean, kidney, green material						DWD Köln-Bonn [a] (25 km)	no	DWD Köln-Bonn [a] (25 km)
	72	11/08/2007	0	5.9	5.94	0		17.2
		12/08/2007	1			0		17.1
		13/08/2007	2			0		18.4
		14/08/2007	3	5.4	5.46	5.3		19.3
		15/08/2007	4			23.6		20.7
		16/08/2007	5			1.3		17.6
		17/08/2007	6	0.31	0.36	0		15.9
		18/08/2007	7			0		15.9
		19/08/2007	8			7.5		16.9
		20/08/2007	9			0.1		15.8
		21/08/2007	10	0.18	0.23	62.4		14.6
		22/08/2007	11			16.5		15.8
		23/08/2007	12			4.4		18.5
		24/08/2007	13	0.09	0.13	0		19.3

[a] https://opendata.dwd.de/climate_environment/CDC/

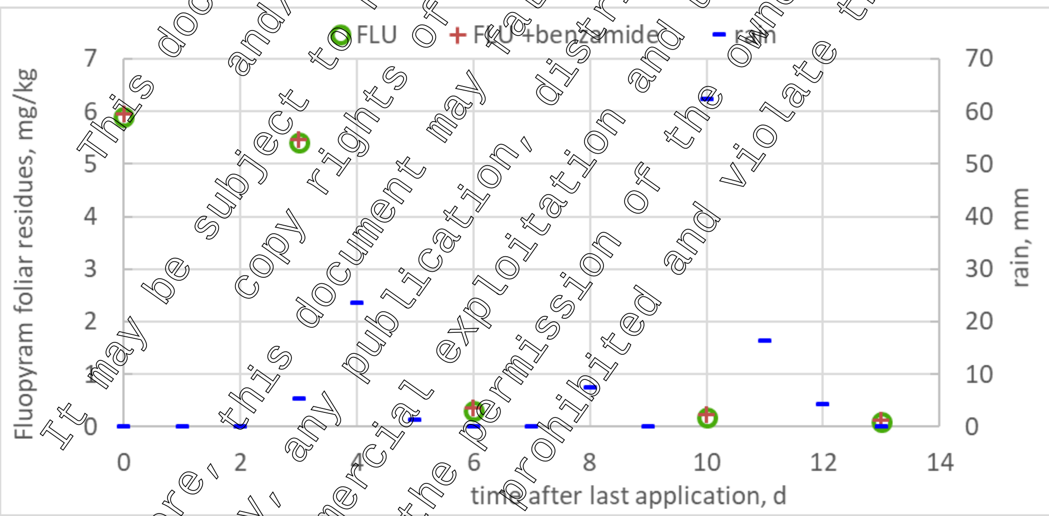


Figure 8.9- 158: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

Rainfall on days 3 and 4 coincides with a marked drop of residue levels, influence likely.

II. CONCLUSION

After two spray applications of Fluopyram SC 500 on kidney bean in five residue trials conducted in northern Europe (2 x Germany, Belgium, northern France and The Netherlands) during the 2007 season the residues of fluopyram in/on kidney bean green material declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ of (0.01 mg/kg) in all samples with a maximum value of 0.06 mg/kg. The metabolite fluopyram-pyridyl-acetic acid was detected above the LOQ in samples of trials R 2007 0546/8 and R 2007 0549/2 with a maximum value of 0.02 mg/kg and metabolite fluopyram-pyridyl-carboxylic acid was always below the LOQ.

Residues of fluopyram in/on kidney bean pod were detectable slightly above the LOQ in all samples and declined markedly. The metabolite fluopyram-benzamide was detected slightly above the LOQ in all trials with a maximum value of 0.02 mg/kg besides trial R 2007 0014/8 where values were below the LOQ. Residues of fluopyram-pyridyl-acetic acid above the LOQ were detected in one sample (0.02 mg/kg) The metabolite fluopyram-pyridyl-carboxylic acid was always below the LOQ.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall and/or irrigation had no influence in two trials (R 2007 0547/6, R 2007 0547/6), possibly slight influence in two trials (R 2007 0014/8, R 2007 0546/8) and a marked influence in trial R 2007 0549/2.

However, rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/35
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 in/on kidney bean after spraying of AE C656948 (500 SC) in the field in Southern France, Italy, Spain and Portugal
Report No:	RA-2512/07
Document No:	M-297564-01-1
Guideline(s) followed in study:	EU 91/414/EEC Annex II, part A, section 6 and Annex III, part A, section 8; EC Guidance Working Document 7029/VI/95 rev. 5 (1997-07-22)
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in Southern Europe (Southern France, Italy, Spain and Portugal) on kidney bean during the 2007 season. Two applications with Fluopyram SC 500 containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on kidney bean, (pod and green material) declined markedly during the sampling period. Residues of fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were detected above the LOQ (0.01 mg/kg) in almost all samples with a maximum value of 0.14 mg/kg in green material and 0.07 mg/kg in pod, 0.09 mg/kg in green material and 0.11 mg/kg in pod and 0.02 mg/kg in green material and pod, respectively

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram (500 SC)

   Batch no.: 2006-010316

   Active substance: Fluopyram

   Storage: Not stated in the report

   Expiry date: 2009-01-09

2. Test commodity: Kidney bean

   Crop part: Pod and green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2512/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on kidney bean (pod and green material) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

Field phase

The study included four supervised residue trials conducted in southern Europe (southern France, Italy, Spain, and Portugal) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 509: Description of the trial locations and cropping information on treated plots

Trial number	R 2007 0035/0	R 2007 0550/6	R 2007 0551/4	R 2007 0552/2
Trial location	F-69380 Chazay d'Azergues (Rhone-Alpes)	I-00055 Ladispoli (RM) (Lazio)	E-46230 Alginet (Comunidad Valenciana)	P-2520-201 Ribafria Peniche (Ribatejo e Oeste)
Country	Southern France	Italy	Spain	Portugal
Area of application	Field	Field	Field	Field
Plot size [m²]	36	80	54	70
Type of soil	Loam	Clay sand	Clay	Silty sand
pH-value of soil (in water)	6.6	6.9	8.1	6.5
Content of organic C [%]	0.6	0.8	0.8	1.2
Test system	Kidney bean	Kidney bean	Kidney bean	Kidney bean
Variety	Contender	Bronco	Cleo	Tradicional
Date of planting/sowing	2007-06-27	2007-06-05	2007-05-15	2007-04-15
Start Flowering	2007-08-06	2007-07-07	2007-06-15	2007-06-01
End Flowering	2007-08-30	2007-08-03	2007-07-15	--
Date of commercial harvest	2007-08-22 to 2007-09-07	2007-07-15 to 2007-08-31	2007-07-01 to 2007-08-15	2007-07-15 to 2007-08-15

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stages between 63-75 and the second between 69-78 with an application rate of 0.25 kg a.s./ha and a water rate of 800-1000 L/ha.

Table 8.9- 510: Overview on application with Fluopyram SC 500 on kidney bean

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2007 0035/0 Southern France	1	T	Fluopyram SC 500	SPI	7	65	14	0.5	1000	Fluopyram	0.25
	2					78	7*	0.5	1000		0.25
R 2007 0550/6 Italy	1	T	Fluopyram SC 500	SPI	7	63	14	0.5	800	Fluopyram	0.25
	2					69	7*	0.5	800		0.25
R 2007 0551/4 Spain	1	T	Fluopyram SC 500	SPI	7	72	14	0.5	1000	Fluopyram	0.25
	2					77	7*	0.5	1000		0.25
R 2007 0552/2 Portugal	1	T	Fluopyram SC 500	SPI	7	75	14	0.5	1000	Fluopyram	0.25
	2	T				75	7*	0.5	1000		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of kidney bean pod and green material. The samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 511: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0035/0 R 2007 0550/6 R 2007 0551/4 R 2007 0552/2	Kidney bean	Pod, green material	C	-0
				3
				7
				14
		Pod, green material	T	-0
				0
				3
				7
				10
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites were analysed within the residue trials samples according to the following method:

Table 8.9- 512: Summary of the analytical method

Method	00984/M001
Extraction	Acetonitrile/water, with centrifugation
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in kidney bean (pod and green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the overall RSD values were below 20%. Details are given in the table below.

Table 8.9- 513: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	103; 95	99	-	0.01
	0.10	98; 95; 94; 94; 101; 98; 99; 98; 104; 105	99	3.9	
	1.0	90	90	-	
	Overall Recovery (n = 13)		**98**	**4.5**	
Kidney bean green material	0.01	106; 92; 96	98	7.4	0.01
	0.10	107; 94; 109; 100; 103; 105; 101	103	4.9	
	1.0	89; 105	97	-	
	10	83	83	-	
	Overall Recovery (n = 13)		**99**	**7.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 514: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	73; 95; 110	93	20.1	0.01
	0.10	66; 95; 98; 100; 97; 84; 76; 91; 79; 74	86	13.8	
	1.0	80	80	-	
	Overall Recovery (n = 14)		**87**	**14.7**	
Kidney bean green material	0.01	102; 88; 113; 100	101	10.2	0.01
	0.10	73; 74; 79; 77; 82; 80; 82	78	4.6	
	1.0	81; 90	86	-	
	10	78	78	-	
	Overall Recovery (n = 14)		**86**	**13.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

Table 8.9- 515: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	92; 97; 92	94	3.1	0.01
	0.10	92; 94; 95; 97; 98; 93; 91; 93; 94; 93	94	2.3	
	1.0	81	81	-	
	Overall Recovery (n = 14)		**93**	**4.4**	
Kidney bean green material	0.01	93; 88; 95; 89	91	3.6	0.01
	0.10	95; 102; 99; 92; 94; 92; 96	96	3.8	
	1.0	86; 96	91	-	
	10	83	83	-	
	Overall Recovery (n = 14)		**93**	**5.5**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram

Table 8.9- 516: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Kidney bean pod	0.01	94; 102; 73	90	16.7	0.01
	0.10	114; 96; 109; 87; 92; 88; 75; 97; 83; 94	94	12.4	
	1.0	84	84	--	
	Overall recovery (n = 14)		**92**	**12.6**	
Kidney bean green material	0.01	97; 96; 91; 106	98	6.4	0.01
	0.10	111; 103; 101; 92; 86; 104	100	9.1	
	1.0	81; 96	89	--	
	10	73	73	--	
	Overall recovery (n = 13)		**95**	**11.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 41 and 97 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water and high protein matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples., except in trial R 2007 0551/4 the control samples were slightly contaminated. The results of the treated samples reflect the residue levels to be expected if the product Fluopyram SC 500 is applied according to the use pattern as specified. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on kidney bean (pod and green material) are summarised in the following table.

Table 8.9- 517: Residue summary of fluopyram in/on kidney bean

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram -pyridyl-carboxylic acid
R 2007 0035/0 Southern France	Pod	78	-0	0.07	<0.01	<0.01	<0.01
	Green material	78	-0	0.52	0.05	<0.01	<0.01
	Pod	78	0	0.45	<0.01	<0.01	<0.01
	Green material	78	0	8.2	0.04	<0.01	<0.01
	Pod	78	3	0.25	0.02	<0.01	0.01
	Green material	78	3	5.7	0.09	<0.01	0.02
	Pod	79	7	0.11	0.02	<0.01	0.02
	Green material	79	7	0.61	0.06	<0.01	0.01
	Pod	79	10	0.10	0.02	<0.01	0.02
	Green material	79	10	0.69	0.08	<0.01	<0.01
	Pod	79	14	0.08	0.03	<0.01	0.02
	Green material	79	14	0.80	0.08	0.01	0.01
R 2007 0550/6 Italy	Pod	69	-0	0.02	<0.01	<0.01	<0.01
	Green material	69	-0	0.28	0.02	<0.01	<0.01
	Pod	69	0	0.47	<0.01	<0.01	<0.01
	Green material	69	0	8.9	0.02	<0.01	<0.01
	Pod	71	3	0.05	<0.01	<0.01	<0.01
	Green material	71	3	0.58	0.03	<0.01	<0.01
	Pod	79	7	0.03	<0.01	<0.01	<0.01
	Green material	79	7	0.26	0.03	<0.01	<0.01
	Pod	79	10	0.02	<0.01	<0.01	<0.01
	Green material	79	10	0.19	0.03	<0.01	<0.01
	Pod	79	14	0.02	<0.01	<0.01	<0.01
	Green material	79	14	0.10	0.03	<0.01	<0.01
R 2007 0551/4 Spain	Pod	77	-0	0.12	<0.01	<0.01	<0.01
	Green material	77	-0	2.6	0.05	<0.01	<0.01
	Pod	77	0	0.17	0.01	<0.01	<0.01
	Green material	77	0	5.9	0.05	<0.01	<0.01
	Pod	78	3	0.26	0.02	0.01	<0.01
	Green material	78	3	3.7	0.06	0.01	<0.01
	Pod	79	7	0.25	0.04	0.03	0.01
	Green material	79	7	4.3	0.13	0.02	0.01
	Pod	79	10	0.19	0.05	0.04	0.01
	Green material	79	10	2.4	0.13	0.03	0.01
	Pod	81	14	0.16	0.06	0.06	0.02
	Green material	81	14	1.2	0.14	0.03	0.01

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0552/2 Portugal	Pod	75	-0	0.30	0.02	0.01	<0.01
	Green material	75	-0	1.7	0.05	0.02	<0.01
	Pod	75	0	0.52	0.01	<0.01	<0.01
	Green material	75	0	7.8	0.06	0.02	<0.01
	Pod	77	3	0.45	0.02	0.02	<0.01
	Green material	77	3	3.4	0.07	0.02	<0.01
	Pod	77	7	0.43	0.05	0.05	0.01
	Green material	77	7	2.2	0.11	0.05	<0.01
	Pod	79	10	0.27	0.05	0.07	0.01
	Green material	79	10	2.8	0.13	0.08	<0.01
	Pod	81	14	0.32	0.07	0.11	0.02
	Green material	81	14	2.0	0.15	0.09	0.02

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on kidney bean

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 518: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0035/0 Chazay d'Azergues, FR,						Meteo France Liergues (11 km), study raw data	no	Meteo France Liergues (11 km), study raw data
M-297564-01-1	78	24/08/2007	0	8.2	8.24	0		19
		25/08/2007	1			0		20.6
bean, kidney, green material		26/08/2007	2			0		21.3
		27/08/2007	3	5.7	5.79	0		22.3
		28/08/2007	4			6		19.4
		29/08/2007	5			40		16
		30/08/2007	6			0		16.2
		31/08/2007	7	0.61	0.67	0		16.4
		01/09/2007	8			0		15.3
		02/09/2007	9			0		16
		03/09/2007	10	0.69	0.77	1		15.3
		04/09/2007	11			0		13.6
		05/09/2007	12			0		13.3
		06/09/2007	13			0		15.1
		07/09/2007	14	0.8	0.88	0		16.1

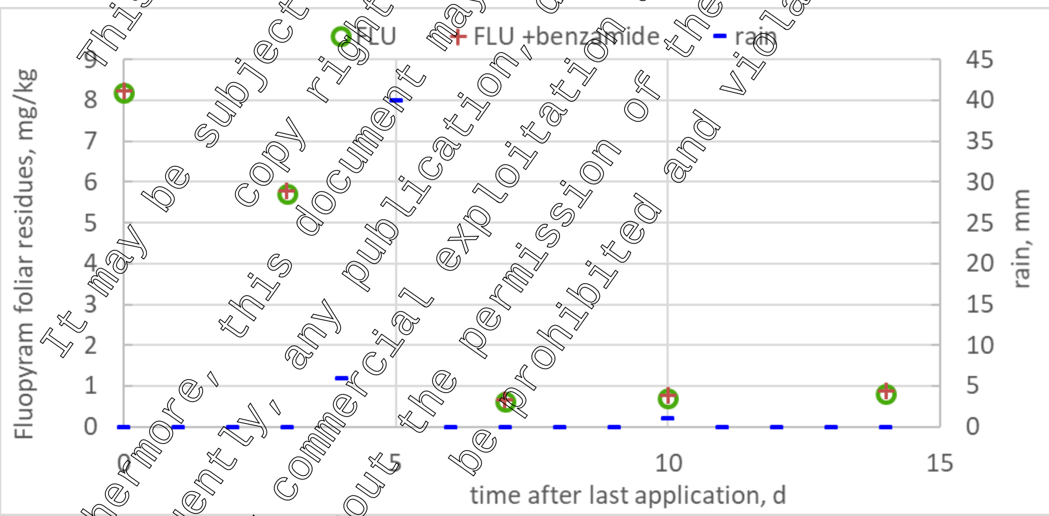


Figure 8.9- 159: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

Rainfall on days 4 and 5 coincides with a marked drop of residue levels, influence likely.

Table 8.9- 519: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0550/6 Ladispoli, IT, M-297564-01-1 bean, kidney, green material						www.ilmeteo.it Ladispoli	drip	www.ilmeteo.it Ladispoli
	69	20/07/2007	0	8.9	8.92	0		25.6
		21/07/2007	1			0		26.1
		22/07/2007	2			0		25.6
		23/07/2007	3	0.58	0.61	0		27.4
		24/07/2007	4			0		28.2
		25/07/2007	5			0		24.8
		26/07/2007	6			0		25.1
		27/07/2007	7	0.26	0.29	0		25.4
		28/07/2007	8			0		25.2
		29/07/2007	9			0		25.3
		30/07/2007	10	0.19	0.22	0		24.7
		31/07/2007	11			0		25.3
		01/08/2007	12			0		24.6
		02/08/2007	13			0		23.9
		03/08/2007	14	0.1	0.13	0		24.2

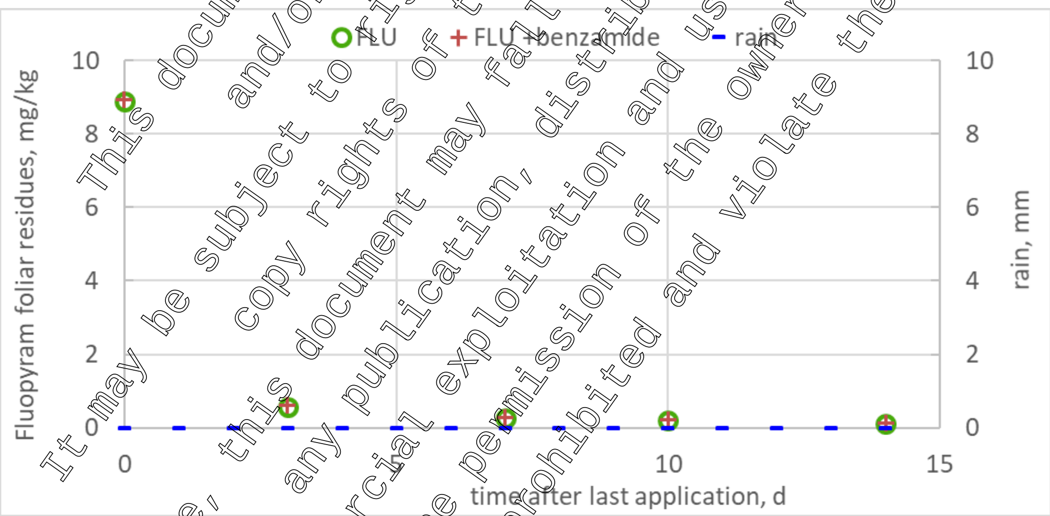


Figure 8.9- 160: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

There as no rainfall and no influence on residue decline.

Table 8.9- 520: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0551/4 Alginet, ES,						Benifaio (5 km), study raw data	flooding	Benifaio (5 km), study raw data
M-297564-01-1	77	10/07/2007	0	5.9	5.95	0		23.02
		11/07/2007	1			0		23.46
bean, kidney, green material		12/07/2007	2			0		23.9
		13/07/2007	3	3.7	3.76	0		24.05
		14/07/2007	4			0		23.77
		15/07/2007	5			0		23.49
		16/07/2007	6			0		24.69
		17/07/2007	7	4.3	4.43	0		24.72
		18/07/2007	8			0		25.15
		19/07/2007	9			0		24.77
		20/07/2007	10	2.4	2.53	0		24.55
		21/07/2007	11			0		26.14
		22/07/2007	12			0.6		25.1
		23/07/2007	13			0		29.29
		24/07/2007	14	1.2	1.34	0		26.05

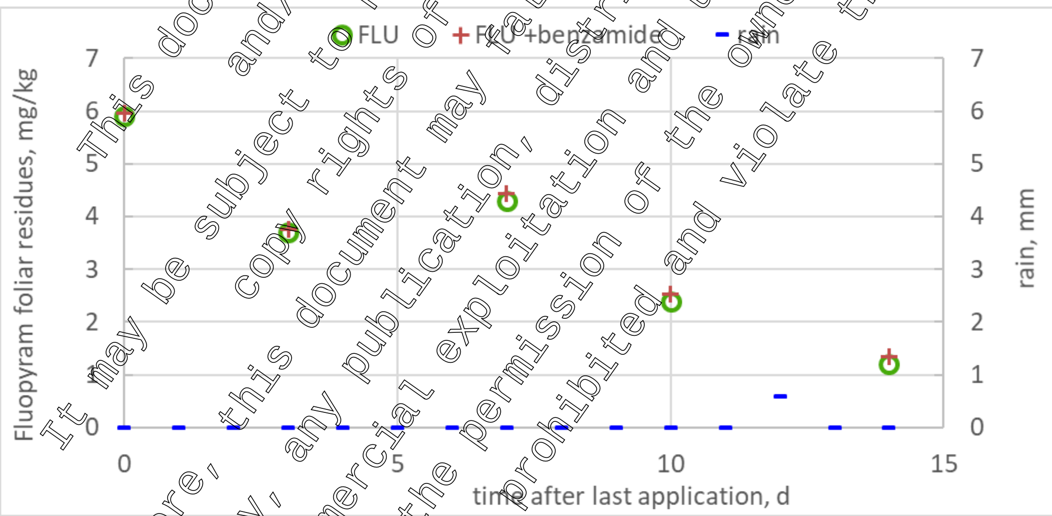


Figure 8.9- 161: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

There was no rainfall until day 12, thus no influence.

Table 8.9- 521: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0552/2 Ribafria Peniche, PT,						Peniche, Salir do Porto (30 km), study raw data	no	Peniche, Salir do Porto (30 km), study raw data
M-297564-01-1	75	16/07/2007	0	7.8	7.86	1.6 (0) [a]		18.6
		17/07/2007	1			0		19.1
bean, kidney, green material		18/07/2007	2			0		19.1
		19/07/2007	3	3.4	3.47	0		18.9
		20/07/2007	4			0		18.5
		21/07/2007	5			0		18.5
		22/07/2007	6			0		19.5
		23/07/2007	7	2.2	2.31	1.2		19.9
		24/07/2007	8			0		19.3
		25/07/2007	9			0		19.5
		26/07/2007	10	2.8	2.93	0		20.0
		27/07/2007	11			0		20.4
		28/07/2007	12			0		22.0
		29/07/2007	13			0		25.2
		30/07/2007	14	2	2.15	0		26.2

[a] no rain within 24 h after application, in study report

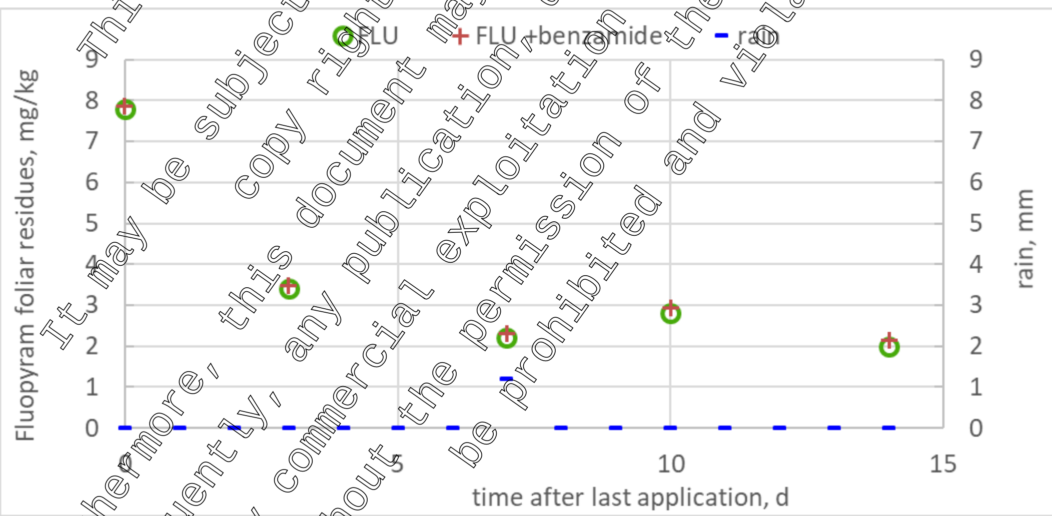


Figure 8.9- 162: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to kidney bean

There was no rainfall except for 1.2 mm on day 7 (no influence).

II. CONCLUSION

After two spray applications of Fluopyram SC 500 on kidney bean in four residue trials conducted in southern Europe (southern France, Italy, Spain, and Portugal) during the 2007 season the residues of fluopyram in/on kidney bean green material declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected above the LOQ of (0.01 mg/kg) in all samples with a maximum value of 0.15 mg/kg. The metabolite fluopyram-pyridyl-acetic acid was detected above the LOQ in almost all samples of trials R 2007 0551/4 and R 2007 0552/2 with a maximum value of 0.09 mg/kg. The metabolite fluopyram-pyridyl-carboxylic acid was detected slightly above the LOQ in almost all samples with a maximum value of 0.02 mg/kg except for trial R 2007 0550/6 where residues were always below the LOQ.

Residues of fluopyram in/on kidney bean pod were detected above the LOQ in all samples and declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ in almost all samples with a maximum value of 0.07 mg/kg except for trial R 2007 0550/6 where residues were below LOQ. The metabolite fluopyram-pyridyl-carboxylic acid was detected slightly above the LOQ in almost all samples except for trial R 2007 0550/6 with a maximum value of 0.02 mg/kg. The metabolite fluopyram-pyridyl-acetic acid was detected in almost all samples of trials R 2007 0551/4 and R 2007 0552/2 with a maximum value of 0.11 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Apart from trial R 2007 0035/0 with heavy rain several days after application, there was no discernable influence from rain or irrigation.

However, rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/36
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 in/on garden pea after spraying of AE C656948 (500 SC) in the field in Netherlands, Germany, Northern France and Belgium
Report No:	RA-2513/07
Document No:	M-298639-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with five residue trials was conducted in the field in northern Europe (The Netherlands, 2 x Germany, northern France and Belgium) on garden pea during the 2007 season. Two applications with Fluopyram SC 500 containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on garden pea (seed green and green material) declined markedly during the sampling period. In garden pea (green seed) fluopyram was detected in all samples with a maximum value of 0.05 mg/kg.

Residues of fluopyram-benzamide were detected above the LOQ (0.01 mg/kg) in almost all samples in green material with a maximum value of 0.17 mg/kg. The residues of metabolite fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were detected in green material and seed green with maximum values slightly above the LOQ (0.02 mg/kg).

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram (500 SC)
	Batch no.:	2006-010316
	Active substance:	Fluopyram
	Storage:	Not stated in the report
	Expiry date:	2009-01-09
2.	Test commodity:	Garden pea
	Crop part:	Green seed and green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2513/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on garden pea (seed green and green material) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

Field phase

The study included five supervised residue trials conducted in northern Europe (The Netherlands, 2 x Germany, northern France and Belgium) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 522: Description of the trial locations and cropping information on treated plots

Trial number	R 2007 0036/9	R 2007 0553/0	R 2007 0554/9	R 2007 0555/7	R 2007 0556/5
Trial location	NL-9606 Kopstukken (Groningen)	D-51399 Burscheid (Nordrhein-Westfalen)	F-80700 Goyencourt (Picardie)	B-5300 Landenne-Sur-Meuse (Namur)	D-53913 Swisttal - Heimerzheim (Nordrhein-Westfalen)
Country	Netherlands	Germany	Northern France	Belgium	Germany
Area of application	Field	Field	Field	Field	Field
Plot size [m^2]	24	108	75	30	77
Type of soil	Clay sand	Sandy loam	Loam	Silty loam	Sandy loam
pH-value of soil (in water)	6.2	6.5	7.4	7.5	6.8
Content of organic C [%]	4.2	1.2	0.8	2.2	1.0
Test system	Garden pea	Garden pea	Garden pea	Garden pea	Garden pea
Variety	Unknown	Wunder von Kelvedon	Arabelle	Tristar	Spring
Date of planting/sowing	- / 2007-05-20	- / 2007-03-15	- / 2007-04-20	- / 2007-05-06	- / 2007-03-16
Start Flowering	2007-07-15	2007-05-17	2007-06-20	2007-06-25	2007-05-09
End Flowering	2007-07-30	2007-05-31	2007-07-11	2007-07-06	2007-05-31
Date of commercial harvest	2007-08-06 to 2007-08-14	2007-06-12 to 2007-06-26	2007-07-18 to 2007-07-22	2007-07-20 to 2007-07-27	2007-06-14 to 2007-06-20

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stages between 69-77 and the second between 75-79 with an application rate of 0.25 kg a.s./ha and a water rate of 300-600 L/ha.

Table 8.9- 523: Overview on application with Fluopyram SC 500 on garden pea

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2007 0036/9 The Netherlands	1	T	Fluopyram SC 500	SPI	7	77	14	0.5	600	Fluopyram	0.25
	2					79	7*	0.5	600		0.25
R 2007 0553/0 Germany	1	T	Fluopyram SC 500	SPI	7	71	14	0.5	300	Fluopyram	0.25
	2					75	7*	0.5	300		0.25
R 2007 0554/9 Northern France	1	T	Fluopyram SC 500	SPI	7	70	14	0.5	300	Fluopyram	0.25
	2					77	7*	0.5	300		0.25
R 2007 0555/7 Belgium	1	T	Fluopyram SC 500	SPI	7	69	14	0.5	400	Fluopyram	0.25
	2	T				75	7*	0.5	400		0.25
R 2007 0556/5 Germany	1	T	Fluopyram SC 500	SPI	7	76	14	0.5	300	Fluopyram	0.25
	2	T				77	7*	0.5	300		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of garden pea (seed green) except trial R 2007 0555/7 when two samples from (DALT 7) only had 800 g and 860 g, respectively, instead of 1 kg. This had no impact on the study. The samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 524: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0036/9 R 2007 0553/0 R 2007 0554/9 R 2007 0555/7 R 2007 0556/5	Garden pea	Green material	C	-0
				7
		Seed green	C	7
		Green material	T	-0
				0
			T	3
		Green material, seed green	T	7
				10
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites were analysed within the residue trials samples according to the following method:

Table 8.9- 525: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in garden pea (seed green and green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 526: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	92; 99	96	--	0.01
	0.1	114; 103	109	--	
	10	99	--	--	
	Overall Recovery (n = 5)		**101**	**8.0**	
Garden pea, seed green	0.01	91; 97	94	--	0.01
	0.1	83; 100	92	--	
	Overall Recovery (n = 4)		**93**	**8.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 527: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	109; 86	98	--	0.01
	0.1	99; 92	96	--	
	10	89	--	--	
	Overall Recovery (n = 5)		**95**	**9.7**	
Garden pea, seed green	0.01	96; 87	92	--	0.01
	0.1	81; 94	88	--	
	Overall Recovery (n = 4)		**90**	**7.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

Table 8.9- 528: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	95; 87	91	--	0.01
	0.1	81; 90	86	--	
	10	87	--	--	
	Overall Recovery (n = 5)		**88**	**5.8**	
Garden pea, seed green	0.01	86; 96	91	--	0.01
	0.1	76; 92	84	--	
	Overall Recovery (n = 4)		**88**	**9.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram

Table 8.9- 529: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	81; 89	85	--	0.01
	0.1	90; 84	87	--	
	10	92	--	--	
	Overall recovery (n = 5)		**87**	**5.2**	
Garden pea, seed green	0.01	86; 99	93	--	0.01
	0.1	88; 91	90	--	
	Overall recovery (n = 4)		**91**	**6.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 76 and 129 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water and high protein matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on garden pea (seed green and green material) are summarised in the following table.

Table 8.9- 530: Residue summary of fluopyram in/on garden pea

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0036/9 The Netherlands	Green material	79	-0	0.29	0.01	<0.01	<0.01
	Green material	79	0	5.7	0.01	<0.01	<0.01
	Green material	79	3	4.9	0.05	<0.01	<0.01
	Green material	79	7	1.9	0.06	0.01	<0.01
	Seed, green	79	7	0.05	0.01	0.01	0.01
	Green material	80	10	1.8	0.05	0.01	<0.01
	Seed, green	80	10	0.04	0.02	0.01	0.01
	Green material	80	14	0.66	0.02	<0.01	<0.01
	Seed, green	80	14	0.03	0.01	0.01	<0.01
R 2007 0553/0 Northern France	Green material	75	-0	2.1	0.02	<0.01	<0.01
	Green material	75	0	6.6	0.03	<0.01	<0.01
	Green material	76	3	1.6	0.03	<0.01	<0.01
	Green material	79	7	1.1	0.04	<0.01	<0.01
	Seed, green	79	7	0.02	<0.01	<0.01	<0.01
	Green material	79	10	0.70	0.02	<0.01	<0.01
	Seed, green	79	10	0.02	<0.01	<0.01	<0.01
	Green material	79	14	0.51	0.02	<0.01	<0.01
	Seed, green	79	14	0.02	<0.01	<0.01	<0.01
R 2007 0554/9 Germany	Green material	77	-0	0.97	0.02	<0.01	<0.01
	Green material	77	0	7.6	0.03	<0.01	<0.01
	Green material	77	3	3.8	0.03	<0.01	<0.01
	Green material	79	7	1.3	0.04	<0.01	<0.01
	Seed, green	79	7	0.03	<0.01	<0.01	<0.01
	Green material	80	10	1.3	0.04	<0.01	<0.01
	Seed, green	80	10	0.03	<0.01	<0.01	0.01
	Green material	87	14	2.3[(a)]	0.06[(c)]	0.02[(b)]	0.01[(d)]
	Seed, green	87	14	0.05	<0.01	0.01	0.02
R 2007 0555/7 Belgium	Green material	75	-0	0.31	0.01	<0.01	<0.01
	Green material	75	0	2.5	0.01	<0.01	<0.01
	Green material	76	3	2.4	0.03	<0.01	<0.01
	Green material	79	7	0.81	0.04	<0.01	<0.01
	Seed, green	79	7	0.02	<0.01	<0.01	<0.01
	Green material	79	10	0.70	0.05	<0.01	<0.01
	Seed, green	79	10	0.02	<0.01	<0.01	<0.01
	Green material	81	14	0.45	0.04	<0.01	<0.01
	Seed, green	81	14	0.02	<0.01	0.01	0.01

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0556/5 Germany	Green material	77	-0	0.58	<0.01	<0.01	<0.01
	Green material	77	0	6.7	0.06	<0.01	<0.01
	Green material	79	3	7.1	0.11	0.01	<0.01
	Green material	79	7	4.3	0.17	0.02	0.01
	Seed, green	79	7	0.02	<0.01	0.02	<0.01
	Green material	81	10	2.5	0.06	0.01	<0.01
	Seed, green	81	10	0.01	<0.01	0.01	0.01
	Green material	82	13	1.1	0.06	0.01	<0.01
	Seed, green	82	13	<0.01	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

(a): This result corresponds to the mean of 3 single values (2.43, 2.38 and 2.22 mg/kg).
(b): This result corresponds to the mean of 3 single values (0.016, 0.017 and 0.016 mg/kg).
(c): This result corresponds to the mean of 3 single values (0.062, 0.058 and 0.057 mg/kg).
(d): This result corresponds to the mean of 3 single values (0.011, 0.010 and 0.011 mg/kg).

2. Climatic conditions and time course of residue concentrations in/on garden pea

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 531: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0036/9 Kopstukken, NL, M-298639-01-1 pea, garden, green material						KMNI Eelde [a] (35 km)	no	KMNI Eelde [a] (35 km)
	79	03/08/2007	0	5.7	5.71	0		15.9
		04/08/2007	1			0		18.1
		05/08/2007	2			0		22.6
		06/08/2007	3	4.9	4.95	1.3		22.1
		07/08/2007	4			3.1		17.2
		08/08/2007	5			6.7		15
		09/08/2007	6			0		16.7
		10/08/2007	7	1.9	1.96	0		16.6
		11/08/2007	8			0		15.4
		12/08/2007	9			3.9		17.3
		13/08/2007	10	1.8	1.85	0.1		16.7
		14/08/2007	11			0.4		18.6
		15/08/2007	12			7.9		19.5
		16/08/2007	13			3.8		15.4
		17/08/2007	14	0.66	0.68	3.8		13.6

[a] http://projects.knmi.nl/klimatologie/daggegevens/selectie.cgi

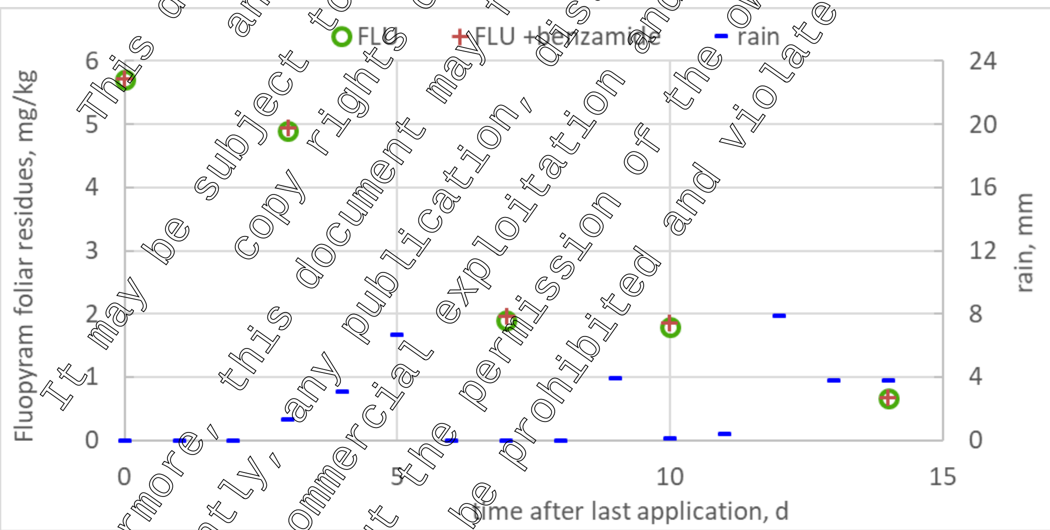


Figure 8.9- 163: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to garden pea

Rainfall on days 3, 4 and 5 coincides with a drop in residue levels. Influence likely.

Table 8.9- 532: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0553/0 Burscheid, DE, M-298639-01-1 pea, garden, green material						ProPlant DB Versuchsgut Höfchen (0 km)	no	ProPlant DB Versuchsgut Höfchen (0 km)
	75	12/06/2007	0	6.6	6.63	0		16.8
		13/06/2007	1			0		19.8
		14/06/2007	2			5.1		19.2
		15/06/2007	3	1.6	1.63	0.6		18.7
		16/06/2007	4			2.2		16.7
		17/06/2007	5			1.4		18.8
		18/06/2007	6			4.7		18.3
		19/06/2007	7	1.1	1.14	0		21.6
		20/06/2007	8			4.6		21.2
		21/06/2007	9			22.3		15.9
		22/06/2007	10	0.7	0.72	0.3		16.2
		23/06/2007	11			9		15.9
		24/06/2007	12			0		18.1
		25/06/2007	13			9.6		16.3
		26/06/2007	14	0.51	0.53	3		13.2

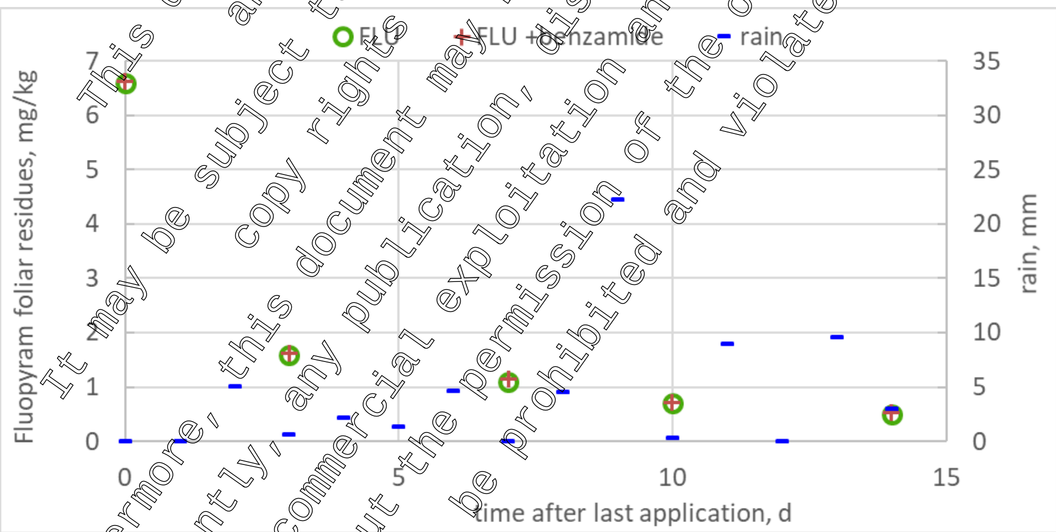


Figure 8.9- 164: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to garden pea

Rainfall on day 2 coincides with a large decrease in residue levels. Influence possible.

Table 8.9- 533: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0554/9 Goyencourt, FR, M-298639-01-1						Meteo France Rouvroy en Santerre (10 km), study raw data	no	Meteo France Rouvroy en Santerre (10 km), study raw data
pea, garden, green material	77	13/07/2007	0	7.6	7.63	0		21.5
		14/07/2007	1			0		21.1
		15/07/2007	2			9.2		22.8
		16/07/2007	3	3.8	3.83	22.2		18.9
		17/07/2007	4			0		18.2
		18/07/2007	5			0		17.9
		19/07/2007	6			4.4		19.4
		20/07/2007	7	1.3	1.34	0		17.2
		21/07/2007	8			0.2		16.6
		22/07/2007	9			1		16.3
		23/07/2007	10	1.3	1.34	12.2		14.8
		24/07/2007	11			0		16.5
		25/07/2007	12			0		17.5
		26/07/2007	13			0		18.8
		27/07/2007	14	2.3	2.36	2		18.2

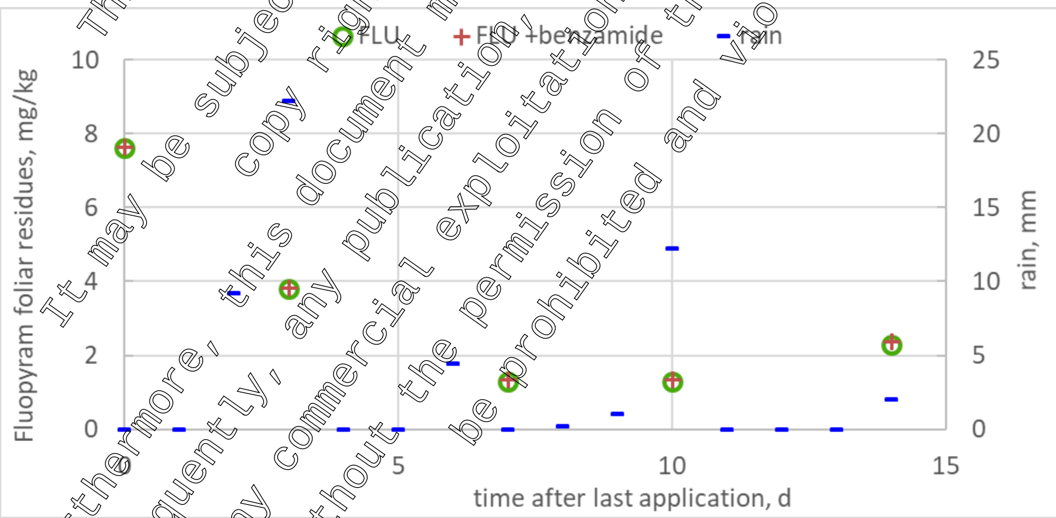


Figure 8.9-165: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the garden pea

Rainfall on day 2 (9.2 mm) and day 3 (22.2 mm) may have influenced residue concentrations, although no marked drop of residue levels is visible.

Table 8.9- 534: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0555/7 Landenne-Sur-Meuse, BE, M-298639-01-1 pea, garden, green material						Eghezee (10 km), study raw data	no	Eghezee (10 km), study raw data
	75	13/07/2007	0	2.5	2.51	0		21
		14/07/2007	1			0		23.2
		15/07/2007	2			0		23.8
		16/07/2007	3	2.4	2.43	0		22.8
		17/07/2007	4			0		19.1
		18/07/2007	5			0		18.5
		19/07/2007	6			0		17.9
		20/07/2007	7	0.81	0.85	2		18
		21/07/2007	8			0		17.4
		22/07/2007	9			0		16.6
		23/07/2007	10	0.7	0.75	3		14.9
		24/07/2007	11			2		16.5
		25/07/2007	12			0		18.2
		26/07/2007	13			0		19.3
		27/07/2007	14	0.45	0.49	1		18.6

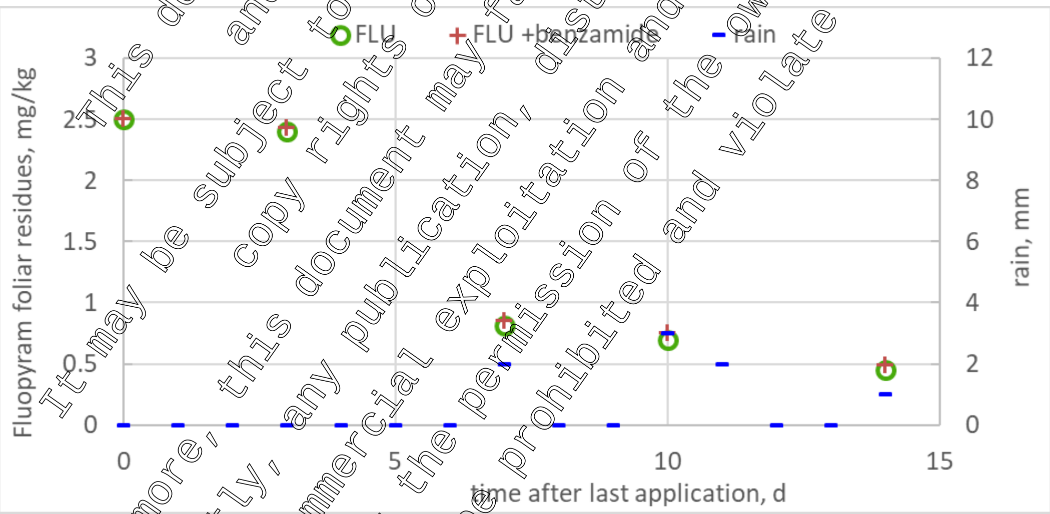


Figure 8.9- 166: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the garden pea

Overall, little rain (first on day 7 with 2 mm), however coinciding with a decrease in residue concentrations. Influence possible.

Table 8.9- 535: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0556/5 Swisttal - Heimerzheim, DE, M-298639-01-1 pea, garden, green material						DWD Köln-Bonn [a] (25 km)	no	DWD Köln-Bonn [a] (25 km)
	77	11/06/2007	0	6.7	6.76	5.5		19.2
		12/06/2007	1			0.1		16.9
		13/06/2007	2			0		19.6
		14/06/2007	3	7.1	7.21	0.7		19.6
		15/06/2007	4			4.5		18.6
		16/06/2007	5			1.5		17
		17/06/2007	6			3.6		19
		18/06/2007	7	4.3	4.47	6.4		18.8
		19/06/2007	8			2		21.3
		20/06/2007	9			0.2		20.9
		21/06/2007	10	2.5	2.56	25.1		16.2
		22/06/2007	11			2.5		15.9
		23/06/2007	12			15.2		16.1
		24/06/2007	13	1.1	1.16	15.1		18

[a] https://opendata.dwd.de/climate_environment/CDC/

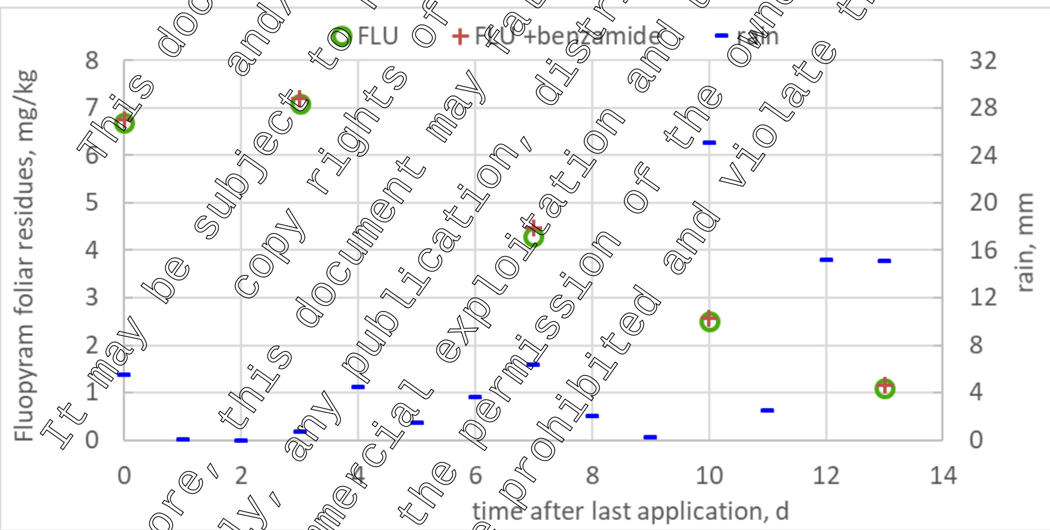


Figure 8.9-167: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the garden pea

Many days with moderate rainfall. Influence on residue levels not discernible but possible.

III. CONCLUSION

After two spray applications of Fluopyram SC 500 on garden pea in five residue trials conducted in northern Europe (The Netherlands, 2 x Germany, northern France and Belgium) during the 2007 season the residues of fluopyram in/on garden pea (green material) declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected above the LOQ of (0.01 mg/kg) in all samples with a maximum value of 0.17 mg/kg. The metabolite fluopyram-pyridyl-acetic acid was detected slightly above the LOQ in samples of three trials with a maximum value of 0.02 mg/kg and metabolite fluopyram-pyridyl-carboxylic acid was detected in two samples with a value of 0.01 mg/kg.

Residues of fluopyram in/on garden pea (seed green) were detectable slightly above the LOQ in all samples with a maximum value of 0.05 mg/kg. The metabolite fluopyram-benzamide was detected slightly above the LOQ in three samples (2 x 0.01 and 0.02 mg/kg). The metabolite fluopyram-pyridyl-carboxylic acid was detected above the LOQ in seven samples with a maximum value of 0.02 mg/kg and metabolite fluopyram-pyridyl-acetic acid was detected above the LOQ in seven samples with a maximum value of 0.02 mg/kg.

Assessment and conclusion by applicant:

Rainfall occurred in all trials of this study, and a slight to moderate influence on residue dissipation is possible. However, rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/37
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 in/on garden pea after spraying of AE C656948 (500 SC) in the field in Southern France and Spain
Report No:	RA-2514/07
Document No:	M-297487-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in southern Europe (southern France and Spain) on garden pea during the 2007 season. Two applications with Fluopyram SC 500 containing 500 g/L fluopyram were conducted. The parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram SC 500 on garden pea (green material) declined markedly during the sampling period. In garden pea (green seed), fluopyram was detected in all samples with a maximum value of 0.03 mg/kg.

Residues of fluopyram-benzamide were detected above the LOQ (0.01 mg/kg) in green material in all samples with a maximum value of 0.23 mg/kg. in almost all samples with a maximum value of 0.05 mg/kg. Residues of metabolites fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were detected slightly above the LOQ with maximum values of 0.03 and 0.06 mg/kg, respectively.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram (500 SC)
	Batch no.:	2006-010316
	Active substance:	Fluopyram
	Storage:	Not stated in the report
	Expiry date:	2009-01-09
2.	Test commodity:	Garden pea
	Crop part:	Green seed, pod and green material

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2514/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on garden pea (seed green, pod and green material) after two spray applications with Fluopyram SC 500, a suspension concentrate formulation containing 500 g/L fluopyram.

Field phase

The study included two supervised residue trials conducted in southern Europe (southern France and Spain) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 536: Description of the trial locations and cropping information on treated plots

Trial number	**R 2007 0037/7**	**R 2007 0557/3**
Trial location	F-69380 Chazay d'Azergues (Rhone-Alpes)	E-41310 Brenes - Sevilla (Andalucia)
Country	Southern France	Spain
Area of application	Field	Field
Plot size [m^2]	91.5	67.5
Type of soil	Loam	Loam
pH-value of soil (in water)	6.6	7.8
Content of organic C [%]	0.6	0.4
Test system	Garden pea	Garden pea
Variety	Douce de provence	Rondo
Date of planting/sowing	- / 2007-04-02	- / 2007-03-07
Start Flowering	2007-05-15	2007-05-07
End Flowering	2007-06-01	2007-05-25
Date of commercial harvest	2007-06-07 to 2007-06-10	2007-05-15 to 2007-06-15

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stages between 67-71 and the second at BBCH stage 74 with an application rate of 0.25 kg a.s./ha and a water rate of 400 L/ha. A deviation occurred within trial R 2007 0037/7 when it rained 1 mm 10.5 hours after the last application. This had no impact on the study.

Table 8.9- 537: Overview on application with Fluopyram SC 500 on garden pea

Trial no. Country	**Appl. No.**	**Plot**	**Formu-lation**	**Appl. mode**	**Interval (days)**	**Growth stage (BBCH code)**	**DBH PHI (days)**	**Test item rate (L/ha)**	**Water rate (L/ha)**	**a.s.**	**Appl. rate (g a.s. /ha)**
R 2007 0037/7 Southern France	1	T	Fluopyram SC 500	SPI	8	67	15	0.5	400	Fluopyram	0.25
	2					74	7*	0.5	400		0.25

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2007 0557/3 Spain	1	T	Fluopyram SC 500	SPI	7	71	14	0.5	400	Fluopyram	0.25
	2					74	7*	0.5	400		0.25

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of garden pea (seed green and green material). The samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 538: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0037/7 R 2007 0557/3	Garden pea	Green material	C	-0
				7
		Seed green	C	7
		Green material	T	-0
				0
		Green material, pod	T	3
		Green material, seed green	T	7
				10
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites were analysed within the residue trials samples according to the following method:

Table 8.9- 539: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in garden pea (seed green, pod and green material))

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 540: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	114	--	--	0.01
	0.1	101	--	--	
	10	86	--	--	
	Overall Recovery (n = 3)		**100**	**14.0**	
Garden pea, seed green	0.01	87; 81	84	**--**	0.01
	0.1	97	--	--	
	Overall Recovery (n = 3)		**88**	**9.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 541: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	109	--	--	0.01
	0.1	95	--	--	
	10	87	--	--	
	Overall Recovery (n = 3)		**97**	**11.5**	
Garden pea, seed green	0.01	99; 92	96	**--**	0.01
	0.1	92	--	**--**	
	Overall Recovery (n = 3)		**94**	**4.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

Table 8.9- 542: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	91	--	--	0.01
	0.1	84	--	--	
	10	77	--	--	
	Overall Recovery (n = 3)		**84**	**8.3**	
Garden pea, seed green	0.01	86; 88	87	**--**	0.01
	0.1	94		**--**	
	Overall Recovery (n = 3)		**89**	**4.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram

Table 8.9- 543: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Garden pea, green material	0.01	87	--	--	0.01
	0.1	86	--	--	
	10	89	--	--	
	Overall recovery (n = 3)		**87**	**1.7**	
Garden pea, seed green	0.01	94; 91	--	**--**	0.01
	0.1	93	--	--	
	Overall recovery (n = 3)		**93**	**1.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid, determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 97 and 174 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water and high protein matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on garden pea (seed green, pod and green material) are summarised in the following table.

Table 8.9- 544: Residue summary of fluopyram in/on garden pea

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram -pyridyl-carboxylic acid
R 2007 0036/9 The Netherlands	Green material	74	-0	0.75	0.09	<0.01	<0.01
	Green material	74	0	7.9	0.11	<0.01	<0.01
	Green material	76	3	6.0	0.20	0.01	0.01
	Green material	80	7	0.93	0.23	0.02	0.02
	Seed, green	80	7	0.03	0.03	0.02	0.03
	Green material	80	10	0.51	0.14	0.01	0.01
	Seed, green	80	10	0.03	0.04	0.03	0.05
	Green material	80	14	0.35	0.10	0.01	0.01
	Seed, green	80	14	0.02	0.03	0.02	0.06
R 2007 0553/0 Northern France	Green material	74	-0	0.30	0.04	<0.01	<0.01
	Green material	74	0	3.4	0.04	<0.01	<0.01
	Green material	76	3	2.2	0.07	<0.01	<0.01
	Green material	79	7	0.45	0.05	<0.01	<0.01
	Seed, green	79	7	0.01	<0.01	<0.01	0.01
	Green material	79	10	0.39	0.06	<0.01	<0.01
	Seed, green	79	10	0.02	<0.01	<0.01	0.02
	Green material	81	14	0.24	0.05	<0.01	<0.01
	Seed, green	81	14	0.01	<0.01	<0.01	0.02

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on garden pea

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 545: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0037/7						Meteo France Liergues (11	no	Meteo France

Chazay d'Azergues, FR,						km), study raw data		Liergues (11 km), study raw data
M-297487-01-1	74	01/06/2007	0	7.9	8.01	8 (0) [a]		12.5
		02/06/2007	1			0		15.4
pea, garden, green material		03/06/2007	2			0		18.3
		04/06/2007	3	6	6.2	19.5		19.4
		05/06/2007	4			0		19.7
		06/06/2007	5			0		19.4
		07/06/2007	6			0		19.9
		08/06/2007	7	0.93	1.16	0		21.1
		09/06/2007	8			0		22.2
		10/06/2007	9			10		21.2
		11/06/2007	10	0.51	0.65	5.5		18.2
		12/06/2007	11			7		19.4
		13/06/2007	12			1		20.3
		14/06/2007	13			3.5		20.7
		15/06/2007	14	0.35	0.45	7		16.4

[a] no rain within 24 h after application, in study report

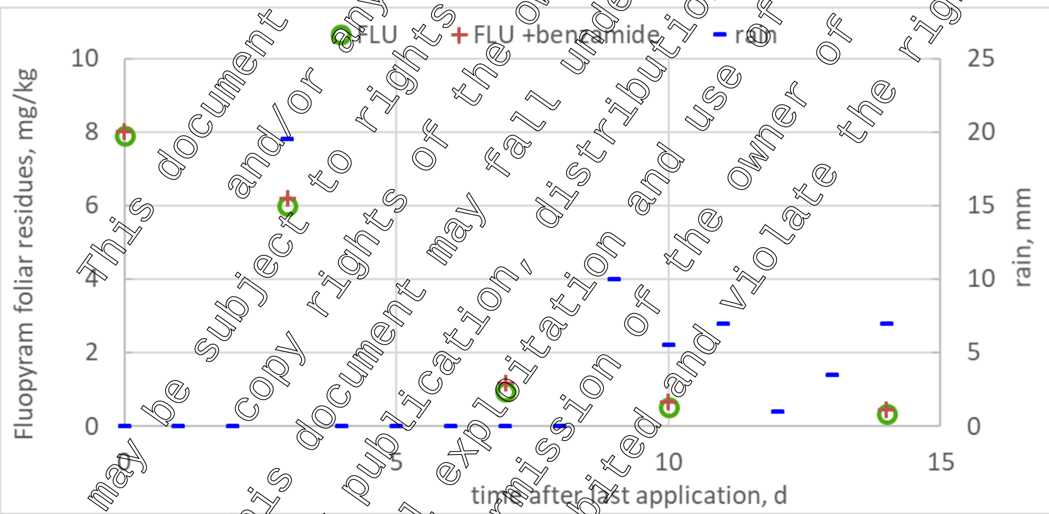


Figure 8.9- 168: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to garden pea

Large rainfall on day 3 coincides with an apparent drop in residue concentrations. Influence likely.

Table 8.9- 546: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0557/3 Brenes, Sevilla, ES,						La Rinconda Sevilla (11 km) [a]	sprinkler	La Rinconda Sevilla (11 km) [a]
M-297487-01-1	74	25/05/2007	0	3.4	3.44	0	18	16.9
		26/05/2007	1			3.6		15.4
pea, garden, green material		27/05/2007	2			0		18
		28/05/2007	3	2.2	2.27	0		18.1
		29/05/2007	4			0		18.9
		30/05/2007	5			0		20.9
		31/05/2007	6			0		19.6
		01/06/2007	7	0.45	0.5	0		20.4
		02/06/2007	8			0		22.9
		03/06/2007	9			0		24.2
		04/06/2007	10	0.39	0.45	0		24.1
		05/06/2007	11			0	18	24.1
		06/06/2007	12			0		23.7
		07/06/2007	13			0		23
		08/06/2007	14	0.24	0.29	0		22.4

a) www.juntadeandalucia.es/agriculturaypesca/ifapa/ria/servlet/FrontController

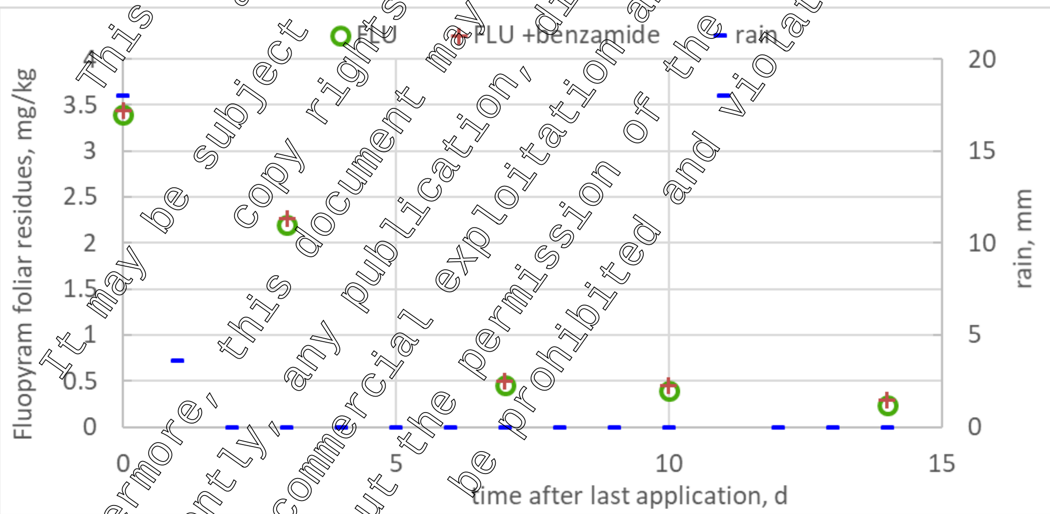


Figure 8.9- 169: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to garden pea

Irrigation on day 0 (likely conducted prior to application) and rain on day 1 (3.6 mm) do not coincide with a marked drop in residue levels, however an influence cannot be excluded.

III. CONCLUSION

After two spray applications of Fluopyram SC 500 on garden pea in two residue trials conducted in southern Europe (southern France, Spain) during the 2007 season the residues of fluopyram in/on garden pea (green material) declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected above the LOQ (0.01 mg/kg) in almost all samples with a maximum value of 0.23 mg/kg. The metabolite fluopyram-pyridyl-acetic acid was detected above the LOQ in almost all samples of trial R 2007 0037/7 with a maximum value of 0.02 mg/kg and metabolite fluopyram-pyridyl-carboxylic acid was detected above the LOQ in almost all samples of trial R 2007 0037/7 with a maximum value of 0.02 mg/kg.

Residues of fluopyram in/on garden pea (seed green) were detectable slightly above the LOQ in all samples with a maximum value of 0.03 mg/kg. The metabolite fluopyram-benzamide was detected slightly above the LOQ in three samples (2 x 0.03 and 0.04 mg/kg). The metabolite fluopyram-pyridyl-carboxylic acid was detected above the LOQ in all samples with a maximum value of 0.06 mg/kg and metabolite fluopyram-pyridyl-acetic acid was detected above the LOQ in all samples of trial R 2007 0037/7 with a maximum value of 0.03 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall and/or irrigation may have slightly influenced the residue decline, but rain is a natural and irrigation a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

In the following section the residue study summaries are presented that have been analysed in the kinetic report in M-763338-01-1:

Data Point:	KCA 8.9/38
Report Author:	[redacted]
Report Year:	2015
Report Title:	Determination of the residues of fluopyram and trifloxystrobin in/on lettuce after spray application of fluopyram & trifloxystrobin SC 500 in Belgium, Germany, the Netherlands and northern France
Report No:	14-2029
Document No:	M-534202-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with five residue trials was conducted in the field in northern Europe (Belgium, The Netherlands, northern France and 2 x Germany) on lettuce during the 2014 season. Two applications with Fluopyram & CGA 279202 SC 500, containing 250 g/L fluopyram and 250 g/L trifloxystrobin (CGA 279202) were conducted. Only the parameters and results relevant to fluopyram and its metabolite fluopyram-benzamide have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram & CGA 279202 SC 500 on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected slightly above the LOQ in 5 samples, with a maximum value of 0.016 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram & CGA 279202 SC 500 (250 +250 g/L)
	Batch no.:	EV57001784
	Active Ingredient:	Fluopyram and trifloxystrobin
	Storage:	Not stated in the report
	Expiry date:	2016-02-17
2.	Test commodity:	Lettuce
	Crop part:	Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 14-2029 was to determine the magnitude of the relevant residues of fluopyram and its metabolite fluopyram-benzamide in/on lettuce (head) after two spray applications with Fluopyram & CGA 279202 SC 500 (250 g/L + 250 g/L)", a suspension concentrate formulation containing 250 g/L fluopyram. This summary focuses only on the residues of fluopyram and its metabolite fluopyram-benzamide.

<u>Field phase</u>

The study included five supervised residue trials conducted in northern Europe (Belgium, The Netherlands, northern France and 2 x Germany) during the 2014 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 547: Description of the trial locations and cropping information on treated plots

Trial number	14-2029-01	14-2029-02	14-2029-03	14-2029-04	14-2029-05
Trial location	6210 Villers-Perwin	67125 Dannstadt-Schauernheim	1681 ND Zwaagdijk	37130 Lignières de Touraine	42799 Leichlingen
Country	Belgium	Germany	The Netherlands	France	Germany
Area of application	Field	Field	Field	Field	Field
Plot size [m^2]	24	15	48	40	45
Type of soil	Silt loam	Sandy Loam	Clay	Loam	Loamy sand
pH-value of soil (in water)	6.6	6.9	7.2	8.2	-
pH-value of soil (in $CaCl_2$)	-	-	-	-	6.5
Content of organic C [%]	2.3	2.6	3.0	1.6	2.3
Test system	Lettuce (open leaf variety)	Lettuce (open leaf variety)	Lettuce (open leaf variety)	Lettuce (open leaf variety)	Lettuce (open leaf variety)
Variety	Sansula (oak leaf variety)	Caverner (Lollo Rosso)	Loka (Lollo Rossa)	Kiribati (oak leaf variety)	Aleppo (Lollo bionda)
Date of planting	2014-05-20	2014-05-13	2014-05-22	2014-05-15	2014-04-28
Date of commercial harvest	2014-07-05 to 2014-07-14	2014-06-20 to 2014-07-04	2014-06-29 to 2014-07-06	2014-06-20 to 2014-07-10	2014-06-10 to 2014-06-20

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stages between 44-47 and the second between 46-48 with an application rate of 0.2 kg a.s./ha and a water rate of 300-900 L/ha.

Table 8.9- 548: Overview on application with Fluopyram & CGA 279202 SC 500 on lettuce

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
14-2029-01 Belgium	1	T	Fluo-pyram & CGA 279202 SC 500	SPI	7	45	14	0.8	900	Fluopyram CGA 279202	0.2
	2					48	7*			Fluopyram CGA 279202	0.2
14-2029-02 Germany	1	T	Fluo-pyram & CGA 279202 SC 500	SPI	7	45	14	0.8	600	Fluopyram CGA 279202	0.2
	2					47	7*			Fluopyram CGA 279202	0.2
14-2029-03 The Netherlands	1	T	Fluo-pyram & CGA 279202 SC 500	SPI	7	45	14	0.8	500	Fluopyram CGA 279202	0.2
	2					46	7*			Fluopyram CGA 279202	0.2
14-2029-04 France	1	T	Fluo-pyram & CGA 279202 SC 500	SPI	7	47	14	0.8	600	Fluopyram CGA 279202	0.2
	2					48	7*			Fluopyram CGA 279202	0.2
14-2029-05 Germany	1	T	Fluo-pyram & CGA 279202 SC 500	SPI	7	44	14	0.8	300	Fluopyram CGA 279202	0.2
	2					47	7*			Fluopyram CGA 279202	0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of lettuce. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the sampling schedule presented in the following table. An exception occurred in trial 14-2029-01 where the maximum temperature during transport was -14°C for a period of 3 hours and 5 minutes. This had no impact on the study since the scenario is considered to be covered by storage stability study M-480441-06-1, (wheat green material, 8 hours at +1°C, followed by 7, 19 & 22 days at 7°C).

Table 8.9- 549: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
	Lettuce	Head	C	-0
				7

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
14-2029-01 14-2029-02 14-2029-03 14-2029-04 14-2029-05			T	-0 0 3 7 14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolite fluopyram-benzamide were analysed within the residue trials samples according to the following method:

Table 8.9- 550: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in lettuce head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 551: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	98; 101; 103	101	2.5	0.01
	0.10	98; 103	101	-	
	1.0	111	-	-	
	2.0	97; 112; 116	108	9.2	
	10	78; 79; 95	84	11.4	
		Overall recovery (n = 12)	**99**	**11.8**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as Fluopyram

Table 8.9- 552: Procedural recoveries for fluopyram-benzamide

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	70; 80; 94	81	14.8	0.01
	0.10	87; 106	97	-	
	1.0	101	-	-	
	2.0	96; 108; 108	104	6.7	
	10	79; 84; 87	83	4.8	
		Overall recovery (n = 12)	**92**	**13.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 136 and 285 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries. In trial 14-2029-05, 3 samples (DALT -0, 7, 14) were measured repeatedly. In the table the mean results are reported.

For fluopyram and its metabolite, the residues levels in/on lettuce head are summarised in the following table.

Table 8.9- 553: Residue summary of fluopyram in/on lettuce, head

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide
14-2029-01 Belgium	Head	48	-0	0.33	<0.01
	Head	48	0	2.5	<0.01
	Head	48	3	1.1	<0.01
	Head	49	7	0.58	0.013
	Head	49	14	0.12	<0.01
14-2029-02 Germany	Head	47	-0	0.27	<0.01
	Head	47	0	2.9	0.012

	Head	47	3	1.3	<0.01
	Head	48	7	0.62	0.012
	Head	49	14	0.17	<0.01
14-2029-03 The Netherlands	Head	46	-0	2.0	<0.01
	Head	46	0	10	<0.01
	Head	48	3	2.7	<0.01
	Head	49	7	0.98	<0.01
	Head	49	14	0.13	<0.01
14-2029-04 France	Head	48	-0	1.8	<0.01
	Head	48	0	7.7	0.016
	Head	49	3	3.1	0.011
	Head	49	7	0.21	<0.01
	Head	49	14	0.012	<0.01
14-2029-05 Germany	Head	47	-0	1.1*	<0.01
	Head	47	0	5.7	<0.01
	Head	48	3	1.8	<0.01
	Head	49	7	0.37*	<0.01
	Head	49	14	0.076*	<0.01

DALT = Days after last treatment
* = in trial 14-2029-05, samples of -0, 7 and 14 DALT were measured repeatedly (means of 2, 3 and 2 measurements, respectively).

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on lettuce

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 554: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2029-01 Villers-Perwin, BE,						Redebel (2.5 km), study raw data	sprinkler	Redebel (2.5 km), study raw data
M-534202-01-1	48	30/06/2014	0	2.5	2.5	0		14.7
		01/07/2014	1			0		15.6
lettuce,		02/07/2014	2			0	3	16.4
green material	48	03/07/2014	3	1.1	1.105 a)	0	3	19.5
		04/07/2014	4			0	3	20.5
		05/07/2014	5			10.9		19

		06/07/2014	6			6.3		18.2
	49	07/07/2014	7	0.58	0.593	0		16.6
		08/07/2014	8			8.8		14.3
		09/07/2014	9			23.5		13.3
		10/07/2014	10			0.8		16.6
		11/07/2014	11			1.3		16.1
		12/07/2014	12			0.3		16.1
		13/07/2014	13			1.3		17.3
	49	14/07/2014	14	0.12	0.125 [a]	0		17.8

[a] for FLU-benzamide 0.5 LOD added

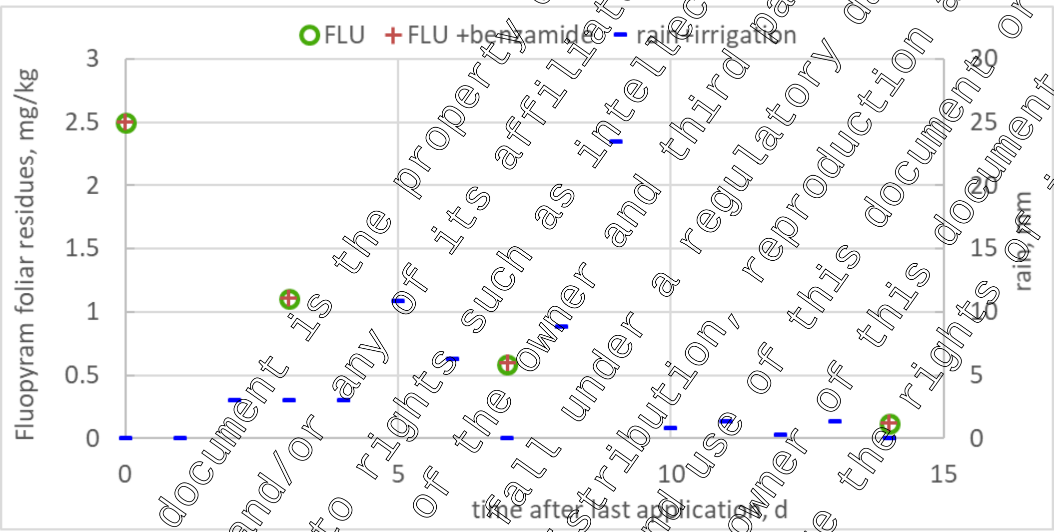


Figure 8.9- 170: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce

Frequent irrigation and rainfall, however no marked influence discernable. Slight influence possible.

Table 8.9- 555: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2029-02 Dannstadt-Schauernheim, DE,						DWD Bad Dürckheim (~10 km) [b]	sprinkler	DWD Bad Dürckheim (~10 km) [b]
M-534202-01-1	47	17/06/2014	0	2.9	2.912	0		17.6
lettuce, green material		18/06/2014	1			0		20.2
		19/06/2014	2			0.1		18.7
	47	20/06/2014	3	1.3	1. [a]	0		16.1
		21/06/2014	4			0	20	16.2
		22/06/2014	5			0		17.8
		23/06/2014	6			0		18
	48	24/06/2014	7	0.62	0.632	0.2		19.5
		25/06/2014	8			0		16.8
		26/06/2014	9			0	20	16.1
		27/06/2014	10			3.2		19.4
		28/06/2014	11			9.2		18.4
		29/06/2014	12			3		16.7
		30/06/2014	13			0.1		17
	49	01/07/2014	14	0.17	0.175 [a]	0		17.8

a) for FLU-benzamide 0.5 LOD added
b) https://opendata.dwd.de/climate_environment/CDC/

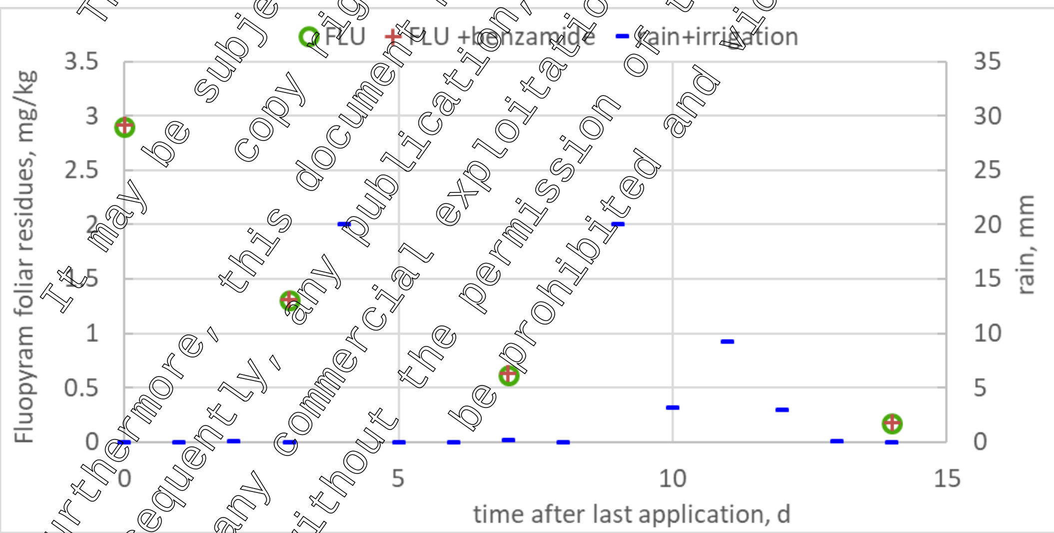


Figure 8.9-171: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce.

Little rainfall until late into the study. Irrigation on days 4 and 9 not associated with discernable change of residue decline. Influence unlikely.

Table 8.9- 556: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2029-03 Zwaagdijk, NL, M-534202-01-1 lettuce, green material						Proeftuin Zwaagdijk (0.1 km), study raw data	no	Proeftuin Zwaagdijk (0.1 km), study raw data
	46	24/06/2014	0	10	FLU-benz	1		14.9
		25/06/2014	1		< LOD	0		15.1
		26/06/2014	2			0		16.1
	48	27/06/2014	3	2.7		1.8		16.4
		28/06/2014	4			0		16.8
		29/06/2014	5			1.4		15.1
		30/06/2014	6			8		13.8
	49	01/07/2014	7	0.98		0		13.5
		02/07/2014	8			0		14.8
		03/07/2014	9			0		18.2
		04/07/2014	10			0		21.1
		05/07/2014	11			1.4		19.2
		06/07/2014	12			7.8		18.7
		07/07/2014	13			0		18
	49	08/07/2014	14	0.13		11		16.1

[a] for FLU-benzamide 0.5 LOD added

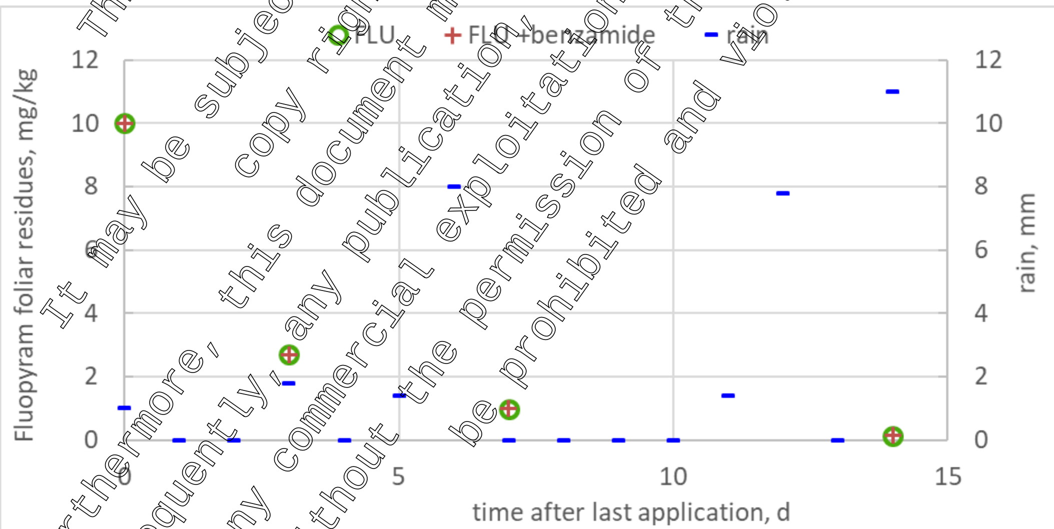


Figure 8.9- 172: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Frequent but little rainfall until day 6 (8 mm). No discernable impact. Slight influence possible.

Table 8.9- 557: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2029-04 Lignières de Touraine, FR,						ProPlant db, Parcay Meslay (26 km)	no	ProPlant db, Parcay Meslay (26 km)
M-534202-01-1	48	20/06/2014	0	7.7	7.716	0		18.6
		21/06/2014	1			0		19.4
lettuce, green material		22/06/2014	2			0		21.8
	49	23/06/2014	3	3.1	3.111	0		18.3
		24/06/2014	4			0		20.5
		25/06/2014	5			0		20.1
		26/06/2014	6			1.4		19
	49	27/06/2014	7	0.21	0.215 [a]	4.8		17.8
		28/06/2014	8			18.4		14.8
		29/06/2014	9			0.2		16.1
		30/06/2014	10			0		16.5
		01/07/2014	11			0		19.9
		02/07/2014	12			0		21.4
		03/07/2014	13			0		24
	49	04/07/2014	14	0.012	0.012	3.6		20.6

[a] for FLU-benzamide 0.5 LOQ added

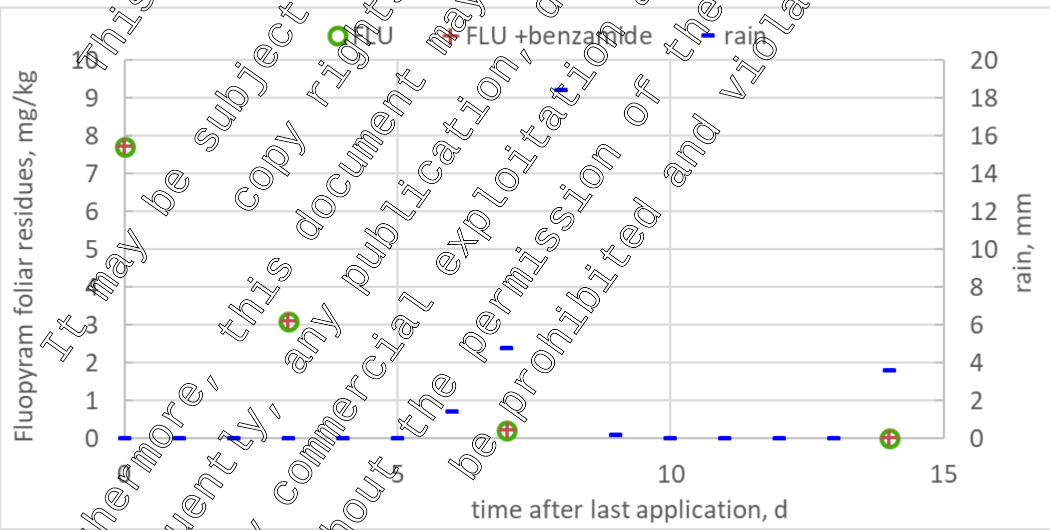


Figure 8.9- 173: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

No rainfall until day 6. No discernible influence.

Table 8.9- 558: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2029-05 Leichlingen, DE,						ProPlant db, Versuchsgut Hoefchen (8.5 km)	no	ProPlant db, Versuchsgut Hoefchen (8.5 km)
M-534202-01-1	47	04/06/2014	0	5.7	FLU-benz	12.6 (3.7) [a]		15.3
		05/06/2014	1		< LOD	1.4		12.4
lettuce, green material		06/06/2014	2			0		17.6
	48	07/06/2014	3	1.8		0		23.2
		08/06/2014	4			0		23.4
		09/06/2014	5			21.7		23.6
		10/06/2014	6			0		22.1
	49	11/06/2014	7	0.37		13.9		18.8
		12/06/2014	8			0		17.2
		13/06/2014	9			0		17.1
		14/06/2014	10			0		15.1
		15/06/2014	11			0		16.2
		16/06/2014	12			0		14
		17/06/2014	13			0		15.2
	49	18/06/2014	14	0.076		0		16.2

[a] 3.7 mm rain within 24 h after application, raining event start 12 h after application

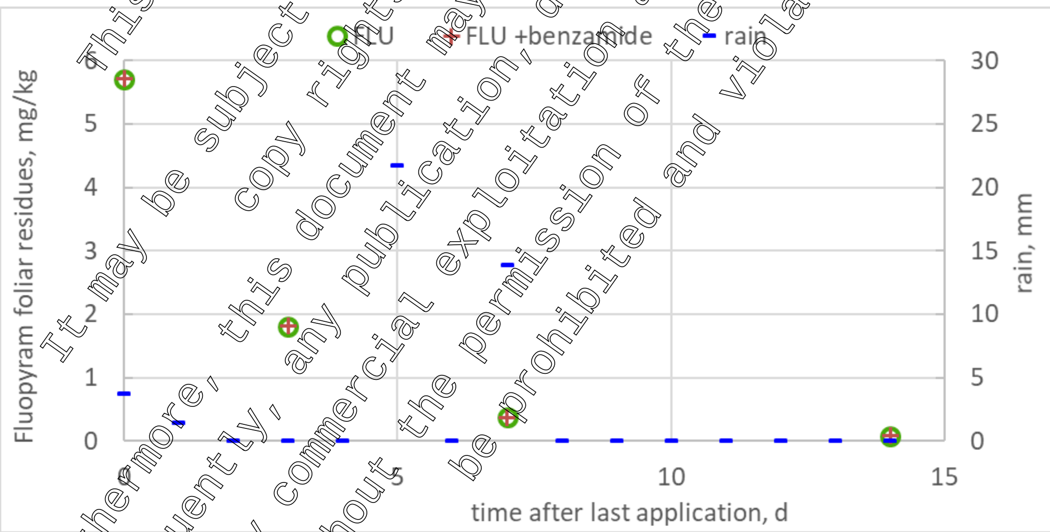


Figure 8.9- 174: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Moderate rainfall on days 0 and 1, and higher amounts on days 5 and 7, may have slightly influenced residue levels, although no impact is discernable.

III. CONCLUSION

After two spray applications of Fluopyram & CGA 279202 SC 500 on lettuce in five residue trials conducted in northern Europe (Belgium, The Netherlands, northern France and 2 x Germany) during the 2014 season, the residues of fluopyram in/on lettuce head declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected in 5 samples with residue values slightly above the LOQ (0.01 mg/kg) with a maximum value of 0.016 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall and/or irrigation may have slightly influenced residue dissipation in 3 of the 5 trials (14-2029-01, 14-2029-03, 14-2029-04) whilst an influence in 14-2029-02 and 14-2029-04 is not visible.

However, rain is a natural and irrigation a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/39
Report Author:	[redacted]
Report Year:	2015
Report Title:	Determination of the residues of fluopyram and trifloxystrobin in/on lettuce after spray application of fluopyram & trifloxystrobin SC 500 in Spain, Italy, southern France and Greece
Report No:	14-2030
Document No:	M-534595-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with five residue trials was conducted in the field in southern Europe (Spain, southern France, Greece and 2 x Italy) on lettuce during the 2014 season. Two applications with Fluopyram & CGA 279202 SC 500, containing 250 g/L fluopyram and 250 g/L trifloxystrobin (CGA 279202) were conducted. Only the parameters and results relevant to fluopyram and its metabolite fluopyram-benzamide have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram & CGA 279202 SC 500 on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected slightly above the LOQ in almost all samples with a maximum value of 0.024 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram & CGA 279202 SC 500 (250+250 g/L)
	Batch no.:	EV57001784
	Active Ingredient:	Fluopyram and trifloxystrobin
	Storage:	Not stated in the report
	Expiry date:	2016-02-17
2.	Test commodity:	Lettuce
	Crop part:	Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 14-2030 was to determine the magnitude of the relevant residues of fluopyram and its metabolite fluopyram-benzamide in/on lettuce (head) after two spray applications with Fluopyram & CGA 279202 SC 500 (250 g/L + 250 g/L), a suspension concentrate formulation containing 250 g/L fluopyram. This summary focuses only on the residues of fluopyram and its metabolite fluopyram-benzamide.

<u>Field phase</u>

The study included five supervised residue trials conducted in southern Europe (Spain, southern France, Greece and 2 x Italy) during the 2014 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 559: Description of the trial locations and cropping information on treated plots

Trial number	14-2030-01	14-2030-02	14-2030-03	14-2030-04	14-2030-05
Trial location	46230 Alginet	95100 C.da Pigno; Catania (CT)	13103 St Etienne du gres	GR-60100 Aronas – Katerini – Pieria	93012 Gela (CL); C.da Mignechi
Country	Spain	Italy	France	Greece	Italy
Area of application	Field	Field	Field	Field	Field
Plot size [m²]	67.5	56	50	55	90
Type of soil	Sandy Loam	Sandy Loam	Clayey sand	Sandy Loam	Loamy sand
pH-value of soil (in water)	8.0	7.8	8.3	7.1	8.1
Content of organic C [%]	1.1	1.0	0.6	0.7	0.5
Test system	Lettuce (open leaf variety)	Lettuce (open leaf variety)	Lettuce (open leaf variety)	Lettuce (open leaf variety)	Lettuce (open leaf variety)
Variety	Paladio (oak leaf variety)	Nauplus – Canasta (Batavia)	Kiribati (oak leaf variety)	Manchester (loose leaf variety)	Nauplus – Canasta (Batavia)
Date of planting	2014-04-15	2014-05-16	2014-03-24	2014-09-21	2014-09-23
Date of commercial harvest	2014-05-25 to 2014-06-15	2014-06-22 to 2014-07-12	2014-05-19 to 2014-06-02	2014-11-14 to 2014-12-19	2014-11-05 to 2014-11-20

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stages between 45-48 and the second between 46-49 with an application rate of 0.2 kg a.s./ha and a water rate of 600-750 L/ha.

Table 8.9- 560: Overview on application with Fluopyram & CGA 279202 SC 500 on lettuce

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
14-2030-01 Spain	1	T	Fluopyram & CGA 279202 SC 500	SPI	7	48	14	0.8	750	Fluopyram CGA 279202	0.2
	2					49	7*			Fluopyram CGA 279202	0.2
14-2030-02 Italy	1	T	Fluopyram & CGA 279202 SC 500	SPI	7	46	14	0.8	600	Fluopyram CGA 279202	0.2
	2					48	7*			Fluopyram CGA 279202	0.2
14-2030-03 France	1	T	Fluopyram & CGA 279202 SC 500	SPI	7	48	14	0.8	600	Fluopyram CGA 279202	0.2
	2					49	7*			Fluopyram CGA 279202	0.2
14-2030-04 Greece	1	T	Fluopyram & CGA 279202 SC 500	SPI	7	45	14	0.8	600	Fluopyram CGA 279202	0.2
	2					46	7*			Fluopyram CGA 279202	0.2
14-2030-05 Italy	1	T	Fluopyram & CGA 279202 SC 500	SPI	7	45	14	0.8	600	Fluopyram CGA 279202	0.2
	2					46	7*			Fluopyram CGA 279202	0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of lettuce. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 561: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
14-2030-01 14-2030-02 14-2030-03 14-2030-04 14-2030-05	Lettuce	Head	C	-0
				7
			T	-0
				0
				3
				7
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolite fluopyram-benzamide were analysed within the residue trials samples according to the following method:

Table 8.9- 562: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in lettuce head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 563: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce, head	0.01	108; 115	112	-	0.01
	0.10	91	-	-	
	1.0	91	-	-	
	10	73	-	-	
		Overall recovery (n = 5)	**96**	**17.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with fluopyram, determined as fluopyram and calculated as fluopyram

Table 8.9- 564: Procedural recoveries for fluopyram-benzamide

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	103; 113	108		0.01
	0.10	96	-	-	
	1.0	98	-	-	
	10	84	-	-	
		Overall recovery (n = 5)	**99**	**10.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as Fluopyram

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 121 and 318 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolite, the residues levels in/on lettuce head are summarised in the following table.

Table 8.9- 565: Residue summary of fluopyram in/on lettuce, head

Trial No. Country	Sample material	BBCH	DALT	Residues [mg/kg] a.s. fluopyram	Residues [mg/kg] fluopyram-benzamide
14-2030-01	Head	49	-0	0.66	<0.01

Spain	Head	49	0	2.0	0.012
	Head	49	3	1.3	0.012
	Head	49	7	0.74	0.010
	Head	49	14	0.25	0.010
14-2030-02 Italy	Head	48	-0	1.4	0.010
	Head	48	0	3.9	0.011
	Head	49	3	3.0	0.015
	Head	49	7	1.5	0.016
	Head	49	14	0.67	<0.01
14-2030-03 France	Head	49	-0	0.53	0.010
	Head	49	0	2.7	0.018
	Head	49	3	1.3	0.022
	Head	49	7	0.60	0.021
	Head	49	14	0.34	0.024
14-2030-04 Greece	Head	46	-0	0.42	<0.01
	Head	46	0	4.7	0.012
	Head	47	3	0.53	<0.01
	Head	49	7	0.55	0.012
	Head	49	14	0.33	<0.01
14-2030-05 Italy	Head	46	-0	0.38	<0.01
	Head	46	0	4.3	0.021
	Head	46	3	3.3	0.013
	Head	48	7	0.71	0.011
	Head	49	14	0.23	0.010

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on lettuce

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 566: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2030-01 Alginet, ES,						Benifaio (5 km), study raw data	drip	Benifaio (5 km), study raw data

M-534595-01-1 lettuce, green material	49	27/05/2014	0	2	2.012	0.1 (0) [a]		18.22
		28/05/2014	1			0.1		19.64
		29/05/2014	2			0.2		19.32
	49	30/05/2014	3	1.3	1.312	0		19.34
		31/05/2014	4			0.1		17.16
		01/06/2014	5			0		18.75
		02/06/2014	6			0		19.79
	49	03/06/2014	7	0.74	0.75	0		20.56
		04/06/2014	8			0		23.23
		05/06/2014	9			0		20.67
		06/06/2014	10			0		20.66
		07/06/2014	11			0		22.34
		08/06/2014	12			0		22.14
		09/06/2014	13			0		22.14
	49	10/06/2014	14	0.25	0.26	0		21.97
[a] no rain 24 h after application								

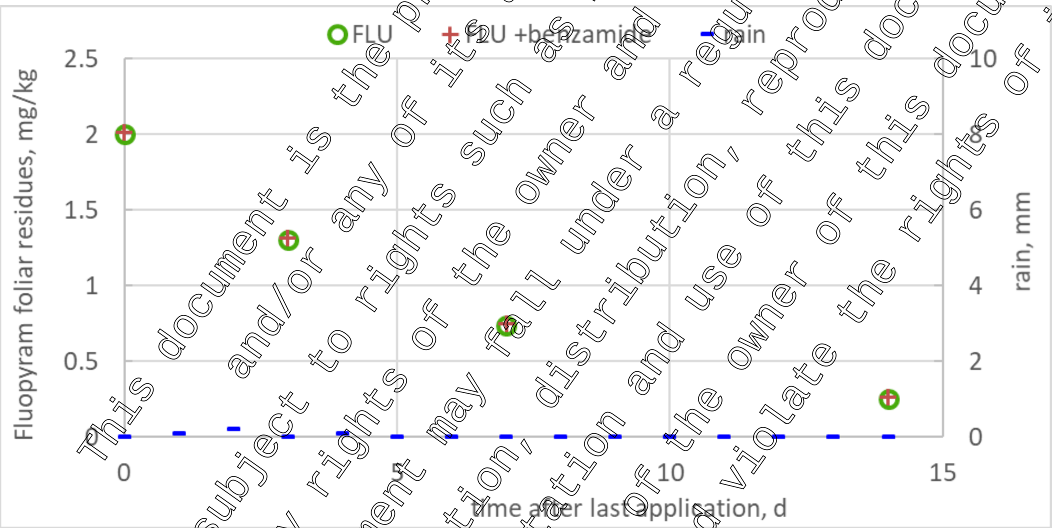


Figure 8.9- 175: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce

There was virtually no rain and no influence on residue decline.

Table 8.9- 567: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2030-02 C.da Pigno, Catania, IT, M-534595-01-1 lettuce, green material						www.ilmeteo.it Catania	drip	www.ilmeteo.it Catania
	48	24/06/2014	0	3.9	3.911	0		28
		25/06/2014	1			0		29
		26/06/2014	2			0		24
	49	27/06/2014	3	3	3.015	0		24
		28/06/2014	4			0		23
		29/06/2014	5			0		24
		30/06/2014	6			0		26
	49	01/07/2014	7	1.5	1.516	0		23
		02/07/2014	8			0		23
		03/07/2014	9			0		25
		04/07/2014	10			0		24
		05/07/2014	11			0		26
		06/07/2014	12			0		24
		07/07/2014	13			0		24
	49	08/07/2014	14	0.67	0.675 [a]	0		25

[a] for FLU-benzamide 0.5 LOD added

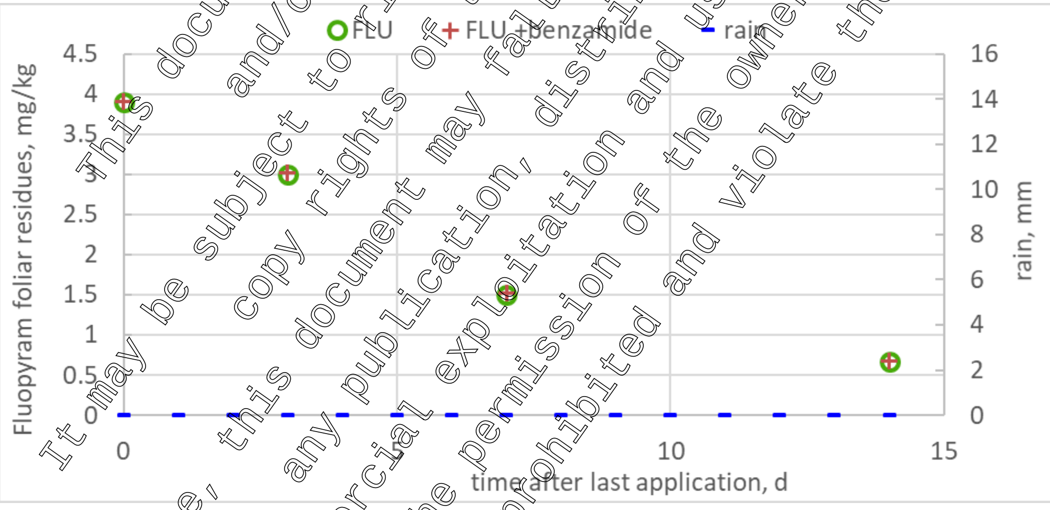


Figure 8.9- 176: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce.

There was no rain and no influence on residue dissipation.

Table 8.9- 568: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2030-03 St Etienne du gres, FR,						St. Etienne du Gres, Bayer (0.1 km)	sprinkler	St. Etienne du Gres, Bayer (0.1 km)
M-534595-01-1	49	19/05/2014	0	2.7	2.718	1.6 (0) [a]		16.5
		20/05/2014	1			0	3.5	19.9
lettuce,		21/05/2014	2			1.6	3.5	22.3
green material	49	22/05/2014	3	1.3	1.322	1.2	3.5	19.4
		23/05/2014	4			10	3.5	16.7
		24/05/2014	5			0.2	3.5	14.7
		25/05/2014	6			0	3.5	15.7
	49	26/05/2014	7	0.6	0.621	0	3.5	15.2
		27/05/2014	8			0.2	3.5	16.5
		28/05/2014	9			0	3.5	16.6
		29/05/2014	10			0	3.5	19.1
		30/05/2014	11			0.4	3.5	19.9
		31/05/2014	12			0	3.5	20.4
		01/06/2014	13			0	3.5	20.3
	49	02/06/2014	14	0.34	0.364	0.2		20.2

[a] no rain 24 h after application

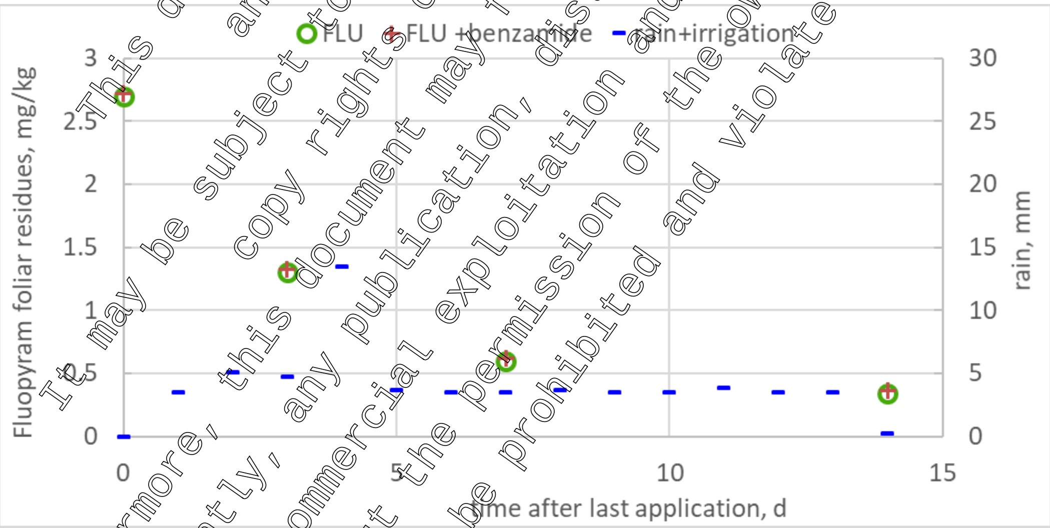


Figure 8.9- 177: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Frequent rainfall and regular sprinkler irrigation. Marked influence not discernible but slight impact likely.

Table 8.9- 569: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2030-04 Aronas - Katerini - Pieria, GR, M-534595-01-1 lettuce, green material						MARS grid 58152 (25×25 km)	drip	MARS grid 58152 (25×25 km)
	46	17/11/2014	0	4.7	4.712	0		15.1
		18/11/2014	1			0		14.1
		19/11/2014	2			9		14.6
	47	20/11/2014	3	0.53	0.535 [a)]	0		13.7
		21/11/2014	4			0		11.5
		22/11/2014	5			0		8.7
		23/11/2014	6			0		7.1
	49	24/11/2014	7	0.55	0.562	0.7		7.2
		25/11/2014	8			0.2		8.6
		26/11/2014	9			0.6		7.4
		27/11/2014	10			3		7.2
		28/11/2014	11			1		9.1
		29/11/2014	12			2		11.3
		30/11/2014	13			0.9		11.9
	49	01/12/2014	14	0.33	0.335 [a)]	0.2		12.4

[a)] for FLU-benzamide 0.5 LOD added

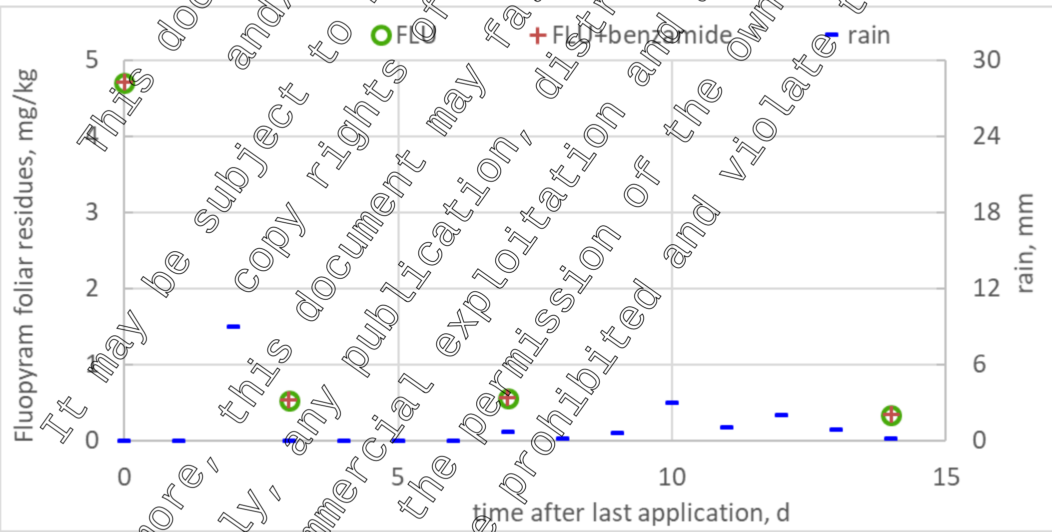


Figure 8.9- 178: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Rainfall on day 2 (9 mm) coincides with marked drop of residue levels. Influence likely

Table 8.9- 570: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2030-05 C.da Mignechi, IT,						MARS grid 41125 (25×25 km)	drip	MARS grid 41125 (25×25 km)
M-534595-01-1	46	31/10/2014	0	4.3	4.321	0 [a]		16.7
		01/11/2014	1			0		16.1
lettuce, green material		02/11/2014	2			0		17
	46	03/11/2014	3	3.3	3.313	0.2		18.1
		04/11/2014	4			17		18.4
		05/11/2014	5			0		20.8
		06/11/2014	6			25		20.6
	48	07/11/2014	7	0.71	0.721	10 (7) [b]		17.1
		08/11/2014	8			0		17.3
		09/11/2014	9			0		17.1
		10/11/2014	10			0		17
		11/11/2014	11			0		18.5
		12/11/2014	12			0.6		17.8
		13/11/2014	13			4		17.3
	49	14/11/2014	14	0.23	0.24	0		17.2

[a] no rain 24 h after application, in study report
[b] 7 mm rain from study report was used

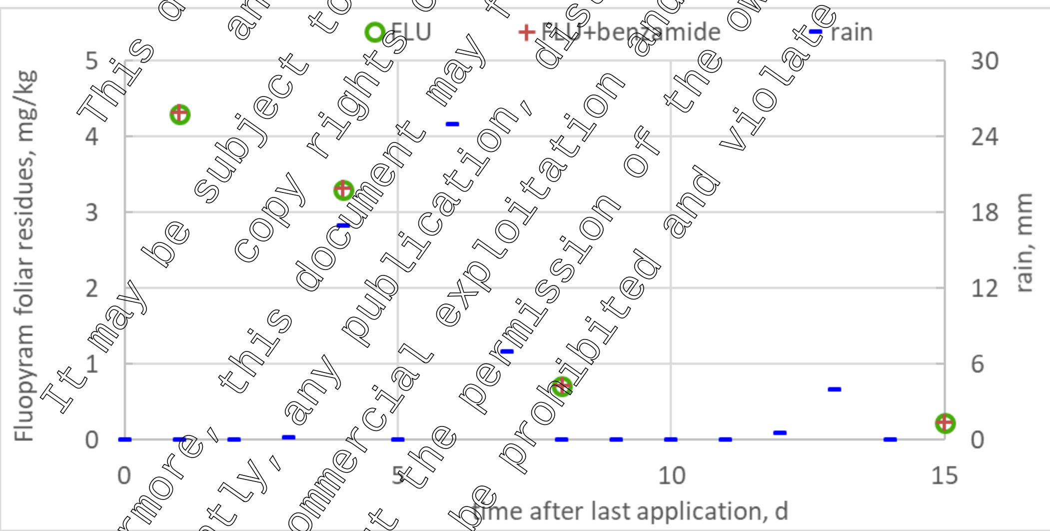


Figure 8.9- 179: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Rainfall on days 4 (17 mm) and day 6 coincides with drop in residue levels. Marked influence likely.

III. CONCLUSION

After two spray applications of Fluopyram & CGA 279202 SC 500 on lettuce in five residue trials conducted in southern Europe (Spain, southern France, Greece and Italy) during the 2014 season, the residues of fluopyram in/on lettuce head declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected slightly above the LOQ of 0.01 mg/kg in almost all samples, with a maximum value of 0.024 mg/kg.

<u>Assessment and conclusion by applicant</u>:

The study and its data are considered as acceptable and reliable for use in risk assessment. Two trials were virtually without rain (14-2030-01, 14-2030-02). A slight influence of rain and irrigation is likely for 14-2030-03, and a marked influence is likely for trials 14-2030-04 and 14-2030-05.

However, rain is a natural and irrigation a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/40
Report Author:	[redacted]
Report Year:	2015
Report Title:	Determination of the residues of fluopyram and trifloxystrobin in/on lettuce after spray application of fluopyram & trifloxystrobin SC 500 in Germany, the Netherlands, Hungary and the United Kingdom
Report No:	14-2184
Document No:	M-536965-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market; OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009); US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in northern Europe (Germany, The Netherlands, Hungary and the United Kingdom) on lettuce during the 2014 season. Two applications with Fluopyram & CGA 279202 SC 500, containing 250 g/L fluopyram and 250 g/L trifloxystrobin (CGA 279202), were conducted. Only the parameters and results relevant to fluopyram and its metabolite fluopyram-benzamide have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram & CGA 279202 SC 500 on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected above the LOQ of 0.01 mg/kg in one sample (0.011 mg/kg).

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram & CGA 279202 SC 500 (250 +250 g/L)

   Batch no.: EV57001784

   Active Ingredient: Fluopyram and trifloxystrobin

   Storage: Not stated in the report

   Expiry date: 2016-02-17

2. Test commodity: Lettuce

   Crop part: head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 14-2184 was to determine the magnitude of the relevant residues of fluopyram and its metabolite fluopyram-benzamide in/on lettuce (head) after two spray applications with Fluopyram & CGA 279202 SC 500 (250 g/L + 250 g/L), a suspension concentrate formulation containing 250 g/L fluopyram. This summary focuses only on the residues of fluopyram and its metabolite fluopyram-benzamide.

<u>Field phase</u>

The study included four supervised residue trials conducted in northern Europe (Germany, The Netherlands, Hungary and the United Kingdom) during the 2014 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 571: Description of the trial locations and cropping information on treated plots

Trial number	14-2184-01	14-2184-02	14-2184-03	14-2184-04
Trial location	16816 Neuruppin	9414 VL Hooghalen	4461 Ferenctanya	Banbury, OX15 6EP
Country	Germany	The Netherlands	Hungary	The United Kingdom
Area of application	Field	Field	Field	Field
Plot size [m^2]	42	42	45	60
Type of soil	Loamy sand	Loamy sand	Loam	Sandy Loam
pH-value of soil (in water)	7.1	5.9	7.2	6.7
Content of organic C [%]	2.1	4.01	1.33	2.97
Test system	Lettuce	Lettuce	Lettuce	Lettuce
Variety	Lollo Rosso (open leaf variety)	Smile (open leaf variety)	Linaro RZ (open leaf variety)	Anaconda (open leaf variety)
Date of planting	2014-08-30	2014-07-10	2014-06-25	2014-04-29
Date of commercial harvest	2014-10-10 to 2014-10-25	2014-08-25 to 2014-09-08	2014-07-22 to 2014-07-29	2014-07-10 to 2014-07-20

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. The first application was performed at BBCH stages between 41-43 and the second between 41-49 with an application rate of 0.2 kg a.s./ha and a water rate of 350-500 L/ha.

Table 8.9- 572: Overview on application with Fluopyram & CGA 279202 SC 500 on lettuce

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
14-2184-01 Germany	1	T	Fluo-pyram & CGA 279202 SC 500	SPI	9	41	17	0.8	500	Fluopyram CGA 279202	0.2
	2					41	8*			Fluopyram CGA 279202	0.2
14-2184-02 The Nether-lands	1	T	Fluo-pyram & CGA 279202	SPI	7	48	14	0.8	400	Fluopyram CGA 279202	0.2
	2					49	7*			Fluopyram CGA 279202	0.2
14-2184-03 Hungary	1	T	Fluo-pyram & CGA 279202	SPI	7	43	14	0.8	500	Fluopyram CGA 279202	0.2
	2					47	7*			Fluopyram CGA 279202	0.2
14-2184-04 The United Kingdom	1	T	Fluo-pyram & CGA 279202	SPI	8	45	15	0.8	350	Fluopyram CGA 279202	0.2
	2					46	7*			Fluopyram CGA 279202	0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of lettuce. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule. A deviation occurred while shipment of the samples of the trials 14-2184-01 and 14-2184-02 when the temperature was above -18°C for a short period. This had no impact on the study.

Table 8.9- 573: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
14-2184-01 14-2184-02 14-2184-03 14-2184-04	Lettuce	Head	C	-0
				7
			T	-0
				0
				3
				7
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolite fluopyram-benzamide were analysed within the residue trials samples according to the following method:

Table 8.9- 574: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in lettuce head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 575: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	105; 112	109	-	0.01
	2.0	98; 100; 102	100	2.0	
	10	103; 104	104	-	
		Overall recovery (n = 7)	**103**	**4.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram

Table 8.9- 576: Procedural recoveries for fluopyram-benzamide

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	93; 94	94	-	0.01
	2.0	96; 98; 102	99	3.1	
	10	113	-	-	
		Overall recovery (n = 6)	**99**	**7.5**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as Fluopyram

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 150 and 264 days. A deviation occurred while storage of the samples 14-2184-03 and 14-2184-04 when the temperature was above -18°C for a short period. This had no impact on the study since the scenario is considered to be covered by storage stability study Lakaschus, S.; Gizler, A.; 2017; M-480441-06-1, (wheat green material, 8 hours at +1°C, followed by 7, 19 & 22 days at 7°C).

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolite, the residues levels in/on lettuce head are summarised in the following table. In trial 14-2184-01 the treated samples at -0 and 0 DALT were most probably inverted at sampling during the field phase. The samples were measured three times and the mean values are reported.

Table 8.9- 577: Residue summary of fluopyram in/on lettuce, head

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide
14-2184-01 Germany	Head	42	-0	1.5	<0.01
	Head	42	0	0.66	<0.01
	Head	42	3	0.22	<0.01
	Head	42	8	0.048	<0.01
	Head	43	15	0.043	<0.01
14-2184-02 The Netherlands	Head	49	-0	0.30	<0.01
	Head	49	0	3.5	0.011
	Head	49	3	2.9	<0.01
	Head	49	7	0.84	<0.01
	Head	49	14	0.56	<0.01
14-2184-03 Hungary	Head	47	-0	0.043	<0.01
	Head	47	0	6.0	<0.01
	Head	47	3	3.0	<0.01
	Head	49	7	0.26	<0.01
	Head	49	13	0.057	<0.01
14-2184-04 The United Kingdom	Head	46	-0	0.10	<0.01
	Head	46	0	2.6	<0.01
	Head	48	3	0.71	<0.01
	Head	49	7	0.11	<0.01
	Head	49	16	0.012	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on lettuce

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 578: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2184-01 Neuruppin, DE,						DWD Neuruppin [c] (5 km)	no	DWD Neuruppin [c] (5 km)
M-536965-01-1	42	10/10/2014	0	1.5 [b]	FLU-benz	0.6 (0) [a]		14.6
		11/10/2014	1		< LOD	3.8		13.7
lettuce, green material		12/10/2014	2			0.5		13.1
	42	13/10/2014	3	0.22		0.2		14.2
		14/10/2014	4			0		13.6
		15/10/2014	5			0		11.7
		16/10/2014	6			0.4		11.5
		17/10/2014	7			0		12.9
	42	18/10/2014	8	0.048		0		13.1
		19/10/2014	9			2.6		15.6
		20/10/2014	10			6.2		13.4
		21/10/2014	11			5.7		12.2
		22/10/2014	12			7.5		9.8
		23/10/2014	13			0		11.1
		24/10/2014	14			0		9
	43	25/10/2014	15	0.043		0.4		7.7

[a] no rain 24 h after application, in study report
[b] FLU residues in study report: -0 DALT 1.5 mg/kg, +0 DALT 0.66 mg/kg. Assumed here that data were most likely be inverted.
[c] https://opendata.dwd.de/climate_environment/CDC/

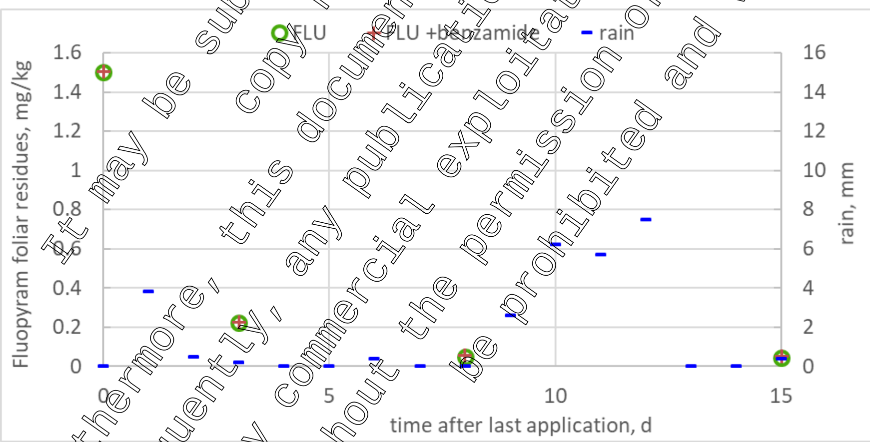


Figure 8.9- 180: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce

Rainfall on day 1 (3.8 mm), day 2 (0.5 mm) and day 3 (0.2 mm) coincide with a marked drop of residue levels. Influence likely.

Table 8.9- 579: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2184-02 Hooghalen, NL,						KMNI Hoogeven (25 km) [c]	no	KMNI Hoogeven (25 km) [c]
M-536965-01-1	49	25/08/2014	0	3.5	3.511	0 (1) [b]		12.4
		26/08/2014	1			0		13.6
lettuce, green material		27/08/2014	2			0		13.9
	49	28/08/2014	3	2.9	2.905 [a]	0		16.8
		29/08/2014	4			0		17.2
		30/08/2014	5			0.6		16.2
		31/08/2014	6			2.3		14.3
	49	01/09/2014	7	0.84	0.84	0		14.8
		02/09/2014	8			0		15.1
		03/09/2014	9			0		15
		04/09/2014	10			0		17.1
		05/09/2014	11			0		18.4
		06/09/2014	12			0.1		17.6
		07/09/2014	13			0		16.4
	49	08/09/2014	14	0.56	0.56	0		14.3

a) for FLU-benzamide 0.5 LOD added
b) 1 mm rain within 24 h after application, raining event start > 6 h after application, in study report
c) http://projects.knmi.nl/klimatologie/daggegevens/selectie.cgi

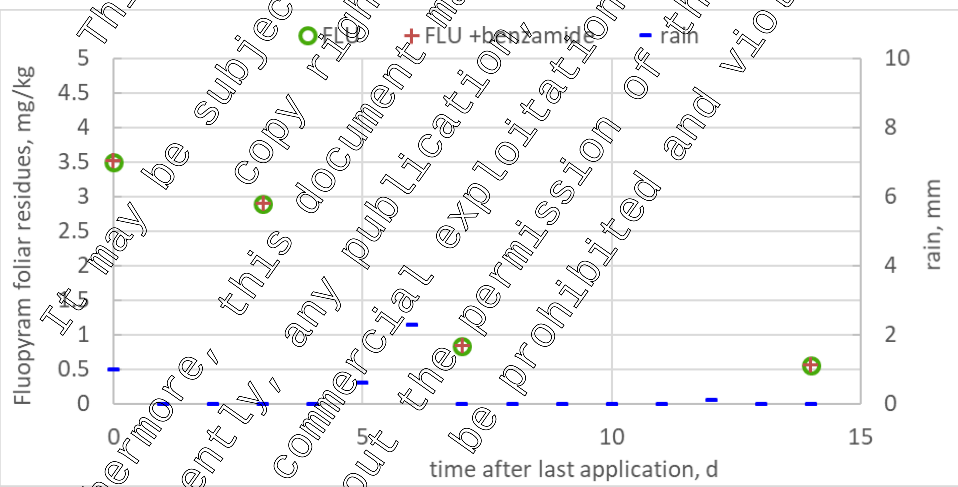


Figure 8.9- 181: Plot of the fluopyram (fluopyram) residues decline with corresponding rainfall, in the days following treatment to lettuce.

Rainfall on day 5 (0.6 mm) and day (2.3 mm) coincide with a slight drop in residue levels. Influence possible.

Table 8.9- 580: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2184-03 Nyiregyhaza, HU,						Nyiregyhaza (15 km), study raw data	sprinkler	Nyiregyhaza (15 km), study raw data
M-536965-01-1	47	15/07/2014	0	6	FLU-benz	0.2 (0) [a]		23.4
		16/07/2014	1		< LOD	0		25.6
lettuce, green material		17/07/2014	2			1.9		23.6
	47	18/07/2014	3	3		0		25.2
		19/07/2014	4			0		25.6
		20/07/2014	5			0	8	25.3
		21/07/2014	6			0		16
	49	22/07/2014	7	0.26		1.1		21.3
		23/07/2014	8			8.2		18.8
		24/07/2014	9			12.8		22.3
		25/07/2014	10			0		23.6
		26/07/2014	11			0	4	24.6
		27/07/2014	12			0		24.8
	49	28/07/2014	13	0.057		0		23.9

[a] no rain 24 h after application, in study report

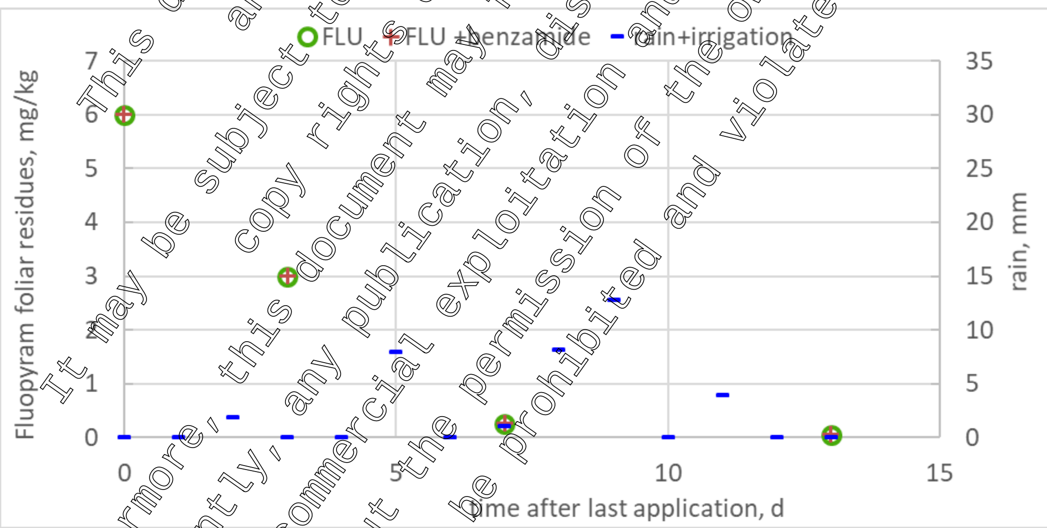


Figure 8.9- 182: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Irrigation on day 5 coincides with a slight drop in residue levels. Influence possible.

Table 8.9- 581: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2184-04 Banbury, GB,						Alkerton (125 m), study raw data	no	Alkerton (125 km), study raw data
M-536965-01-1	46	03/07/2014	0	2.6	FLU-benz	0		17.4
		04/07/2014	1		< LOD	2.8		16.7
lettuce, green material		05/07/2014	2			6.9		15.6
	48	06/07/2014	3	0.71		1.5		13.7
		07/07/2014	4			3.3		13.7
		08/07/2014	5			0.3		14
		09/07/2014	6			0		15.4
	49	10/07/2014	7	0.11		0		17.2
		11/07/2014	8			0		16.2
		12/07/2014	9			0		18.9
		13/07/2014	10			1.3		16.7
		14/07/2014	11			0.3		16.1
		15/07/2014	12			0.8		17.6
		16/07/2014	13			0.3		18
		17/07/2014	14			0		19.6
		18/07/2014	15			6.3		21.2
	49	19/07/2014	16	0.012		21.8		18.9

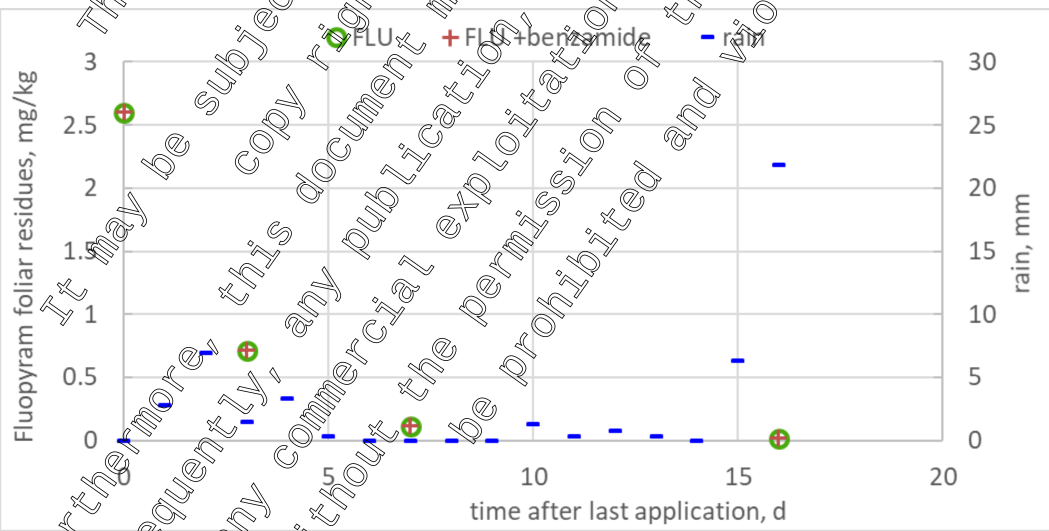


Figure 8.9- 183: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Frequent early rainfall may have markedly influenced residue levels.

III. CONCLUSION

After two spray applications of Fluopyram & CGA 279202 SC 500 on lettuce in four residue trials conducted in northern Europe (Germany, The Netherlands, Hungary and the United Kingdom) during the 2014 season the residues of fluopyram in/on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected above the LOQ of 0.01 mg/kg only in one sample (0.011 mg/kg).

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall and/or irrigation may have influenced residue decline markedly in trials 14-2184-01 and 14-2184-04, but only slightly in trials 14-2184-02 and 14-2184-03.

However, rain is a natural and irrigation a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/41
Report Author:	[redacted]
Report Year:	2015
Report Title:	Determination of the residues of fluopyram and trifloxystrobin in/on lettuce after spray application of fluopyram & trifloxystrobin SC 500 in Italy, Spain and Greece
Report No:	14-2185
Document No:	M-536963-01-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market; OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009); US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in southern Europe (Italy, 2 x Spain and Greece) on lettuce during the 2014 season. Two applications with Fluopyram & CGA 279202 SC 500, containing 250 g/L fluopyram and 250 g/L trifloxystrobin (CGA 279202), were conducted. Only the parameters and results relevant to fluopyram and its metabolite fluopyram-benzamide have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram & CGA 279202 SC 500 on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected slightly above the LOQ in 9 samples with a maximum value of 0.020 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram & CGA 279202 SC 500 (250 +250 g/L)
	Batch no.:	EV57001784
	Active Ingredient:	Fluopyram and trifloxystrobin
	Storage:	Not stated in the report
	Expiry date:	2016-02-17
2.	Test commodity:	Lettuce
	Crop part:	Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 14-2185 was to determine the magnitude of the relevant residues of fluopyram and its metabolite fluopyram-benzamide in/on lettuce (head) after two spray applications with Fluopyram & CGA 279202 SC 500 (250 g/L + 250 g/L)", a suspension concentrate formulation containing 250 g/L fluopyram. This summary focuses only on the residues of fluopyram and its metabolite fluopyram-benzamide.

Field phase

The study included four supervised residue trials conducted in southern Europe (Italy, 2 x Spain and Greece) during the 2014 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 582: Description of the trial locations and cropping information on treated plots

Trial number	14-2185-01	14-2185-02	14-2185-03	14-2185-04
Trial location	20060 Mediglia	14400 Pozoblanco Cordoba	18128 Zafarraya	57008 Nea Magnisia
Country	Italy	Spain	Spain	Greece
Area of application	Field	Field	Field	Field
Plot size [m^2]	40.5	42	42	75
Type of soil	Sandy Loam	Sandy Clay Loam	Silty Clay Loam	Sandy Loam
pH-value of soil (in water)	7.0	7.7	7.9	8.1
Content of organic C [%]	0.9	1.7	1.1	1.0
Test system	Lettuce (open leaf variety)	Lettuce (open leaf variety)	Lettuce (open leaf variety)	Lettuce (open leaf variety)
Variety	Gentilina	Aitana	Isasa Romana	Manchester F1
Date of planting	2014-05-05	2014-09-15	2014-04-12	2014-05-16
Date of commercial harvest	2014-06-10 to 2014-06-17	2014-10-27 to 2014-11-03	2014-05-19 to 2014-05-26	2014-06-20 to 2014-06-30

The actual application data are presented in the following table. This data reflects the intended application scheme except for the initial application in trial 14-2185-02, where the application rate was overdosed by 6.6%. This was within the acceptable range and has therefore no negative impact on the study. The first application was performed at BBCH stages between 37-44 and the second between 43-47 with an application rate of 0.2-0.213 kg a.s./ha and a water rate of 350-533 L/ha.

Table 8.9- 583: Overview on application with Fluopyram & CGA 279202 SC 500 on lettuce

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
14-2185-01 Italy	1	T	Fluopyram & CGA 279202 SC 500	SPI	7	44	17	0.8	500	Fluopyram CGA 279202	0.2
	2					47	7*			Fluopyram CGA 279202	0.2
14-2185-02 Spain	1	T	Fluopyram & CGA 279202 SC 500	SPI	7	43	14	0.853	533	Fluopyram CGA 279202	0.213
	2					46	7*	0.8	500	Fluopyram CGA 279202	0.213
14-2185-03 Spain	1	T	Fluopyram & CGA 279202 SC 500	SPI	7	37	14	0.8	500	Fluopyram CGA 279202	0.2
	2					43	7*			Fluopyram CGA 279202	0.2
14-2185-04 Greece	1	T	Fluopyram & CGA 279202 SC 500	SPI	7	44	15	0.8	800	Fluopyram CGA 279202	0.2
	2					45	7*			Fluopyram CGA 279202	0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of lettuce. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule presented in the following table. An exception occurred in trials 14-2185-01, -02 and -03 where the maximum temperature during transport was above -18°C for a short period in each trial. This had no impact on the study since the scenario is considered to be covered by storage stability study M-480441-06-1, (wheat green material, 8 hours at +1°C, followed by 7, 19 & 22 days at 7°C).

Table 8.9- 584: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
14-2185-01 14-2185-02 14-2185-03 14-2185-04	Lettuce	Head	C	-0
				7
			T	-0
				0
				3
				7
				14

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolite fluopyram-benzamide were analysed within the residue trials samples according to the following method:

Table 8.9- 585: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in lettuce head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 586: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce, head	0.01	99; 100	100	-	0.01
	0.10	97	-	-	
	10	99	-	-	
		Overall recovery (n = 4)	**99**	**1.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 587: Procedural recoveries for fluopyram-benzamide

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Lettuce / head	0.01	92; 100	96	-	0.01
	0.10	95	-	-	
	10	101	-	-	
		Overall recovery (n = 4)	**97**	**4.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 157 and 332 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolite, the residues levels in/on lettuce head are summarised in the following table.

Table 8.9- 588: Residue summary of fluopyram in/on lettuce, head

Trial No. Country	Sample material	BBCH	DALT	Residues [mg/kg] a.s. fluopyram	Residues [mg/kg] fluopyram-benzamide
14-2185-01 Germany	Head	47	-0	0.22	<0.01
	Head	47	0	3.7	0.011
	Head	48	3	0.50	<0.01
	Head	49	7	0.14	<0.01
	Head	49	14	0.020	<0.01
14-2185-02 The Netherlands	Head	46	-0	0.049	<0.01
	Head	46	0	3.1	<0.01
	Head	47	3	2.2	<0.01
	Head	49	7	1.2	<0.01
	Head	49	14	0.062	<0.01
14-2185-03 Hungary	Head	43	-0	1.7	0.010
	Head	43	0	5.4	0.017
	Head	46	3	3.4	0.012
	Head	49	7	2.2	0.013
	Head	49	14	0.47	0.011
14-2185-04 The United Kingdom	Head	45	-0	0.16	<0.01
	Head	45	0	4.1	0.014
	Head	45	3	1.7	0.014
	Head	47	7	0.57	0.020
	Head	49	14	0.093	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on lettuce

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 589: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2185-01 Mediglia, IT,						Rodano (5 km), study raw data	mist	Rodano (5 km), study raw data
M-536963-01-1	47	03/06/2014	0	3.7	3.711	0		20.5
		04/06/2014	1			5.8		19
lettuce, green material		05/06/2014	2			0.2	3	20.4
	48	06/06/2014	3	0.5	0.505 [a]	0		22
		07/06/2014	4			0	3	23.6
		08/06/2014	5			0		25.9
		09/06/2014	6			0	3	28.1
	49	10/06/2014	7	0.14	0.14	0		28.3
		11/06/2014	8			0		27.7
		12/06/2014	9			0	3	28.4
		13/06/2014	10			9.6		25.7
		14/06/2014	11			47.6		22.8
		15/06/2014	12			2.4		20.5
		16/06/2014	13			1.4		21.5
	49	17/06/2014	14	0.02	0.02	1		19.7

[a] for FLU-benzamide 0.5 LOD added

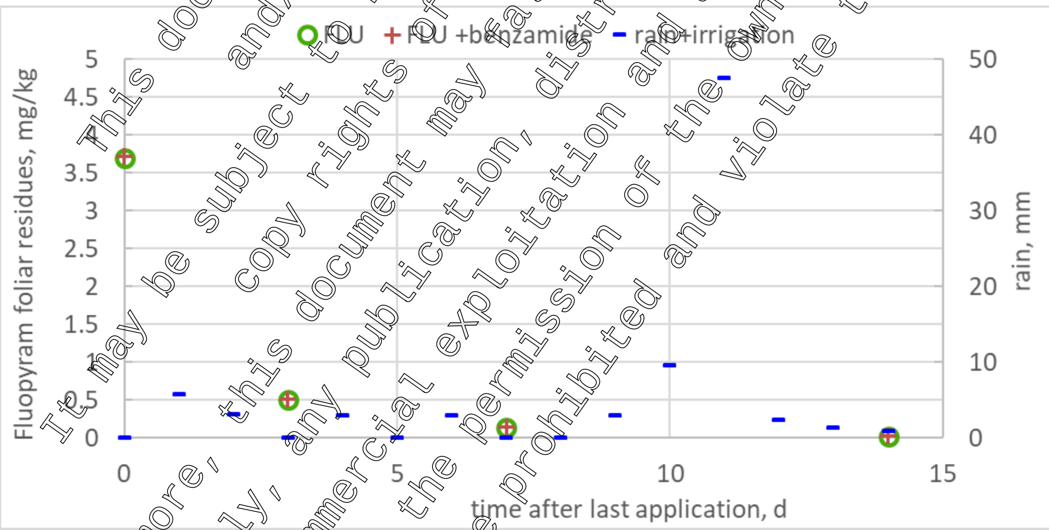


Figure 8.9- 184: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce

Early rainfall and irrigation may have markedly influenced residue levels.

Table 8.9- 590: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2185-02 Pozoblanco, ES,						Hinojosa del Duque (25.66 km) [a]	drip	Hinojosa del Duque (25.66 km) [a]
M-536963-01-1	46	20/10/2014	0	3.1	FLU-benz	0		18.6
		21/10/2014	1		< LOD	0		18.8
lettuce, green material		22/10/2014	2			0		18.4
	47	23/10/2014	3	2.2		0		16.4
		24/10/2014	4			0		16.2
		25/10/2014	5			0		16.6
		26/10/2014	6			0		15.8
	49	27/10/2014	7	1.2		0		15.6
		28/10/2014	8			0		15.7
		29/10/2014	9			0		16.3
		30/10/2014	10			0.1		15.5
		31/10/2014	11			0		15.1
		01/11/2014	12			0		14.2
		02/11/2014	13			0.1		14
	49	03/11/2014	14	0.062		1.3		12.9

[a] https://www.juntadeandalucia.es/agriculturaypesca/ifapa/ria/servlet/FrontController

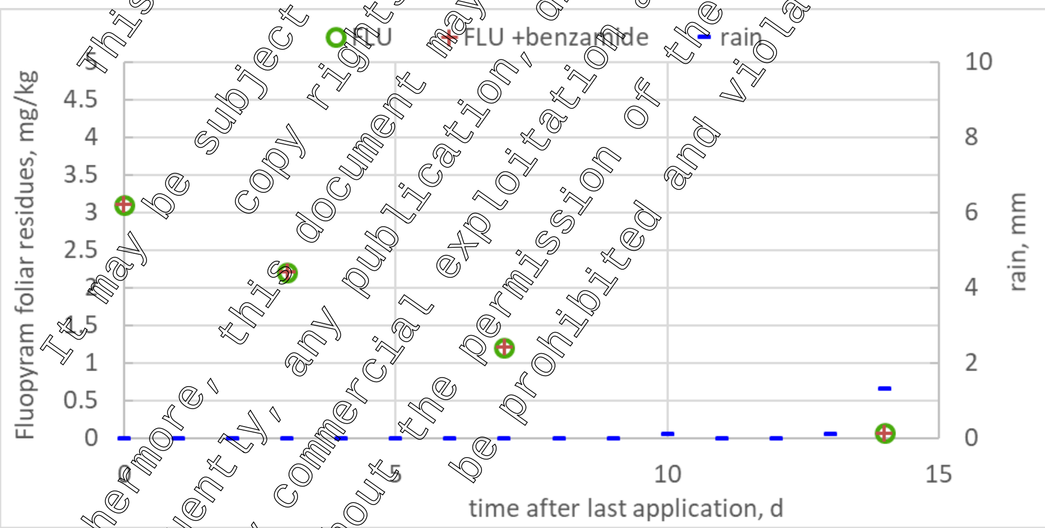


Figure 8.9- 185: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to lettuce.

Virtually no rain and no influence.

Table 8.9- 591: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2185-03 Zafarraya, ES,						Vélez Málaga (7 km) [a]	drip	Vélez Málaga (7 km) [a]
M-536963-01-1	43	12/05/2014	0	5.4	5.417	0		20.7
		13/05/2014	1			0		19
		14/05/2014	2			0		20
lettuce, green material	46	15/05/2014	3	3.4	3.412	0		18.1
		16/05/2014	4			0		18.5
		17/05/2014	5			0		18
		18/05/2014	6			0		18.3
	49	19/05/2014	7	2.2	2.213	0		18.4
		20/05/2014	8			0		19.7
		21/05/2014	9			3.6		17.9
		22/05/2014	10			0		17.7
		23/05/2014	11			0		21.3
		24/05/2014	12			0		18.2
		25/05/2014	13			0		18.7
	49	26/05/2014	14	0.47	0.481	0		19.8

[a] https://www.juntadeandalucia.es/agriculturaypesca/ifapa/ria/servlet/FrontController

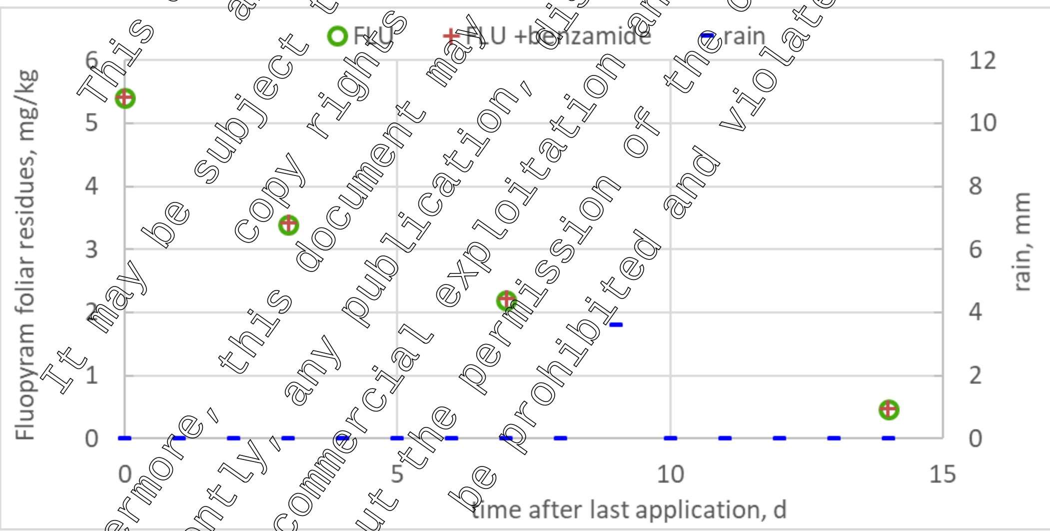


Figure 8.9- 186: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

No rain until day 9. Influence unlikely.

Table 8.9- 592: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
14-2185-04 Nea Magnisia, GR,						Thessaloniki (2.5 km), study raw data	no	Thessaloniki (2.5 km), study raw data
M-536963-01-1	45	16/06/2014	0	4.1	4.114	0.2		22.9
		17/06/2014	1			0		23.4
lettuce, green material		18/06/2014	2			1.6		24.1
	45	19/06/2014	3	1.7	1.714	9.6		21.5
		20/06/2014	4			8.2		23.5
		21/06/2014	5			0		23.3
		22/06/2014	6			0		24.4
	47	23/06/2014	7	0.57	0.59	0		23.8
		24/06/2014	8			0		24.3
		25/06/2014	9			0		25.5
		26/06/2014	10			0		27.7
		27/06/2014	11			0.8		26.7
		28/06/2014	12			0		24.8
		29/06/2014	13			0		24.7
	49	30/06/2014	14	0.093	0.098 a)	0		23.8

a) for FLU-benzamide 0.5 LOD added

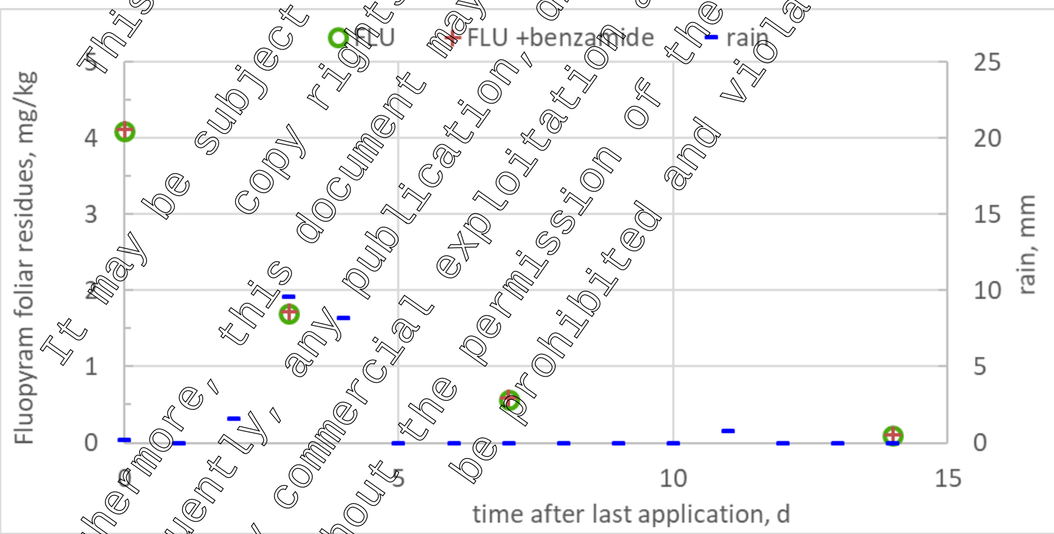


Figure 8.9- 187: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to the lettuce.

Rain on days 2 (1.6 mm), 3 (9.6 mm) and 4 (8.2 mm) coincide with any marked change in the residue decline curve; however slight influence possible.

III. CONCLUSION

After two spray applications of Fluopyram & CGA 279202 SC 500 on lettuce in four residue trials conducted in southern Europe (Italy, 2 x Spain and Greece) during the 2014 season the residues of fluopyram in/on lettuce head declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in 9 samples with residue values slightly above the LOQ of 0.01 mg/kg with a maximum value of 0.020 mg/kg.

Assessment and conclusion by applicant: The study and its data are considered as acceptable and reliable for use in risk assessment. Early rainfall and irrigation may have had a marked influence in trial 14-2185-01. No influence is seen in trials 14-2185-02 and 14-2185-03, whilst a slight influence is possible in 14-2185-04. However, rain is a natural and irrigation a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	28.9/42
Report Author:	[redacted]
Report Year:	2017
Report Title:	Determination of the residues of fluopyram and trifloxystrobin in/on field pea, after spray application of AE C656948 & CGA 279202 SC 500 in Denmark, Germany, Spain and Italy
Report No:	15-2030
Document No:	M-566823-03-1
Guideline(s) followed in study:	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations from current test guideline:	Current Guideline, not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in northern and southern Europe (Denmark, Germany, Spain, Italy) in/on pea, field during the seasons 2015 and 2016. Two applications with Fluopyram & CGA 279202 SC 500, containing 250 g/L fluopyram (AE C656948) and 250 g/L trifloxystrobin (CGA 279202) were conducted. Only the parameters and results relevant to fluopyram and its metabolite fluopyram-benzamide have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram & CGA 279202 SC 500 on pea, field (green material, pod, seed, dry and seed, green) declined markedly during the sampling period. Residues of the metabolite fluopyram-benzamide were detected in the matrix green material in almost all samples with a maximum value of 0.11 mg/kg. In all other matrices, no residues of fluopyram-benzamide above the LOQ of 0.01 mg/kg were detectable besides in trial 15-2030-02.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram & CGA 279202 SC 500 (250 +250 g/L)
	Batch no.:	EV65000048
	Active Ingredient:	Fluopyram and trifloxystrobin
	Storage:	Not stated in the report
	Expiry date:	2018-02-12
2.	Test commodity:	Pea, field
	Crop part:	Green material, pod, seed, dry and seed, green

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 15-2030 was to determine the magnitude of the relevant residues of fluopyram and its metabolite fluopyram-benzamide in/on pea, field (green material, pod, seed, dry and seed, green) after two spray applications with “Fluopyram & CGA 279202 SC 500 (250 g/L + 250 g/L)”, a suspension concentrate formulation containing 250 g/L fluopyram. This summary focuses only on the residues of fluopyram and its metabolite fluopyram-benzamide.

<u>Field phase</u>

The study included four supervised residue trials conducted in northern and southern Europe (Denmark, Germany, Spain, Italy) during the seasons 2015 and 2016. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 593: Description of the trial locations and cropping information on treated plots

Trial number	15-2030-01	15-2030-02	15-2030-03	15-2030-04
Trial location	6200 Abenraa	77694 Kehl-Bodersweier	18680 Salobreña	20060 Mediglia
Country	Denmark	Germany	Spain	Italy
Area of application	Field	Field	Field	Field
Plot size [m^2]	51	60	66	45
Type of soil	Sand	Sandy Loam	Sandy clay loam	Sandy loam
pH-value of soil (in water)	4.6	7.1	8.1	7.0
Content of organic C [%]	1.1	1.16	1.0	0.9
Test system	Pea, field	Pea, field	Pea, field	Pea, field
Variety	Maxigold	Astronaut	Dorian	Nano Progress
Date of sowing	2015-06-12	2015-03-21	2015-12-01	2016-02-20
Date of commercial harvest	2015-10-01	2015-07-11	2016-04-04 to 2016-04-12	2016-05-18

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range. Application rates are reported as the nominal values if the measured rates were within +/- 5% of the planned rates. The first application was performed at BBCH stages between 65-73 and the second between 71-75 with an application rate of 0.2 kg a.s./ha and a water rate of 300-400 L/ha.

Table 8.9- 594: Overview on application with Fluopyram & CGA 279202 SC 500 on pea, field

Trial no. Country	Appl. No.	Plot	Formu-lation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
15-2030-01 Denmark	1	T	Fluo-pyram & CGA 279202 SC 500	SPI	7	65	20	0.8	300	Fluopyram CGA 279202	0.2
	2					71	13*			Fluopyram CGA 279202	0.2
15-2030-02 Germany	1	T	Fluo-pyram & CGA 279202 SC 500	SPI	7	72	21	0.8	400	Fluopyram CGA 279202	0.2
	2					75	14*			Fluopyram CGA 279202	0.2
15-2030-03 Spain	1	T	Fluo-pyram & CGA 279202 SC 500	SPI	6	73	19	0.8	400	Fluopyram CGA 279202	0.2
	2					75	13*			Fluopyram CGA 279202	0.2
15-2030-04 Italy	1	T	Fluo-pyram & CGA 279202 SC 500	SPI	7	71	21	0.8	400	Fluopyram CGA 279202	0.2
	2					73	14*			Fluopyram CGA 279202	0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as PHI (Pre-harvest interval)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 500 g of pea, field . They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the sampling schedule presented in the following table. An exception occurred in trial 15-2030-01 where sampling took place at DALT 13 instead of DALT 14. In trial 15-2030-02, due to hot weather conditions, peas ripened faster, and sampling took place at BBCH 79. Since this had an impact on the study, sampling was adjusted and moisture determination using microwave was decided to be not relevant.

Table 8.9- 595: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	Growth stage BBCH	DALT
15-2030-01 15-2030-03 15-2030-04	Pea, field	Green material	C	-	-0
		Pod, seed, green			14
		Green material			21
		Pod, seed, green			
		Seed, dry		89	
		Green material	T	-	0
					-0
		Pod, seed, green			0
		Green material			7
		Pod, seed, green			
		Green material			14
		Pod, seed, green			
		Green material			21
		Pod, seed, green			
		Seed, dry		89	
15-2030-02	Pea, field	Green material	C	-	-0
		Seed, dry			14
					21
		Green material	T	-	0
					-0
		Pod			0
		Green material			7
		Pod, seed, green			7
		Seed, dry			14
				89	21

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolite fluopyram-benzamide were analysed within the residue trials samples according to the following method:

Table 8.9- 596: Summary of the analytical method

Method	00984/M003
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite expressed as parent equivalents in pea, field green material, pod, seed, dry and seed, green)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 597: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Pea, field / green material	0.01	97; 98; 102	99	2.7	0.01
	0.10	100; 100; 102	101	1.1	
	1.0	104; 105	105		
	10	105; 107; 116	109		
		Overall recovery (n = 11)	**103**	**5.1**	
Pea, field / pod	0.01	99			0.01
	0.10	101			
		Overall recovery (n = 2)	**100**	**-**	
Pea, field / seed, dry	0.01	96; 98; 100	98	2.0	0.01
	0.10	98; 100; 105	101	3.6	
		Overall recovery (n = 6)	**100**	**3.1**	
Pea, field / seed, green	0.01	99; 102; 104; 106	103	2.9	0.01
	0.10	98; 99; 100	99	1.0	
		Overall recovery (n = 7)	**101**	**2.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram

Table 8.9- 598: Procedural recoveries for fluopyram-benzamide

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Pea, field / green material	0.01	90; 90; 95	92	3.1	0.01
	0.10	88; 94; 95	92	4.1	
	1.0	99; 102	101	-	
	10	98; 108; 112	106	6.8	
		Overall recovery (n = 11)	**97**	**7.8**	
Pea, field / pod	0.01	98			0.01
	0.10	100			
		Overall recovery (n = 2)	**99**	**--**	
Pea, field / seed, dry	0.01	99; 105; 111	105	5.7	0.01
	0.10	93; 96; 98	96	2.6	
		Overall recovery (n = 6)	**100**	**6.5**	
Pea, field / seed, green	0.01	83; 84;103;104	94	12.4	0.01
	0.10	95; 100; 102	99	3.6	
		Overall recovery (n = 10)	**96**	**9.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 43 and 410 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolite, the residues levels in/on pea, field (green material, pod, seed, dry and seed, green) are summarised in the following table.

Table 8.9- 599: Residue summary of fluopyram in/on pea, field , green material, pod, seed, dry and seed, green

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] a.s. fluopyram	Residue [mg/kg] fluopyram-benzamide
15-2030-01 Denmark	Green material	71	-0	1.7	0.010
	Green material	71	0	5.1	0.013
	Pod	71	0	0.63	<0.01
	Green material	75	7	1.0	0.025
	Pod	75	7	0.070	<0.01
	Green material	79	13	0.56	0.024
	Seed, green	79	13	0.016	<0.01
	Pod	79	13	0.078	<0.01
	Green material	79	19	0.43	0.020
	Seed, green	79	19	0.019	<0.01
	Seed, dry	89	36	0.016	0.01
15-2030-02 Germany	Green material	75	-0	0.18	0.014
	Green material	75	0	2.8	0.014
	Pod	75	0	0.61	<0.01
	Green material	79	6	3.7	0.11
	Pod	79	6	0.53	0.027
	Seed, green	79	6	0.024	0.013
	Seed, dry	89	14	0.050	0.015
	Seed, dry	89	21	0.053	0.017
15-2030-03 Spain	Green material	75	-0	4.0	<0.01
	Green material	75	0	8.1	<0.01
	Pod	75	0	0.96	<0.01
	Green material	77	7	9.9	0.029
	Pod	77	7	0.79	<0.01
	Green material	79	13	9.9	0.043
	Seed, green	79	13	0.064	<0.01
	Pod	79	13	0.66	<0.01
	Green material	79	21	2.1	0.065
	Seed, green	79	21	0.032	<0.01
	Seed, dry	89	29	0.10	<0.01
15-2030-04 Italy	Green material	73	-0*	3.5**	0.010
	Green material	73	0*	0.29**	<0.01
	Pod	73	0	0.43	<0.01
	Green material	74	7	0.59	0.011
	Pod	74	7	0.072	<0.01
	Green material	79	14	0.29	0.028
	Seed, green	79	14	<0.01	<0.01
	Pod	79	14	0.032	<0.01
	Green material	81	21	0.15	0.021
	Seed, green	81	21	<0.01	<0.01
	Seed, dry	89	48	<0.01	<0.01

DALT = Days after last treatment
* Obviously these samples have been interchanged
**The samples green material, BBCH 73, -0 DALT and green material, BBCH 73, 0 DALT were measured three times to verify the residue results.

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on pea, field

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 600: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
15-2030-01 Abenraa, DK,						Abenraa (9.62 km), study raw data	no	Abenraa (9.62 km), study raw data
M-566823-03-1 Pea, field, green material	71	26/08/2015	0	5.1	5.113	5.6 (0) [a]		18.6
		27/08/2015	1			11.2		17.7
		28/08/2015	2			1.5		16
		29/08/2015	3			0		15.3
		30/08/2015	4			0		17.5
		31/08/2015	5			23.9		17.2
		01/09/2015	6			0.8		17
		02/09/2015	7	1	1.025	1.5		15.2
		03/09/2015	8			1.5		14
		04/09/2015	9			0.8		13.1
		05/09/2015	10			6.3		12.8
		06/09/2015	11			0		13.4
		07/09/2015	12			0		12.9
		08/09/2015	13	0.56	0.584	0		13.3
		09/09/2015	14			0		12.6
		10/09/2015	15			2		12.8
		11/09/2015	16			4.3		14.2
		12/09/2015	17			1.5		15.2
		13/09/2015	18			12.7		17
		14/09/2015	19	0.43	0.45	13.5		16.9

[a] no rain 24 h after application, in study report

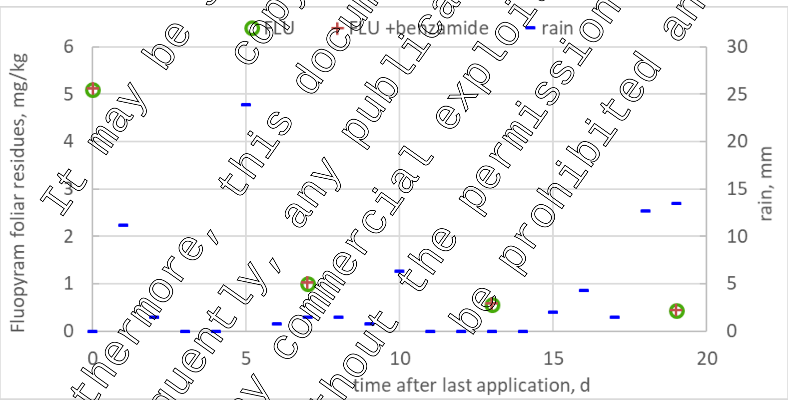


Figure 8.9- 188: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to pea, field

Heavy rainfall on day 1 and day 5 coincides with a marked drop in residue levels, impact likely.

Table 8.9- 601: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
15-2030-03 Salobreña, ES, M-566823-03-1 Pea, field, green material						Almuñecar (9.7 km)	flooding	Almunecar (9.7 km)
	75	22/03/2016	0	8.1	8.105 [a]	0		11.5
		23/03/2016	1			0		13.9
		24/03/2016	2			0		15.1
		25/03/2016	3			0.2		13.7
		26/03/2016	4			0.4		14.5
		27/03/2016	5			0		16.4
		28/03/2016	6			0		14.6
		29/03/2016	7	9.9	9.929	0		12.9
		30/03/2016	8			0		13.5
		31/03/2016	9			0		15.1
		01/04/2016	10			0		16.5
		02/04/2016	11			0		12.3
		03/04/2016	12			0		13.7
		04/04/2016	13	9.9	9.943	44.4		13.1
		05/04/2016	14			0		16.2
		06/04/2016	15			0		16.1
		07/04/2016	16			0		14.1
		08/04/2016	17			0.2		14.6
		09/04/2016	18			0		13.5
		10/04/2016	19			0		14.4
		11/04/2016	20			0		15
		12/04/2016	21	2.1	2.165	0		15.3

[a] for FLU-benzamide 0.5 LOD added

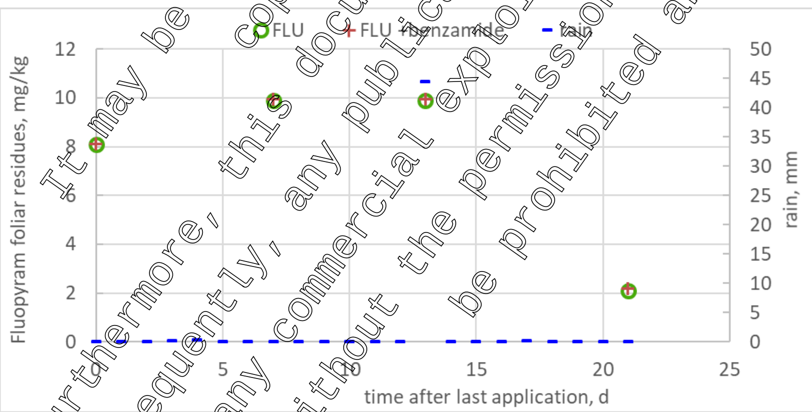


Figure 8.9- 189: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to pea, field.

Heavy rainfall on day 13 coincides with a drop in residue levels, influence likely.

Table 8.9- 602: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
15-2030-04 Mediglia, IT, M-566823-03-1 Pea, field, green material						Rodano (6.3 km), study raw data	no	Rodano (6.3 km), study raw data
	73	27/04/2016	0	3.5 [b]	3.505 [a]	0		10.4
		28/04/2016	1			0		10.1
		29/04/2016	2			0		12.2
		30/04/2016	3			7.4		12.7
		01/05/2016	4			9.2		10.6
		02/05/2016	5			0		13.7
		03/05/2016	6			0		16.3
		04/05/2016	7	0.59	0.601	0		17.7
		05/05/2016	8			0		17.1
		06/05/2016	9			0		17.1
		07/05/2016	10			0		18.5
		08/05/2016	11			0		19.1
		09/05/2016	12			3		15.6
		10/05/2016	13			3.6		15.9
		11/05/2016	14	0.29	0.318	22.2		14.5
		12/05/2016	15			4.8		15.5
		13/05/2016	16			1.8		15.9
		14/05/2016	17			0		17.5
		15/05/2016	18			0		18.3
		16/05/2016	19			1.4		16.3
		17/05/2016	20			0.2		16.4
		18/05/2016	21	0.15	0.171	0		17.3

[a] for FLU-benzamide 0.5 LOD added
[b] FLU residues in original study report: -0 DALT 3.5 mg/kg, +0 DALT 0.29 mg/kg. However, interchange of both values is already reported in study report.

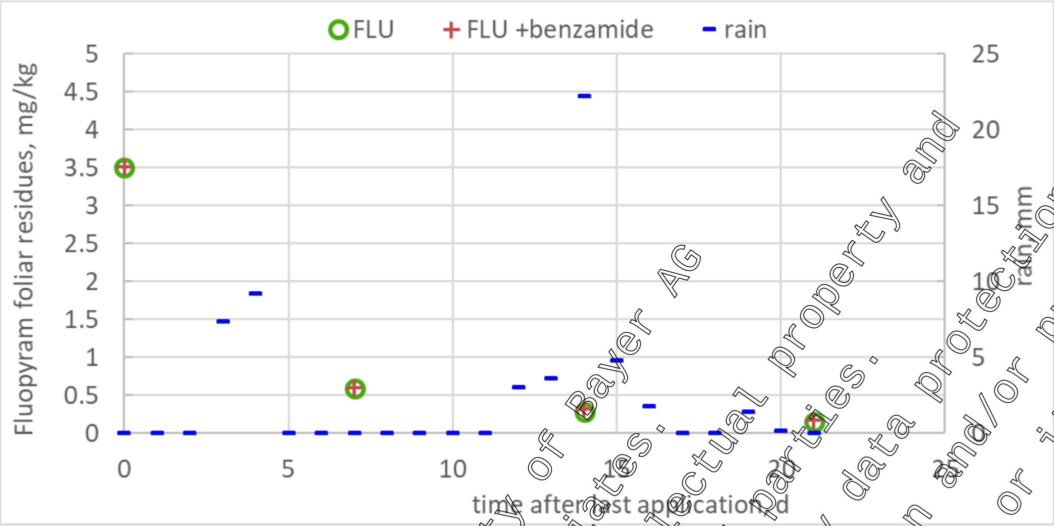


Figure 8.9- 190: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to pea, field.

Rainfall on days 3 and 4 coincides with a drop in residue levels, influence likely.

III. CONCLUSION

After two spray applications of Fluopyram & CGA 279202 SC 500 on pea, field in four residue trials conducted in northern and southern Europe (Denmark, Germany, Spain, Italy) during the 2015 and 2016 seasons, the residues of fluopyram in/on pea, field green material, pod, seed, dry and seed, green declined markedly during the sampling period. The metabolite fluopyram-benzamide was detected in green material in almost all samples with a maximum value of 0.11 mg/kg. In all other matrices, no residues above the LOQ of 0.01 mg/kg were detectable besides trial 15-2030-02.

Assessment and conclusion by applicant:
The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall may have influenced the residue decline in 15-2030-01 (marked), 15-2030-02 (marked) and 15-2030-03 (slightly).   However, rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

In the following section the residue study summaries are presented that have been analysed in the kinetic report in M-763354-02-1:

Data Point:	KCA 8.9/43
Report Author:	[redacted]
Report Year:	2012
Report Title:	Determination of the residues of fluopyram and tebuconazole in/on leek after spray applicaton of fluopyram & tebuconazole SC 400 in northern France, Germany and Belgium
Report No:	11-2029
Document No:	M-442996-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed, EC Guidance working document 7029/VI/95 rev.5 (1997-07-22) US EPA OCSPP Guideline No. 860.1500.SUPP
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in northern Europe (northern France, Belgium and 2 x Germany) on leek during the 2011 season. One application with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram (AE C656948), was conducted. Only the parameters and results relevant to fluopyram and its metabolite fluopyram-benzamide have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram + Tebuconazole 400 SC on leek (whole plants without roots) declined markedly during the sampling period. Residues of its metabolite fluopyram-benzamide were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram + Tebuconazole 400 SC

   Batch no.: 2009-008489

   Active Ingredient: Fluopyram + tebuconazole

   Storage: Not stated in the report

   Expiry date: 2012-03-10

2. Test commodity: Leek

   Crop part: Whole plant without roots

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 11-2029 was to determine the magnitude of the relevant residues of fluopyram and its metabolite in/on leek (whole plant without roots) after one spray applications with Fluopyram + Tebuconazole 400 SC a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolite fluopyram-benzamide.

Field phase

The study included four supervised residue trials conducted in northern Europe (2 x Germany, northern France and Belgium) during the 20011 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 603: Description of the trial locations and cropping information on treated plots

Trial number	11-2029-01	11-2029-02	11-2029-03	11-2029-04
Trial location	F-41230 Soings en Sologne	D-59457 Werl-Westönnen	D-40764 Langenfeld	B-6210 Villers-Perwin
Country	France	Germany	Germany	Belgium
Area of application	Field	Field	Field	Field
Plot size [m^2]	40	31.25	33	30
Type of soil	Sand	Loess	Loamy sand	Silt loam
pH-value of soil (in water)	7.8	-	-	6.9
pH-value of soil (in $CaCl_2$)	-	6.6	6.9	-
Content of organic C [%]	0.6	1.8	3.2	2.0
Test system	Leek	Leek	Leek	Leek
Variety	Davincy	F1 Hybrid Parton F1	Prelina Leek	Belton Variety hybrid from Nunhems
Date of planting	2011-06-15	2011-05-19	2011-05-12	2011-05-25
Date of commercial harvest	2011-09-15 to 2011-10-15	2011-08-25 to 2011-12-30	2011-08-01 to 2011-08-15	2011-09-08 to 2011-09-30

The actual application data are presented in the following table. This data reflects the intended application scheme. Deviations occurred as it rained after the application in trial 11-2029-03 and -04 but only 1 mm in two hours and 1.5 mm within five hours after the application, respectively. This had no impact on the study. The application was performed at BBCH stages between 47-49 with an application rate of 0.2 kg a.s./ha and a water rate of 300-600 L/ha.

Table 8.9- 604: Overview on application with Fluopyram +Tebuconazole SC 400 on leek

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (kg a.s./ha)
11-2029-01 Northern France	1	T	Fluopyram + Tebuconazole SC 400	SPI	47	14	1	600	Fluopyram + tebucon-azole	0.2
11-2029-02 Germany	1	T	Fluopyram + Tebuconazole SC 400	SPI	49	14	1	300	Fluopyram + tebucon-azole	0.2
11-2029-03 Germany	1	T	Fluopyram + Tebuconazole SC 400	SPI	47	14	1	300	Fluopyram + tebucon-azole	0.2
11-2029-04 Belgium	1	T	Fluopyram + Tebuconazole SC 400	SPI	47	14	1	450	Fluopyram + tebucon-azole	0.2

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of leek. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 605: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
11-2029-01 11-2029-02 11-2029-03 11-2029-04	Leek	Whole plant without root	C	-0
				14
			T	0
				7
				14
				21

DALT: Days after last treatment “-0”: before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolite fluopyram-benzamide were analysed within the residue trials samples according to the following method:

Table 8.9- 606: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolite fluopyram-benzamide expressed as parent equivalents in leek whole plant without root)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and its metabolites were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 607: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	78			0.01
	0.1	95			
	1.0	71			
		Overall recovery (n = 3)	**81**	**15.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 608: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	89			0.01
	0.1	90			
	1.0	75			
		Overall recovery (n = 3)	**85**	**9.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 314 and 391 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide the residues levels in/on leek (whole plant without root) are summarised in the following table.

Table 8.9- 609: Residue summary of fluopyram in/on leek, whole plant without root

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide
11-2029-01	Whole plant without root	47	0	0.60	<0.01
	Whole plant without root	48	7	0.067	<0.01
	Whole plant without root	49	14	0.026	<0.01
	Whole plant without root	49	21	<0.01	<0.01
11-2029-02	Whole plant without root	49	0	0.49	<0.01
	Whole plant without root	49	7	0.070	<0.01
	Whole plant without root	49	14	0.034	<0.01
	Whole plant without root	49	21	0.027	<0.01
11-2029-03	Whole plant without root	47	0	0.30	<0.01
	Whole plant without root	48	7	0.045	<0.01
	Whole plant without root	49	14	0.013	<0.01
	Whole plant without root	49	21	<0.01	<0.01
11-2029-04	Whole plant without root	47	0	0.36	<0.01
	Whole plant without root	48	7	0.049	<0.01
	Whole plant without root	49	14	0.020	<0.01
	Whole plant without root	49	21	0.013	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on leek

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 610: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
11-2029-01 Soings en Sologne, FR,						Parcay Meslay (52 km), study raw data	no	Parcay Meslay (52 km), study raw data
M-442996-01-1	47	05/09/2011	0	0.6	FLU-benz	0.2 (0) [b]		16.3
		06/09/2011	1		<LOD	1		17.7
Leek, green material		07/09/2011	2			0		16.9
		08/09/2011	3			0.2		18.1
		09/09/2011	4			0.2		20.9
		10/09/2011	5			0		21.8
		11/09/2011	6			19.6		17.2
		12/09/2011	7	0.067		2.4		18.5
		13/09/2011	8			0.4		16.1
		14/09/2011	9			0		14.3
		15/09/2011	10			2.8		15.3
		16/09/2011	11			0.6		18
		17/09/2011	12			3.8		14.8
		18/09/2011	13			4.8		12.8
		19/09/2011	14	0.026		0		15.1
		20/09/2011	15			0		15.5
		21/09/2011	16			0		15.7
		22/09/2011	17			0		15.5
		23/09/2011	18			0.2		14.9
		24/09/2011	19			0		16.9
		25/09/2011	20			0		18.7
		26/09/2011	21	0.005 [a]		0		19.5

[a] for FLU 0.5 LOD added;
[b] no rain 24 h after application, in study report

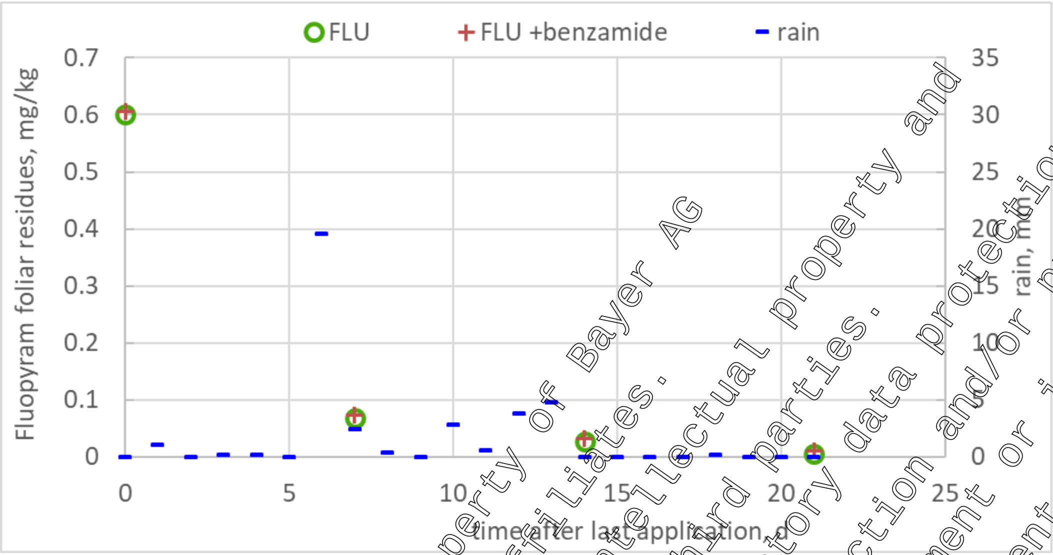


Figure 8.9- 191: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek

Heavy rainfall on day 6 (19.6 mm) coincides with a marked drop of residue levels, influence likely.

Table 8.9- 611: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
11-2029-02 Werl-Westoennen, DE, M-442996-01-1 Leek, green material						DWD Werl (5 km) [a]	no	DWD Werl (5 km) [a]
	49	09/09/2011	0	0.49	FLU-benz	0.6		17.4
		10/09/2011	1		<LOD	0		22.4
		11/09/2011	2			12.4		19.1
		12/09/2011	3			0		18.3
		13/09/2011	4			0		16.8
		14/09/2011	5			0		14.5
		15/09/2011	6			0		13.7
		16/09/2011	7	0.07		0		13.8
		17/09/2011	8			0.9		17
		18/09/2011	9			2.5		12.9
		19/09/2011	10			0		13.3
		20/09/2011	11			0		14.4
		21/09/2011	12			0.2		15.8
		22/09/2011	13			0		14.7
		23/09/2011	14	0.034		0		13.2
		24/09/2011	15			0		14.1
		25/09/2011	16			0		16.1
		26/09/2011	17			0		18.5
		27/09/2011	18			0		17
		28/09/2011	19			0		16
		29/09/2011	20			0		17.2
		30/09/2011	21	0.027		0		17.5

[a] https://opendata.dwd.de/climate_environment/CDC/

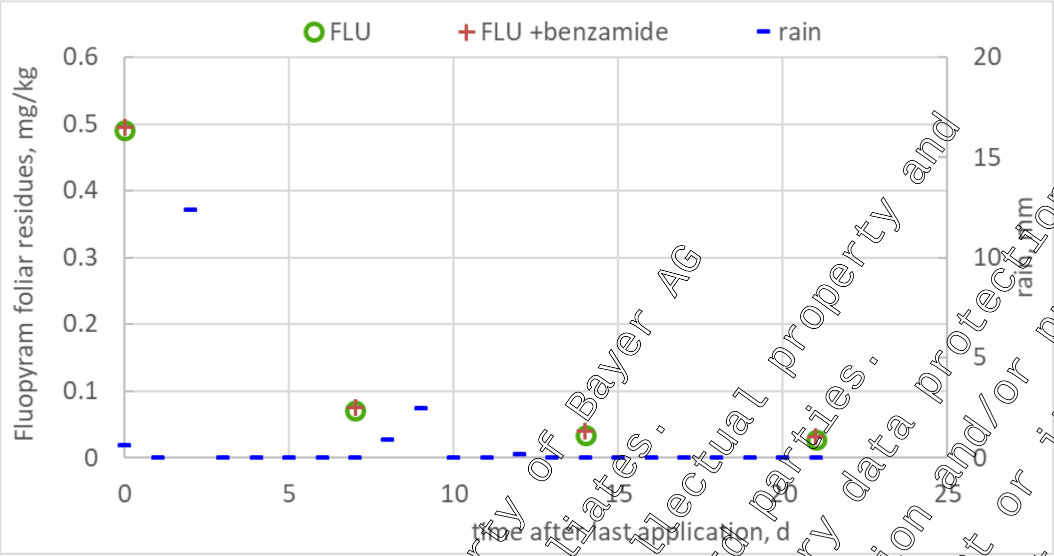


Figure 8.9- 192: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Rainfall on day 2 (12.4 mm) coincides with a marked drop of residue levels, influence likely.

Table 8.9- 612: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
11-2029-03 Langenfeld, DE,						ProPlant DB LWZ Monheim (2 km)	no	ProPlant DB LWZ Monheim (2 km)
M-442996-01-1	47	18/07/2011	0	0.3	FLU-benz	1.1		17.4
		19/07/2011	1		<LOD	9.1		17.4
Leek, green material		20/07/2011	2			2.9		17
		21/07/2011	3			5.3		17
		22/07/2011	4			na [b]		na [b]
		23/07/2011	5			0		13.9
		24/07/2011	6			19.9		12.6
		25/07/2011	7	0.045		0		16.2
		26/07/2011	8			0.9		16.9
		27/07/2011	9			9.3		17.7
		28/07/2011	10			4.1		18.3
		29/07/2011	11			0		17.5
		30/07/2011	12			0		15
		31/07/2011	13			0		15.4
		01/08/2011	14	0.013		0		18.3
		02/08/2011	15			0		23.1
		03/08/2011	16			0.9		20.8
		04/08/2011	17			6.1		21.7
		05/08/2011	18			0.4		20
		06/08/2011	19			6.7		20.5
		07/08/2011	20			0.2		17.8
		08/08/2011	21	0.005 [a]		11.6		15.6

[a] for FLU 0.5 LOD added
[b] missing data in ProPlant DB

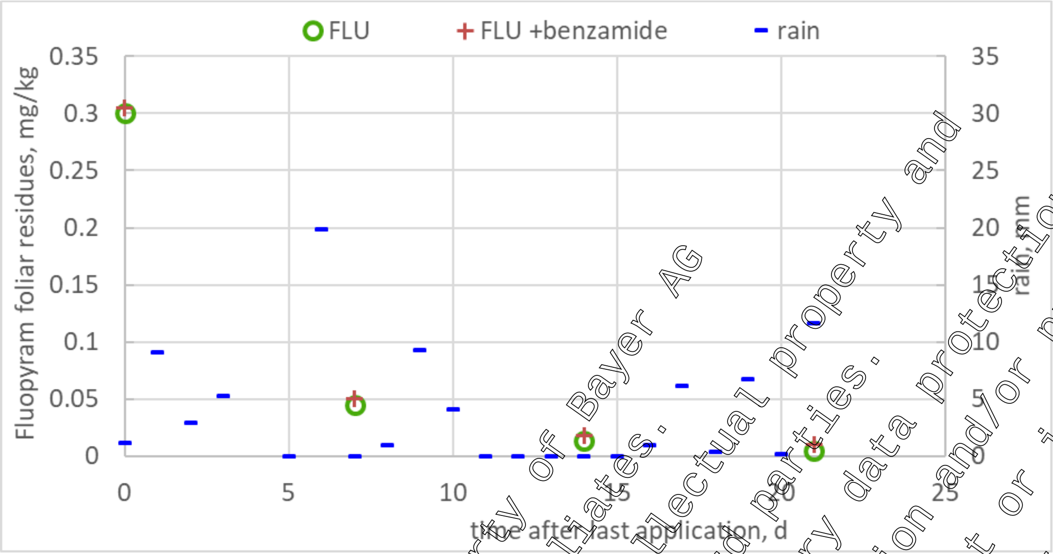


Figure 8.9- 193: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Frequent early rainfall coincides with a marked decline of the residue level. Influence likely.

Table 8.9- 613: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
11-2029-04 Villers-Perwin, BE,						Redebel (2.5 km), study raw data	no	Redebel (2.5 km), study raw data
M-442996-01-1 Leek, green material	47	25/08/2011	0	0.36	FLU-benz	1.5		18.6
		26/08/2011	1		<LOD	4.3		17.2
		27/08/2011	2			4.3		14.7
		28/08/2011	3			0		14.3
		29/08/2011	4			0		13.7
		30/08/2011	5			0		12.4
		31/08/2011	6			0		13.6
		01/09/2011	7	0.049		0		15.2
		02/09/2011	8			0		20
		03/09/2011	9			1.5		22.3
		04/09/2011	10			10.4		19
		05/09/2011	11			0.5		14.7
		06/09/2011	12			3.8		15
		07/09/2011	13			2.5		14.8
		08/09/2011	14	0.02		0.5		14
		09/09/2011	15			2.5		18.4
		10/09/2011	16			0		22.2
		11/09/2011	17			0.3		17.5
		12/09/2011	18			0.3		16.9
		13/09/2011	19			0		16.2
		14/09/2011	20			0		13.7
		15/09/2011	21	0.013		0		14.2

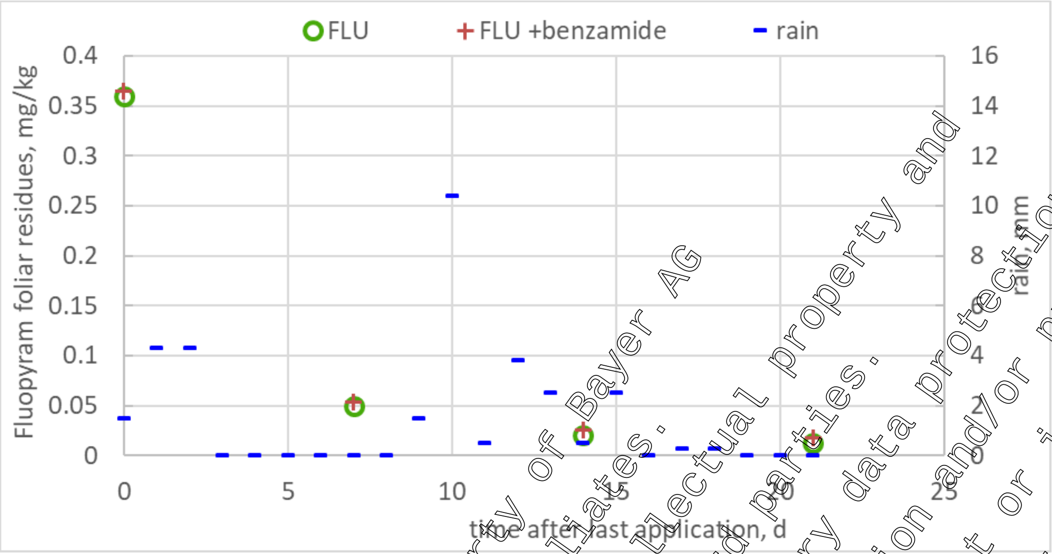


Figure 8.9- 194: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Rainfall on days 0, 1 and 2 coincides with a marked decline in residue levels, influence possible

III. CONCLUSION

After one spray application of Fluopyram + Tebuconazole SC 400 on leek in four residue trials conducted in northern Europe (Belgium, 2 x Germany and northern France) during the 2011 season, the residues of fluopyram in/on leek (whole plant without root) declined markedly during the sampling period. Residues of its metabolite fluopyram-benzamide were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall may have markedly influenced the residue decline in all 4 trials, but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/44
Report Author:	[redacted]
Report Year:	2007
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on onion, Welsh after spraying of AE C656948 & HWG 1608 (400 SC) in the field in (the) northern France and Germany
Report No:	RA-2565/06
Document No:	M-292996-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in northern Europe (northern France and Germany) on onion, Welsh during the 2006 season. Two applications with Fluopyram + Tebuconazole (HWG 1608) 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram, were conducted. Only the parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after two spray applications of the Fluopyram + Tebuconazole 400 SC on onion, Welsh declined markedly during the sampling period Residues of fluopyram-benzamide were detected in all samples of trial R 2006 0504/8 with a maximum value of 0.09 mg/kg. Residues of fluopyram-pyridyl-carboxylic acid were detected in one sample (0.01 mg/kg) and residues of fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram + Tebuconazole 400 SC
	Batch no.:	2006-000763
	Active Ingredient:	Fluopyram + tebuconazole
	Storage:	Not stated in the report
	Expiry date:	2007-02-14
2.	Test commodity:	Onion, Welsh
	Crop part:	Whole plant without roots

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2565/06 was to determine the magnitude of the relevant residues of fluopyram (AE C656948) and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on onion, Welsh (whole plant without roots) after two spray applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included two supervised residue trials conducted in northern Europe (northern France and Germany) during the 2006 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 614: Description of the trial locations and cropping information on treated plots

Trial number	R 2006 0337/1	R 2006 0504/8
Trial location	F-80700 Tilloloy (Picardie)	D-51399 Burscheid (Nordrhein-Westfalen)
Country	Northern France	Germany
Area of application	Field	Field
Plot size [m^2]	30	30
Type of soil	Clay loam	Loamy silt
pH-value of soil (in water)	7.4	6.2
Content of organic C [%]	0.8	1.7
Test system	Onion, Welsh	Onion, Welsh
Variety	Barletta	Feast
Date of sowing	2006-04-05	2006-05-02
Date of commercial harvest	2006-07-07 to 2006-07-21	2006-07-01 to 2006-09-01

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stages between 14-45 and the second at BBCH 44-45 with an application rate of 0.188-0.2 kg a.s./ha and a water rate of 300-500 L/ha. In trial R 2006 0337/1 there was a deviation from the study plan when the second application was 6 % underdosed due to a technical problem at the moment of the application (electrical variator). This was considered acceptable.

Table 8.9- 615: Overview on application with Fluopyram +Tebuconazole SC 400 on onion, Welsh

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
R 2006 0337/1 Northern France	1	T	Fluopyram + Tebucon-azole SC 400	SPI	7	14	14	1	500	Fluopyram, tebucon-azole	0.2
	2					44	7*		470		0.188
R 2006 0504/8 Germany	1	T	Fluopyram + Tebucon-azole SC 400	SPI	7	45	14	1	300	Fluopyram, tebucon-azole	0.2
	2					45	7*				0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of onion, Welsh. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 616: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2006 0337/1 R 2006 0504/8	Onion, Welsh	Whole plant without roots	C	-0
				7
				14
			T	-0
				0
				7
				14
				21

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 617: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in onion, Welsh, whole plant without roots)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The mean values of the concurrent recoveries were within the acceptable range of 70 – 110% except at 1 mg/kg for all the products. Nevertheless, all the results are considered as valid since overall mean recoveries were between 70 and 110% and the overall RSD were always below 20%.

Table 8.9- 618: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	70; 91; 94; 105	90	16.3	0.01
	0.1	97; 95; 94; 97	96	1.6	
	1	130	130	--	
		Overall recovery (n = 9)	**97**	**16.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 619: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	78; 100; 102; 98; 92	94	10.3	0.01
	0.1	99; 93; 99; 93	96	3.6	
	1	130	130	--	
		Overall recovery (n = 10)	**98**	**13.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 620: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	73; 84; 77; 78	78	5.8	0.01
	0.1	90; 86; 82; 86	86	3.8	
	1	128	128	--	
		Overall recovery (n = 9)	**87**	**18.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 621: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	90; 93; 81; 105; 80	90	11.3	0.01
	0.1	88; 94; 90; 82	89	5.6	
	1	125	125	-	
		Overall recovery (n = 10)	**93**	**14.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 286 and 308 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on onion, Welsh (whole plant without roots) are summarised in the following table.

Table 8.9- 622: Residue summary of fluopyram in/on Onion, Welsh, whole plant without roots

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0337/1 Northern France	Whole plant without roots	44	-0	0.33	<0.01	<0.01	<0.01
	Whole plant without roots	44	0	2.6	<0.01	<0.01	<0.01
	Whole plant without roots	45	7	0.70	<0.01	<0.01	<0.01
	Whole plant without roots	51	14	0.41	<0.01	<0.01	<0.01
	Whole plant without roots	51	21	0.29	<0.01	<0.01	<0.01
R 2006 0504/8 Germany	Whole plant without roots	45	-0	0.08	0.01	<0.01	<0.01
	Whole plant without roots	45	0	0.99	0.01	<0.01	<0.01
	Whole plant without roots	45	7	0.39	0.01	<0.01	<0.01
	Whole plant without roots	49	14	0.10	0.01	<0.01	<0.01
	Whole plant without roots	45	21	0.07	0.09[a]	<0.01	0.01[b]

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

[a]: this result corresponds to the mean of 3 single values: 0.088, 0.091 and 0.097 mg/kg.
[b]: this result corresponds to the mean of 3 single values: 0.014, 0.014 and 0.015 mg/kg.

2. Climatic conditions and time course of residue concentrations in/on onion, Welsh

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 623: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0337/1 Tilloloy, FR, M-292996-01-1						Meteo France Rouvroy en Santerre (15 km), study raw data	sprinkler	Meteo France Rouvroy en Santerre (15 km), study raw data
Onion, green material	44	28/06/2006	0	2.6	FLU-benz	0		16.3
		29/06/2006	1		<LOD	0		17.3
		30/06/2006	2			0		19.1
		01/07/2006	3			0		21.5
		02/07/2006	4			0		21.4
		03/07/2006	5			0	18	21.9
		04/07/2006	6			36.6		21.2
		05/07/2006	7	0.7		0		21.1
		06/07/2006	8			0		19
		07/07/2006	9			0.8		17.5
		08/07/2006	10			3.4		17.5
		09/07/2006	11			0		19
		10/07/2006	12			0		20.4
		11/07/2006	13			0		19.2
		12/07/2006	14	0.41		0		19.5
		13/07/2006	15			0		19.4
		14/07/2006	16			0		18.1
		15/07/2006	17			0		19.5
		16/07/2006	18			0		21.3
		17/07/2006	19			0		22.6
		18/07/2006	20			0		23.5
		19/07/2006	21	0.29		5		24.3

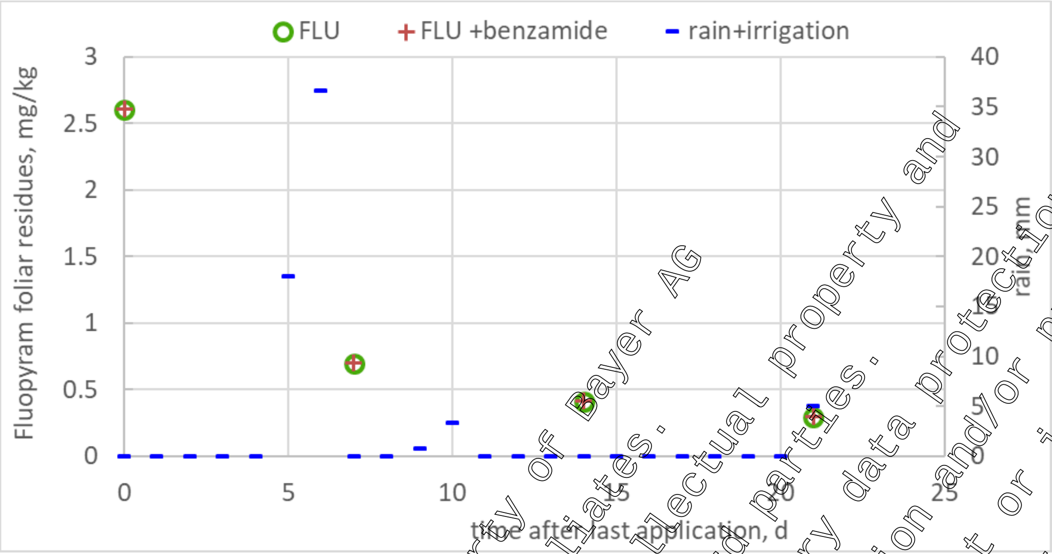


Figure 8.9- 195: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to onion, Welsh

Irrigation (18 mm on day 5) and rainfall (36.6 mm on day 6) coincide with a moderate drop of the residue level , influence likely.

Table 8.9- 624: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0504/8 Burscheid, DE, M-292996-01-1 Onion, Welsh / green, green material						ProPlant DB Höfchen (< 1 km) + Monheim (~10 km)	sprinkler	ProPlant DB Höfchen (< 1 km) + Monheim (~10 km)
	45	12/07/2006	0	0.99	1	0		22.6
		13/07/2006	1			0 [a]		24.1
		14/07/2006	2			0 [a]	30	19.8
		15/07/2006	3			0 [a]		20.9
		16/07/2006	4			0 [a]		23
		17/07/2006	5			0 [a]		23.7
		18/07/2006	6			0 [a]		25.7
		19/07/2006	7	0.39	0.4	0 [a]		27.6
		20/07/2006	8			3.8		26.5
		21/07/2006	9			0		25.9
		22/07/2006	10			0.2		24.2
		23/07/2006	11			0	30	23.9
		24/07/2006	12			0		24.4
		25/07/2006	13			2.2		27.3
		26/07/2006	14	0.1	0.11	0		27.1
		27/07/2006	15			0		25.5
		28/07/2006	16			4.5		21.9
		29/07/2006	17			0		21.9
		30/07/2006	18			4.4		21.8
		31/07/2006	19			0		19.3
		01/08/2006	20			9.5		17
		02/08/2006	21	0.07	0.16	11.4		15.5

[a] ProPlant DB Höfchen: missing data 12.7.– 19.7.2006; data from close station ProPlant DB LWZ Monheim was used instead

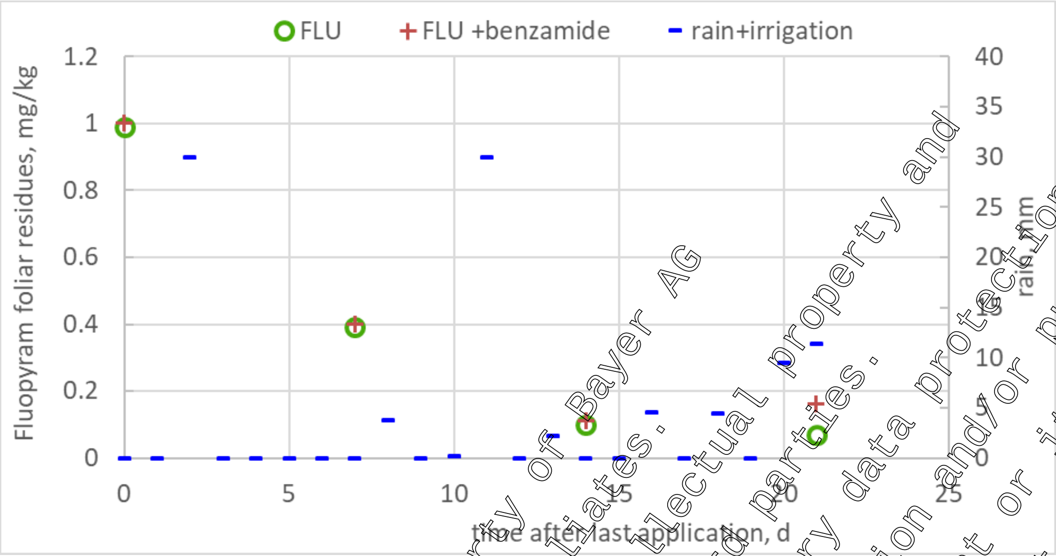


Figure 8.9- 196: Plot of the fluopyram residues decline with corresponding rainfall in the days following treatment to onion, Welsh.

Irrigation on day 2 and day 11 coincide with moderate drops of residue levels, influence possible.

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400 on onion, Welsh in two residue trials conducted in northern Europe (northern France and Germany) during the 2006 season, the residues of fluopyram in/on onion, Welsh (whole plant without roots) declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in all samples of trial R 2006 0504/8 with a maximum value of 0.09 mg/kg. Residues of fluopyram-pyridyl-carboxylic acid were detected in one sample (0.01 mg/kg) and residues of fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall and/or irrigation in both trials may have slightly influenced the residue decline.

However, rain is a natural and irrigation a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/45
Report Author:	[redacted].
Report Year:	2007
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on onion, Welsh after spraying of AE C656948 & HWG 1608 (400 SC) in the field in (the) Southern France and Italy
Report No:	RA-2566/06
Document No:	M-292098-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in southern Europe (southern France and Italy) in/on onion, Welsh during the 2006 season. Two applications with Fluopyram (AE C656948) + Tebuconazole (HWG 1608) 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram, were conducted. Only the parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after two spray applications of the Fluopyram + Tebuconazole 400 SC on onion, Welsh declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in eight samples with a maximum value of 0.06 mg/kg. Residues of fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram + Tebuconazole 400 SC

   Batch no.: 2006-000763

   Active Ingredient: Fluopyram + tebuconazole

   Storage: Not stated in the report

   Expiry date: 2007-02-14

2. Test commodity: Onion, Welsh

   Crop part: Whole plant without roots

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2566/06 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on onion, Welsh (whole plant without roots) after two spray applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included two supervised residue trials conducted in southern Europe (southern France and Italy) during the 2006 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 625: Description of the trial locations and cropping information on treated plots

Trial number	R 2006 0339/8	R 2006 0505/6
Trial location	F-69720 Saint Bonnet de Mure (Rhone-Alpes)	I-45020 Lusia (RO) (Veneto)
Country	Southern France	Italy
Area of application	Field	Field
Plot size [m^2]	40	27
Type of soil	Sandy loam	Sand
pH-value of soil (in water)	7.2	7.3
Content of organic C [%]	1.2	1.7
Test system	Onion, Welsh	Onion, Welsh
Variety	Barletta	Bianco di Lisbona
Date of sowing	2006-03-01	2006-04-10
Date of commercial harvest	2006-05-28 to 2006-06-02	2006-07-01 to 2006-07-31

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stage 45 and the second at BBCH 15-47 with an application rate of 0.2 kg a.s./ha and a water rate of 400-600 L/ha. For trial R 2006 0337/1 no BBCH stage for the first application was presented.

Table 8.9- 626: Overview on application with Fluopyram +Tebuconazole SC 400 on onion, Welsh

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2006 0339/8 Southern France	1	T	Fluopyram + Tebucon-azole SC 400	SPI	7	--	14	1	400	Fluopyram, tebucon-azole	0.2
	2					15	7*				0.2
R 2006 0505/6 Italy	1	T	Fluopyram + Tebucon-azole SC 400	SPI	7	45	14	1	600	Fluopyram, tebucon-azole	0.2
	2					47	7*				0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of onion, Welsh. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 627: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2006 0339/8 R 2006 0505/6	Onion, Welsh	Whole plant without roots	C	-0
				7
				14
			T	-0
				0
				7
				14
				21

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 628: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in onion, Welsh, whole plant without roots)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The mean values of the concurrent recoveries were within the acceptable range of 70 – 110%. Overall relative standard deviation were below 20%. Details are given in the table below.

Table 8.9- 629: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	95	95	--	0.01
	1	102	102	--	
	10	97	97	--	
		Overall recovery (n = 3)	**98**	**3.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 630: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	109	109	--	0.01
	1	90	90	--	
	10	92	92	--	
		Overall recovery (n = 3)	**97**	**10.8**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 631: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	90	90	--	0.01
	1	82	82	--	
	10	80	80	--	
		Overall recovery (n = 3)	**84**	**6.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 632: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	98	98	--	0.01
	1	84	84	--	
	10	97	97	--	
		Overall recovery (n = 3)	**93**	**8.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 281 and 356 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on onion, Welsh (whole plant without roots) are summarised in the following table.

Table 8.9- 633: Residue summary of fluopyram in/on Onion, Welsh, whole plant without roots

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0339/8 Southern France	Whole plant without roots	15	-0	0.23	0.03	<0.01	<0.01
	Whole plant without roots	15	0	3.8	0.03	<0.01	<0.01
	Whole plant without roots	41	7	1.2	0.02	<0.01	<0.01
	Whole plant without roots	43	14	0.47	0.05	<0.01	<0.01
	Whole plant without roots	45	21	0.27	0.06	<0.01	<0.01
R 2006 0505/6 Italy	Whole plant without roots	47	-0	0.68	0.01	<0.01	<0.01
	Whole plant without roots	47	0	2.1	0.01	<0.01	<0.01
	Whole plant without roots	49	7	0.41	0.01	<0.01	<0.01
	Whole plant without roots	49	14	0.23	<0.01	<0.01	<0.01
	Whole plant without roots	49	21	0.10	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on onion, Welsh

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 634: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date (dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0339/8 Saint Bonnet de Mure, FR, M-292098-01-1 onion, green material						Meteo France St. Georges de Reneins (15 km), study raw data	sprinkler	Meteo France St. Georges de Reneins (15 km), study raw data
	15	23/05/2006	0	3.8	3.83	0		13.8
		24/05/2006	1			0		12.5
		25/05/2006	2			0		14.2
		26/05/2006	3			0		17.8
		27/05/2006	4			0		19
		28/05/2006	5			0		19.2
		29/05/2006	6			0.6		15.1
		30/05/2006	7	1.2	1.22	0	10	10.6
		31/05/2006	8			3.2		9.5
		01/06/2006	9			1.8		10.2
		02/06/2006	10			0		11.1
		03/06/2006	11			0		15
		04/06/2006	12			0		16.4
		05/06/2006	13			0		16.7
		06/06/2006	14	0.47	0.52	0		15.5
		07/06/2006	15			0	10	15.6
		08/06/2006	16			0		16.5
		09/06/2006	17			0		18.6
		10/06/2006	18			0		19.8
		11/06/2006	19			0		20.9
		12/06/2006	20			0		22
		13/06/2006	21	0.27	0.33	0	15	21.8

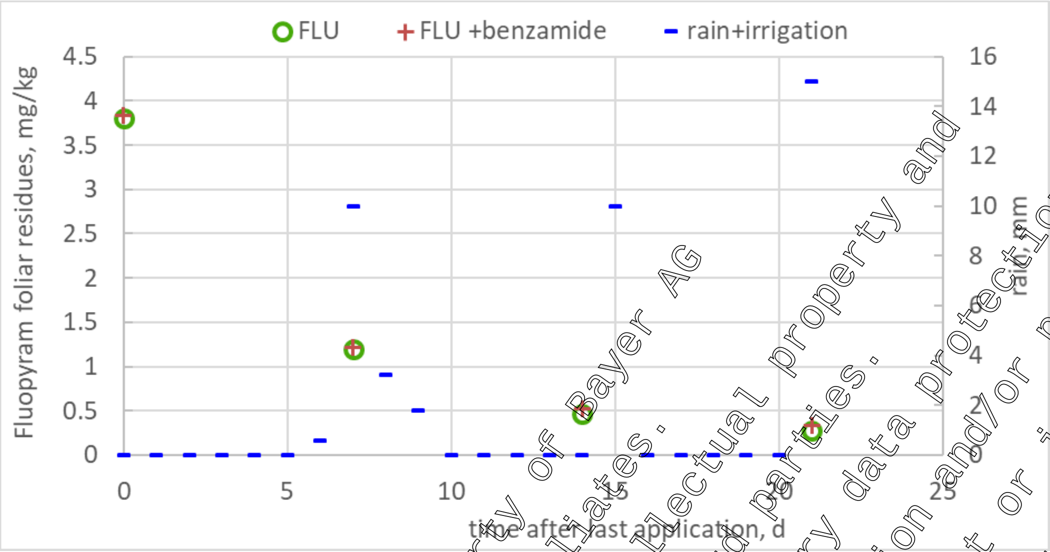


Figure 8.9- 197: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Onion, Welsh

Irrigation on day 7 coincides with a moderate decline of residue levels (influence possible). Later rainfall or irrigation likely without influence.

Table 8.9- 635: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0505/6 Lusia, IT,						MARS grid 76115 (25 km x 25 km)	sprinkler	MARS grid 76115 (25 km x 25 km)
M-292098-01-1	47	17/07/2006	0	2.1	2.11	0		25.2
		18/07/2006	1			0		24.7
onion, Welsh / green, green material		19/07/2006	2			0		26.3
		20/07/2006	3			0		27.2
		21/07/2006	4			0		28.4
		22/07/2006	5			0	30	28.3
		23/07/2006	6			0		29.1
		24/07/2006	7	0.41	0.42	0		29.2
		25/07/2006	8			0		29.2
		26/07/2006	9			0		29.8
		27/07/2006	10			0		29.3
		28/07/2006	11			0.2		29.4
		29/07/2006	12			0		26.4
		30/07/2006	13			0		27.7
		31/07/2006	14	0.23	0.235 [a)]	0		28.3
		01/08/2006	15			2.2		24
		02/08/2006	16			0		24.7
		03/08/2006	17			8		21.4
		04/08/2006	18			0		19.9
		05/08/2006	19			0		21.1
		06/08/2006	20			0		22.8
		07/08/2006	21	0.1	0.105 [a)]	0		23.7

[a)] for FLU-benzamide 0.5 LOD added

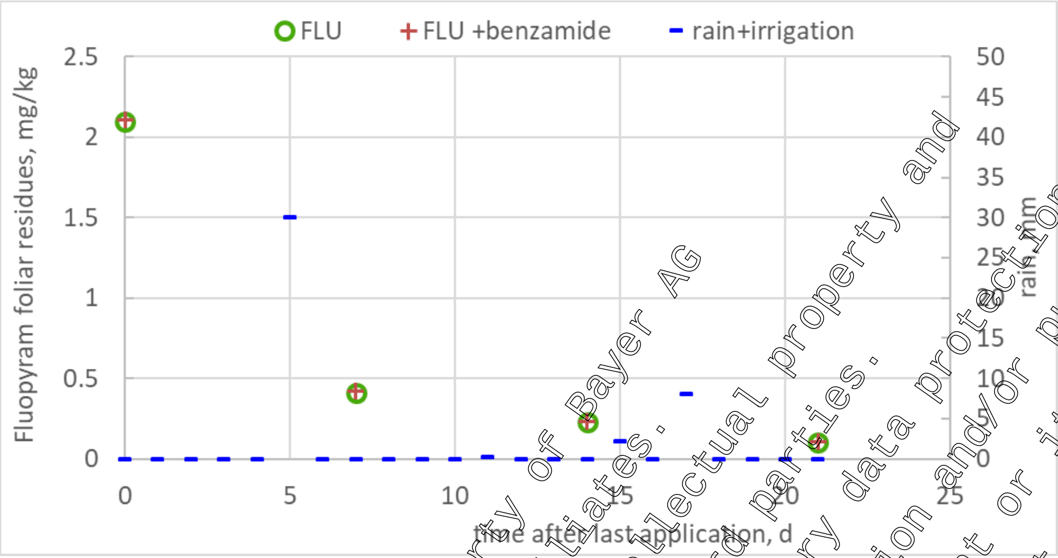


Figure 8.9- 198: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to onion, Welsh.

Irrigation on day 5 coincides with a moderate decline of residue levels at day 7 (influence likely)

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400 on onion, Welsh in two residue trials conducted in southern Europe (southern France and Italy) during the 2006 season, the residues of fluopyram in/on onion, Welsh (whole plant without roots) declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in eight samples with a maximum value of 0.06 mg/kg. Residues of fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

<u>**Assessment and conclusion by applicant:**</u> The study and its data are considered as acceptable and reliable for use in risk assessment. Irrigation in both trials may have moderately influenced residue decline, but irrigation a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/46
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on leek after spraying of AE C656948 & HWG 1608 (400 SC) in the field in (the) Northern France, Germany and United Kingdom
Report No:	RA-2569/06
Document No:	M-292101-02-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 - Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in northern Europe (northern France, United Kingdom, and 2 x Germany) on leek during the 2006 season. Two applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram were conducted. Only the parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after two spray applications of the Fluopyram + Tebuconazole 400 SC on leek whole plants without roots declined markedly during the sampling period. The residues of metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram + Tebuconazole 400 SC
	Batch no.:	2006-000763
	Active Ingredient	Fluopyram + tebuconazole
	Storage:	Not stated in the report
	Expiry date:	2007-02-14
2.	Test commodity:	Leek
	Crop part:	Whole plant without roots

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2569/06 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on leek (whole plant without roots) after two spray applications with Fluopyram + Tebuconazole 400 SC a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included four supervised residue trials conducted in northern Europe (northern France, United Kingdom, and 2 x Germany) during the 2006 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 636: Description of the trial locations and cropping information on treated plots

Trial number	R 2006 0343/6	R 2006 0465/3	R 2006 0466/1	R 2006 0468/8
Trial location	F-80500 Faverolles (Picardie)	D-40764 Langenfeld-Reusrath (Nordrhein-Westfalen)	GB-PE15 6NA CHATTERIS (Cambridgeshire)	D-53332 Bornheim - Sechtem (Nordrhein-Westfalen)
Country	Northern France	Germany	United Kingdom	Germany
Area of application	Field	Field	Field	Field
Plot size [m^2]	45	33	25	52.5
Type of soil	Clay silt	Loamy sand	Bog soil	Sandy loam
pH-value of soil (in water)	7.9	6.9	7.0	7.0
Content of organic C [%]	1.4	1.7	18.6	1.0
Test system	Leek	Leek	Leek	Leek
Variety	Diana	Pandora	Shelton	Amundo
Date of sowing	2006-03-15	2006-04-22	2006-05-03	2006-07-10
Date of commercial harvest	2006-11-16 to 2006-11-30	2006-08-15 to 2006-09-05	2006-11-30	2006-10-09 to 2006-11-10

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stages between 43-47 and the second at BBCH 45-49 with an application rate of 0.2 kg a.s./ha and a water rate of 300 L/ha.

Table 8.9- 637: Overview on application with Fluopyram +Tebuconazole SC 400 on leek

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
R 2006 0343/6 Northern France	1	T	Fluopyram + Tebuconazole SC 400	SPI	14	47	28	1	300	Fluopyram tebucon-azole	0.2
	2					48	14*				0.2
R 2006 0465/3 Germany	1	T	Fluopyram + Tebuconazole SC 400	SPI	14	43	28	1	300	Fluopyram tebucon-azole	0.2
	2					45	14*				0.2
R 2006 0466/1 United Kingdom	1	T	Fluopyram + Tebuconazole SC 400	SPI	14	45	28	1	300	Fluopyram tebucon-azole	0.2
	2					45	14*				0.2
R 2006 0468/8 Germany	1		Fluopyram + Tebuconazole SC 400	SPI	14	44	28	1	300	Fluopyram tebucon-azole	0.2
	2					49	14*				0.2

a.s.: Active substance; Appl.: Application; SPI: Spraying
DBH: Days before harvest; PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of leek. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 638: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2006 0343/6 R 2006 0465/3 R 2006 0466/1 R 2006 0468/8	Leek	Whole plant without roots	C	-0
				14
				21
			T	-0
				0
				7
				7
				14
				28

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 639: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in leek whole plant without root)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram, fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 640: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	108; 100; 96; 107; 102	103	4.9	0.01
	0.1	102; 105; 99; 104	103	2.6	
	2	92	92	--	
		Overall recovery (n = 10)	**102**	**4.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 641: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	90; 84; 86; 109; 90	92	10.8	0.01
	0.1	101; 103; 103; 100	102	1.5	
	2	87	87	--	
		Overall recovery (n = 10)	**95**	**9.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 642: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	98; 83; 100; 86; 83	90	9.3	0.01
	0.1	84; 80; 82; 86	83	3.1	
	2	80	80	--	
		Overall recovery (n = 10)	**86**	**8.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 643: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	97; 69; 89; 113; 94	92	17.2	0.01
	0.1	82; 90; 86; 93	88	5.5	
	2	93	93	--	
		Overall recovery (n = 10)	**91**	**12.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 181 and 308 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on leek (whole plant without root) are summarised in the following table.

Table 8.9- 644: Residue summary of fluopyram in/on leek, whole plant without root

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0343/6 Northern France	Whole plant without root	48	-0	0.18	<0.01	<0.01	<0.01
	Whole plant without root	48	0	2.1	<0.01	<0.01	<0.01
	Whole plant without root	48	7	1.2	<0.01	<0.01	<0.01
	Whole plant without root	49	14	0.67	<0.01	<0.01	<0.01
	Whole plant without root	49	21	0.32	<0.01	<0.01	<0.01
	Whole plant without root	49	28	0.20	<0.01	<0.01	<0.01
R 2006 0465/3 Germany	Whole plant without root	45	-0	0.06	<0.01	<0.01	<0.01
	Whole plant without root	45	0	0.68	<0.01	<0.01	<0.01
	Whole plant without root	47	7	0.08	<0.01	<0.01	<0.01
	Whole plant without root	47	14	0.03	<0.01	<0.01	<0.01
	Whole plant without root	49	21	0.02	<0.01	<0.01	<0.01
	Whole plant without root	49	28	0.02	<0.01	<0.01	<0.01
R 2006 0466/1 United Kingdom	Whole plant without root	45	-0	0.06	<0.01	<0.01	<0.01
	Whole plant without root	45	0	1.1	<0.01	<0.01	<0.01
	Whole plant without root	45	7	0.55	<0.01	<0.01	<0.01
	Whole plant without root	45	15	0.12	<0.01	<0.01	<0.01
	Whole plant without root	45	21	0.06	<0.01	<0.01	<0.01
	Whole plant without root	45	28	0.07	<0.01	<0.01	<0.01
R 2006 0468/8 Germany	Whole plant without root	49	-0	0.27	<0.01	<0.01	<0.01
	Whole plant without root	49	0	0.97	<0.01	<0.01	<0.01
	Whole plant without root	49	7	0.67	<0.01	<0.01	<0.01
	Whole plant without root	49	15	0.23	<0.01	<0.01	<0.01
	Whole plant	49	22	0.17	<0.01	<0.01	<0.01

	without root						
	Whole plant without root	49	28	0.14	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on leek

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 645: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0343/6 Faverolles, FR, M-292101-02-1						Meteo France Rouvroy en Santerre (25 km), study raw data	no	Meteo France Rouvroy en Santerre (25 km), study raw data
leek, green material	48	02/11/2006	0	2.1	FLU-benz	0		5.6
		03/11/2006	1		<LOD	0		6.4
		04/11/2006	2			0		4.9
		05/11/2006	3			0		4.5
		06/11/2006	4			0		6
		07/11/2006	5			0		5.2
		08/11/2006	6			2.4		8.1
		09/11/2006	7	1.2		0		8.5
		10/11/2006	8			4.8		3.6
		11/11/2006	9			0.8		9.4
		12/11/2006	10			0		8.5
		13/11/2006	11			1.4		11.5
		14/11/2006	12			0.2		13.1
		15/11/2006	13			0		12.8
		16/11/2006	14	0.67		4.4		13
		17/11/2006	15			1.2		10.5
		18/11/2006	16			8.4		8
		19/11/2006	17			1.2		6.2
		20/11/2006	18			1.6		8.3
		21/11/2006	19			5.2		6.9
		22/11/2006	20			3.4		6.7
		23/11/2006	21	0.32		4		11
		24/11/2006	22			1.4		11
		25/11/2006	23			0.6		13.2
		26/11/2006	24			0		9.8
		27/11/2006	25			0		10.5
		28/11/2006	26			1		9.6
		29/11/2006	27			0		6.7
		30/11/2006	28	0.2		0		4.6

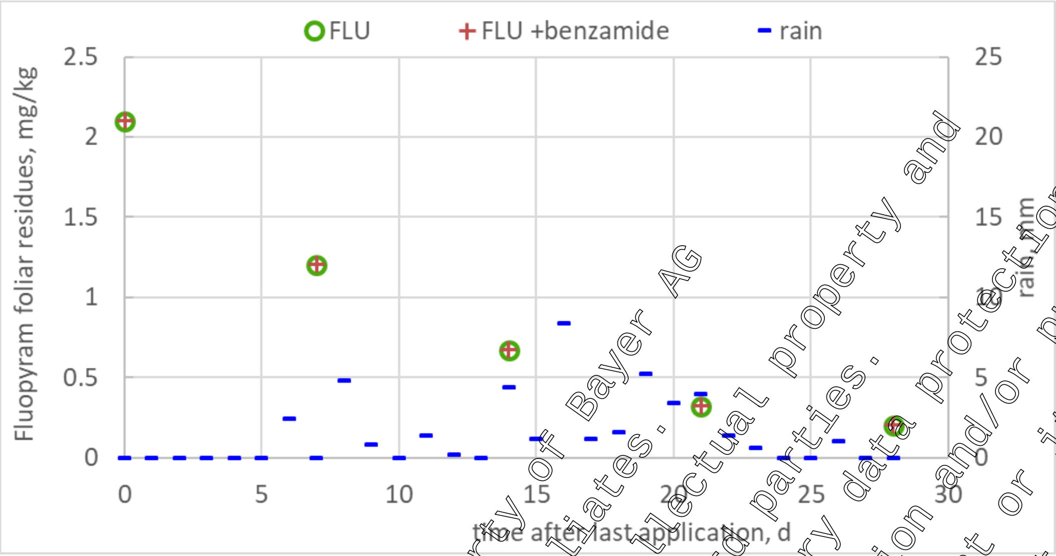


Figure 8.9- 199: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek

Frequent rainfall occurred following day 6 of the trial, an influence is not discernable.

Table 8.9- 646: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0465/3 Langenfeld-Reusrath, DE, M-292101-02-1 leek, green material						ProPlant DB LWZ Monheim (3 km)	no	ProPlant DB LWZ Monheim (3 km)
	45	08/08/2006	0	0.68	FLU-benz	0		17.5
		09/08/2006	1		<LOD	3.1		15.5
		10/08/2006	2			6.3		13.1
		11/08/2006	3			4.4		12.9
		12/08/2006	4			4.5		13.5
		13/08/2006	5			0		14.9
		14/08/2006	6			4.1		13.5
		15/08/2006	7	0.08		16.9		15.3
		16/08/2006	8			0		17.1
		17/08/2006	9			1.5		18.8
		18/08/2006	10			30.2		18.4
		19/08/2006	11			4.5		17.4
		20/08/2006	12			2.6		16.2
		21/08/2006	13			9.8		15.6
		22/08/2006	14	0.03		2.1		15.8
		23/08/2006	15			0		16.3
		24/08/2006	16			4.7		15.8
		25/08/2006	17			1.9		15.1
		26/08/2006	18			3		15.4
		27/08/2006	19			1.8		15.5
		28/08/2006	20			26.8		12.8
		29/08/2006	21	0.02		6.9		12.1
		30/08/2006	22			1.8		12.4
		31/08/2006	23			0		14.4
		01/09/2006	24			0		19.3
		02/09/2006	25			0		18.7
		03/09/2006	26			3.4		19.8
		04/09/2006	27			0		19
		05/09/2006	28	0.02		0		17.1

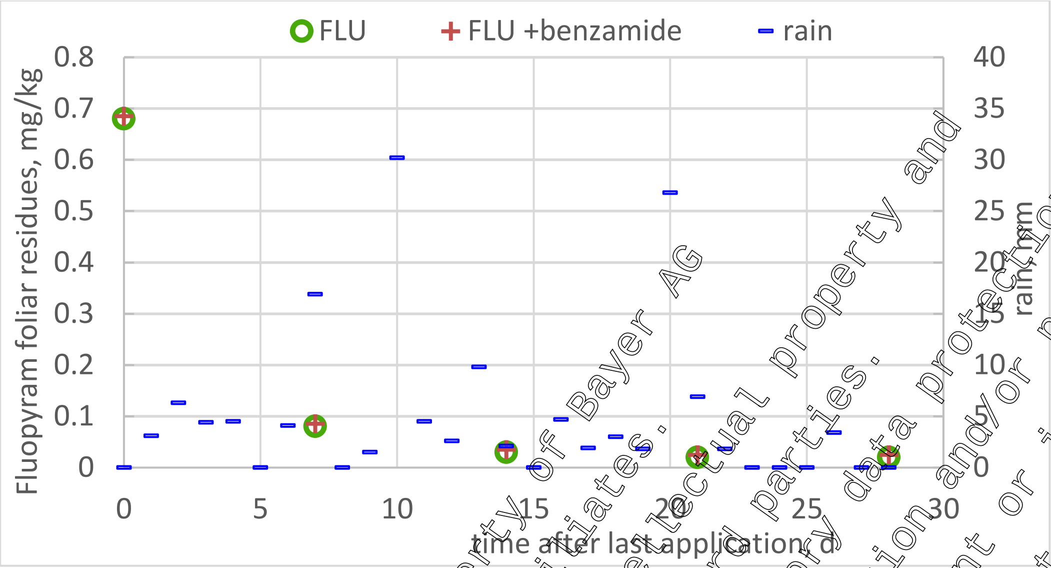


Figure 8.9- 200: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Frequent early rainfall coincides with a marked drop of residue levels, influence likely.

Table 8.9- 647: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0466/1 Chatteris, GB,						Brooms Barn (32 km) Bayer raw data	no	Brooms Barn (32 km) Bayer raw data
M-292101-02-1	45	02/11/2006	0	1.1	FLU-benz	0		4.3
		03/11/2006	1		<LOD	0		5.2
leek, green material		04/11/2006	2			0		6
		05/11/2006	3			0		8.2
		06/11/2006	4			0.2		8.75
		07/11/2006	5			0		6.05
		08/11/2006	6			0.4		9.1
		09/11/2006	7	0.55		0.2		7.6
		10/11/2006	8			4.9		6.1
		11/11/2006	9			1.5		7.8
		12/11/2006	10			3.5		8.85
		13/11/2006	11			0		10.2
		14/11/2006	12			5.5		10.85
		15/11/2006	13			7.5		12.45
		16/11/2006	14			3.3		10
		17/11/2006	15	0.12		20.5		8.15
		18/11/2006	16			0.2		5.75
		19/11/2006	17			0.9		6.5
		20/11/2006	18			0		8.35
		21/11/2006	19			0.4		5.85
		22/11/2006	20			14.1		7.95
		23/11/2006	21	0.06		0		7.85
		24/11/2006	22			6		9.75
		25/11/2006	23			5.7		10.3
		26/11/2006	24			0.5		8.5
		27/11/2006	25			1.1		11.05
		28/11/2006	26			0.5		10.5
		29/11/2006	27			0		8.05
		30/11/2006	28	0.07		0.5		7.8

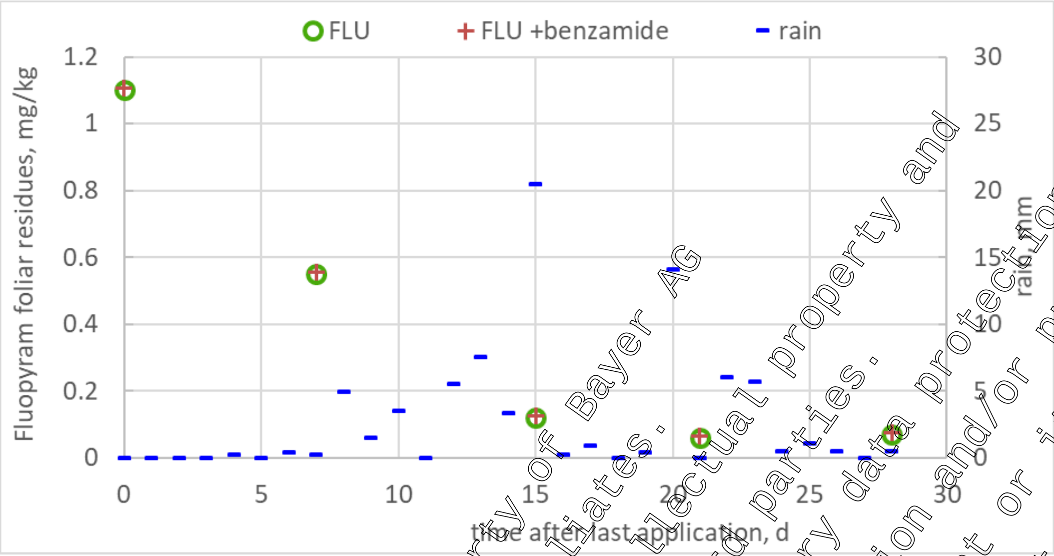


Figure 8.9- 201: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Frequent rainfall after day 7 did not seem to have any discernable influence on residue dissipation

Table 8.9- 648: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg ai eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0468/8 Bornheim – Sechtem, DE, M-292101-02-1 leek, green material						DWD Köln-Bonn (25 km) [a]	trickle and sprinkler	DWD Köln-Bonn (25 km) [a]
	49	25/09/2006	0	0.97	FLU-benz	0		16.5
		26/09/2006	1		<LOD	0.8		16.3
		27/09/2006	2			0		15.9
		28/09/2006	3			0		16.2
		29/09/2006	4			3.2		17.5
		30/09/2006	5			1.5		17.7
		01/10/2006	6			0.1		17.3
		02/10/2006	7	0.67		0		16.1
		03/10/2006	8			2.3		13.9
		04/10/2006	9			4		12.7
		05/10/2006	10			8.1		13
		06/10/2006	11			7.3		15
		07/10/2006	12			0.2		13.1
		08/10/2006	13			0		11.4
		09/10/2006	14			0	30	13.7
		10/10/2006	15	0.23		0		15
		11/10/2006	16			0		15.2
		12/10/2006	17			0.3		16.5
		13/10/2006	18			0		15.1
		14/10/2006	19			0		12.7
		15/10/2006	20			0		10.8
		16/10/2006	21			0		9.8
		17/10/2006	22	0.17		0		11.2
		18/10/2006	23			0		13.6
		19/10/2006	24			1.5		14.1
		20/10/2006	25			1.3		15.8
		21/10/2006	26			0		15.4
		22/10/2006	27			1		15.2
		23/10/2006	28	0.14		6.9		16.6

[a] https://opendata.dwd.de/climate_environment/CDC/

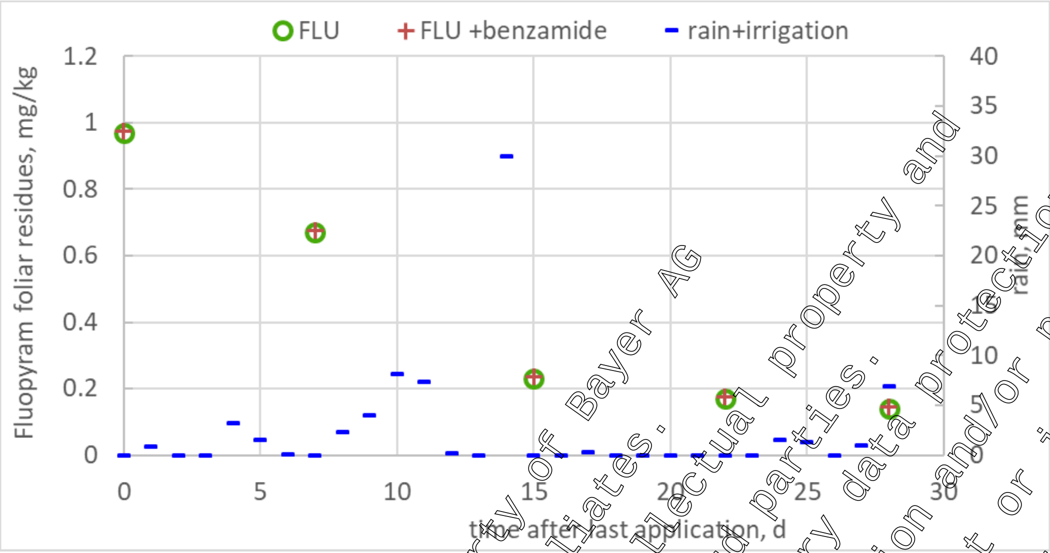


Figure 8.9- 202: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Frequent rainfall after day 7, and 30 mm irrigation on day 14 coincide with a moderate drop of residue levels on day 15 (influence likely).

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400" on leek in four residue trials conducted in northern Europe (northern France, United Kingdom, and 2 x Germany) during the 2006 season, the residues of fluopyram in/on leek (whole plant without root) declined markedly during the sampling period. The residues of metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Frequent rainfall occurred in all 4 trials but did not seem to have any observable influence on residue levels in trials R 2006 0343/6 and R 2006 0466/1 where the rainfall occurred later than in R 2006 0465/3 where early rainfall coincided with a marked decline of residues. In trial R 2006 0468/8, frequent late rainfall and heavy irrigation coincide with a moderate drop of residue levels on day 15.

However, rain is a natural and irrigation a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/47
Report Author:	[redacted]
Report Year:	2007
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on leek after spraying of AE C656948 & HWG 1608 (400 SC) in the field in (the) Southern France and Spain
Report No:	RA-2570/06
Document No:	M-292082-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 - Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in southern Europe (southern France and Spain) on leek during the 2006 season. Two applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram were conducted. Only the parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after two spray applications of the Fluopyram + Tebuconazole 400 SC on leek (whole plants without roots) declined markedly during the sampling period. Residues of fluopyram-benzamide and fluopyram-pyridyl-carboxylic acid were detected slightly above the LOQ of 0.01 mg/kg in 6 samples with a maximum value of 0.02 mg/kg and in 3 samples with a maximum value of 0.01 mg/kg, respectively. The residues of metabolite fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram + Tebuconazole 400 SC
   Batch no.: 2006-000763
   Active Ingredient: Fluopyram + tebuconazole
   Storage: Not stated in the report
   Expiry date: 2007-02-14
2. Test commodity: Leek
   Crop part: Whole plant without roots

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2570/06 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on leek (whole plant without roots) after two spray applications with Fluopyram + Tebuconazole 400 SC a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included two supervised residue trials conducted in in southern Europe (southern France and Spain) during the 2006 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 649: Description of the trial locations and cropping information on treated plots

Trial number	R 2006 0344/4	R 2006 0469/6
Trial location	F-69270 Cailloux sur Fontaines (Rhone-Alpes)	E-41740 Lebrija Sevilla (Andalucia)
Country	Southern France	Spain
Area of application	Field	Field
Plot size [m^2]	20	33.8
Type of soil	Silty loam	Loamy sand
pH-value of soil (in water)	7.2	8.4
Content of organic C [%]	0.7	0.3
Test system	Leek	Leek
Variety	Ahton	Shelton
Date of planting	2006-06-14	2006-02-02
Date of commercial harvest	2006-09-20 to 2006-10-30	2006-05-05 to 2006-06-30

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stages between 43-44 and the second at BBCH 45 with an application rate of 0.2 kg a.s./ha and a water rate of 400-600 L/ha.

Table 8.9- 650: Overview on application with Fluopyram +Tebuconazole SC 400 on leek

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
R 2006 0344/4 Southern France	1	T	Fluopyram + Tebucon-azole SC 400	SPI	14	44	28	1	600	Fluopyram, tebucon-azole	0.2
	2					45	14				0.2
R 2006 0469/6 Spain	1	T	Fluopyram + Tebucon-azole SC 400	SPI	14	43	28	1	400	Fluopyram, tebucon-azole	0.2
	2					45	14				0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of leek. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 651: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2006 0344/4 R 2006 0469/6	Leek	Whole plant without root	C	-0
				14
				21
			T	-0
				0
				7
				7
				14
				28

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 652: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in leek whole plant without root)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The mean values of the concurrent recoveries were within the acceptable range of 70 – 110%. Consequently, all the results are considered as valid although the RSD values for fluopyram and fluopyram-benzamide were not below 20%. Details are given in the table below.

Table 8.9- 653: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	118	118	-	0.01
	0.5	105	105	-	
	2	78	78	-	
		Overall recovery (n = 3)	**100**	**20.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 654: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	129	129	-	0.01
	0.5	98	98	-	
	2	80	80	-	
		Overall recovery (n = 3)	**102**	**24.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 655: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	96	96	-	0.01
	0.5	92	92	-	
	2	71	71	-	
		Overall recovery (n = 3)	**86**	**15.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 656: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	110	110	-	0.01
	0.5	85	85	-	
	2	98	98	-	
		Overall recovery (n = 3)	**98**	**12.8**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 238 and 364 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on leek (whole plant without root) are summarised in the following table.

Table 8.9- 657: Residue summary of fluopyram in/on leek, whole plant without root

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0344/4 Southern France	Whole plant without root	45	-0	0.12	<0.01	<0.01	<0.01
	Whole plant without root	45	0	1.1	0.01	<0.01	<0.01
	Whole plant without root	45	7	0.37	0.02	<0.01	<0.01
	Whole plant without root	47	14	0.28	0.02	<0.01	<0.01
	Whole plant without root	47	21	0.17	0.01	<0.01	<0.01
	Whole plant without root	47	29	0.05	<0.01	<0.01	<0.01
R 2006 0469/6 Spain	Whole plant without root	45	-0	0.02	0.01	<0.01	<0.01
	Whole plant without root	45	0	0.32	0.01	<0.01	<0.01
	Whole plant without root	45	7	0.18	<0.01	<0.01	<0.01
	Whole plant without root	47	14	0.07	<0.01	<0.01	0.01
	Whole plant without root	48	20	0.04	<0.01	<0.01	0.01
	Whole plant without root	48	28	0.02	<0.01	<0.01	0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on leek

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 658: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0344/4 Cailloux sur Fontaines, FR,						Meteo France Lyon Bron (14 km), study raw data	sprinkler	Meteo France Lyon Bron (14 km), study raw data
M-292082-01-1	45	07/09/2006	0	1.1	1.11	0	-	24.2
		08/09/2006	1			0		19.2
leek, green material		09/09/2006	2			0		21.4
		10/09/2006	3			0		24.2
		11/09/2006	4			0		23.9
		12/09/2006	5			0		23.2
		13/09/2006	6			1.6		22.7
		14/09/2006	7	0.37	0.39	9.2		21.5
		15/09/2006	8			25		18
		16/09/2006	9			0		18.2
		17/09/2006	10			0		19.3
		18/09/2006	11			0		19
		19/09/2006	12			0		18.2
		20/09/2006	13			0.2		18.4
		21/09/2006	14	0.28	0.3	0		21.7
		22/09/2006	15			0		21.5
		23/09/2006	16			0.2		21.7
		24/09/2006	17			4.2		19
		25/09/2006	18			0		15.4
		26/09/2006	19			0		16.3
		27/09/2006	20			0		15.5
		28/09/2006	21	0.17	0.18	0.2		16.5
		29/09/2006	22			2.2		18.8
		30/09/2006	23			3.8		20.5
		01/10/2006	24			4.2		19.5
		02/10/2006	25			0		20.7
		03/10/2006	26			10.8		17.6
		04/10/2006	27			0.4		12.7
		05/10/2006	28			0		13.4
		06/10/2006	29	0.05	0.055 a)	5.2		15.9

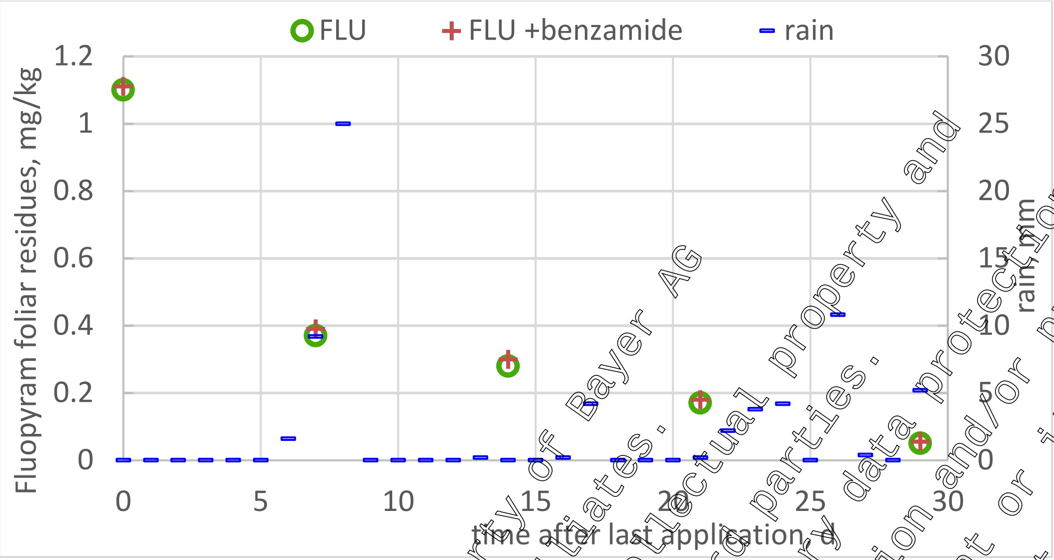


Figure 8.9- 203: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek

Rainfall on days 6 (1.6 mm) and 7 (9.2 mm) coincides with a moderate decline of residue levels (influence possible). Later rainfall does not seem to have influenced residue levels.

Table 8.9- 659: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0469/6 Lebrija, ES, M-292082-01-1 leek, green material						Lebrija 1 (6 km) [b]	sprinkler	Lebrija 1 (6 km) [b]
	45	26/05/2006	0	0.32	0.33	0		21.3
		27/05/2006	1			0	32	25.1
		28/05/2006	2			0		26.1
		29/05/2006	3			0		22.3
		30/05/2006	4			0.2	32	19.7
		31/05/2006	5			0		20.7
		01/06/2006	6			0		20.1
		02/06/2006	7	0.18	0.185 [a]	13.8	32	21.1
		03/06/2006	8			0		22.5
		04/06/2006	9			0		22.8
		05/06/2006	10			0		23.3
		06/06/2006	11			0	32	24.4
		07/06/2006	12			0.6		22.7
		08/06/2006	13			0.2		23.2
		09/06/2006	14	0.07	0.07	0	32	22.5
		10/06/2006	15			0		22.7
		11/06/2006	16			0		24.5
		12/06/2006	17			0		24.6
		13/06/2006	18			1.2	32	24.3
		14/06/2006	19			1.8		21.9
		15/06/2006	20	0.04	0.04	0		20.8
		16/06/2006	21			4		20.2
		17/06/2006	22			3	32	19.6
		18/06/2006	23			0		21.6
		19/06/2006	24			0		23.9
		20/06/2006	25			0		24.4
		21/06/2006	26			0	32	25.3
		22/06/2006	27			0		26.7
		23/06/2006	28	0.02	0.02	0		24.6

[a] for FLU-benzamide 0.5 LOD added
[b] https://www.juntadeandalucia.es/agriculturaypesca/ifapa/ria/servlet/FrontController

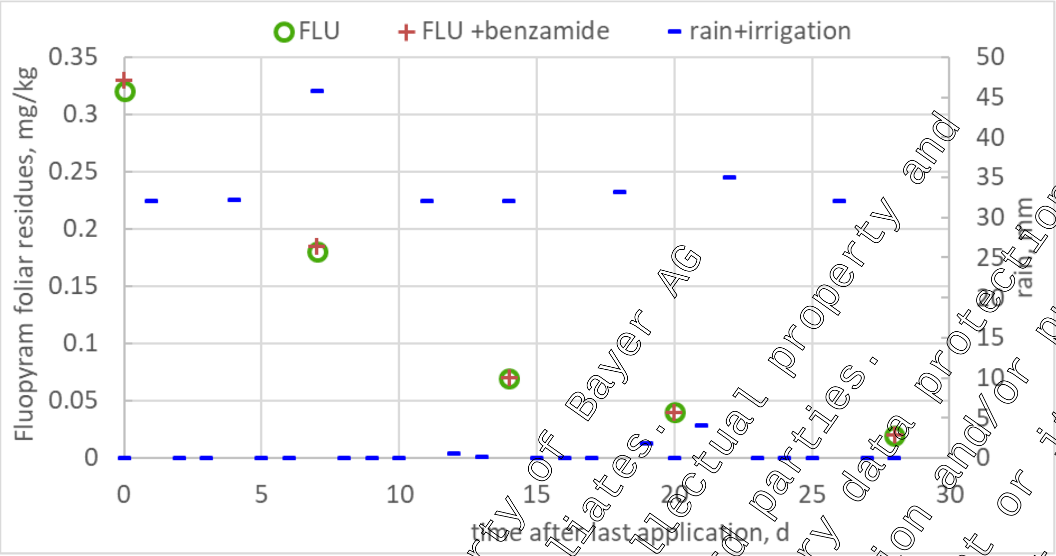


Figure 8.9- 204: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Frequent irrigation and occasional rainfall may have influenced residue dissipation, although this is not discernable in the decline pattern.

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400 on leek in two residue trials conducted in southern Europe (southern France and Spain) during the 2006 season the residues of fluopyram in/on leek (whole plant without root) declined markedly during the sampling period. Residues of fluopyram-benzamide and fluopyram-pyridyl-carboxylic acid were detected slightly above the LOQ of 0.01 mg/kg in 6 samples with a maximum value of 0.02 mg/kg and in 3 samples with a maximum value of 0.01 mg/kg, respectively. The residues of metabolite fluopyram-pyridyl-acetic acid were

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. In trial R 2006 0344/4 rainfall on day 6 and 7 may have slightly influenced residue dissipation. In trial R 2006 0469/6, frequent irrigation and occasional rainfall may have markedly influenced residue dissipation, although this is not discernable in the decline pattern.

However, rain is a natural and irrigation a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/48
Report Author:	[redacted].
Report Year:	2007
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on Chinese cabbage after spraying of AE C656948 & HWG 1608 (400 SC) in the field in (the) Northern France and United Kingdom
Report No:	RA-2573/06
Document No:	M-292103-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in northern Europe (northern France and United Kingdom) on Chinese cabbage during the 2006 season. Two applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram, were conducted. Only the parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after two spray applications of the Fluopyram + Tebuconazole 400 SC on Chinese cabbage declined markedly during the sampling period. Residues of fluopyram-benzamide, fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram + Tebuconazole 400 SC

   Batch no.: 2006-000763

   Active Ingredient: Fluopyram + tebuconazole

   Storage: Not stated in the report

   Expiry date: 2007-02-14

2. Test commodity: Chinese cabbage

   Crop part: Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2573/06 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on Chinese cabbage (head) after two spray applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included two supervised residue trials conducted in in northern Europe (northern France and United Kingdom) during the 2006 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 660: Description of the trial locations and cropping information on treated plots

Trial number	R 2006 0347/9	R 2006 0543/9
Trial location	F-78410 Bouafle (Ile-de-France)	GB-CB2 5EU Little Shelford (Cambridgeshire)
Country	Northern France	United Kingdom
Area of application	Field	Field
Plot size [m^2]	50	30
Type of soil	Clay silt	Sandy loam
pH-value of soil (in water)	8.4	8.4
Content of organic C [%]	0.6	1.3
Test system	Chinese cabbage	Chinese cabbage
Variety	Chorus F1	F1 The Blues
Date of planting/sowing	2006-08-18 / 2006-07-21	2006-06-29 / 2006-06-02
Date of commercial harvest	2006-10-20 to 2006-11-02	2006-08-11 to 2006-08-25

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stage between 19 and the second at BBCH 42-45 with an application rate of 0.2-0.212 kg a.s./ha and a water rate of 300-500 L/ha. In trial R 2006-0543/9, the second application was delayed 2 days due to wet and windy weather. In addition, the second application was 6% overdosed. This has no impact on the study since this scenario is considered to be acceptable according to current European guideline.

Table 8.9- 661: Overview on application with Fluopyram +Tebuconazole SC 400 on Chinese cabbage

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
R 2006 0347/9 Northern France	1	T	Fluopyram + Tebucon-azole SC 400	SPI	14	19	28	1	500	Fluopyram tebucon-azole	0.2
	2					45	14*				0.2
R 2006 0543/9. United Kingdom	1	T	Fluopyram + Tebucon-azole SC 400	SPI	14	19	30	1	300	Fluopyram tebucon-azole	0.2
	2					42	14*		319		0.212

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of Chinese cabbage. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 662: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2006 0347/9 R 2006 0543/9	Chinese cabbage	Head	C	-0
				14
			T	-0
				0
				3
				7
				14
				21

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 663: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in Chinese cabbage, head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The mean values of the concurrent recoveries were within the acceptable range of 70 – 110%. Details are given in the table below.

For the analysis of fluopyram-benzamide AE F148815, the MRM transition 190>170 was used due to the presence of an interfering peak at the transition 190>102.

Table 8.9- 664: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	98; 87; 86	90	7.4	0.01
	0.1	95; 96; 92; 96	95	2.0	
	5	100	--	--	
		Overall recovery (n = 8)	**94**	**5.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 665: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	98; 96; 91	95	3.8	0.01
	0.1	90; 94; 95; 88	92	3.6	
	5	94		--	
		Overall recovery (n = 8)	**93**	**3.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 666: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	86; 88; 89	88	1.7	0.01
	0.1	88; 93; 88; 91	90	2.7	
	5	89		--	
		Overall recovery (n = 8)	**89**	**2.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 667: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	96; 79; 91	89	9.9	0.01
	0.1	90; 92; 97; 87	92	4.6	
	5	92		--	
		Overall recovery (n = 8)	**91**	**6.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 226 and 315 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on Chinese cabbage (head) are summarised in the following table.

Table 8.9- 668: Residue summary of fluopyram in/on Chinese cabbage, head

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0347/9 Northern France	Head	45	-0	0.26	<0.01	<0.01	<0.01
	Head	45	0	1.5	<0.01	<0.01	<0.01
	Head	45	3	0.43	<0.01	<0.01	<0.01
	Head	47	7	0.22	<0.01	<0.01	<0.01
	Head	49	14	0.16	<0.01	<0.01	<0.01
	Head	49	21	0.12	<0.01	<0.01	<0.01
R 2006 0543/9 United Kingdom	Head	42	-0	0.13	<0.01	<0.01	<0.01
	Head	42	0	1.6	<0.01	<0.01	<0.01
	Head	43	3	1.3	<0.01	<0.01	<0.01
	Head	45	7	0.84	<0.01	<0.01	<0.01
	Head	49	14	0.15	<0.01	<0.01	<0.01
	Head	49	21	0.05	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on Chinese cabbage

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 669: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0347/9 Bouafle, FR, M-292103-01-1 cabbage, Chinese, green material						Meteo France Trappes (45 km), study raw data	no	Meteo France Trappes (45 km), study raw data
	45	09/10/2006	0	1.5	FLU-benz	0.4 (0) [a]		14
		10/10/2006	1		<LOD	0		16.1
		11/10/2006	2			1.2		16.2
		12/10/2006	3	0.43		0.2		14.2
		13/10/2006	4			0		13.9
		14/10/2006	5			0		15.8
		15/10/2006	6			0		13.5
		16/10/2006	7	0.22		0.2		14.3
		17/10/2006	8			2.2		13.9
		18/10/2006	9			1.4		14.5
		19/10/2006	10			0.2		14.9
		20/10/2006	11			0.6		14.1
		21/10/2006	12			0.6		13.7
		22/10/2006	13			2.4		15.9
		23/10/2006	14	0.16		4.6		16.2
		24/10/2006	15			1.4		12.5
		25/10/2006	16			0		14.3
		26/10/2006	17			0		17.5
		27/10/2006	18			0.4		15
		28/10/2006	19			0		14.9
		29/10/2006	20			2.4		14.8
		30/10/2006	21	0.12		0.2		10.9

[a] no rain 24 h after application, in study report

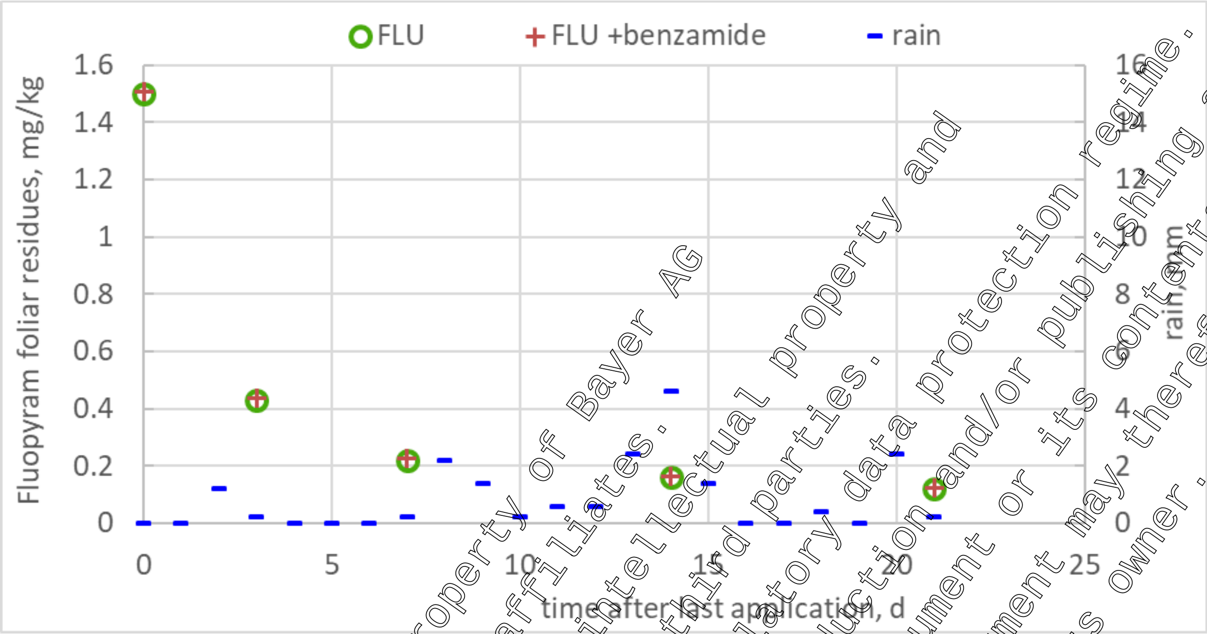


Figure 8.9- 205: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Chinese cabbage

Overall, there is frequent rainfall but in small amounts which are unlikely to have markedly influenced residue levels.

Table 8.9- 670: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0543/9 Little Shelford, GB,						Little Shelford (0 km) Bayer raw data	no	Little Shelford (0 km) Bayer raw data
M-292103-01-1	42	04/08/2006	0	1.6	FLU-benz	0		17.4
		05/08/2006	1		<LOD	0		22.1
cabbage, Chinese, green material		06/08/2006	2			0		23.6
		07/08/2006	3	1.3		0		18.2
		08/08/2006	4			1.4		21.2
		09/08/2006	5			0		18.1
		10/08/2006	6			0		17.4
		11/08/2006	7	0.84		0.8		16.3
		12/08/2006	8			5.4		14.5
		13/08/2006	9			0.4		17.7
		14/08/2006	10			0.2		14.9
		15/08/2006	11			0.2		17.1
		16/08/2006	12			0		18.3
		17/08/2006	13			11.95		18.2
		18/08/2006	14	0.15		2.78		17.9
		19/08/2006	15			10.15		17.6
		20/08/2006	16			5.98		17.8
		21/08/2006	17			4.59		17.5
		22/08/2006	18			0		17.3
		23/08/2006	19			11.94		17.5
		24/08/2006	20			0.6		16.3
		25/08/2006	21	0.05		1.8		17.7

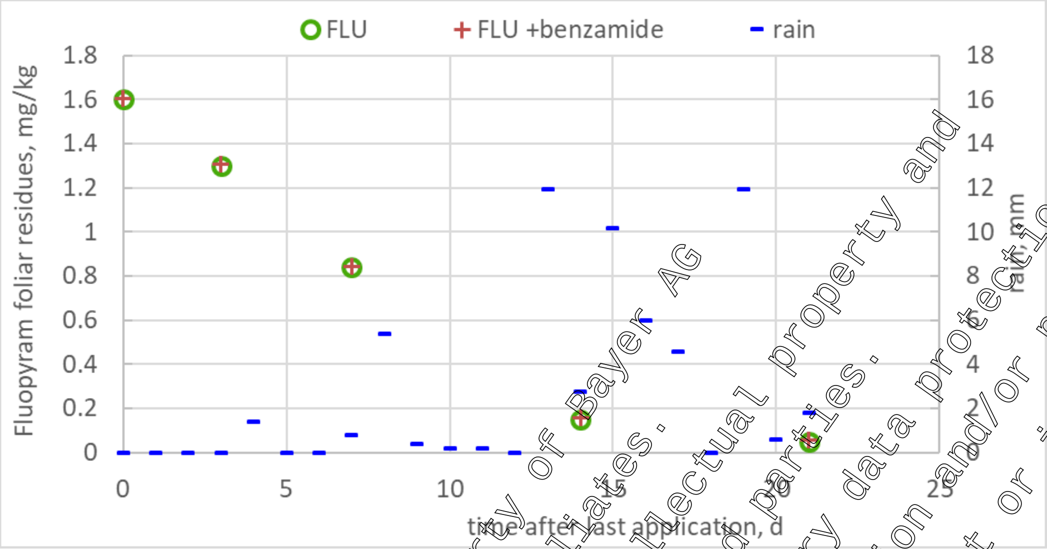


Figure 8.9- 206: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Chinese cabbage.

There was little rainfall until day 8. An influence on residue dissipation is not discernable.

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400 on Chinese cabbage in two residue trials conducted in northern Europe (northern France and United Kingdom) during the 2006 season the residues of fluopyram in/on Chinese cabbage (head) declined markedly during the sampling period. Residues of fluopyram-benzamide, fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant: The study and its data are considered as acceptable and reliable for use in risk assessment. Rainfall did not appear to influence the residue decline.

Data Point:	KCA 8.9/49
Report Author:	[redacted]
Report Year:	2007
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on Chinese cabbage after spraying of AE C656948 & HWG 1608 (400 SC) in the field in (the) Southern France and Italy
Report No:	RA-2574/06
Document No:	M-293182-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 - Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in southern Europe (southern France and Italy) on Chinese cabbage during the 2006 season. Two applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram were conducted. Only the parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after two spray applications of the Fluopyram + Tebuconazole 400 SC on Chinese cabbage declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in seven samples above the LOQ and residues of fluopyram-pyridyl-carboxylic acid were detected in four samples above the LOQ, both analytes with maximum values of 0.03 mg/kg. Residues of fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram + Tebuconazole 400 SC
   Batch no.: 2006-000763
   Active Ingredient: Fluopyram + tebuconazole
   Storage: Not stated in the report
   Expiry date: 2007-02-14
2. Test commodity: Chinese cabbage
   Crop part: Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2574/06 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on Chinese cabbage (head) after two spray applications with Fluopyram + Tebuconazole 400 SC a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included two supervised residue trials conducted in in southern Europe (southern France and Italy) during the 2006 season. A deviation occurred in trial no R 2006 0544/7. Due to unexpected high temperatures in this period in Southern Italy the sampling size of Chinese cabbage had to be reduced from 12 to 8. There is no impact on the study. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 671: Description of the trial locations and cropping information on treated plots

Trial number	**R 2006 0348/7**	**R 2006 0544/7**
Trial location	F-86380 Ouzilly (Poitou-Charentes)	I-70031 Andria (BA) (Puglia)
Country	Southern France	Italy
Area of application	Field	Field
Plot size [m^2]	30	80
Type of soil	Silty sand	Clay sand
pH-value of soil (in water)	8.2	8.0
Content of organic C [%]	1.2	1.7
Test system	Chinese cabbage	Chinese cabbage
Variety	Kaboko	Taranko
Date of planting/sowing	- / 2006-07-11	2006-08-23 / -
Date of commercial harvest	2006-09-15 to 2006-09-30	2006-11-01 to 2006-11-30

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stages 43-44 and the second at BBCH stage 47 with an application rate of 0.2 kg a.s./ha and a water rate of 600 L/ha.

Table 8.9- 672: Overview on application with Fluopyram +Tebuconazole SC 400 on Chinese cabbage

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2006 0348/7 Southern France	1	T	Fluopyram + Tebucon-azole SC 400	SPI	14	43	28	1	600	Fluopyram tebucon-azole	0.2
	2					47	14*				0.2
R 2006 0544/7 Italy	1	T	Fluopyram + Tebucon-azole SC 400	SPI	14	44	28	1	600	Fluopyram tebucon-azole	0.2
	2					47	14*				0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of Chinese cabbage. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 673: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2006 0348/7 R 2006 0544/7	Chinese cabbage	Head	C	-0
				14
			T	-0
				0
				3
				7
				14
				21

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 674: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in Chinese cabbage, head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The mean values of the concurrent recoveries were within the acceptable range of 70 – 110%. Details are given in the table below.

Table 8.9- 675: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	95	--	--	0.01
	0.1	97	--	--	
	5	90	--	--	
		Overall recovery (n = 3)	**94**	**3.8**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 676: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	98	--	--	0.01
	0.1	105	--	--	
	5	92	--	--	
		Overall recovery (n = 3)	**98**	**6.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 677: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	95	--	--	0.01
	0.1	92	--	--	
	5	86	--	--	
		Overall recovery (n = 3)	**91**	**5.0**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 678: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	104	--	--	0.01
	0.1	89	--	--	
	5	93	--	--	
		Overall recovery (n = 3)	**95**	**8.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 208 and 280 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on Chinese cabbage (head) are summarised in the following table.

Table 8.9- 679: Residue summary of fluopyram in/on Chinese cabbage, head

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2006 0348/7 Southern France	Head	47	-0	0.12	<0.01	<0.01	<0.01
	Head	47	0	1.50	<0.01	<0.01	<0.01
	Head	47	3	0.44	0.01	<0.01	<0.01
	Head	48	7	0.21	<0.01	<0.01	<0.01
	Head	49	14	0.17	<0.01	<0.01	<0.01
	Head	49	21	0.08	<0.01	<0.01	<0.01
R 2006 0544/7 Italy	Head	47	-0	0.02	0.02	<0.01	<0.01
	Head	47	0	0.57	0.02	<0.01	<0.01
	Head	47	3	0.13	0.03	<0.01	0.02
	Head	48	7	0.10	0.03	<0.01	0.02
	Head	49	14	0.03	0.03	<0.01	0.03
	Head	49	21	0.03	0.02	<0.01	0.03

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on Chinese cabbage

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 680: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0348/7 Ouzilly, FR, M-293182-01-1						Meteo France Portiers Biard (20 km), study raw data	no	Meteo France Portiers Biard (20 km), study raw data
cabbage, Chinese, green material	47	05/09/2006	0	1.5	FLU-benz	0		23.3
		06/09/2006	1		<LOD	0		22.8
		07/09/2006	2			0		22.5
		08/09/2006	3	0.44		0		18.9
		09/09/2006	4			0		18.5
		10/09/2006	5			0.2		20.2
		11/09/2006	6			0		22.6
		12/09/2006	7	0.21		0		20.2
		13/09/2006	8			4.4		20.8
		14/09/2006	9			13.8		16.4
		15/09/2006	10			24		15.3
		16/09/2006	11			10.4		16.6
		17/09/2006	12			0.2		17.2
		18/09/2006	13			0.2		17.3
		19/09/2006	14	0.17		1.2		16.3
		20/09/2006	15			0		18.7
		21/09/2006	16			9.2		21.5
		22/09/2006	17			4.6		17.6
		23/09/2006	18			0.6		17
		24/09/2006	19			4.4		15.9
		25/09/2006	20			0.2		15
		26/09/2006	21	0.08		0		13.8

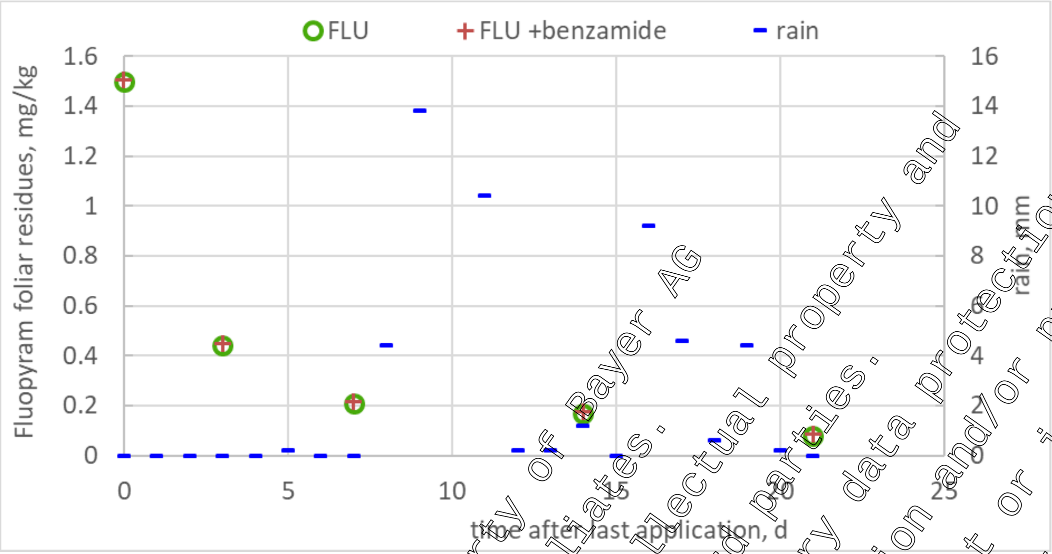


Figure 8.9- 207: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Chinese cabbage

There was little rainfall until day 8. An influence on residue dissipation is not discernible.

Table 8.9- 681: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2006 0544/7 Andria, IT, M-293182-01-1						Bonifica di Capitanata, Trinitapoli (21 km), study raw data	trickle	Bonifica di Capitanata, Trinitapoli (21 km), study raw data
cabbage, Chinese, green material	47	27/10/2006	0	0.57	0.59	0.2 (0) [a]		17.37
		28/10/2006	1			0		19.07
		29/10/2006	2			0.2		17.33
		30/10/2006	3	0.13	0.16	0.4		16.31
		31/10/2006	4			0		11.71
		01/11/2006	5			0		13.04
		02/11/2006	6			2		12.59
		03/11/2006	7	0.1	0.13	1.6		6.89
		04/11/2006	8			0.2		4.49
		05/11/2006	9			0		7.87
		06/11/2006	10			0		11.55
		07/11/2006	11			0		10.32
		08/11/2006	12			0		10.42
		09/11/2006	13			0		11.22
		10/11/2006	14	0.03	0.06	6.4		11.41
		11/11/2006	15			0		9.29
		12/11/2006	16			0.8		11.19
		13/11/2006	17			0		10.49
		14/11/2006	18			0		9.68
		15/11/2006	19			0.2		10.15
		16/11/2006	20			0		11.58
		17/11/2006	21	0.03	0.05	0		12.93

[a] no rain 24 h after application, in study report.

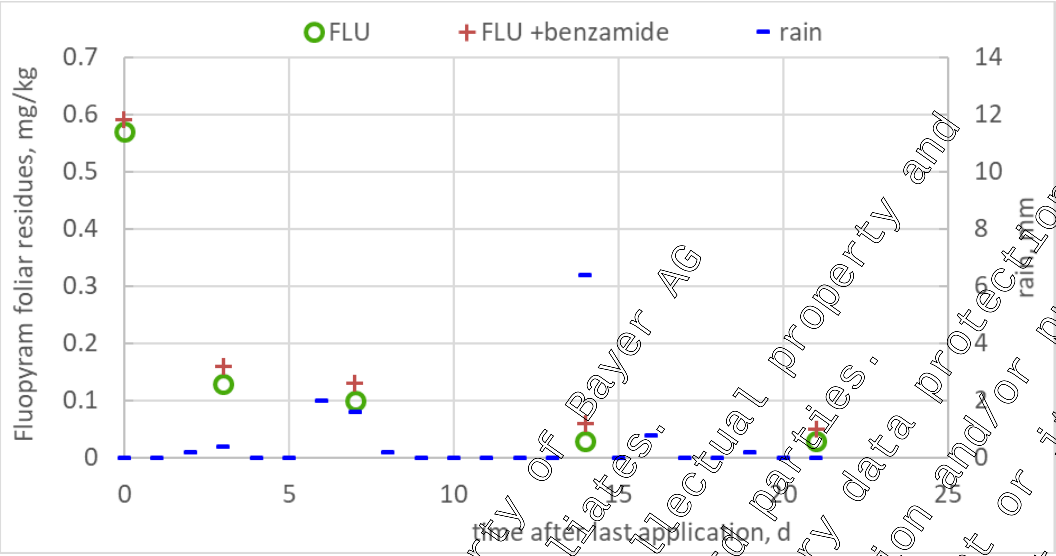


Figure 8.9- 208: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Chinese cabbage.

Very little rainfall until day 14, no influence expected or discernable

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400 on Chinese cabbage in two residue trials conducted in southern Europe (southern France and Italy) during the 2006 season the residues of fluopyram in/on Chinese cabbage (head) declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in seven samples above the LOQ and residues of fluopyram-pyridyl-carboxylic acid were detected in four samples above the LOQ, both analytes with maximum values of 0.03 mg/kg. Residues of fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant: The study and its data are considered as acceptable and reliable for use in risk assessment. There was little rainfall until late into the sampling period, and no discernable influence on residue dissipation.

Data Point:	KCA 8.9/50
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on onion, welsh after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Southern France and Italy
Report No:	RA-2520/07
Document No:	M-302325-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in southern Europe (southern France and Italy) on onion, Welsh during the 2007 season. Two applications with Fluopyram + Tebuconazole (HWG 1608) 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram, were conducted. Only the parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after two spray applications of the Fluopyram + Tebuconazole 400 SC on onion, Welsh declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in eight samples with a maximum value of 0.07 mg/kg. Residues of fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram + Tebuconazole 400 SC

   Batch no.: 2006-010059

   Active Ingredient: Fluopyram + tebuconazole

   Storage: Not stated in the report

   Expiry date: 2008-12-14

2. Test commodity: Onion, Welsh

   Crop part: Whole plant without roots

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2520/07 was to determine the magnitude of the relevant residues of fluopyram (AE C656948) and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on onion, Welsh (whole plant without roots) after two spray applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included two supervised residue trials conducted in southern Europe (southern France and Italy) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 682: Description of the trial locations and cropping information on treated plots

Trial number	R 2007 0043/1	R 2007 0568/9
Trial location	F-31200 Toulouse (Midi-Pyrenees)	I-45020 Lusia (RO) (Veneto)
Country	Southern France	Italy
Area of application	Field	Field
Plot size [m^2]	45	45
Type of soil	Clay sand	Sand
pH-value of soil (in water)	6.8	7.3
Content of organic C [%]	1.0	1.7
Test system	Onion, Welsh	Onion, Welsh
Variety	Elodie	Bianco di Lisbona
Date of planting/sowing	2007-07-06 / 2007-06-15	- / 2007-05-03
Date of commercial harvest	2007-09-15 to 2007-09-30	2007-07-25 to 2007-08-30

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stages between 43-45 and the second at BBCH 43-47 with an application rate of 0.2 kg a.s./ha and a water rate of 600 L/ha.

Table 8.9- 683: Overview on application with Fluopyram +Tebuconazole SC 400 on onion, Welsh

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2007 0043/1 Southern France	1	T	Fluopyram + Tebucon-azole SC 400	SPI	7	43	14	1	600	Fluopyram, tebucon-azole	0.2
	2					43	7*				0.2
R 2007 0568/9 Italy	1	T	Fluopyram + Tebucon-azole SC 400	SPI	7	45	14	1	600	Fluopyram, tebucon-azole	0.2
	2					47	7*				0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of onion, Welsh. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 684: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0043/1 R 2007 0568/9	Onion, Welsh	Whole plant without roots	C	-0
				7
				14
			T	-0
				0
				7
				14
				21

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 685: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in onion, Welsh, whole plant without roots)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The mean values of the concurrent recoveries were within the acceptable range of 70 – 110% with a relative standard deviation below 20% except for AE C657188 (RSD = 20.4). Details are given in the table below.

Table 8.9- 686: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	92; 90	91	--	0.01
	0.1	99	99	--	
	5	101	101	--	
		Overall recovery (n = 4)	**96**	**5.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 687: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	105; 91	98	--	0.01
	0.1	98	98	--	
	5	94	94	--	
		Overall recovery (n = 4)	**97**	**6.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 688: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	89; 84	87	--	0.01
	0.1	96	96	--	
	5	87	87	--	
		Overall recovery (n = 4)	**89**	**5.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 689: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	65; 109	87	--	0.01
	0.1	90	90	--	
	5	94	94	--	
		Overall recovery (n = 4)	**90**	**20.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 186 and 252 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on onion, Welsh (whole plant without roots) are summarised in the following table.

Table 8.9- 690: Residue summary of fluopyram in/on Onion, Welsh, whole plant without roots

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0043/1 Southern France	Whole plant without roots	43	-0	0.49	0.01	<0.01	<0.01
	Whole plant without roots	43	0	2.1	0.01	<0.01	<0.01
	Whole plant without roots	45	7	0.27	0.05	<0.01	<0.01
	Whole plant without roots	89	14	0.24	0.07	<0.01	<0.01
	Whole plant without roots	47	21	0.17	0.06	<0.01	<0.01
R 2007 0568/9 Italy	Whole plant without roots	47	-0	0.59	0.01	<0.01	<0.01
	Whole plant without roots	47	0	2.2	0.02	<0.01	<0.01
	Whole plant without roots	48	7	0.61	0.02	<0.01	<0.01
	Whole plant without roots	48	14	0.29	<0.01	<0.01	<0.01
	Whole plant without roots	48	21	0.18	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on onion, Welsh

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 691: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0043/1						Meteo France Lherm (27	sprinkler	Meteo France

Toulouse, FR,						km), study raw data		Lherm (27 km), study raw data
M-302325-01-1 Onion, Welsh / green, green material	47	07/09/2007	0	2.1	2.11	0		17.7
		08/09/2007	1			0.2		17.8
		09/09/2007	2			0.2		19.3
		10/09/2007	3			0	5	18.1
		11/09/2007	4			0		17.9
		12/09/2007	5			0		16.8
		13/09/2007	6			0		18.6
		14/09/2007	7	0.27	0.32	0		21.2
		15/09/2007	8			0		22.6
		16/09/2007	9			0		20.8
		17/09/2007	10			22	5	21.4
		18/09/2007	11			0.2		17.5
		19/09/2007	12			0.2		13.5
		20/09/2007	13			0.2		13.6
		21/09/2007	14	0.24	0.31	0.4		16.6
		22/09/2007	15			0.8		18.9
		23/09/2007	16			0.8		17.9
		24/09/2007	17			2.4	5	18.1
		25/09/2007	18			0		15.8
		26/09/2007	19			9		14.3
		27/09/2007	20			0.4		10.5
		28/09/2007	21	0.17	0.23	0		11.6

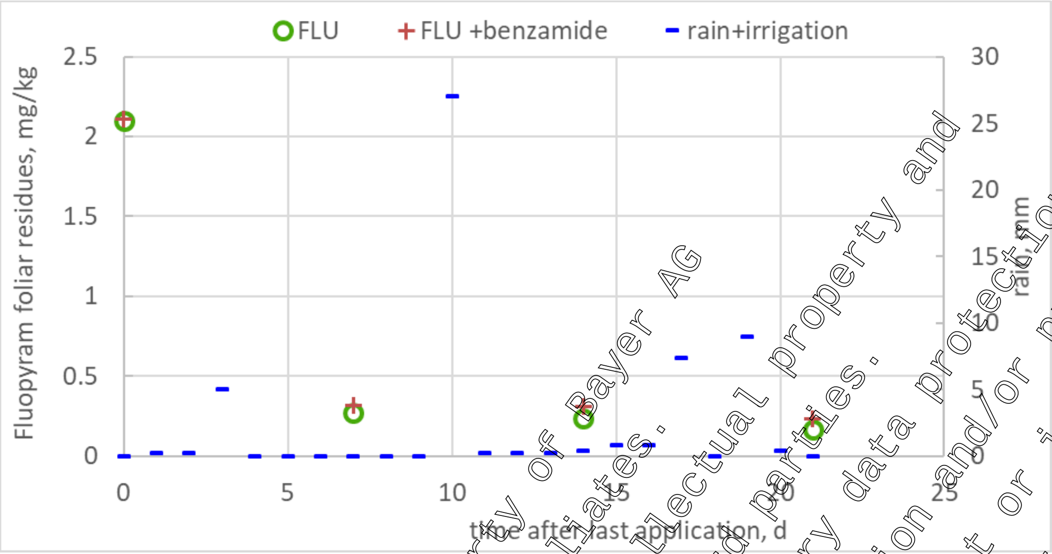


Figure 8.9- 209: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Onion, Welsh

Irrigation on day 3 (5 mm) coincides with a marked drop in residue levels. Later irrigation or rainfall had no discernible influence.

Table 8.9- 692: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0568/9 Lusia, IT, M-302325-01-1 Onion, Welsh / green, green material						www.ilmeteo.it Lusia	sprinkler	www.ilmeteo.it Lusia
	47	26/07/2007	0	2.2	2.22	0		29.6
		27/07/2007	1			0		32.2
		28/07/2007	2			0		32.7
		29/07/2007	3			0		30.9
		30/07/2007	4			0		30.6
		31/07/2007	5			0		24.6
		01/08/2007	6			0		26.2
		02/08/2007	7	0.61	0.63	0		26.5
		03/08/2007	8			0		25.4
		04/08/2007	9			0		27.6
		05/08/2007	10			0	30	27.3
		06/08/2007	11			0		28.1
		07/08/2007	12			0		29.8
		08/08/2007	13			na		27.6
		09/08/2007	14	0.29	0.295 a)	na (0) b)		24.2
		10/08/2007	15			0		24.3
		11/08/2007	16			0.8		26.6
		12/08/2007	17			0		29.1
		13/08/2007	18			0		29.2
		14/08/2007	19			0		28.7
		15/08/2007	20			0		30.2
		16/08/2007	21	0.18	0.185 a)	0		30.8

a) for FLU-benzamide 0.5 LOD added
b) missing data in ilmeteo.it; at 9.8.2007 0 mm, in study report

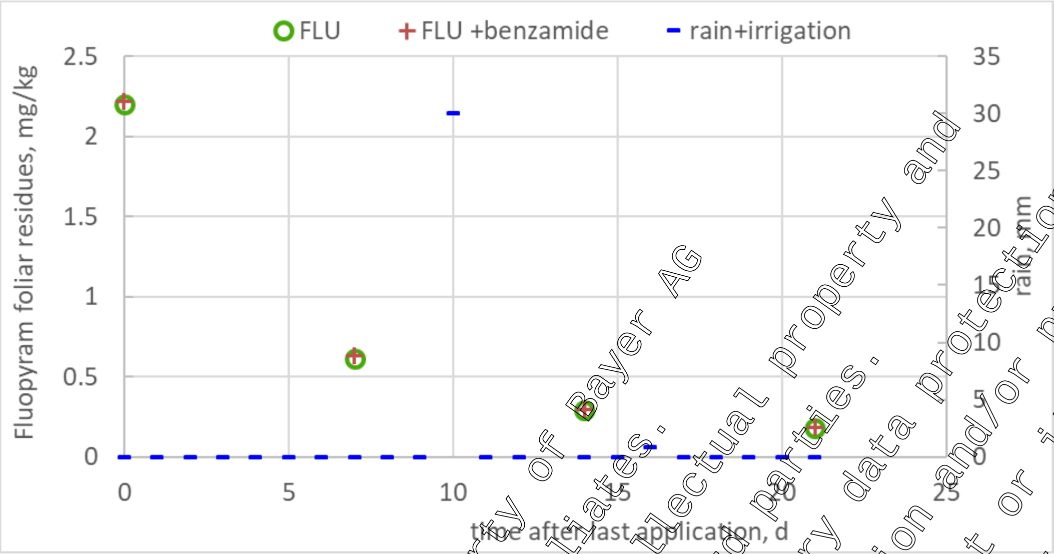


Figure 8.9- 210: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to onion, Welsh.

There was no rainfall and no discernable influence of irrigation on residue decline.

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400 on onion, Welsh in two residue trials conducted in southern Europe (southern France and Italy) during the 2007 season, the residues of fluopyram in/on onion, Welsh (whole plant without roots) declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in eight samples with a maximum value of 0.07 mg/kg. Residues of fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. There appeared to be a marked influence from early irrigation on residue decline in R 2007 0043/1 but no influence from late irrigation in R 2007 0568/9.

However, irrigation is a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/51
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on leek after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Germany, Northern France and Netherlands
Report No:	RA-2521/07
Document No:	M-304288-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 - Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with four residue trials was conducted in the field in northern Europe (2 x Germany, northern France and The Netherlands) on leek during the 2007 season. Two applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram were conducted. Only the parameters and results relevant to fluopyram and its metabolites have been reported within this study summary.

The residues of fluopyram after spray application of Fluopyram + Tebuconazole 400 SC on leek (whole plants without roots) declined markedly during the sampling period. Residues of its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram + Tebuconazole 400 SC
	Batch no.:	2006-010059
	Active Ingredient:	Fluopyram + tebuconazole
	Storage:	Not stated in the report
	Expiry date:	2008-12-14
2.	Test commodity:	Leek
	Crop part:	Whole plant without roots

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2521/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on leek (whole plant without roots) after two spray applications with Fluopyram + Tebuconazole 400 SC a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included four supervised residue trials conducted in northern Europe (2 x Germany, northern France and The Netherlands) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 693: Description of the trial locations and cropping information on treated plots

Trial number	R 2007 0056/3	R 2007 0569/7	R 2007 0570/0	R 2007 0571/9
Trial location	D-67125 Schauernheim (Rheinland-Pfalz)	F-78410 Bouafle (Ile-de-France)	NL-1681 ND Zwaagdijk-Oost (Noord-Holland)	D-40764 Langenfeld-Reusrath (Nordrhein-Westfalen)
Country	Germany	Northern France	Netherlands	Germany
Area of application	Field	Field	Field	Field
Plot size [m^2]	30	57.5	28	33
Type of soil	Sandy loam	Sand	Clay	Loamy sand
pH-value of soil (in water)	6.9	8.3	7.0	6.9
Content of organic C [%]	0.9	0.9	3.1	1.7
Test system	Leek	Leek	Leek	Leek
Variety	Nobel	St Vistor	Roxton	Pandora
Date of planting	2007-03-13	2007-07-19	2007-05-14	2007-05-03
Date of commercial harvest	2007-07-03 to 2007-07-30	2007-10-15 to 2007-12-20	2007-08-24 to 2007-09-06	2007-08-01 to 2007-08-30

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stages between 41-47 and the second at BBCH stages between 45-49 with an application rate of 0.2 kg a.s./ha and a water rate of 300-600 L/ha.

Table 8.9- 694: Overview on application with Fluopyram +Tebuconazole SC 400 on leek

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
R 2007 0056/3 Germany	1	T	Fluopyram + Tebuconazole SC 400	SPI	14	43	28	1	600	Fluopyram tebucon-azole	0.2
	2					49	14*				0.2
R 2007 0569/7 Northern France	1	T	Fluopyram + Tebuconazole SC 400	SPI	14	41	28	1	500	Fluopyram tebucon-azole	0.2
	2					45	14*				0.2
R 2007 0570/0 Nether-lands	1	T	Fluopyram + Tebuconazole SC 400	SPI	14	47	28	1	600	Fluopyram tebucon-azole	0.2
	2					48	14*				0.2
R 2007 0571/9 Germany	1		Fluopyram + Tebuconazole SC 400	SPI	14	45	28	1	300	Fluopyram tebucon-azole	0.2
	2					45	14*				0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of leek. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 695: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0056/3 R 2007 0569/7 R 2007 0570/0 R 2007 0571/9	Leek	Whole plant without root	C	-0
				14
				21
			T	-0
				0
				7
				7
				14
				28

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were analysed within the residue trials samples according to the following method:

Table 8.9- 696: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in leek whole plant without root)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 697: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	93	93		0.01
	0.1	95	95		
	0.5	91	91		
	2	97	97		
		Overall recovery (n = 4)	**94**	**2.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 698: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	86	86		0.01
	0.1	93	93		
	0.5	92	92		
	2	85	85		
		Overall recovery (n = 4)	**89**	**4.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 699: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	87	87		0.01
	0.1	85	85		
	0.5	90	90		
	2	85	85		
		Overall recovery (n = 4)	**87**	**2.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 700: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	90	90		0.01
	0.1	85	85		
	0.5	96	96		
	2	89	89		
		Overall recovery (n = 4)	**90**	**5.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 110 and 208 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on leek (whole plant without root) are summarised in the following table.

Table 8.9- 701: Residue summary of fluopyram in/on leek, whole plant without root

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0056/3 Germany	whole plant without root	49	-0	0.10	<0.01	<0.01	<0.01
	whole plant without root	49	0	0.41	<0.01	<0.01	<0.01
	whole plant without root	49	7	0.08	<0.01	<0.01	<0.01
	whole plant without root	49	14	0.04	<0.01	<0.01	<0.01
	whole plant without root	53	21	0.03	<0.01	<0.01	<0.01
	whole plant without root	54	28	0.02	<0.01	<0.01	<0.01
R 2007 0569/7 Northern France	whole plant without root	45	-0	0.05	<0.01	<0.01	<0.01
	whole plant without root	45	0	1.6	<0.01	<0.01	<0.01
	whole plant without root	47	7	0.22	<0.01	<0.01	<0.01
	whole plant without root	49	14	0.15	<0.01	<0.01	<0.01
	whole plant without root	49	21	0.09	<0.01	<0.01	<0.01
	whole plant without root	49	28	0.11	<0.01	<0.01	<0.01
R 2007 0570/0 The Nether-lands	whole plant without root	48	-0	0.07	<0.01	<0.01	<0.01
	whole plant without root	48	0	0.48	<0.01	<0.01	<0.01
	whole plant without root	48	7	0.08	<0.01	<0.01	<0.01
	whole plant without root	48	14	0.05	<0.01	<0.01	<0.01
	whole plant without root	48	21	0.02	<0.01	<0.01	<0.01
	whole plant without root	48	28	0.02	<0.01	<0.01	<0.01
R 2007 0571/9 Germany	whole plant without root	45	-0	0.25	<0.01	<0.01	<0.01
	whole plant without root	45	0	1.7	<0.01	<0.01	<0.01
	whole plant without root	47	7	0.26	<0.01	<0.01	<0.01
	whole plant without root	49	14	0.02	<0.01	<0.01	<0.01
	whole plant	49	21	0.01	<0.01	<0.01	<0.01

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
	without root						
	whole plant without root	49	28	<0.01	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on leek

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 702: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0056/3 Schauernheim, DE,						DWD Bad Dürkheim (~10 km) [a]	no	DWD Bad Dürkheim (~10 km) [a]
M-304288-01-1	49	03/07/2007	0	0.41	FLU-benz	7		15.4
		04/07/2007	1		<LOD	2		15.2
leek, green material		05/07/2007	2			1.1		15.4
		06/07/2007	3			0		17.7
		07/07/2007	4			0		17.5
		08/07/2007	5			6.6		18.6
		09/07/2007	6			0		17.3
		10/07/2007	7	0.08		0.4		15.2
		11/07/2007	8			0.1		15.9
		12/07/2007	9			0		18
		13/07/2007	10			0		21.7
		14/07/2007	11			0		24.2
		15/07/2007	12			0		26.3
		16/07/2007	13			0.1		29.2
		17/07/2007	14	0.04		0		23.5
		18/07/2007	15			3.9		23.6
		19/07/2007	16			11.7		20.3
		20/07/2007	17			0.2		21.7
		21/07/2007	18			2.3		18
		22/07/2007	19			0		18.2
		23/07/2007	20			5.5		16.6
		24/07/2007	21	0.03		0		17.4
		25/07/2007	22			0		19
		26/07/2007	23			0		21.4
		27/07/2007	24			0		21.2
		28/07/2007	25			1.1		19.9
		29/07/2007	26			1.6		17.5
		30/07/2007	27			0		15.2
		31/07/2007	28	0.02		0		14

[a] https://opendata.dwd.de/climate_environment/CDC/

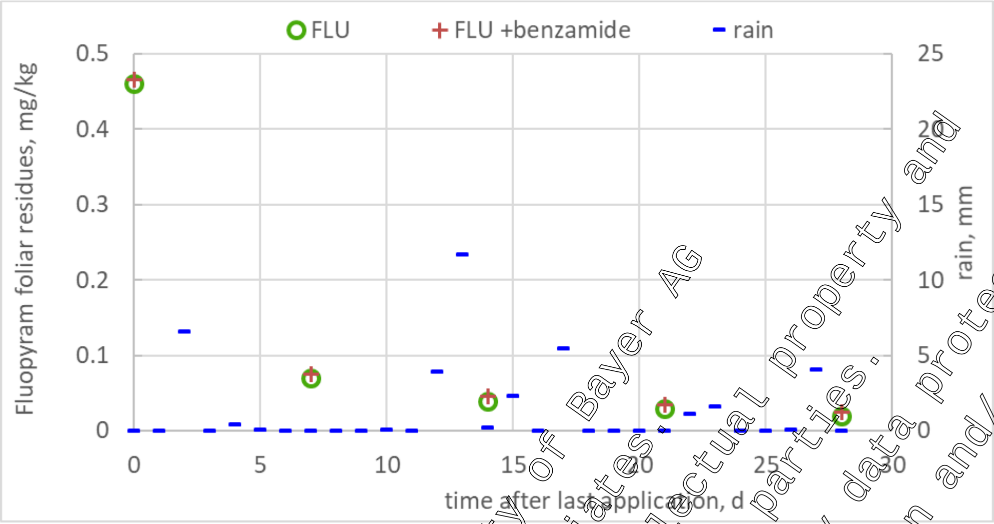


Figure 8.9- 211: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek

Early rainfall coincided with a moderate drop (influence likely).

Table 8.9- 703: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0569/7 Bouafle, FR, M-304288-01-1 leek, green material						Meteo France Trappes (23 km), study raw data	sprinkler	Meteo France Trappes (23 km), study raw data
	45	05/10/2007	0	1.6	FLU-benz	0	-	13.8
		06/10/2007	1		<LOD	0.2		13.1
		07/10/2007	2			0		12.2
		08/10/2007	3			0		12.1
		09/10/2007	4			10.2		13.3
		10/10/2007	5			0.2		12
		11/10/2007	6			0.2		11.8
		12/10/2007	7	0.22		0		12.5
		13/10/2007	8			0.2		13.2
		14/10/2007	9			0.2		12.5
		15/10/2007	10			0		10.5
		16/10/2007	11			0.8		13.6
		17/10/2007	12			0		11.8
		18/10/2007	13			0		9.2
		19/10/2007	14	0.15		0.2		8.1
		20/10/2007	15			0		6.5
		21/10/2007	16			0		5.4
		22/10/2007	17			0		7.3
		23/10/2007	18			0		5.4
		24/10/2007	19			0		5.6
		25/10/2007	20			0		7.7
		26/10/2007	21	0.09		0		8.3
		27/10/2007	22			0		8.5
		28/10/2007	23			7.8		8.2
		29/10/2007	24			19		9.2
		30/10/2007	25			0		7.8
		31/10/2007	26			0		7
		01/11/2007	27			0		9.3
		02/11/2007	28	0.11		1		11.6

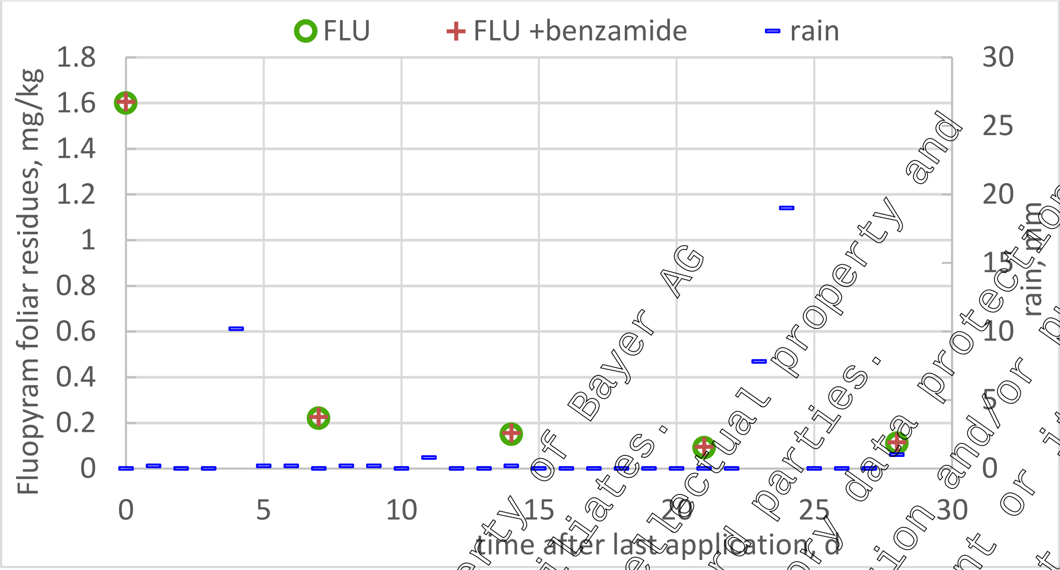


Figure 8.9- 212: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Rainfall on day 4 (10.2 mm) coincides with a marked drop in residue level (influence likely)

Table 8.9- 704: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0570/0 Zwaagdijk-Oost, NL,						KMNI De Kooy, Den Helder (35 km) [a]	no	KMNI De Kooy, Den Helder (35 km) [a]
M-304288-01-1 leek, green material	48	16-08-2007	0	0.48	FLU-benz	2.5		16
		17-08-2007	1		<LOD	7.8		15.5
		18-08-2007	2			<0.05		16.1
		19-08-2007	3			<0.05		18.2
		20-08-2007	4			4.3		17.3
		21-08-2007	5			1.4		18.1
		22-08-2007	6			0.1		19.3
		23-08-2007	7	0.08		1.1		18.7
		24-08-2007	8			0		17.9
		25-08-2007	9			0		17.8
		26-08-2007	10			0		17.2
		27-08-2007	11			0		15.5
		28-08-2007	12			0		14.2
		29-08-2007	13			0		14.1
		30-08-2007	14	0.05		0.1		16.5
		31-08-2007	15			0.3		16.6
		01-09-2007	16			0		17.2
		02-09-2007	17			4.6		17.5
		03-09-2007	18			4.1		14.3
		04-09-2007	19			1.1		13.5
		05-09-2007	20			1.4		13.8
		06-09-2007	21	0.02		0		17
		07-09-2007	22			0		16.9
		08-09-2007	23			0.2		16.6
		09-09-2007	24			<0.05		15.2
		10-09-2007	25			2.6		15.1
		11-09-2007	26			0		14.7
		12-09-2007	27			0		15.3
		13-09-2007	28	0.02		0		14

[a] http://projects.knmi.nl/klimatologie/daggegevens/selectie.cgi

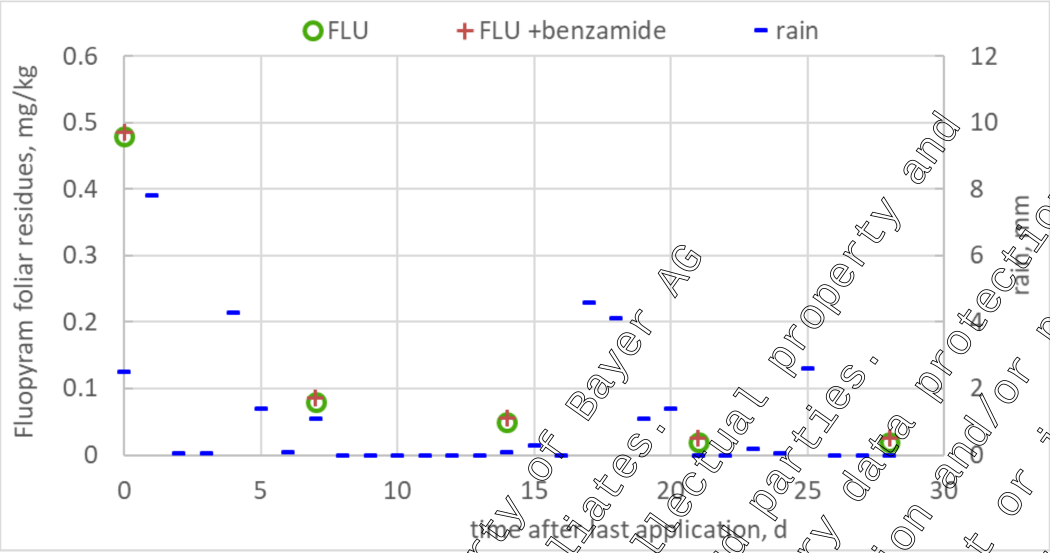


Figure 8.9- 213: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Early rainfall coincides with a marked drop in residue levels (influence likely.

Table 8.9- 705: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0571/9 Langenfeld-Reusrath, DE, M-304288-01-1 leek, green material						ProPlant DB LWZ Monheim (2.5 km)	no	ProPlant DB LWZ Monheim (2.5 km)
	45	26/07/2007	0	1.7	FLU-benz	0		21
		27/07/2007	1		<LOD	0		19.3
		28/07/2007	2			23		18
		29/07/2007	3			25.3		14.2
		30/07/2007	4			2.8		12.2
		31/07/2007	5			0		13.9
		01/08/2007	6			0		17.2
		02/08/2007	7	0.26		9.2		15.4
		03/08/2007	8			0		16.9
		04/08/2007	9			0		19.5
		05/08/2007	10			0		22.7
		06/08/2007	11			1		23.2
		07/08/2007	12			2.6		16.8
		08/08/2007	13			2.9		15.1
		09/08/2007	14	0.02		57		14.6
		10/08/2007	15			1.9		16.9
		11/08/2007	16			0		17.5
		12/08/2007	17			1.5		17.8
		13/08/2007	18			0.4		18
		14/08/2007	19			1.6		19.8
		15/08/2007	20			6.9		20.1
		16/08/2007	21	0.01		2.6		16.7
		17/08/2007	22			0		15.2
		18/08/2007	23			0		16.1
		19/08/2007	24			4.4		17.3
		20/08/2007	25			2.5		15.8
		21/08/2007	26			21.2		14.9
		22/08/2007	27			7.3		15.5
		23/08/2007	28	0.005 [a]		8.7		18.3

[a] for FLU 0.5 LOD added

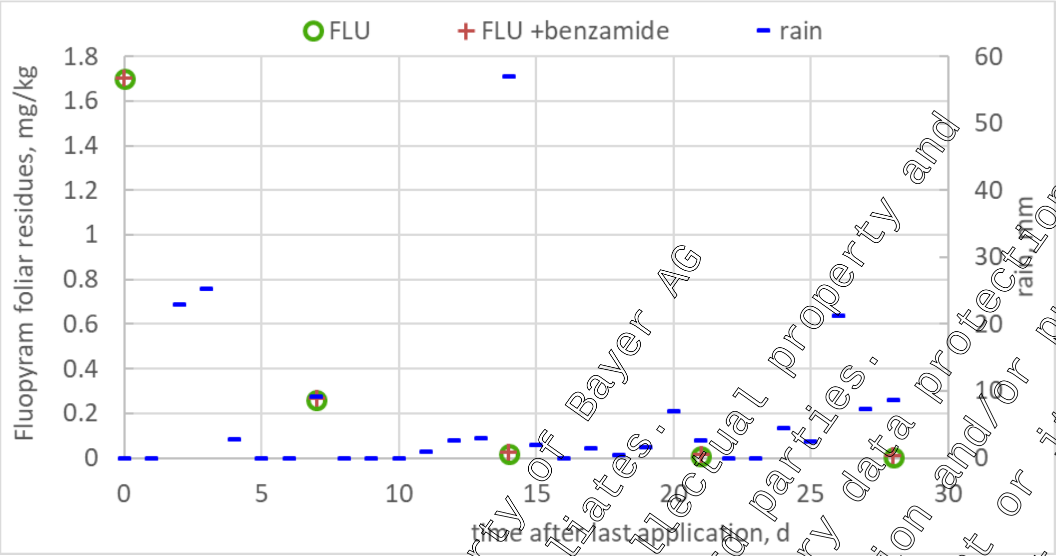


Figure 8.9- 214: Plot of the fluopyram residues decline with corresponding rainfall in the days following treatment to leek.

Early rainfall coincides with marked drop of residue levels (influence likely)

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400 on leek in four residue trials conducted in northern Europe (2 x Germany, northern France and The Netherlands)) during the 2007 season the residues of fluopyram in/on leek (whole plant without root) declined markedly during the sampling period. Residues of its metabolites fluopyram-benzamide, fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. In all 4 trials, early rainfall appeared to have influenced residue decline. However, rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/52
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 in/on leek after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Southern France and Italy
Report No:	RA-2522/07
Document No:	M-302775-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in southern Europe (southern France and Italy) on leek during the 2007 season. Two applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram were conducted. Only the parameters and results relevant to fluopyram and its metabolites have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram + Tebuconazole 400 SC on leek (whole plants without roots) declined markedly during the sampling period. Residues of fluopyram-benzamide were detectable above the LOQ (0.01 mg/kg) in two samples with a maximum value of 0.02 mg/kg. The residues of metabolites fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram + Tebuconazole 400 SC
	Batch no.:	2006-010059
	Active Ingredient:	Fluopyram + tebuconazole
	Storage:	Not stated in the report
	Expiry date:	2008-12-14
2.	Test commodity:	Leek
	Crop part:	Whole plant without roots

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2522/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on leek (whole plant without roots) after two spray applications with Fluopyram + Tebuconazole 400 SC a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included two supervised residue trials conducted in southern Europe (southern France and Italy) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 706: Description of the trial locations and cropping information on treated plots

Trial number	**R 2007 0057/1**	**R 2007 0572/7**
Trial location	F-82100 Castelsarrasin (Midi-Pyrenees)	I-45020 Lusia (RO) (Veneto)
Country	Southern France	Italy
Area of application	Field	Field
Plot size [m^2]	37.5	33.8
Type of soil	Sandy silt	Sand
pH-value of soil (in water)	7.6	7.3
Content of organic C [%]	1.0	1.7
Test system	Leek	Leek
Variety	Porbella	Sabina
Date of planting/sowing	- / 2007-06-10	2007-06-11 / -
Date of commercial harvest	2007-11-25 to 2007-12-30	2007-08-10 to 2007-09-15

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stages between 43-45 and the second at BBCH 45-47 with an application rate of 0.2 kg a.s./ha and a water rate of 600 L/ha.

Table 8.9- 707: Overview on application with Fluopyram +Tebuconazole SC 400 on leek

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2007 0057/1 Southern France	1	T	Fluopyram + Tebuconazole SC 400	SPI	14	45	28	1	600	Fluopyram, tebucon-azole	0.2
	2					47	14*				0.2
R 2007 0572/7 Italy	1	T	Fluopyram + Tebuconazole SC 400	SPI	14	43	28	1	600	Fluopyram, tebucon-azole	0.2
	2					45	14*				0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
*designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of leek. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 708: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0057/1 R 2007 0572/7	Leek	Whole plant without root	C	-0
				14
				21
			T	-0
				0
				7
				7
				14
				28

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 709: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in leek whole plant without root)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 710: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	102; 96	99		0.01
	0.1	103	103		
	1	96	96	--	
	5	111	111		
		Overall recovery (n = 5)	**102**	**6.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 711: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	100; 99	100		0.01
	0.1	94	94		
	1	94	94	--	
	5	97	97		
		Overall recovery (n = 5)	**97**	**2.9**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 712: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	85; 87	86		0.01
	0.1	91	91		
	1	93	93		
	5	93	93	--	
		Overall recovery (n = 5)	**90**	**4.0**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 713: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	70; 85	78		0.01
	0.1	72	72		
	1	92	92		
	5	90	90	--	
		Overall recovery (n = 5)	**82**	**12.5**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 89 and 139 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on leek (whole plant without root) are summarised in the following table.

Table 8.9- 714: Residue summary of fluopyram in/on leek, whole plant without root

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0057/1 Southern France	Whole plant without root	47	-0	0.35	<0.01	<0.01	<0.01
	Whole plant without root	47	0	2.8	<0.01	<0.01	<0.01
	Whole plant without root	47	7	0.39	<0.01	<0.01	<0.01
	Whole plant without root	47	14	0.31	<0.01	<0.01	<0.01
	Whole plant without root	49	21	0.24	<0.01	<0.01	<0.01
	Whole plant without root	49	28	0.25	<0.01	<0.01	<0.01
R 2007 0572/7 Italy	Whole plant without root	45	-0	0.06	<0.01	<0.01	<0.01
	Whole plant without root	45	0	2.1	<0.01	<0.01	<0.01
	Whole plant without root	47	7	0.15	<0.01	<0.01	<0.01
	Whole plant without root	48	14	0.16	0.02	<0.01	<0.01
	Whole plant without root	48	21	0.03	0.01	<0.01	<0.01
	Whole plant without root	48	28	0.02	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on leek

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 715: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0057/1 Castelsarrasin, FR,						Meteo France Castelsarrasin (7 km), study raw data	sprinkler	Meteo France Castelsarrasin (7 km), study raw data
M-302775-01-1	47	08/11/2007	0	2.8	FLU-benz	0.2		5.6
leek, green material		09/11/2007	1		<LOD	0		9.5
		10/11/2007	2			0	20	5.2
		11/11/2007	3			0		9
		12/11/2007	4			0		10.9
		13/11/2007	5			0.2		7.7
		14/11/2007	6			0		9
		15/11/2007	7	0.39		0		3.1
		16/11/2007	8			0		0.6
		17/11/2007	9			0		na
		18/11/2007	10			0		na
		19/11/2007	11			0		na
		20/11/2007	12			1.6		15.8
		21/11/2007	13			0.8		13.1
		22/11/2007	14	0.31		0		6.9
		23/11/2007	15			0		9.7
		24/11/2007	16			0		7.8
		25/11/2007	17			0		3.6
		26/11/2007	18			0		7.3
		27/11/2007	19			0.2		4.5
		28/11/2007	20			0		0
		29/11/2007	21	0.24		0		1.7
		30/11/2007	22			0		7.5
		01/12/2007	23			2.8		7.4
		02/12/2007	24			2.2		10.8
		03/12/2007	25			1.2		11.9
		04/12/2007	26			2		10.6
		05/12/2007	27			1		7.4
		06/12/2007	28	0.25		0.8		11.7

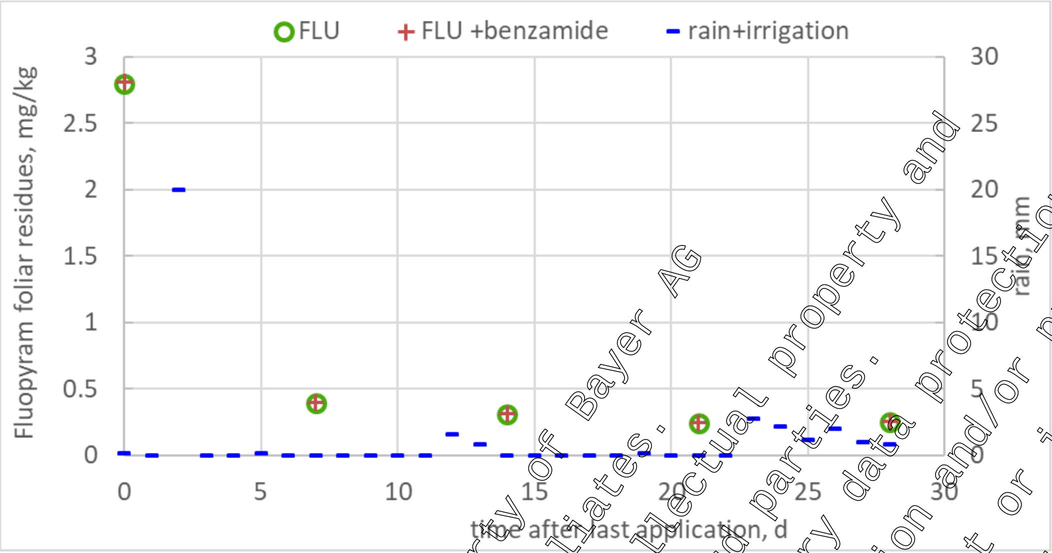


Figure 8.9- 215: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek

Irrigation (20 mm) on day 2 coincides with marked drop of residue levels (influence likely).

Table 8.9- 716: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0572/7 Lusia, IT, M-302775-01-1 leek, green material						www.ilmeteo.it Lusia	sprinkler	www.ilmeteo.it Lusia
	45	09/08/2007	0	2.1	2.1	na (0) [b]		24.2
		10/08/2007	1			0		24.3
		11/08/2007	2			0.8		26.6
		12/08/2007	3			0		29.1
		13/08/2007	4			0		29.2
		14/08/2007	5			0		28.7
		15/08/2007	6			0	25	30.2
		16/08/2007	7	0.15	0.155 [a]	0		30.8
		17/08/2007	8			0		30.9
		18/08/2007	9			0		26.6
		19/08/2007	10			0		28.2
		20/08/2007	11			na		21.8
		21/08/2007	12			0		21.3
		22/08/2007	13			0.8		21.9
		23/08/2007	14	0.16	0.18	na (9) [b]		19.3
		24/08/2007	15			0		17
		25/08/2007	16			0		25.8
		26/08/2007	17			0		29.1
		27/08/2007	18			0		29.2
		28/08/2007	19			na		na
		29/08/2007	20			0		28.4
		30/08/2007	21	0.03	0.04	0		26.8
		31/08/2007	22			4.1		21
		01/09/2007	23			0		24
		02/09/2007	24			0		23.9
		03/09/2007	25			0		24.6
		04/09/2007	26			7.1		17.3
		05/09/2007	27			0		18.7
		06/09/2007	28	0.02	0.025 [a]	0		19.3

[a] for FLU-benzamide 0,5 LOD added
[b] missing data in ilmeteo.it: at 9.8.2007 0 mm rain, at 23.8.2007 9 mm rain, reported in study report.

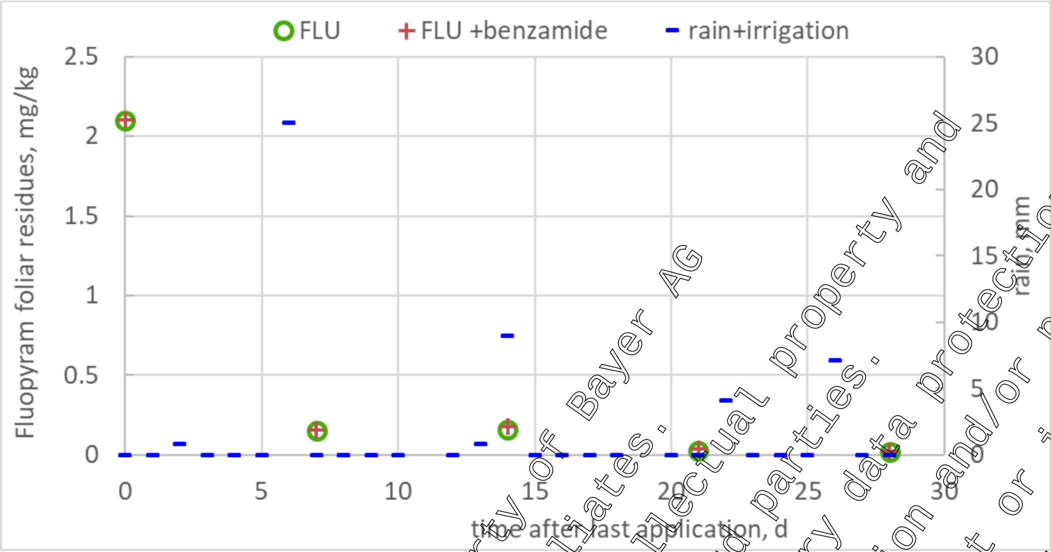


Figure 8.9- 216: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Early irrigation coincides with marked drop of residues (influence likely).

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400 on leek in two residue trials conducted in southern Europe (southern France and Italy) during the 2007 season the residues of fluopyram in/on leek whole plant without root declined markedly during the sampling period. Residues of fluopyram-benzamide were detectable above the LOQ (0.01 mg/kg) in two samples with a maximum value of 0.02 mg/kg. The residues of metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant:
The study and its data are considered as acceptable and reliable for use in risk assessment. In both trials, early irrigation may have markedly influence residue decline, but irrigation is a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/53
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on chinese cabbage after spraying of AE C656948 & HWG 1608 (400 SC) in the field in United Kingdom and Germany
Report No:	RA-2533/07
Document No:	M-302101-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in northern Europe (Germany and United Kingdom) on Chinese cabbage during the 2007 season. Two applications with Fluopyram (AE C656948) + Tebuconazole (HWG 1608) 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram, were conducted. Only the parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after two spray applications of the Fluopyram + Tebuconazole 400 SC on Chinese cabbage declined markedly during the sampling period. Residues of fluopyram-benzamide, fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item: Fluopyram + Tebuconazole 400 SC

   Batch no.: 2006-010059

   Active Ingredient: Fluopyram + tebuconazole

   Storage: Not stated in the report

   Expiry date: 2008-12-14

2. Test commodity: Chinese cabbage

   Crop part: Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2533/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on Chinese cabbage (head) after two spray applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included two supervised residue trials conducted in northern Europe (Germany and United Kingdom) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 717: Description of the trial locations and cropping information on treated plots

Trial number	R 2007 0078/4	R 2007 0599/9
Trial location	GB-PE33 9SA Broad Fen Drove/ Wissington (Norfolk)	D-88074 Meckenbeuren (Baden-Württemberg)
Country	United Kingdom	Germany
Area of application	Field	Field
Plot size [m^2]	36	30
Type of soil	Sandy loam	Sandy loam
pH-value of soil (in water)	6.1	6.3
Content of organic C [%]	2.9	4.8
Test system	Chinese cabbage	Chinese cabbage
Variety	Onekilo	Orient Express
Date of planting/sowing	2007-05-01 / -	- / 2007-08-03
Date of commercial harvest	2007-06-25 to 2007-06-27	2007-10-15 to 2007-11-02

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stage 18 and the second at BBCH 41-43 with an application rate of 0.2 kg a.s./ha and a water rate of 300 L/ha.

Table 8.9- 718: Overview on application with Fluopyram +Tebuconazole SC 400 on Chinese cabbage

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2007 0078/4 United Kingdom	1	T	Fluopyram + Tebucon-azole SC 400	SPI	14	18	28	1	300	Fluopyram, tebucon-azole	0.2
	2					41	14*				0.2
R 2007 0599/9 Germany	1	T	Fluopyram + Tebucon-azole SC 400	SPI	14	18	28	1	300	Fluopyram, tebucon-azole	0.2
	2					43	14*				0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of Chinese cabbage. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 719: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0078/4 R 2007 0599/9	Chinese cabbage	Head	C	-0
				14
			T	-0
				0
				7
				14
				21

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 720: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in Chinese cabbage, head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The mean values of the concurrent recoveries were within the acceptable range of 70 – 110%. Details are given in the table below.

Table 8.9- 721: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	88	88	--	0.01
	0.1	101	101	--	
	6	98	98	--	
		Overall recovery (n = 3)	**96**	**7.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 722: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	103	103	--	0.01
	0.1	93	93	--	
	6	94	94	--	
		Overall recovery (n = 3)	**97**	**5.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 723: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	93	93	--	0.01
	0.1	89	89	--	
	6	89	89	--	
		Overall recovery (n = 3)	**90**	**2.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 724: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	88	88	--	0.01
	0.1	91	91	--	
	6	89	89	--	
		Overall recovery (n = 3)	**89**	**1.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 132 and 164 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on Chinese cabbage (head) are summarised in the following table.

Table 8.9- 725: Residue summary of fluopyram in/on Chinese cabbage, head

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0078/4 United Kingdom	Head	41	-0	0.01	<0.01	<0.01	<0.01
	Head	41	0	4.4	<0.01	<0.01	<0.01
	Head	45	7	0.42	<0.01	<0.01	<0.01
	Head	48	14	0.03	<0.01	<0.01	<0.01
	Head	49	21	<0.01	<0.01	<0.01	<0.01
R 2007 0599/9 Germany	Head	43	-0	0.06	<0.01	<0.01	<0.01
	Head	43	0	3.8	<0.01	<0.01	<0.01
	Head	44	7	0.29	<0.01	<0.01	<0.01
	Head	47	14	0.23	<0.01	<0.01	<0.01
	Head	49	21	0.11	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on Chinese cabbage

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 726: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0078/4 Broad Fen Drove, Wissington, GB, M-302101-01-1 Cabbage, Chinese, green material						Brooms Barn (32 km) Bayer raw data	no	Brooms Barn (32 km) Bayer raw data
	41	05/06/2007	0	4.4	FLU-benz	0		14.25
		06/06/2007	1		<LOD	0.4		11.7
		07/06/2007	2			3.3		15.25
		08/06/2007	3			2		14.65
		09/06/2007	4			0.2		17.4
		10/06/2007	5			0		15
		11/06/2007	6			0		14.85
		12/06/2007	7	0.42		0		17.1
		13/06/2007	8			11.5		17.9
		14/06/2007	9			32.2		16.5
		15/06/2007	10			0.2		17.85
		16/06/2007	11			4.8		15.05
		17/06/2007	12			0.7		16.1
		18/06/2007	13			7.8		15.7
		19/06/2007	14	0.03		5.2		16.5
		20/06/2007	15			0		17.4
		21/06/2007	16			0.9		16.15
		22/06/2007	17			1.5		16.35
		23/06/2007	18			3.3		16.45
		24/06/2007	19			10.7		13.5
		25/06/2007	20			2.6		14.5
		26/06/2007	21	0.005 [a]		0		10.95

[a] for FLU 0.5 LOD added

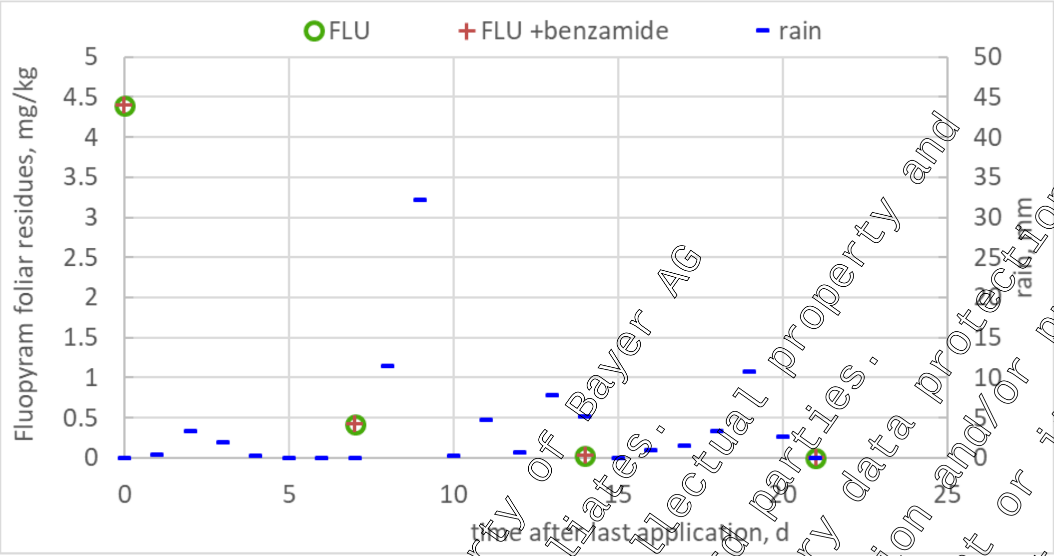


Figure 8.9- 217: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Chinese cabbage

Moderate early rainfall coincides with a marked drop in residues (influence possible).

Table 8.9- 727: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0599/9 Meckenbeuren, DE,						DWD Konstanz (33 km) [a]	no	DWD Konstanz (33 km) [a]
M-302101-01-1	43	01/10/2007	0	3.8	FLU-benz	0		15
		02/10/2007	1		<LOD	0		15.2
Cabbage, Chinese, green material		03/10/2007	2			0.3		17.2
		04/10/2007	3			1		17.2
		05/10/2007	4			0		17.1
		06/10/2007	5			0		13.9
		07/10/2007	6			0		12.1
		08/10/2007	7	0.29		0		11.5
		09/10/2007	8			0		11.1
		10/10/2007	9			0		11.3
		11/10/2007	10			0		10.5
		12/10/2007	11			0		10.5
		13/10/2007	12			0		12.2
		14/10/2007	13			0		8
		15/10/2007	14	0.23		0		10.1
		16/10/2007	15			0		10.8
		17/10/2007	16			3.6		13.2
		18/10/2007	17			0.4		9.2
		19/10/2007	18			0.6		6.4
		20/10/2007	19			0		3.8
		21/10/2007	20			0.8		2.9
		22/10/2007	21	0.11		0		3.5

[a] https://opendata.dwd.de/climate_environment/CDC/

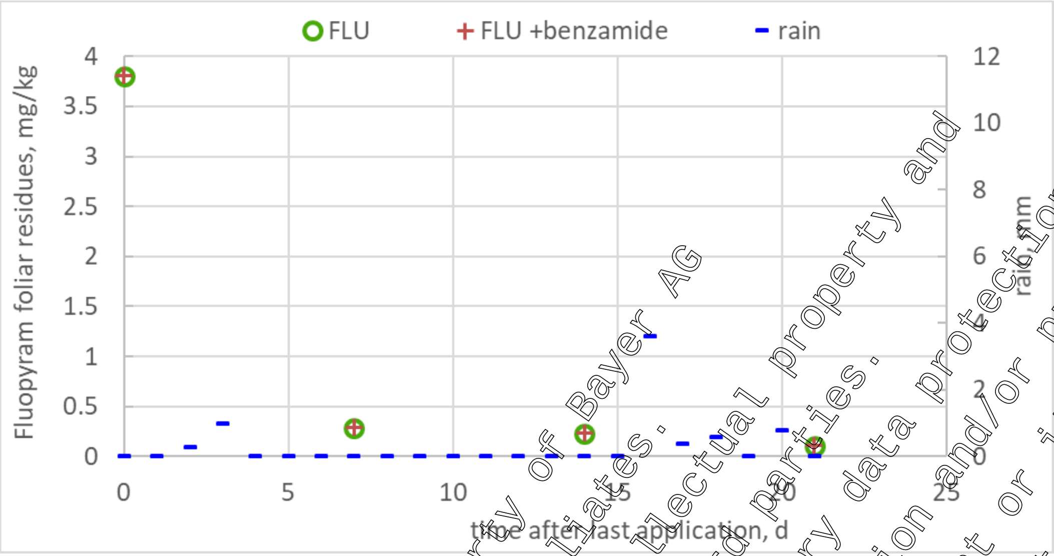


Figure 8.9- 218: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Chinese cabbage.

There is a marked decline until the second sampling but very little rainfall (influence unlikely.

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400 on Chinese cabbage in two residue trials conducted in northern Europe (Germany and United Kingdom) during the 2007 season the residues of fluopyram in/on Chinese cabbage (head) declined markedly during the sampling period. Residues of fluopyram-benzamide, fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Early rainfall may have contributed to marked residue decline in R 2007 0078/4, which was also observed in R 2007 0599/9 despite nearly no early rainfall.

However, rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/54
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on Chinese cabbage after spraying of AE C656948 & HWG 1608 (400 SC) in the field in southern France and Spain
Report No:	RA-2534/07
Document No:	M-302044-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in southern Europe (southern France and Spain) on Chinese cabbage during the 2007 season. Two applications with Fluopyram (AE C656948) + Tebuconazole (HWG 1608) 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram, were conducted. Only the parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after two spray applications of the Fluopyram + Tebuconazole 400 SC on Chinese cabbage declined markedly during the sampling period. Residues of fluopyram-benzamide, fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always at or below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram + Tebuconazole 400 SC
	Batch no.:	2006-010059
	Active Ingredient:	Fluopyram + tebuconazole
	Storage:	Not stated in the report
	Expiry date:	2008-12-14
2.	Test commodity:	Chinese cabbage
	Crop part:	Head

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2534/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on Chinese cabbage (head) after two spray applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included two supervised residue trials conducted in southern Europe (southern France and Spain) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 728: Description of the trial locations and cropping information on treated plots

Trial number	**R 2007 0079/2**	**R 2007 0600/6**
Trial location	F-86380 Ouzilly (Poitou-Charentes)	E-41310 Brenes Sevilla (Andalucia)
Country	Southern France	Spain
Area of application	Field	Field
Plot size [m^2]	30	56.3
Type of soil	Clay sand	Loam
pH-value of soil (in water)	8.1	7.8
Content of organic C [%]	1.1	0.4
Test system	Chinese cabbage	Chinese cabbage
Variety	Kaboko	Sumiko
Date of planting/sowing	- / 2007-07-11	2007-04-03 / -
Date of commercial harvest	2007-09-07 to 2007-09-25	2007-04-15 to 2007-06-30

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stage 41 and the second at BBCH 43-44 with an application rate of 0.2 kg a.s./ha and a water rate of 400-600 L/ha.

Table 8.9- 729: Overview on application with Fluopyram +Tebuconazole SC 400 on Chinese cabbage

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
R 2007 0079/2 southern France	1	T	Fluopyram + Tebucon-azole SC 400	SPI	14	41	28	1	600	Fluopyram, tebucon-azole	0.2
	2					43	14*				0.2
R 2007 0600/6 Spain	1	T	Fluopyram + Tebucon-azole SC 400	SPI	14	41	28	1	400	Fluopyram, tebucon-azole	0.2
	2					44	14*				0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of Chinese cabbage. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 730: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0079/2 R 2007 0600/6	Chinese cabbage	Head	C	-0
				14
			T	-0
				0
				7
				14
				21

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 731: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in Chinese cabbage, head)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The mean values of the concurrent recoveries were within the acceptable range of 70 – 110%. Details are given in the table below.

Table 8.9- 732: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.01	92	92	--	0.01
	0.4	99	99	--	
	4	98	98	--	
	6	97	97	--	
		Overall recovery (n = 3)	**97**	**3.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 733: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.010	102	102	--	0.01
	0.4	101	101	--	
	4	96	96	--	
	6	90	90	--	
		Overall recovery (n = 3)	**97**	**5.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 734: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.010	87	87	--	
	0.4	95	95	--	
	4	94	94	--	0.01
	6	97	97	--	
		Overall recovery (n = 3)	**93**	**4.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 735: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Chinese cabbage (head)	0.010	89	89	--	
	0.4	92	92	--	
	4	83	83	--	0.01
	6	90	90	--	
		Overall recovery (n = 3)	**89**	**4.4**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 73 and 170 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on Chinese cabbage (head) are summarised in the following table.

Table 8.9- 736: Residue summary of fluopyram in/on Chinese cabbage, head

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0079/2 Southern France	Head	43	-0	0.19	<0.01	<0.01	<0.01
	Head	43	0	5.4	<0.01	<0.01	<0.01
	Head	46	7	0.88	<0.01	<0.01	<0.01
	Head	49	14	0.49	<0.01	<0.01	<0.01
	Head	49	21	0.42	<0.01	<0.01	<0.01
R 2007 0600/6 Spain	Head	44	-0	0.22	<0.01	<0.01	<0.01
	Head	44	0	1.7	0.01	<0.01	0.01
	Head	45	7	0.44	0.01	<0.01	<0.01
	Head	49	14	0.21	<0.01	<0.01	<0.01
	Head	49	21	0.13	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on Chinese cabbage

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 737: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date (dd/mm/ yyyy)	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0079/2 Ouzilly, FR, M-302044-01-1						Meteo France Poitiers Biard (21 km), study raw data	no	Meteo France Poitiers Biard (21 km), study raw data
Cabbage, Chinese, green material	43	27/08/2007	0	5.4	FLU-benz	0		22
		28/08/2007	1		<LOD	0		19.2
		29/08/2007	2			0.2		16.8
		30/08/2007	3			0		15.3
		31/08/2007	4			0		15.4
		01/09/2007	5			0		15.5
		02/09/2007	6			0.2		15.2
		03/09/2007	7	0.88		3.8		15.2
		04/09/2007	8			0.2		13.8
		05/09/2007	9			0		13.4
		06/09/2007	10			0		16.3
		07/09/2007	11			0		17.9
		08/09/2007	12			0		17.4
		09/09/2007	13			0		16.7
		10/09/2007	14	0.49		0.2		15.8
		11/09/2007	15			0		15.6
		12/09/2007	16			0		15.8
		13/09/2007	17			0		16.7
		14/09/2007	18			0		16.8
		15/09/2007	19			0.2		16.2
		16/09/2007	20			0		17.5
		17/09/2007	21	0.42		2.6		15.7

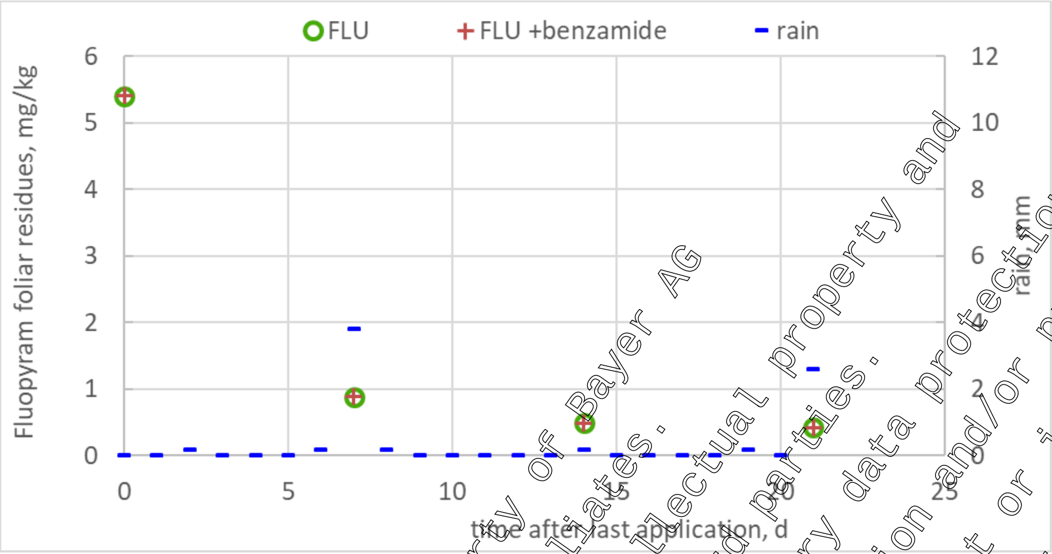


Figure 8.9- 219: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Chinese cabbage

Very little rainfall until day 7 (3.8 mm) coincides with a marked drop of residues (influence questionable).

Table 8.9- 738: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0600/6 Brenes, ES, M-302044-01-1 Cabbage, Chinese, green material						La Rinconada (11 km) Bayer raw data	trickle	La Rinconada (11 km) Bayer raw data
	44	23/05/2007	0	1.7	1.71	28.2 (1.5) [b]		16.1
		24/05/2007	1			0.2		17.5
		25/05/2007	2			0		16.9
		26/05/2007	3			3.6		15.4
		27/05/2007	4			0		18
		28/05/2007	5			0		18.1
		29/05/2007	6			0		18.9
		30/05/2007	7	0.44	0.45	0		20.9
		31/05/2007	8			0		19.6
		01/06/2007	9			0		20.4
		02/06/2007	10			0		22.9
		03/06/2007	11			0		24.2
		04/06/2007	12			0		24.1
		05/06/2007	13			0		24.1
		06/06/2007	14	0.21	0.215 [a]	0		23.7
		07/06/2007	15			0		23
		08/06/2007	16			0		22.4
		09/06/2007	17			3.2		20.3
		10/06/2007	18			0		19.3
		11/06/2007	19			0.2		21.1
		12/06/2007	20			0		21.4
		13/06/2007	21	0.13	0.13	0		20.2

[a] for FLU-benzamide 0.5 LOD added
[b] 1.5 mm rain within 24 h after application, starting 7 h after application, in study report.

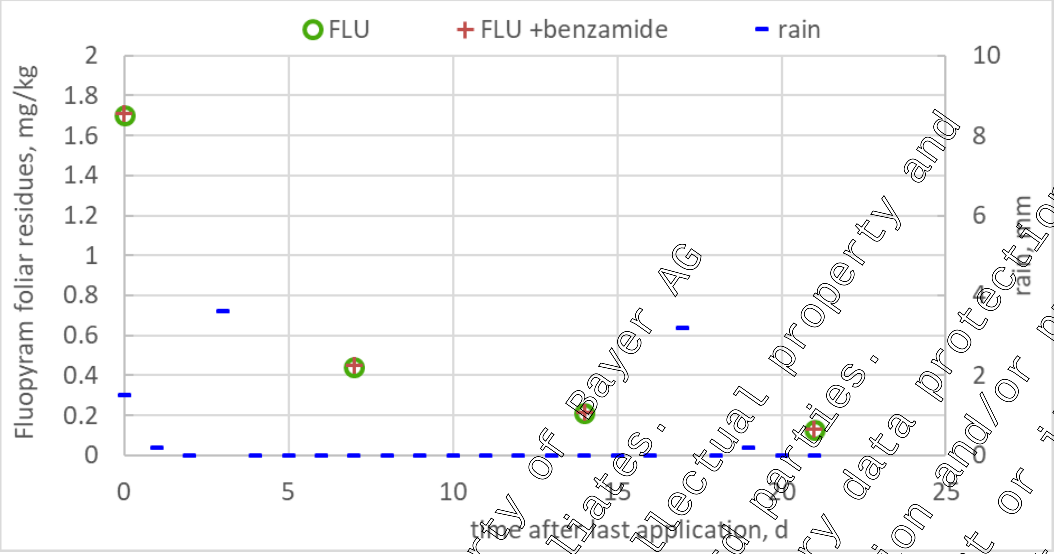


Figure 8.9- 220: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Chinese cabbage.

Moderate early rainfall is not associated with a marked decline (influence unlikely).

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400 on Chinese cabbage in two residue trials conducted in southern Europe (southern France and Spain) during the 2007 season the residues of fluopyram in/on Chinese cabbage (head) declined markedly during the sampling period. Residues of fluopyram-benzamide, fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always at or below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. In trial R 2007 0079/2 a marked decline but little early rain occurred until the 2nd sampling (influence questionable).

In trial R 2007 0600/6, moderate early rainfall did not coincide with a marked decline (influence unlikely).

However, rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/55
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on leek after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Germany, Northern France and Netherlands
Report No:	RA-2609/07
Document No:	M-304276-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 - Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with three residue trials was conducted in the field in northern Europe (northern France, The Netherlands, and Germany) on leek during the 2007 season. Three applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram, were conducted. Only the parameters and results relevant to fluopyram and its metabolites have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram + Tebuconazole 400 SC on leek (whole plants without roots) declined markedly during the sampling period. Residues of its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram + Tebuconazole 400 SC
	Batch no.:	2006-010059
	Active Ingredient:	Fluopyram + tebuconazole
	Storage:	Not stated in the report
	Expiry date:	2008-12-14
2.	Test commodity:	Leek
	Crop part:	Whole plant without roots

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2609/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites in/on leek (whole plant without roots) after three spray applications with Fluopyram + Tebuconazole 400 SC a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188).

Field phase

The study included three supervised residue trials conducted in northern Europe (Germany, northern France and The Netherlands) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 739: Description of the trial locations and cropping information on treated plots

Trial number	R 2007 0249/3	R 2007 0573/5	R 2007 0574/3
Trial location	D-67125 Schauernheim (Rheinland-Pfalz)	F-78410 Bouafle (Ile-de-France)	NL-1681 ND Zwaagdijk-Oost (Noord-Holland)
Country	Germany	Northern France	Netherlands
Area of application	Field	Field	Field
Plot size [m^2]	30	57.5	28
Type of soil	Sandy loam	Sand	Clay
pH-value of soil (in water)	6.9	8.3	7.0
Content of organic C [%]	0.9	0.9	3.1
Test system	Leek	Leek	Leek
Variety	Nobel	St Victor	Roxton
Date of planting	2007-03-13	2007-07-19	2007-05-14
Date of commercial harvest	2007-07-03 to 2007-07-30	2007-10-15 to 2007-12-20	2007-08-24 to 2007-09-06

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stages between 19-43, the second application between 41-47 and the third application between 45-49 with an application rate of 0.15 kg a.s./ha and a water rate of 500-600 L/ha. The spray interval was 20-22 days.

Table 8.9- 740: Overview on application with Fluopyram +Tebuconazole SC 400 on leek

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2007 0249/3 Germany	1	T	Fluopyram + Tebuconazole SC 400	SPI	-	43	56	0.75	600	Fluopyram + tebucon-azole	0.15
	2				22	45	34				0.15
	3				20	49	14*				0.15
R 2007 0573/5 Northern France	1	T	Fluopyram + Tebuconazole SC 400	SPI	-	19	56	0.75	500	Fluopyram + tebucon-azole	0.15
	2				21	41	35				0.15
	3				21	45	14*				0.15
R 2007 0574/3 The Nether-lands	1	T	Fluopyram + Tebuconazole SC 400	SPI	-	44	56	0.75	600	Fluopyram + tebucon-azole	0.15
	2				21	47	35				0.15
	3				21	48	14*				0.15

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of leek. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 741: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0249/3 R 2007 0573/5 R 2007 0574/3	Leek	Whole plant without root	C	-0
				14
				21
			T	-0
				0
				7
				7
				14
				28

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were analysed within the residue trials samples according to the following method:

Table 8.9- 742: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in leek whole plant without root)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and its metabolites were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 743: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	98; 108	103		0.01
	0.5	90	90		
	1	96	96	--	
		Overall recovery (n = 4)	**98**	**7.6**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 744: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	91; 117	104		0.01
	0.5	91	91		
	1	93	93	--	
		Overall recovery (n = 4)	**98**	**13.0**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 745: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	98; 87	93		0.01
	0.5	81	81		
	1	88	88	--	
		Overall recovery (n = 4)	**89**	**8.0**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 746: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	79; 73	76		0.01
	0.5	70	70		
	1	90	90	--	
		Overall recovery (n = 4)	**78**	**11.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 119 and 294 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on leek (whole plant without root) are summarised in the following table.

Table 8.9- 747: Residue summary of fluopyram in/on leek, whole plant without root

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0249/3 Germany	Whole plant without root	49	-0	0.02	<0.01	<0.01	<0.01
	Whole plant without root	49	0	0.46	<0.01	<0.01	<0.01
	Whole plant without root	49	7	0.07	<0.01	<0.01	<0.01
	Whole plant without root	53	14	0.04	<0.01	<0.01	<0.01
	Whole plant without root	53	21	0.03	<0.01	<0.01	<0.01
	Whole plant without root	54	28	0.02	<0.01	<0.01	<0.01
R 2007 0573/5 Northern France	Whole plant without root	45	-0	0.04	<0.01	<0.01	<0.01
	Whole plant without root	45	0	1.2	<0.01	<0.01	<0.01
	Whole plant without root	47	7	0.24	<0.01	<0.01	<0.01
	Whole plant without root	49	14	0.11	<0.01	<0.01	<0.01
	Whole plant without root	49	21	0.10	<0.01	<0.01	<0.01
	Whole plant without root	49	28	0.05	<0.01	<0.01	<0.01
R 2007 0574/3 Nether-lands	Whole plant without root	48	-0	0.01	<0.01	<0.01	<0.01
	Whole plant without root	48	0	0.24	<0.01	<0.01	<0.01
	Whole plant without root	48	7	0.04	<0.01	<0.01	<0.01
	Whole plant without root	48	14	0.02	<0.01	<0.01	<0.01
	Whole plant without root	48	21	0.01	<0.01	<0.01	<0.01
	Whole plant without root	48	28	<0.01	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on leek

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 748: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0249/3 Schauernheim, DE, M-304276-01-1 leek, green material						DWD Bad Dürckheim (~10 km) [a]	no	DWD Bad Dürckheim (~10 km) [a]
	49	06/07/2007	0	0.46	FLU-benz	0 [b]		17.7
		07/07/2007	1		<LOD	0		17.5
		08/07/2007	2			26.6		18.6
		09/07/2007	3			0		17.3
		10/07/2007	4			0.4		15.2
		11/07/2007	5			0.1		15.9
		12/07/2007	6			0		18
		13/07/2007	7	0.07		0		21.7
		14/07/2007	8			0		24.2
		15/07/2007	9			0		26.3
		16/07/2007	10			0.1		29.2
		17/07/2007	11			0		23.5
		18/07/2007	12			3.9		23.6
		19/07/2007	13			11.7		20.3
		20/07/2007	14	0.04		0.2		21.7
		21/07/2007	15			2.3		18
		22/07/2007	16			0		18.2
		23/07/2007	17			5.5		16.6
		24/07/2007	18			0		17.4
		25/07/2007	19			0		19
		26/07/2007	20			0		21.4
		27/07/2007	21	0.03		0		21.2
		28/07/2007	22			1.1		19.9
		29/07/2007	23			1.6		17.5
		30/07/2007	24			0		15.2
		31/07/2007	25			0		14
		01/08/2007	26			0.1		16.4
		02/08/2007	27			4.1		17.7
		03/08/2007	28	0.02		0		18.8

a) https://opendata.dwd.de/climate_environment/CDC/
b) no rain wirthin 24 h after application, in study report

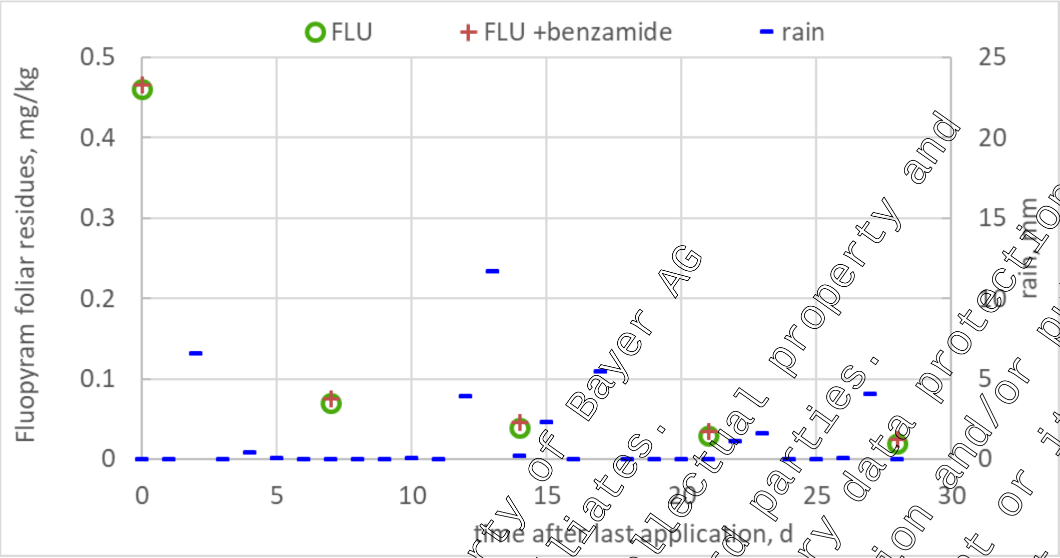


Figure 8.9- 221: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek

Early rainfall coincides with a marked drop of residues (influence likely).

Table 8.9- 749: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0573/5 Bouafle, FR, M-304276-01-1 leek, green material						Meteo France Trappes (23 km), study raw data	no	Meteo France Trappes (23 km), study raw data
	45	05/10/2007	0	1.2	FLU-benz	0		13.8
		06/10/2007	1		<LOD	0.2		13.1
		07/10/2007	2			0		12.2
		08/10/2007	3			0		12.1
		09/10/2007	4			10.2		13.3
		10/10/2007	5			0.2		12
		11/10/2007	6			0.2		11.8
		12/10/2007	7	0.24		0		12.5
		13/10/2007	8			0.2		13.2
		14/10/2007	9			0.2		12.5
		15/10/2007	10			0		10.5
		16/10/2007	11			0.8		13.6
		17/10/2007	12			0		11.8
		18/10/2007	13			0		9.2
		19/10/2007	14	0.11		0.2		8.1
		20/10/2007	15			0		6.5
		21/10/2007	16			0		5.4
		22/10/2007	17			0		7.3
		23/10/2007	18			0		5.4
		24/10/2007	19			0		5.6
		25/10/2007	20			0		7.7
		26/10/2007	21	0.1		0		8.3
		27/10/2007	22			0		8.5
		28/10/2007	23			7.8		8.2
		29/10/2007	24			19		9.2
		30/10/2007	25			0		7.8
		31/10/2007	26			0		7
		01/11/2007	27			0		9.3
		02/11/2007	28	0.05		1		11.6

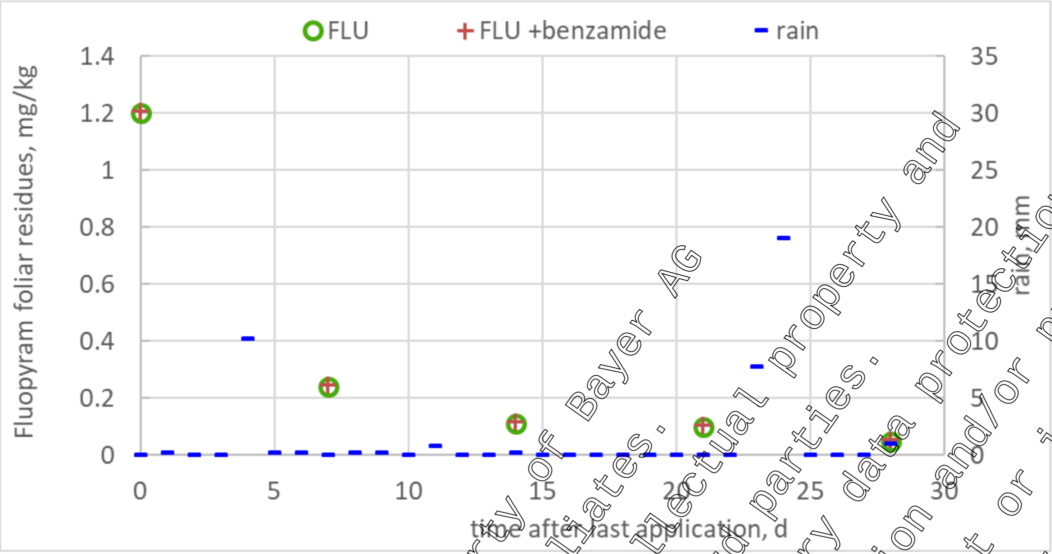


Figure 8.9- 222: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Early rainfall coincides with marked drop (influence likely)

Table 8.9- 750: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0574/3 Zwaagdijk-Oost, NL,						KMNI De Kooy, Den Helder (35 km) [b]	no	KMNI De Kooy, Den Helder (35 km) [b]
M-304276-01-1	48	16/08/2007	0	0.24	FLU-benz	2.5		16
		17/08/2007	1		<LOD	7.8		15.5
leek, green material		18/08/2007	2			<0.05		16.1
		19/08/2007	3			<0.05		18.2
		20/08/2007	4			4.3		17.3
		21/08/2007	5			1.4		18.1
		22/08/2007	6			0.1		19.3
		23/08/2007	7	0.04		1.1		18.7
		24/08/2007	8			0		17.9
		25/08/2007	9			0		17.8
		26/08/2007	10			0		17.2
		27/08/2007	11			0		15.5
		28/08/2007	12			0		14.2
		29/08/2007	13			0		14.1
		30/08/2007	14	0.02		0.1		16.5
		31/08/2007	15			0.3		16.6
		01/09/2007	16			0		17.2
		02/09/2007	17			4.6		17.5
		03/09/2007	18			4.1		14.3
		04/09/2007	19			1.1		13.5
		05/09/2007	20			1.4		13.8
		06/09/2007	21	0.01		0		17
		07/09/2007	22			0		16.9
		08/09/2007	23			0.2		16.6
		09/09/2007	24			<0.05		15.2
		10/09/2007	25			2.6		15.1
		11/09/2007	26			0		14.7
		12/09/2007	27			0		15.3
		13/09/2007	28	0.005 [a]		0		14

[a] for FLU 0.5 LOD added
[b] http://projects.knmi.nl/klimatologie/daggegevens/selectie.cgi

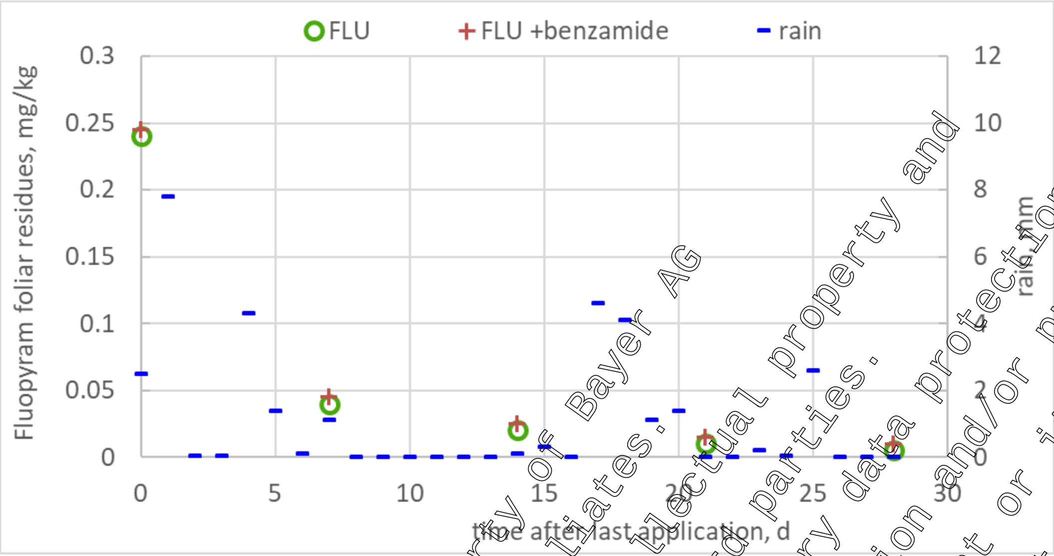


Figure 8.9- 223: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek.

Early rainfall coincides with marked drop (influence likely)

III. CONCLUSION

After three spray applications of Fluopyram + Tebuconazole SC 400 on leek in three residue trials conducted in northern Europe (Netherlands, Germany, and France) during the 2006 season the residues of fluopyram in/on leek (whole plant without root) declined markedly during the sampling period. Residues of its metabolites were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant:
The study and its data are considered as acceptable and reliable for use in risk assessment. In all 3 trials, early rainfall coincided with marked drop (influence likely). However, rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/56
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on leek after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Southern France
Report No:	RA-2610/07
Document No:	M-302780-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with a single residue trial was conducted in the field in southern Europe (southern France) on leek during the 2007 season. Three applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram were conducted. Only the parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after spray application of the Fluopyram + Tebuconazole 400 SC on leek (whole plants without roots) declined markedly during the sampling period. Residues of its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram + Tebuconazole 400 SC
	Batch no.:	2006-010059
	Active Ingredient:	Fluopyram + Tebuconazole
	Storage:	Not stated in the report
	Expiry date:	2008-12-14
2.	Test commodity:	Leek
	Crop part:	Whole plant without roots

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2610/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on leek (whole plant without roots) after three spray applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

<u>Field phase</u>

The study included a single supervised residue trial conducted in southern Europe (southern France) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 751: Description of the trial locations and cropping information on treated plots

Trial number	**R 2007 0250/7**
Trial location	F-82100 Castelsarrasin (Midi-Pyrenees)
Country	Southern France
Area of application	Field
Plot size [m^2]	37.5
Type of soil	Sandy silt
pH-value of soil (in water)	7.6
Content of organic C [%]	1.0
Test system	Leek
Variety	Porbella
Date of planting/sowing	-/ 2007-06-10
Date of commercial harvest	2007-11-25 to 2007-12-30

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH 41, the second at BBCH 45 and the third at BBCH 47 with an application rate of 0.15 kg a.s./ha and a water rate of 600 L/ha.

Table 8.9- 752: Overview on application with Fluopyram +Tebuconazole SC 400 on leek

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s. /ha)
R 2007 0250/7 Southern France	1	T	Fluopyram + Tebuconazole SC 400	SPI	-	41	56	0.75	600	Fluopyram + tebucon-azole	0.15
	2				21	45	35				0.15
	3				21	47	14*				0.15

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of leek. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 753: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0250/7	Leek	Whole plant without root	C	-0
				14
				21
			T	-0
				0
				7
				7
				14
				28

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 754: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in leek whole plant without root)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and its metabolites were not corrected for apparent residues in the control samples used for these recoveries. The average recoveries were generally within the acceptable range of 70 – 110% and the RSD values were below 20%. Details are given in the table below.

Table 8.9- 755: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	99	99		0.01
	0.1	105	105		
	1	93	93	--	
		Overall recovery (n = 3)	**99**	**6.1**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 756: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	97	97		0.01
	0.1	101	101		
	1	99	99	--	
		Overall recovery (n = 3)	**99**	**2.0**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 757: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	96	96		0.01
	0.1	99	99		
	1	95	95	--	
		Overall recovery (n = 3)	**97**	**2.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 758: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Leek / whole plant without root	0.01	87	87		0.01
	0.1	87	87		
	1	98	98	--	
		Overall recovery (n = 3)	**91**	**7.0**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 104 and 131 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on leek (whole plant without root) are summarised in the following table.

Table 8.9- 759: Residue summary of fluopyram in/on leek, whole plant without root

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0250/7 Southern France	Whole plant without root	47	-0	0.24	<0.01	<0.01	<0.01
	Whole plant without root	47	0	1.7	<0.01	<0.01	<0.01
	Whole plant without root	47	7	0.63	<0.01	<0.01	<0.01
	Whole plant without root	49	14	0.52	<0.01	<0.01	<0.01
	Whole plant without root	49	21	0.34	<0.01	<0.01	<0.01
	Whole plant without root	49	27	0.26	<0.01	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on leek

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 760: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0250/7 Castelsarrasin, FR,						Meteo France Castelsarrasin (7 km), study raw data	sprinkler	Meteo France Castelsarrasin (7 km), study raw data
M-302780-01-1 leek, green material	47	15/11/2007	0	1.7	FLU-benz	0		3.1
		16/11/2007	1		<LOD	0		0.6
		17/11/2007	2			0	20	na
		18/11/2007	3			0		na
		19/11/2007	4			0		na
		20/11/2007	5			1.6		15.8
		21/11/2007	6			0.8		13.1
		22/11/2007	7	0.63		0		6.9
		23/11/2007	8			0		9.7
		24/11/2007	9			0		7.8
		25/11/2007	10			0		3.6
		26/11/2007	11			0		7.3
		27/11/2007	12			0.2		4.5
		28/11/2007	13			0		0
		29/11/2007	14	0.52		0		1.7
		30/11/2007	15			0		7.5
		01/12/2007	16			2.8		7.4
		02/12/2007	17			2.2		10.8
		03/12/2007	18			1.2		11.9
		04/12/2007	19			2		10.6
		05/12/2007	20			1		7.4
		06/12/2007	21	0.34		0.8		11.7
		07/12/2007	22			4.6		11.8
		08/12/2007	23			26.2		9.8
		09/12/2007	24			13.7		11
		10/12/2007	25			0.4		8.8
		11/12/2007	26			0		6.4
		12/12/2007	27	0.26		0		2.4

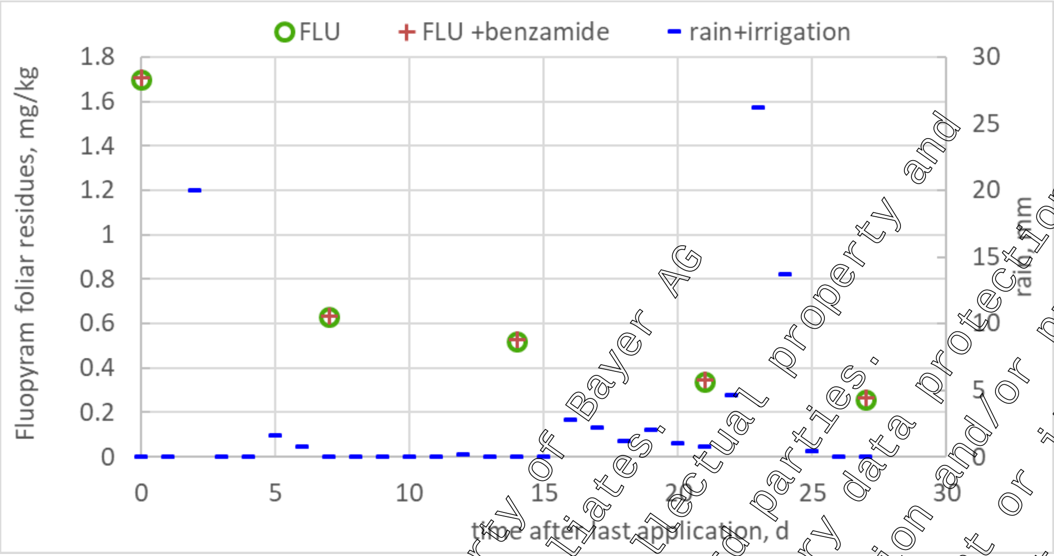


Figure 8.9- 224: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to leek

Early irrigation (20 mm day 2) coincided with a moderate drop of residues (influence likely).

III. CONCLUSION

After three spray applications of Fluopyram + Tebuconazole SC 400 on leek in a single residue trial conducted in southern Europe (southern France) during the 2007 season, the residues of fluopyram in/on leek (whole plant without root) declined markedly during the sampling period. Residues of its metabolites fluopyram-benzamide, fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant:

The study and its data are considered as acceptable and reliable for use in risk assessment. Early irrigation coincided with a moderate drop of residues (influence likely), but irrigation is a frequently necessary factor for agriculture and should thus not be excluded from realistic risk assessments.

Data Point:	KCA 8.9/57
Report Author:	[redacted]
Report Year:	2008
Report Title:	Determination of the residues of AE C656948 and tebuconazole in/on onion, welsh after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Germany and United Kingdom
Report No:	RA-2519/07
Document No:	M-302330-01-1
Guideline(s) followed in study:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations from current test guideline:	Current Guideline: not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary

An open field study with two residue trials was conducted in the field in northern Europe (Germany and United Kingdom) on onion, Welsh during the 2007 season. Two applications with Fluopyram (AE C656948) + Tebuconazole (HWG 1608) 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram, were conducted. Only the parameters and results relevant to fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid have been reported within this study summary.

The residues of fluopyram after two spray applications of the Fluopyram + Tebuconazole 400 SC on onion, Welsh declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in four samples with a maximum value of 0.07 mg/kg. Residues of fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test Item:	Fluopyram + Tebuconazole 400 SC
	Batch no.:	2006-010059
	Active Ingredient:	Fluopyram + tebuconazole
	Storage:	Not stated in the report
	Expiry date:	2008-12-14
2.	Test commodity:	Onion, Welsh
	Crop part:	Whole plant without roots

B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study RA-2519/07 was to determine the magnitude of the relevant residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) in/on onion, Welsh (whole plant without roots) after two spray applications with Fluopyram + Tebuconazole 400 SC, a suspension concentrate formulation containing 200 g/L fluopyram and 200 g/L tebuconazole. This summary focuses on the residues of fluopyram and its metabolites fluopyram-benzamide, fluopyram-pyridyl-acetic acid and fluopyram-pyridyl-carboxylic acid.

Field phase

The study included two supervised residue trials conducted in northern Europe (Germany and United Kingdom) during the 2007 season. Details on trial locations and cropping information on the treated plots is given within the following table:

Table 8.9- 761: Description of the trial locations and cropping information on treated plots

Trial number	R 2007 0042/3	R 2007 0567/0
Trial location	D-51399 Burscheid (Nordrhein-Westfalen)	GB-DA13 9NH Southfleet/ Gravesend (Kent)
Country	Germany	United Kingdom
Area of application	Field	Field
Plot size [m^2]	60	72
Type of soil	Sandy loam	Sandy loam
pH-value of soil (in water)	6.4	6.1
Content of organic C [%]	1.3	1.5
Test system	Onion, Welsh	Onion, Welsh
Variety	Vaugirard	Laser
Date of planting/sowing	- / 2007-03-28	- / 2007-05-01
Date of commercial harvest	2007-06-20 to 2007-07-20	2007-08-01 to 2007-09-30

The actual application data are presented in the following table. This data reflects the intended application scheme. The first application was performed at BBCH stage 45 and the second at BBCH 45-47 with an application rate of 0.2 kg a.s./ha and a water rate of 300 L/ha. The second application for trial R 2007 0567/0 was performed one day earlier (with an interval of 6 days between the two applications instead of 7) due to bad weather forecast. Sampling still took place 7 days after the last application.

Table 8.9- 762: Overview on application with Fluopyram +Tebuconazole SC 400 on onion, Welsh

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Interval (days)	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
R 2007 0042/3 Germany	1	T	Fluopyram + Tebucon-azole SC 400	SPI	7	45	14	1	300	Fluopyram, tebucon-azole	0.2
	2					47	7*				0.2
R 2007 0567/0 United Kingdom	1	T	Fluopyram + Tebucon-azole SC 400	SPI	6	45	13	1	300	Fluopyram, tebucon-azole	0.2
	2					45	7*				0.2

a.s.: Active substance
Appl.: Application
SPI: Spraying
DBH: Days before harvest
PHI: Pre-harvest interval
* designated as Pre-harvest interval (PHI)

Samples were collected in a manner designed to obtain representative samples. Each sample consisted of at least 1000 g of onion, Welsh. Samples were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22) and according to the following sampling schedule:

Table 8.9- 763: Planned sampling schedule

Trial	Crop	Sample material	Control (C) Treated (T)	DALT
R 2007 0042/3 R 2007 0567/0	Onion, Welsh	Whole plant without roots	C	-0
				7
				14
			T	-0
				0
				7
				14
				21

DALT: Days after last treatment "-0": before the last application

2. Description of Analytical Procedures

Residues of fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were analysed within the residue trials samples according to the following method:

Table 8.9- 764: Summary of the analytical method

Method	00984
Extraction	Acetonitrile/water, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopyram and its metabolites expressed as parent equivalents in onion, Welsh, whole plant without roots)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANTE/2020/12830, Rev.1.

In the following, data concerning fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) will be discussed in the summary.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study. Procedural recoveries of fluopyram and fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188) were not corrected for apparent residues in the control samples used for these recoveries. The mean values of the concurrent recoveries were within the acceptable range of 70 – 110%. Details are given in the tables below.

Table 8.9- 765: Procedural recoveries for fluopyram

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	106	106	--	0.01
	0.1	105	105	--	
	2	74	74	--	
	4	102	102	--	
		Overall recovery (n = 4)	**97**	**15.8**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram, determined as fluopyram and calculated as fluopyram.

Table 8.9- 766: Procedural recoveries for fluopyram-benzamide (AE F148815)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	98	98	--	0.01
	0.1	103	103	--	
	2	72	72	--	
	4	99	99	--	
		Overall recovery (n = 4)	**93**	**15.2**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-benzamide, determined as fluopyram-benzamide and calculated as fluopyram.

Table 8.9- 767: Procedural recoveries for fluopyram-pyridyl-acetic acid (BCS-AA10139)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	90	90	--	0.01
	0.1	100	100	--	
	2	73	73	--	
	4	96	96	--	
		Overall recovery (n = 4)	**90**	**13.3**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-acetic acid, determined as fluopyram-pyridyl-acetic acid and calculated as fluopyram.

Table 8.9- 768: Procedural recoveries for fluopyram-pyridyl-carboxylic acid (AE C657188)

Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Onion, Welsh (whole plant without roots)	0.01	103	103	--	0.01
	0.1	84	84	--	
	2	82	82	--	
	4	87	87	--	
		Overall recovery (n = 4)	**89**	**10.7**	

RSD = Relative standard deviation, LOQ = Practical limit of quantification
Fortified with fluopyram-pyridyl-carboxylic acid determined as fluopyram-pyridyl-carboxylic acid and calculated as fluopyram.

3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopyram ranged between 118 and 139 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopyram when stored in high water matrices (at -18°C or below) for up to 36 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopyram were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

1. Residue results:

No residues of fluopyram or its metabolites above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

For fluopyram and its metabolites fluopyram-benzamide (AE F148815), fluopyram-pyridyl-acetic acid (BCS-AA10139) and fluopyram-pyridyl-carboxylic acid (AE C657188), the residues levels in/on onion, Welsh (whole plant without roots) are summarised in the following table.

Table 8.9- 769: Residue summary of fluopyram in/on Onion, Welsh, whole plant without roots

Trial No. Country	Sample material	BBCH	DALT	Residue [mg/kg] fluopyram	Residue [mg/kg] fluopyram-benzamide	Residue [mg/kg] fluopyram-pyridyl-acetic acid	Residue [mg/kg] fluopyram-pyridyl-carboxylic acid
R 2007 0042/3 Germany	Whole plant without roots	47	-0	0.08	<0.01	<0.01	<0.01
	Whole plant without roots	47	0	0.86	<0.01	<0.01	<0.01
	Whole plant without roots	49	7	0.11	0.01	<0.01	<0.01
	Whole plant without roots	49	14	0.12	0.01	<0.01	<0.01
	Whole plant without roots	49	21	0.12	<0.01	<0.01	<0.01
R 2007 0567/0 United Kingdom	Whole plant without roots	45	-0	0.96	<0.01	<0.01	<0.01
	Whole plant without roots	45	0	3.3	<0.01	<0.01	<0.01
	Whole plant without roots	45	7	0.61	<0.01	<0.01	<0.01
	Whole plant without roots	45	13	0.23	0.03	<0.01	<0.01
	Whole plant without roots	45	21	0.11	0.07	<0.01	<0.01

DALT = Days after last treatment

Analyte:	Final determination as:	Residues calculated as:
Fluopyram	Fluopyram	Fluopyram
Fluopyram-benzamide	Fluopyram-benzamide	Fluopyram
Fluopyram-pyridyl-acetic acid	Fluopyram-pyridyl-acetic acid	Fluopyram
Fluopyram-pyridyl-carboxylic acid	Fluopyram-pyridyl-carboxylic acid	Fluopyram

2. Climatic conditions and time course of residue concentrations in/on onion, Welsh

Climatic data recording was not conducted according to GLP. In the following weather data (mean temperature and rainfall, including irrigation if it did impact the leaf surfaces) is given originating from different sources; sources are indicated below each table. These weather data may slightly deviate from weather data as given in the report, as the precise origin of data may vary or due to rounding effects; there is no negative impact on the study results.

Table 8.9- 770: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s, eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0042/3 Burscheid, DE,						ProPlant DB Versuchsgut Höfchen (0 km)	no	ProPlant DB Versuchsgut Höfchen (0 km)
M-302330-01-1	47	19/06/2007	0	0.86	0.865 [a]	0		21.6
		20/06/2007	1			4.6		21.2
Onion, Welsh / green, green material		21/06/2007	2			22.3		15.9
		22/06/2007	3			0.3		16.2
		23/06/2007	4			9		15.9
		24/06/2007	5			0		18.1
		25/06/2007	6			9.6		16.3
		26/06/2007	7	0.11	0.12	3		13.2
		27/06/2007	8			0		13.1
		28/06/2007	9			0.8		15
		29/06/2007	10			1.3		14.8
		30/06/2007	11			0		16.6
		01/07/2007	12			1.7		20.1
		02/07/2007	13			6.3		17.4
		03/07/2007	14	0.12	0.13	4.1		14.8
		04/07/2007	15			18.1		13.2
		05/07/2007	16			3		14.6
		06/07/2007	17			1.9		15.4
		07/07/2007	18			0		16.6
		08/07/2007	19			1.4		17.6
		09/07/2007	20			0.4		15.1
		10/07/2007	21	0.12	0.125 [a]	0		15.1

[a] for FLU-benzamide 0.5 LOD added

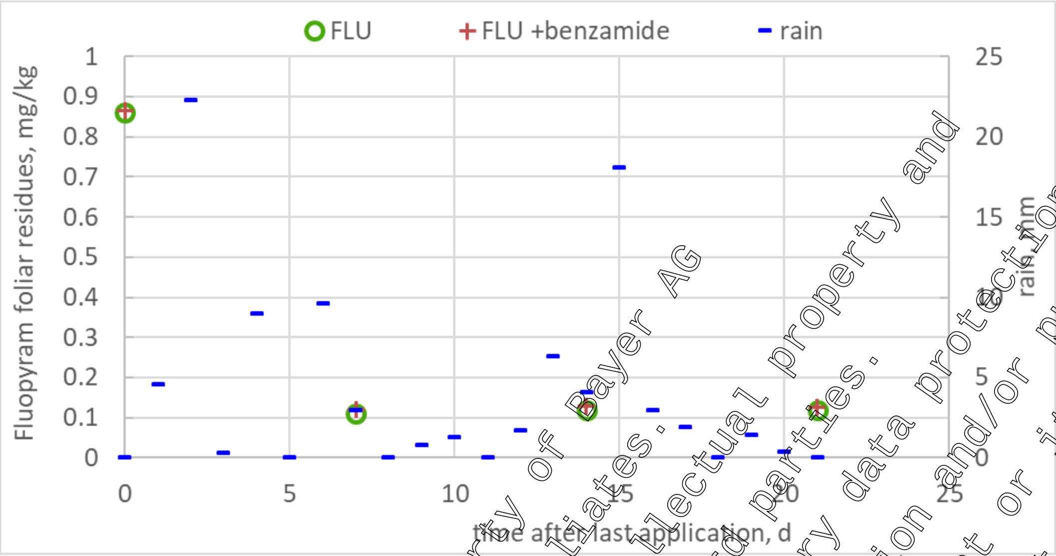


Figure 8.9- 225: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to Onion, Welsh

Early rainfall coincides with marked drop (influence likely)

Table 8.9- 771: Climatic conditions and residue concentration

Study trial, crop	BBCH growth stage	Date dd/mm/ yyyy	Time after treatment (d)	FLU (mg/kg)	FLU + FLU-benzamide (mg a.s. eq./kg)	Precipitation (rain) (mm)	Irrigation over leafs (mm)	Mean temp. (°C)
R 2007 0567/0 Southfleet/ Gravesend, GB,						MARS grid 105083 (25×25 km)	no	MARS grid 105083 (25×25 km)
	43	11/07/2007	0	3.3	3.3	0		15.7
M-302330-01-1		12/07/2007	1			0.9		17.1
		13/07/2007	2			0.4		19.4
Onion, Welsh / green, green material		14/07/2007	3			4.2		19.3
		15/07/2007	4			3.4		18.2
		16/07/2007	5			0.2		19.3
		17/07/2007	6			0		17.5
		18/07/2007	7	0.61	0.615 a)	0		17.8
		19/07/2007	8			19		16.9
		20/07/2007	9			7		17.4
		21/07/2007	10			3		16.6
		22/07/2007	11			0.2		16.3
		23/07/2007	12			12		15.6
		24/07/2007	13			0		17
		25/07/2007	14	0.23	0.26	2		16.9
		26/07/2007	15			2.2		17.4
		27/07/2007	16			6		17.3
		28/07/2007	17			10		17.2
		29/07/2007	18			0		16.1
		30/07/2007	19			0		15.5
		31/07/2007	20			0		15.3
		01/08/2007	21	0.11	0.18	0		16.2

a) for FLU-benzamide 0.5 LOD added

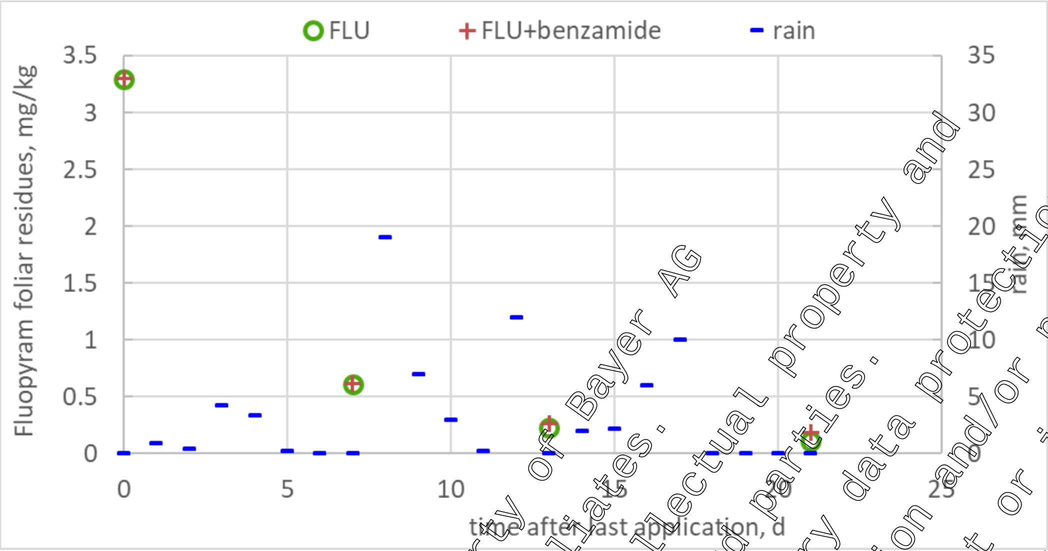


Figure 8.9- 226: Plot of the fluopyram residues decline with corresponding rainfall, in the days following treatment to onion, Welsh.

Early rainfall coincides with marked drop (influence likely).

III. CONCLUSION

After two spray applications of Fluopyram + Tebuconazole SC 400 on onion, Welsh in two residue trials conducted in northern Europe (Germany and United Kingdom) during the 2007 season, the residues of fluopyram in/on onion, Welsh (whole plant without roots) declined markedly during the sampling period. Residues of fluopyram-benzamide were detected in four samples with a maximum value of 0.07 mg/kg. Residues of fluopyram-pyridyl-carboxylic acid and fluopyram-pyridyl-acetic acid were always below the LOQ of 0.01 mg/kg.

Assessment and conclusion by applicant: The study and its data are considered as acceptable and reliable for use in risk assessment. Early rainfall coincided with a moderate drop of residues (influence likely), but rain is a natural and necessary factor for agriculture and should thus not be excluded from realistic risk assessments.