



Document Title

**Summary of the residues in or on treated products, food and feed for  
Deltamethrin**

Data Requirements

**EU Regulation 1107/2009 & EU Regulation 283/2013**

**Document MCA**

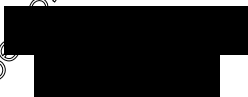
**Section 6: Residues in or on treated products, food and feed**

According to the guidance document, SANCO 10181/2013, for  
preparing dossiers for the approval of a chemical active substance

Date

**2016-12-15**

Author(s)



**Bayer CropScience**

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### Version history

Date	Data points containing amendments or additions <sup>1</sup> and brief description	Document identifier and version number
2015-12-01	Update of - CA 6.1: position paper M-536440-01-1 added summarising the freezer storage data for the various matrices of study M-139715-01-1. - CA 6.2: two position papers M-533554-02-1 and M-539732-01-1 on metabolic pathways in rats, in plants, goats and the environment added. -CA 6.4: position paper M-536726-01-1 added on the exposure of livestock to the alpha-R- and trans-isomer of deltamethrin - CA 6.7.2: The representative uses do not trigger a change for the existing EU-MRLs (reconfirmed in September 2015).	M-478543-02
2016-12-15	Update of sections with answers to requests by the RMS: - CA 6.2: inclusion of additional information M-560000-01-1 - CA 6.2.3: inclusion of additional information M-559823-01-1 - CA 6.4: inclusion of additional information M-559648-01-1 - CA 6.5.3: inclusion of additional information M-559765-01-1	M-478543-03-1

<sup>1</sup> 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

Additions to the document after the Completeness Check are highlighted in yellow. Content not necessary anymore is crossed out.

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CA 6 RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED

This document contains only summaries of studies, which were not available at the time of the first Annex I inclusion of deltamethrin and were therefore not evaluated during the first EU review of this compound. In order to facilitate discrimination between new and original information, the old information is written in grey letters. All studies, which were already submitted by Bayer CropScience for the first Annex I inclusion, are contained in the Monograph, its Addenda, and in the original (baseline) dossier provided by Bayer CropScience and are not summarised in this document.

CA 6.1 Storage stability of residues

The following studies were evaluated during the first EU Annex I inclusion of deltamethrin

**Report:** KCA 6.1/01; [redacted], A. F.:1990  
**Title:** Storage stability study for combined residues of tralofluthrin, deltamethrin and trans-deltamethrin in lettuce in a freezer stability study.  
**Report No:** A73531  
**Document No:** M-151815-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.1/02; [redacted], F.:1991  
**Title:** Supplement 6: Determination of the combined residues of tralofluthrin, deltamethrin and trans-deltamethrin in lettuce in a freezer stability study.  
**Report No:** A71112  
**Document No:** M-149583-01-1  
**Guidelines:** USEPA (40 CFR) 161-4(e) Deviation not specified  
**GLP/GEP:** Y

The wide range of studies conducted demonstrates that residues of deltamethrin remain stable in all crop types, irrespective of whether they are predominantly water, oil, protein or starch containing matrices. Consequently, although the storage periods in some crop residue studies have exceeded the periods specifically validated for those crops in storage stability tests, it is considered that the overall database is sufficient to support adequate stability in all crop matrix types stored in deep freeze for at least 24 months.

Nevertheless in the wide variety of the tested matrices, the acidic matrix was not yet tested. In 2009, a storage stability study was initiated in orange. This study is presented here above.

New data for AIR:

**Report:** KCA 6.1/03; [redacted], C., 2012  
**Title:** Storage stability of residues of deltamethrin (AE F032640) and its isomers AE F108569 and AE 0035073 in orange during deep freeze storage for up to 24 months  
**Report No:** 09-07  
**Edition Number:** M-441996-01-1  
**Guidelines:** Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, No.



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7032/VI/95 rev.5: Appendix H Storage Stability of Residues Samples, July, 1997; Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances; US EPA Residue Chemistry Test Guidelines, OPPTS 860.1380 Storage Stability Data, August 1996; OECD Guideline for the Testing of Chemicals No 506, adopted 16 October 2007

GLP Yes

The study was conducted to evaluate the stability of deltamethrin and its isomers AE F108569 ( $\alpha$ -R isomer of deltamethrin) and AE 0035073 (trans isomer of deltamethrin) in frozen condition ( $\leq -18^\circ\text{C}$ ) for a period of 24 months in orange (fruit).

Individual aliquots of orange (fruit) were fortified with deltamethrin, AE F108569, AE 0035073 at 0.20 mg/kg. The samples stored in HDPE Nalgene containers at an average temperature of  $-18^\circ\text{C}$  or below, were analyzed at the nominal storage intervals of 0, 6, 12, 18, and 25 months.

The results for the all storage intervals are presented in this final study report.

At each storage interval deltamethrin and its isomers were determined in the stored control samples and in the stored spiked samples according to the analytical method 00855/M004. Concurrent recovery experiments at fortification levels of 0.01 mg/kg and 0.20 mg/kg were also performed for each analyte at each storage intervals. The residues are quantified by reversed phase HPLC with Electrospray and MS/MS-detection in a single run for the determination of all of the three analytes. The quantification was carried out by internal standardization using internal stable labelled standard for each corresponding analyte. Validation recoveries on orange fruit were conducted in the study. Concurrent recoveries were conducted at 0.01 mg/kg (except at storage interval 0 days) and 0.20 mg/kg at each analytical point.

In the control samples, residues of deltamethrin, AE F108569 ( $\alpha$ -R isomer of deltamethrin) and AE 0035073 (trans isomer of deltamethrin) were below the Limit of Quantification ( $< 0.01$  mg/kg) for each test item.

For deltamethrin, all the concurrent recovery means were within the acceptable range of 70-110% with corresponding RSD (relative standard deviation)  $< 20\%$ .

For AE F108569 ( $\alpha$ -R isomer of deltamethrin), all the concurrent recovery means were within the acceptable range of 70-110% with corresponding RSD (relative standard deviation)  $< 20\%$ .

For AE 0035073 (trans isomer of deltamethrin), all the concurrent recovery means were within the acceptable range of 70-110% with corresponding RSD (relative standard deviation)  $< 20\%$ .

For all storage intervals, only one compound had been spiked on each stored spiked sample: deltamethrin, AE F108569 ( $\alpha$ -R isomer of deltamethrin) and AE 0035073 (trans isomer of deltamethrin), but in each case, all the compounds mentioned above were analysed to monitor any formation of other non-spiked compounds. Some concurrent recoveries and associated control samples analyses were done to validate these experiences. These results were not reported because this phenomenon was not observed during the study.

Orange (fruit) samples were spiked at a level of 0.2 mg/kg of deltamethrin or AE F108569 ( $\alpha$ -R isomer of deltamethrin) or AE 0035073 (trans isomer of deltamethrin) on day 0. In summary, deltamethrin and its isomers ( $\alpha$ -R- and the trans isomer of deltamethrin) fortified to control samples were shown to be stable during deep-frozen storage for at least 25 months (751 days). These results of stored spiked samples (%) were corrected by the mean of concurrent recovery samples at a level of 0.2 mg/kg (%).

**Conclusion**



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For the sample material orange (fruit), deltamethrin and its isomers ( $\alpha$ -R- and the trans isomers of deltamethrin) were shown to be stable for at least 25 months (751 days) under freezer conditions at about -18 °C or below, after correction of the results by the mean of concurrent recoveries.

**Report:** KCA 6.1/04; [REDACTED] 1996  
**Title:** Amended summary report covering submission guidelines for magnitude of the residue (171-4(k)), processed food/feed (171-4(l)), residue methodology (171-4(c)) and storage stability (171-4(e)) for residues of deltamethrin and its metabolites  
**Report No.:** A55828  
**Edition Number:** M-139715-01-1  
**Guidelines:** USEPA (=EPA): 171-4(k),(l),(c),(e)  
**GLP:** Yes

In the growing seasons 1989 and 1990, a total of 13 field corn trials were conducted in various states of USA, in order to establish tolerances for deltamethrin on corn and its processed commodities.

Corn grain samples for processing were harvested 21 days after the 5th (last) application in the 1989 trial (Iowa) and 35 days after the 5th (last) application in the 1990 trial (Illinois). All samples were maintained in a frozen condition until sample analysis. The treated field corn samples were analyzed according to previously validated analytical methodology designated HRAV-10. This method determines residues of cis-, trans- and alpha-R-deltamethrin using gas chromatography equipped with electron capture detection (GC/ECD). The validated limit of quantitation (LOQ) for the deltamethrin analyses is 0.02 ppm.

All residue samples were analyzed in conjunction with fortified control samples, to demonstrate the performance of the method at the time of field sample analysis. Recovery results are provided along with the field sample data in the attached analytical laboratory reports. These data indicate acceptable method performance.

In the course of this study a storage stability study was conducted over 3 years on representative corn sample commodities.

The purpose of this study was to determine the freezer storage stability of tralomethrin, cis-, trans- and alpha-R-deltamethrin in selected raw agricultural commodities (corn grain, forage and fodder) and selected processed fractions (corn starch, flour and oil). The study was conducted according to EN-CAS Analytical Protocol 89-0030 HOE, entitled "Stability of Tralomethrin, cis-Deltamethrin, and trans-Deltamethrin in Corn Grain and Corn Forage under Freezer Storage Conditions".

Alpha-R-deltamethrin and additional matrices (corn fodder, starch, flour and oil) were added to the study by amendment.

Samples were fortified at 0.20 ppm with either tralomethrin, cis-, trans-, or alpha-R-deltamethrin and stored frozen at temperatures ranging from -23°C to -27°C. An unfortified control and freshly fortified controls were analyzed concurrently with stored fortification samples to determine procedural recovery at each analysis interval. The analysis results indicated tralomethrin, cis-, trans-, and alpha-R-deltamethrin were stable for at least 36 months in corn grain, 35 months in corn forage, 36 months in corn fodder, 36 months in corn starch, 36 months in corn flour and 36 months in corn oil. The percent recoveries of tralomethrin, cis-, trans- and alpha-R-deltamethrin from individual corn matrices are described below:

Corn grain: The recoveries of tralomethrin, cis-, trans-, and alpha-R-deltamethrin from corn grain ranged from 60% to 112% both uncorrected and corrected for procedural recovery. Procedural recoveries analyzed concurrently with the stored fortifications ranged from 76% to 115%.

Corn Forage: The recoveries of tralomethrin, cis-, trans-, and alpha-R-deltamethrin from corn forage ranged from 74% to 134% uncorrected and 87% to 123% corrected (with the exception of one 151%

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recovery) for procedural recovery. Procedural recoveries analyzed concurrently with the stored fortifications ranged from 74% to 117%.

**Corn Fodder:** The recoveries of tralomethrin, cis-,trans-, and alpha-R-deltamethrin from corn fodder ranged from 63% to 115% uncorrected and 73% to 124% corrected for procedural recovery. Procedural recoveries analyzed concurrently with the stored fortifications ranged from 78% to 109%.

**Corn Starch:** The Day-0 recoveries of tralomethrin, cis-,trans-, and alpha-R-deltamethrin from corn starch ranged from 88% to 118%. The 20 month and 36 month recoveries from stored fortifications ranged from 85% to 130% uncorrected (with the exception of one 91% recovery) and 67% to 133% corrected for procedural recovery. Procedural recoveries analyzed concurrently with the stored fortifications ranged from 76% to 116%.

**Corn Flour:** The Day-0 recoveries of tralomethrin, cis-,trans-, and alpha-R-deltamethrin from corn flour ranged from 79% to 98%. The 21 month and 36 month recoveries from stored fortifications ranged from 76% to 113% uncorrected and 76% to 136% corrected for procedural recovery. Procedural recoveries analyzed concurrently with the stored fortifications ranged from 77% to 130%.

**Corn Oil:** The Day-0 recoveries of tralomethrin, cis-, trans-, and alpha-R-deltamethrin from corn oil ranged from 80% to 124%. The 22 month and 36 month recoveries from stored fortifications ranged from 65% to 101% uncorrected and 67% to 125% corrected for procedural recovery. Procedural recoveries analyzed concurrently with the stored fortifications ranged from 81% to 110%.

During the study, the analytical methodology was modified and subsequently re-validated (October 1991 to April 1992) resulting in analytical method HRAV-10 entitled Analytical Method for the Gas Chromatographic Determination of Tralomethrin and Deltamethrin (cis-Deltamethrin, trans-deltamethrin and alpha-R-Deltamethrin) in Corn Matrices (Raw Agricultural Commodities and processed Fractions). Method HRAV-10 was used for analysis of all samples presented in this report.

**Conclusion**

Stored fortification results indicate stability of tralomethrin, cis-, and trans-deltamethrin under freezer storage conditions of 23°C to -27°C, in corn forage for 35 months, in corn grain and corn fodder for 37 months, and in corn starch, corn flour and corn crude oil for 36 months. Results indicate stability of alpha-R-deltamethrin under the same storage conditions in all matrices for 36 months.

Upon request by RMS UK CRD the notifier has prepared the following position paper M-536440-01-1 summarising the freezer storage data for the various matrices from the above mentioned study M-139715-01-1. For each crop fraction and analyte the following information is given:

- on the levels found in mg/kg,
- the recoveries for the samples,
- the recoveries normalized to day zero and
- the recoveries of the freshly fortified samples.

**CA 6.2 Metabolism, distribution and expression of residues**

Upon request by the RMS UK the notifier Bayer CropScience has prepared the two position papers M-53254-02-1 and M-539732-01-1 providing a comparison of the metabolic pathway in rat with those in plants, goats and the environment. The document M-539732-01-1 also includes a table of all significant metabolites identified in the different compartments and their quantitative occurrence. Additional information to several studies was provided on request to the Rapporteur (M-560007-01-1).



### CA 6.2.1 Plants

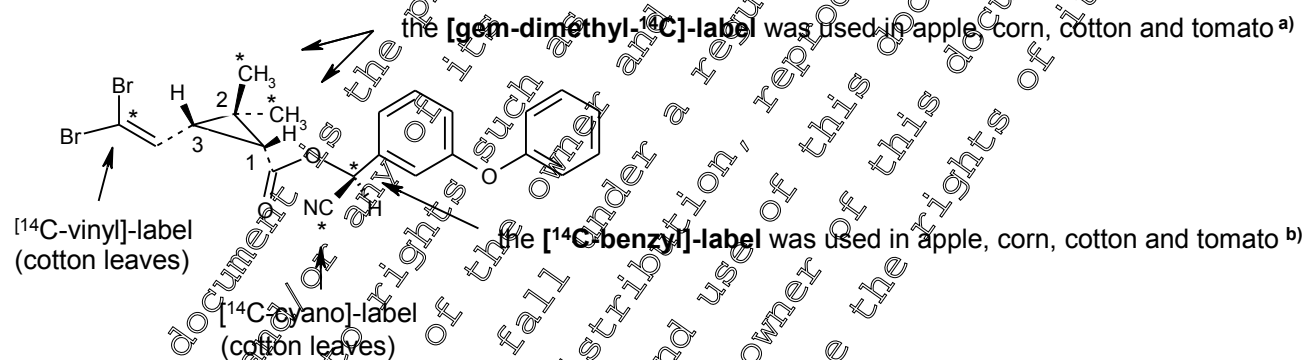
The metabolism of deltamethrin was studied after application to apples (M-149515-01-1), field corn (M-149571-01-1), tomato (M-125042-01-1), and cotton (M-093407-01-1, M-149567-01-1 and M-191128-02-1).

All metabolism data were already evaluated during the first EU review process for inclusion on Annex I.

The detailed metabolism studies were already evaluated and concluded to be representative for the crop categories fruits, leafy crops and cereals.

A short summary of these already evaluated studies is given below.

In these studies deltamethrin was radio labelled with <sup>14</sup>C in one of four different positions as indicated in the figure below:



a) note: the [gem-dimethyl-<sup>14</sup>C]-label was called [C-acid] label in apple and corn. In some reports, one arrow was directed to the intermediate cyclopropyl-C-atom which could be misleading.

b) note: the [<sup>14</sup>C-benzyl]-label was called [<sup>14</sup>C-alcohol] label in apple and corn, but [<sup>14</sup>C-methylene] label in tomatoes.

The major identified products of deltamethrin metabolism are similar in all crop types and are analogous to those in mammals, differing only in the conjugating moieties involved.

The proposed degradation and metabolism pathway involves isomerisation, hydrolysis, ester cleavage, reduction, oxidation and hydroxylation. The only quantifiable constituents of terminal residues are deltamethrin and the two isomers *trans*-<sup>2</sup> and  $\alpha$ -R-deltamethrin, with deltamethrin itself being consistently the major component.

As stated in the EU Monograph (Annex B Residue Data) for Annex I listing of deltamethrin, the relevant residue in plant commodities for the estimation of dietary intake for consumers is defined as deltamethrin only.

The proposed residue definition for the temporary MRLs has been redefined as *cis*-deltamethrin by the former Rapporteur Member State, Sweden. This decision was agreed and voted at the Residue Working



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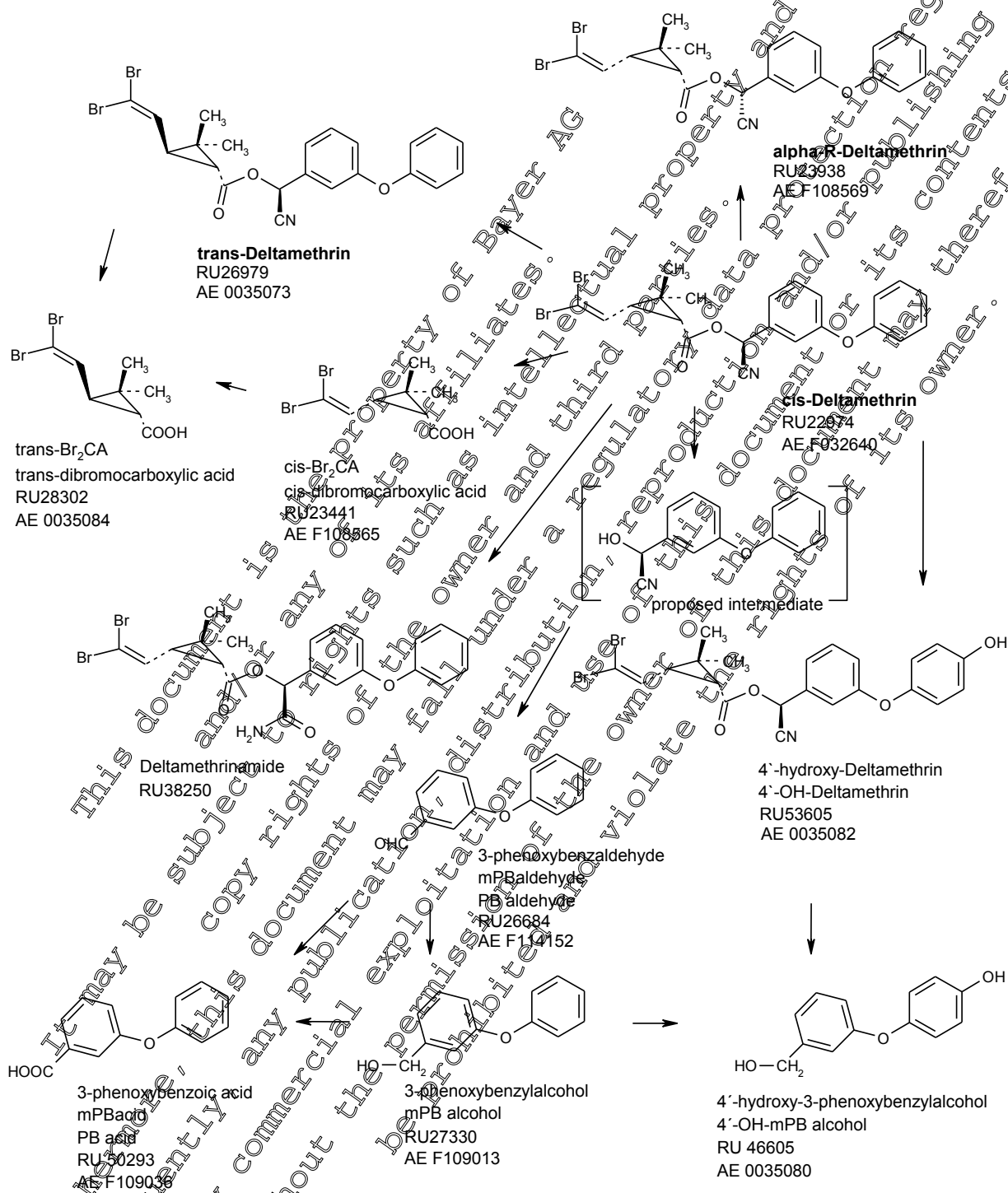
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Group held in March 2006 and implemented in the current Directive 2006/59/EC, listing the EU MRLs for deltamethrin.

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The proposed metabolic pathway in plants is depicted in the figure below (major metabolites are highlighted in bold writing):









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chemical active substance according to regulation (EU) no 283/2013 and regulation (EU) No 284/2013”, Bayer CropScience did not conduct a specific study.

Nevertheless, a number of existing fish studies are available and indicate that parent deltamethrin is a valid marker for residues in fish edible tissues.

For all studies submitted during the frame of the Annex I inclusion, please refer to references printed in grey typeface below and to the corresponding section in the Monograph and in the baseline dossier.

Data already evaluated during the first EU review process for inclusion on Annex I.

Bioconcentration studies (ecotoxicology)

**Report:** KCA 8.2.2.3 /01: [redacted] (1990)  
**Title:** Supplemental information to the study "Deltamethrin - bioconcentration and elimination" (14C-residues by Bluegill (*Lepomis macrochirus*)" (ZPA MKID No. 416/1040)  
**Report No:** A97600  
**Document No:** M-174973-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** No

**Report:** KCA 8.2.2.3 /01: [redacted] (1990)  
**Title:** Deltamethrin - Bioconcentration and elimination of 14C-residues by bluegill (*Lepomis macrochirus*).  
**Report No:** A4117  
**Document No:** M-13555-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** Yes

A bioconcentration study with 14C-benzyl]deltamethrin has been conducted in 1990 on Bluegill ([redacted], reference IIA 8.2.3 from the 2000 Monograph (M-174973-01-1). Bioconcentration factors (BCFs) were determined from a 28 day period with a continuous exposure to a mean measured concentration of 16 ng/L. Deltamethrin reached steady state in edible tissue on day 3 (BCF: 310X) and on day 10 for nonedible tissue (BCF: 2800X). This corresponded to a whole body bioconcentration factor of 1400X. Depuration of accumulated residues occurred rapidly, with a half-life of the residues between 3 and 7 days. Due to the low 14C content in fish tissues, metabolite characterisation was not possible.

New data for AIR:

Another study was therefore conducted with 14C-benzyl]-deltamethrin in 1993.

**Report:** KCA 6.2.5/01: [redacted], M. J.; 1993  
**Title:** Deltamethrin: Bioconcentration exposure with Bluegill Sunfish (*Lepomis macrochirus*) and identification of resulting metabolites  
**Report No:** 9341-5038  
**Edition Number:** M-149401-01-1  
**Guidelines:** Not applicable  
**GLP:** Yes

**Summary**



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The study was conducted over a longer period of time (49 days) and higher water concentration (27.5 ng/L). Bioconcentration factors (BCF) were calculated to be 189X, 3630X and 698X for edible, viscera and whole body tissues, respectively, based on the mean exposure water concentration of 27.5 ng/L over the 49-day exposure period.

This study showed that the metabolism of deltamethrin by bluegill sunfish under flow-through conditions appeared to be minimal. After 49 days of exposure, approximately 78% and 83% of total radioactive residues was identified to be deltamethrin in edible and viscera tissue, respectively. An unknown metabolite, more polar than deltamethrin, was found in both tissue types. The concentration of this unknown metabolite averaged approximately 0.5 and 9 ppb in edible and viscera tissue, respectively. Protein-associated radioactivity, released as a result of protease digestion, averaged approximately 10% and 3% of the TRR for edible and viscera tissue, respectively. Tissue-bound residues remaining after solvent extraction and protease treatment were below 10% of TRR for all samples processed.

**Conclusion**

From these results, it can be demonstrated that parent deltamethrin accounted for the vast majority of radioactivity in the tissues.

Metabolism studies from veterinary uses

Although not marketed by Bayer, deltamethrin is also used as a product for veterinary uses in fin fish to treat sea lice.

In the summary report from 2004 (EMA/MRL/792/03 Final June 2001), the studies mentioned above are described, as well as two radiolabelled studies conducted in Atlantic salmon with intravenous and bath administrations.

In the document, The Committee for Veterinary Medicinal Products (CVMP) wrote:

*“According to the Note for guidance on the establishment of maximum residue limits for salmonidae and other fin fish (EMA/CVMP/1531/97-FINAL), an extrapolation can be made as an MRL has already been established for muscle in several major mammalian species. [...], and the parent compound is acceptable as a valid marker residue in salmonidae and other fin fish.”*

Deltamethrin was therefore included in Annex I of Council Regulation (EEC) No 2377/90 in accordance with the following MRL (as taken from EMA/MRL/893/03 - Final - June 2004):

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions
Deltamethrin	Deltamethrin	Fin fish	10 µg/kg	Muscle and skin in natural proportions	-

**General conclusion**

Deltamethrin is acceptable as a valid marker residue in fish edible tissues.



**CA 6.3 Magnitude of residue trials in plants**

**CA 6.3.1 Cauliflower**

The intended GAP for the AIR dossier is the following:

**(1-2) x 7.5 g a.s /ha, BBCH 10-49, PHI: 7 days**

The following residue studies were submitted during the frame of the Annex I inclusion. Please refer to references printed in grey typeface below and to the corresponding section in the Monograph and in the baseline dossier.

Data already evaluated during the first EU review process for inclusion on Annex I.

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**Report:** KCA 6.3.1 /01: [redacted] [redacted]:1983  
**Title:** Berichtsbogen fuer Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln (Blumenkohl).  
**Report No:** A25151  
**Document No:** M-098086-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.3.1 /02: [redacted] [redacted]:1983  
**Title:** Berichtsbogen fuer Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln (Blumenkohl).  
**Report No:** A25152  
**Document No:** M-098087-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.3.1 /03: [redacted] [redacted]:1983  
**Title:** Berichtsbogen fuer Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln (Blumenkohl).  
**Report No:** A25153  
**Document No:** M-098088-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.3.1 /04: [redacted] [redacted]:1983  
**Title:** Berichtsbogen fuer Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln (Blumenkohl).  
**Report No:** A25154  
**Document No:** M-098089-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.3.1 /05: [redacted]:2000  
**Title:** Decline of residues in cauliflower, European Union (Northern zone) 2000 Deltamethrin emulsifiable concentrate (EC) 2.81 % w/w (25 g/L) Code: AE F032640 00 EC B00 C0155  
**Report No:** C0155  
**Document No:** M-200735-01-1  
**Guidelines:** EU=EEC: 702/VI/97, rev. 5-22/07/97; Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.3.1 /06: [redacted] 1999  
**Title:** Residues at harvest in cauliflowers / broccoli European Union (southern zone) 1997 Deltamethrin emulsifiable granule (EG) 6.25% w/w Code: AE F032640 00 EG01A105  
**Report No:** C01462  
**Document No:** M-182691-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** yes

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Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin

**Report:** KCA 6.3.1 /07: [REDACTED] : [REDACTED] :1999  
**Title:** Residues at harvest in cauliflower and broccoli European Union, Southern zone  
 1998 Deltamethrin emulsifiable granule (EG) 6.25 % w/w Code: AE EG 032640  
 EG06 A106  
**Report No:** C005163  
**Document No:** M-191503-02-1  
**Guidelines:** EU (=EEC): Working document 7029/VI/95 rev 8; Deviation not specified  
**GLP/GEP:** yes

**Report:** KCA 6.3.1 /08: [REDACTED] :1995  
**Title:** Deltamethrine: Residues data summary from supervised trials in vegetables  
 Brassica: Broccoli and Cauliflower.  
**Report No:** A71668  
**Document No:** M-150062-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** n.a.

**Report:** KCA 6.3.1 /08: [REDACTED] :2001  
**Title:** Residue data summary from supervised trials in flowering brassicas: cauliflower and  
 broccoli Additional data Deltamethrin Code: AE EG 032640  
**Report No:** C0157  
**Document No:** M-200128-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.3.1 /10: [REDACTED] :198  
**Title:** Berichtsbogen fuer Rueckstandsuntersuchungen (Hoe 032640, Brassica oleracea  
 var sabullica)  
**Report No:** A41657  
**Document No:** M-124552-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.3.1 /11: [REDACTED] : [REDACTED] 1989  
**Title:** Berichtsbogen fuer Rueckstandsuntersuchungen (Hoe 032640, Brassica oleracea  
 var oboellia)  
**Report No:** A7456  
**Document No:** M-124551-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.3.1 /11: [REDACTED] : [REDACTED] 1989  
**Title:** Berichtsbogen fuer Rueckstandsuntersuchungen (Hoe 032640, Brassica oleracea  
 var sabullica)  
**Report No:** A414  
**Document No:** M-124553-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

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Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin

A summary of the overall residue data is presented below. The summary includes also the trials reviewed during the last deltamethrin EU review (evaluated by the former RMS Sweden).

Crop	Region	Application Scheme	Residues (mg/kg)	STMR (mg/kg)	HR (mg/kg)
<b>Deltamethrin</b>					
Cauliflower	North	3 x 7.5 g/ha PHI 7 days	2 x <0.005, 8 x <0.01	0.01*	0.01*
Cauliflower	South	2 x 12.5 g/ha PHI 7 days	5 x <0.02	0.01*	0.01*

\*Residue level at the LOQ

New data for AIR:

The following studies were not evaluated during the last EU review and are submitted for review:

**Northern European GAP**

**Report:**

KCA 6.3.1/13; [redacted]; 2002

Title:

Residue study with Deltamethrin in cauliflower. European Union (Northern zone) 2001. Code: AE F032640 00 EC03 B018 (=EXP05610A). Deltamethrin, AE F032640 emulsifiable concentrate (EC) 24.8 g/L (25 g/L nominal)

Report No.:

01R054

Edition Number:

M-214429-01-1

Guidelines:

OECD Guidelines as Revised in 1997, DECRET No. 98-1312

GLP

Yes

**Material and Methods:**

Three trials were conducted in 2001 on cauliflower. The intended use consisted of 3 applications of deltamethrin 25 EC (25 g/l of emulsifiable concentrate) at a dose rate of 7.5 g/ha, with an interval of 7 days (17 days in one trial between the 2<sup>nd</sup> and the last application) with a PHI of 7 days.

The samples from the 2001 trial were analysed according to method AGR/MOA/DEL-1 using GC/ECD with a LOQ of 0.01 mg/kg in inflorescences.

**Findings:**

In the following table, the application information and the residues found in/on cauliflower are summarised. Residues in all of the trials were found to be below LOQ <0.01 mg/kg.

**Table 6.3.1-1: Residues in cauliflower in Northern Europe (3 x 7.5 g a.s./ha, PHI 7 days)**

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues		
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	Deltamethrin (mg/kg)
01R054 01R054-1 GLP yes 2001 M-214429-01-1	Cauliflower Amsterdam	France [redacted] Europe, North	25 EC	3	0.0075	0.0014- 0.0015	45	curd	0 7	<0.01 <0.01



Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues		
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	Deltamethrin (mg/kg)
01R054 01R054-2 GLP yes 2001 M-214429-01-1	Cauliflower Fremont	France [redacted] Europe, North	25 EC	3	0.0075	0.0015-0.0017	49	curd	0 7	<0.01 0.01
01R054 01R054-3 GLP yes 2001 M-214429-01-1	Cauliflower Aviso	France [redacted] Europe, North	25 EC	3	0.0075	0.0014-0.0015	80% of the head diameter reached	curd	0	<0.01 0.01

Southern European GAP

**Report:** KCA 6.3.1/14, [redacted], [redacted] 2008  
**Title:** Determination of the residues of deltamethrin in/on cauliflower after spraying of deltamethrin EW 15 (015 EW) in the field in Spain and Italy  
**Report No & Document No:** RA-2555/06  
 M-303449-01-1  
**Guidelines:** EU-Ref.: Directive 91/414/EEC Residues in or on Treated Products, Food and Feed  
**GLP:** Yes

**Report:** KCA 6.3.1/15, [redacted], [redacted] 2008  
**Title:** Determination of the residues of deltamethrin in/on cauliflower after spraying of deltamethrin EW 15 (015 EW) in the field in Spain and Italy  
**Report No & Document No:** RA-2547/0  
 M-308923-01-1  
**Guidelines:** EU-Ref.: Directive 91/414/EEC Residues in or on Treated Products, Food and Feed  
**GLP:** Yes

Material and Methods:

Four field residue trials were conducted in Southern Europe during the 2006 and 2007 growing seasons on cauliflower. The intended use consisted of 3 applications of Deltamethrin 15 EW (15 g/l of oil in water emulsion) at a dose rate of 18 g a.s./ha, with an interval of 7 days and a PHI of 7 days. Curds were sampled on the last day of application and at harvest, 7 days after the final application for two trials and for the two others, sampled on the last day of application and on day 1, day 3, day 4 and at harvest, 7 days after the last application. The cauliflower curd samples were analysed using method 00855/M002 with a LOQ of 0.01 mg/kg.

Findings:

In Table 6.3.1-2, the application information and the residues found in/on cauliflower are summarised. Initial residues in/on the curds ranged between under the LOQ of 0.01 mg/kg and 0.02 mg/kg. At the proposed harvest date, 7 days after the last application, the residues in/on curd samples were all below the LOQ of 0.01 mg/kg.



Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin

Table 6.3.1-2: Residues in cauliflower in Southern Europe (3 x 18 g a.s./ha, PHI 7 days)

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues		
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DAIT (days)	Deltamethrin (mg/kg)
RA-2547/07 R 2007 0048 2 0048-07 GLP yes 2008 M-308923-01-1	Cauliflower Optimus	Spain  Europe, South	15 EW	3	0.0180	0.00225	49	curd	0* 0 1 4 7	<0.01 <0.01 <0.01 <0.01 <0.01
RA-2547/07 R 2007 0049 0 0049-07 GLP yes 2007 M-308923-01-1	Cauliflower ISI 16037 F1	Italy  Europe, South	15 EW	3	0.0180	0.00225	49	curd	0 7	<0.01 <0.01
RA-2555/06 R 2006 0305 3 0305-06 GLP yes 2006 M-303449-01-1	Cauliflower Movidich	Spain  Europe, South	15 EW	3	0.0180	0.00225	48	curd	0 0 1 3 4	<0.01 <0.01 <0.01 <0.01 <0.01
RA-2555/06 R 2006 0306 1 0306-06 GLP yes 2006 M-303449-01-1	Cauliflower Trevi	Italy  Europe, South	15 EW	3	0.0180	0.00225	48	curd	0 7	0.02 <0.01

**Conclusion:**

In the Northern European region, ten residue trials were conducted according to an intended use of 3 applications at a dose rate of 7.5 g/ha, with an interval of 14 days and the last application taking place 7 days before harvest. In all the curd samples collected 7 days after the last application the residue level was found below the respective LOQ of the method of analysis either, 0.005 mg/kg or 0.01 mg/kg.

In the Southern European region, five residue trials were conducted according to an intended use of 2 applications at 7 days interval and at a dose rate of 12.5 g/ha with a PHI of 7 days. Four additional residue trials were conducted at a higher GAP, consisting of 3 applications at 7 day interval and at a dose rate of 18 g/ha with a PHI of 7 days. In all the curd samples collected 7 days after the last application the residue level was found below the respective LOQ of the method of analysis either, 0.02 mg/kg or 0.01 mg/kg.

**CA 6.3.2 Sugarbeet**

The intended GAP for the MRL dossier is the following:

- 1 x 7.5 g a.s /ha, BBCH 10-49, PHI: 30 days.

The following residue study was submitted during the frame of the Annex I inclusion. Please refer to the reference printed in grey typeface below and to the corresponding section in the Monograph and in the baseline dossier.

Data already evaluated during the first EU review process for inclusion on Annex I.





Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin

Report: KCA 6.3.2 /01; [redacted] 1995

Title: Deltamethrin: Residues data summary from supervised trials in root and tuber vegetables.

Report No: A71585

Document No: M-149986-01-1

Guidelines: Deviation not specified

GLP/GEP: n.a.

A summary of the overall residue data is presented below. The summary includes also the trials reviewed during the last deltamethrin EU review (evaluated by the former RMS Sweden).

Crop	Region	Application Scheme	Residues (mg/kg)	n	STMR (mg/kg)	MRL (mg/kg)
<b>Deltamethrin</b>						
Sugarbeet	North	1 x 12.5 g/ha PHI 14 days	4 x < 0.02	4	0.02	0.02*
Sugarbeet	North	3-4 x 25 g/ha PHI 9-34 days	4 x < 0.02	4	0.02*	0.02*
Sugarbeet	North	2 x 7.5 g/ha PHI 16-34	5 x < 0.01	5	0.01*	0.01*
Sugarbeet	North	4 x 7 g/ha PHI 28-43 days	3 x < 0.005 3 x < 0.01 0.01	5	0.01*	0.01*

\*Residue level at the MRL

New data for AIR

The following studies were not evaluated during the last EU review and are submitted for review:

Report: KCA 6.3.2/02; [redacted] 2001

Title: Residues at harvest of sugar beets, European Union, Northern zone 2000. Deltamethrin, AE F032640 emulsifiable concentrate (EC) 2.81 % w/w (=25 g/L)

Report No.: DR 00/EUN 425

Edition Number: M-200812-01-1

Guidelines: EU Commission Working Document 7029/VI/95 rev. 5 – 22/07/97

GLP: Yes

Report: KCA 6.3.2/03; [redacted] 2002

Title: Residue study with Deltamethrin in sugar beets. European Union (Northern zone) 2001. Deltamethrin, AE F032640 emulsifiable concentrate (EC) 24.8 g/L (25 g/L nominal)

Report No.: QR051 or C023401

Edition Number: M-214930-01-1

Guidelines: EU Commission Working Document 7029/VI/95 rev. 5 – 22/07/97

GLP: Yes

Report: KCA 6.3.2/04; [redacted] 2001



**Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin**

Title: Residues at harvest in sugar beets. European Union, Southern zone 2000.  
Deltamethrin, AE F032640 emulsifiable concentrate (EC) 2.81 % w/w (25 g/l).  
Report No.: DR 00 EUS 413  
Edition Number: M-204224-01-1  
Guidelines: EU Commission Working Document 7029/VI/95 rev. 5 – 22/07/97  
GLP Yes

**Report: KCA 6.3.2/05; [REDACTED] 2002**  
Title: Residue study with Deltamethrin in sugar beets. European Union (Southern zone) 2001. Deltamethrin, AE F032640 emulsifiable concentrate (EC) 2.81 g/L (25 g/L nominal)  
Report No.: 01R052  
Edition Number: M-216175-01-1  
Guidelines: EU Commission Working Document 7029/VI/95 rev. 5 – 22/07/97  
GLP Yes

**Material and Methods:**

In the Northern European region, four residue decline trials and five harvest trials were carried out in Belgium, France, Germany and the United Kingdom. In the Southern European region, four residue decline trials and five harvest trials were conducted in Greece, Italy and Spain. A 25 g/l emulsifiable concentrate of deltamethrin was applied in these trials.

In all trials, deltamethrin was applied once, at a nominal rate of 12.5 g a.s./ha. Leaves with tops and roots were sampled at harvest 28 – 31 days after application. Only in the harvest trials, leaves with tops and roots were also sampled on the day of application. Samples of whole sugar beet plants were taken on days 0, 7, 14 and 21 (20) in the decline trials.

The samples were analysed either according to method DGM F01/97-1 with a LOQ of 0.02 mg/kg in leaves (with tops) and roots, or to method AGR/MOA/BEL-1 with a LOQ of 0.01 mg/kg in leaves (with tops), roots and whole plant.

**Findings:**

In Tables 6.3.2-1/6.3.2-2, the application information and the residues found in sugar beets in Northern and Southern Europe are summarised.

In Northern Europe, initial residues in leaves with tops ranged between 0.17 - 0.32 mg/kg, while the corresponding root samples were free of residues above the limit of quantification (< 0.02 mg/kg). Initial residues in whole plant samples ranged between 0.03 – 0.19 mg/kg. At harvest (PHI = 28 – 31 days) residues in leaves with tops had declined to <0.01 – 0.04 mg/kg. In roots, no residues above the LOQ were detected at harvest (<0.02 mg/kg, <0.01 mg/kg).

In Southern Europe, initial residues in leaves with tops ranged between 0.07 - 0.21 mg/kg, while the corresponding root samples were free of residues above the limit of quantification (< 0.02 mg/kg). Initial residues in whole plant samples ranged between 0.03 – 0.13 mg/kg. At harvest (PHI = 28 – 31 days)



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residues in leaves with tops had declined below the LOQ. In roots, no residues above the LOQ were detected at harvest (<0.02 mg/kg, <0.01 mg/kg).

Table 6.3.2-1: Residues in sugarbeet in Northern Europe (1 x 12.5 g a.s./ha, PHI 30 days).

Study Trial No. GLP Year	Crop Variety	Country	Application					Residues		
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALY (days)	Deltamethrin (mg/kg)
DR00EUN425 DR00EUN425DE U0301 GLP yes 2000 M-203812-01-1	Beet, sugar Tatjana	Germany [redacted] Europe, North	25 EC	1	0.0125	0.00417	49	leaf with root collar root	0 31	0.19 0.04 0.02
DR00EUN425 DR00EUN425DE U0601 GLP yes 2000 M-203812-01-1	Beet, sugar Wiebke	Germany [redacted] Europe, North	25 EC	1	0.0125	0.00417	49	leaf with root collar root	0 30	0.30 0.04 0.02
DR00EUN425 DR00EUN425FR A0101 GLP yes 2000 M-203812-01-1	Beet, sugar Roberta	France [redacted] Europe, North	25 EC	1	0.0125	0.00500	39	leaf with root collar root	0 31	0.28 <0.02 <0.02
DR00EUN425 DR00EUN425GB R0101 GLP yes 2000 M-203812-01-1	Beet, sugar Duke	United Kingdom [redacted] Europe, North	25 EC	1	0.0125	0.00625	39	leaf with root collar root	0 30	0.32 0.02 <0.02
DR00EUN425 DR00EUN425GB R0102 GLP yes 2000 M-203812-01-1	Beet, sugar Roberta	United Kingdom [redacted] Europe, North	25 EC	1	0.0125	0.00424	39	leaf with root collar root	0 30	0.17 <0.02 <0.02
01R051 01R051-1 GLP yes 2001 M-214930-01-1	Beet, sugar Sherif	France [redacted] Europe, North	25 EC	1	0.012488	0.00416	39	whole plant with root leaf with root collar root	0 7 14 21 28	0.19 0.05 0.02 <0.01 0.03
01R051 01R051-2 GLP yes 2001 M-214930-01-1	Beet, sugar Roberta	France [redacted] Europe, North	25 EC	1	0.012336	0.00418	39	whole plant with root leaf with root collar root	0 7 14 21 28	0.06 0.01 <0.01 <0.01 0.02
01R051 01R051-3 GLP yes 2001 M-214930-01-1	Beet, sugar Ariana	Belgium [redacted] Europe, North	25 EC	1	0.013748	0.00414	50 % of roots reach harvestable size	whole plant with root leaf with root collar root	0 7 14 21 30 30	0.04 0.03 0.02 0.01 0.03 <0.01
01R051 01R051-4 GLP yes 2001 M-214930-01-1	Beet, sugar Corinna	Germany [redacted] Europe, North	25 EC	1	0.011984	0.00413	leaves cover 70% of ground	whole plant with root leaf with root collar root	0 7 14 21 30	0.03 0.02 0.02 0.01 0.01



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Deltamethrin

Table 6.3.2-2: Residues in sugarbeet in Southern Europe (1 x 12.5 g a.s /ha, PHI 30 days)

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues		
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DAIT (days)	Deltamethrin (mg/kg)
DR00EUS413 DR00EUS413ES P0201 GLP yes 2000 M-204224-01-1	Beet, sugar Claudia	Spain [redacted] Europe, South	25 EC	1	0.0125	0.00417	49	leaf with root collar root	0 31	0.05 0.02 0.02 0.02
DR00EUS413 DR00EUS413ES P0202 GLP yes 2000 M-204224-01-1	Beet, sugar Napoli	Spain [redacted] Europe, South	25 EC	1	0.0125	0.00417	49	leaf with root collar root	0 29 29	0.12 0.02 0.02 0.02
DR00EUS413 DR00EUS413GR C0101 GLP yes 2000 M-204224-01-1	Beet, sugar Alexandra	Greece [redacted] Europe, South	25 EC	1	0.0125	0.00250	49	leaf with root collar root	0 31 0 31	0.07 0.02 0.02 0.02
DR00EUS413 DR00EUS413IT A0101 GLP yes 2000 M-204224-01-1	Beet, sugar Bushel	Italy [redacted] Europe, South	25 EC	1	0.0125	0.00250	39	leaf with root collar root	0 30 0 30	0.18 0.02 0.02 0.02
DR00EUS413 DR00EUS413IT A0102 GLP yes 2000 M-204224-01-1	Beet, sugar Rizor	Italy [redacted] Europe, South	25 EC	1	0.0125	0.00208	39	leaf with root collar root	0 30 0 30	0.21 0.02 0.02 0.02
01R052 01R052-1 GLP yes 2001 M-216175-01-1	Beet, sugar Safrane	Spain [redacted] Europe, South	25 EC	1	0.01286	0.00353	45	whole plant with root leaf with root collar root	0 7 14 21 30 30	0.04 0.03 0.01 0.01 0.01 0.01
01R052 01R052-2 GLP yes 2001 M-216175-01-1	Beet, sugar Khazar	Spain [redacted] Europe, South	25 EC	1	0.012964	0.00360	50% of the expected root diameter reached	whole plant with root leaf with root collar root	0 7 14 21 30 30	0.07 0.05 0.02 0.02 0.01 0.01
01R052 01R052-3 GLP yes 2001 M-216175-01-1	Beet, sugar Monodoro	Italy [redacted] Europe, South	25 EC	1	0.012684	0.00415	roots beginning to expand	whole plant with root leaf with root collar root	0 7 14 20 30 30	0.13 0.03 0.01 0.01 0.01 0.01
01R052 01R052-4 GLP yes 2001 M-216175-01-1	Beet, sugar Nubia	Italy [redacted] Europe, South	25 EC	1	0.012656	0.00313	roots beginning to expand	whole plant with root leaf with root collar root	0 7 14 21 30 30	0.03 0.01 0.01 0.01 0.01 0.01





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Deltamethrin

Conclusion:

Eighteen residue trials were conducted with Deltamethrin 25 EC on sugar beet in Northern (9) and Southern Europe (9). The product was applied once at a rate of 12.5 g a.s /ha and the trials were carried out according to GLP principles. The results presented above demonstrate that:

- In Northern Europe, the maximum residue level obtained in leaves with tops that are used as animal feed is 0.04 mg/kg. In roots, no residues above the LOQ (0.01 mg/kg) were detected.
- In Southern Europe, no residues above the LOQ (0.01 mg/kg or 0.02 mg/kg) were detected in leaves with tops and roots.

CA 6.3.3 Wheat

The intended GAP for the AIR dossier is the following:

**2 x 6.25 g a.s /ha, BCH 10-83, PHI: not applicable**

The following residue studies were submitted during the frame of the Annex I inclusion. Please refer to the reference printed in grey typeface below and to the corresponding section in the Monograph and in the baseline dossier.

Data already evaluated during the first EUC review process for inclusion on Annex I

- Report:** KCA 6.3/01- [redacted] 1993  
**Title:** Determination of cis-deltamethrin, trans-deltamethrin and alpha-R-deltamethrin in various grains, grain fractions and grain dusts under 20.C, 30.C and frozen storage conditions.  
**Report No:** A71102  
**Document No:** M-149575-01-1  
**Guidelines:** USEPA, EPA; O, 17-4; Deviation not specified  
**GLP/GEP:** es
- Report:** KCA 6.3/02- [redacted] 1995  
**Title:** Deltamethrin: Residue data summary from supervised trials in 1/ Cereals: Wheat, Barley, Oats  
**Report No:** A76008  
**Document No:** M-15029-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** n.a.
- Report:** KCA 6.3/03- [redacted] 1998  
**Title:** Residues data summary from supervised trials in cereals (wheat, winter variety). Additional data Deltamethrin  
**Report No:** C0544  
**Document No:** M-192094-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** n

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Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin

**Report:** KCA 6.3.3 /04: [redacted] : [redacted] :1997  
**Title:** Deltamethrin; emulsifiable granules 6.25 % w/w; Code: AE F032640 00 F006 A103 - Residue trials in winter-wheat to confirm maximum residue level compliance. Determination of active substance at harvest following two applications. European un  
**Report No:** A56788  
**Document No:** M-140573-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** yes

**For information, at EU level, the EU MRL on cereals is derived from the post-harvest use of deltamethrin on stored cereal grains.**

New data for AIR:

The following studies were not evaluated during the last EU review and are submitted for review:

A new residue post-harvest study was conducted in 2008 according to more recent standards for method of analysis on wheat grain, in order to confirm the residue levels found in the trials performed in the eighties.

**Report:** KCA 6.3.3/05; [redacted]; [redacted] 2009  
**Title:** Determination of the residues of deltamethrin in/on winter wheat after mixing of Deltamethrin & Piperonyl butoxide EC 275 in the Room, hall, store, ... in Germany, Greece, Portugal and the United Kingdom  
**Report No.:** 08-2214  
**Edition Number:** M-360749-01-1  
**Guidelines:** OECD on 12 May 1981 [Annex 2 to C (81) 30 (Final)], endorsed for use in the European Union by Directive 82/18 of 18 December 1986  
**GLP** Yes

**Material and methods**

The purpose of the study was to determine the magnitude of residues of deltamethrin in/on grain wheat which was treated by one mixing application in the storage room with deltamethrin & piperonyl butoxide EC 275 (250 g/L of piperonyl butoxide and 25 g/L of deltamethrin) at a dose rate corresponding to an application of 0.5 g/t of deltamethrin and 5 g/t of piperonyl butoxide. The treatment was done after normal harvesting in 4 locations in northern Europe (the United Kingdom and Germany) and southern Europe (Portugal and Greece). According to the locations the modalities of application are slightly different but all used a cement mixer. The bins were covered with a tissue or a net after application.

The grain samples were analysed for deltamethrin (cis-deltamethrin) only, with the LC-MS/MS method, 00855/M002 with the limit of quantification of 0.01 mg/kg.

**Findings**

The maximum storage period observed for the deep frozen grain samples, in this study is 462 days, period which is covered by the different stability studies. The mean of the concurrent recoveries were for grain and for all fortification levels within acceptable range of 70-110%. The residue levels observed in the grain samples at different times of storage are reported in the following table.



**Table 6.3.3-1: Results of residue trials conducted with deltamethrin & piperonylbutoxide EC 275 on stored wheat grain**

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues		
			FL	No	g/dt (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	deltamethrin (mg/kg)
08-2214MAN 08-2214-01 GLP: yes 2008	Wheat, winter Hereward	United Kingdom [Redacted] Europe, North	250 EC	1	0.050	0.050	99	grain	0 8 23 92	0.28 0.30 0.29 0.44
08-2214MAN 08-2214-02 GLP: yes 2008	Wheat, winter Hermann	Germany [Redacted] Europe, North	250 EC	1	0.050	0.050	99	grain	0 7 23 88	0.40 0.45 0.44 0.43
08-2214MAN 08-2214-03 GLP: yes 2008	Wheat, winter Pirico	Portugal [Redacted] Europe, South	250 EC	1	0.050	0.050	99	grain	0 7 23 91	0.27 0.29 0.33
08-2214MAN 08-2214-04 GLP: yes 2008	Wheat, winter Cosmodur	Greece [Redacted] Europe, South	250 EC	1	0.050	0.050	99	grain	0 7 23 92	0.54 0.34 0.33 0.49

**Conclusion**

As expected, the residue levels found in the samples collected after different periods of storage are very close to the dose rate applied. The residue values ranged from 0.33 mg/kg to 0.49 mg/kg. These values are in line with the current MRL of 2 mg/kg derived from the post-harvest use of deltamethrin on cereal grains.

The representative use supported in this dossier is the field spray use of deltamethrin on wheat. The field residue trials presented here below are supporting this use pattern.

**Supported pre-harvest GAP for AIR**

**Northern European Pre-Harvest GAP, 1+2 x 6.25 g/ha, PHI 30 days**



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Deltamethrin

Report: KCA 6.3.3/04; [redacted]; [redacted] 1997  
 Title: Deltamethrin; emulsifiable granules 6.25 % w/w; Code: AE F032640 00 F006 A103 - Residue trials in winter-wheat to confirm maximum residue level compliance. Determination of active substance at harvest following typical applications. European union.  
 Report No.: ER95ECN795  
 Edition Number: M-140573-01-1  
 Guidelines: OECD on 12 May 1981 [Annex to C (81) 30 (final)], endorsed for use in the European Union by Directive 87/48 of 18 December 1986  
 GLP Yes

Report: **KCA 6.3.3/06; [redacted] 2011**  
 Title: Determination of residues of deltamethrin in/on wheat after spraying of Decis EC 025 in the field in UK and Poland 2010  
 Report No.: S10-00009  
 Edition Number: M-411373-01-1  
 Guidelines: 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)  
 GLP Yes

Report: **KCA 6.3.3/07; [redacted] 2012**  
 Title: Determination of the residues of deltamethrin in/on winter wheat after spray application of Decis EC 025 in the field in Belgium, northern France, United Kingdom, Germany, southern France, Italy, Spain and Portugal  
 Report No.: 10-2036  
 Edition Number: M-435250-01-1  
 Guidelines: 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)  
 GLP Yes

**Material and Methods:**

In Europe, one of the pre-harvest uses of deltamethrin on winter varieties of cereals is 3 applications at 6.25 g a.s./ha, with the first application taking place in autumn and the following ones in spring with a spray interval of 14-21 days.

Four residue trials were conducted in 1995, in Northern Europe in/on winter wheat. Deltamethrin formulated as a 62.5% emulsifiable granule was applied twice as a foliar spray, pre-harvest treatment at a nominal rate of 6.25 g a.s./ha and 7 g a.s./ha for the last application with a PHI of 30 days.

In this study, the application in autumn was omitted, while the next applications were made according to the intended use pattern. As the autumn application does not significantly contribute to the residue behaviour in wheat, these trials can be used to describe the residue behaviour under the supported AIR use.

Residue analysis was conducted using method V/974/OIL/01/01 using GC-ECD with a LOQ of 0.02 mg/kg for grain, ear and straw.

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Deltamethrin

Additionally, in 2010, 8 residue trials were performed in Northern European region on winter wheat. The use pattern consisted in one application in autumn at 6.25 g/ha of deltamethrin formulated as a 25 g/l emulsifiable concentrate, followed in spring with 2 applications with an interval of 14 days, the last application being sprayed at BBCH 83. The samples of green material or plant without roots were collected at 0 days after last application and the samples of grain and straw were collected at harvest (growth stage BBCH 89). Residue analysis was conducted using method 00855/M004 using LC-MS/MS with a LOQ of 0.01 mg/kg for grain and a LOQ of 0.05 mg/kg for green material, plant without roots and straw.

**Findings:**

The maximum storage period observed for the deep-frozen grain samples, in the 2010 studies is 365 days, period which is covered by the different stability studies. The mean of the concurrent recoveries were for grain and for all fortification levels within acceptable range of 70-100%. The following table summarizes the residues found in winter wheat in Northern Europe. Residues in all of the trials were found to be below the LOQ of 0.01 or 0.02 mg/kg in/on the grain at harvest corresponding to a PHI from 12 to 43 days.

**Table 6.3.3-2: Residues in winter wheat – pre harvest trials (3 x 6.25 g a.s./ha)**

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application				Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DAIT (days)	Deltamethrin (mg/kg)
ER95ECN795 ER95ECN795 DEU0401 GLP yes 1995	Wheat, winter Rektor	Germany [Redacted] Europe North	6.25 EG	2	0.0063	0.0021-	71	ear	0	0.14
					-	0.0025				
					0.0075					
ER95ECN795 ER95ECN795 DEU0601 GLP yes 1995	Wheat, winter Kontrast	Germany [Redacted] Europe North	6.25 EG	2	0.0063	0.0021-	71	ear	0	0.12
					-	0.0025				
					0.0075					
ER95ECN795 ER95ECN795 FRA0001 GLP yes 1995	Wheat, winter Rechal	France [Redacted] Europe North	6.25 EG	2	0.0063	0.0021-	85	ear	0	0.15
					-	0.0025				
					0.0075					
ER95ECN795	Wheat, winter	United Kingdom	6.25 EG	2		0.0031-0.0038	75	ear grain	0	0.07
									30	<0.02



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues		
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	Deltamethrin (mg/kg)
ER95ECN795 GBR0001 GLP yes 1995	Riband	Europe, North			0.0063 - 0.007			straw		0.41
S10-00009 S10-00009-01 GLP: yes 2010	Wheat, winter Gladiato r	United Kingdom Europe, North	25 EC	3	0.0060 - 0.0064	0.0021 - 0.0021	83	whole plant without roots grain straw	0 29 29	0.23 <0.01 0.30
S10-00009 S10-00009-02 GLP: yes 2010	Wheat, winter Hevenar d	United Kingdom Europe, North	25 EC	3	0.0065 - 0.0065	0.0021 - 0.0021	85	whole plant without roots grain straw	0 21 21	0.20 <0.01 0.28
S10-00009 S10-00009-03 GLP: yes 2010	Wheat, winter Alzar	Poland Europe, North	25 EC	3	0.0060 - 0.0065	0.0021 - 0.0021	83	whole plant without roots grain straw	0 26 26	0.23 <0.01 0.25
S10-00009 S10-00009-04 GLP: yes 2010	Wheat, winter Bogarra	Poland Europe, North	25 EC		0.0065 - 0.0021-0.0021	0.0021 - 0.0021	83	whole plant without roots grain straw	0 12 12	0.45 <0.01 0.36
10-2036MAN 10-2036-01 10-2036-01-T GLP: yes 2010	Wheat, winter Julius	Belgium Europe, North	25 EC		0.0063 - 0.0066	0.0021-0.00209	83	green material grain straw	0 34 34	<0.05 <0.01 <0.05
10-2036MAN 10-2036-02 10-2036-02-T GLP: yes 2010	Wheat, winter Pienio	France Europe, North	25 EC	3	0.0063	0.0021	83	green material grain straw	0 41 41	<0.05 <0.01 <0.05
10-2036MAN 10-2036-03 10-2036-03-T GLP: yes 2010	Wheat, winter Duxford	United Kingdom Europe, North	25 EC	3	0.0063	0.0033	85	green material grain straw	0 19 19	<0.05 <0.01 <0.05



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues		
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	Deltamethrin (mg/kg)
10-2036MAN 10-2036-04 10-2036-04-T GLP: yes 2010	Wheat, winter Manager	Germany	25 EC	3	0.0063	0.0021	83	green material	28	0.05
		█						grain		0.01
		Europe, North						straw		0.05

**Conclusion:**

- Residues found in/on winter wheat grain following pre harvest treatments were all below the LOQ of 0.01 or 0.02 mg/kg.
- Residues found in straw at harvest ranged from below the LOQ of 0.05 mg/kg and 0.41 mg/kg

Two use patterns were envisaged for the Southern European region,

- 1 application at a dose rate of 12.5 g/ha and a PHI of 30 days
- 2 applications at a dose rate of 6.25 g/ha and a PHI of 30 days

Since it was not possible to forecast what will be the critical GAP, two set of trials were performed in 2010 reflecting both use patterns.

**Southern European Pre-Harvest GAP, 1x 12.5 g/ha, PHI 30 days**

Report: **KCA 6.3.3/08; █; 2011**  
 Title: Determination of the residues of deltamethrin in/on wheat after spray application of Decis EC 025 in the field in Southern France, Italy, Spain and Greece  
 Report No.: 10-2233  
 Edition Number: M-413997-01-1  
 Guidelines: 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)  
 GLP: Yes

Report: **KCA 6.3.3/09; █; 2011**  
 Title: Determination of residues of deltamethrin in/on wheat after spraying of Decis EC 025 in the field in France and Italy 2010  
 Report No.: S10-00006  
 Edition Number: M-411367-01-1  
 Guidelines: 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)  
 GLP: Yes



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**Material and Methods:**

Eight residue trials were conducted in 2010 in Southern Europe (Southern France (3), Greece (1), Italy (3) and Spain (1)) in/on winter wheat. Deltamethrin formulated as a 25 g/l emulsifiable concentrate was applied once as a foliar spray pre-harvest treatment, at a nominal rate of 12.5 g a.s./ha. The samples of whole plant without roots or green material were collected at 0 days after last application and the samples of grain and straw were collected at harvest (growth stage BBCH 89) corresponding to a PHI from 15 to 32 days (proposed PHI 30 days).

Residue analysis was conducted using method 00865/M004 using LC-MS/MS with a LOQ of 0.01 mg/kg for grain and a LOQ of 0.05 mg/kg for whole plant or green material and straw.

**Findings:**

The maximum storage period observed for the deep frozen grain samples, in the 2000 studies is 243 days, period which is covered by the different stability studies. The mean of the concurrent recoveries were for grain and for all fortification levels within acceptable range of 76-110%.

Table 6.3.3-3 summarises the residues found in/on winter wheat in Southern Europe. Residues in the trials ranged between < 0.01 to 0.02 mg/kg in/on the grain at harvest corresponding to a PHI from 15 to 32 days.

**Table 6.3.3-3: Residues in winter wheat – pre-harvest trials (1 x 12.5 g a.s./ha, PHI 30 days)**

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues		
			EL	N o	kg/ha (a.s.)	kg/ha (a.s.)	GS	Portion analysed	DAL T (days)	Deltamethrin (mg/kg)
10-2233 10-2233-01 GLP: yes 2010	Wheat Quality	France	25 EC	1	0.013	0.0042	83	green material	0	0.22
		Europe, South						grain	28	<0.01
								straw	28	0.18
10-2233 10-2233-02 GLP: yes 2010	Wheat Artico	Italy	25 EC	1	0.013	0.0031	83	green material	0	0.37
		Europe, South						grain	20	0.02
								straw	20	0.21
10-2233 10-2233-03 GLP: yes 2010	Wheat Montcada	Spain	25 EC	1	0.013	0.0031	83	green material	0	0.18
		Europe, South						grain	23	<0.01
								straw	23	0.21
10-2233 10-2233-04 GLP: yes	Wheat Passarino	Greece	25 EC	1	0.013	0.0042	83	green material	0	0.18
								grain	18	<0.01





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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues		
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DAL T (days)	Deltamethrin (mg/kg)
2010		[REDACTED] Europe, South						straw		0.28
S10-00006 S10-00006-01 GLP: yes 2010	Wheat, winter Bologna	France [REDACTED] Europe, South	25 EC	1	0.0128	0.00417	83	whole plant without roots	27	0.11
								grain	27	<0.01
								straw	27	0.20
S10-00006 S10-00006-02 GLP: yes 2010	Wheat, winter Biensur	France [REDACTED] Europe, South	25 EC	1	0.0128	0.00417	83	whole plant without roots	15	0.08
								grain	15	<0.01
								straw	15	0.09
S10-00006 S10-00006-03 GLP: yes 2010	Wheat, winter Mieti	Italy [REDACTED] Europe, South	25 EC	1	0.0132	0.00417	83	whole plant without roots	32	0.17
								grain	32	<0.01
								straw	32	0.16
S10-00006 S10-00006-04 GLP: yes 2010	Wheat, winter Blaslo	Italy [REDACTED] Europe, South	25 EC	1	0.0131	0.00419	83	whole plant without roots	27	0.16
								grain	27	<0.01
								straw	27	0.14

**Conclusion:**

- Residues found in/on winter wheat grain after pre harvest treatments were all below the LOQ of 0.01 except in one trial where 0.02 mg/kg of deltamethrin was found in grain sample.
- Residues found in straw at harvest ranged from below the LOQ of 0.09 mg/kg and 0.28 mg/kg.

**Southern European Pre-Harvest GAP, 1+2 x 6.5 g/ha, PHI 30 days**

Report: **KCA 6.3.3/07; [REDACTED]; 2012**  
 Title: Determination of the residues of deltamethrin in/on winter wheat after spray application of Decis EC 025 in the field in Belgium, northern France, United Kingdom, Germany, southern France, Italy, Spain and Portugal  
 Report No.: 10-2036  
 Edition Number: M435250-01-1  
 Guidelines: 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)  
 GLP: Yes



Document MCA: Section 6 Residues in or on treated products, food and feed  
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Report: **KCA 6.3.3/10; [REDACTED]; 2011**  
 Title: Determination of residues of deltamethrin in/on wheat after spraying of Decis EC 025 in the field in France and Spain 2010  
 Report No.: S10-00010  
 Edition Number: M-433851-01-1  
 Guidelines: 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 029/V/95 rev. 5 (1997-07-22)  
 GLP: Yes

**Material and Methods:**

Seven residue trials were conducted in 2010 in Southern Europe (Southern France (1), Italy (2), Portugal and Spain (2)) in/on winter wheat. Deltamethrin formulated as a 25 g/l emulsifiable concentrate was applied once as a foliar spray pre-harvest treatment, at a nominal rate of 12.5 g a.s./ha. The samples of whole plant without roots or green material were collected at 0 days after last application and the samples of grain and straw were collected at harvest (growth stage BBCH 89) corresponding to a PHI from 15 to 32 days (proposed PHI 30 days). Residue analysis was conducted using method 00875/M004 using LC-MS/MS with a LOQ of 0.01 mg/kg for grain and a LOQ of 0.05 mg/kg for whole plant or green material and straw.

**Findings:**

The maximum storage period observed for the deep frozen grain samples, in 2010 studies is 365 days, period which is covered by the different stability studies. The mean of the concurrent recoveries were for grain and for all fortification levels within acceptable range of 70-110%.

Table 6.3.3-4 summarises the residues found in/on winter wheat in Southern Europe. Residues levels found in the grain samples at harvest were all below the LOQ of 0.01 mg/kg. The PHI ranged between 22 to 43 days.

**Table 6.3.3-4: Residues in winter wheat – pre harvest trials (1+2 x 6.25 g a.s /ha, last application at BBCH 83)**

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues		
			PL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	Deltamethrin (mg/kg)
S10-00010 M-433851-01-1 S10-00010-01 GLP: yes 2010	Wheat winter Quality	France [REDACTED] Europe, South	25	3	0.0065 - 0.0065	0.0021	83	whole plant without roots  grain straw	0  22 22	<0.05  <0.01 0.08



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Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues		
			FL No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	Deltamethrin (mg/kg)	
S10-00010 M-433851-01-1 S10-00010-04 GLP: yes 2010	Wheat, winter Boticelli	Spain [redacted] Europe, South	25 EC	3	0.0060 - 0.0065	0.0021- 0.0021	83	whole plant without roots grain straw	0 32 0	<0.05 0.01 0
S10-00010 M-433851-01-1 S10-00010-05 GLP: yes 2010	Wheat, winter Isangrain	Spain [redacted] Europe, South	25 EC	3	0.0064 - 0.0064	0.0021	83	whole plant without roots grain straw	0 29 29	<0.05 <0.01 0.06
M-435250-01-110-2036MAN 10-2036-05 10-2036-05-T GLP: yes 2010	Wheat, winter Esperia	France [redacted] Europe, South	25 E	3	0.0063	0.0021	83	green material grain straw	0 36 36	<0.05 <0.01 0.06
M-435250-01-110-2036MAN 10-2036-06 10-2036-06-T GLP: yes 2010	Wheat, winter Serio	Italy [redacted] Europe, South	25 EC	3	0.0063	0.0016	83	green material grain straw	0 21 21	<0.05 <0.01 <0.05
M-435250-01-110-2036MAN 10-2036-07 10-2036-07-T GLP: yes 2011	Wheat, winter ST-4	Spain [redacted] Europe, South	25 EC	3	0.0062	0.0021	83	green material grain straw	0 43 43	<0.05 <0.01 <0.05
M-435250-01-1 10-2036MAN 10-2036-08 10-2036-08-T GLP: yes 2010	Wheat, winter Artumilho Soft wheat	Portugal [redacted] Europe, South	25 EC	3	0.0063	0.0016	83	green material grain straw	0 35 35	<0.05 <0.01 <0.05

**Conclusion:**

- Residue levels found in/on winter wheat grain after pre harvest treatment were all below the LOQ of 0.01 mg/kg.
- Residue levels found on straw after pre-harvest treatment ranged from below the LOQ of 0.05 mg/kg to 0.08 mg/kg.



CA 6.4 Feeding studies

Deltamethrin is sought for use on wheat and sugar-beet with parts of these crops being fed to livestock as straw and sugar-beet leaves.

The maximum dietary burdens were therefore calculated for different groups of livestock as described in the OECD Guidance Document on Residues in Livestock (ENV/JM/MONO(2013)8 dated of 04-Sep-2013). The input values for all relevant commodities are summarized in Table 6.4 - 1.

Table 6.4 - 1: Input values for the dietary burden calculation – OECD methodology

Commodity	Input value (mg/kg)	Comment
<b>Risk assessment residue definition: cis-isomer of deltamethrin</b>		
Straw	0.41	Highest residue
Sugar-beet leaves	0.04	Highest residue
Wheat grain	0.01	STMR

The results of the calculations are reported in Table 6.4 - 2.

Table 6.4 - 2: Results of the dietary burden calculation - OECD methodology

	Maximum dietary burden (mg/kg bw/day)	Max dietary burden (mg/kg DM)	Highest contributing commodity
Cattle - Beef	0.002	0.098	straw
Cattle - Dairy	0.004	0.098	straw
Sheep – Rams/Ewes	0.006	0.191	straw
Sheep – Lambs	0.008	0.193	straw
Swine - Breeding	0.001	0.025	grain
Swine - Finishing	0.000	0.008	grain
Poultry - Broiler	0.001	0.008	grain
Poultry - Layer	0.004	0.054	straw
Poultry - Turkey	0.000	0.006	grain

The calculated dietary burdens for all categories of livestock were found to be below the 1x dose level of the cow and hen feeding studies, which was at 2 mg/kg in feed. The current EU MRLs are based on the residue levels observed in the different animal matrices of this dose group. The representative uses do not lead to an increase of the estimated dietary burden. Therefore there is no need to consider a change for the MRLs of the animal commodities.

Upon request by the RMS UK, the notifier Bayer CropScience has prepared the position paper M-536726-01-1 demonstrating with document M-448284-01-1 'Estimation of trans-isomer of deltamethrin exposure - Applicability of the TTC concept' that livestock is not exposed to the alpha-R isomer, and only slightly exposed to the trans isomer of deltamethrin with a conservative approach. Cis-deltamethrin is the major component of the dietary burden. (Moreover, in the metabolism studies, all isomers of deltamethrin were determined as one cumulated analyte. Therefore, if livestock was exposed to isomers of deltamethrin, the study was able to take them into account.)

The summary of the trials is also available in dRR format.





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**Report:** KCA 6.4/02; [redacted] 2016; M-559648-01-1  
**Title:** Compilation of dRR tables for deltamethrin residue studies from 2009 onwards. Results displayed for cis-deltamethrin, trans isomer and alpha-R isomer  
**Report No.:** M-559648-01-1  
**Document No.:** M-559648-01-1  
**Guideline(s):** none  
**Guideline deviation(s):** none  
**GLP/GEP:** no

**CA 6.4.1 Poultry**

A laying hen feeding study was previously evaluated during the first EU review process for inclusion on Annex I. Therefore, no new studies were conducted.

Please refer to the reference printed in grey typeface below and to the corresponding section in the Monograph and in the baseline dossier.

Data already evaluated during the first EU review process for inclusion on Annex I.

**Report:** KCA 6.4/01; [redacted] 1995; M-149375-01-1  
**Title:** Effects of a supplemented deltamethrin and piperonyl butoxide diet on levels of residues in products of animal origin a2. Feeding studies in poultry  
**Report No:** A70891  
**Document No:** M-149375-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** yes

**Report:** KCA 6.4.1/02; [redacted] 1994; M-134680-01-1  
**Title:** Determination of freezer residue stability for deltamethrin (alpha-R, cis, and trans) and thalomethrin in poultry tissue  
**Report No:** A54435  
**Document No:** M-134680-01-1  
**Guidelines:** VSEPA, EPA, O, 17-4; Deviation not specified  
**GLP/GEP:** yes

**Report:** KCA 6.4.1/03; [redacted] 1994; M-149579-01-1  
**Title:** Magnitude of the residues in meat and eggs for tralomethrin (RU 25474) and its major metabolite deltamethrin (RU 22974) in white Leghorn chickens.  
**Report No:** A11106  
**Document No:** M-149579-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** yes

**CA 6.4.2 Ruminants**

A dairy cow feeding study was previously evaluated during the first EU review process for inclusion on Annex I. Therefore, no new studies were conducted.



Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin

Please refer to the reference printed in grey typeface below and to the corresponding section in the Monograph and in the baseline dossier.

Data already evaluated during the first EU review process for inclusion on Annex I.

**Report:** KCA 6.4.2 /01- [REDACTED] : [REDACTED] : [REDACTED] :1988; Amended: 2000-05-23  
**Title:** Feeding study of a mixture of tralomethrin and deltamethrin in dairy cows and magnitude of the combined residues of tralomethrin, deltamethrin and trans-deltamethrin in milk and tissues of dairy cattle. (2 volumes).  
**Report No:** A70946  
**Document No(s):** Report includes Trial Nos.:  
 HRAV Proj. #87-0123  
 HRAV Project No: 87-0123  
 M-149428-03-1  
**Guidelines:** USEPA (=EPA): 171-4 Deviation not specified  
**GLP/GEP:** yes

**Report:** KCA 6.4.2 /02- [REDACTED] : [REDACTED] : [REDACTED] :1992  
**Title:** Deltamethrin residues in milk and tissues of lactating dairy cows.  
**Report No:** A70892  
**Document No:** M-149376-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.4.2 /03- [REDACTED] : [REDACTED] : [REDACTED] :2000  
**Title:** Calculation of the 100 dosage rate for deltamethrin in a ruminant livestock feeding study (according to EU document 7031/VI/95 Rev.4, 22.07.1996 (draft))  
**Report No:** 009555  
**Document No:** M-198796-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.4.2 /04- [REDACTED] : [REDACTED] : [REDACTED] :2001  
**Title:** Survey Reports on Analysis for Deltamethrin in Milk from Cows and Humans  
**Report No:** B0034  
**Document No:** M-200501-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** no

**Report:** KCA 6.4.2 /05- [REDACTED] : [REDACTED] : [REDACTED] :1991; Amended: 1995-11-07  
**Title:** Metabolism of 14C-benzyl-tralomethrin and 14C-gem-dimethyl-tralomethrin in lactating dairy cattle and storage stability of tralomethrin and deltamethrin in cow milk and tissues.  
**Report No:** A70945  
**Document No(s):** Report includes Trial Nos.:  
 HR-01-88  
 M-148609-02-1  
**Guidelines:** USEPA (=EPA): 171-4(b); Deviation not specified  
**GLP/GEP:** yes

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**Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin****CA 6.4.3 Pigs**

As the metabolic pathways in rats didn't differ significantly from those in cow and hen, a pig metabolism study was not required. Hence a pig feeding study is also not necessary for this dossier.

**CA 6.4.4 Fish**

No metabolism study or feeding study in fish was conducted (refer to MCA 6.2.5). Currently, no test method or guidance document is available for conducting a feeding study in fish. Also, no feeding table with plant commodities for fish feeding is available. Therefore, it cannot be decided whether fish might be exposed to residues of deltamethrin in parts of plant that have been treated with deltamethrin.

In these cases, waiving of this particular data requirement is considered acceptable according to the "Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and the renewal of approval of the chemical active substance according to regulation (EU) No. 283/2013 and regulation (EU) No. 284/2013" (SANCO/10181/2013 rev.2 of 2-May-2013).

**CA 6.5 Effects of processing****CA 6.5.1 Nature of the residue**

The processing study (M-204204-01-1) was performed and evaluated (see Addendum to the Monograph Annex B from July 2002). It was designed to determine the nature and quantity of residues which might be formed during processing of raw agricultural commodities.

Three different hydrolysis conditions were applied simulating pasteurisation; brewing / baking / boiling and sterilisation. The sterilisation condition was carried out with two different label positions, [<sup>14</sup>C]-benzyl deltamethrin and [<sup>14</sup>C]-gemdimethyl deltamethrin. Analysis was performed with LSC and HPLC. The results of the study showed that under simulated pasteurisation (90°C, pH 4, 20 min.), brewing, baking and boiling (100°C, pH 5, 60 min.) deltamethrin is stable. Results of the sterilisation process (120°C, pH 6, 20 min) showed that deltamethrin was degraded under this conditions mainly to two metabolites; 3-phenoxybenzaldehyde and (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylic acid (Br<sub>2</sub>CA). The former was detected in quantities from 59 to 75% and the latter one in quantities from 39 to 47% of applied radioactivity. These two substances are known plant metabolites and none of them was considered as a relevant residue.

Br<sub>2</sub>CA has been identified also in rat metabolism and is considered of lower toxicity than parent compound. Regarding 3-phenoxybenzaldehyde, no toxicological data is available but evidence from the rat studies has shown that it is toxicologically covered, as explained in the following statement.

New data for MR:

The following study was not evaluated during the last EU review and is submitted for review:



Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin

Report: KCA 6.5.1/02; [REDACTED]; 2013  
 Title: Deltamethrin: Metabolic behaviour of 3-phenoxybenzaldehyde  
 Edition Number: M-466413-01-1  
 Guidelines: Not applicable.  
 GLP No

This document explains that, although 3-phenoxybenzaldehyde was not seen in the rat metabolism studies, the studies indicate that it is an intermediate that can account for metabolites in amounts greater than 10% of the TRR. Moreover, investigations on *in vitro* human metabolism of permethrin published in the literature show that 3-phenoxybenzaldehyde is oxidised by ALDH5 (aldehyde dehydrogenase) to the corresponding acid and 3-phenoxybenzaldehyde does not accumulate during microsomal incubation.

A detailed review of the existing rat metabolism studies show that the anticipated intermediate metabolite 3-phenoxybenzaldehyde was not detected in the rat because this metabolite was rapidly oxidised to three subsequent oxidation products (3-phenoxybenzoic acid, 4'-hydroxy-3-phenoxybenzoic acid, and 4'-hydroxy-3-phenoxybenzoic acid sulfate) which were all found in urine. In total 8 metabolites were identified in urine and feces which were chemically representing oxidation products of 3-phenoxybenzaldehyde. From these studies it appears that 3-phenoxybenzaldehyde is a transitory compound, rapidly oxidised into higher oxidation products and subsequently excreted. For these reasons, this metabolite should not be considered as toxicologically relevant.

**CA 6.5.2 Distribution of the residue in peel and pulp**

Not relevant for the representative uses for AIR

**CA 6.5.3 Magnitude of residues in processed commodities**

Some studies were already evaluated during the last EU Annex I review. Please refer to the reference printed in grey typeface below and to the corresponding section in the Monograph and in the baseline dossier

Data already evaluated during the first EU review process for inclusion on Annex I.

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**Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin**

**Report:** KCA 6.5.3 /01: [redacted]; 1999  
**Title:** Magnitude of deltamethrin residues in or on apples and processed apple commodities resulting from three applications of Decis (R) insecticide USA, 1998  
**Report No:** C002139  
**Document No:** M-183978-01-1  
**Guidelines:** USEPA (=EPA): OPPTS 860.1520; Deviation not specified  
**GLP/GEP:** yes

**Report:** KCA 6.5.3 /02: [redacted]; 1999  
**Title:** Magnitude of deltamethrin residues in or on tomatoes and processed tomato commodities resulting from six applications of Decis (R) insecticide USA, 1998  
**Report No:** C002859  
**Document No:** M-185190-01-1  
**Guidelines:** USEPA (=EPA): OPPTS 860.1520; Deviation not specified  
**GLP/GEP:** yes

**Report:** KCA 6.5.3 /03: [redacted]; 2000  
**Title:** Residues at harvest in fruit and processed fractions, European Union, Southern zone 1997 Deltamethrin AE F032640 emulsifiable granule 6.00% w/w Code AE F032640 00 EG06 A105  
**Report No:** C01014  
**Document No:** M-238971-01-1  
**Guidelines:** EU Commission Working Document 7029/VI/97, rev. 5/22/07; not specified  
**GLP/GEP:** yes

**Report:** KCA 6.5.3 /04: [redacted]; 2001  
**Title:** Investigation of the nature of the potential residues in the products of industrial processing of household preparation Code AE F032640  
**Report No:** C01797  
**Document No:** M-204204-01-1  
**Guidelines:** Deviation not specified  
**GLP/GEP:** yes

New data for AIR

The following study was not evaluated during the last EU review and is submitted for review.

The purpose of the study was to determine the magnitude of residues of deltamethrin in/on processed fractions resulting of the bread and pasta making processes (flour, white bread, white flour bran, wholemeal, wholemeal bread, semolina, semolina bran, germ, fresh pasta, cooked pasta, dry pasta, cooking water of fresh and dry pasta, and dried and cooked pasta) of winter wheat.

**Report:** KCA 6.5.3 /05; [redacted]; [redacted]; 2010  
**Title:** Determination of the residues of deltamethrin in/on winter wheat and processed fractions after mixing of Deltamethrin & Piperonylbutoxide EC 275 in the room, hall store ... in Germany, Greece, Portugal and the United Kingdom  
**Report No:** 08-3214  
**Edition Number:** M-363957-01-1  
**Guidelines:** OECD on 12 May 1981 [Annex 2 to C (81) 30 (Final)], endorsed for use in the European Union by Directive 87/18 of 18 December 1986  
**GLP** Yes



Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin

**Material and methods**

Winter wheat was treated by one mixing application in the storage room with deltamethrin & piperonyl butoxide EC 275. The treatment was done after normal harvesting in northern Europe (the United Kingdom and Germany) and southern Europe (Portugal and Greece). Samples for processing were taken in the conduct of study 08-2214 (M-360719-01-1) (KCA 6.3.3/05).

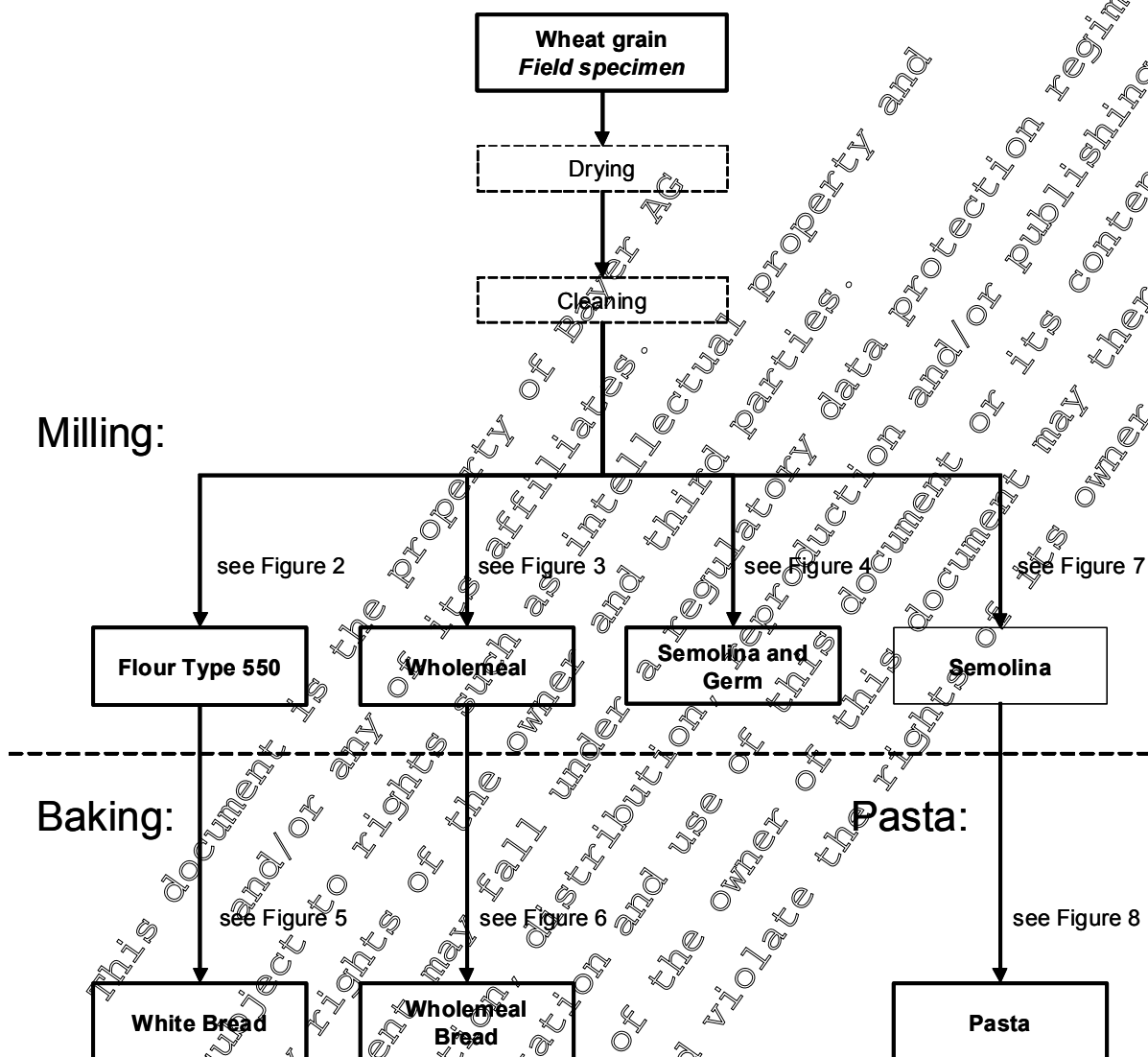
The processing phase of winter wheat grain into the processed fractions (flour, white bread, white flour bran, wholemeal, wholemeal bread, semolina, semolina bran, germ, fresh pasta, cooked pasta, dry pasta, cooking water of fresh and dry pasta, and dried and cooked pasta) was carried out

The processing of winter wheat grain samples into processed fractions (flour, white bread, white flour bran, wholemeal, wholemeal bread, semolina, semolina bran, germ, fresh pasta, cooked pasta, dry pasta, cooking water of fresh and dry pasta, and dried and cooked pasta) was performed in a specialized pilot plant to simulate industrial procedures. The pilot plant is fully comparable to the industrial preparation of flour, white bread, white flour bran, wholemeal, wholemeal bread, semolina, semolina bran, germ as well as industrial and homely preparation of fresh pasta, cooked pasta, dry pasta, cooking water of fresh and dry pasta, and dried and cooked pasta. Summaries of the procedures are given below.

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Figure 1: Overview over the Entire Processing of Wheat Grain



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Figure 2: Flow-chart of the Processing of Flour (Type 550)

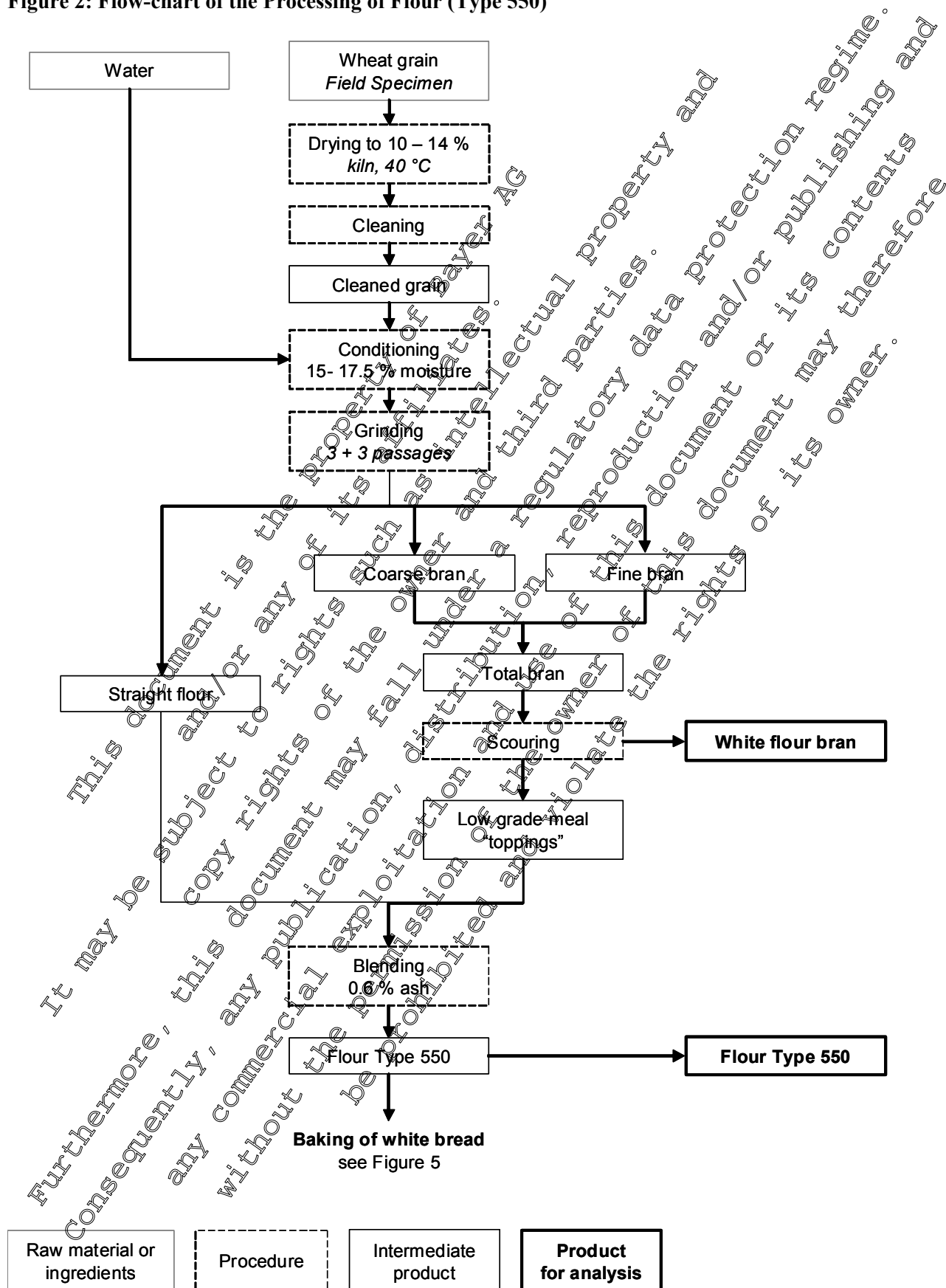




Figure. 3: Flow-chart of the Processing of Wholemeal

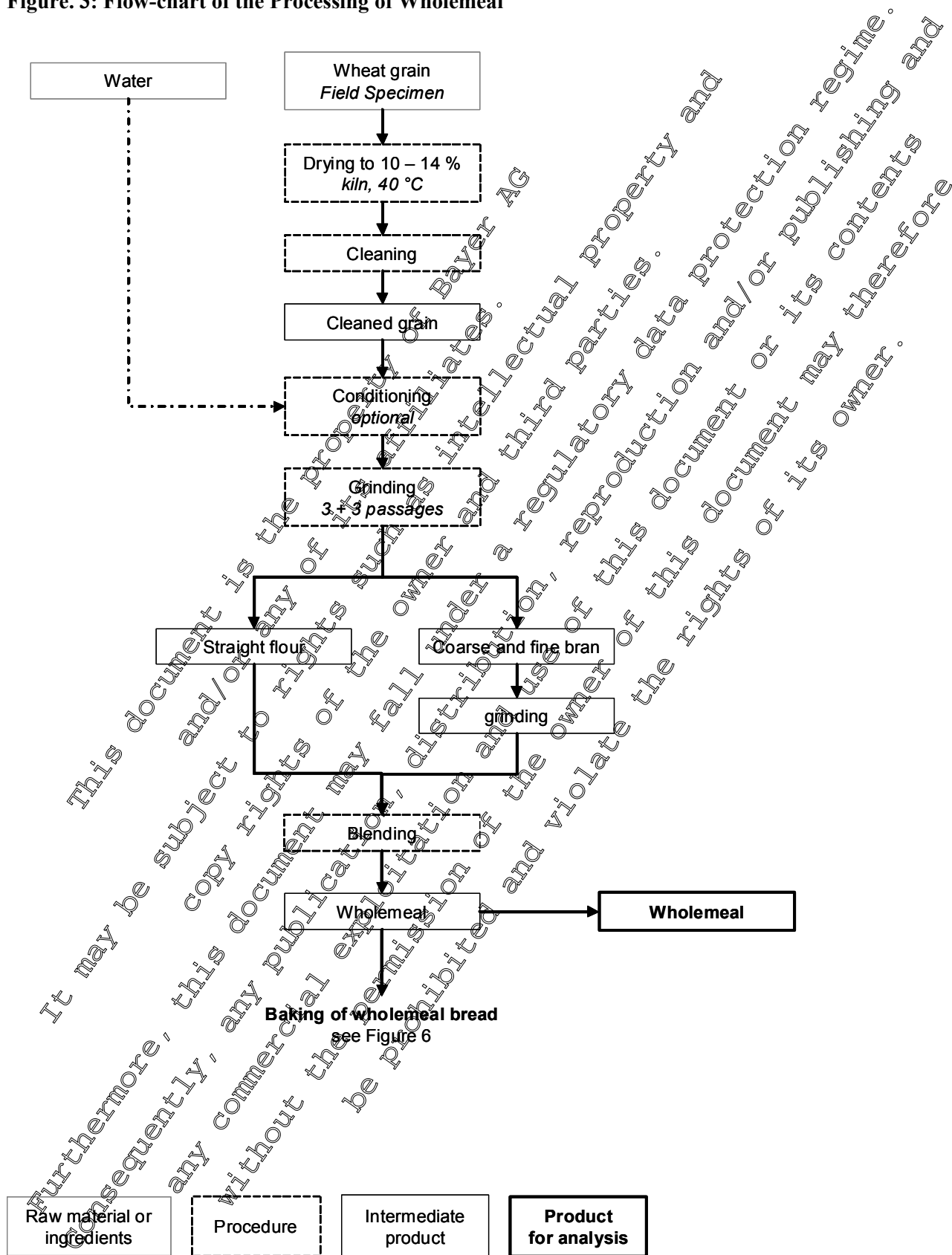
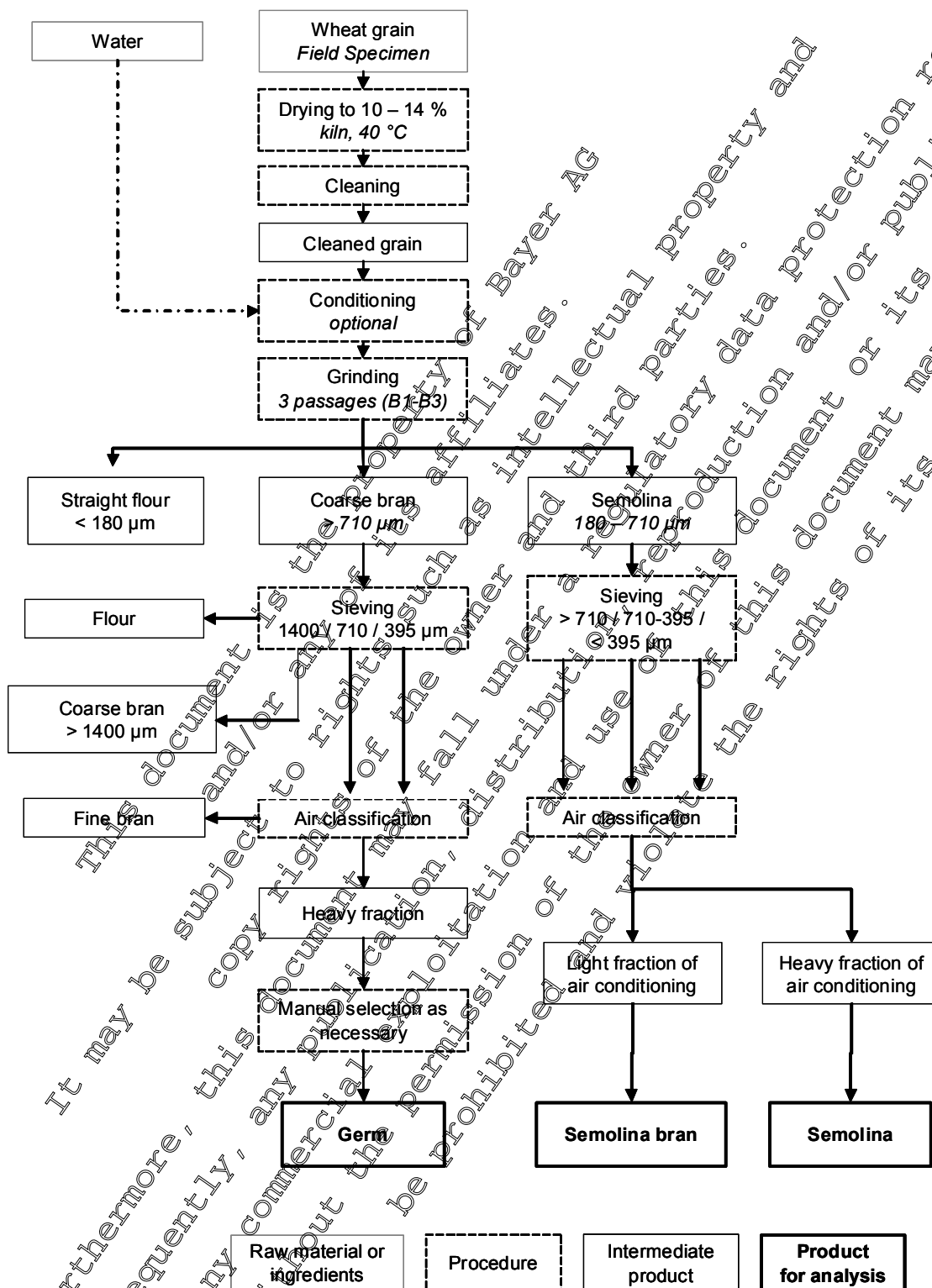


Figure 4: Flow-chart of the Processing of Semolina and Germ



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Figure 5: Flow-chart of Baking of White Bread

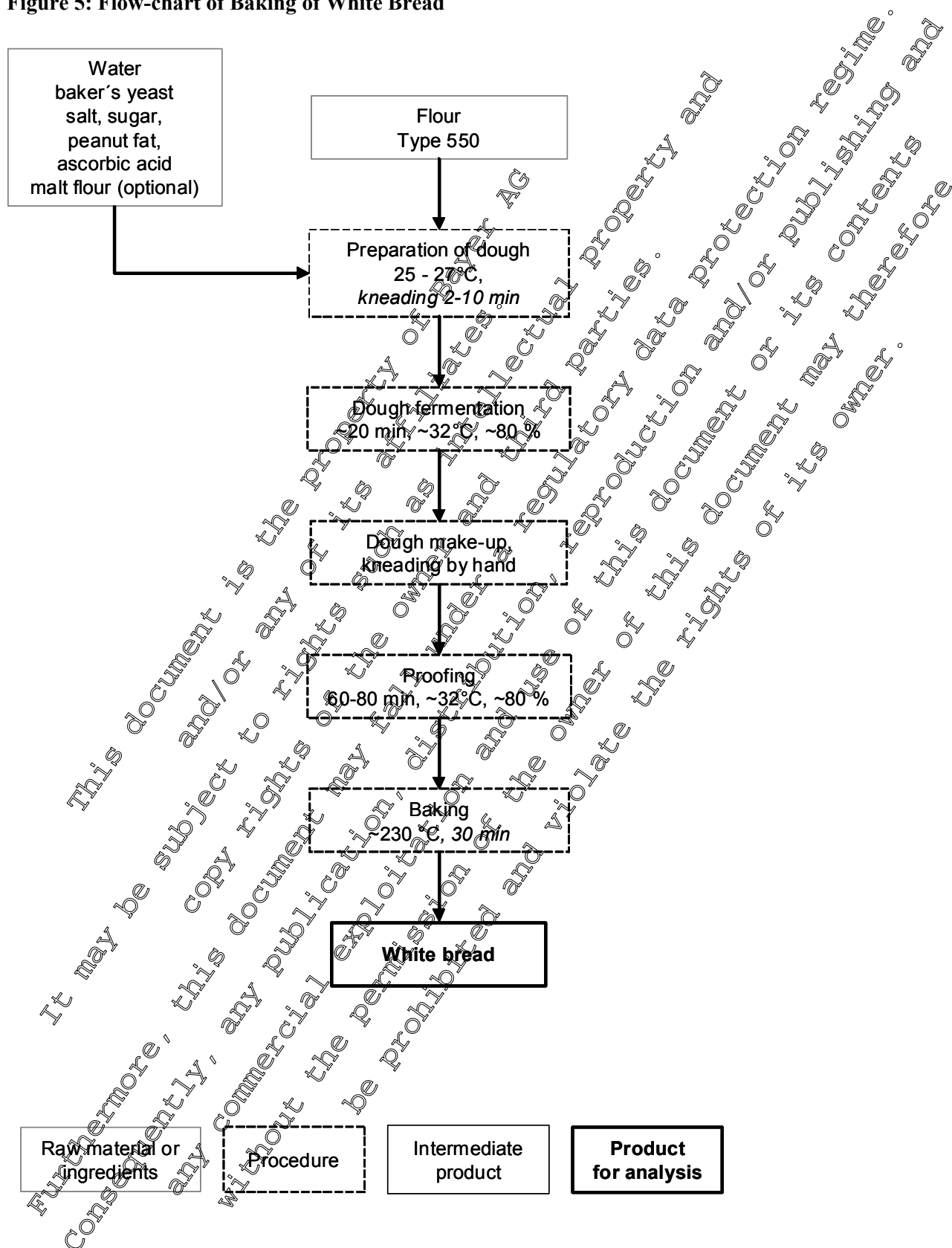
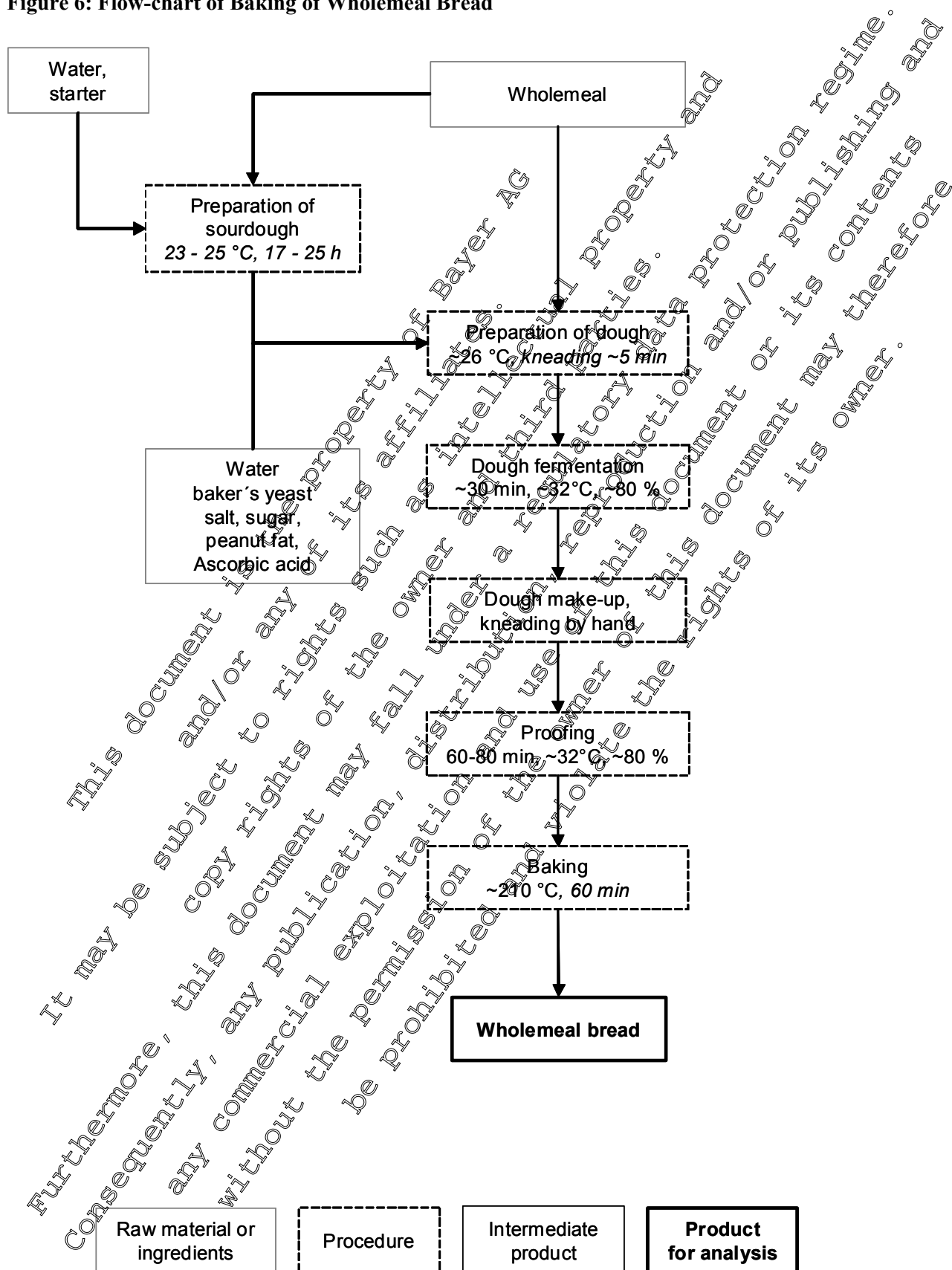


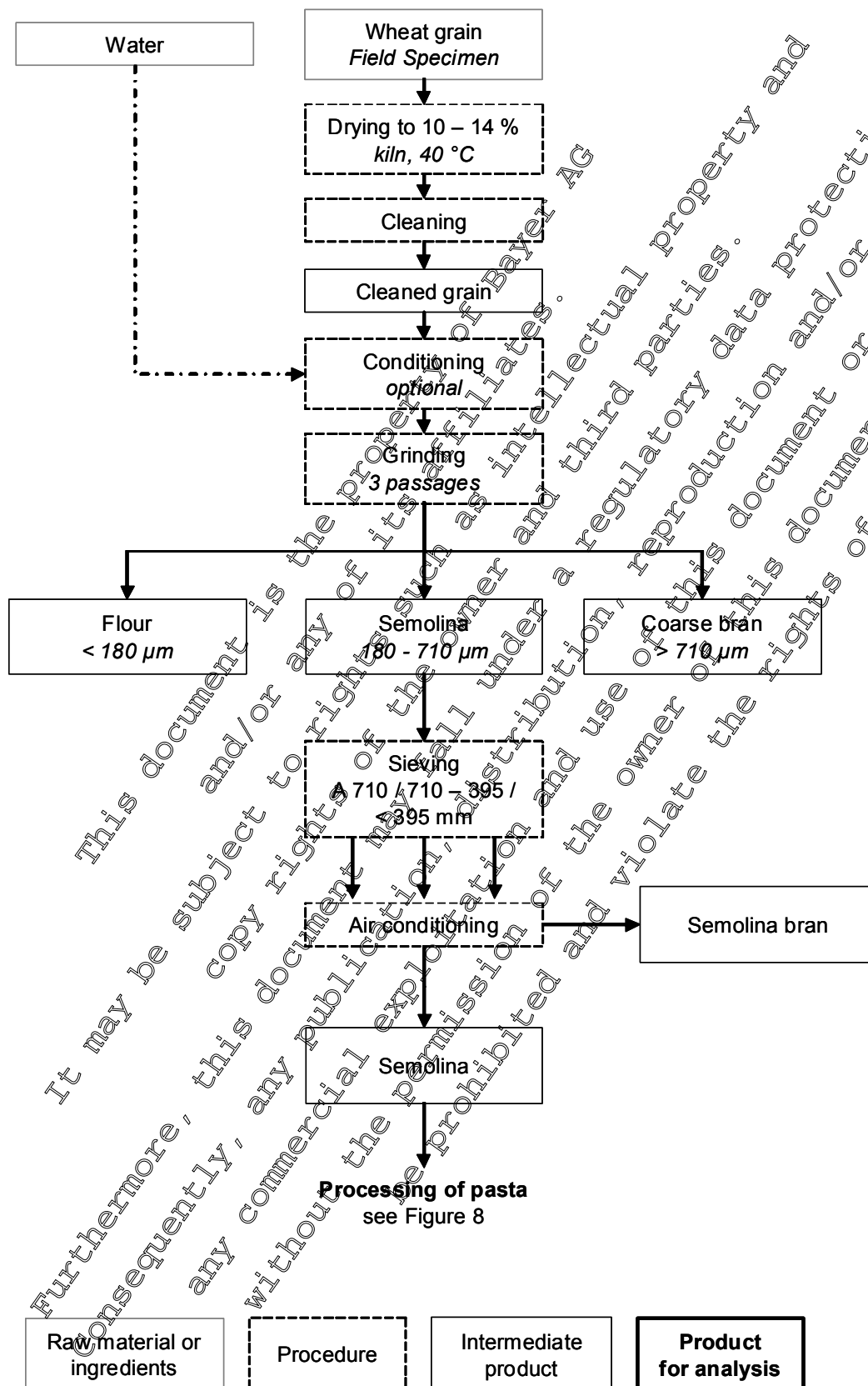
Figure 6: Flow-chart of Baking of Wholemeal Bread



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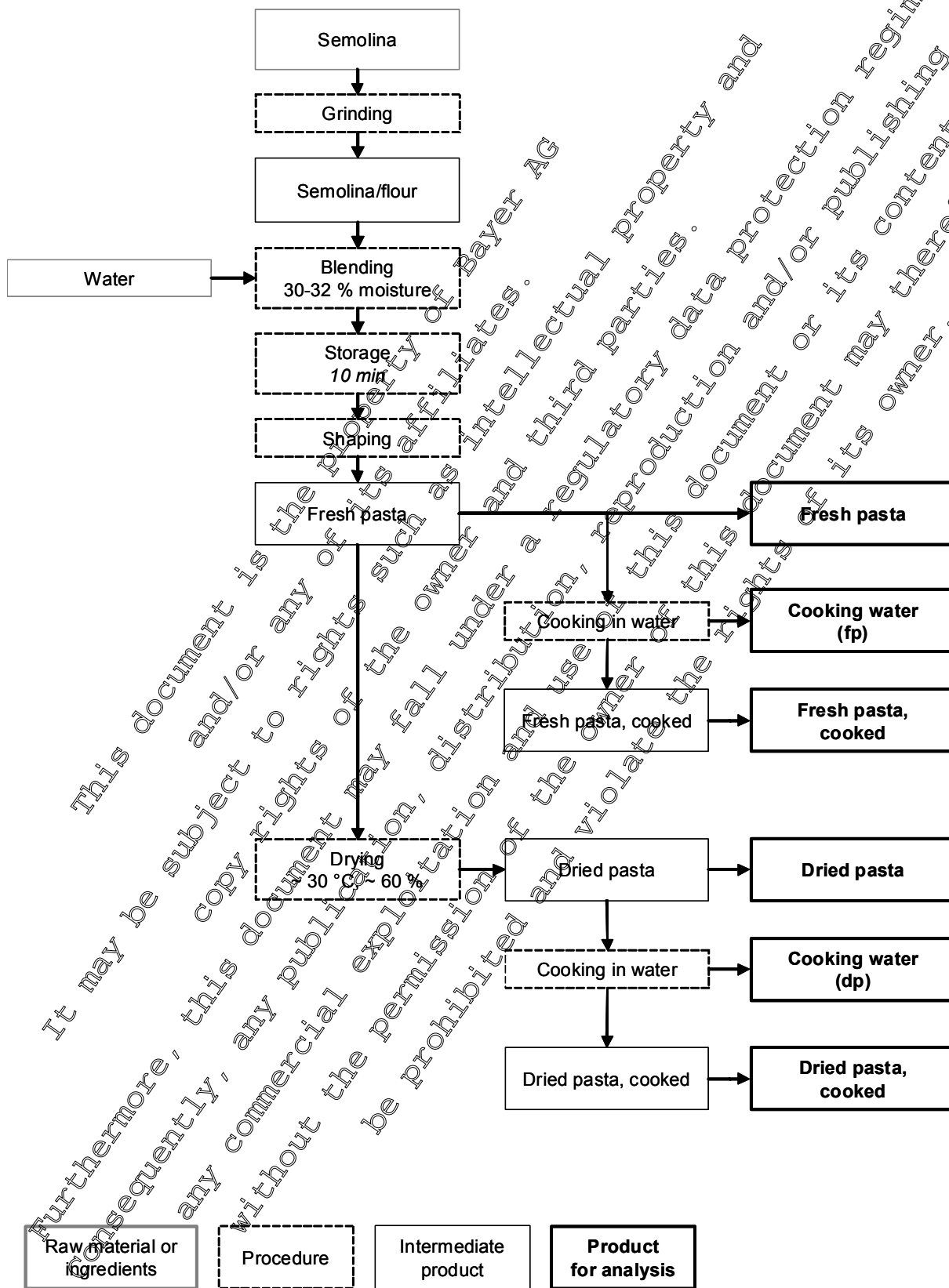
Figure 7: Flow-chart of the Processing of pasta - Step 1: Preparation of Semolina



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Figure 8: Flow-chart of the Processing of Pasta - Step 2: Pasta Products







Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	g/dt (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	Deltamethrin (mg/kg)	
08-2214MAN  08-2214-02 GLP: yes 2008		Germany  [redacted] Europe, North							white bread 89	0.05	
								whiteflour 89	1.7		
								bran 89	0.39		
								whole meal 89	0.24		
								wholemeal 89	0.05		
								bread 89	0.29		
								semolina 89	0.31		
								semolina 89	0.04		
								bran 89	<0.01		
								germ 89	<0.01		
								pasta, fresh 89	<0.01		
								pasta, 89	0.02		
								cooked 89	<0.01		
								cooking 89	<0.01		
								water 89	0.02		
								pasta, dry 89	<0.01		
								pasta, dried 89	0.27		
								and cooked 89	0.29		
08-2214MAN  08-2214-03 GLP: yes 2008	Wheat winter Pigeon	Portugal  [redacted] Europe, South	250 EC	1	0.050	0.050	99	grain 7	0.33	0.27	
								23	0.08	0.29	
								91	0.02	0.33	
								flour 91	1.2	0.08	
								white bread 91	0.38	0.02	
								whiteflour 91	0.14	1.2	
								bran 91	0.06	0.38	
								whole meal 91	0.18	0.14	
								wholemeal 91	0.39	0.06	
								bread 91	0.18	0.39	
								semolina 91	0.03	0.03	
								semolina 91	<0.01	0.03	
								bran 91	<0.01	<0.01	
								germ 91	<0.01	<0.01	
								pasta, fresh 91	0.03	0.03	
								pasta, 91	<0.01	<0.01	
								cooked 91	0.03	0.03	
								cooking 91	<0.01	<0.01	
								water 91	0.03	<0.01	
								pasta, dry 91	0.03	0.03	
								pasta, dried 91	<0.01	<0.01	
								and cooked 91	0.54	0.54	
08-2214MAN  08-2214-04 GLP: yes 2008	Wheat, winter Cosmodur	Greece  [redacted] Europe, South	250 EC	1	0.050	0.050	99	grain 7	0.34	0.34	
								23	0.33	0.33	
								92	0.49	0.49	
								flour 92	0.06	0.06	
								white bread 92	0.02	0.02	





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Deltamethrin

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application				Residues			
			FL	No	g/dt (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	Deltamethrin (mg/kg)
								white flour	92	0.92
								bran		
								whole meal	92	0.36
								wholemeal bread	92	0.19
								semolina	92	0.06
								semolina bran	92	0.36
								germ	92	0.44
								pasta fresh	92	0.04
								pasta, cooked	92	0.01
								cooking water	92	<0.01
									92	<0.01
								pasta, dry	92	0.02
								pasta, dried and cooked	92	0.01

Based on the residue levels in the processing products transfer factors were calculated. The transfer factors for the processing products are calculated according to the following equation:

$$\text{Transfer Factor} = \frac{\text{Residue concentration in the processed product [mg/kg]}}{\text{Residue concentration in the RAC [mg/kg]}}$$

RAC: Raw Agricultural Commodity (analysed in the conduct of study 08-3214).

Transfer factors were calculated on a worst-case basis. For this purpose, residues < LOQ were set at the LOQ.

The following table summarizes the transfer factors observed for the different processed fractions.

Table 6.53-2: Transfer factors for residue of deltamethrin in wheat processed fractions

Processed Fractions	Transfer Factors for cis-Deltamethrin			
	08-3214-01	08-3214-02	08-3214-03	08-3214-04
flour (type 550)	0.30	0.37	0.24	0.12
white flour bran	3.0	4.0	3.6	1.9
white bread	0.05	0.12	0.06	0.04
wholemeal	1.2	1.1	0.87	1.4
wholemeal bread	0.32	0.56	0.42	0.39
germ	0.57	0.72	1.18	0.90
semolina	0.11	0.12	0.18	0.14



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Deltamethrin

Processed Fractions	Transfer Factors for cis-Deltamethrin			
	08-3214-01	08-3214-02	08-3214-03	08-3214-04
semolina bran	0.70	0.67	0.55	0.73
pasta, fresh	0.07	0.09	0.09	0.08
pasta, cooked	0.02*	0.02*	0.03*	0.02
cooking water	0.02*	0.02*	0.03*	0.02*
pasta, dry	0.05	0.05	0.09	0.04
pasta, dried and cooked	0.02*	0.02*	0.03*	0.02
cooking water	0.02*	0.02*	0.03*	0.02*

\* = For calculation of the transfer factor the residue in the processed fraction was set at 100.

**Conclusion**

The transfer factors for cis-deltamethrin processing flour (type 550) ranged between 0.12 - 0.37, between 1.9 - 4.0 for white flour bran and between 0.04 - 0.12 for white bread. The transfer factor for wholemeal ranged between 0.87 - 1.4, for the wholemeal bread between 0.32 - 0.56.

For germ, semolina and semolina bran the transfer factors ranged between 0.57 - 1.18, 0.11 - 0.18 and 0.55 - 0.73, respectively.

During the processing of pasta the following transfer factors were found: 0.07 - 0.09 for fresh pasta, 0.02 - 0.03 for cooked pasta, 0.02 - 0.03 for cooking water of fresh pasta, 0.04 - 0.09 for dried pasta, 0.02 - 0.03 for dried and cooked pasta and 0.02 - 0.03 for cooking water of dried pasta.

As expected, the residue are located into the external envelops of the grain, therefore all the processed fractions which corresponds to internal part of the grain like white flour, white bread, semolina and pasta show a reduction in residue content. An average transfer factor of 0.26 was observed into the white flour which is in agreement to the transfer factor of 0.2 derived from former processing studies.

Additional information submitted to the Rapporteur:

**Report:** KCA 6.5.3.06; [redacted] 2016; M-559765-01-1  
**Title:** Additional chromatograms of study report 08-3214: Determination of the residues of deltamethrin in/on winter wheat and processed fractions after mixing of deltamethrin & piperonyl butoxide EC 275 in the room, hall store ... in Germany, Greece, Portugal and the United Kingdom  
**Report No.:** M-559765-01-1  
**Document No.:** M-559765-01-1  
**Guideline(s):** none  
**Guideline deviation(s):** none  
**GLP/GEP:** no

**CA 6.6 Residues in rotational crops**

**CA 6.6.1 Metabolism in rotational crops**

In 1991, a confined rotational crop study was performed in the USA with [<sup>14</sup>C]-benzyl deltamethrin. The study was previously evaluated during the first EU review process for inclusion on Annex I:



Document MCA: Section 6 Residues in or on treated products, food and feed  
Deltamethrin

Please refer to the reference printed in grey typeface below and to the corresponding section in the Monograph and in the baseline dossier.

Data already evaluated during the first EU review process for inclusion on Annex I.

Report: KCA 6.2 /05; [redacted]; [redacted]; [redacted] 191 /1994  
 (amended version);  
 Title: C-14 Deltamethrin: Confined Accumulation in Rotational Crops 3 and 20 Day Experiment  
 Report No: A47914  
 Document No: M-136651-02-1 (amended version)  
 Guidelines: Deviation not specified  
 GLP/GEP: yes

Lettuce, carrots and barley were planted back into soil 30 and 120 days after 10 applications to soil at an elevated rate of 0.045 kg as/ha. No significant total radioactive residues (0.01 mg/kg) were found in edible parts of succeeding crops, with the exception of barley straw (0.023 mg/kg maximum). The study showed that these residues were very polar in nature with the only identifiable components being the *trans*-isomer of deltamethrin and the *α-R*-isomer of deltamethrin.

New data for AIR:

In 2012, a confined rotational crop study was performed with [<sup>14</sup>C]-gemdimethyl deltamethrin. It is presented below.

**Report:** KCA 6.6 /01; [redacted]; [redacted]; 2012  
**Title:** Metabolism of [gemdimethyl-<sup>14</sup>C] deltamethrin in confined rotational crops  
**Report No.:** MEF-14/669  
**Edition Number:** M-401769-01-1  
**Guidelines:** OECD on 12 May 1981, Annex 2 to C (81) 30 (Final), endorsed for use in the European Union by Directive 87/18 of 18 December 1986  
**GLP** Yes

**Test system**

The objective of this study was to investigate the metabolism of deltamethrin in rotational crops after one pre-emergent spray application onto bare soil. The application rate of the test compound [gemdimethyl-<sup>14</sup>C] deltamethrin formulated as an EW015, was aimed to be about 10% above the highest annual field dose of approx. 37.5 g a.s./ha to compensate for possible losses during treatment. The rotational crops used were Swiss chard, turnips and spring wheat. The intended timeframe for sowing was approx. 30, 150 and 365 days after soil treatment for the first, the second and the third rotation, respectively.

Immature raw agricultural commodities (RACs) investigated were Swiss chard intermediate leaves and forage and hay of wheat. All other RAC (Swiss chard leaves, turnip leaves and roots and wheat straw and grain) were harvested at maturity. The study was concluded after two rotations due to the very low TRRs (0.01 mg/kg) in all of the collected matrices.

**Findings**

The TRR values were generally very low and ranged from values below the LOD (=LOQ) in turnip leaves and roots and wheat forage of the 2nd rotation to 0.009 mg/kg in wheat straw of the 1st rotation.



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Deltamethrin**

The TRRs in the edible RACs were very low. The TRRs of all samples showed a more or less noticeable decrease from the 1st to the 2nd rotation.

The TRR values for all matrices are shown in the following table:

**Table 6.6.1-1: Total radioactive residue (TRR) in rotational crops with (gemdimethyl-<sup>14</sup>C) deltamethrin**

Matrix	TRR (mg/kg)	
	First rotation	Second rotation
Swiss chard intermediate leaves	0.007	0.001
Swiss chard leaves	0.002	0.001
Turnip leaves	0.002	0.001
Turnip roots	0.001	<0.001
Wheat forage	0.002	0.001
Wheat hay	0.006	0.002
Wheat straw	0.009	0.002
Wheat grain	0.003	0.002

No extraction of plant matrices was conducted during this study because of the very low TRR values. The radioactivity in all samples was exclusively determined by combustion followed by LSC.

**Conclusion**

There was no significant metabolism of deltamethrin detectable in confined rotational crops. Results from earlier studies show that uptake and translocation of the parent compound and potential metabolites seems to be very limited in plants. It is also known that under aerobic conditions deltamethrin is rapidly metabolised in soil and that the formed metabolites are readily mineralised to carbon dioxide.

**CA 6.6.2 Magnitude of residues in rotational crops**

The metabolism studies on rotational crops (ECA 6.6.1/01) show that residues of deltamethrin are expected to be < 0.01 mg/kg in rotational crops. Therefore studies on the magnitude of residues in rotational crops are not needed.

**CA 6.7 Proposed residue definitions and maximum residue levels**

**CA 6.7.1 Proposed residue definitions**

Deltamethrin is a first stage active substance according to Directive 91/414/EEC. It has been peer reviewed in 2002 and is included in Annex I to Directive 91/414/EEC by Commission Directive 2003/5/EC for uses as an insecticide only. The peer review concluded that deltamethrin (cis-deltamethrin) only was the residue definition for the dietary risk assessment and the enforcement. This is in line with the residue definition established in the Regulation (EC) No 396/2005.

Here is the extract of the document “deltamethrin - proposals to revise existing MRLs” from the former Rapporteur Member State, Sweden, dated on June 2005:





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“The residue is predominantly cis-deltamethrin and its isomers alpha-R deltamethrin and trans-deltamethrin. The existing residue database consists of a proportion of residue data representing sum of cis-deltamethrin and its two isomers and residue data representing cis-deltamethrin only. Studies on 20 crops show that the combined contribution from both of the isomers alpha-R deltamethrin and trans-deltamethrin would be unlikely to exceed around 20%. In principle, such a contribution does not seem to influence the choice of MRL class to a greater extent at the levels found. There is no information, available to us, indicating that the two isomers should be more toxic than cis-deltamethrin.  
- Proposed residue definition for the temporary MRLs: cis-deltamethrin”

This decision was agreed and voted at the Residue Working Group held in March 2006 and implemented in the current Directive 2006/59/EC, listing the EU MRLs for Deltamethrin.

**CA 6.7.2 Proposed MRLs and justification of the acceptability of the levels proposed**

The EU MRLs for deltamethrin were published in the Annex II and Annex III Part B of the Regulation (EC) No. 396/2005 via the Regulation (EC) No. 441/2012. See EU MRLs for the crops supported in this dossier in [Table 6.7.2 - 1](#)). This regulation states an EU MRL of 2 mg/kg for wheat which is derived from the current post-harvest use of deltamethrin on cereals and an EU MRL of 0.1 mg/kg on cauliflower

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which is a group MRL for flowering brassica, broccoli and cauliflower, based on the Southern European cGAP (critical GAP) with 3 applications at 17.5 g a.i./ha and an EU MRL of 0.5 mg/kg for sugar beet.

The EU MRLs are based on the residue definition of the cis-deltamethrin.

The representative uses supported in this dossier, do not trigger change for the existing EU MRLs, neither for plant commodities nor animal commodities. This was reconfirmed by the notifier Bayer CropScience to the RMS UK in September 2015.

**Table 6.7.2 - 1: EU MRLs for the uses of deltamethrin**

Crop / animal commodities	EU MRL (mg/kg) Regulation (EC) No. 396/2005	STMR (mg/kg) (a)	HR (mg/kg) (a)
Cauliflower	0.1	0.01*	0.01*
Sugar beet	0.5	0.01*	0.01*
Wheat	2	0.04*	0.02
Meat	0.05*		
Fat	0.5		
Liver	0.03*		
Kidney	0.03*		
Poultry meat	0.1		
Poultry fat	0.1		
Poultry liver	0.1		
Poultry kidney	0.1		
Poultry edible offal	0.1		
Milk and cream	0.05		
Bird eggs	0.05*		

(a) Indicates the values observed in the residue package of the representative uses presented in this dossier.

(\*) Indicates lower limit of analytical determination.

**CA 6.7.3 Proposed MRLs and justification of the acceptability of the levels proposed for imported products (import tolerance)**

MRL settings based on imported products are not proposed with this dossier.

**CA 6.8 Proposed safety intervals**

There is no need to propose safety intervals.

**CA 6.9 Estimation of the potential and actual exposure through diet and other sources**

**Acceptable Daily Intake (ADI) and Dietary Exposure Calculation**

In order to evaluate the potential chronic exposure to deltamethrin residues through the diet, the Theoretical Maximum Dietary Intakes (TMDI) were calculated using:



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- The EFSA PRIMo model (revision 2). For the evaluation of the chronic exposure the model uses 5 WHO diets relevant to the EU and 22 national diets from 13 different EU Member States.
- An ADI of 0.01 mg/kg bw/day
- The STMRs corresponding to the residue data package presented in this dossier for supporting the representative uses of deltamethrin in/on cauliflower, on sugar beet and on wheat respectively 0.01 mg/kg for each crop.
- As a worse case, current EU MRLs for animal commodities were considered

For animal commodities, calculations were made using the lowest aggregation level of food commodities meaning that in the spreadsheet the MRLs were not entered at commodity group levels (e.g. “milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curds”) but at individual crop levels (e.g. “milk and milk products Cattle”, “milk and milk products Sheep”, etc.).

As shown in [Table 6.9 - 1](#), the highest TMDI represents **22.7% of the ADI** and was calculated for the NL child diet.

**Therefore, a long-term intake of residues of deltamethrin is unlikely to present a public health concern**

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**Table 6.9 - 1: TMDI calculations using proposed MRLs and the EFSA model (rev 2.0)**

Highest calculated TMDI values in % of ADI		MS Diet	No of diets exceeding ADI:		TMDI (range) in % of ADI minimum - maximum		pTMRLs at LOQ (in % of ADI)	
Highest contributor to MS diet (in % of ADI)		Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)		Commodity / group of commodities		3rd contributor to MS diet (in % of ADI)	
22.7	NL child	Milk and milk products: Cattle	6.0	Bovine: Meat	0.7	Poultry: Meat		
16.8	FR infant	Milk and milk products: Cattle	6.0	Bovine: Meat	0.6	Poultry: Meat		
16.5	ES child	Bovine: Meat	6.2	Milk and milk products: Cattle	1.3	Poultry: Meat		
10.9	WHO regional European diet	Bovine: Meat	2.4	Milk and milk products: Cattle	0.9	Poultry: Meat		
10.5	DE child	Milk and milk products: Cattle	1.7	Bovine: Meat	0.6	Poultry: Meat		
10.5	WHO Cluster diet B	Bovine: Meat	1.5	Milk and milk products: Cattle	1.0	Poultry: Meat		
9.0	FR toddler	Bovine: Meat	0.8	Poultry: Meat	0.6	Bovine: Edible offal		
8.3	WHO Cluster diet F	Bovine: Meat	2.0	Milk and milk products: Cattle	0.5	Poultry: Meat		
8.3	WHO cluster diet D	Bovine: Meat	2.4	Milk and milk products: Cattle	0.7	Wheat		
8.3	ES adult	Bovine: Meat	2.5	Milk and milk products: Cattle	0.9	Sheep: Meat		
7.9	WHO cluster diet E	Bovine: Meat	2.5	Milk and milk products: Cattle	1.0	Poultry: Meat		
7.8	NL general	Bovine: Meat	3.3	Milk and milk products: Cattle	0.3	Poultry: Meat		
7.0	SE general population 90th percentile	Milk and milk products: Cattle	0.4	Birds' eggs	0.3	Wheat		
6.6	IE adult	Bovine: Meat	1.9	Sheep: Meat	1.4	Milk and milk products: Cattle		
5.3	FR all population	Bovine: Meat	1.3	Milk and milk products: Cattle	0.6	Poultry: Meat		
3.8	LT adult	Milk and milk products: Cattle	1.3	Bovine: Meat	0.3	Poultry: Meat		
3.2	DK adult	Bovine: Meat	0.2	Wheat	0.2	Birds' eggs		
3.1	UK Toddler	Sugar beet (root)	0.4	Birds' eggs	0.4	Wheat		
2.0	UK Infant	Sugar beet (root)	0.7	Birds' eggs	0.3	Wheat		
1.0	DK child	Wheat	0.4	Birds' eggs	0.0	Bovine: Liver		
0.8	UK vegetarian	Sugar beet (root)	0.2	Wheat	0.2	Birds' eggs		
0.7	UK Adult	Sugar beet (root)	0.2	Wheat	0.2	Birds' eggs		
0.7	IT kids/toddler	Wheat	0.0	Cauliflower		FRUIT (FRESH OR FROZEN)		
0.4	IT adult	Wheat	0.0	Cauliflower		FRUIT (FRESH OR FROZEN)		
0.4	RT General population	Wheat		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		
0.2	FI adult	Birds' eggs	0.1	Wheat	0.0	Cauliflower		
0.0	PL general population	Cauliflower		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		

Explain choice of toxicological reference values.  
 The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

**Chronic risk assessment**

TMDI (range) in % of ADI minimum - maximum		23	
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Highest calculated TMDI values in % of ADI		MS Diet	No of diets exceeding ADI:		TMDI (range) in % of ADI minimum - maximum		pTMRLs at LOQ (in % of ADI)	
Highest contributor to MS diet (in % of ADI)		Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)		Commodity / group of commodities		3rd contributor to MS diet (in % of ADI)	
22.7	NL child	Milk and milk products: Cattle	6.0	Bovine: Meat	0.7	Poultry: Meat		
16.8	FR infant	Milk and milk products: Cattle	6.0	Bovine: Meat	0.6	Poultry: Meat		
16.5	ES child	Bovine: Meat	6.2	Milk and milk products: Cattle	1.3	Poultry: Meat		
10.9	WHO regional European diet	Bovine: Meat	2.4	Milk and milk products: Cattle	0.9	Poultry: Meat		
10.5	DE child	Milk and milk products: Cattle	1.7	Bovine: Meat	0.6	Poultry: Meat		
10.5	WHO Cluster diet B	Bovine: Meat	1.5	Milk and milk products: Cattle	1.0	Poultry: Meat		
9.0	FR toddler	Bovine: Meat	0.8	Poultry: Meat	0.6	Bovine: Edible offal		
8.3	WHO Cluster diet F	Bovine: Meat	2.0	Milk and milk products: Cattle	0.5	Poultry: Meat		
8.3	WHO cluster diet D	Bovine: Meat	2.4	Milk and milk products: Cattle	0.7	Wheat		
8.3	ES adult	Bovine: Meat	2.5	Milk and milk products: Cattle	0.9	Sheep: Meat		
7.9	WHO cluster diet E	Bovine: Meat	2.5	Milk and milk products: Cattle	1.0	Poultry: Meat		
7.8	NL general	Bovine: Meat	3.3	Milk and milk products: Cattle	0.3	Poultry: Meat		
7.0	SE general population 90th percentile	Milk and milk products: Cattle	0.4	Birds' eggs	0.3	Wheat		
6.6	IE adult	Bovine: Meat	1.9	Sheep: Meat	1.4	Milk and milk products: Cattle		
5.3	FR all population	Bovine: Meat	1.3	Milk and milk products: Cattle	0.6	Poultry: Meat		
3.8	LT adult	Milk and milk products: Cattle	1.3	Bovine: Meat	0.3	Poultry: Meat		
3.2	DK adult	Bovine: Meat	0.2	Wheat	0.2	Birds' eggs		
3.1	UK Toddler	Sugar beet (root)	0.4	Birds' eggs	0.4	Wheat		
2.0	UK Infant	Sugar beet (root)	0.7	Birds' eggs	0.3	Wheat		
1.0	DK child	Wheat	0.4	Birds' eggs	0.0	Bovine: Liver		
0.8	UK vegetarian	Sugar beet (root)	0.2	Wheat	0.2	Birds' eggs		
0.7	UK Adult	Sugar beet (root)	0.2	Wheat	0.2	Birds' eggs		
0.7	IT kids/toddler	Wheat	0.0	Cauliflower		FRUIT (FRESH OR FROZEN)		
0.4	IT adult	Wheat	0.0	Cauliflower		FRUIT (FRESH OR FROZEN)		
0.4	RT General population	Wheat		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		
0.2	FI adult	Birds' eggs	0.1	Wheat	0.0	Cauliflower		
0.0	PL general population	Cauliflower		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		



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Acute Reference Dose (ARfD) and Dietary Exposure Calculation

In order to evaluate the potential acute exposure to deltamethrin residues through the diet, the International Estimated Short Term Intakes (IESTI) were calculated using:

- The EFSA PRIMo model (revision 2). For the evaluation of the acute exposure 19 national diets from 11 different EU Member States are used.
- An ARfD of 0.01 mg/kg bw/day
- The Highest Residue values observed for the representative uses respectively: 0.01 mg/kg for cauliflower, 0.01 mg/kg for sugar-beet body and 0.02 mg/kg for wheat grain.
- As a worse case, the current EU-MRLs for animal commodities as mentioned into Reg. 396/2005 were considered

For animal commodities, calculations were made using the lowest aggregation level of food commodities meaning that in the spreadsheet the MRLs were not entered at commodity group levels (e.g. "milk and cream, not concentrated, not containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curds") but at individual crop levels (e.g. "milk and milk products Cattle", "milk and milk products Sheep", etc...).

The highest IESTI represents 63.0% of the ARfD and was calculated for Towing meat consumed by children. Please note that this value is a conservative one as Bayer CropScience would like to argue against the ARfD set during the last Annex I inclusion review. As a matter of fact, Bayer CropScience would like to propose an ARfD of 0.05 mg/kg based on deltamethrin acute neurotoxicity study in the rat with a NOAEL of 5 mg/kg and a 100-fold safety factor, as established and re-discussed by the WHO/JMPR in 2000 and 2006 (refer to MCA Section 5). Therefore, a short-term intake of residues of deltamethrin is unlikely to present a public health concern.

Table 6.9- 2: IESTI calculations using proposed MRLs and the EFSA model (rev 2.0)

Acute risk assessment / children				Acute risk assessment / adults / general population				
The acute risk assessment is based on the ARfD.								
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.								
In the IESTI 1 calculation the variability factors were 10, 7 and 5 (according to JMPR manual 2002, for lettuce a variability factor of 3 was used).								
In the IESTI 2 calculation the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.								
Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.								
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):		No of commodities for which ARfD/ADI is exceeded (IESTI 2):		No of commodities for which ARfD/ADI is exceeded (IESTI 1):		No of commodities for which ARfD/ADI is exceeded (IESTI 2):	
	IESTI 1		IESTI 2		IESTI 1		IESTI 2	
	Highest % of ARfD/ADI	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	pTMRL/ threshold MRL (mg/kg)
63.9	Bovine: Meat	0.5 / -	63.9	Bovine: Meat	0.5 / -	29.8	Bovine: Meat	0.5 / -
62.1	Milk and milk	0.5 / -	62.1	Milk and milk	0.5 / -	25.0	Swine: Meat	0.5 / -
51.7	Sheep: Meat	0.5 / -	51.7	Sheep: Meat	0.5 / -	23.8	Sheep: Meat	0.5 / -
42.4	Swine: Meat	0.5 / -	42.4	Swine: Meat	0.5 / -	14.8	Bovine: Edible offal	0.5 / -
36.4	Bovine: Edible offal	0.5 / -	36.4	Bovine: Edible	0.5 / -	12.4	Other farm animals: Meat	0.5 / -

CA 6.10 Other studies  
Non





**CA 6.10.1 Effect on the residue level in pollen and bee products**

The effect on the residue level in pollen and bee products are considered as not relevant for the investigated representative uses (cauliflower, sugar beet and wheat) because they are not medicinal crops.

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