MON 52276
(360 g/L glyphosate acid)

DOCUMENT M-CP, Section 10

ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

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Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number
22nd July 2020	Citrus added to Use 4a, 4b and 4c – typo correction Update version number of cited documents	Doc ID: 110054-MCP10_GRG_Rev 1_Jul_2020 Replaces the Doc ID 110054-MCP10_GRG_Jun_2020 – Changes are given in yellow

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

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CP 10 ECOTOXICOLOGICAL STUDIES ON PLANT PROTECTION PRODUCTS

Introduction

Commission Directive 2001/99/EC included glyphosate as an active substance in Annex I to Council Directive 91/414/EEC. Following a peer review organised by the European Commission, glyphosate was included in Annex I of Council Directive 91/414/EEC with Commission Directive 2001/99/EC, entering into force on 01st July 2002. According to Regulation (EU) No 540/2011, glyphosate was deemed for approval under Regulation (EC) No 1107/2009 as well.

In agreement with Article 4 of Regulation (EC) No 1141/2010 Monsanto Europe S.A./N.V. (now Bayer Agriculture BV) on behalf of the then European Glyphosate Task Force submitted an application to Germany as RMS and Slovakia as Co-RMS notifying the intention to renew the existing approval of glyphosate on 24th March 2011 during the AIR 2 process. A collective supplementary dossier from the Glyphosate Task Force comprising 24 applicants was submitted on 25th May 2012.

On 12th November 2015, the European Food Safety Authority (EFSA) published its conclusions on the peer review of the pesticide risk assessment of the active substance glyphosate in the framework of the renewal of the approval under Commission Regulation (EU) No 1141/2010 (EFSA Journal 2015;13(11):4302)[1].

EFSA was requested by the European Commission (EC) to consider available information on the potential endocrine activity of the pesticide active substance glyphosate in accordance with Article 31 of Regulation (EC) No 178/2002. The assessment concluded that the weight of evidence indicates glyphosate does not possess endocrine disrupting properties via oestrogen, androgen, thyroid or steroidogenesis modes of action based on a comprehensive database available in the toxicology area.

On 17th March 2016, the rapporteur Member State, Germany, submitted a dossier to the European Chemical Agency for harmonised classification and labelling of the substance glyphosate. The proposal document was prepared in accordance with Article 37 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council.

The Committee for Risk Assessment (RAC) assessed the hazards presented by glyphosate against the criteria in the Classification, Labelling and Packaging Regulation[2]. The RAC concluded that the available scientific evidence did not meet the criteria in the CLP Regulation and that glyphosate would not be classified as possessing STOT (specific target organ toxicity), carcinogenicity, mutagenicity or reproductive toxicity.

The AIR 2 process at EU level, concluded that it has been established with respect to one or more representative uses of at least one plant protection product containing the active substance glyphosate that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. Thus, the approval criteria of demonstrating a safe use were deemed to be satisfied. It was therefore appropriate to renew the active substance glyphosate[3]. Glyphosate was renewed (date of approval) on 16th December 2017 with the expiration of approval set up for 15th December 2022.

[1] Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate in the framework of the renewal of the approval under Commission Regulation (EU) No 1141/2010; EFSA Journal 2015;13(11):4302, 107 pp; doi:10.2903/j.efsa.2015.4302.

[2] RAC Opinion proposing harmonised classification and labelling at EU level of glyphosate (ISO); N (phosphono-methyl)glycine. CLH-O-0000001412-86-149/F. Adopted 15 Mar 2017.

[3] COMMISSION IMPLEMENTING REGULATION (EU) 2017/2324.

Bayer Agriculture BV[4] submits the dossier on behalf of the Glyphosate Renewal Group (GRG) for the AIR 5 process.

In the frame of the pre-submission meeting held between the GRG and the Assessment Group on Glyphosate (AGG) on 27th September 2019, the AGG provided a reference document to GRG on the process to be considered when summarizing studies from past submissions in the June 2020 renewal dossier[5].

In 1995, glyphosate active substance dossiers were submitted by both task force and individual companies comprising a total of 19 applicants. The majority of applicants of the 1995 submissions did not join the 2012 Glyphosate Task Force (GTF) nor the GRG submitting the AIR 5 dossier in 2020. The GRG was not able to get access to a total of 46 study reports from three companies that were part of the submissions in 1995 (for details please refer to the Document B, Doc ID: 110054-B-GRG_Rev 1_Jul_2020), because some of the companies involved in the submissions in 1995 have subsequently been acquired by/merged with other companies or have since exited the market. Therefore, the GRG contacted Germany as the former RMS for glyphosate to discuss options available in order for AGG to get access to all said 46 study reports. A list of all these studies was sent to BVL (letter from 03rd March 2020). BVL replied to this request on 24th March 2020, advising the AGG to send a "request for administrative assistance (Art. 39 of Regulation (EC) No. 1107/2009)" to the BVL. Then, BVL will forward the respective studies directly to the AGG. In the present AIR 5 Dossier, information on those inaccessible studies has been summarised based on the 2000 monograph documents[6] and are identified (as Category 4a and 4b) in the present AIR 5 dossier[7]. In these cases, GRG was unable to provide updated Appendix E summaries due to lack of access to these studies.

A number of new regulatory studies, generated after the previous EU renewal process and/or not previously submitted at EU level, are presented as part of the data package of this AIR 5 dossier. To date, those new studies have not been peer-reviewed at EU level (please refer to the Application document Rev 3 Dated July 2020 – Document F, Doc ID: 110054-F-GRG_Rev 1_Jul_2020).

A literature search for the active substance glyphosate and metabolites was performed in accordance with the provisions of the EFSA Guidance "Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) 1107/2009" and according to the updated Appendix to this Guidance document[8]. The scientific literature review was performed for the period of 01st January 2010 until 31st December 2019, please refer to M-CA Section Ecotoxicology (Doc ID: 110054-MCA8_GRG_Rev 1_Jul_2020). The identified relevant and reliable articles are presented as appendix E summaries in the M-CA Section Ecotoxicology. For further detailed information on the Literature Review Report (LRR) and the corresponding evaluation, please refer to M-CA Section 9 "Literature". In the frame of the pre-submission meeting held on 27th September 2019, the AGG provided a reference document to GRG on the process to be considered when presenting literature in the June 2020 submission dossier[9].

[4] Due to the Bayer-Monsanto acquisition in 2018, the legal entity name Monsanto Europe S.A. / N.V. has been changed to Bayer Agriculture BV.

[5] AGG_Advice to GTF2_Literature search_Final Oct 2019 "HOW TO SUMMARISE STUDIES IN DOSSIERS FROM 1998 AND 2012 IN THE DOSSIER TO BE SUBMITTED JUNE 2020"

[6] Monograph and Addendum to the monograph EU 2001: Glyphosate monograph

[7] In the AIR 5 dossier, in each M document, a category has been assigned to each regulatory study included in the AIR 5 dossier (for details please refer to the Doc ID: 110054-B-GRG_Jun_2020).

[8] Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances approved 27 March 2019 (doi: 10.2903/sp.efsa.2019.EN-1612)

[9] AGG_Advice to GTF2_Literature search_Final Oct 2019 "ADVICE TO GTF2: HOW TO PRESENT THE LITERATURE SEARCH IN THE DOSSIER TO BE SUBMITTED JUNE 2020"

During the former EU processes, public literature data was evaluated, listed and reported by the RMS. An appendix, containing information about all previously submitted and/or included public literature articles from the former EU process is presented, for sake of completeness, as Annex to the M-CA Section 8 at the end of this document.

The representative formulation MON 52276, is a soluble concentrate (SL) herbicide containing 360 g/L glyphosate as isopropylamine salt. The content of glyphosate in the GAP (Table 10-1) is expressed as glyphosate acid, which corresponds to MON 52276 at 360 g/L.

Ecotoxicological studies have been conducted with the active substance glyphosate, glyphosate acid, glyphosate salts and its metabolites and are detailed in the document M-CA Section 8. Where applicable, ecotoxicological studies have been conducted with the representative formulation MON 52276 to compare the toxicity of the active substance with that of MON 52276.

Studies with the active substance that are relevant to the risk assessment are presented in tabular form at the beginning of each section, alongside the studies conducted with MON 52276. Full summaries for MON 52276 studies are provided for each organism groups. Irrespective of the test item, all presented endpoints for MON 52276 and glyphosate are given in glyphosate acid equivalents (i.e. recalculated to acid equivalents).

Risk assessments according to current and relevant guidance documents have been conducted for each organism group according to the proposed uses of MON 52276 to control broadleaf weeds in field crops, orchards, vineyards, railroad tracks and for the control of invasive species in agricultural and non-agricultural areas. A risk assessment strategy is presented at the beginning of each section to demonstrate how the proposed uses of MON 52276 are addressed for each organism group.

Full details of the proposed uses are provided in the table below.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code)	**MON 52276**	**Formulation type:**	**SL**
active substance 1	**glyphosate as isopropylammonium salt**	**Conc. of as 1:**	**360 g/L (486 g/L isopropylammonium salt)**
safener	**-**	**Conc. of safener:**	**-**
synergist	**-**	**Conc. of synergist:**	**-**
Applicant:	**GRG**	**professional use**	☒
Zone(s):	**central, southern and northern**	**non-professional use**	☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**		**e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures**
	PRE-SOWING, PRE-PLANTING												
1a		EU	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet	F	Emerged annual weeds, emerged perennial and biennial weeds BBCH > 13	Tractor mounted broadcast spray	Pre-sowing, Pre-planting, Pre-emergence of the crop	a) 1 b) 1	a) 4 L/ha b) 4 L/ha	a) 1.44 kg as/ha b) 1.44 kg as/ha	100 – 400	N/A	Also applicable to renovation / change of land use applications. Application to 100 % of the field. Use 75 % drift reducing nozzles. Maximum application rate of 1.44 kg as/ha glyphosate in any 12 months period.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1**	**MON 52276** **glyphosate as isopropylammonium salt**	**Formulation type:** **Conc. of as 1:**	**SL** **360 g/L (486 g/L isopropylammonium salt)**
safener **synergist**	**-** **-**	**Conc. of safener:** **Conc. of synergist:**	**-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**kg, L product/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		**e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
1b		EU	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet	F	Emerged annual weeds, emerged perennial and biennial weeds (BBCH 13 – 21)	Tractor mounted broadcast spray	Pre-sowing, Pre-planting, Pre-emergence of the crop	a) 1 b) 1	a) 3 L/ha b) 3 L/ha	a) 1.08 kg as/ha b) 1.08 kg as/ha	100 – 400	N/A	Also applicable to renovation / change of land use applications. Application to 100 % of the field. Use 75 % drift reducing nozzles. Maximum application rate of 1.08 kg as/ha glyphosate in any 12 months period.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1** **safener** **synergist**	**MON 52276** **glyphosate as isopropylammonium salt** **-** **-**	**Formulation type:** **Conc. of as 1:** **Conc. of safener:** **Conc. of synergist:**	**SL** **360 g/L (486 g/L isopropylammonium salt)** **-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
1c		EU	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet	F	Emerged annual weeds	Tractor mounted broadcast spray	Pre-sowing, Pre-planting, Pre-emergence of the crop	a) 1 b) 1	a) 2 L/ha b) 2 L/ha	a) 0.72 kg as/ha b) 0.72 kg as/ha	100 – 400	N/A	Also applicable to renovation / change of land use applications. Application to 100 % of the field. Use 75 % drift reducing nozzles. Maximum application rate of 0.72 kg as/ha glyphosate in any 12 months period.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1**	**MON 52276** **glyphosate as isopropylammonium salt**	**Formulation type:** **Conc. of as 1:**	**SL** **360 g/L (486 g/L isopropylammonium salt)**
safener **synergist**	**-** **-**	**Conc. of safener:** **Conc. of synergist:**	**-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application** **Method / Kind**	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Application rate** **kg, L product/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**	**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
	POST-HARVEST, PRE-SOWING, PRE-PLANTING												
2a		EU	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet	F	Emerged annual, perennial and biennial weeds	Tractor mounted broadcast spray	Post-harvest, pre-sowing, pre-planting	a) 1 – 2 (28 days) b) 1 – 2 (28 days)	a) 3 – 4 L/ha b) 6 L/ha	a) 1.08 – 1.44 kg as/ha b) 2.16 kg as/ha	100 – 400	N/A	Application to existing row cropland after harvest for removal of remaining crop / stubble and for control of actively growing weeds and mature annual weeds with hardened-off surface Application to 100 % of the field. Use 75 % drift reducing nozzles. Maximum application rate of 2.16 kg as/ha glyphosate in any 12 months period.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1**	**MON 52276** **glyphosate as isopropylammonium salt**	**Formulation type:** **Conc. of as 1:**	**SL** **360 g/L (486 g/L isopropylammonium salt)**
safener **synergist**	**-** **-**	**Conc. of safener:** **Conc. of synergist:**	**-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**kg, L product/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
2b		EU	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet	F	Emerged annual, perennial and biennial weeds	Tractor mounted broadcast spray	Post-harvest, pre-sowing, pre-planting	a) 1 – 3 (28 days) b) 1 – 3 (28 days)	a) 2 – 3 L/ha b) 6 L/ha	a) 0.72 – 1.08 kg as/ha b) 2.16 kg as/ha	100 – 400	N/A	Application to existing row cropland after harvest for removal of remaining crop / stubble and for control of actively growing weeds. Application to 100 % of the field. Use 75 % drift reducing nozzles. Maximum application rate of 2.16 kg as/ha glyphosate in any 12 months period.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1** **safener** **synergist**	**MON 52276** **glyphosate as isopropylammonium salt** **-** **-**	**Formulation type:** **Conc. of as 1:** **Conc. of safener:** **Conc. of synergist:**	**SL** **360 g/L (486 g/L isopropylammonium salt)** **-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**kg, L product/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
2c		EU	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet	F	Emerged annual weeds	Tractor mounted broadcast spray	Post-harvest, pre-sowing, pre-planting	a) 1 – 3 (28 days) b) 1 – 3 (28 days)	a) 2 L/ha b) 6 L/ha	a) 0.72 kg as/ha b) 2.16 kg as/ha	100 – 400	N/A	Application to existing row cropland after harvest for removal of remaining crop / stubble and for control of actively growing annual weeds Application to 100 % of the field. Use 75 % drift reducing nozzles. Maximum application rate of 2.16 kg as/ha glyphosate in any 12 months period.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1**	**MON 52276** **glyphosate as isopropylammonium salt**	**Formulation type:** **Conc. of as 1:**	**SL** **360 g/L (486 g/L isopropylammonium salt)**
safener **synergist**	**-** **-**	**Conc. of safener:** **Conc. of synergist:**	**-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		**e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
3a		EU	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet	F	Cereal volunteers	Tractor mounted broadcast spray	Post-harvest, pre-sowing, pre-planting	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) 0.54 kg as/ha b) 0.54 kg as/ha	100 – 400	N/A	Application to existing row cropland after harvest for removal of cereal volunteers. Maximum application rate of 0.54 kg as/ha glyphosate in any 12 months period.
3b		EU	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet	F	Cereal volunteers	Tractor mounted broadcast spray	Post-harvest, pre-sowing, pre-planting	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) 0.54 kg as/ha b) 0.54 kg as/ha	100 – 400	N/A	Application to existing row cropland after harvest for removal of cereal volunteers once every three years. Maximum application rate of 0.54 kg as/ha glyphosate in any 36 months period.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1**	**MON 52276** **glyphosate as isopropylammonium salt**	**Formulation type:** **Conc. of as 1:**	**SL** **360 g/L (486 g/L isopropylammonium salt)**
safener **synergist**	**-** **-**	**Conc. of safener:** **Conc. of synergist:**	**-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**kg, L product/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
	POST-EMERGENCE OF WEEDS												
4a		EU	Orchard crops (citrus, stone and pome fruits, kiwi, tree nuts, banana, and table olives)	F	Emerged annual, biennial and perennial weeds	Ground directed, shielded spray, band application	Post-emergence of weeds	a) 1 – 2 (28 days) b) 1 – 2 (28 days)	a) 3 – 4 L/ha b) 8 L/ha	a) 1.08 – 1.44 kg as/ha b) 2.88 kg as/ha	100 – 400	7	Avoid crop contamination during treatment. Maximum application rate of 2.88 kg as/ha treated area glyphosate in any 12 months period. Band application in the rows below the trees or as spot treatments. The treated area represents not more than 50 % of the total orchard area. The application rate with reference to the total orchard surface area is not more than 50 % of the stated dose rate.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1** **safener** **synergist**	**MON 52276** **glyphosate as isopropylammonium salt** **-** **-**	**Formulation type:** **Conc. of as 1:** **Conc. of safener:** **Conc. of synergist:**	**SL** **360 g/L (486 g/L isopropylammonium salt)** **-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**kg, L product/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
4b		EU	Orchard crops (citrus, stone and pome fruits, kiwi, tree nuts, banana, and table olives)	F	Emerged annual, biennial and perennial weeds	Ground directed, shielded spray, band application	Post-emergence of weeds	a) 1 – 3 (28 days) b) 1 – 3 (28 days)	a) 2 – 3 L/ha b) 8 L/ha	a) 0.72 – 1.08 kg as/ha b) 2.88 kg as/ha	100 – 400	7	Avoid crop contamination during treatment. Maximum application rate of 2.88 kg as/ha treated area glyphosate in any 12 months period. Band application in the rows below the trees or as spot treatments. The treated area represents not more than 50 % of the total orchard area. The application rate with reference to the total orchard surface area is not more than 50 % of the stated dose rate.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1**	**MON 52276** **glyphosate as isopropylammonium salt**	**Formulation type:** **Conc. of as 1:**	**SL** **360 g/L (486 g/L isopropylammonium salt)**
safener **synergist**	**-** **-**	**Conc. of safener:** **Conc. of synergist:**	**-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
4c		EU	Orchard crops (citrus, stone and pome fruits, kiwi, tree nuts, banana, and table olives)	F	Emerged annual weeds	Ground directed, shielded spray, band application	Post-emergence of weeds	a) 1 – 3 (28 days) b) 1 – 3 (28 days)	a) 2 L/ha b) 6 L/ha	a) 0.72 kg as/ha b) 2.16 kg as/ha	100 – 400	7	Avoid crop contamination during treatment. Maximum application rate of 2.16 kg as/ha treated area glyphosate in any 12 months period. Band application in the rows below the trees or as spot treatments. The treated area represents not more than 50 % of the total orchard area. The application rate with reference to the total orchard surface area is not more than 50 % of the stated dose rate.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1**	**MON 52276** **glyphosate as isopropylammonium salt**	**Formulation type:** **Conc. of as 1:**	**SL** **360 g/L (486 g/L isopropylammonium salt)**
safener **synergist**	**-** **-**	**Conc. of safener:** **Conc. of synergist:**	**-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
5a		EU	Vines (table and wine grape, leaves not intended for human consumption)	F	Emerged annual, biennial and perennial weeds	Ground directed, shielded spray, band application	Post-emergence of weeds	a) 1 – 2 (28 days) b) 1 – 2 (28 days)	a) 3 – 4 L/ha b) 8 L/ha	a) 1.08 – 1.44 kg as/ha b) 2.88 kg as/ha	100 – 400	7	Avoid crop contamination during treatment. Maximum application rate of 2.88 kg as/ha treated area glyphosate in any 12 months period. Band application in the rows below the vine stock or as spot treatments. The treated area represents not more than 50 % of the total vineyard area. The application rate with reference to the total vineyard surface area is not more than 50 % of the stated dose rate.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1** **safener** **synergist**	**MON 52276** **glyphosate as isopropylammonium salt** **-** **-**	**Formulation type:** **Conc. of as 1:** **Conc. of safener:** **Conc. of synergist:**	**SL** **360 g/L (486 g/L isopropylammonium salt)** **-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
5b		EU	Vines (table and wine grape, leaves not intended for human consumption)	F	Emerged annual, biennial and perennial weeds	Ground directed, shielded spray, band application	Post-emergence of weeds	a) 1 – 3 (28 days) b) 1 – 3 (28 days)	a) 2 – 3 L/ha b) 8 L/ha	a) 0.72 – 1.08 kg as/ha b) 2.88 kg as/ha	100 – 400	7	Avoid crop contamination during treatment. Maximum application rate of 2.88 kg as/ha treated area glyphosate in any 12 months period. Band application in the rows below the vine stock or as spot treatments. The treated area represents not more than 50 % of the total vineyard area. The application rate with reference to the total vineyard surface area is not more than 50 % of the stated dose rate.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1** **safener** **synergist**	**MON 52276** **glyphosate as isopropylammonium salt** **-** **-**	**Formulation type:** **Conc. of as 1:** **Conc. of safener:** **Conc. of synergist:**	**SL** **360 g/L (486 g/L isopropylammonium salt)** **-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application** **Method / Kind**	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Application rate** **kg, L product/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**	**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
5c		EU	Vines (table and wine grape, leaves not intended for human consumption)	F	Emerged annual weeds	Ground directed, shielded spray, band application	Post-emergence of weeds	a) 1 – 3 (28 days) b) 1 – 3 (28 days)	a) 2 L/ha b) 6 L/ha	a) 0.72 kg as/ha b) 2.16 kg as/ha	100 – 400	7	Avoid crop contamination during treatment. Maximum application rate of 2.16 kg as/ha treated area glyphosate in any 12 months period. Band application in the rows below the vine stock or as spot treatments. The treated area represents not more than 50% of the total vineyard area. The application rate with reference to the total vineyard surface area is not more than 50 % of the stated dose rate.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1**	**MON 52276** **glyphosate as isopropylammonium salt**	**Formulation type:** **Conc. of as 1:**	**SL** **360 g/L (486 g/L isopropylammonium salt)**
safener **synergist**	**-** **-**	**Conc. of safener:** **Conc. of synergist:**	**-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
6a		EU	Vegetables (Root and tuber vegetables Bulb vegetables, Fruiting vegetables Legume vegetables Leafy vegetables)	F	Emerged annual, biennial and perennial weeds	Inter-row application: ground directed, shielded spray	Crop BBCH < 20	a) 1 b) 1	a) 3 L/ha b) 3 L/ha	a) 1.08 kg as/ha b) 1.08 kg as/ha	100 – 400	60	Avoid crop contamination during treatment. Maximum application rate of 1.08 kg as/ha glyphosate in any 12 months period. Applications are performed between the crop rows. The rate refers to the treated area only, which represents not more than 50 % of the total area. The application rate with reference to the total surface area is not more than 50 % of the stated dose rate

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1** **safener** **synergist**	**MON 52276** **glyphosate as isopropylammonium salt** **-** **-**	**Formulation type:** **Conc. of as 1:** **Conc. of safener:** **Conc. of synergist:**	**SL** **360 g/L (486 g/L isopropylammonium salt)** **-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
6b		EU	Vegetables (Root and tuber vegetables Bulb vegetables, Fruiting vegetables Legume vegetables Leafy vegetables)	F	Emerged annual weeds	Inter-row application: ground directed, shielded spray	Crop BBCH < 20	a) 1 b) 1	a) 2 L/ha b) 2 L/ha	a) 0.72 kg as/ha b) 0.72 kg as/ha	100 – 400	60	Avoid crop contamination during treatment. Maximum application rate 0.72 kg as/ha glyphosate in any 12 months period. Applications are performed between the crop rows. The rate refers to the treated area only, which represents not more than 50 % of the total area. The application rate with reference to the total surface area is not more than 50 % of the stated dose rate

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1**	**MON 52276** **glyphosate as isopropylammonium salt**	**Formulation type:** **Conc. of as 1:**	**SL** **360 g/L (486 g/L isopropylammonium salt)**
safener **synergist**	**-** **-**	**Conc. of safener:** **Conc. of synergist:**	**-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**kg, L product/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		**e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
7a		EU	Railroad tracks	F	Emerged annual, biennial and perennial weeds	Ground directed, spray	Post-emergence of weeds	a) 2 (90 days) b) 2 (90 days)	a) 5 L/ha b) 10 L/ha	a) 1.8 kg as/ha b) 3.6 kg as/ha	100 – 400	N/A	Application by spray train Maximum application rate 3.6 kg as/ha glyphosate in any 12 months period.
7b		EU	Railroad tracks	F	Emerged annual, biennial and perennial weeds	Ground directed, spray	Post-emergence of weeds	a) 1 b) 1	a) 5 L/ha b) 5 L/ha	a) 1.8 kg as/ha b) 1.8 kg as/ha	100 – 400	N/A	Application by spray train Maximum application rate 1.8 kg as/ha glyphosate in any 12 months period.
8		EU	Invasive species in agricultural and non-agricultural areas	F	Giant hogweed (*Heracleum mantegazzianum*)	Spot treatment (shielded)	Post-emergence of invasive species	a) 1 b) 1	a) 5 L/ha b) 5 L/ha	a) 1.8 kg as/ha b) 1.8 kg as/ha	5 – 400	N/A	Maximum application rate 1.8 kg as/ha glyphosate in any 12 months period.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1**	**MON 52276** **glyphosate as isopropylammonium salt**	**Formulation type:** **Conc. of as 1:**	**SL** **360 g/L (486 g/L isopropylammonium salt)**
safener **synergist**	**-** **-**	**Conc. of safener:** **Conc. of synergist:**	**-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
9		EU	Invasive species in agricultural and non-agricultural areas	F	Japanese knotweed (*Reynoutria japonica*)	Spot treatment (shielded), cut stem spray application	Late summer, early fall	a) 1 b) 1	a) 5 L/ha b) 5 L/ha	a) 1.8 kg as/ha b) 1.8 kg as/ha	5 – 400	N/A	Maximum application rate 1.8 kg as/ha glyphosate in any 12 months period.
10a		EU	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet	F	Couch grass (*Elymus repens*)	Spot treatment (shielded)	Post-harvest, pre-sowing, pre-planting	a) 1 b) 1	a) 3 L/ha b) 3 L/ha	a) 1.08 kg as/ha b) 1.08 kg as/ha	100 – 400	N/A	Application to existing row cropland after harvest for removal of couch grass. Maximum application rate of 1.08 kg as/ha glyphosate in any 12 months period. The treated area represents not more than 20 % of the cropland.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1**	**MON 52276** **glyphosate as isopropylammonium salt**	**Formulation type:** **Conc. of as 1:**	**SL** **360 g/L (486 g/L isopropylammonium salt)**
safener **synergist**	**-** **-**	**Conc. of safener:** **Conc. of synergist:**	**-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		**e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
10b		EU	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet	F	Couch grass (*Elymus repens*)	Spot treatment (shielded)	Post-harvest, pre-sowing, pre-planting	a) 1 b) 1	a) 2 L/ha b) 2 L/ha	a) 0.72 kg as/ha b) 0.72 kg as/ha	100 – 400	N/A	Application to existing row cropland after harvest for removal of couch grass. Maximum application rate of 0.72 kg as/ha glyphosate in any 12 months period. The treated area represents not more than 20 % of the cropland.

Table 10-1 : MON 52276 (360 g/L glyphosate)

PPP (product name/code) **active substance 1** **safener** **synergist**	**MON 52276** **glyphosate as isopropylammonium salt** **-** **-**	**Formulation type:** **Conc. of as 1:** **Conc. of safener:** **Conc. of synergist:**	**SL** **360 g/L (486 g/L isopropylammonium salt)** **-** **-**
Applicant: **Zone(s):**	**GRG** **central, southern and northern**	**professional use** **non-professional use**	☒ ☐
Verified by MS:	**y/n**		

1		2	3	4	5	6	7	8	10	11	12	13	14
Use-No.		**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**
						Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**kg, L product/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
10c		EU	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet	F	Couch grass (*Elymus repens*)	Spot treatment (shielded)	Post-harvest, pre-sowing, pre-planting	a) 1 b) 1	a) 2 L/ha b) 2 L/ha	a) 0.72 kg as/ha b) 0.72 kg as/ha	100 – 400	N/A	Application to existing row cropland after harvest for removal of couch grass once every three years. Maximum application rate of 0.72 kg as/ha glyphosate in any 36 months period. The treated area represents not more than 20 % of the cropland.

Remarks table heading:
(a) e g wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e g fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e g biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
6 Method, e g high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e g overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e g : g/m³ in case of fumigation of empty rooms See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
11 The dimension (g, kg) must be clearly specified (Maximum) dose of a s per treatment (usually g, kg or L product / ha)
12 If water volume range depends on application equipments (e g ULVA or LVA) it should be mentioned under “application: method/kind”
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

CP 10.1 Effects on Birds and Other Terrestrial Vertebrates

CP 10.1.1 Effects on birds

Studies considering the toxicity of glyphosate and relevant metabolites to birds were assessed for their validity to current and relevant guidelines. The results of these studies demonstrate that glyphosate and AMPA are of low acute and chronic toxicity to avian species.

Relevant and reliable studies for the risk assessment for birds of glyphosate and relevant metabolites are summarised in the tables below. Details of the acute studies are summarised in the Document M-CA, Section 8, point 8.1.1.1.

Table 10.1.1-1: Relevant endpoints for risk assessment: Acute oral toxicity of glyphosate and AMPA to birds

Reference	Substance	Species	Test design	LD_{50} (mg a.e./kg bw)
CA 8.1.1.1	Glyphosate	Bird[1]	Acute oral	**Extrapolated LD_{50} = 4334 mg/kg bw/day[2]**
[redacted] 1991 CA 8.1.1.1/009	AMPA	*Colinus virginianus*	Acute oral	LD_{50} > 2250 mg/kg bw/day

[1] Tested species: Bobwhite quail (*Colinus virginianus*), Japanese quail (*Coturnix coturnix japonica*), Mallard duck (*Anas platyrhynchos*)
[2] All acute oral bird studies resulted in endpoints > 2000 mg/kg bw (see Section CA 8.1.1.1). Therefore an extrapolations factor of 2.167 as recommended in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438) was applied.
Endpoints in **bold** are used for risk assessment

Details of this reproduction study is summarised in the Document M-CA, Section 8, point 8.1.1.3.

Table 10.1.1-2: Relevant endpoints for risk assessment: Reproductive toxicity of glyphosate to birds

Reference	Substance	Species	Test design	NOAEL (mg a.e./kg feed)	NOAEL (mg a.e./kg bw/d)
[redacted] 1978 CA 8.1.1.3/003	Glyphosate technical	*Colinus virginianus*	17 weeks reproduction	1000	96.3

a.e.: acid equivalents

Risk assessment for metabolites

The primary metabolite of glyphosate is aminomethylphosphonic acid (AMPA). Most of the parent glyphosate is eliminated unchanged and only a small amount (less than 1 % of the applied dose) is transformed to aminomethylphosphonic acid (AMPA). The metabolite AMPA has been tested in several mammal toxicity studies which demonstrated that it is of lower toxicity than glyphosate acid (see Section CA 5.8). Avian toxicity tests with metabolites of glyphosate showed equally low acute toxicity as glyphosate.

Following application to plant tissues, unchanged glyphosate was the only significant residue. In presence of soil as a substrate the active substance is quickly degraded, leaving AMPA at rates comparable or even higher than parent glyphosate. However, the uptake via the roots and the translocation in the plants was very low, not resulting in significant residue levels as confirmed by plant metabolism and confined rotational crop studies. A major part of the glyphosate was degraded into CO_2. Therefore, it can be concluded that the risk to birds will be acceptably low and no further quantitative risk assessment is conducted.

Risk assessment for the representative formulation

An acute oral mammalian study is available with the formulation which is presented in the toxicological section under Section CP 7.1.1/01. This study shows, that the acute toxicity of the formulation (>5000 mg/kg bw) is not more elevated than the toxicity of the active substance alone (>2000 mg/kg bw). Therefore the avian risk assessment for the representative formulation is considered to be covered by the avian risk assessment presented for the active substance glyphosate.

There are no literature articles and peer-reviewed published data considered to be relevant and reliable or reliable with restrictions with regards to the impact of glyphosate or its relevant metabolites on avian species. Full literature evaluation is provided in document M-CA Section 9. A summary of previously evaluated peer reviewed literature from the RAR 2015 is also available in Annex M-CA 8-01 of the M-CA Section 8. For discussions of literature regarding toxicity to birds, please refer to document M-CP Section 10.2.

Risk assessment for birds

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438); hereafter referred to as EFSA/2009/1438.

The table below summarises how the risk assessment for birds considers all the proposed uses and the application rates presented in the GAP.

Table 10.1.1-3: Risk assessment strategy for birds

GAP number and summary of use	Application rate considered (28 day interval unless otherwise stated)									
	1 × 540 g/ha	**1 × 720 g/ha**	**1 × 1080 g/ha**	**2 × 720 g/ha**	**1 × 1440 g/ha**	**3 × 720 g/ha**	**1 × 1800 g/ha**	**2 × 1080 g/ha[1]**	**2 × 1440 g/ha**	**2 × 1800 g/ha (90 days apart)**
Uses 1a-c: Applied to weeds; pre-sowing, pre-planting, pre emergence of **field crops.**		X	X		X					
Uses 2 a-c: Applied to weeds; post-harvest, pre-sowing, pre-planting of **field crops.**		X	X	X	X	X		X		
Use 3 a-b: Applied to cereal volunteers; post-harvest, pre-sowing, pre-planting of **field crops.**	X									
Use 4 a-c: Applied to weeds (post emergence) below trees in **orchards.**		X	X	X	X	X		X	X	
Use 5 a-c: Applied to weeds (post emergence) below vines in **vineyards**		X	X	X	X	X		X	X	
Use 6 a-b: Applied to weeds (post emergence) in **field crops BBCH <20**		X	X							
Use 7 a-b: Applied to weeds (post emergence) around **railroad tracks**							X			X
Use 8 and 9: Applied to invasive species (post emergence) in							X			

Table 10.1.1-3: Risk assessment strategy for birds

GAP number and summary of use	Application rate considered (28 day interval unless otherwise stated)									
	1 × 540 g/ha	1 × 720 g/ha	1 × 1080 g/ha	2 × 720 g/ha	1 × 1440 g/ha	3 × 720 g/ha	1 × 1800 g/ha	2 × 1080 g/ha[1]	2 × 1440 g/ha	2 × 1800 g/ha (90 days apart)
agricultural and non-agricultural areas										
Uses 10 a-c: Applied to couch grass; post-harvest, pre-sowing, pre-planting of **field crops**		X	X							

X = this use is covered by the application rate indicated.
[1] Due to the long spray interval of 28 days this use covers also the following possible application pattern: 2 × 1080 g a.e./ha plus 1 × 720 g a.e./ha (28 day interval between each application)

For the screening assessment; crops that maybe present at time of application to target weeds and the relevant application rates shown in the table above are considered. The acute and long-term screening assessment results are presented below according to the following main uses:

- in **field crops** (covering GAP uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c); pre-sowing, pre-planting pre-emergence, post-harvest. Exposure to birds via grassland, bare soil and field crops is considered and is covered by the general screening scenarios grassland, bare soil and bulb and onion like crops (etc.).
- in **orchards** (covering GAP uses 4 a-c) applied to weeds post emergence exposure below trees; exposure to small insectivorous birds in orchards is considered and is covered by the general screening scenario orchards (etc.)
- in **vineyards** (covering GAP uses 5 a-c) applied to weeds post emergence exposure below vines; exposure to small omnivorous birds in vineyards is considered and is covered by the general screening scenario vineyard.
- in **railroad tracks** (covering GAP uses 7 a-b) and in the **control of invasive species** (covering GAP uses 8 and 9) applied to weeds post emergence; exposure to birds via grassland, bare soil and field crops is considered and is covered by the general screening scenarios grassland, bare soil and bulb and onion like crops (etc.).

Screening assessment

Field crops

Table 10.1.1-4: Screening assessment of the acute risk for birds due to the use of glyphosate in field crops: Uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		4334					
TER criterion		10					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg,	1 × 1440	Grassland	Large herbivorous birds	30.5	1	43.9	98.7
		Bare soil	Small granivorous birds	24.7	1	35.6	122
		Bulb and	Small	158.8	1	229	19.0

Table 10.1.1-4: Screening assessment of the acute risk for birds due to the use of glyphosate in field crops: Uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		4334					
TER criterion		10					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
leafy veg, Sugar beet.		onion like crops	omnivorous birds				
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet.	2 × 1080 (28 d)	Grassland	Large herbivorous birds	30.5	1.1	36.2	120
		Bare soil	Small granivorous birds	24.7	1.1	29.3	148
		Bulb and onion like crops	Small omnivorous birds	158.8	1.1	189	23.0
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet.	1 × 540	Grassland	Large herbivorous birds	30.5	1	16.5	263
		Bare soil	Small granivorous birds	24.7	1	13.3	325
		Bulb and onion like crops	Small omnivorous birds	158.8	1	85.8	50.5
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet.	1 × 720	Grassland	Large herbivorous birds	30.5	1	22.0	197
		Bare soil	Small granivorous birds	24.7	1	17.8	244
		Bulb and onion like crops	Small omnivorous birds	158.8	1	114	37.9
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet.	2 × 720 (28 d)	Grassland	Large herbivorous birds	30.5	1.1	24.2	179
		Bare soil	Small granivorous birds	24.7	1.1	19.6	222
		Bulb and onion like crops	Small omnivorous birds	158.8	1.1	126	34.5

Table 10.1.1-4: Screening assessment of the acute risk for birds due to the use of glyphosate in field crops: Uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		4334					
TER criterion		10					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet.	1 × 1080	Grassland	Large herbivorous birds	30.5	1	32.9	132
		Bare soil	Small granivorous birds	24.7	1	26.7	163
		Bulb and onion like crops	Small omnivorous birds	158.8	1	172	25.3
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet.	3 × 720 (28 d)	Grassland	Large herbivorous birds	30.5	1.1	24.2	179
		Bare soil	Small granivorous birds	24.7	1.1	19.6	222
		Bulb and onion like crops	Small omnivorous birds	158.8	1.1	126	34.5

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

Table 10.1.1-5: Screening assessment of the long-term/reproductive risk for birds due to the use of glyphosate in field crops: Uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c

Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	1 × 1440	Grassland	Large herbivorous birds	16.2	1.0 × 0.53	12.4	7.80
		Bare soil	Small granivorous birds	11.4	1.0 × 0.53	8.70	11.1
		Bulb and onion like crops	Small omnivorous birds	64.8	1.0 × 0.53	49.5	**1.95**
Pre-sow, pre-planting, pre-emergence & post-harvest of;	2 × 1080 (28 d)	Grassland	Large herbivorous birds	16.2	1.1 × 0.53	10.2	9.44

Table 10.1.1-5: Screening assessment of the long-term/reproductive risk for birds due to the use of glyphosate in field crops: Uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c

Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds		Bare soil	Small granivorous birds	11.4	1.1 × 0.53	7.18	13.4
		Bulb and onion like crops	Small omnivorous birds	64.8	1.1 × 0.53	40.8	**2.36**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	1 × 540	Grassland	Large herbivorous birds	16.2	1.0 × 0.53	4.64	20.8
		Bare soil	Small granivorous birds	11.4	1.0 × 0.53	3.26	29.5
		Bulb and onion like crops	Small omnivorous birds	64.8	1.0 × 0.53	18.6	5.19
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	1 × 720	Grassland	Large herbivorous birds	16.2	1.0 × 0.53	6.18	15.6
		Bare soil	Small granivorous birds	11.4	1.0 × 0.53	4.35	22.1
		Bulb and onion like crops	Small omnivorous birds	64.8	1.0 × 0.53	24.7	**3.89**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	2 × 720 (28 d)	Grassland	Large herbivorous birds	16.2	1.1 × 0.53	6.80	14.2
		Bare soil	Small granivorous birds	11.4	1.1 × 0.53	4.79	20.1
		Bulb and onion like crops	Small omnivorous birds	64.8	1.1 × 0.53	27.2	**3.54**

Table 10.1.1-5: Screening assessment of the long-term/reproductive risk for birds due to the use of glyphosate in field crops: Uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c

Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	1 × 1080	Grassland	Large herbivorous birds	16.2	1.0 × 0.53	9.27	10.4
		Bare soil	Small granivorous birds	11.4	1.0 × 0.53	6.53	14.8
		Bulb and onion like crops	Small omnivorous birds	64.8	1.0 × 0.53	37.1	**2.60**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	3 × 720 (28 d)	Grassland	Large herbivorous birds	16.2	1.2 × 0.53	7.42	13.0
		Bare soil	Small granivorous birds	11.4	1.2 × 0.53	5.22	18.5
		Bulb and onion like crops	Small omnivorous birds	64.8	1.2 × 0.53	29.7	**3.25**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

Orchards

Table 10.1.1-6: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of glyphosate in orchards: Uses 4 a-c

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		4334					
TER criterion		10					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards post-emergence of weeds	2 × 1440 (28 d)	Orchards	Small insectivorous birds	46.8	1.1	74.1	58.5
Orchards post-emergence of weeds	1 × 720	Orchards	Small insectivorous birds	46.8	1.0	33.7	129
Orchards post-emergence of weeds	1 × 1080	Orchards	Small insectivorous birds	46.8	1.0	50.5	85.7
Orchards post-emergence of weeds	2 × 720 (28 d)	Orchards	Small insectivorous birds	46.8	1.1	37.1	117
Orchards post-emergence of weeds	1 × 1440	Orchards	Small insectivorous birds	46.8	1.0	67.4	64.3
Orchards post-emergence of weeds	3 × 720 (28 d)	Orchards	Small insectivorous birds	46.8	1.1	37.1	117
Orchards post-emergence of weeds	2 × 1080 (28 d)	Orchards	Small insectivorous birds	46.8	1.1	55.6	78.0
Reprod. Toxicity (mg/kg bw/d) TER criterion		96.3 5					
GAP crop	**Application rate**	**Crop scenario**	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards post-emergence of weeds	2 × 1440 (28 d)	Orchards	Small insectivorous birds	18.2	1.1 × 0.53	15.3	6.30
Orchards post-emergence of weeds	1 × 720	Orchards	Small insectivorous birds	18.2	1.0 × 0.53	6.95	13.9
Orchards post-emergence of weeds	1 × 1080	Orchards	Small insectivorous birds	18.2	1.0 × 0.53	10.4	9.24
Orchards post-emergence of weeds	2 × 720 (28 d)	Orchards	Small insectivorous birds	18.2	1.1 × 0.53	7.64	12.6

Table 10.1.1-6: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of glyphosate in orchards: Uses 4 a-c

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		4334					
TER criterion		10					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards post-emergence of weeds	1 × 1440	Orchards	Small insectivorous birds	18.2	1.0 × 0.53	13.9	6.93
Orchards post-emergence of weeds	3 × 720 (28 d)	Orchards	Small insectivorous birds	18.2	1.2 × 0.53	8.33	11.6
Orchards post-emergence of weeds	2 × 1080 (28 d)	Orchards	Small insectivorous birds	18.2	1.1 × 0.53	11.5	8.40

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

Vineyards

Table 10.1.1-7: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of glyphosate in vineyards: Uses 5 a-c

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		4334					
TER criterion		10					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard post-emergence of weeds	2 × 1440 (28 d)	Vineyard	Small omnivorous birds	95.3	1.1	151	28.7
Vineyard post-emergence of weeds	1 × 720	Vineyard	Small omnivorous birds	95.3	1.0	68.6	63.2
Vineyard post-emergence of weeds	1 × 1080	Vineyard	Small omnivorous birds	95.3	1.0	103	42.1
Vineyard post-emergence of weeds	2 × 720 (28 d)	Vineyard	Small omnivorous birds	95.3	1.1	75.5	57.4
Vineyard post-emergence of weeds	3 × 720 (28 d)	Vineyard	Small omnivorous birds	95.3	1.1	75.5	57.4
Vineyard post-emergence of weeds	1 × 1440	Vineyard	Small omnivorous birds	95.3	1.0	137	31.6

Table 10.1.1-7: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of glyphosate in vineyards: Uses 5 a-c

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		4334					
TER criterion		10					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard post-emergence of weeds	2 × 1080 (28 d)	Vineyard	Small omnivorous birds	95.3	1.1	113	38.3
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard post-emergence of weeds	2 × 1440 (28 d)	Vineyard	Small omnivorous birds	38.9	1.1 × 0.53	32.7	**2.95**
Vineyard post-emergence of weeds	1 × 720	Vineyard	Small omnivorous birds	38.9	1.0 × 0.53	14.8	6.49
Vineyard post-emergence of weeds	1 × 1080	Vineyard	Small omnivorous birds	38.9	1.0 × 0.53	22.3	**4.32**
Vineyard post-emergence of weeds	2 × 720 (28 d)	Vineyard	Small omnivorous birds	38.9	1.1 × 0.53	16.3	5.90
Vineyard post-emergence of weeds	3 × 720 (28 d)	Vineyard	Small omnivorous birds	38.9	1.2 × 0.53	17.8	5.41
Vineyard post-emergence of weeds	1 × 1440	Vineyard	Small omnivorous birds	38.9	1.0 × 0.53	29.7	**3.24**
Vineyard post-emergence of weeds	2 × 1080 (28 d)	Vineyard	Small omnivorous birds	38.9	1.1 × 0.53	24.5	**3.93**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Railroad tracks and control of invasive species

Table 10.1.1-8: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of glyphosate on railroad tracks and to control invasive species: Uses 7a-b, 8, 9

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		4334					
TER criterion		10					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Railroad tracks – application by spray train. Post emergence of weeds (90d apart).	2 × 1800 (90 d)	Grassland	Large herbivorous birds	30.5	1.0	54.9	78.9
		Bare soil	Small granivorous birds	24.7	1.0	44.5	97.5
	1 × 1800	Grassland	Large herbivorous birds	30.5	1.0	54.9	78.9
		Bare soil	Small granivorous birds	24.7	1.0	44.5	97.5
Invasive species in agricultural and non-agricultural areas. Post emergence of invasive species.	1 × 1800	Grassland	Large herbivorous birds	30.5	1.0	54.9	78.9
		Bare soil	Small granivorous birds	24.7	1.0	44.5	97.5
		Bulb and onion like crops	Small omnivorous birds	158.8	1.0	286	15.2
Reprod. Toxicity (mg/kg bw/d) TER criterion		96.3 5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario**	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Railroad tracks – application by spray train. Post emergence of weeds (90d apart).	2 × 1800 (90 d)	Grassland	Large herbivorous birds	16.2	1.0 × 0.53	15.5	6.23
		Bare soil	Small granivorous birds	11.4	1.0 × 0.53	10.9	8.85
	1 × 1800	Grassland	Large herbivorous birds	16.2	1.0 × 0.53	15.5	6.23
		Bare soil	Small granivorous birds	11.4	1.0 × 0.53	10.9	8.85
Invasive species in agricultural and non-agricultural areas. Post emergence of invasive species.	1 × 1800	Grassland	Large herbivorous birds	16.2	1.0 × 0.53	15.5	6.23
		Bare soil	Small granivorous birds	11.4	1.0 × 0.53	10.9	8.85
		Bulb and onion like crops	Small omnivorous birds	64.8	1.0 × 0.53	61.8	**1.56**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

The screening TER_a values for all proposed uses of MON 52276 in field crops, orchards, vineyards, railroad tracks and control of invasive species are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to birds is acceptable following the proposed use patterns for these crops.

Field crops (Uses: 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c)

The screening TER_{lt} values for use of MON 52276 in field crops for the scenarios “bare soil” and “grassland” are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5. For the use rate of 1 × 540 g a.e./ha (*Uses 3 a-b)* acceptable long-term risk for the “bulbs and onion like crops” scenario is concluded in the screening assessment. However, regarding the scenario “bulbs and onion like crops” a Tier 1 risk assessment is necessary for the application rates 1 × 1440 g a.e./ha, 2 × 1080 g a.e./ha, 1 × 720 g a.e./ha, 1 × 1080 g a.e./ha and 3 × 720 g a.e./ha.

Orchards (Uses: 4 a-c)

The screening TER_{lt} values for use of MON 52276 are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that the long-term risk to birds is acceptable following the proposed use patterns in orchards.

Vineyards (Uses: 5a-c)

The screening TER_{lt} values for use of MON 52276 are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5 for the application rates; 2 × 720 g a.e./ha, 3 × 720 g a.e./ha, 1 × 1440 g a.e./ha and 2 × 1080 g a.e./ha, indicating that the long-term risk to birds is acceptable following the proposed use patterns in vineyards. For the application rates of 2 × 1440 g a.e./ha and 1 × 1080 g a.e./ha a Tier 1 risk assessment is necessary.

Railroad tracks – application by spray train (Uses: 7a-c)

The screening TER_{lt} values for use of MON 52276 on railroad tracks are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that the long-term risk to birds is acceptable following the proposed use patterns around railroad tracks.

Invasive species in agricultural and non-agricultural areas (Uses: 8 and 9)

The screening TER_{lt} values for use of MON 52276 on invasive species in agricultural and non-agricultural areas for the scenarios “bare soil” and “grassland” are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that the long-term risk to birds is acceptable following the proposed use pattern. Regarding the scenario “bulbs and onion like crops” a Tier 1 risk assessment is necessary for the intended application rate of 1 × 1800 g a.e./ha.

Tier 1 assessment

The Tier 1 risk assessment is conducted for those proposed uses, for which the calculated TER_{lt} values are below the trigger of 5 in the screening assessment e.g. uses in field crops (except use 3 a-b), uses in vineyards and uses to control invasive species. The Tier 1 assessment initially requires identification of the appropriate crop groupings and generic focal bird species from Appendix A of EFSA/2009/1438.

Due to the proposed uses of the product MON 52276 in agricultural and non-agricultural areas, justifications are provided below considering which scenarios are relevant for the risk assessment. For those proposed uses where a large number of scenarios is relevant (Field crops: Use 2 a-c, 6 a-b, 10 a-c, Control of invasive species: Use 8 - 9) an approach has been taken to present only the worst-case risk assessment in this section. Therefore the worst-case scenarios have been selected based on the relevant generic focal species with the highest short-cut values as these are considered protective of the other scenarios with lower short-cut values. For completeness, a full and complete avian Tier I risk assessment that considers all other scenarios and focal species is presented in Annex M-CP 10-01 of this document.

A summary of **all** relevant scenarios and focal species (includes those presented in this section and in Annex M-CP 10-01 of this document) is provided in the table below. Please note that numbers in brackets refer to the bird scenarios stated in the Appendix A of EFSA/2009/1438.

<u>Field crops (Use 1 a-c, 2 a-c, 6 a-b, 10 a-c)</u>

For the Tier 1 assessment of the crop group "field crops", the intended use of MON 52276 includes several general uses on field crops as described further below. The applications are intended to be made by tractor-mounted sprayers (*Uses 1 a-c, 2 a-c, 6 a-b*) or by hand-held equipment (*Uses 10 a-c*).

Use 1 a-c is, the "pre-sowing, pre-planting, pre-emergence" use, where the intention of this use is to prepare a non-agricultural area for agriculture use, meaning that the product is applied when no agricultural crop is present. Therefore the "bare soil", the "grassland" and the "leafy vegetable" scenarios are considered relevant. As an acceptable risk for the "bare soil" and "grassland" scenarios was concluded at the screening assessment, a Tier 1 risk assessment will be presented only for "leafy vegetables". The "leafy vegetables" scenario was considered relevant to cover species that feed on broad-leaved weeds; the small granivorous bird "finch" (71, 72), the small omnivorous bird "lark" (79, 81), the medium herbivorous/granivorous bird "pigeon" (82) and the small insectivorous bird "wagtail" (83, 84) are taken into account.

Uses 2 a-c and 10 a-c are the "post-harvest, pre-sowing, pre-planting" use where the product can be applied to existing cropland after harvest for removal of remaining crops. Thus, for this use almost all field crops need to be considered. Only for those crops where safe risk could be concluded in the screening assessment, i.e. "bare soil" and "grassland" and for crops which are generally not considered relevant ("cotton") or for spatial cultures like "bush & cane fruit", "hops", "orchards", "ornamentals/nursery" and "vineyards" a risk assessment is not considered necessary. As the product is applied after post-harvest, late crop stages will be taken into account for risk assessment. Frugivorous bird scenarios were not taken into account, as the product is intended to be applied after harvest and will not be applied at typical crop stages when fruits are ripe. For the same reason also the two cereals scenario (late post emergence (May-June), BBCH 71 – 89 (19); late season, seed heads (35)) and the sunflower scenario (Late (Flowering, seed ripening) BBCH 61 – 92 (216) are not considered relevant.

Thus, for the Tier 1 risk assessment for the uses 2 a-c and 10 a-c, the relevant generic focal species with the highest short-cut values at late crop stages <u>across</u> all relevant crop scenarios were taken into account; the medium granivorous bird "gamebird" in maize (101), the medium herbivorous / granivorous bird "pigeon" in maize (117), the small insectivorous bird "dunnock" (120), the small granivorous bird "finch" in oilseed rape (122), the small insectivorous bird "wagtail" in bulbs & onion like crops (18) and the small omnivorous bird "lark" in bulbs & onion like crops (16). These selected scenarios cover the risk for all relevant scenarios. For completeness, a risk assessment for all other relevant scenarios and species is presented in Annex M-CP 10-01 of this document.

Uses 6 a-b are the "shielded ground directed inter-row application" uses at crop stages <BBCH 20 and all crops scenarios at early growth stages are taken into account, which are presented in the GAP, i.e. vegetables (root and tuber vegetables, bulb vegetables, fruiting vegetables, legume vegetables and leafy vegetables). To avoid exposure of crops, a shielded sprayer is used to ensure that the product is only applied to grasses and weeds in the inter-row. Therefore, only those vegetables crop scenarios are considered relevant where the generic focal species does not directly feed on the crop. In addition, the "bare soil" and the "grassland" scenario are considered relevant. However, as an acceptable risk was concluded for these scenarios already at the screening assessment the Tier 1 risk assessment is not required.

Thus, for the tier 1 risk assessment for the uses 6a-b, the relevant generic focal species with the highest short-cut values at early crop stages (<BBCH 20) <u>across</u> all relevant crops scenarios were taken into account, i.e. the medium herbivorous/granivorous bird "pigeon" in leafy vegetables (82), the small insectivorous bird "wagtail" in bulbs & onion like crops (17), the small omnivorous bird "lark" in bulbs & onion like crops (14) and the small granivorous bird "finch" in leafy vegetables (71). These selected scenarios cover the risk for all relevant scenarios. For completeness, a risk assessment for all other relevant scenarios and species is presented in Annex M-CP 10-01 of this document.

<u>Vineyards (Use 5 a-c)</u>
For the crop grouping "vines" all non-frugivorous bird scenarios were taken into account, i.e. the small insectivorous bird "redstart" (217, 218), the small granivorous bird "finch" (219, 220, 221) and the small omnivorous bird "lark" (231, 232, 233) are taken into account.

<u>Invasive species in agricultural and non-agricultural areas (Use 8-9)</u>
For the use on invasive species in agricultural and non-agricultural areas, almost all crops need to be considered. Only for those crops where safe risk could be proven in the screening assessment, i.e. "bare soil" and "grassland" or which are not considered relevant ("cotton") do not need to be assessed in the Tier 1 risk assessment. In general, those scenarios need to be taken into account, where a downward application of the product is relevant. Frugivorous bird scenarios were not taken into account, as the product is intended to be applied only on the invasive species Giant hogweed (*Heracleum mantegazzianum*) and Japanese knotweed (*Reynoutria japonica*) and due to the specific application method (handheld, spraying shield) fruits will not be exposed to the product. For the same reason also the cereal scenario (late season, seed heads; 35) and the sunflower scenario (Late (Flowering, seed ripening) BBCH 61 – 92 (216) are not considered relevant.

Thus, for the Tier 1 risk assessment for uses 8 and 9, the relevant generic focal species with the highest short-cut values across all relevant crop scenarios were taken into account, i.e. the large herbivorous bird "goose" in cereals (22), the medium granivorous bird "gamebird" in maize (99), the medium herbivorous granivorous bird "pigeon" in leafy vegetables (82), the small granivorous bird "finch" in leafy vegetables (71), the small insectivorous bird "dunnock" in oilseed rape (120), the small insectivorous bird "finch" in hop (66), the small insectivorous bird "passerine" in cereals (21), the small insectivorous bird "tit" in orchards (141), the small insectivorous bird "wagtail" in bulbs and onion like crops (17), the small insectivorous bird "warbler" in bush and cane fruit (20), the small insectivorous bird "redstart" in vineyards (217), the small insectivorous / worm feeding species "thrush" in maize (102), and the small omnivorous bird "lark" (14). These selected scenarios cover the risk for all relevant scenarios. For completeness, a risk assessment for all other relevant scenarios and species is presented in Annex M-CP 10-01 of this document.

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
Field crops (Pre-sowing, pre-planting, pre-emergence): Use 1 a-c				
No. 71	**Leafy vegetables BBCH 10 – 49**	**Small granivorous bird "finch" Serin (*Serinus serinus*)**	**12.6**	**MCP 10.1.1**
No. 72	**Leafy vegetables BBCH ≥ 50**	**Small granivorous bird "finch" Serin (*Serinus serinus*)**	**3.8**	**MCP 10.1.1**
No. 79	**Leafy vegetables BBCH 10 – 49**	**Small omnivorous bird "lark" Woodlark (*Lullula arborea*)**	**10.9**	**MCP 10.1.1**
No. 81	**Leafy vegetables BBCH ≥ 50**	**Small omnivorous bird "lark" Woodlark (*Lullula arborea*)**	**3.3**	**MCP 10.1.1**
No. 82	**Leafy vegetables Leaf development BBCH 10 – 19**	**Medium herbivorous/granivorous bird "pigeon"**	**22.7**	**MCP 10.1.1**
No. 83	**Leafy vegetables BBCH 10 – 19**	**Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)**	**11.3**	**MCP 10.1.1**
No. 84	**Leafy vegetables BBCH ≥ 20**	**Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)**	**9.7**	**MCP 10.1.1**
Field crops (Post-harvest, pre-sowing, pre-planting): Use 2 a-c, 10 a-c				
No. 7	Bulb and onion like crops BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	6.9	Annex M-CP 10-01 (Covered by scenario no. 122)
No. 16	**Bulb and onion like crops BBCH ≥ 40**	**Small omnivorous bird "lark" Woodlark (*Lullula arborea*)**	**6.5**	**MCP 10.1.1 (Worst case scenario)**
No. 18	**Bulb and onion like crops BBCH ≥ 20**	**Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)**	**9.7**	**MCP 10.1.1 (Worst case scenario)**
No. 34	Cereals BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no. 16)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 49	Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	Annex M-CP 10-01 (Covered by scenario no. 7)
No. 58	Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no 16)
No. 61	Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 18)
No. 72	Leafy vegetables BBCH ≥ 50	Small granivorous bird "finch" Serin (*Serinus serinus*)	3.8	Annex M-CP 10-01 (Covered by scenario no. 7)
No. 81	Leafy vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no 16)
No. 84	Leafy vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 18)
No. 86	Legume forage BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	Annex M-CP 10-01 (Covered by scenario no. 7)
No. 95	Legume forage BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no 16)
No. 98	Legume forage BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 18)
No. 101	**Maize BBCH ≥ 40**	**Medium granivorous bird "gamebird" Partridge (*Perdix perdix*)**	**0.8**	**MCP 10.1.1 (Worst case scenario)**
No. 114	Maize BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	Annex M-CP 10-01 (Covered by scenario no 16)
No. 117	**Maize BBCH ≥ 40**	**Medium herbivorous/granivorous bird "pigeon"**	**5.7**	**MCP 10.1.1 (Worst case scenario)**
No. 119	Maize BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	4.8	Annex M-CP 10-01 (Covered by scenario no. 18)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 120	**Oilseed rape** **Late (with seeds) BBCH 30 – 99**	**Small insectivorous bird "dunnock"** **Dunnock (*Prunella modularis*)**	**2.7**	**MCP 10.1.1** **(Worst case scenario)**
No. 122	**Oilseed rape** **Late (with seeds) BBCH 80 – 99**	**Small granivorous bird "finch"** **Linnet (*Carduelis cannabina*)**	**11.4**	**MCP 10.1.1** **(Worst case scenario)**
No. 134	Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	Annex M-CP 10-01 (Covered by scenario no 16)
No. 138	Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	0.9	Annex M-CP 10-01 (Covered by scenario no 117)
No. 160	Potatoes BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no 16)
No. 162	Potatoes BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 18)
No. 164	Pulses BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	Annex M-CP 10-01 (Covered by scenario no. 7)
No. 173	Pulses BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no 16)
No. 176	Pulses BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 18)
No. 178	Root & stem vegetables BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	Annex M-CP 10-01 (Covered by scenario no. 7)
No. 187	Root & stem vegetables BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no 16)
No. 189	Root & stem vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 18)
No. 198	Strawberries BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	4.4	Annex M-CP 10-01 (Covered by scenario no 16)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 201	Strawberries BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 18)
		Field crops (Shielded ground directed inter-row application): Use 6a, b		
No. 6	Bulbs and onion like crops BBCH 10 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 14	**Bulbs and onion like crops BBCH 10 – 39**	**Small omnivorous bird "lark" Woodlark (*Lullula arborea*)**	**10.9**	**MCP 10.1.1 (Worst case scenario)**
No. 17	**Bulbs and onion like crops BBCH 10 – 19**	**Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)**	**11.3**	**MCP 10.1.1 (Worst case scenario)**
No. 48	Fruiting vegetables BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 56	Fruiting vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 60	Fruiting vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 71	**Leafy vegetables BBCH 10 – 49**	**Small granivorous bird "finch" Serin (*Serinus serinus*)**	**12.6**	**MCP 10.1.1 (Worst case scenario)**
No. 79	Leafy vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 82	**Leafy vegetables Leaf development BBCH 10 – 19**	**Medium herbivorous/granivorous bird "pigeon"**	**22.7**[1]	**MCP 10.1.1 (Worst case scenario)**
No. 83	Leafy vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 85	Legume forage BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 93	Legume forage BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 97	Legume forage BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 158	Potatoes BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 161	Potatoes BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 163	Pulses BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 171	Pulses BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 174	Pulses Leaf development BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	Annex M-CP 10-01 (Covered by scenario no. 82)
No. 175	Pulses BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 177	Root & stem vegetables BBCH 10 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 185	Root & stem vegetables BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 188	Root & stem vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 206	Sugar beet Early (spring) (BBCH 10 – 19)	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 207	Sugar beet BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	5.9	Annex M-CP 10-01 (Covered by scenario no. 17)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
Vineyard: Use 5 a-c				
No. 217	**Vineyard BBCH 10 – 19**	**Small insectivorous bird "redstart" Black redstart (*Phoenicurus ochruros*)**	**11.5**	**MCP 10.1.1**
No. 218	**Vineyard BBCH 20 – 39**	**Small insectivorous bird "redstart" Black redstart (*Phoenicurus ochruros*)**	**9.9**	**MCP 10.1.1**
No. 219	**Vineyard BBCH 10 – 19**	**Small granivorous bird "finch" Linnet (*Carduelis cannabina*)**	**6.9**	**MCP 10.1.1**
No. 220	**Vineyard BBCH 20 – 39**	**Small granivorous bird "finch" Linnet (*Carduelis cannabina*)**	**5.7**	**MCP 10.1.1**
No. 221	**Vineyard BBCH ≥ 40**	**Small granivorous bird "finch" Linnet (*Carduelis cannabina*)**	**3.4**	**MCP 10.1.1**
No. 231	**Vineyard BBCH 10 – 19**	**Small omnivorous bird "lark" Woodlark (*Lullula arborea*)**	**6.5**	**MCP 10.1.1**
No. 232	**Vineyard BBCH 20 – 39**	**Small omnivorous bird "lark" Woodlark (*Lullula arborea*)**	**5.4**	**MCP 10.1.1**
No. 233	**Vineyard BBCH ≥ 40**	**Small omnivorous bird "lark" Woodlark (*Lullula arborea*)**	**3.3**	**MCP 10.1.1**
Control of invasive species in agricultural and non-agricultural areas: Use 8 - 9				
No. 6	Bulbs and onion like crops BBCH 10 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 7	Bulb and onion like crops BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	6.9	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 14	**Bulbs and onion like crops BBCH 10 – 39**	**Small omnivorous bird "lark" Woodlark (*Lullula arborea*)**	**10.9**	**MCP 10.1.1 (Worst case scenario)**

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 16	Bulb and onion like crops BBCH ≥ 40	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	6.5	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 17	**Bulbs and onion like crops BBCH 10 – 19**	**Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)**	**11.3**	**MCP 10.1.1 (Worst case scenario)**
No. 18	Bulb and onion like crops BBCH ≥ 20	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 20	**Bush & cane fruit Whole season BBCH 00 – 79 Currants**	**Small insectivorous bird “warbler” Willow warbler (*Phylloscopus trochilus*)**	**20.3**	**MCP 10.1.1 (Worst case scenario)**
No. 21	**Cereals Late post-emergence (May-June) BBCH 71 – 89**	**Small insectivorous bird “passerine” Fan tailed warbler**	**22.4**	**MCP 10.1.1 (Worst case scenario)**
No. 22	**Cereals Early (shoots) autumn-winter BBCH 10 – 29**	**Large herbivorous bird “goose” Pink-foot goose (*Anser brachyrhynchus*)**	**16.2**	**MCP 10.1.1 (Worst case scenario)**
No. 31	Cereals BBCH 10 – 29	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 33	Cereals BBCH 30 – 39	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	5.4	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 34	Cereals BBCH ≥ 40	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 48	Fruiting vegetables BBCH 10 – 49	Small granivorous bird “finch” Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 49	Fruiting vegetables BBCH ≥ 50	Small granivorous bird “finch” Linnet (*Carduelis cannabina*)	3.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 56	Fruiting vegetables BBCH 10 – 49	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 58	Fruiting vegetables BBCH ≥ 50	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no. 14)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 60	Fruiting vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 61	Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 66	**Hops** **BBCH 10 – 19**	**Small insectivorous bird "finch"** **Chaffinch (*Fringilla colebs*)**	**9.1**	**MCP 10.1.1** **(Worst case scenario)**
No. 67	Hops BBCH ≥ 20	Small insectivorous bird "finch" Chaffinch (*Fringilla colebs*)	10.6	Annex M-CP 10-01 (Covered by scenario no. 66)
No. 68	Hops BBCH 10 – 19	Small granivorous bird "finch" Goldfinch (*Carduelis carduelis*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 69	Hops BBCH 20 – 39	Small granivorous bird "finch" Goldfinch (*Carduelis carduelis*)	5.7	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 70	Hops BBCH ≥ 40	Small granivorous bird "finch" Goldfinch (*Carduelis carduelis*)	3.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 71	**Leafy vegetables** **BBCH 10 – 49**	**Small granivorous bird "finch"** **Serin (*Serinus serinus*)**	**12.6**	**MCP 10.1.1** **(Worst case scenario)**
No. 72	Leafy vegetables BBCH ≥ 50	Small granivorous bird "finch" Serin (*Serinus serinus*)	3.8	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 79	Leafy vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 81	Leafy vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 82	**Leafy vegetables** **Leaf development BBCH 10 – 19**	**Medium herbivorous/granivorous bird "pigeon"**	**22.7**[1]	**MCP 10.1.1** **(Worst case scenario)**
No. 83	Leafy vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 84	Leafy vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 85	Legume forage BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 86	Legume forage BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 93	Legume forage BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 94	Legume forage BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 96	Legume forage Leaf development BBCH 21 – 49	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 97	Legume forage BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 98	Legume forage BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 99	**Maize BBCH 10 – 29**	**Medium granivorous bird "gamebird" Partridge (*Perdix perdix*)**	**3.0**	**MCP 10.1.1 (Worst case scenario)**
No. 100	Maize BBCH 30 – 39	Medium granivorous bird "gamebird" Partridge (*Perdix perdix*)	1.5	Annex M-CP 10-01 (Covered by scenario no. 99)
No. 101	Maize BBCH ≥ 40	Medium granivorous bird "gamebird" Partridge (*Perdix perdix*)	0.8	Annex M-CP 10-01 (Covered by scenario no 99)
No. 102	**Maize Leaf development BBCH 10 – 19**	**Small insectivorous / worm feeding species "thrush"**	**5.7**	**MCP 10.1.1 (Worst case scenario)**
No. 111	Maize BBCH 10 – 29	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 113	Maize BBCH 30 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	5.4	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 114	Maize BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 115	Maize BBCH 10 – 29	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 116	Maize BBCH 30 – 39	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 117	Maize BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	5.7	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 118	Maize BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 119	Maize BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	4.8	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 120	**Oilseed rape Late (with seeds) BBCH 30 – 99**	**Small insectivorous bird "dunnock" Dunnock (*Prunella modularis*)**	**2.7**	**MCP 10.1.1 (Worst case scenario)**
No. 121	Oilseed rape Early (shoots) BBCH 10 – 19	Large herbivorous bird "goose" Greylag goose (*Anser anser*)	15.9	Annex M-CP 10-01 (Covered by scenario no. 22)
No. 122	Oilseed rape Late (with seeds) BBCH 80 – 99	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 131	Oilseed rape BBCH 10 – 29	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 133	Oilseed rape BBCH 30 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 134	Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	Annex M-CP 10-01 (Covered by scenario no. 14)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 135	Oilseed rape BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 136	Oilseed rape BBCH 20 – 29	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	3.5	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 137	Oilseed rape BBCH 30 – 39	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	1.1	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 138	Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	0.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 139	Oilseed rape BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	5.9	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 140	Oilseed rape BBCH 20 – 29	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	2.8	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 141	**Orchard** **Spring Summer**	**Small insectivorous bird "tit"** **Bluetit (*Parus caeruleus*)**	**18.2**	**MCP 10.1.1** **(Worst case scenario)**
No. 142	Orchard Not crop directed application all season	Small insectivorous/worm feeding species "thrush" Robin (*Erithacus rubecula*)	2.7	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 146	Orchard Not crop directed application all season	Small granivorous bird "finch" Serin (*Serinus serinus*)	12.6	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 158	Potatoes BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 160	Potatoes BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 161	Potatoes BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 162	Potatoes BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 17)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 163	Pulses BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 164	Pulses BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 171	Pulses BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 173	Pulses BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 174	Pulses Leaf development BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 175	Pulses BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 176	Pulses BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motcailla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 177	Root & stem vegetables BBCH 10 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 178	Root & stem vegetables BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 185	Root & stem vegetables BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 187	Root & stem vegetables BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 188	Root & stem vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 189	Root & stem vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 17)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 196	Strawberries BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 198	Strawberries BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	4.4	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 200	Strawberries BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 201	Strawberries BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 202	Sugar beet Late (summer / autumn)	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 206	Sugar beet Early (spring) (BBCH 10 – 19)	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 207	Sugar beet BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	5.9	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 209	Sugar beet BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	5.9	Annex M-CP 10-01[2] (Covered by scenario no. 17)
No. 210	Sugar beet BBCH 20 – 49	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 214	Sunflower Early germination / Leaf development (BBCH 00	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 215	Sunflower Early germination / Leaf development (BBCH 00	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	Annex M-CP 10-01 (Covered by scenario no. 17)
No. 217	**Vineyard BBCH 10 – 19**	**Small insectivorous species "redstart" Black redstart "*Phoenicurus ochruros*"**	**11.5**	**MCP 10.1.1 (Worst case scenario)**
No. 218	Vineyard BBCH ≥ 20	Small insectivorous species "redstart" Black redstart "*Phoenicurus ochruros*"	9.9	Annex M-CP 10-01 (Covered by scenario no. 217)

Table 10.1.1-9: Summary of avian scenarios presented for Tier 1

EFSA Appendix A Scenario Number	Tier 1 scenario	Generic focal species	SV_m	Risk assessment presented
No. 219	Vineyard BBCH 10 – 19	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	6.9	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 220	Vineyard BBCH 20 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	5.7	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 221	Vineyard BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	Annex M-CP 10-01 (Covered by scenario no. 71)
No. 231	Vineyard BBCH 10 – 19	Small omnivorous bird "lark" Wood lark (*Lullula arborea*)	6.5	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 232	Vineyard BBCH 20 – 39	Small omnivorous bird "lark" Wood lark (*Lullula arborea*)	5.4	Annex M-CP 10-01 (Covered by scenario no. 14)
No. 233	Vineyard BBCH ≥ 40	Small omnivorous bird "lark" Wood lark (*Lullula arborea*)	3.3	Annex M-CP 10-01 (Covered by scenario no. 14)

Worst case scenarios are indicated in **bold**.

[1] The given short-cut value is corrected and deviates from the short-cut value presented in the Appendix A of the EFSA/2009/1438. In the Appendix A for the wood pigeon (*Columba palumbus*) a short-cut value of 37.0 is stated. This value was calculated by multiplication of the FIR/BW (1.29) with the mean RUD value (28.7). As the correct FIR/BW for the wood pigeon is 0.79, as stated for all other crop scenarios in the Appendix A the risk assessment was done with the corrected short-cut value of 22.7 (28.7 × 0.79).

[2] Same scenario like scenario 207. Only presented once in the Annex M-CP 10-01.

The Tier 1 risk assessment is presented in the following tables for the relevant uses in field crops (except use 3 a-b), uses in vineyards and uses to control invasive species, taking into account those generic focal species scenarios which were indicated in bold in the table above.

Field crops

Table 10.1.1-10: Tier 1 assessment of the long-term/reproductive risk for birds due the use of glyphosate in field crops (Pre-sowing, pre-planting, pre-emergence): Use 1 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Pre-sowing, pre-planting, pre-emergence)	1 × 1440	Leafy vegetables BBCH 10 – 49	Small granivorous bird "finch" Serin (*Serinus serinus*)	12.6	1.0 × 0.53	9.62	10.0
		Leafy vegetables BBCH ≥50	Small granivorous bird "finch" Serin (*Serinus serinus*)	3.8	1.0 × 0.53	2.90	33.2
		Leafy vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	8.32	11.6
		Leafy vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	2.52	38.2
		Leafy vegetables Leaf development BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	17.3	5.60
		Leafy vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	8.62	11.2
		Leafy vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	7.40	13.0
	1 × 1080	Leafy vegetables BBCH 10 – 49	Small granivorous bird "finch" Serin (*Serinus serinus*)	12.6	1.0 × 0.53	7.21	13.4
		Leafy vegetables BBCH ≥ 50	Small granivorous bird "finch" Serin (*Serinus serinus*)	3.8	1.0 × 0.53	2.18	44.3
		Leafy vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	6.24	15.4
		Leafy vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.89	51.0
		Leafy vegetables Leaf development BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	13.0	7.40

Table 10.1.1-10: Tier 1 assessment of the long-term/reproductive risk for birds due the use of glyphosate in field crops (Pre-sowing, pre-planting, pre-emergence): Use 1 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Leafy vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	6.47	14.9
		Leafy vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	5.55	17.3
	1 × 720	Leafy vegetables BBCH 10 – 49	Small granivorous bird "finch" Serin (*Serinus serinus*)	12.6	1.0 × 0.53	4.81	20.0
		Leafy vegetables BBCH ≥ 50	Small granivorous bird "finch" Serin (*Serinus serinus*)	3.8	1.0 × 0.53	1.45	66.4
		Leafy vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	4.16	23.2
		Leafy vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.26	76.5
		Leafy vegetables Leaf development BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	8.66	11.1
		Leafy vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	4.31	22.3
		Leafy vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	3.70	26.0

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio

Table 10.1.1-11: Tier 1 assessment of the long-term/reproductive risk for birds due the use of glyphosate in field crops (Post-harvest, pre-sowing, pre-planting): Use 2 a-c, 10 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1440	Maize BBCH ≥ 40	Medium granivorous bird “gamebird” Partridge (*Perdix perdix*)	0.8	1.0 × 0.53	0.612	158
		Maize BBCH ≥ 40	Medium herbivorous/granivorous bird “pigeon” Wood pigeon (*Columba palumbus*)	5.7	1.0 × 0.53	4.35	22.1
		Oilseed rape Late (with seeds) BBCH 30 – 99	Small insectivorous bird “dunnock” Dunnock (*Prunella modularis*)	2.7	1.0 × 0.53	2.06	46.7
		Oilseed rape Late (with seeds) BBCH 80 – 99	Small granivorous bird “finch” Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	8.70	11.1
		Bulbs and onion like crops BBCH ≥ 20	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	7.40	13.0
		Bulbs & onion like crops BBCH ≥ 40	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	6.5	1.0 × 0.53	4.96	19.4
	2 × 1080 (28 d)	Maize BBCH ≥ 40	Medium granivorous bird “gamebird” Partridge (*Perdix perdix*)	0.8	1.1 × 0.53	0.504	191
		Maize BBCH ≥ 40	Medium herbivorous/granivorous bird “pigeon” Wood pigeon (*Columba palumbus*)	5.7	1.1 × 0.53	3.59	26.8
		Oilseed rape Late (with seeds) BBCH 30 – 99	Small insectivorous bird “dunnock” Dunnock (*Prunella modularis*)	2.7	1.1 × 0.53	1.70	56.6
		Oilseed rape Late (with seeds) BBCH 80 – 99	Small granivorous bird “finch” Linnet (*Carduelis cannabina*)	11.4	1.1 × 0.53	7.18	13.4
		Bulbs and onion like crops BBCH ≥ 20	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	6.11	15.8
		Bulbs & onion like crops BBCH ≥ 40	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	6.5	1.1 × 0.53	4.09	23.5

Table 10.1.1-11: Tier 1 assessment of the long-term/reproductive risk for birds due the use of glyphosate in field crops (Post-harvest, pre-sowing, pre-planting): Use 2 a-c, 10 a-c

Active substance	Glyphosate						
Reprod. toxicity (mg/kg bw/d)	96.3						
TER criterion	5						
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
	1 × 720	Maize BBCH ≥ 40	Medium granivorous bird "gamebird" Partridge (*Perdix perdix*)	0.8	1.0 × 0.53	0.305	315
		Maize BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	5.7	1.0 × 0.53	2.18	44.3.
		Oilseed rape Late (with seeds) BBCH 30 – 99	Small insectivorous bird "dunnock" Dunnock (*Prunella modularis*)	2.7	1.0 × 0.53	1.13	85.0
		Oilseed rape Late (with seeds) BBCH 80 – 99	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	4.79	20.1
		Bulbs and onion like crops BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	3.70	26.0
		Bulbs & onion like crops BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	6.5	1.0 × 0.53	2.48	38.8
	2 × 720 (28 d)	Maize BBCH ≥ 40	Medium granivorous bird "gamebird" Partridge (*Perdix perdix*)	0.8	1.1 × 0.53	0.336	287
		Maize BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	5.7	1.1 × 0.53	2.39	40.2
		Oilseed rape Late (with seeds) BBCH 30 – 99	Small insectivorous bird "dunnock" Dunnock (*Prunella modularis*)	2.7	1.1 × 0.53	1.13	85.0
		Oilseed rape Late (with seeds) BBCH 80 – 99	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.1 × 0.53	4.79	20.1
		Bulbs and onion like crops BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	4.07	23.7
		Bulbs & onion like crops BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	6.5	1.1 × 0.53	2.73	35.3
	1 × 1080	Maize BBCH ≥ 40	Medium granivorous bird "gamebird" Partridge (*Perdix perdix*)	0.8	1.0 × 0.53	0.458	210

Table 10.1.1-11: Tier 1 assessment of the long-term/reproductive risk for birds due the use of glyphosate in field crops (Post-harvest, pre-sowing, pre-planting): Use 2 a-c, 10 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Maize BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	5.7	1.0 × 0.53	3.26	29.5
		Oilseed rape Late (with seeds) BBCH 30 – 99	Small insectivorous bird "dunnock" Dunnock (*Prunella modularis*)	2.7	1.0 × 0.53	1.55	62.3
		Oilseed rape Late (with seeds) BBCH 80 – 99	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	6.52	14.8
		Bulbs and onion like crops BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	5.55	17.3
		Bulbs & onion like crops BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	6.5	1.0 × 0.53	3.72	25.9
	3 × 720 (28 d)	Maize BBCH ≥ 40	Medium granivorous bird "gamebird" Partridge (*Perdix perdix*)	0.8	1.2 × 0.53	0.366	263
		Maize BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	5.7	1.2 × 0.53	2.61	36.9
		Oilseed rape Late (with seeds) BBCH 30 – 99	Small insectivorous bird "dunnock" Dunnock (*Prunella modularis*)	2.7	1.2 × 0.53	1.24	77.9
		Oilseed rape Late (with seeds) BBCH 80 – 99	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.2 × 0.53	5.22	18.4
		Bulbs and onion like crops BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.2 × 0.53	4.44	21.7
		Bulbs & onion like crops BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	6.5	1.2 × 0.53	2.98	32.4

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

Table 10.1.1-12: Tier 1 assessment of the long-term/reproductive risk for birds due the use of glyphosate in field crops (Shielded ground directed inter-row application): Use 6 a-b

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Shielded ground directed inter-row application)	1 × 1080	Bulbs and onion like crops BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	6.47	14.9
		Bulbs & onion like crops BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	6.24	15.4
		Leafy vegetables BBCH 10 – 49	Small granivorous bird "finch" Serin (*Serinus serinus*)	12.6	1.0 × 0.53	7.21	13.4
		Leafy vegetables Leaf development BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	13.0	7.40
	1 × 720	Bulbs and onion like crops BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	4.31	22.3
		Bulbs & onion like crops BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	4.16	23.2
		Leafy vegetables BBCH 10 – 49	Small granivorous bird "finch" Serin (*Serinus serinus*)	12.6	1.0 × 0.53	4.81	20.0
		Leafy vegetables Leaf development BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	8.66	11.1

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

The Tier 1 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to birds is acceptable following the proposed use patterns in field crops (Uses 1 a-c, 2 a-c, 10 a-c and 6 a-b).

<u>Vineyard</u>

Table 10.1.1-13: Tier 1 assessment of the long-term/reproductive risk for birds due the use of glyphosate in vineyards: Use 5 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard post-emergence of weeds	2 × 1440 (28 d)	Vineyard BBCH 10 – 19	Small insectivorous bird "redstart" Black Redstart (*Phoenicurus ochrurus*)	11.5	1.1 × 0.53	9.65	9.97
		Vineyard BBCH 20 – 39	Small insectivorous bird "redstart" Black Redstart (*Phoenicurus ochrurus*)	9.9	1.1 × 0.53	8.31	11.6
		Vineyard BBCH 10 – 19	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	6.9	1.1 × 0.53	5.79	16.6
		Vineyard BBCH 20 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	5.7	1.1 × 0.53	4.79	20.1
		Vineyard BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.1 × 0.53	2.85	33.7
		Vineyard BBCH 10 – 19	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	6.5	1.1 × 0.53	5.46	17.6
		Vineyard BBCH 20 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	5.4	1.1 × 0.53	4.53	21.2
		Vineyard BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	2.77	34.8
	1 × 1080	Vineyard BBCH 10 – 19	Small insectivorous bird "redstart" Black Redstart (*Phoenicurus ochrurus*)	11.5	1.0 × 0.53	6.58	14.6
		Vineyard BBCH 20 – 39	Small insectivorous bird "redstart" Black Redstart (*Phoenicurus ochrurus*)	9.9	1.0 × 0.53	5.67	17.0
		Vineyard BBCH 10 – 19	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	6.9	1.0 × 0.53	3.95	24.4
		Vineyard BBCH 20 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	5.7	1.0 × 0.53	3.26	29.5

Table 10.1.1-13: Tier 1 assessment of the long-term/reproductive risk for birds due the use of glyphosate in vineyards: Use 5 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Vineyard BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	1.95	49.5
		Vineyard BBCH 10 – 19	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	6.5	1.0 × 0.53	3.72	25.9
		Vineyard BBCH 20 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	5.4	1.0 × 0.53	3.09	31.2
		Vineyard BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.89	51.0
	1 × 1440	Vineyard BBCH 10 – 19	Small insectivorous bird "redstart" Black Redstart (*Phoenicurus ochrurus*)	11.5	1.0 × 0.53	8.78	11.0
		Vineyard BBCH 20 – 39	Small insectivorous bird "redstart" Black Redstart (*Phoenicurus ochrurus*)	9.9	1.0 × 0.53	7.56	12.7
		Vineyard BBCH 10 – 19	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	6.9	1.0 × 0.53	5.27	18.3
		Vineyard BBCH 20 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	5.7	1.0 × 0.53	4.35	22.1
		Vineyard BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	2.59	37.1
		Vineyard BBCH 10 – 19	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	6.5	1.0 × 0.53	4.96	19.4
		Vineyard BBCH 20 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	5.4	1.0 × 0.53	4.12	23.4
		Vineyard BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	2.52	38.2

Table 10.1.1-13: Tier 1 assessment of the long-term/reproductive risk for birds due the use of glyphosate in vineyards: Use 5 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
	2 × 1080	Vineyard BBCH 10 – 19	Small insectivorous bird "redstart" Black Redstart (*Phoenicurus ochrurus*)	11.5	1.1 × 0.53	7.24	13.3
		Vineyard BBCH 20 – 39	Small insectivorous bird "redstart" Black Redstart (*Phoenicurus ochrurus*)	9.9	1.1 × 0.53	6.23	15.4
		Vineyard BBCH 10 – 19	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	6.9	1.1 × 0.53	4.34	22.2
		Vineyard BBCH 20 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	5.7	1.1 × 0.53	3.59	26.8
		Vineyard BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.1 × 0.53	2.14	45.0
		Vineyard BBCH 10 – 19	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	6.5	1.1 × 0.53	4.09	23.5
		Vineyard BBCH 20 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	5.4	1.1 × 0.53	3.40	28.3
		Vineyard BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	2.08	46.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

The Tier 1 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to birds is acceptable following the proposed use patterns in vineyards (Uses 5 a-c).

Control of invasive species

Table 10.1.1-14: Tier 1 assessment of the long-term/reproductive risk for birds due the use of glyphosate on invasive species in agricultural and non-agricultural areas: Use 8, 9

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Invasive species in agricultural and non-agricultural areas. Post emergence of invasive species.	1 × 1800	Cereals Early (shoots) autumn-winter BBCH 10 – 29	Large herbivorous bird “goose” Pink-foot goose (*Anser brachyrhynchus*)	16.2	1.0 × 0.53	15.5	6.20
		Maize BBCH 10 – 29	Medium granivorous bird “gamebird” Partridge (*Perdix perdix*)	3.0	1.0 × 0.53	2.86	33.6
		Leafy vegetables BBCH 10 – 19	Medium herbivorous/granivorous bird “pigeon” Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	21.7	**4.40**
		Leafy vegetables BBCH 10 – 49	Small granivorous bird “finch” Serin (*Serinus serinus*)	12.6	1.0 × 0.53	12.0	8.00
		Oilseed rape Late (with seeds) BBCH 30 – 99	Small insectivorous bird “dunnock” Dunnock (*Prunella modularis*)	2.7	1.0 × 0.53	2.58	37.4
		Hops BBCH 10 – 19	Small insectivorous bird “finch” Chaffinch (*Fringilla coelebs*)	9.1	1.0 × 0.53	8.68	11.1
		Cereals Late post – emergence (May – June) BBCH 71 – 89	Small insectivorous bird “passerine” Fan tailed warbler	22.4	1.0 × 0.53	21.4	**4.50**
		Orchards Spring Summer	Small insectivorous bird “tit” Bluetit (*Parus caeruleus*)	18.2	1.0 × 0.53	17.4	5.50
		Bulbs and onion like crops BBCH 10 – 19	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	10.8	8.90

Table 10.1.1-14: Tier 1 assessment of the long-term/reproductive risk for birds due the use of glyphosate on invasive species in agricultural and non-agricultural areas: Use 8, 9

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	Application rate (g a.e./ha)	Crop scenario Growth stage	Generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
		Bush and cane fruit Whole season BBCH 00 – 79 Currants	Small insectivorous bird "warbler" Willow warbler (*Phylloscopus trochilus*)	20.3	1.0 × 0.53	19.4	**4.97**
		Vineyard BBCH 10 – 19	Small insectivorous bird "redstart" Black redstart (*Phoenicurus ochruros*)	11.5	1.0 × 0.53	11.0	8.78
		Maize Leaf development BBCH 10 – 19	Small insectivorous / worm feeding species "thrush" Robin (*Erithacus rubecula*)	5.7	1.0 × 0.53	5.44	17.7
		Bulbs and onion like crops BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0	10.4	9.30

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

The Tier 1 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to birds is acceptable following the proposed use patterns for all the crops in the use to control invasive species considered except in the following two scenarios where a refined risk assessment is required:

- cereals; the small insectivorous bird "passerine" Fan tailed warbler
- bulb and onion like vegetables; the small insectivorous bird "warbler" Willow warbler
- leafy vegetables; the medium herbivorous/granivorous bird "pigeon" Wood pigeon

Higher tier assessment

Long-term Tier 2 exposure was calculated for those intended uses, for which the Tier 1 risk assessment indicates need for a refined long-term risk assessment.

Refinement of TWA and MAF based on glyphosate residue decline on grass

In Tier 2, TWA and MAF values for glyphosate can be refined based on measured residues on grass foliage.

The methodology used to calculate the TWA for glyphosate on grass foliage for the long-term risk assessment follows the procedure described in the Guidance Document on Terrestrial Ecotoxicology

(2002). According to the approach outlined in the Guidance Document on Terrestrial Ecotoxicology, the dissipation of glyphosate in grass was estimated using the standard first-order dissipation model:

$$Ct = Ci \times e^{-kt}$$

k	=	first order rate constant
Ci	=	initial residue concentration
Ct	=	residue concentration at time t

The decline of glyphosate residue on grass was characterised using data from 22 residue trials each of which had a day 0 value. Based on this data, the k value for grass foliage was calculated to be 0.2476 $days^{-1}$ (Renewal Assessment Report for glyphosate, 29 January 2015, Volume 3, Annex B.9, B.9.13**)**. For convenience these calculations are reproduced without change, in Annex M-CP 10-02 to this document.

Residue half-life times (DT_{50}) in days were calculated with following equation:

$$DT_{50} = \frac{-\ln 0.5}{k}$$

The average DT_{50} for grass foliage was **2.8 days**.

The 21-day time weighted average (TWA) for glyphosate on grass foliage has been calculated according to the following formula:

$$TWA = \frac{(1 - e^{-kt})}{kt}$$

The 21-day TWA is calculated to be **0.19** for the active substance glyphosate acid and grass. For the refined risk assessment this value is applied for the medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*). Although the calculated 21-day TWA of 0.19 is based on residue decline on "grass" it is considered to be valid for "non-grass herbs" as well. This assumption can be supported by Ebeling & Wang (2018)[10], who evaluated the residue dissipation of 30 active substances (including glyphosate) on grasses / cereals (177 trials) and non-grass herbs (101 trials). No significant difference between residue dissipation on grasses / cereals and non-grass herbs was found. In addition also in the EFSA Conclusion for glyphosate (2015)[11] (EFSA Journal 2015;13(11):4302) the 21-day TWA of 0.19 was applied to refine the risk to the medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*).

Use specific considerations

Control of invasive species

For the use on invasive species on agricultural and non-agricultural areas *(*Use 8-9*)* the product MON 52276 is intended to be applied on the two invasive species; Giant hogweed (*Heracleum montegazzianum*) and Japanese knotweed (*Reynoutrica japonica*). Both species are easy recognisable, are usually well known by operators and can reach impressive sizes (more than 2 m height).

Control of invasive plant species that pose a risk to man and society, may be achieved by direct targeted overspray of the plant or by first cutting back the plants and applying directly to fresh regrowth. In both cases, the aim is to achieve exposure of the plant systemically, targeting all growing areas of the plant. The type of plant to be controlled and the density of plants in the target area, will dictate the management approach that is ultimately used. In all cases, the spray applications made, will be directed and targeted to a specific plant or stand of plants. This approach contrasts with a boom spray application where the entire

[10] Ebeling, M., Wang, M. Dissipation of Plant Protection Products from Foliage. Environmental Toxicology and Chemistry (2018). Wiley Online Library.

[11] Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate (2015). European Food Safte Authority (EFSA), Parma, Italy.

area under the boom is exposed, whether there is a target plant present or not. It is therefore appropriate when considering applications made to control invasive plant species, that the total applied area considered in the risk calculation, is reduced compared to a boom spray application, given the very directed and targeted application method used, which includes use of shielded sprayers that further reduces the risk to non-target plants.

When spraying invasive plant species, different plant density scenarios are applicable. A small reduction in the application rate (10-30 % reduction) would reflect a scenario where a high density of invasive species can be expected. Such a scenario is considered relevant in non-agricultural fields where higher densities of the invasive plant species Giant hogweed or Japanese knotweed may occur. The only scenario which is considered relevant in non-agricultural fields and did not pass the Tier 1 risk assessment is the leafy vegetables scenario with the medium herbivorous/granivorous bird “pigeon” Wood pigeon (82). Therefore, as a conservative worst case approach, a reduction of the application rate to 90 % applied is taken into account for the chronic risk assessment in non-agricultural areas.

In agricultural areas farmers won’t tolerate higher amounts of invasive plant species in their fields. Thus the density in comparison to non-agricultural fields is much lower and plants are more dispersed as they are not allowed to spread over several years. The product is applied by hand-held equipment to invasive plant species at BBCH stages when the intended crop is present, it can be expected that only few invasive plant species are present and that the operator avoids exposure of the intended crops. In conclusion to address the lower plant density of invasive species in agricultural fields, a 40% reduction in the application rate based on the reduced total area is applied and considered appropriate to cover the chronic risk to birds.

Control of invasive species (Non-agricultural areas): Use 8-9

Table 10.1.1-15: Tier 2 assessment of the long-term/reproductive risk for birds due the use of glyphosate on invasive species in non-agricultural areas: Use 8-9

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic Focal species**	**SVm**	**MAF$_m$ × TWA**	**DDD$_m$ (mg/kg bw/d)**	**TER$_{lt}$**
Invasive species in non-agricultural areas. Post emergence of invasive species.	1 × 1620[1]	Leafy vegetables BBCH 10 – 19	Medium herbivorous/granivorous bird “pigeon” Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.19	6.99	13.8

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger
[1] Equivalent to 90 % of 1 × 1800 g a.e./ha

Control of invasive species (Agricultural areas): Use 8-9

Table 10.1.1-16: Tier 2 assessment of the long-term/reproductive risk for birds due the use of glyphosate on invasive species in agricultural areas: Use 8-9

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.e./ha)**	**Crop scenario Growth stage**	**Generic Focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Invasive species in agricultural areas. Post emergence of invasive species.	1 × 1080[1]	Leafy vegetables BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.19	4.66	20.7
		Cereals Late post-emergence (May-June) BBCH 71 – 89	Small insectivorous bird "passerine" Fan tailed warbler (*Cisticola juncidis*)	20.3	1.0 × 0.53	11.6	8.29
		Bush and cane fruit Whole season BBCH 00 – 79 Currants	Small insectivorous bird "warbler" Willow warbler (*Phylloscopus trochilus*)	22.4	1.0 × 0.53	12.8	7.51

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger
[1] Equivalent to 60% of 1 × 1800 g a.e./ha

The refined TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to birds is acceptable following the proposed use patterns for the use on invasive species in agricultural and non-agricultural areas (Uses 8, 9).

Drinking water exposure

There are two scenarios provided in the EFSA Guidance Document for assessing the risk from drinking water.

Leaf scenario

The 'Leaf scenario' is relevant for birds taking water that is collected in leaf whorls after application and applies to leafy vegetables forming heads or with a morphology that facilitates collection of rain / irrigation water sufficiently to attract birds, i.e. for the before named crops at BBCH ≥ 41.

Since none of the proposed uses falls into these categories, the leaf scenario does not apply to the use of MON 52276.

Puddle scenario

The 'Puddle scenario' is relevant for birds taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil. This is therefore relevant for all uses of MON 52276 and should therefore be assessed.

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary since the ratio of effective application rate (in g/ha) to acute and long-term endpoint (in mg/kg bw/d) does not exceed 50 (K_{OC} < 500 L/kg) or 3000 ($K_{OC} \geq$ 500 L/kg), as specified in EFSA/2009/1438.

As pointed out in EFSA/2009/1438, specific calculations of exposure and TER values are only necessary when the ratio of effective application rate (in g a.e./ha) to relevant endpoint (in mg a.e./kg bw/d) exceeds 50 in the case of less sorptive (K_{OC} < 500 L/kg) or 3000 in the case of more sorptive ($K_{OC} \geq$ 500 L/kg) substances.

For glyphosate, the ratio of highest application rate (1800 g a.e./ha) to lowest relevant endpoint (NOAEL = 96.3 mg a.e./kg bw/d) is 19. As the $K_{f,OC}$ for glyphosate is 4245 mL/g (See MCA section 7) the risk can be considered acceptable without the need for further calculations.

Effects of secondary poisoning

According to the EFSA/2009/1438, substances with a log $P_{OW} \geq 3$ have potential for bioaccumulation and should be assessed for the risk of biomagnification in aquatic and terrestrial food chains.

Since the log P_{OW} values of glyphosate is log P_{OW} < -3.2 (pH 2 – 5, 20 °C), the active substance is deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment from secondary poisoning is therefore required.

The primary metabolite of glyphosate is aminomethylphosphonic acid (AMPA). Most of the parent glyphosate is eliminated unchanged and only a small amount (less than 1 % of the applied dose) is transformed to aminomethylphosphonic acid (AMPA). The metabolite AMPA has been tested in several mammal toxicity studies which demonstrated that it is of lower toxicity than glyphosate acid (see Section CA 5.8). Furthermore, the log P_{OW} for AMPA – estimated via EpiSuite Program and SMILES code (C(N)P(=O)(O)O) – is -2.47 and does not indicate a potential for bioaccumulation (EFSA Journal 2015;13(11): 4302).

Indirect effects via trophic interactions

A large regulatory data package exists with acute and long-term studies to inform the avian risk assessments (MCA section 8.1.1). The results of the avian risk assessment (Section 10.1.1) demonstrate that under the intended uses of glyphosate there is negligible risk from direct effects.

An assessment of indirect effects is in part covered by the current EFSA Birds and Mammals assessment guidance through an evaluation of the potential for secondary poisoning (e.g., consumption of earthworms, fish, drinking water) as discussed above.

However, methodology for assessing indirect effects through trophic interaction resulting from in-crop weed control is not addressed. Throughout the development of the EFSA (2009) bird and mammal guidance document, it was raised that indirect effects through trophic interactions should be eventually be addressed, and it was decided when the guidance on how this could be achieved was finalized, that this topic would need to be addressed by revised guidance. However, many experts in the Member States who reviewed the guidance document commented that this is area that requires further research and that it may be preferable to manage indirect effects to birds through mechanisms other than that pesticide approvals (e.g., farmland management and/or conservation policies).

Furthermore, concerning specifically potential impacts on biodiversity, there currently is no EU wide guidance on how this should be assessed at the taxa group level within the context of a single active substance renewal risk assessment.

Further information on the biodiversity assessment for glyphosate may be found in the [doc number] accompanying this dossier submission.

Scientific literature that informs the avian and mammal indirect effects assessment

Farmland is the most important habitat for bird conservation in Europe, harbouring more than 50% of bird species in the European Union (EU) and 55 % of European bird species listed in the IUCN Red List (Burfield, 2005; Donald *et al.*, 2006).

In Europe, trend data are available from the Pan-European Common Bird Monitoring Scheme, which is currently implemented in 18 countries (Gregory *et al.* 2003; Traba and Morales, 2019). The data show trends in farmland and woodland birds since 1980. On average, populations of woodland birds in Europe have remained stable. In contrast, populations of farmland birds in Europe declined particularly in the 1980s and the downward trend over the next two decades continued, but at a slower rate (trend 1980–2002, 29 %). This rapid decrease in farmland birds is believed to reflect deterioration in the quality of farmland habitats in Europe (Traba and Morales, 2019).

Several reviews and studies on indirect effects through trophic interactions to populations of farmland bird species are available. These studies and reviews mainly focus on arable landscapes in the UK (Campbell *et al.* 1997; Marshall *et al.*, 2001; Boatman *et al.* 2004; DEFRA 2005; Bright *et al.* 2008; Jahn *et al.* 2013; Traba and Morales, 2019).

After forestry applications, changes in bird community composition, and reductions in abundance, densities and species richness of bird populations often occurred in the first few years after glyphosate application (Guiseppe *et al.* 1986, Easton and Martin, 1998, Santillo *et al.* 1989b), and in Santillo *et al.* (1989b) the decline in bird densities was correlated with the decline in habitat complexity. These changes were assessed against untreated control sites to differentiate the effects of glyphosate from other background environmental factors such as the recovery trajectory following tree harvest and showed similar declines in bird densities where habitats removed following the use of other herbicides commonly used in managed forests (Guvnn *et al.*, 2004).

Sullivan and Sullivan (2003) published a comprehensive glyphosate assessment addressing vegetation management and ecosystem disturbance focusing on plant and animal biodiversity that considered both direct effects at the individual level, but also indirect effects on habitats / refuges and resource. Their analysis was based on 60 published studies of terrestrial plants and animals in temperate forests and agroecosystems. Species richness of plants was either unaffected or increased in the case of herbaceous species in those receiving glyphosate treatments. Species richness and diversity of songbirds, in open habitats representative of agricultural lands, did not appear to be negatively impacted in glyphosate use areas. In fact, conservation tillage, which is enabled by glyphosate, promoted greater abundance of songbirds and other fowl compared with ploughed fields (McLaughlin and Mineau, 1995; Cunningham *et al.*, 2005).

Overall, the magnitude of changes in species richness and diversity of plants, birds, and small mammals in the studies reviewed by Sullivan and Sullivan (2003) were within the mean range of natural fluctuations and considered direct and indirect effects.

The following approach has been taken to assess potential indirect effects via trophic interactions, considers the proposed Specific Protection Goals drawn from the existing EU guidance and working documents, and the 2016 EFSA Guidance on developing protection goals for ecological risk assessments (ERA) for pesticides. The SPGs based on direct effects assessment considering representative sensitive populations across the tested trophic levels. The biodiversity assessment, aimed to develop a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals, that includes considering indirect effects via trophic interaction. For example, reduced application rates relative to previous Annex I renewals, a reduced overall application volume of product on the land, and inclusion of no-spray buffer zones - a standard mitigation measure to protect non-target terrestrial plant communities in off-target areas, which indirectly supports bird biodiversity by maintaining habitat and refuges for birds to nest and feed. Therefore, where an acceptable direct effects risk assessment is concluded upon after incorporation of standard mitigation measures to reduce off-target movement via drift to off-target areas, coupled with the standard mitigation measures, is considered protective of indirect effects occurring outside of the target area. When defining SPGs for birds that reflects both direct and indirect effects, it is the responsibility of the risk assessors in the Member States to acknowledge existing protection goals and regulatory data requirements, to propose possible SPG options, and describe the possible environmental consequences of each option. The risk assessors within the Member States will need to propose realistic SPGs and exposure assessment goals and the interrelationships between them in a clear and transparent manner.

In the following table, the specific protection goals relevant to birds are presented with the relationship between the SPGs, the direct effects study types, assessment and measurement endpoints. The assessment endpoint is an explicit expression of an environmental entity and the specific property of that entity to be protected. Measurement endpoints relates directly to the effects study endpoints.

A conclusion that a given data requirement has been satisfied, requires that an acceptable level of risk has been achieved (i.e. there is a protective margin of exposure or through a weight of evidence).

Based on the measurement endpoints from the study types, and the direct effects assessment presented above in this section, it is anticipated that for the proposed uses on the GAP table, that there will be no reduction in bird survival, growth, development and reproduction of avian populations and this in turn meets the specific protection goal for birds.

Table 10.1.1-17: Protection goals and associated assessment and measurement endpoints for birds.

Specific Protection Goals[1]	Assessment Endpoints	Measurement Endpoints	Glyphosate Study Types
No visible mortality and long-term impacts on abundance and diversity	No reduction in survival, growth, development, reproduction of avian populations.	Survival, growth, development and reproduction	Acute oral avian and rat Avian reproduction
Avian Biodiversity Assessment Based on the current direct effects risk assessment for glyphosate, there is acceptable acute and long-term risk assessments based on current guidance and the intended use patterns for glyphosate. However, if additional risk mitigation measures are determined to be required, to mitigate indirect effects resulting from in-crop weed control on avian populations, options to be considered by risk assessors and risk managers within Member States are presented in Table 10.1.1-18.			

[1] When protection goals are defined more precisely by risk managers or legislators to address indirect effect, then the protection goals and assessment procedures should be revised.

Conclusion on Indirect effects to birds via trophic interactions

Based on the current direct effects risk assessment for glyphosate, there is acceptable acute and long-term risk assessments based on current guidance and the intended use patterns for glyphosate. Currently, the EFSA (2009) guidance for birds and mammals does not include assessment methodology for indirect effects through trophic interactions. Addressing potential indirect effects to birds by limiting in-crop weed control may be better handled though policies and programs outside the PPP framework. However, if additional risk mitigation measures are determined to be required, to mitigate indirect effects resulting from in-crop weed control on avian populations, options to be considered by risk assessors and risk managers within Member States are presented in the following tables.

Table 10.1.1-18: Examples of standard mitigation measures as described in MAgPIE (2017) across the various Member States to mitigate effects of glyphosate on biodiversity.

Type of Mitigation Measure	Risk Mitigation Measure	Benefits	Glyphosate renewal dossier (2020)
Restrictions or modifications of products' conditions of application	Application rate, Application frequency, application timing, and interval between applications	Lower transfers to groundwater and surface water; Reduces exposure of organisms in-crop and off-crop.	**Significant reductions (50 % in volume) in newly proposed application rates** compared with the representative use presented in the 2012 renewal dossier. See [12]**Appendix 2 of the biodiversity document accompanying this submission**. **Treated area restriction** 1. for the representative use GAPs: applying to only 50 % of the total area in orchard/vineyard area. 2. maximum of 50 % of the total area for broad acre vegetable inter-row 3. Invasive species control e.g., couch grass – maximum of 20 % of the cropland + extended application intervals. **Limited frequency and timing of application:** 28-day interval between applications and no pre-harvest applications
Application equipment with Spray Drift Reduction Technology (SDRT)	Spray drift reduction nozzles (SDRN), shields, Precision treatment, etc.	Reduces exposure of organisms in-crop (precision treatment) and off-crop	**Reduction of spray drift to the off-field**: 1. Use 75 % drift reducing nozzles for pre-sowing/pre-planting in arable crops. 2. Use of ground directed, shielded spray for band application in orchards / vineyards and broad-acre vegetable inter-row application.
Buffer zones	Non-sprayed zone at the edge of a crop	Reduces exposure of organisms and off-crop	**Establishment of buffer zones:** Buffer zones of varying size (depending on the type of SDRT) are required as protection for off-crop NTTP communities from spray drift.

References relied upon in Indirect effects via trophic interaction for Birds discussion

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CP 10.1.1.1 Acute oral toxicity

An avian acute oral toxicity study with the formulation MON 52276 is not considered required for the following reasons:

A comparison between the acute oral toxicity of glyphosate acid technical and MON 52276 to mammals indicates that no increased risk needs to be expected from the product over that posed from the technical grade. Furthermore, all available toxicity data for birds demonstrate that glyphosate acid is of relatively low toxicity to birds. Thus, it was concluded that toxicity can be reasonably predicted based on the data for the active substances.

In addition, a risk assessment for birds was performed in accordance with the recommendations of the EFSA/2009/1438 and showed acceptable risk for all intended uses of the representative formulation MON 52276.

In conclusion, for reasons listed above and for reasons of animal welfare (in order to avoid unnecessary testing on terrestrial vertebrates in particular with regard to the European legislation on animal welfare, (e.g. Articles 61 and 62 of the Regulation (EC) No 1107/2009), it is not considered necessary to conduct an avian acute oral toxicity study with the product MON 52276 in addition to the data available for the active substance.

CP 10.1.1.2 Higher tier data on birds

Additional studies are not considered required, since an acceptable risk for birds in consideration of each potential route of exposure was concluded (see data point CP 10.1.1).

CP 10.1.2 Effects on terrestrial vertebrates other than birds

Studies considering the toxicity of glyphosate and relevant metabolites to mammals were assessed for their validity to current and relevant guidelines. The results of these studies demonstrate that glyphosate and AMPA are of low acute and chronic toxicity to mammals and are summarised in the tables below.

A detailed evaluation is provided in Annex M-CA 8-02 of the document M-CA Section 8 which outlines the selection of endpoints and the discussion surrounding those used in the risk assessment.

Details of the acute studies are summarised in the document M-CA, Section 5.

Table 10.1.2-1: Relevant endpoints for risk assessment: Acute oral toxicity of glyphosate and AMPA to mammals

Reference	Substance	Species	Test design	LD_{50}
KCA 5.2.1/001 to KCA 5.2.1/039	Glyphosate acid	Rat/Mice	Acute toxicity	Screening Step / Tier 1: **> 2000 mg a.e./kg bw**
KCA 5.2.1/001 to KCA 5.2.1/039	Glyphosate acid	Rat/Mice	Acute toxicity	Tier 2: **3694.1 mg a.e./kg bw**
M-CA Section 5	AMPA	Mouse	Acute toxicity	> 5000 mg/kg bw

a.e.: acid equivalents
Endpoints in **bold** are used for risk assessment

Details of the reproduction studies are summarised in the document M-CA, Section 5.

Table 10.1.2-2: Relevant endpoints for risk assessment: Reproductive toxicity of glyphosate and AMPA to mammals

Reference	Substance	Species	Test design	NOAEL
M-CA Section 5	Glyphosate acid	Rabbit	Developmental toxicity (long-term)	Screening Step / Tier 1: **50 mg a.e./kg bw/d**
M-CA Section 5	Glyphosate acid	Rabbit	Developmental toxicity (long-term)	Tier 2: **100 mg a.e./kg bw/d**
M-CA Section 5	Glyphosate acid	Rat	Developmental toxicity (long-term)	Tier 3: **300 mg a.e./kg bw/d**
M-CA Section 5	AMPA	Rat	13 week oral	> 1000 mg/kg bw/d

a.e.: acid equivalents
Endpoints in **bold** are used for risk assessment

Risk assessment for metabolites
The primary metabolite of glyphosate is aminomethylphosphonic acid (AMPA). Most of the parent glyphosate is eliminated unchanged and only a small amount (less than 1 % of the applied dose) is transformed to aminomethylphosphonic acid (AMPA). The metabolite AMPA has been tested in several mammal toxicity studies which demonstrated that it is of lower toxicity than glyphosate acid (see Section CA 5.8).

Following application to plant tissues, unchanged glyphosate was the only significant residue. In presence of soil as a substrate the active substance is quickly degraded, leaving AMPA at rates comparable or even higher than parent glyphosate. However, the uptake via the roots and the translocation in the plants was very low, not resulting in significant residue levels as confirmed by plant metabolism and confined rotational crop studies. A major part of the glyphosate was degraded into CO_2. Therefore, it can be concluded that the risk to mammals will be acceptably low and no further quantitative risk assessment on the main metabolite is conducted.

Risk assessment for the representative formulation
An acute oral mammalian study is available with the formulation which is presented in the toxicological section under document M-CP Section 7.1.1/01. This study shows, that the acute toxicity of the formulation (>5000 mg/kg bw) is not more elevated than the toxicity of the active substance alone (>2000 mg/kg bw). Therefore the mammalian risk assessment for the representative formulation is considered to be covered by the mammalian risk assessment presented for the active substance glyphosate.

Table 10.1.2-3: Relevant endpoints for risk assessment: Acute oral toxicity of MON 52276 to mammals

Reference	Substance	Species	Test design	LD_{50}
[redacted], 1991 CP 7.1.1/001	MON 52276	Rat	Acute toxicity	**> 5000 mg a.e./kg bw**

There are no literature articles and peer-reviewed published data considered to be relevant and reliable or reliable with restrictions with regards to the impact of glyphosate or its relevant metabolites on mammals. Full literature evaluation is provided in document M-CA Section 9. A summary of previously evaluated peer reviewed literature from the RAR 2015 is also available in Annex M-CA 8-01 of the document M-CA Section 8. In common with the previous literature review, there were no endpoints considered relevant for use in the mammalian risk assessment. In the previous literature review, reference is made to the literature on amphibians - which is discussed within this dossier.

Effects on vertebrates by the action of surface-active substances in glyphosate based formulations was also discussed in the previous literature review, with two papers relating to mammals, Santilio *et al.*, (1989) and Sullivan *et al.*, (2003) which were both considered in the previous RMS concluding weight of evidence. The conclusion by the RMS to the first paper on the 'Response of small mammals and habitat to glyphosate application on clearcuts' was to emphasise that herbicides cause indirect effects and highlighted the need for risk mitigation measures by the Member States, proposing compensation measures as a suitable tool. The second paper on 'Ecosystem disturbance: Impact of glyphosate herbicide on plant and animal diversity in terrestrial systems' was considered supporting information. This paper considered the impact of Anglo-Saxon practice of managing the vegetation for purposes of enhancing forest and other crop yields. This paper considered roadside vegetation management and its role in the maintenance of ecological processes in terrestrial ecosystems. There were four other papers considered in the weight of evidence for vertebrates – specifically birds.

Concerning effects at the ecosystem level – specifically indirect effects on mammals via trophic interactions, and considering impacts on biodiversity at a wider landscape level, a biodiversity assessment is presented at the end of this section.

For the mammalian risk assessment, supporting information are presented on endpoint selection and on the population dynamics of small herbivorous mammals that is considered relevant to the risk assessment. These data are presented in Annex M-CA 8-02 of the document M-CA Section 8.

Risk assessment for other terrestrial vertebrates

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

The table below summarises how the risk assessment for mammals considers all the proposed uses and the application rates presented in the GAP.

Table 10.1.2- 4: Risk assessment strategy for mammals

GAP number and summary of use	Application rate considered (28 day interval unless otherwise stated)									
	1 × 540 g/ha	1 × 720 g/ha	1 × 1080 g/ha	2 × 720 g/ha	1 × 1440 g/ha	3 × 720 g/ha	1 × 1800 g/ha	2 × 1080 g/ha[1]	2 × 1440 g/ha	2 × 1800 g/ha (90 days apart)
Uses 1a-c: Applied to weeds; pre-sowing, pre-planting, pre emergence of **field crops.**		X	X		X					
Uses 2 a-c: Applied to weeds; post-harvest, pre-sowing, pre-planting of **field crops.**		X	X	X	X	X		X		
Use 3 a-b: Applied to cereal volunteers; post-harvest, pre-sowing, pre-planting of **field crops.**	X									
Use 4 a-c: Applied to weeds (post emergence) below trees in **orchards.**		X	X	X	X	X		X	X	
Use 5 a-c: Applied to weeds (post emergence) below vines in **vineyards**		X	X	X	X	X		X	X	
Use 6 a-b: Applied to weeds (post emergence) in **field crops BBCH < 20**		X	X							
Use 7 a-b: Applied to weeds (post emergence) around **railroad tracks**							X			X
Use 8 and 9: Applied to invasive species (post emergence) in **agricultural and non-agricultural areas**							X			
Uses 10 a-c: Applied to couch grass; post-harvest, pre-sowing, pre-planting of **field crops**		X	X							

X = this use is covered by the application rate indicated.
[1] Due to the long spray interval of 28 days this use covers also the following possible application pattern: 2 × 1080 g a.s./ha plus 1 × 720 g a.s./ha (28 day interval between each application)

For the screening assessment, crops that maybe present at time of application to target weeds and the relevant application rates shown in the table above are considered. The acute and long-term screening assessment results are presented below according to the following main uses:

- in **field crops** (covering GAP uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c); pre-sowing, pre-planting pre emergence, post-harvest. Exposure to mammals via grassland, bare soil and field crops is considered and is covered by the general screening scenarios bare soil, bulb and onion like crops (etc.) and fruiting vegetables (etc.).

- in **orchards and vineyards** (covering GAP uses 4 a-c, 5a-c) applied to weeds post emergence exposure below trees; exposure to small herbivorous mammals in orchards and vineyards is considered and is covered by the general screening scenario fruiting vegetables (etc.).

- in **railroad tracks** (covering GAP uses 7 a-b) applied to weeds pots emergence; exposure to mammals via grassland, bare soil and field crops (leafy vegetables) is considered and is covered by the general screening scenarios bare soil and fruiting vegetables (etc.).

- In control of **invasive species** (covering GAP uses 8 and 9) applied; exposure to mammals via grassland, bare soil and field crops is considered and is covered by the general screening scenarios bare soil bush and cane fruit, bulb and onion like crops (etc.) and fruiting vegetables (etc.).

Screening assessment

Field crops

Table 10.1.2- 5: Screening assessment of the acute risk for mammals due to the use of glyphosate in field crops: Uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c.

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		> 2000					
TER criterion		10					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Pre-sow, pre-planting, post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	1 × 1440	Bare soil	Small granivorous mammal	14.4	1.0	20.7	96.6
		Bulb and onion like crops	Small herbivorous mammal	118.4	1.0	170	11.7
		Fruiting vegetables	Small herbivorous mammal	136.4	1.0	196	10.2
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	2 × 1080 (28 d)	Bare soil	Small granivorous mammal	14.4	1.1	17.1	117
		Bulb and onion like crops	Small herbivorous mammal	118.4	1.1	141	14.2
		Fruiting vegetables	Small herbivorous mammal	136.4	1.1	162	12.3
Pre-sow, pre-planting, post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	1 × 540	Bare soil	Small granivorous mammal	14.4	1.0	7.78	257
		Bulb and onion like crops	Small herbivorous mammal	118.4	1.0	63.9	31.3
		Fruiting vegetables	Small herbivorous mammal	136.4	1.0	73.7	27.1
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like	1 × 720	Bare soil	Small granivorous mammal	14.4	1.0	10.4	192
		Bulb and onion like crops	Small herbivorous mammal	118.4	1.0	85.2	23.5

Table 10.1.2- 5: Screening assessment of the acute risk for mammals due to the use of glyphosate in field crops: Uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c.

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		> 2000					
TER criterion		10					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds Sugar beet. Post-emergence of weeds		Fruiting vegetables	Small herbivorous mammal	136.4	1.0	98.2	20.4
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds Sugar beet. Post-emergence of weeds	2 × 720 (28 d)	Bare soil	Small granivorous mammal	14.4	1.1	11.4	175
		Bulb and onion like crops	Small herbivorous mammal	118.4	1.1	93.8	21.3
		Fruiting vegetables	Small herbivorous mammal	136.4	1.1	108	18.5
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	1 × 1080	Bare soil	Small granivorous mammal	14.4	1.0	15.6	128
		Bulb and onion like crops	Small herbivorous mammal	118.4	1.0	128	15.6
		Fruiting vegetables	Small herbivorous mammal	136.4	1.0	147	13.6
Pre-sow, pre-planting, post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	3 × 720 (28 d)	Bare soil	Small granivorous mammal	14.4	1.1	11.4	175
		Bulb and onion like crops	Small herbivorous mammal	118.4	1.1	93.8	21.3
		Fruiting vegetables	Small herbivorous mammal	136.4	1.1	108	18.5

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

Table 10.1.2- 6: Screening assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops: Use 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c.

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_{90} (mg/kg bw/d)**	**TER_{lt}**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	1 × 1440	Bare soil	Small granivorous mammal	6.6	1.0 × 0.53	5.04	9.92
		Bulb and onion like crops	Small herbivorous mammal	48.3	1.0 × 0.53	36.9	**1.36**
		Fruiting vegetables	Small herbivorous mammal	72.3	1.0 × 0.53	55.2	**0.91**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	2 × 1080 (28 d)	Bare soil	Small granivorous mammal	6.6	1.1 × 0.53	4.16	12.0
		Bulb and onion like crops	Small herbivorous mammal	48.3	1.1 × 0.53	30.4	**1.64**
		Fruiting vegetables	Small herbivorous mammal	72.3	1.1 × 0.53	45.5	**1.10**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	1 × 540	Bare soil	Small granivorous mammal	6.6	1.0 × 0.53	1.89	26.5
		Bulb and onion like crops	Small herbivorous mammal	48.3	1.0 × 0.53	13.8	**3.62**
		Fruiting vegetables	Small herbivorous mammal	72.3	1.0 × 0.53	20.7	**2.42**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	1 × 720	Bare soil	Small granivorous mammal	6.6	1.0 × 0.53	2.52	19.9
		Bulb and onion like crops	Small herbivorous mammal	48.3	1.0 × 0.53	18.4	**2.71**
		Fruiting vegetables	Small herbivorous mammal	72.3	1.0 × 0.53	27.6	**1.81**

Table 10.1.2- 6: Screening assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops: Use 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c.

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_{90} (mg/kg bw/d)**	**TER_{lt}**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	2 × 720 (28 d)	Bare soil	Small granivorous mammal	6.6	1.1 × 0.53	2.77	18.0
		Bulb and onion like crops	Small herbivorous mammal	48.3	1.1 × 0.53	20.3	**2.47**
		Fruiting vegetables	Small herbivorous mammal	72.3	1.1 × 0.53	30.3	**1.65**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	1 × 1080	Bare soil	Small granivorous mammal	6.6	1.0 × 0.53	3.78	13.2
		Bulb and onion like crops	Small herbivorous mammal	48.3	1.0 × 0.53	27.7	**1.81**
		Fruiting vegetables	Small herbivorous mammal	72.3	1.0 × 0.53	41.38	**1.21**
Pre-sow, pre-planting, pre-emergence & post-harvest of; Root and Stem veg, Potato Bulb and onion like crops, fruiting veg, leafy veg, Sugar beet. Post-emergence of weeds	3 × 720 (28 d)	Bare soil	Small granivorous mammal	6.6	1.2 × 0.53	3.02	16.5
		Bulb and onion like crops	Small herbivorous mammal	48.3	1.2 × 0.53	22.1	**2.26**
		Fruiting vegetables	Small herbivorous mammal	72.3	1.2 × 0.53	33.1	**1.51**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Orchards and vineyards

Table 10.1.2- 7: Screening assessment of the acute risk for mammals due to the use of glyphosate in orchards and vineyards: Uses 4 a-c, 5 a-c.

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		> 2000					
TER criterion		10					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards / vineyards post-emegence of weeds	2 × 1440 (28 d)	Fruiting vegetables	Small herbivorous mammal	136.4	1.1	216	**9.3**
Orchards / vineyards post-emegence of weeds	1 × 720	Fruiting vegetables	Small herbivorous mammal	136.4	1.0	98.2	20.4
Orchards / vineyards post-emegence of weeds	1 × 1080	Fruiting vegetables	Small herbivorous mammal	136.4	1.0	147	13.6
Orchards / vineyards post-emegence of weeds	2 × 720 (28 d)	Fruiting vegetables	Small herbivorous mammal	136.4	1.1	108	18.5
Orchards / vineyards post-emegence of weeds	3 × 720 (28 d)	Fruiting vegetables	Small herbivorous mammal	136.4	1.1	108	18.5
Orchards / vineyards post-emegence of weeds	1 × 1440	Fruiting vegetables	Small herbivorous mammal	136.4	1.0	196	10.2
Orchards / vineyards post-emegence of weeds	2 × 1080 (28 d)	Fruiting vegetables	Small herbivorous mammal	136.4	1.1	162	12.3

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 10.1.2- 8: Screening assessment of the long-term/reductive risk for mammals due to the use of glyphosate in orchards and vineyards: Uses 4 a-c, 5 a-c.

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_{90} (mg/kg bw/d)**	**TER_{lt}**
Orchards / vineyards post-emegence of weeds	2 × 1440 (28 d)	Fruiting vegetables	Small herbivorous mammal	72.3	1.1 × 0.53	60.7	**0.82**
Orchards / vineyards post-emegence of weeds	1 × 720	Fruiting vegetables	Small herbivorous mammal	72.3	1 × 0.53	27.6	**1.81**
Orchards / vineyards post-emegence of weeds	1 × 1080	Fruiting vegetables	Small herbivorous mammal	72.3	1 × 0.53	41.4	**1.21**
Orchards / vineyards post-emegence of weeds	2 × 720 (28 d)	Fruiting vegetables	Small herbivorous mammal	72.3	1.1 × 0.53	30.3	**1.65**
Orchards / vineyards post-emegence of weeds	3 × 720 (28 d)	Fruiting vegetables	Small herbivorous mammal	72.3	1.2 × 0.53	33.1	**1.51**
Orchards / vineyards post-emegence of weeds	1 × 1440	Fruiting vegetables	Small herbivorous mammal	72.3	1 × 0.53	55.2	**0.91**
Orchards / vineyards post-emegence of weeds	2 × 1080 (28 d)	Fruiting vegetables	Small herbivorous mammal	72.3	1.1 × 0.53	45.5	**1.10**

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 10.1.2- 9: Screening assessment of the acute risk for mammals due to the use of glyphosate on railroad tracks and to control invasive species: Uses 7a-b, 8 and 9.

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		> 2000					
TER criterion		10					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Railroad tracks – application by spray train. Post emergence of weeds (90d apart).	2 × 1800 (90 d)	Bare soil	Small granivorous mammal	14.4	1.1	28.5	70.1
		Fruiting vegetables	Small herbivorous mammal	136.4	1.1	270	**7.41**
	1 × 1800	Bare soil	Small granivorous mammal	14.4	1.0	25.9	77.2
		Fruiting vegetables	Small herbivorous mammal	136.4	1.0	246	**8.13**
Invasive species in agricultural and non-agricultural areas. Post emergence of invasive species.	1 × 1800	Bare soil	Small granivorous mammal	14.4	1	25.9	77.2
		Bush and cane fruit	Small herbivorous mammal	81.9	1	147	13.6
		Bulbs and onion like crops	Small herbivorous mammal	118.4	1	213	**9.38**
		Fruiting vegetables	Small herbivorous mammal	136.4	1	246	**8.13**

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 10.1.2- 10: Screening assessment of the long-term/reductive risk for mammals due to the use of glyphosate on railroad tracks and to control invasive species: Uses 7a-b, 8 and 9.

Active substance		**Glyphosate**					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Railroad tracks – application by spray train. Post emergence of weeds (90d apart).	2 × 1800 (90 d)	Bare soil	Small granivorous mammal	6.6	1.0 × 0.53	6.30	7.94
		Fruiting vegetables	Small herbivorous mammal	72.3	1.0 × 0.53	69.0	**0.72**
	1 × 1800	Bare soil	Small granivorous mammal	6.6	1.0 × 0.53	6.30	7.94
		Fruiting vegetables	Small herbivorous mammal	72.3	1.0 × 0.53	69.0	**0.72**
Invasive species in agricultural and non-agricultural areas. Post emergence of invasive species.	1 × 1800	Bare soil	Small granivorous mammal	6.6	1.0 × 0.53	6.30	7.94
		Bush and cane fruit	Small herbivorous mammal	43.4	1.0 × 0.53	41.4	**1.21**
		Bulbs and onion like crops	Small herbivorous mammal	48.3	1.0 × 0.53	46.1	**1.09**
		Fruiting vegetables	Small herbivorous mammal	72.3	1.0 × 0.53	69.0	**0.72**

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Field crops (Uses: 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c)

The screening TER_a values for use of MON 52276 in field crops for all scenarios are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to mammals is acceptable following use the proposed use patterns for these crops.

The screening TER_{lt} values for use of MON 52276 in field crops for the scenario "bare soil" are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5. Regarding the scenarios "bulbs and onion like crops" and "fruiting vegetables" a long-term Tier 1 risk assessment is necessary for all intended application rates.

Orchards and vineyards (Uses: 4 a-c and 5 a-c)

The screening TER_a values for use of MON 52276 in orchards and vineyards for the scenario "fruiting vegetables" are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10 for the application rates 1 × 720 g a.s./ha, 1 × 1080 g a.s./ha, 2 × 720 g a.s./ha, 3 × 720 g a.s./ha, 1 × 1440 g a.s./ha and 2 × 1080 g a.s./ha. For the application rate of 2 × 1440 the TER_a value is slightly below the trigger of 10. Therefore, an acute Tier 1 risk assessment is necessary for this rate.

The screening TER_{lt} values for use of MON 52276 in orchards and vineyards for the scenario "fruiting vegetables" are below the Commission Regulation (EU) No. 546/2011 trigger of 5. Therefore, a long-term Tier 1 risk assessment is necessary for all intended application rates.

Railroad tracks – application by spray train (Uses: 7 a-b)

The screening TER_a and TER_{lt} values for use of MON 52276 on railroad tracks for the scenario "bare soil" are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10 and 5 respectively. The screening TER_a and TER_{lt} values for the “fruiting vegetables” scenario are below the Commission Regulation (EU) No. 546/2011 trigger of 10 and 5, respectively. Therefore, an acute and long-term Tier 1 risk assessment is necessary for all intended application rates.

Invasive species in agricultural and non-agricultural areas (Uses: 8 and 9)

The screening TER_a values for use of MON 52276 on invasive species in agricultural and non-agricultural areas for the scenarios “bare soil” and “bush and cane fruit” are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10. The screening TER_a values for the “bulbs and onion like crops” and “fruiting vegetables” scenarios are below the Commission Regulation (EU) No. 546/2011 trigger of 10. Therefore an acute Tier 1 risk assessment is necessary for the intended application rate of 1 × 1800 g a.s./ha.

The screening TER_{lt} values for use of MON 52276 on invasive species in agricultural and non-agricultural area for the scenario “bare soil” are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5. The screening TER_{lt} values for the “bush and cane fruit”, “bulbs and onion like crops” and “fruiting vegetables” scenarios are below the trigger of 5. Therefore a long-term Tier 1 risk assessment is necessary for the intended application rate of 1 × 1800 g a.s./ha.

Tier 1 assessment

Tier 1 risk assessment is conducted for those intended uses, for which the calculated TER_a or TER_{lt} values were below the trigger of 10 or 5, respectively, e.g. for uses in field crops, uses in orchards and vineyards, uses on railroad tracks and uses to control invasive species in agricultural and non-agricultural areas. The Tier 1 assessment initially requires identification of the appropriate crop groupings and generic focal mammalian species from Appendix A of EFSA/2009/1438.

Due to the proposed uses of the product MON 52276 in agricultural and non-agricultural areas, justifications are provided below considering which scenarios are relevant for the risk assessment. For those proposed uses where a large number of scenarios is relevant (Field crops: Use 2 a-c, 6 a, b, 10 a-c, Control of invasive species: Use 8 - 9) an approach has been taken to present only the worst-case risk assessment in this section. Therefore the worst-case scenarios have been selected based on the relevant generic focal species with the highest short-cut values as these are considered protective of the other scenarios with lower short-cut values. For completeness, a full and complete mammalian Tier I risk assessment that considers all other scenarios and focal species is presented in Annex M-CP 10-03 to this document.

A summary of **all** relevant scenarios and focal species (includes those presented in this section and in Annex M-CP 10-03) is provided in the Table below. Please note that numbers in brackets refer to the mammals’ scenarios stated in the Appendix A of EFSA/2009/1438.

Field crops (Uses: 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c)

For the Tier 1 assessment of the crop group “field crops”, the intended use of MON 52276 includes several general uses on field crops as described further below. The applications are intended to be made by tractor mounted sprayers (*Uses 1 a-c, 2 a-c, 3 a-b, 6 a-b*) or by hand-held equipment (*Uses 10 a-c*).

Use 1 a-c is, the “pre-sowing, pre-planting, pre-emergence” use, where the intention of this use is to prepare a non-agricultural area for agriculture use, meaning that the product is applied when no agricultural crop is present. Therefore the “bare soil”, the “grassland” and the “leafy vegetable” scenarios are considered relevant. As an acceptable risk for the “bare soil” scenario was concluded at the screening assessment, a Tier 1 risk assessment will be presented only for “grassland” and “leafy vegetables”. The “grassland” scenario was considered relevant to cover species that feed on grass; the large herbivorous mammal “lagomorph” (72), the small insectivorous mammal “shrew” (73), the small herbivorous mammal “vole” (74) and the small omnivorous mammal “mouse” (75) are taken into account. The “leafy vegetables” scenario was considered relevant to cover species that feed on broad-leaved weeds; the small insectivorous mammal “shrew” (91, 92), the small herbivorous mammal “vole” (93, 94), the large herbivorous mammal "lagomorph" (95) and the small omnivorous mammal "mouse" (102, 103) are taken into account.

Uses 2 a-c, 3 a-b and 10 a-c are the "post-harvest, pre-sowing, pre-planting" use where the product can be applied to existing cropland after harvest for removal of remaining crops. Thus, for this use almost all field crops need to be considered. Only for the crop where safe risk could be concluded in the screening assessment, i.e. "bare soil" and for crops which are generally not considered relevant ("cotton") or for spatial cultures like "bush & cane fruit", "hops", "orchards", "ornamentals/nursery" and "vineyards" a risk assessment is not considered necessary. As the product is applied after post-harvest, late crop stages will be taken into account for risk assessment. Frugivorous mammal scenarios were not taken into account, as the product is intended to be applied after harvest and will not be applied at typical crop stages when fruits are ripe. For the same reason also the pulses scenario (pre harvest seed, BBCH 81-99) is not considered relevant.

Thus, for the Tier 1 risk assessment for the uses 2 a-c, 3 a-b and 10 a-c, the relevant generic focal species with the highest short-cut values at late crop stages across all relevant crop scenarios were taken into account; the small insectivorous mammal "shrew" in bulb and onion like crops (5), the large herbivorous mammal "lagomorph" in grassland (72), the small herbivorous mammal "vole" in grassland (74) and the small omnivorous mammal "mouse" in grassland (75). These selected scenarios cover the risk for all relevant scenarios. For completeness, a risk assessment for all other relevant scenarios and species is presented in Annex M-CP 10-03.

Uses 6 a-b are the "shielded ground directed inter-row application" uses at crop stages < BBCH 20 and all crops scenarios at early growth stages are taken into account, which are presented in the GAP, i.e. vegetables (root and tuber vegetables, bulb vegetables, fruiting vegetables, legume vegetables and leafy vegetables). To avoid exposure of crops, a shielded sprayer is used to ensure that the product is only applied to grasses and weeds in the inter-row. Therefore, only those vegetables crop scenarios are considered relevant where the generic focal species does not directly feed on the crop. In addition, the "bare soil" and the "grassland" scenario are considered relevant. However, as an acceptable risk was concluded for the "bare soil" scenario already at the screening assessment the Tier 1 risk assessment is not required for this scenario.

Thus, for the Tier 1 risk assessment for the uses 6 a-b, the relevant generic focal species with the highest short-cut values at early crop stages (< BBCH 20) across all relevant crops scenarios were taken into account, i.e. the small insectivorous mammal "shrew" in bulb and onion like crops (4), the small omnivorous mammal "mouse" (13) in bulbs and onion like crops, the small herbivorous mammal "vole" in fruiting vegetables (62) and the large herbivorous mammal "lagomorph" (95) in leafy vegetables.

Orchards (Uses: 4 a-c)

For the crop grouping "orchards" due to the downward application of the product all generic focal species for not "crop directed" applications were taken into account, i.e. the small insectivorous mammal "shrew" (148), the small herbivorous mammal "vole" (149), the large herbivorous mammal "lagomorph" (154) and the small omnivorous mammal "mouse" (170).

Vineyards (Uses: 5 a-c)

For the crop grouping "vineyards" due to the downward application of the product all generic focal species, for not "crop directed" applications were taken into account, i.e. the large herbivorous mammal "lagomorph" (267, 268, 269, 270), the small insectivorous mammal "shrew" (271, 272), the small herbivorous mammal "vole" (273) and the small omnivorous mammal "mouse" (287).

Railroad tracks – application by spray train (Uses: 7 a-b)

For the use on railroad tracks the same scenarios were selected like for use 1 a-c, i.e. the "bare soil", the "grassland" and the "leafy vegetable" were considered relevant. As an acceptable risk for the "bare soil" scenario was concluded at the screening assessment a Tier 1 risk assessment will be presented only for "grassland" and "leafy vegetables". The "grassland" scenario was considered relevant to cover species that feed on grass; the large herbivorous mammal "lagomorph" (72), the small insectivorous mammal "shrew" (73), the small herbivorous mammal "vole" (74) and the small omnivorous mammal "mouse" (75) are taken into account. The "leafy vegetables" scenario was considered relevant to cover species that feed on broad-leaved weeds; the small insectivorous mammal "shrew" (91, 92), the small herbivorous mammal "vole" (93, 94), the large herbivorous mammal "lagomorph" (95) and the small omnivorous mammal "mouse" (102, 103) are taken into account.

Invasive species in agricultural and non-agricultural areas (Uses: 8 - 9)

For the use on invasive species in agricultural and non-agricultural areas, almost all crops need to be considered. Only for the crop where safe risk could be concluded in the screening assessment, i.e. "bare soil" and for crops which are generally not considered relevant ("cotton") do not need to be assessed in the Tier 1 risk assessment. In general, those scenarios need to be taken into account, where a downward application of the product is relevant. Frugivorous mammal scenarios were not taken into account, as the product is intended to be applied only on the invasive species Giant hogweed (*Heracleum mantegazzianum*) and Japanese knotweed (*Reynoutria japonica*) and due to the specific application method (handheld, spraying shield) fruits will not be exposed to the product. For the same reason also the pulses scenario (pre harvest seed, BBCH 81-99) is not considered relevant.

Thus, for the Tier 1 risk assessment for uses 8 and 9, the relevant generic focal species with the highest short-cut values across all relevant crop scenarios were taken into account, i.e. the small insectivorous mammal "shrew" in bulb and onion like crops (4), the small omnivorous mammal "mouse" in bulb and onion like crops (13), the large herbivorous mammal "lagomorph" in cereals (35) and the small herbivorous mammal "vole" in fruiting vegetables (62). These chosen scenarios cover the risk for all relevant scenarios. For completeness, a risk assessment for all other relevant scenarios and species is presented in Annex M-CP 10-03 of this document.

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
Field crops (Pre-sowing, pre-planting, pre-emergence): Use 1 a-c					
No. 72	**Grassland** **All season**	**Large herbivorous mammal "lagomorph"** **Brown hare (*Lepus europaeus*)**	**-**	**17.3**	**MCP 10.1.2**
No. 73	**Grassland** **Late**	**Small insectivorous mammal "shrew"** **Common shrew (*Sorex araneus*)**	**-**	**1.9**	**MCP 10.1.2**
No. 74	**Grassland** **All season**	**Small herbivorous mammal "vole"** **Common vole (*Microtulus arvalis*)**	**-**	**72.3**	**MCP 10.1.2**
No. 75	**Grassland** **Late season (seed heads)**	**Small omnivorous mammal "mouse"** **Wood mouse (*Apodemus sylvaticus*)**	**-**	**6.6**	**MCP 10.1.2**
No. 91	**Leafy vegetables** **BBCH 10 - 19**	**Small insectivorous mammal "shrew"** **Common shrew (*Sorex araneus*)**	**-**	**4.2**	**MCP 10.1.2**
No. 92	**Leafy vegetables** **BBCH ≥ 20**	**Small insectivorous mammal "shrew"** **Common shrew (*Sorex araneus*)**	**-**	**1.9**	**MCP 10.1.2**
No. 93	**Leafy vegetables** **BBCH 40 - 49**	**Small herbivorous mammal "vole"** **Common vole (*Microtulus arvalis*)**	**-**	**72.3**	**MCP 10.1.2**
No. 94	**Leafy vegetables** **BBCH ≥ 50**	**Small herbivorous mammal "vole"** **Common vole (*Microtulus arvalis*)**	**-**	**21.7**	**MCP 10.1.2**
No. 95	**Leafy vegetables** **All season**	**Large herbivorous mammal "lagomorph"** **Rabbit (*Oryctolagus cuniculus*)**	**-**	**14.3**	**MCP 10.1.2**
No. 102	**Leafy vegetables** **BBCH 10 – 49**	**Small omnivorous mammal "mouse"** **Wood mouse (*Apodemus sylvaticus*)**	**-**	**7.8**	**MCP 10.1.2**
No. 103	**Leafy vegetables** **BBCH ≥ 50**	**Small omnivorous mammal "mouse"** **Wood mouse (*Apodemus sylvaticus*)**	**-**	**2.3**	**MCP 10.1.1**

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
Field crops (Post-harvest, pre-sowing, pre-planting): Use 2 a-c, 3 a-b, 10 a-c					
No. 5	**Bulbs and onion like crops** **BBCH ≥ 20**	**Small insectivorous mammal "shrew"** **Common shrew (*Sorex araneus*)**	**-**	**1.9**	**MCP 10.1.2** **(Worst case scenario)**
No. 6	Bulbs and onion like crops BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	-	43.4	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 14	Bulbs and onion like crops BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	-	4.7	Annex M-CP 10-03 (Covered by scenario no. 75)
No. 33	Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 34	Cereals BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	-	21.7	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 46	Cereals BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	-	2.3	Annex M-CP 10-03 (Covered by scenario no. 75)
No. 61	Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 63	Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	-	21.7	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 71	Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	-	2.3	Annex M-CP 10-03 (Covered by scenario no. 75)
No. 72	**Grassland** **All season**	**Large herbivorous mammal "lagomorph"** **Brown hare (*Lepus europaeus*)**	**-**	**17.3**	**MCP 10.1.2** **(Worst case scenario)**
No. 73	Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 74	**Grassland** **All season**	**Small herbivorous mammal "vole"** **Common vole (*Microtus arvalis*)**	**-**	**72.3**	**MCP 10.1.2** **(Worst case scenario)**

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 75	**Grassland** **Late season (seed heads)**	**Small omnivorous mammal "mouse"** **Wood mouse (*Apodemus sylvaticus*)**	**-**	**6.6**	**MCP 10.1.2** **(Worst case scenario)**
No. 92	Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 94	Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	-	21.7	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 95	Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	-	14.3	Annex M-CP 10-03 (Covered by scenario no. 72)
No. 103	Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	-	2.3	Annex M-CP 10-03 (Covered by scenario no. 75)
No. 105	Legume forage BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 107	Legume forage BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	-	21.7	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 116	Legume forage BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	-	2.3	Annex M-CP 10-03 (Covered by scenario no. 75)
No. 118	Maize BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 121	Maize BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	-	18.1	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 132	Maize BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 75)
No. 134	Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 135	Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	-	18.1	Annex M-CP 10-03 (Covered by scenario no. 74)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 136	Oilseed rape All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	-	14.3	Annex M-CP 10-03 (Covered by scenario no. 72)
No. 147	Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 75)
No. 186	Potatoes BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 187	Potatoes BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	-	21.7	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 189	Potatoes BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	-	4.3	Annex M-CP 10-03 (Covered by scenario no. 72)
No. 197	Potatoes BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	-	2.3	Annex M-CP 10-03 (Covered by scenario no. 75)
No. 199	Pulses BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 201	Pulses BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	-	21.7	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 203	Pulses BBCH ≥ 50	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	-	4.3	Annex M-CP 10-03 (Covered by scenario no. 72)
No. 212	Pulses BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	-	2.3	Annex M-CP 10-03 (Covered by scenario no. 75)
No. 214	Root and stem vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 215	Root and stem vegetables BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	-	21.7	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 223	Root and stem vegetables BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	-	2.3	Annex M-CP 10-03 (Covered by scenario no. 75)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 225	Strawberries BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 226	Strawberries BBCH ≥ 40	Small herbivorous mammal “vole Common vole (*Microtus arvalis*)	-	28.9	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 228	Strawberries BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	-	5.7	Annex M-CP 10-03 (Covered by scenario no. 72)
No. 236	Strawberries BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	-	3.1	Annex M-CP 10-03 (Covered by scenario no. 75)
No. 238	Sugar beet BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 239	Sugar beet BBCH ≥ 40	Small herbivorous mammal “vole Common vole (*Microtus arvalis*)	-	18.1	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 241	Sugar beet BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	-	3.6	Annex M-CP 10-03 (Covered by scenario no. 72)
No. 249	Sugar beet BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 75)
No. 251	Sunflower BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 5)
No. 252	Sunflower BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	-	18.1	Annex M-CP 10-03 (Covered by scenario no. 74)
No. 255	Sunflower BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	-	3.6	Annex M-CP 10-03 (Covered by scenario no. 72)
No. 266	Sunflower BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	-	1.9	Annex M-CP 10-03 (Covered by scenario no. 75)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
Field crops (Shielded ground directed inter-row application): Use 6 a, b					
No. 4	**Bulbs & onion like crops BBCH 10 – 19**	**Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)**	**-**	**4.2**	**MCP 10.1.2 (Worst case scenario)**
No. 13	**Bulbs & onion like crops BBCH 10 – 39**	**Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)**	**-**	**7.8**	**MCP 10.1.2 (Worst case scenario)**
No. 60	Fruiting vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	-	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 62	**Fruiting vegetables BBCH 10 – 49**	**Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)**	**-**	**72.3**	**MCP 10.1.2 (Worst case scenario)**
No. 70	Fruiting vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	-	7.8	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 91	Leafy vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	-	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 95	**Leafy vegetables All season**	**Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)**	**-**	**14.3**	**MCP 10.1.2 (Worst case scenario)**
No. 102	Leafy vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	-	7.8	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 104	Legume forage BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	-	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 115	Legume forage BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	-	7.8	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 185	Potatoes BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	-	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 188	Potatoes BBCH 10 – 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	-	14.3	Annex M-CP 10-03 (Covered by scenario no. 95)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 196	Potatoes BBCH 10 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	-	7.8	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 198	Pulses BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	-	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 202	Pulses BBCH 10 – 49	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	-	14.3	Annex M-CP 10-03 (Covered by scenario no. 95)
No. 211	Pulses BBCH 10 – 49	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	-	7.8	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 213	Root & stem vegetables BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	-	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 222	Root & stem vegetables BBCH 10 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	-	7.8	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 237	Sugar beet BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	-	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 240	Sugar beet BBCH 10 – 39	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	-	14.3	Annex M-CP 10-03 (Covered by scenario no. 95)
No. 248	Sugar beet BBCH 10 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	-	7.8	Annex M-CP 10-03 (Covered by scenario no. 4)
Orchards: Use 4 a-c					
No. 148	**Orchards** **Application crop directed BBCH < 10 or not crop directed**	**Small insectivorous mammal “shrew”** **Common shrew (*Sorex araneus*)**	**5.4**	**1.9**	**MCP 10.1.2**
No. 149	**Orchards** **Application crop directed BBCH < 10 or not crop directed**	**Small herbivorous mammal “vole”** **Common vole (*Microtus arvalis*)**	**136.4**	**72.3**	**MCP 10.1.2**

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 154	**Orchards Application crop directed BBCH < 10 or not crop directed**	**Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)**	**35.1**	**14.3**	**MCP 10.1.2**
No. 170	**Orchards Application crop directed BBCH < 10 or not crop directed**	**Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)**	**17.2**	**7.8**	**MCP 10.1.2**
Vineyards: Use 5 a-c					
No. 267	**Vineyard Application ground directed**	**Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)**	**27.2**	**11.1**	**MCP 10.1.2**
No. 268	**Vineyard BBCH 10 – 19**	**Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)**	**16.3**	**6.7**	**MCP 10.1.2**
No. 269	**Vineyard BBCH 20 – 39**	**Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)**	**13.6**	**5.5**	**MCP 10.1.2**
No. 270	**Vineyard BBCH ≥ 40**	**Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)**	**8.1**	**3.3**	**MCP 10.1.2**
No. 271	**Vineyard BBCH 10 – 19**	**Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)**	**7.6**	**4.2**	**MCP 10.1.2**
No. 272	**Vineyard BBCH ≥ 20**	**Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)**	**5.4**	**1.9**	**MCP 10.1.2**
No. 273	**Vineyard Application ground directed**	**Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)**	**136.4**	**72.3**	**MCP 10.1.2**
No. 287	**Vineyard Application ground directed**	**Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)**	**17.2**	**7.8**	**MCP 10.1.2**
Railroad tracks – application by spray train: Use 7a-b					
No. 72	**Grassland All season**	**Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)**	**32.6**	**17.3**	**MCP 10.1.2**

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 73	**Grassland Late**	**Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)**	**5.4**	**1.9**	**MCP 10.1.2**
No. 74	**Grassland All season**	**Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)**	**136.4**	**72.3**	**MCP 10.1.2**
No. 75	**Grassland Late season (seed heads)**	**Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)**	**14.4**	**6.6**	**MCP 10.1.2**
No. 91	**Leafy vegetables BBCH 10 - 19**	**Small insectivorous mammal "shrew" Commnon shrew (*Sorex araneus*)**	**7.6**	**4.2**	**MCP 10.1.2**
No. 92	**Leafy vegetables BBCH ≥ 20**	**Small insectivorous mammal "shrew" Commnon shrew (*Sorex araneus*)**	**5.4**	**1.9**	**MCP 10.1.2**
No. 93	**Leafy vegetables BBCH 40 - 49**	**Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)**	**136.4**	**72.3**	**MCP 10.1.2**
No. 94	**Leafy vegetables BBCH ≥ 50**	**Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)**	**40.9**	**21.7**	**MCP 10.1.2**
No. 95	**Leafy vegetables All season**	**Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)**	**35.1**	**14.3**	**MCP 10.1.2**
No. 102	**Leafy vegetables BBCH 10 – 49**	**Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)**	**17.2**	**7.8**	**MCP 10.1.2**
No. 103	**Leafy vegetables BBCH ≥ 50**	**Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)**	**5.2**	**2.3**	**MCP 10.1.1**
Control of invasive species in agricultural and non-agricultural areas: Use 8-9					
No. 4	**Bulbs & onion like crops BBCH 10 – 19**	**Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)**	**7.6**	**4.2**	**MCP 10.1.2 (Worst case scenario)**
No. 5	Bulbs & onion like crops BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 6	Bulbs & onion like crops BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	81.9	43.4	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 13	**Bulbs & onion like crops BBCH 10 – 39**	**Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)**	**17.2**	**7.8**	**MCP 10.1.2 (Worst case scenario)**
No. 14	Bulbs & onion like crops BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	10.3	4.7	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 15	Bush & cane fruit BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 16	Bush & cane fruit BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 17	Bush & cane fruit BBCH 10 – 19	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	81.9	43.4	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 18	Bush & cane fruit BBCH 20 – 39	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	68.2	36.1	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 19	Bush & cane fruit BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	40.9	21.7	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 29	Bush & cane fruit BBCH 10 – 19	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	10.3	4.7	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 30	Bush & cane fruit BBCH 20 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	8.6	3.9	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 31	Bush & cane fruit BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	5.2	2.3	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 32	Cereals BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 33	Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 34	Cereals BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	40.9	21.7	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 35	**Cereals Early (shoots)**	**Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)**	**42.1**	**22.3**	**MCP 10.1.2 (Worst case scenario)**
No. 44	Cereals BBCH 10 – 29	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 45	Cereals BBCH 30 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	8.6	3.9	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 46	Cereals BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	5.2	2.3	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 60	Fruiting vegetables BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 61	Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 62	**Fruiting vegetables BBCH 10 – 49**	**Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)**	**136.4**	**72.3**	**MCP 10.1.2 (Worst case scenario)**
No. 63	Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	40.9	21.7	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 70	Fruiting vegetables BBCH 10 – 49	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No.71	Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	5.2	2.3	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 72	Grassland All season	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	32.6	17.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 73	Grassland Late	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 74	Grassland All season	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	136.4	72.3	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 75	Grassland Late season (seed heads)	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	14.4	6.6	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 77	Hop BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 78	Hop BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 79	Hop BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	40.9	21.7	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 88	Hop BBCH 10 – 19	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 89	Hop BBCH 20 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	8.6	3.9	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 90	Hop BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	5.2	2.3	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 91	Leafy vegetables BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 92	Leafy vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 93	Leafy vegetables BBCH 40 – 49	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	136.4	72.3	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 94	Leafy vegetables BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	40.9	21.7	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 95	Leafy vegetables All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	35.1	14.3	Annex M-CP 10-03 (Covered by scenario no. 35)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 102	Leafy vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 103	Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	5.2	2.3	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 104	Legume forage BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 105	Legume forage BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 106	Legume forage BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	136.4	72.3	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 107	Legume forage BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	40.9	21.7	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 108	Legume forage Leaf development BBCH 21 – 49	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	35.1	14.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 115	Legume forage BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 116	Legume forage BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	5.2	2.3	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 117	Maize BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 118	Maize BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 119	Maize BBCH 10 -29	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	136.4	72.3	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 120	Maize BBCH 30 – 39	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	68.2	36.1	Annex M-CP 10-03 (Covered by scenario no. 62)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 121	Maize BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	34.1	18.1	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 130	Maize BBCH 10 – 29	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 131	Maize BBCH 30 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	8.6	3.9	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 132	Maize BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	4.3	1.9	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 133	Oilseed rape BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 134	Oilseed rape BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 135	Oilseed rape BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	34.1	18.1	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 136	Oilseed rape All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	35.1	14.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 145	Oilseed rape BBCH 10 – 29	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 146	Oilseed rape BBCH 30 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	5.2	2.3	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 147	Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	4.3	1.9	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 148	Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 149	Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	136.4	72.3	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 154	Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	35.1	14.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 170	Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 175	Ornamentals/nursery BBCH 40 – 49	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	136.4	72.3	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 176	Ornamentals/nursery BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	68.2	36.1	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 185	Potatoes BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 186	Potatoes BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 187	Potatoes BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	40.9	21.7	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 188	Potatoes BBCH 10 – 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	35.1	14.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 189	Potatoes BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	10.5	4.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 196	Potatoes BBCH 10 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 197	Potatoes BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	5.2	2.3	Annex M-CP 10-03 (Covered by scenario no. 13)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 198	Pulses BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 199	Pulses BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 200	Pulses BBCH 40 – 49	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	136.4	72.3	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 201	Pulses BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	40.9	21.7	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 202	Pulses BBCH 10 – 49	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	35.1	14.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 203	Pulses BBCH ≥ 50	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	10.5	4.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 211	Pulses BBCH 10 – 49	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 212	Pulses BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	5.2	2.3	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 213	Root & stem vegetables BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 214	Root & stem vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 215	Root & stem vegetables BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	40.9	21.7	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 222	Root & stem vegetables BBCH 10 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 223	Root & stem vegetables BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	5.2	2.3	Annex M-CP 10-03 (Covered by scenario no. 13)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 224	Strawberries BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 225	Strawberries BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 226	Strawberries BBCH ≥ 40	Small herbivorous mammal “vole Common vole (*Microtus arvalis*)	54.6	28.9	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 227	Strawberries BBCH 10 – 39	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	35.1	14.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 228	Strawberries BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.0	5.7	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 235	Strawberries BBCH 10 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 236	Strawberries BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	6.9	3.1	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 237	Sugar beet BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 238	Sugar beet BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 239	Sugar beet BBCH ≥ 40	Small herbivorous mammal “vole Common vole (*Microtus arvalis*)	34.1	18.1	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 240	Sugar beet BBCH 10 – 39	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	35.1	14.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 241	Sugar beet BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	8.8	3.6	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 248	Sugar beet BBCH 10 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 249	Sugar beet BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	4.3	1.9	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 250	Sunflower BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 251	Sunflower BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 252	Sunflower BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	34.1	18.1	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 253	Sunflower BBCH 10 – 19	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	35.1	14.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 254	Sunflower BBCH 20 – 39	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	17.6	7.2	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 255	Sunflower BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	8.8	3.6	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 264	Sunflower BBCH 10 – 19	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)
No.265	Sunflower BBCH 20 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	8.6	3.9	Annex M-CP 10-03 (Covered by scenario no. 13)
No.266	Sunflower BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	4.3	1.9	Annex M-CP 10-03 (Covered by scenario no. 13)
No. 267	Vineyard Application ground directed	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	27.2	11.1	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 268	Vineyard BBCH 10 – 19	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	16.3	6.7	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 269	Vineyard BBCH 20 – 39	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	13.6	5.5	Annex M-CP 10-03 (Covered by scenario no. 35)

Table 10.1.2- 11: Tier 1 mammalian scenarios

EFSA Appendix A Scenario	Tier 1 scenario given by glyphosate RAR	Generic focal species	SV_{90}	SV_m	Risk assessment presented under
No. 270	Vineyard BBCH ≥ 40	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	8.1	3.3	Annex M-CP 10-03 (Covered by scenario no. 35)
No. 271	Vineyard BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	7.6	4.2	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 272	Vineyard BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	5.4	1.9	Annex M-CP 10-03 (Covered by scenario no. 4)
No. 273	Vineyard Application ground directed	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	136.4	72.3	Annex M-CP 10-03 (Covered by scenario no. 62)
No. 287	Vineyard Application ground directed	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	7.8	Annex M-CP 10-03 (Covered by scenario no. 13)

Worse case scenarios are indicated in **bold**.

The Tier 1 risk assessment is presented in the following tables for the relevant uses in field crops, orchards, vineyards, for the uses on railroad tracks and for the uses to control invasive species in agricultural and non-agricultural areas, taking into account those generic focal species scenarios which were indicated in bold in the table above.

Field crops

Table 10.1.2- 12: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops (Pre-sowing, pre-planting, pre-emergence); Uses 1 a-c

Active substance	Glyphosate						
Reprod. toxicity (mg/kg bw/d)	50						
TER criterion	5						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_t**
Field crops (Pre-sowing, pre-planting, pre-emergence)	1 × 1440	Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.53	13.2	**3.79**
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	55.2	**0.91**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	6.6	1.0 × 0.53	5.04	9.93
		Leafy vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	3.21	15.6
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	55.2	**0.91**
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	16.6	**3.02**
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	10.9	**4.58**
		Leafy vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	5.95	8.40
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.76	28.5
	1 × 1080	Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.53	9.90	5.05

Table 10.1.2- 12: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops (Pre-sowing, pre-planting, pre-emergence); Uses 1 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg b w/d)**	**TER_t**
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	41.4	**1.21**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	6.6	1.0 × 0.53	3.78	13.2
		Leafy vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	2.40	20.8
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	41.4	**1.21**
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	12.4	**4.03**
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	8.19	6.11
		Leafy vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	4.47	11.2
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.32	38.0
	1 × 720	Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.53	6.60	7.57
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.73	69.0
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	27.6	**1.81**

Table 10.1.2- 12: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops (Pre-sowing, pre-planting, pre-emergence); Uses 1 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg b w/d)**	**TER_t**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	6.6	1.0 × 0.53	2.52	19.9
		Leafy vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	1.60	31.2
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.73	69.0
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	27.6	**1.81**
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	8.28	6.04
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	5.46	9.16
		Leafy vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	2.98	16.8
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.88	57.0

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 1 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns in field crops (Pre-sowing, pre-planting, pre-emergence, Uses 1 a-c) except for the following scenarios where a refined risk assessment is required for some or all intended application rates:

- Grassland; the large herbivorous mammal "lagomorph" brown hare (1 × 1440 g a.s./ha).
- Grassland; the small herbivorous mammal "vole" common vole (1 × 1440 g a.s./ha, 1 × 1080 g a.s./ha, 1 × 720 g a.s./ha).
- Leafy vegetables; the small herbivorous mammal "vole" common vole (1 × 1440 g a.s./ha, 1 × 1080 g a.s./ha, 1 × 720 g a.s./ha).

- Leafy vegetables; the large herbivorous mammal "lagomorph" rabbit (1 × 1440 g a.s./ha).

Table 10.1.2- 13: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops (Post-harvest, pre-sowing, pre-planting): Use 2 a-c, 3 a-b, 10 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1440	Bulbs and onion like crops BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.53	13.2	**3.8**
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	55.2	**0.90**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	6.6	1.0 × 0.53	5.04	9.90
	2 × 1080 (28 d)	Bulbs and onion like crops BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.1 × 0.53	10.9	**4.60**
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.1 × 0.53	45.5	**1.10**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	6.6	1.1 × 0.53	4.16	12.0
	1 × 540	Bulbs and onion like crops BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.53	4.95	10.1
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	20.7	**2.40**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	6.6	1.0 × 0.53	1.89	26.5

Table 10.1.2- 13: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops (Post-harvest, pre-sowing, pre-planting): Use 2 a-c, 3 a-b, 10 a-c

Active substance	Glyphosate						
Reprod. toxicity (mg/kg bw/d)	50						
TER criterion	5						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
	1 × 720	Bulbs and onion like crops BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.53	6.60	7.60
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	27.6	**1.80**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	6.6	1.0 × 0.53	2.52	19.9
	2 × 720 (28 d)	Bulbs and onion like crops BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.1 × 0.53	7.26	6.90
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.1 × 0.53	30.4	**1.60**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	6.6	1.1 × 0.53	2.77	18.0
	1 × 1080	Bulbs and onion like crops BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.53	9.90	5.00
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	41.4	**1.20**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	6.6	1.0 × 0.53	3.78	13.2
	3 × 720 (28 d)	Bulbs and onion like crops BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5

Table 10.1.2- 13: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops (Post-harvest, pre-sowing, pre-planting): Use 2 a-c, 3 a-b, 10 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.2 × 0.53	7.92	6.30
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.2 × 0.53	33.1	**1.50**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	6.6	1.2 × 0.53	3.02	16.5

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 1 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns in field crops (Post-harvest, pre-sowing, pre-planting, Use 2 a-c, 3 a-b, 10 a-c) except for the following scenarios where a refined risk assessment is required for some or all intended application rates:

- Grassland; the large herbivorous mammal "lagomorph" brown hare (1 × 1440 g a.s./ha, 2 × 1080 g a.s./ha).
- Grassland; the small herbivorous mammal "vole" common vole (1 × 1440 g a.s./ha, 2 × 1080 g a.s./ha, 1 × 540 g a.s./ha, 1 × 720 g a.s./ha, 2 × 720 g a.s./ha, 1 × 1080 g a.s./ha, 3 × 720 g a.s./ha).

Table 10.1.2- 14: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops (Shielded ground directed inter-row application): Use 6 a-b

Active substance	Glyphosate						
Reprod. toxicity (mg/kg bw/d)	50						
TER criterion	5						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Shielded ground inter-row application)	1 × 1080	Bulbs & onion like crops BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	2.40	20.8
		Bulbs & onion like crops BBCH 10 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	4.46	11.2
		Fruiting vegetables BBCH 10 – 49	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	41.4	**1.21**
		Leafy vegetables All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	8.19	6.11
	1 × 720	Bulbs & onion like crops BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	1.60	31.2
		Bulbs & onion like crops BBCH 10 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	2.98	16.8
		Fruiting vegetables BBCH 10 – 49	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	27.6	**1.81**
		Leafy vegetables All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	5.46	9.16

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 1 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns in field crops (Shielded ground directed inter-row application, uses 6 a-b) except for the following scenario where a refined risk assessment is required for all intended application rates:

- Fruiting vegetables; the small herbivorous mammal “vole” common vole (1 × 1080 g a.s./ha, 1 × 720 g a.s./ha).

<u>Orchards</u>

Table 10.1.2- 15: Tier 1 assessment of the acute risk for mammals due to the use of glyphosate in orchards: Uses 4 a-c

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		> 2000					
TER criterion		10					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchard Post-emergence of weeds	2 × 1440 (28 d)	Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	5.4	1.1	8.55	234
		Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	136.4	1.1	216	**9.26**
		Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	35.1	1.1	55.6	36.0
		Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	17.2	1.1	27.2	73.4

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 1 TER_a values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to mammals is acceptable following the proposed use patterns in orchards (Uses 4 a –c) except for the following scenario where a refined risk assessment is required for one intended application rate:

- Orchards; the small herbivorous mammal "vole" common vole (2 × 1440 g a.s./ha).

Table 10.1.2- 16: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in orchards: Use 4 a-c

Active substance	Glyphosate						
Reprod. toxicity (mg/kg bw/d)	50						
TER criterion	5						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard Post-emergence of weeds	2 × 1440 (28 d)	Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.60	31.3
		Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.1 × 0.53	60.7	**0.82**
		Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.1 × 0.53	12.0	**4.16**
		Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.1 × 0.53	6.55	7.64
	1 × 720	Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	27.6	**1.81**
		Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	5.46	9.16
		Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	2.98	16.8
	1 × 1080	Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Orchards Application crop directed BBCH < 10 or not crop	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	41.4	**1.21**

Table 10.1.2- 16: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in orchards: Use 4 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		directed					
		Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	8.19	6.11
		Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	4.47	11.2
	2 × 720 (28 d)	Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.90	62.7
		Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.1 × 0.53	72.3	**1.65**
		Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.1 × 0.53	14.3	8.33
		Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.1 × 0.53	7.80	15.3
	3 × 720 (28 d)	Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.87	57.5
		Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.2 × 0.53	33.1	**1.51**
		Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.2 × 0.53	6.55	7.64
		Orchards Application crop directed BBCH	Small omnivorous mammal “mouse” Wood mouse (*Apodemus*	7.8	1.2 × 0.53	3.57	14.0

Table 10.1.2- 16: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in orchards: Use 4 a-c

Active substance	Glyphosate						
Reprod. toxicity (mg/kg bw/d)	50						
TER criterion	5						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		< 10 or not crop directed	*sylvaticus*)				
	1 × 1440	Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	55.2	**0.91**
		Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	10.9	**4.58**
		Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	5.95	8.40
	2 × 1080 (28 d)	Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.1 × 0.53	45.5	**1.10**
		Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.1 × 0.53	9.00	5.55
		Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.1 × 0.53	4.91	10.2

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 1 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns in orchards (Uses 4 a-c) except for the following scenario where a refined risk assessment is required for some or all intended application rates:

- Orchards; the small herbivorous mammal "vole" common vole (2 × 1440 g a.s./ha, 1 × 720 g a.s./ha, 1 × 1080 g a.s./ha, 2 × 720 g a.s./ha, 3 × 720 g a.s./ha, 1 × 1440 g a.s./ha, 2 × 1080 g a.s./ha).
- Orchards: the large herbivorous mammal "lagomorph" rabbit (2 × 1440 g a.s./ha, 1 × 1440 g a.s./ha).

Vineyards

Table 10.1.2- 17: Tier 1 assessment of the acute risk for mammals due to the use of glyphosate in vineyards: Use 5 a-c

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		> 2000					
TER criterion		10					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard Post-emergence of weeds	2 × 1440 (28 d)	Vineyard Application ground directed	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	27.2	1.1	43.1	46.4
		Vineyard BBCH 10 – 19	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	16.3	1.1	25.8	77.5
		Vineyard BBCH 20 – 39	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	13.6	1.1	21.5	92.8
		Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	8.1	1.1	12.8	156
		Vineyard BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	7.6	1.1	12.0	166
		Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	5.4	1.1	8.55	234
		Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	136.4	1.1	216	**9.26**
		Vineyard Application ground directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	17.2	1.1	27.2	73.4

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 1 TER_a values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to mammals is acceptable following the proposed use patterns in vineyards (Uses 5 a-c) except for the following scenario where a refined risk assessment is required for one application rate:

- Vineyards; the small herbivorous mammal “vole” common vole (2 × 1440 g a.s./ha).

Table 10.1.2- 18: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in vineyards: Use 5 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard Post-emergence of weeds	2 × 1440 (28 d)	Vineyard Application ground directed	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	11.1	1.1 × 0.53	9.32	5.37
		Vineyard BBCH 10 – 19	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	6.7	1.1 × 0.53	5.62	8.89
		Vineyard BBCH 20 – 39	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	5.5	1.1 × 0.53	4.62	10.8
		Vineyard BBCH ≥ 40	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	3.3	1.1 × 0.53	2.77	18.0
		Vineyard BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	4.2	1.1 × 0.53	3.53	14.2
		Vineyard BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.60	31.3
		Vineyard Application ground directed	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.1 × 0.53	60.7	**0.82**
		Vineyard Application ground directed	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.1 × 0.53	6.55	7.64
	1 × 720	Vineyard Application ground directed	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	11.1	1.0 × 0.53	4.24	11.8
		Vineyard BBCH 10 – 19	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	6.7	1.0 × 0.53	2.56	19.6
		Vineyard BBCH 20 – 39	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	5.5	1.0 × 0.53	2.10	23.8

Table 10.1.2- 18: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in vineyards: Use 5 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	3.3	1.0 × 0.53	1.26	39.7
		Vineyard BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	1.60	31.2
		Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	27.6	**1.81**
		Vineyard Application ground directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	2.98	16.8
	1 × 1080	Vineyard Application ground directed	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	11.1	1.0 × 0.53	6.35	7.90
		Vineyard BBCH 10 – 19	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	6.7	1.0 × 0.53	3.84	13.0
		Vineyard BBCH 20 – 39	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	5.5	1.0 × 0.53	3.15	15.9
		Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	3.3	1.0 × 0.53	1.89	26.5
		Vineyard BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	2.40	20.8
		Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	41.4	**1.21**
		Vineyard Application ground directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	4.47	11.2

Table 10.1.2- 18: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in vineyards: Use 5 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
	2 × 720 (28 d)	Vineyard Application ground directed	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	11.1	1.1 × 0.53	4.66	10.7
		Vineyard BBCH 10 – 19	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	6.7	1.1 × 0.53	2.81	17.8
		Vineyard BBCH 20 – 39	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	5.5	1.1 × 0.53	2.31	21.7
		Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	3.3	1.1 × 0.53	1.39	36.1
		Vineyard BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.1 × 0.53	1.76	28.4
		Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.1 × 0.53	30.4	**1.65**
		Vineyard Application ground directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.1 × 0.53	3.27	15.3
	3 × 720 (28 d)	Vineyard Application ground directed	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	11.1	1.2 × 0.53	5.08	9.84
		Vineyard BBCH 10 – 19	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	6.7	1.2 × 0.53	3.07	16.3
		Vineyard BBCH 20 – 39	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	5.5	1.2 × 0.53	2.52	19.9
		Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	3.3	1.2 × 0.53	1.51	33.1
		Vineyard BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.2 × 0.53	1.92	26.0

Table 10.1.2- 18: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in vineyards: Use 5 a-c

Active substance	Glyphosate						
Reprod. toxicity (mg/kg bw/d)	50						
TER criterion	5						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.87	57.5
		Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.2 × 0.53	33.1	**1.51**
		Vineyard Application ground directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.2 × 0.53	3.57	14.0
	1 × 1440	Vineyard Application ground directed	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	11.1	1.0 × 0.53	8.47	5.90
		Vineyard BBCH 10 – 19	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	6.7	1.0 × 0.53	5.11	9.78
		Vineyard BBCH 20 – 39	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	5.5	1.0 × 0.53	4.20	11.9
		Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	3.3	1.0 × 0.53	2.52	19.9
		Vineyard BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	3.21	15.6
		Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	55.2	**0.91**
		Vineyard Application ground directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	5.95	8.40
	2 × 1080 (28 d)	Vineyard Application ground directed	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	11.1	1.1 × 0.53	6.99	7.15
		Vineyard BBCH 10 – 19	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	6.7	1.1 × 0.53	4.22	11.9

Table 10.1.2- 18: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in vineyards: Use 5 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Vineyard BBCH 20 – 39	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	5.5	1.1 × 0.53	3.46	14.4
		Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	3.3	1.1 × 0.53	2.08	24.1
		Vineyard BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.1 × 0.53	2.64	18.9
		Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.1 × 0.53	45.5	**1.10**
		Vineyard Application ground directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.1 × 0.53	4.91	10.2

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 1 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns in vineyards (Uses 5 a-c) except for the following scenario where a refined risk assessment is required for all intended application rates:

- Vineyards; the small herbivorous mammal "vole" common vole (2 × 1440 g a.s./ha, 1 × 720 g a.s./ha, 1 × 1080 g a.s./ha, 2 × 720 g a.s./ha, 3 × 720 g a.s./ha, 1 × 1440 g a.s./ha, 2 × 1080 g a.s./ha).

Railroad tracks – application by spray train

Table 10.1.2- 19: Tier 1 assessment of the acute risk for mammals due to the use of glyphosate on railroad tracks: Use 7 a-b

Active substance	Glyphosate						
Acute toxicity (mg/kg bw)	> 2000						
TER criterion	10						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Railroad tracks – application by spray train. Post emergence of weeds (90d apart).	2 × 1800 (90 d)	Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	32.6	1.0	58.7	34.1
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	5.4	1.0	9.72	206
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	136.4	1.0	246	**8.15**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	14.4	1.0	25.9	77.2
		Leafy vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Commnon shrew (*Sorex araneus*)	7.6	1.0	13.7	146
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	5.4	1.0	9.72	206
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	136.4	1.0	246	**8.15**
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	40.9	1.0	73.6	27.2
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	35.1	1.0	63.2	31.7
		Leafy vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	17.2	1.0	31.0	64.6
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	5.2	1.0	9.36	214
	1 × 1800	Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	32.6	1.0	58.7	34.1
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	5.4	1.0	9.72	206

		Grassland All season	Small herbivorous mammal “vole” Common vole (*Microtulus arvalis*)	136.4	1.0	246	**8.15**
		Grassland Late season (seed heads)	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	14.4	1.0	25.9	77.2
		Leafy vegetables BBCH 10 – 19	Small insectivorous mammal “shrew” Commnon shrew (*Sorex araneus*)	7.6	1.0	13.7	146
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Commnon shrew (*Sorex araneus*)	5.4	1.0	9.72	206
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal “vole” Common vole (*Microtulus arvalis*)	136.4	1.0	246	**8.15**
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtulus arvalis*)	40.9	1.0	73.6	27.2
		Leafy vegetables All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	35.1	1.0	63.2	31.7
		Leafy vegetables BBCH 10 – 49	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	17.2	1.0	31.0	64.6
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	5.2	1.0	9.36	214

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 1 TER_a values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to mammals is acceptable following the proposed use patterns on railroad tracks (Uses 7a-b) except for the following scenarios where a refined risk assessment is required for all intended application rates:

- Grassland; the small herbivorous mammal “vole” common vole (2 × 1800 g a.s./ha, 1 × 1800 g a.s./ha).
- Leafy vegetables; the small herbivorous mammal “vole” common vole (2 × 1800 g a.s./ha, 1 × 1800 g a.s./ha).

Table 10.1.2- 20: Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate on railroad tracks: Use 7 a-b

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Railroad tracks – application by spray train. Post emergence of weeds (90d apart).	2 × 1800 (90 d)	Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.53	16.5	**3.03**
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	72.3	1.0 × 0.53	69.0	**0.720**
		Grassland Late season (seed heads)	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	6.6	1.0 × 0.53	6.30	7.94
		Leafy vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Commnon shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	72.3	1.0 × 0.53	69.0	**0.720**
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	21.7	1.0 × 0.53	20.7	**2.42**
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	13.6	**3.67**
		Leafy vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8
	1 × 1800	Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.53	16.5	**3.03**
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6

		Grassland All season	Small herbivorous mammal “vole” Common vole (*Microtulus arvalis*)	72.3	1.0 × 0.53	69.0	**0.720**
		Grassland Late season (seed heads)	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	6.6	1.0 × 0.53	6.30	7.94
		Leafy vegetables BBCH 10 – 19	Small insectivorous mammal “shrew” Commnon shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Commnon shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal “vole” Common vole (*Microtulus arvalis*)	72.3	1.0 × 0.53	69.0	**0.720**
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtulus arvalis*)	21.7	1.0 × 0.53	20.7	**2.42**
		Leafy vegetables All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	13.6	**3.67**
		Leafy vegetables BBCH 10 – 49	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 1 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns on railroad tracks (Uses 7 a-b) except for the following scenarios where a refined risk assessment is required for all intended application rates:

- Grassland; the large herbivorous mammal “lagomorph” brown hare (2 × 1800 g a.s./ha, 1 × 1800 g a.s./ha).
- Grassland; the small herbivorous mammal “vole” common vole (2 × 1800 g a.s./ha, 1 × 1800 g a.s./ha).
- Leafy vegetables; the small herbivorous mammal “vole” common vole (2 × 1800 g a.s./ha, 1 × 1800 g a.s./ha).
- Leafy vegetables: the large herbivorous mammal “lagomorph” rabbit (2 × 1800 g a.s./ha, 1 × 1800 g a.s./ha).

Control of invasive species

Table 10.1.2- 21: Tier 1 assessment of the acute risk for mammals due to the use of glyphosate on invasive species in agricultural and non-agricultural areas: Uses 8, 9

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		> 2000					
TER criterion		10					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Invasive species in agricultural and non-agricultural areas. Post emergence of invasive species.	1 × 1800	Bulbs & onion like crops BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	7.6	1.0	13.7	146
		Bulbs & onion like crops BBCH 10 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	17.2	1.0	31.0	64.6
		Cereals Early (shoots)	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	42.1	1.0	75.8	26.4
		Fruiting vegetables BBCH 10 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	136.4	1.0	246	**8.15**

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 1 TER_a values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to mammals is acceptable following the proposed use patterns on invasive species (Uses 8 and 9) except for the following scenario where a refined risk assessment is required for the intended application rates:

- Fruiting vegetables; the small herbivorous mammal "vole" common vole (1 × 1800 g a.s./ha).

Table 10.1.2- 22:Tier 1 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate on invasive species in agricultural and non-agricultural areas: Uses 8, 9

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Invasive species in agricultural and non-agricultural areas. Post emergence of invasive species.	1 × 1800	Bulbs & onion like crops BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Bulbs & onion like crops BBCH 10 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.70
		Cereals Early (shoots)	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	22.3	1.0 × 0.53	21.3	**2.40**
		Fruiting vegetables BBCH 10 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	69.0	**0.725**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 1 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns on invasive species (Uses 8 and 9) except for the following scenarios where a refined risk assessment is required for the intended application rate:

- Cereals; the large herbivorous mammal "lagomorph" rabbit (1 × 1800 g a.s./ha).
- Fruiting vegetables; the small herbivorous mammal "vole" common vole (1 × 1800 g a.s./ha).

Higher tier assessment (Tier 2)

Acute and long-term Tier 2 exposure was calculated for those intended uses, for which the Tier 1 risk assessment indicates the need for a refined acute or long-term risk assessment. As indicated in the tables above further refinements are needed for herbivorous mammals, i.e. the small herbivorous mammal "vole" and the large herbivorous mammal "lagomorph" (hare, rabbit).

Refinement of TWA and MAF based on glyphosate residue decline on grass

In Tier 2, TWA and MAF values for glyphosate can be refined based on measured residues on grass foliage.

The methodology used to calculate the TWA for glyphosate on grass foliage for the long-term risk assessment follows the procedure described in the Guidance Document on Terrestrial Ecotoxicology (2002). According to the approach outlined in the Guidance Document on Terrestrial Ecotoxicology, the dissipation of glyphosate in grass was estimated using the standard first-order dissipation model:

$Ct = Ci \times e^{-kt}$

k	=	first order rate constant
Ci	=	initial residue concentration
Ct	=	residue concentration at time t

The decline of glyphosate residue on grass was characterized using data from 22 residue trials each of which had a day 0 value. Based on this data, the k value for grass foliage was calculated to be 0.2476 $days^{-1}$ (Renewal Assessment Report for glyphosate, 29 January 2015, Volume 3, Annex B.9, B.9.13**)**. For convenience these calculations are reproduced without change, in Annex M-CP 10-02 to this document.

Residue half-life times (DT_{50}) in days were calculated with following equation:

$$DT_{50} = \frac{-\ln 0.5}{k}$$

The average DT_{50} for grass foliage was **2.8 days**.

The 21-day time weighted average (TWA) for glyphosate on grass foliage has been calculated according to the following formula:

$$TWA = \frac{(1 - e^{-kt})}{kt}$$

The 21-day TWA is calculated to be **0.19** for the active substance glyphosate acid and grass. For the refined risk assessment this value is applied for the small herbivorous mammal "vole" Common vole (*Microtus arvalis*), the large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*) and the large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*). Although the calculated 21-day TWA of 0.19 is based on residue decline on "grass" it is considered to be valid for "non-grass herbs" as well. This assumption can be supported by Ebeling & Wang (2018)[13], who evaluated the residue dissipation of 30 active substances (including glyphosate) on grasses / cereals (177 trials) and non-grass herbs (101 trials). No significant difference between residue dissipation on grasses / cereals and non-grass herbs was found. In addition also in the EFSA Conclusion for glyphosate (2015)[14] (EFSA Journal 2015;13(11):4302) the 21-day TWA of 0.19 was applied to refine the risk for the large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*) feeding on "Non-grass herbs" (Diet according to Appendix A of EFSA/2009/1438).

In addition, MAF_{90} and MAF_m values for the application intervals of 28 and 90 days and based on the measured foliar half-life were calculated using the formula in Appendix H of EFSA/2009/1438. Resulting MAF values for two and three applications are presented in the following table.

Table 10.1.2- 23: MAF_{90}, MAF_m and $MAF_m \times TWA$ values based on a measured foliar DT_{50} of 2.8 days

Number of applications	Application interval (d)	Measured foliar DT_{50} (d)	MAF_{90}	MAF_m	$MAF_m \times TWA$
2	28	2.8	1.00	1.00	0.19
3	28	2.8	1.00	1.00	0.19
2	90	2.8	1.00	1.00	0.19

13 Ebeling, M., Wang, M. Dissipation of Plant Protection Products from Foliage. Environmental Toxicology and Chemistry (2018). Wiley Online Library.

14 Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate (2015). European Food Safety Authority (EFSA), Parma, Italy.

Refined endpoints
At Tier 2, a refined endpoint of 3694.1 mg/kg bw is used for the acute risk assessment and a refined endpoint of 100 mg/kg bw/d for the chronic risk assessment. Detailed justifications for the acute and chronic Tier 2 endpoints are presented in Annex M-CA 8.02 of the document M-CA Section 8.

Field crops

Table 10.1.2- 24: Tier 2 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops (Pre-sowing, pre-planting, pre-emergence): Use 1 a-c

Active substance	Glyphosate						
Reprod. toxicity (mg/kg bw/d)	100						
TER criterion	5						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Pre-sowing, pre-planting, pre-emergence)	1 × 1440	Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.19	4.73	21.1
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	19.8	5.06
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	19.8	5.06
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.19	5.94	16.8
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.19	3.91	25.6
	1 × 1080	Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	14.8	6.74
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	14.8	6.74
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.19	4.45	22.5
	1 × 720	Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	10.1
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	10.1

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 2 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns in field crops (Pre-sowing, pre-planting, pre-emergence, Uses 1 a-c).

Table 10.1.2- 25: Tier 2 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops (Post-harvest, pre-sowing, pre-planting): Use 2 a-c, 3 a-b, 10 a-c

Active substance	Glyphosate						
Reprod. toxicity (mg/kg bw/d)	100						
TER criterion	5						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1440	Grassland All season	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.19	4.73	21.1
		Grassland All season	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	19.8	5.06
	2 × 1080 (28 d)	Grassland All season	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.19	3.55	28.2
		Grassland All season	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	14.8	6.74
	1 × 540	Grassland All season	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	7.42	13.5
	1 × 720	Grassland All season	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	10.1
	2 × 720 (28 d)	Grassland All season	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	10.1
	1 × 1080	Grassland All season	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	14.8	6.74
	3 × 720 (28 d)	Grassland All season	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	10.1

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

The Tier 2 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns in field crops (Post-harvest, pre-sowing, pre-planting, Uses 2 a-c, 3 a-b and 10 a-c).

Table 10.1.2- 26: Tier 2 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in field crops (Shielded ground directed inter-row application): Use 6 a-b

Active substance	Glyphosate						
Reprod. toxicity (mg/kg bw/d)	100						
TER criterion	5						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Shielded ground inter-row application)	1 × 1080	Fruiting vegetables BBCH 10 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	14.8	6.74
	1 × 720	Fruiting vegetables BBCH 10 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	10.1

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

The Tier 2 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns in field crops (Uses 6 a-b); shielded ground directed inter-row application.

Orchards

Table 10.1.2- 27: Tier 2 assessment of the acute risk for mammals due to the use of glyphosate in orchards: Uses: 4 a-c

Active substance	Glyphosate						
Acute toxicity (mg/kg bw)	3694.1						
TER criterion	10						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchard Post-emergence of weeds	2 × 1440 (28 d)	Orchards Application crop directed BBCH < 10 or not crop	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	136.4	1.0	196	18.8

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

The Tier 2 TER_a value is greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to mammals is acceptable following the proposed use patterns in orchards.

Table 10.1.2- 28: Tier 2 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in orchards: Uses: 4 a-c

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		100					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchard Post-emergence of weeds	2 × 1440 (28 d)	Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	19.8	5.06
		Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.19	3.91	25.6
	1 × 720	Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	10.1
	1 × 1080	Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	14.8	6.74
	2 × 720 (28 d)	Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	10.1
	3 × 720 (28 d)	Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	10.1
	1 × 1440	Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	19.8	5.06
		Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.19	3.91	25.6
	2 × 1080 (28 d)	Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	14.8	6.74

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

The Tier 2 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns in orchards (Uses 4 a-c).

Vineyards

Table 10.1.2- 29: Tier 2 assessment of the acute risk for mammals due to the use of glyphosate in vineyards: Uses 5 a-c

Active substance	Glyphosate						
Acute toxicity (mg/kg bw)	3694.1						
TER criterion	10						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Vineyard Post-emergence of weeds	2 × 1440 (28 d)	Vineyard Application ground directed	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	136.4	1.0	196	18.8

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

The Tier 2 TER_a value is greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to mammals is acceptable following the proposed use patterns in vineyards.

Table 10.1.2- 30: Tier 2 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate in vineyards: Use 5 a-c

Active substance	Glyphosate						
Reprod. toxicity (mg/kg bw/d)	100						
TER criterion	5						
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Vineyard Post-emergence of weeds	2 × 1440 (28 d)	Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	19.8	5.06
	1 × 720	Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	10.1
	1 × 1080	Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	14.8	6.74
	2 × 720 (28 d)	Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	10.1
	3 × 720 (28 d)	Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	9.89	5.06
	1 × 1440	Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	19.8	5.06
	2 × 1080 (28 d)	Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	14.8	6.74

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

The Tier 2 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns in vineyards (Uses 5 a-c).

Railroad tracks – application by spray train

Table 10.1.2- 31: Tier 2 assessment of the acute risk for mammals due to the use of glyphosate on railroad tracks: Use 7 a-b

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		3694.1					
TER criterion		10					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Railroad tracks – application by spray train. Post emergence of weeds (90d apart).	2 × 1800 (90 d)	Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	136.4	1.0	246	15.0
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	136.4	1.0	246	15.0
	1 × 1800	Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	136.4	1.0	246	15.0
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	136.4	1.0	246	15.0

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

The Tier 2 TER_a values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to mammals is acceptable following the proposed use patterns on railroad tracks.

Table 10.1.2- 32: Tier 2 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate on railroad tracks: Use 7 a-b

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		100					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Railroad tracks – application by spray train. Post emergence of weeds (90d apart).	2 × 1800 (90 d)	Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.19	5.92	16.9
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	72.3	1.0 × 0.19	24.7	**4.04**
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	72.3	1.0 × 0.19	24.7	**4.04**
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	21.7	1.0 × 0.19	7.42	13.5
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.19	4.89	20.5
	1 × 1800	Grassland All season	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.19	5.92	16.9
		Grassland All season	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	72.3	1.0 × 0.19	24.7	**4.04**
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	72.3	1.0 × 0.19	24.7	**4.04**
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtulus arvalis*)	21.7	1.0 × 0.19	7.42	13.5
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.19	4.89	20.5

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 2 TER_{lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns on railroad tracks (uses 7a-b) except for the following scenarios where a refined risk assessment is required for all intended application rates:

- Grassland; the small herbivorous mammal "vole" common vole (2 × 1800 g a.s./ha, 1 × 1800 g a.s./ha).

- Leafy vegetables; the small herbivorous mammal "vole" common vole (2 × 1800 g a.s./ha, 1 × 1800 g a.s./ha).

Control of invasive species

Table 10.1.2- 33:Tier 2 assessment of the acute risk for mammals due to the use of glyphosate on invasive species in agricultural and non-agricultural areas: Uses 8 and 9

Active substance		Glyphosate					
Acute toxicity (mg/kg bw)		3694.1					
TER criterion		10					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Invasive species in agricultural and non-agricultural areas. Post emergence of invasive species.	1 × 1800	Fruiting vegetables BBCH 10 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	136.4	1.0	246	15.0

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 2 TER_a value is greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to mammals is acceptable following the proposed use patterns on invasive species.

Table 10.1.2-34: Tier 2 assessment of the long-term/reproductive risk for mammals due to the use of glyphosate on invasive species in agricultural and non-agricultural areas: Uses 8 and 9

Active substance		Glyphosate					
Reprod. toxicity (mg/kg bw/d)		100					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Invasive species in agricultural and non-agricultural areas. Post emergence of invasive species.	1 × 1800	Cereals Early (shoots)	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	22.3	1.0 × 0.19	7.63	13.1
		Fruiting vegetables BBCH 10 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.19	24.7	**4.04**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The Tier 2 TER_{Lt} values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to mammals is acceptable following the proposed use patterns on invasive species (Uses 8 and 9) except for the following scenarios where a refined risk assessment is required for the intended application rate:

- Fruiting vegetables; the small herbivorous mammal "vole" common vole (1 × 1800 g a.s./ha).

Higher tier – Long-term mammalian refined (Tier 3) assessment

As indicated in the tables above, further refinements of the long-term mammal risk assessment are required for the small herbivorous mammal "vole" considering two exposure scenarios, namely the 'Grassland – all season' scenario and the leafy vegetable (BBCH 40 – 49) scenario for applications to control invasive and noxious weeds and for application to railroad tracks at 1800 g/ha.
In addition to the refined TWA and MAF values applied for the Tier 2 assessment, use specific considerations and a further refined chronic mammalian endpoint is considered for risk assessment.
Annex M-CA 8.02 of the document M-CA Section 8, presents further information to support a further refinement of the chronic mammalian endpoint. In the toxicology section of the dossier submission (M-CA Section 5), a weight of evidence position is presented concerning the relevance of the rabbit developmental toxicology study for use in risk assessment. The toxicology section presents a weight of evidence to support the conclusion that the observed maternal effects in this study type are not due to systemic exposure to glyphosate, but are due to GI-tract irritation resulting from the dosing route.
An additional endpoint is presented in Annex M-CA 8-02 of the document M-CA Section 8, based on the results of seven rat developmental toxicity studies, where an endpoint of 300 mg/kg bw/day is concluded.

Applying this endpoint to the chronic mammal risk assessment considering single and multiple applications at 1800 g/ha to control invasive species or for application on railroad tracks with a daily dietary dose value of 24.7 mg/kg diet (
and Table 10.1.2-34) for the two exposure scenarios as described above, results in TER values of 12.1 for both scenarios, which exceeds the trigger value of 5. Thus, indicating that an acceptable exposure risk to small herbivorous mammals can be achieved for application of MON 52276 to control invasive and noxious weeds and for application on railroad tracks.

The results of multi-generational studies in rats are also discussed in Annex M-CA 8-02 of the document M-CA Section 8. The 700 mg/kg bw/day NOAEL achieved for this study type demonstrate the expected reduction in the risk, where animals are exposed via the diet, which would be the route of exposure in the field.

Further considerations are presented in the following to support an acceptable chronic exposure risk to mammals for all proposed GAP table uses of MON 52276.

Railroad tracks

The application of the product on railroad tracks is done by spray trains. These trains are equipped with high resolution cameras and are able to identify weeds on the tracks. The product is applied very targeted to the weeds and only on those sections were weeds are present. Thus this application method is not comparable to a standard broadcast application where application takes place on the whole area. In general railroad tracks are placed on aggregate, i.e. small rocks, providing an environment for plants which are adapted to dryer conditions. Due to management and rather dry and hostile conditions that a railroad track provides, it is not expected that dense and long grass vegetation would be present, thus creating an uninviting habitat for small mammals to exist, feed and burrow.

According to Le Louarn & Quere (2003)[15] the common vole is a grassland species and inhabit meadows, set-aside land, flower strips as primary habitats. It lives in shallow burrows rarely more than about 30 cm

[15] Le Louarn, H., Quéré, J. P. Les Rongeurs de France. Faunistique et biologie. INRA Editions, Paris, France, pp. 1-256 (2003)

deep (Stein, 1958)[16]. These primary habitats provide food and shelter from predators so that monthly survival of voles in primary habitats like set-aside grasslands is about 0.5 – 0.6, while being close to zero in arable fields (Jacob & Halle 2001)[17]. According to Stein (1958)[4] secondary habitats for voles are cropped areas such as grain cereals, oilseed rape, peas, beans, carrots and occasionally sugar beet and potato fields. Jacob *et al.* (2014)[18] conclude that those secondary habitats may be invaded by voles when the carrying capacity (critical population density) of primary habitats is exceeded. According to Frank (1957)[19] and Briner et al (2005)[20] common voles of both sexes tend to be highly territorial, when population densities are low.
Railroad tracks might be occasionally visited by voles when population densities are high in [9]primary habitats but it can be assumed that they don't spend much time in such hostile environments. Due to disturbance, rather dry conditions and the risk from predators, typical primary or secondary habitats provide better environmental conditions for voles than railroad tracks. Therefore the small herbivorous mammal "vole" should not be regarded as a relevant focal species on railroad tracks. Therefore, to provide a conservative approach for the application on railroad tracks 50 % of the application rate could be taken into account for an alternative refined chronic risk assessment.

By virtue of the very high residues per unit dose (RUD) value for common voles feeding on 100 % grasses as stated in the EFSA /2009/1438 guidance document, the vole is considered the worst-case exposure model / focal species. An acceptable risk assessment for the common vole is considered protective of all focal mammal species in the EFSA guidance. It is highly probable that other mammal species may frequent the habitats associated with railroad tracks. However, the Tier I level of the risk assessment – for both the small omnivorous (e.g., woodmouse) and large herbivorous mammals (e.g. rabbits and hares) was considered acceptable across all proposed GAP table uses.

An additional point is that across the EU, different vole species exist and for some EU member states, different small mammal species are considered more relevant to the risk assessment, based on the local situation or due to the level of protection for this particular being considered differently in different member states. ([21]Jacobs *et al.*, 2014).

A full risk assessment covering all focal mammal species is presented in the Annex M-CP 10-03 to this dossier section that covers all mammal focal species feeding guilds. Worst case representative focal species from each of the feeding guilds across all mammal species in the EFSA guidance are considered in the presented assessment above.

<u>Control of invasive species</u>

For the use on invasive species on agricultural and non-agricultural areas (Uses 8-9) the product MON 52276 is intended to be applied on the two invasive species; Giant hogweed (*Heracleum montegazzianum*) and Japanese knotweed (*Reynoutrica japonica*). Both species are easily recognisable, are usually well known by operators and can reach impressive sizes (more than 2 m height).

[16] Stein, G.H.W. Die Feldmaus. Franckh'sche Verlagshandlung, Stuttgart, Germany (1958).
[17] Jacob, J., Halle, S. The importance of land management for population parameters and spatial behaviour in common voles (*Microtus arvalis*). Advances in Vertebrate Pest Management II. Filander Verlag, Fürth, Germany, pp. 319-330 (2001)
[18] Jacob, J., Manson, P., Barfknecht, R., Fredricks, T. Common vole (Microtus arvalis) ecology and management: implications for risk assessment of plant protection products. Published online in Wiley Online Library (15th January 2014).
[19] Frank, F. The causality of microtine cycles in Germany. The Journal of Wildlife Management 21(2): 113-121 (1957)
[20] Briner, T., Nentwig, W, Airolid, J.P. Habitat quality of wildflower strips for common voles (*Microtus arvalis*) and its relevance for agriculture. Agriculture, Ecosystems & Environment 105:173-179 (2005)
[21] Jacob, J., Manson, P., Barfknecht, R., Fredricks, T. (2014) Common vole (Microtus arvalis) ecology and management: implications for risk assessment of plant protection products. Pest Management Science 70:869-878

Control of invasive plant species that pose a risk to man and society, may be achieved by direct targeted overspray of the plant or by first cutting back the plants and applying directly to fresh regrowth. In both cases, the aim is to achieve exposure of the plant systemically, targeting all growing areas of the plant. The type of plant to be controlled and the density of plants in the target area, will dictate the management approach that is ultimately used. In all cases, the spray applications made, will be directed and targeted to a specific plant or stand of plants. This approach contrasts with a boom spray application where the entire area under the boom is exposed, whether there is a target plant present or not. It is therefore appropriate when considering applications made to control invasive species, that the total applied area considered in the risk calculation, is reduced compared to a boom spray application, given the very directed and targeted application method used, which includes use of shielded sprayers that further reduces the risk to non-target plants.

When spraying invasive species, different plant density scenarios are applicable. A small reduction in the application rate (10 – 30 % reduction) would reflect a scenario where a high density of invasive species can be expected. Such a scenario is considered relevant in non-agricultural fields where higher densities of the invasive species Giant hogweed or Japanese knotweed may occur. Therefore, as a conservative worst case approach a reduction of the application rate to 90 % can be taken into account for an alternative chronic risk assessment in non-agricultural areas.

In agricultural areas farmers won't tolerate higher amounts of invasive species in their fields. Thus, the density in comparison to non-agricultural fields is much lower and plants are more dispersed as they are not allowed to spread over several years. In case the product is applied by hand-held equipment to invasive species at BBCH stages when the intended crop is present it can be expected that only few invasive species are present and that the operator avoids exposure of cultured crops. In conclusion, to address the lower plant density of invasive species in agricultural fields, a 40 % reduction in the application rate based on the reduced total area can be applied in an alternative risk assessment. This is also considered appropriate to cover the chronic risk to mammals.

Drinking water exposure

Only the puddle scenario is relevant for risk assessment for mammals through drinking water.

Puddle scenario

The 'Puddle scenario' is relevant for mammals taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil. This is therefore relevant for all uses of MON 52276 and should therefore be assessed.

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary since the ratio of effective application rate (in g/ha) to acute and long-term endpoint (in mg/kg bw/d) does not exceed 50 (K_{OC} < 500 L/kg) or 3000 ($K_{OC} \geq$ 500 L/kg), as specified in EFSA/2009/1438.

As pointed out in EFSA/2009/1438, specific calculations of exposure and TER values are only necessary when the ratio of effective application rate (in g a.s./ha) to relevant endpoint (in mg a.s./kg bw/d) exceeds 50 in the case of less sorptive (K_{OC} < 500 L/kg) or 3000 in the case of more sorptive ($K_{OC} \geq$ 500 L/kg) substances.

For glyphosate, the ratio of highest application rate (1800 g a.s./ha) to lowest relevant endpoint (NOAEL = 100 mg a.s./kg bw/d) is 18. As the $K_{f,OC}$ for glyphosate is 4245 mL/g (See M-CA Section 7) the risk can be considered acceptable without the need for further calculations.

Effects of secondary poisoning

According to the EFSA/2009/1438, substances with a log $P_{OW} \geq 3$ have potential for bioaccumulation and should be assessed for the risk of biomagnification in aquatic and terrestrial food chains.

Since the log Pow values of glyphosate is log $P_{OW} < -3.2$ (pH 2 – 5, 20 °C), the active substance is deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment from secondary poisoning is therefore required.

The primary metabolite of glyphosate is aminomethylphosphonic acid (AMPA). Most of the parent glyphosate is eliminated unchanged and only a small amount (less than 1 % of the applied dose) is transformed to aminomethylphosphonic acid (AMPA). The metabolite AMPA has been tested in several mammal toxicity studies which demonstrated that it is of lower toxicity than glyphosate acid (see Section CA 5.8). Furthermore, the log P_{OW} for AMPA – estimated via EpiSuite Program and SMILES code (C(N)P(=O)(O)O) – is -2.47 and does not indicate a potential for bioaccumulation (EFSA Journal 2015;13(11): 4302).

Indirect Effects Via Trophic Interaction

A large regulatory dataset exists with acute and long-term studies to inform the wild mammal risk assessments, with the results of the wild mammal risk assessments (MCP 10.1.2) that demonstrate that under the intended uses of glyphosate there is negligible risk of direct effects.

An assessment of indirect effects is in part covered by the current EFSA Birds and Mammals assessment guidance through an evaluation of the potential for secondary poisoning (e.g., consumption of earthworms, fish, drinking water). However, methodology for assessing indirect effects through trophic interaction resulting from in-crop weed control was not addressed. Throughout the development of the EFSA (2009) guidance document, it was raised that indirect effects through trophic interactions should be eventually be addressed, and it was decided when the guidance was finalized that this topic would need to be addressed in revised guidance. However, many experts in the Member States who reviewed the birds and mammals guidance document commented that this is an area that requires further research and that it may be preferable to manage indirect effects to birds and mammals through mechanisms other than pesticide approvals (e.g., farmland management and/or conservation policies).

The following assessment approach considers both direct effects and the potential for indirect effects via trophic interactions, based on the proposed Specific Protection Goals drawn from the existing EU guidance and working documents, and the 2016 EFSA Guidance on developing protection goals for ecological risk assessments (ERA) for pesticides. The SPGs based on direct effects assessment considering representative sensitive populations across the tested trophic levels. The biodiversity assessment, aimed to develop a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals, that includes considering indirect effects via trophic interaction. For example, reduced application rates relative to previous Annex I renewals, a reduced overall application volume of product on the land, and inclusion of no-spray buffer zones as a standard mitigation measure to protect edge of field surface waters. When defining SPGs for mammals, it is the responsibility of the risk assessors in the Member States to acknowledge existing protection goals and regulatory data requirements, to propose possible SPG options, and describe the possible environmental consequences of each option. The risk assessors within the Member States will need to propose realistic SPGs and exposure assessment goals and the interrelationships between them in a clear and transparent manner.

Biodiversity Assessment.

The assessment approach – as previously defined aims to assess the potential indirect effects via trophic interactions and the impact on biodiversity, by developing a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals. In the following table, the specific protection goals relevant to mammals are presented with the relationship between the SPGs, the direct effects study types, assessment and measurement endpoints. The assessment endpoint is an explicit expression of an environmental entity and the specific property of that entity to be protected. Measurement endpoints relates directly to the effects study endpoints.

A conclusion that a given data requirement has been satisfied, requires that an acceptable level of risk has been achieved (i.e. there is a protective margin of exposure or through a weight of evidence).

Based on the measurement endpoints from the study types, and the direct effects assessment presented above in this section, direct effects from glyphosate on aquatic organisms are not anticipated.

The impact on mammalian species will be additionally supported by the required in-field no spray buffer area for the NTTPs, which will protect mammals occurring in field margins.

The following table assessment illustrates that ecological function of wild mammals in off-target areas/ edge of field, will be sufficiently maintained to achieve the SPG for wild mammals according to the protection goals as defined in the EFSA guidance that sustains habitat and food resources for other organisms.

Table 10.1.2-35: Protection Goals and Associated Assessment and Measurement Endpoints for Wild Mammals.

Specific Protection Goals[1]	Assessment Endpoints	Measurement Endpoints	Glyphosate Study Types
No visible mortality and long-term impacts on abundance and diversity	No reduction in survival, growth, development, reproduction of avian populations.	Survival, growth, development and reproduction	Acute oral avian and rat Avian reproduction Rabbit teratology Rat 2-generation
Wild Mammal Biodiversity Assessment Based on the current direct effects risk assessment for glyphosate, there is acceptable acute and long-term risk assessments based on current guidance and the intended use patterns for glyphosate. However, if additional risk mitigation measures are determined to be required based on local conditions, to mitigate indirect effects resulting from in-crop weed control on mammalian populations, options to be considered by risk assessors and risk managers within Member States are presented in Table 10.1.2- **36**.			

[1] When protection goals are defined more precisely by risk managers or legislators to address indirect effect, then the protection goals and assessment procedures should be revised.

Scientific literature that informs the wild mammal indirect effects assessment

The residue left over on the soil surface from practicing conservation tillage increases cover and benefits to wildlife. The general rule is that the greater the amount of crop residue a tillage practice leaves on the surface, particularly standing residue, the better the practice is for small mammals, acting as a refuge from predation but also providing a habitat in which food items will occur. The studies on the benefits of conservation tillage have shown that fields using conservation tillage, where there may be an increase in crop residue, tend to increase the diversity of small mammals in crop fields. In addition, crop residues also harbor insects and other arthropods that are an important food source for wild mammals.

For mammals, studies on indirect effects through trophic interactions at the population level are generally lacking. However, a number of studies have investigated the potential for indirect effects of on birds and mammals in managed forest systems. Studies on small mammals (i.e., rodents, shrews, voles, chipmunks) have shown that some short-term changes after forestry applications of glyphosate were observed at the species (Anthony and Morrison, 2985; D'Anieri *et al.* 1987; Gagné *et al.* 1999) and functional feeding group levels (Santillo *et al.*, 1989a), which the authors attributed to the reduction in invertebrates, plant cover, and food. At the population level, glyphosate did not appear to have significant or long-lasting effects in the first few years after application (D'Anieri *et al.* 1987; Santillo *et al.*, 1989a; Sullivan *et al.* 1987). Similar to small mammals, changes in bird community composition, and reductions in abundance, densities and species richness of bird populations often occurred in the first few years after glyphosate application (Guiseppe *et al.* 1986, Easton and Martin, 1998, Santillo *et al.* 1989b), and in Santillo *et al.* (1989b) the decline in bird densities was correlated with the decline in habitat complexity. These changes were assessed against untreated control sites to differentiate the effects of glyphosate from other background environmental factors such as the recovery trajectory following tree harvest and showed similar responses to other herbicides commonly used in managed forests (Guvnn *et al.*, 2004).

Sullivan and Sullivan (2003) published a comprehensive glyphosate assessment addressing vegetation management and ecosystem disturbance focusing on plant and animal biodiversity that consider direct and indirect effects. Their analysis was based on 60 published studies of terrestrial plants and animals in temperate forests and agroecosystems. Species richness of plants was either unaffected or increased in the case of herbaceous species in those receiving glyphosate treatments. Species richness and diversity of songbirds, in open habitats representative of agricultural lands, did not appear to be negatively impacted in glyphosate use areas. In fact, conservation tillage, which is enabled by glyphosate, promoted greater abundance of songbirds and other fowl compared with ploughed fields (McLaughlin and Mineau, 1995; Cunningham *et al.*, 2005). Similarly, in studies on small mammal communities, there was no long-term negative impact on species richness and diversity. When there were declines in some species of small mammals, they were transient and other species of small mammals in those systems increased likely because they were better generalists in these systems. Larger mammalian herbivores (e.g., rabbit, deer) were not negatively affected by glyphosate treatments. However, assessment of a wide range of terrestrial invertebrate taxa showed variable responses in abundance and their diversity is largely a function of the degree of vegetation control. Overall, the magnitude of changes in species richness and diversity of plants, birds, small mammals in the studies reviewed by Sullivan and Sullivan were within the mean range of natural fluctuations and considered direct and indirect effects.

Conclusion:
Based on the current direct effects risk assessment for glyphosate, there is acceptable acute and long-term risk based on current guidance and the intended use patterns for glyphosate. Currently, the EFSA birds and mammals guidance does not include assessment methodology for indirect effects through trophic interactions. Addressing potential indirect effects to birds and mammals by limiting in-crop weed control or compensating for its effects may be better handled though policies and programs outside the PPP framework. However, if additional risk mitigation measures are concluded to be required, to mitigate indirect effects resulting from in-crop weed control on avian populations, options to be considered by risk assessors and risk managers within Member States are presented in Table 10.1.2-36. These mitigation options will bring the greatest ecological benefit when implemented in simplified landscapes or in intensified production areas, where the refuge areas for insects, birds and mammals are limited. It is anticipated that this measure will not bring a high ecological benefit in complex landscapes where enough refuges are available off-field.

Risk mitigation options to address direct and indirect effects to ecological species
Environmental risk mitigation measures are a key component in defining the conditions of use of pesticides in crop protection in Europe ((EC) No 1107/2009) and (EU) No 547/2011). These risk mitigation measures are derived directly from the evaluation of pesticide products and the risk assessment conducted for each use and are specific of the type of risk they are intended to mitigate. They therefore range from the adjustment of the conditions of use, to minimizing transfers to surface and groundwater, to the setting of buffer zones at the edge of the crop, and to requiring compensatory measures (e.g., field margins).

Risk mitigation measures can be divided into "standard" mitigation measures where an impact can be calculated in the frame of environmental risk assessment and "non-standard" mitigation measures where the impact on biodiversity cannot be directly expressed in numerical values. It needs to be noted that biodiversity related mitigation measures need to be adapted to the local Member State level, to the local environmental circumstances (e.g. landscape), to the local biodiversity conservation status and to the desired protection and conservation goals.

It is therefore appropriate to consider the available mitigation tools available across the EU that could be applied by risk managers. Currently, the most up-to-date compilation of plant protection mitigation tools available across Europe was compiled during a series of workshops in 2013 under the auspices of the

Society of Environmental Toxicology and Chemistry (SETAC) and the European Commission. The goal of the MAgPIE workshops was to develop a toolbox of mitigation measures from across the EU. The outcome of these workshops was a proceedings published in 2017 "Mitigating the Risks of Plant Protection Products in the Environment MAgPIE.

The MAgPIE workshop proceedings and associated publications were inventories of the available risk mitigation options across the various Member States in the EU and included a toolbox of recommendations in view of future implementation.

Examples of the standard mitigation measures considered applicable at the EU level (MAgPIE, 2017) are presented in the following table. Many of these have been considered in the current dossier submission.

Table 10.1.2- 36: Types of standard risk mitigation measures described in MAgPIE across the various Member States to mitigate effects on biodiversity and how they could be applied to glyphosate products.

Type of Mitigation Measure	Risk Mitigation Measure	Benefits	Glyphosate renewal dossier (2020)
Restrictions or modifications of products' conditions of application	Application rate, Application frequency, application timing, and interval between applications	Lower transfers to groundwater and surface water; Reduces exposure of organisms in-crop and off-crop.	**Significant reductions (50 % in volume) in newly proposed application rates** compared with the representative use presented in the 2012 renewal dossier. See[22] **Appendix 2** of the biodiversity report that accompanies this submission. **Treated area restriction** 4. for the representative use GAPs: applying to only 50 % of the total area in orchard/vineyard area. 5. maximum of 50 % of the total area for broad acre vegetable inter-row 6. Invasive species control e.g., couch grass – maximum of 20 % of the cropland + extended application intervals. **Limited frequency and timing of application:** 28-day interval between applications and no pre-harvest applications
Application equipment with Spray Drift Reduction Technology (SDRT)	Spray drift reduction nozzles (SDRN), shields, Precision treatment, etc.	Reduces exposure of organisms in-crop (precision treatment) and off-crop	**Reduction of spray drift to the off-field**: 3. Use 75 % drift reducing nozzles for pre-sowing/pre-planting in arable crops. 4. Use of ground directed, shielded spray for band application in orchards / vineyards and broad-acre vegetable inter-row application.
Buffer zones	Non-sprayed zone at the edge of a crop	Reduces exposure of organisms and off-crop	**Establishment of buffer zones:** Buffer zones of varying size (depending on the type of SDRT) are required as protection for off-crop NTTP communities from spray drift.

For example in the current dossier;

[22] [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

- Reductions in maximum annual application rates of up to 50 % are considered in this dossier compared to the maximum rates applied for in the 2012 Annex I renewal dossier.
    - In 2012, the maximum annual application rate was 4.32 kg/ha.
    - In the current dossier submission, the maximum annual application rate is 2.16 kg/ha

- Reducing the total area being applied on a per hectare basis for certain uses, will reduce the total volume of product being applied to the landscape.
    - For example, controlling actively growing weeds in vineyards, orchards where a reduced area, up to a maximum of 50 % of the total application area is proposed e.g. using strip or band applications. Applications target weeds around the base of trees within tree rows, leaving the area between tree rows unsprayed, which is typically managed using mechanical methods.

- The use of shielded or hooded sprayers, hand-held sprayers and drift reducing technologies, e.g. 75% drift reducing nozzles are recommended for all applications made for the control of actively growing weeds when applied to control invasive species. These measures will further reduce the off-target exposure risk.

- For weed control on railroad tracks, recommendations are made in the GAP table to use precision application equipment on spray trains, that detects and targets spray directly onto unwanted plants, thereby reducing the amount of product being applied, whilst maintaining an acceptable level of safety on the railroad tracks.

- No spray buffer areas in-field, are necessary to meet the specific protection goals for avoiding direct effects on non-target plants in off-target areas. This measure will in turn support non-target arthropod communities in off-field areas and reduces further, the potential for indirect effects on bees through trophic interaction.

In addition to the standard mitigation measures, 'non-standard mitigation measures' could also be considered where a local and specific mitigation need is identified. For example, in simplified landscapes or landscapes that are intensively managed, where typically there are limited refuge areas for insects, birds and mammals. Non-standard mitigation measures options could include for example, creation of off-target habitats, utilizing edge of field habitats and semi-field habitats that assist biodiversity by improving wildlife connectivity. However, these measures will bring the greatest ecological benefit when implemented in simplified landscapes or in intensified production areas, where the refuge areas for insects, birds and mammals are limited. It is anticipated that this measure will not bring a high ecological benefit in complex landscapes where enough refuges are available off-field.

For further information on mitigation measures pleased refer to the supplementary information document[23] titled 'Glyphosate: Indirect Effects via Trophic Interaction – A Practical Approach to Biodiversity Assessment.' that accompanies this dossier submission.

CP 10.1.2.1 Higher tier data on mammals

Additional studies are not considered to be required, since sufficient information is available from studies performed with the active substance and the representative product. Furthermore, the risk assessment for mammals indicates an acceptable ecotoxicological risk for mammals in consideration of each potential route of exposure from the proposed uses in the GAP; in field crops, orchards, vineyards, railroad tracks and non-agricultural areas.

See MCA Section 5 for detailed summary of the acute study conducted with MON 52276.

[23] [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

CP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A consideration of the potential effects of glyphosate and glyphosate products on amphibians was part of the previous Annex I renewal of glyphosate in the EU (Glyphosate RAR 11 Vol. 3 CA-CP_B9, 2015).

The RAR (2015) produced by the UBA for the last Annex I submission for the renewal glyphosate in the EU contained an extensive review of the available public domain literature on amphibians and the potential for effects on amphibians. Since the last Annex I renewal guidance on how to conduct environmental risk assessment on amphibians – specifically terrestrial phase amphibians has not been forthcoming. The assessment for both, the aquatic and terrestrial life phases, is still considered to be covered by the risk assessments on aquatic organisms (covering the aquatic life phases) and the terrestrial vertebrates covering the terrestrial life phases.

In the previous Annex I renewal RAR (2015), a review was presented that considered acute and chronic amphibian toxicity studies in the public domain literature, conducted with glyphosate and / or commercial glyphosate-based formulations. The RMS (UBA) considered acute effects based on studies with 96 hours or less duration. Chronic studies were evaluated that focused mostly on lethality effects, with some studies considering effects of glyphosate formulations on body weights and/or performance at metamorphosis. There were very few studies considering effects on terrestrial stages of amphibians.

In the current literature review to support the 2020 submission for Annex I renewal in the EU, the available [24]guidance have been used to distinguish which public domain literature are relevant and reliable for inclusion into the ecotoxicological risk assessment.

There were a number of acute toxicity endpoints presented in the RAR (2015) for amphibians exposed to glyphosate and its salts range from >17.9 to >466 mg a.s./L (see table below), which were summarised in the following way:

[24] EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092. 49 pp. doi:10.2903/j.efsa.2011.2092

Table 10.1.3-1: Effect values reported in peer reviewed literature for amphibians of glyphosate acid and salts of glyphosate

Species	Substance	Study duration	LC_{50} (mg a.s./L)	Reference
Crinia insignifera tadpoles	Glyphosate acid	96 h	103.2	Bidwell & Gorrie 1995 glyphnosubm_023
Crinia insignifera adult	Glyphosate acid	96 h	75.0	Bidwell & Gorrie 1995 glyphnosubm_023
Litoria moorei tadpoles	Glyphosate acid	48 h	81.2	Mann & Bidwell 1999 glyphnosubm_024
Litoria moorei tadpoles	Glyphosate acid	48 h	121.0	Mann & Bidwell 1999 glyphnosubm_024
Crinia insignifera adult	Glyphosate acid	48 h	83.6	Mann & Bidwell 1999 glyphnosubm_024
Rana clamitans	Glyphosate IPA	96 h	> 17.91	Howe *et al.*, 2004 glyphecotox_025
Lymnodynastes dorsalis tadpoles	Glyphosate IPA	48 h	> 400.0	Mann & Bidwell 1999 glyphnosubm_024
Litoria moorei tadpoles	Glyphosate IPA	48 h	> 343.0	Mann & Bidwell 1999 glyphnosubm_024
Crinia insignifera tadpoles	Glyphosate IPA	48 h	> 466.0	Mann & Bidwell 1999 glyphnosubm_024
Heleioporus eyrei tadpoles	Glyphosate IPA	48 h	> 373.0	Mann & Bidwell 1999 glyphnosubm_024

Of note in the previous Annex I evaluation was the influence of surfactants on the toxicity of glyphosate-based herbicides containing specific surfactant classes, to amphibians, being far lower than for glyphosate acid or its salts. The surfactants displaying a high toxicity in glyphosate-based formulations belonged typically to the classes of poly-oxyethoxylated alkylamines (POEA; e.g. ethoxylated tallow- and cocoamines) - or are e.g. fatty nitrogen derivate etheramines. The representative formulation (MON 52276) does not contain surfactants belonging to these classes of compounds. Across 26 different studies that were considered in the RAR (2015), considering glyphosate-based products that contained POEA based surfactants or surfactants considered to be very similar, the acute LC_{50} values ranged between 1.1 and 17.9 mg a.e./L. The products considered were IPA salt-based formulations containing a similar loading of glyphosate compared to the representative formulation.

Based on the aquatic toxicity profile of MON 52276, it is evident that the formulated product is less sensitive to a range of aquatic organisms compared to the technical material.

Further information on the effects of surfactants such as POEA and the implications of exposure to these types of surfactants by amphibians are described in detail in the previous literature review presented in the RAR (2015), Section B9.11.

Concerning terrestrial phase amphibians, the risk assessment for birds and mammals is considered protective of terrestrial phase amphibians in terrestrial environments.

In the conclusions drawn by the RMS (UBA), it is indicated that the findings from the reviewed public literature data on amphibians pointed towards toxicity of surfactants in the glyphosate-based formulations. In some cases, the experimental difficulties or set-ups were considered contributing factors, but overall the results indicate effects of ethoxylated surfactants on amphibians and that there were implications for registering glyphosate-based products containing these types of surface-active chemicals. The representative formulation does not contain POEA or ethoxylated surfactants known to be of toxic concern to amphibians. In fact, the aquatic toxicity profile of MON 52276 is substantially protected by the ecotoxicological profile of the active substance.

Risk assessment / Weight of evidence

Of the current literature reviewed for the Annex I renewal, the following paper was considered to have been conducted according to an appropriate test guideline and is reviewed below.

Table 10.1.3-2: Literature on toxicity of representative formulation to Amphibians

Study	Study type	Substance(s)	Status	Remark
Daam *et al.*, 2019	Lethal toxicity of the herbicides acetochlor, ametryn, glyphosate and metribuzin to tropical frog larvae.	Glyphosate technical (99.2 % purity)	Relevant and reliable	The 96 h LC_{50} for glyphosate technical exposure to two tropical frog species; *Physalaemus cuvieri* and *Hypsiboas pardalis* were determined to be 115 and 106 mg a.s./L,respectively. The author concluded that these data were protective of tropical amphibians.

In Daam *et al.*, (2019) despite some uncertainty over the analytical integrity of the studies i.e., analytical exposure could not be confirmed from the paper, effects of a glyphosate-based herbicide on tadpoles of the tropical amphibian species using a recognised experimental approach, with tadpoles exposed for 96 hours after dispersion of the test substance into water. Data previously evaluated by the RMS (UBA) from the paper by Bidwell (1999) was also considered, where it was concluded that glyphosate based herbicides were much less toxic than technical glyphosate. The achieved endpoints in Daam, are not considered in the risk assessment as the assessment for fish is considered protective.

From the reviewed papers that were part of the literature review, but that were not considered relevant to the assessment as they were not conducted on a formulation related to the representative formulation, terrestrial phase and aquatic phase amphibians were assessed. The findings from these studies are considered briefly in the following paragraphs to address the possible impacts of glyphosate-based herbicides on terrestrial phase amphibians.

In the relevant but supplemental studies by Edge *et al.*, 2012, 2013 and 2014, larval and juvenile amphibians were exposed to glyphosate-based herbicides in extended field experiments. In Edge, (2012) a replicated field experiment in a wetland habitat, demonstrated that exposing amphibian larvae to a glyphosate-based herbicide under field conditions (Roundup Vision) at applications rates up to 2.88 kg a.e./ha had negligible impact on survival or growth of green frogs (*Lithobates clamitans*). In Edge, (2013) both laboratory and field experiments were conducted with exposure of two frog species to a glyphosate-based herbicide to assess the effects on survival, liver somatic index, body condition and the incidence of disease caused by *Batachochyrtrium dendrotalis*. The results concluded that glyphosate-based herbicide (Roundup WeatherMax) was unlikely to cause significant deleterious effects on juvenile amphibians at rates applied in silviculture up to 8.64 kg a.e./ha. A similar conclusion was drawn in Edge (2014) where amphibians growth and survival of wood frogs was also monitored following wetland exposure, with no toxicity observed in exposed individuals up to a maximum rate of 2.88 kg a.e./ha. Whilst these studies were not conducted with the representative formulation, they demonstrates that under field conditions, those endpoints achieved under laboratory conditions are ameliorated when exposure occurs in the field.

Considering the direct effects risk assessment, there is an amphibian toxicity test that is submitted as part of the submission. The study by [redacted] (2012) was a Glyphosate: Amphibian Metamorphosis assay for the detection of thyroid active substances. The study was conducted at water concentrations up to 90 mg a.e./L, and despite a slight increase in the wet weight of *Xenopus laevis* tadpoles at 90 mg a.e./L, there were no other effects observed in the study with no effects on growth and development, no mortality and no effects on the thyroid, following a 21 day exposure period.

Based on the available evidence from the current literature and the information presented in the previous RAR (2015), the risk to amphibians from exposure to the representative formulation, is considered to be within the toxicity profile of the active substance and as such, the risk assessments presented for aquatic organisms, specifically fish and also those for terrestrial vertebrates are considered to be protective.

For mammals, studies on indirect effects through trophic interactions at the population level are generally lacking. However, a number of studies have investigated the potential for indirect effects on birds and mammals in managed forest systems.

From a diversity and abundance perspective, studies on small mammals (i.e., rodents, shrews, voles, chipmunks) have shown that some short-term changes after forestry applications of glyphosate were observed at the species (Anthony and Morrison, 2985; D'Anieri *et al.* 1987; Gagné *et al.* 1999) and functional feeding group levels (Santillo *et al.*, 1989a), which the authors attributed to the reduction in invertebrates, plant cover, and food. At the population level, glyphosate did not appear to have significant or long-lasting effects in the first few years after application (D'Anieri *et al.* 1987; Santillo *et al.*, 1989a; Sullivan *et al.* 1987). Similar to small mammals, changes in bird community composition, and reductions in abundance, densities and species richness of bird populations often occurred in the first few years after glyphosate application (Guiseppe *et al.* 1986, Easton and Martin, 1998, Santillo *et al.* 1989b), and in Santillo *et al.* (1989b) the decline in bird densities was correlated with the decline in habitat complexity. These changes were assessed against untreated control sites to differentiate the effects of glyphosate from other background environmental factors such as the recovery trajectory following tree harvest and showed similar responses to other herbicides commonly used in managed forests (Guvnn *et al.*, 2004).

Sullivan and Sullivan (2003) published a comprehensive glyphosate assessment addressing vegetation management and ecosystem disturbance focusing on plant and animal biodiversity that consider direct and indirect effects. Their analysis was based on 60 published studies of terrestrial plants and animals in temperate forests and agroecosystems. Species richness of plants was either unaffected or increased in the case of herbaceous species in those receiving glyphosate treatments. Species richness and diversity of songbirds, in open habitats representative of agricultural lands, did not appear to be negatively impacted in glyphosate use areas. Similarly, in studies on small mammal communities, there was no long-term negative impact on species richness and diversity. When there were declines in some species of small mammals, they were transient and other species of small mammals in those systems increased likely because they were better generalists in these systems. Larger mammalian herbivores (e.g., rabbit, deer) were not negatively affected by glyphosate treatments. However, assessment of a wide range of terrestrial invertebrate taxa showed variable responses in abundance and their diversity is largely a function of the degree of vegetation control. Overall, the magnitude of changes in species richness and diversity of plants, birds, small mammals in the studies reviewed by Sullivan and Sullivan were within the mean range of natural fluctuations and considered direct and indirect effects.

Indirect effects via Trophic Interactions

Amphibians have both aquatic and terrestrial habitats. The biodiversity assessments presented for the aquatic organisms and for terrestrial invertebrates are considered protective of effects on amphibians occurring in both aquatic and terrestrial habitats. The no spray buffer area required to support the direct effects risk assessment for non-target terrestrial plants in off-target areas, is considered to also be protective of indirect effects on amphibians through loss of habitat and prey items in area surrounding the application areas.

Refer to the CP 10.1,1 10.1.2 and 10.2 for further information on the indirect effects assessment. In addition, please refer to [redacted]t. V (2020), Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment, submitted with this dossier submission.

Additional References relied upon in the Indirect Effects via Trophic Interactions Discussions

Anthony RG, Morrison ML, Influence of glyphosate herbicide on small-mammal populations in western Oregon. Northwest Sci. 1985, 59, 159–168.

D'Anieri P, Leslie D Jr, McCormack M. 1987. Small mammals in glyphosate-treated clearcuts in northern Maine. Can. Field-Nat. Ottawa ON, 101:547–550.

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Edge CB, Thompson DG, Hao C, Houlahan JE. 2012 A silviculture application of the glyphosate-based herbicide VisionMAX to wetlands has limited direct effects on amphibian larvae. Environ Toxicol Chem. 31:2375-83. doi: 10.1002/etc.1956. Epub 2012 Aug 16.

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Edge C, Thompson D, Hao C, Houlahan J. 2014. The response of amphibian larvae to exposure to a glyphosate-based herbicide (Roundup WeatherMax) and nutrient enrichment in an ecosystem experiment. Ecotoxicol Environ Saf. 109:124-32.

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Gagné N, Bélanger L, J Huot. 1999. Comparative responses of small mammals, vegetation, and food sources to natural regeneration and conifer release treatments in boreal balsam fir stands of Quebec. Can. J. For. Res. 29:1128–1140.

Guynn DC, Guynn ST, Wigley TB, DA Miller 2004. Herbicides and forest biodiversity-what do we know and where do we go from here? Wildl. Soc. Bull. 32:1085–1092.

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Santillo DJ, Leslie DM, Brown PW. 1989a. Responses of small mammals and habitat to glyphosate application on clearcuts. J. Wildl. Manag. 53:164–172.

Santillo DJ, Brown PW, Leslie DM. 1989b. Response of songbirds to glyphosate-induced habitat changes on clearcuts. J. Wildl. Manag. 53:64–71.

Sullivan DS, TP Sullivan. 2000. Non-target impacts of the herbicide glyphosate: A compendium of references and abstracts. 5th Edition. Applied Mammal Research Institute, Summerland, British Columbia, Canada.

Sullivan TP, Sullivan DS. 2003. Vegetation management and ecosystem disturbance: impact of glyphosate herbicides on plant and animal diversity in terrestrial systems. Env Rev 11:37-59.

McLaughlin A, Mineau P. 1995. The impact of agricultural practices on biodiversity. Agriculture, Ecosystems and Environment 55:201-212.

CP 10.2 Effects on Aquatic Organisms

Relevant and reliable studies for the risk assessment of aquatic organisms from the active substance glyphosate and the relevant metabolites (AMPA and HMPA) are summarised in the tables below, presenting the most sensitive endpoints for each organism group. Details of these studies are summarised in the document M-CA, Section 8, point 8.2 and relevant endpoints for the risk assessment are provided in the tables below.

Table 10.2-1: Endpoints and effect values of glyphosate relevant for the risk assessment for aquatic organisms

Reference	Test item	Species	Test design	Endpoint based on	LC/EC$_{50}$ (mg a.e./L)	NOEC (mg a.e./L)
Fish						
[redacted] 1995 CA 8.2.1/009	Glyphosate acid	*Lepomis macrochirus*	Acute, 96 h, static	nom	**47**	32
[redacted] 2010 CA 8.2.2.1/001	Glyphosate acid	*Oncorhynchus mykiss*	Chronic, 85 d (60 days post-hatch) ELS, flow-through	gm	-	**≥ 9.63**
Aquatic invertebrate						
[redacted] 1996 CA 8.2.4.2/003	Glyphosate acid	*Crassostrea gigas*	48h static	nom	**40**	32
[redacted] 1999 CA 8.2.5.1/001	Glyphosate acid	*Daphnia magna*	21 d Reproduction semi-static	nom	-	**12.5**
Algae						
[redacted] 1996 CA 8.2.6.2/006	Glyphosate acid	*Skeletonema costatum*	72h static	nom	E_rC_{50} = **13.5** E_yC_{50} = 9.0	-

Table 10.2-1: Endpoints and effect values of glyphosate relevant for the risk assessment for aquatic organisms

Reference	Test item	Species	Test design	Endpoint based on	LC/EC50 (mg a.e./L)	NOEC (mg a.e./L)
Aquatic macrophytes						
[redacted] 2012 CA 8.2.7/010	Glyphosate acid	*Myriophyllum aquaticum*	14 d static	nom	Relative increase: TSL: 78.7 FW: 12.3 DW: 25.2 RL: 18.0 Growth rate: TSL: 276 FW: 23.4 DW: 30.2 RL: > 500	Relative increase: TSL: 5.0 FW: < 5.0 DW: 50.0 RL: < 5.0 Growth rate: TSL: 5.0 FW: < 5.0 DW: 50.0 RL: < 5.0

a.e.: acid equivalents; nom: nominal; gm: geometric mean measured, GR: growth rate; Y: yield; TSL: total shoot length; FW: fresh weight; DW: dry weight; RL: root length.
Endpoints in **bold** are used for risk assessment

Table 10.2-2: Endpoints and effect values of AMPA and HMPA relevant for the risk assessment for aquatic organisms.

Reference	Test item	Species	Test design	Endpoint based on	LC/EC50 (mg/L)	NOEC (mg/L)
Fish						
[redacted] 1991 CA 8.2.1/019	AMPA	*Oncorhynchus mykiss*	Acute, 96 h, static	nom	**520**	-
[redacted] 2011 CA 8.2.2.1/003	AMPA	*Pimephales promelas*	Chronic, 33 d (7 days post-hatch) ELS, flow-through	nom	-	**≥ 12**
Aquatic invertebrates						
[redacted] 1991 CA 8.2.4.1/014	AMPA	*Daphnia magna*	48h static	nom	**690**	-
[redacted] 2011 CA 8.2.4.1/015	HMPA	*Daphnia magna*	48h static	nom	**> 100**	-
[redacted] 2011 CA 8.2.5.1/007	AMPA	*Daphnia magna*	21 d Reproduction semi-static	nom	-	**15**
Algae						
[redacted] 1998 CA 8.2.6.1/016	AMPA	*Pseudokirchneriella subcapitata* *(Raphidocelis subcapitata)*	72 h static	nom	**E_rC_{50} = 191** E_yC_{50} = 110	-

Table 10.2-2: Endpoints and effect values of AMPA and HMPA relevant for the risk assessment for aquatic organisms.

Reference	Test item	Species	Test design	Endpoint based on	LC/EC50 (mg/L)	NOEC (mg/L)
[redacted] 2011 CA 8.2.6.1/019	HMPA	*Pseudokirchneriella subcapitata* *(Raphidocelis subcapitata)*	72h static	nom	**E_rC_{50} > 120** E_yC_{50} > 120	-
Aquatic macrophytes						
[redacted] 2012 CA 8.2.7/011	AMPA	*Myriophyllum aquaticum*	14 d static	gm	Relative increase: TSL: 103.3 FW: 70.8 DW: 63.2 RL: 31.1 Growth rate: TSL: > 94.6 FW: 97.3 **DW: 72.0** RL: 150.1	Relative increase: TSL: 14.3 FW: 14.3 DW: 37.1 RL: 5.4 Growth rate: TSL: 14.3 FW: 14.3 DW: 37.1 RL: 5.4
[redacted] 2011 CA 8.2.7/012	HMPA	*Lemna gibba*	7 d	am	Fronds: **GR:> 123** Y:> 123 Biomass: GR: > 123 Y: > 123	≥ 123

a.e.: acid equivalents; nom: nominal; gm: geometric mean measured; am: arithmetic mean measured; GR: growth rate; Y: yield; TSL: total shoot length; FW: fresh weight; DW: dry weight; RL: root length.
Endpoints in **bold** are used for risk assessment

Studies on effects of the representative formulation MON 52276 on aquatic organisms to fulfil the data requirements according to EU Regulation No 284/2013 are presented in the following. Studies previously evaluated in either the monograph 2001 or the RAR 2015 were also included in this assessment. Studies considering the effects of MON 52276 on aquatic organisms were assessed for their validity to current and relevant guidelines and are presented in the following tables.

Table 10.2-3:Studies on the toxicity of MON 52276 to aquatic organisms

Annex point	Study	Study type	Test species	Substance(s)	Status	Remark
CP 10.2.1/001	[redacted] 1992	Acute, static	*Oncorhynchus mykiss*	MON 52276	Valid	
CP 10.2.1/002	[redacted] 1992	Acute, static	*Cyprinus carpio*	MON 52276	Valid	
CP 10.2.1/003	[redacted] 1992	Acute, flow-through	*Daphnia magna*	MON 52276	Valid	
CP 10.2.1/004	[redacted] 1992	Acute, static	*Selenastrum capricornutum* *(Raphidocelis subcapitata)*	MON 52276	Supportive[1]	No analytical verification of test concentrations
CP 10.2.1/005	[redacted], 2002	Acute, semi-static	*Lemna gibba*	MON 52276	Supportive[2]	Bacterial contamination

Table 10.2-3:Studies on the toxicity of MON 52276 to aquatic organisms

Annex point	Study	Study type	Test species	Substance(s)	Status	Remark
CP 10.2.1/006	[redacted], 2012	Acute, static	*Myriophyllum aquaticum*	MON 52276	Valid	

[1] The product study on algae ([redacted] 1992) was performed according to the valid test guideline at the time of conduct. In the last Annex I renewal, this study was evaluated and considered acceptable for use in risk assessment. See study summary for more details (CP 10.2.1/004).
[2] Concerning the product study performed on *Lemna gibba* ([redacted] 2002), the study was conducted according to the draft OECD 221 test guideline from October 2000. The currently adopted test guideline is largely unchanged from the draft guideline. In the last Annex I renewal, this study was evaluated and considered acceptable for use in risk assessment. See study summary for more details (CP 10.2.1/005).

Literature articles and peer-reviewed published data considered to be relevant and reliable or reliable with restrictions with regards to the impact of glyphosate on aquatic organisms are summarised in the table below. Full literature evaluation is provided in document M-CA Section 9. A summary of previously evaluated peer reviewed literature from the RAR 2015 is also available in Annex M-CA 8-01 of the document M-CA Section 8. Each literature article summary is presented below according to the respective annex point. For discussions of literature regarding toxicity to aquatic organisms, please see below.

Table 10.2-4: Literature on toxicity of glyphosate, metabolites and MON 52276 to aquatic organisms

Annex point	Study	Study type	Substance(s)	Status	Remark
CP 10.2.1/007	Gabriel, 2010. Toxicity of roundup (a glyphosate product) to fingerlings of *Clarias gariepinus.*	Acute study on African catfish	Roundup containing 360 g/l glyphosate	Relevant and reliable with restrictions	The effects of Roundup were tested in an acute test with *C. gariepinus* fingerlings. The 96 hour-LC_{90} was determined to be 19.91 mg prod./L.

In the last Annex I submission (RAR, 2015), 30 peer reviewed papers were submitted for the algal group, approximately 42 papers submitted on aquatic invertebrates and 60 papers submitted on aquatic vertebrates, with the majority of papers cited being conducted on formulated products and not with the active substance. The formulated product was not the representative formulation and therefore could not be directly related to the risk assessment to EU renewal. The conclusion by the RMS (UBA) was that there were no critical data that could directly be included in the environmental risk assessment for the active substance. The literature review from the previous Annex I renewal is included in Annex M-CA 8-01 of the document M-CA Section 8.

Concerning the recent literature review for the 2020 submission:

The document M-CA Sections 8.2.1 to 8.2.7 and Table 10.2-4 above, present relevant and reliable articles in the area of aquatic ecotoxicology, considered relevant to include in this section. The papers are considered relevant and reliable according to the EFSA guidance on submitting peer-reviewed open (EFSA (2011) literature review guidance.

In Antunes A. M. *et al.* (2017), KCA 8.2.1/021: Gender-specific histopathological responses in guppies *Poecilia reticulata* exposed to glyphosate or its metabolite aminomethylphosphonic acid, were assessed. This study was considered relevant and reliable with restrictions, due mainly to the lack of analytical dose verification. The study determined the acute exposure effects of glyphosate and AMPA to guppies after a 96 h exposure period. The test was conducted according to USEPA acute toxicity testing methods, and 96 h acute LC_{50} values for male and female guppies of 68.78 and 70.87 mg/L, and for AMPA of 80 and 164.32 mg/L, respectively were determined. Histopathological examination of tissues was also performed in the study, but it is not possible to relate the histopathological information presented in the paper, to a risk assessment for Annex I renewal from an ecotox perspective. The achieved endpoints do not affect the acute fish endpoints selected for the risk assessment and the outcome is unchanged.

Gholami *et al.*, (2013) KCA 8.2.1/022; Toxicity of roundup (a glyphosate product) to fingerlings of *Cyprinus carpio*. The acute toxicity of glyphosate was tested in an acute fish toxicity test with *C. carpio* fingerlings, where a 96 h-LC_{50} of 6.753 mg/L was achieved. The study is not however considered relevant to the EU Annex I renewal risk assessment, as the identity of the test substance cannot be confirmed and the fact there was no study validity criteria presented and test item exposure was not confirmed. Based on the available regulatory study toxicity data for glyphosate acid (96 hr LC_{50} > 100 mg a.e./L) and the representative formulation – MON 52276 (96 hr LC_{50} > 277 mg a.e./L), that are considered relevant and reliable, the achieved endpoint in this study should be treated with a high degree of caution. It is not therefore considered reliable for use in risk assessment.

In Daam M.A *et al.*,(2019), KCA 8.2.8/001: Lethal toxicity of the herbicides acetochlor, ametryn, glyphosate and metribuzin to tropical frog larvae, the acute exposure of glyphosate to *Phsalaemus cuvieri* and *Hypsiboas paradalis* amphibians, in 96 h acute toxicity tests according to ASTM and OECD methods were determined. For glyphosate the 96 hr LC_{50} values for *P. cuvieri* and *H. paradalis* were 115 and 106 mg/L, respectively. This study was conducted according to elements of OECD 241. However, validity criteria were not reported and it is unknown if the larvae were exposed to any other chemicals as no analysis of watershed water was provided. The source of the animals is also not reported. With no analytical verification of test concentrations reported in the article, exposure is difficult to confirm. Based on these uncertainties, this study is considered not to provide additional information to inform on the endpoint list and the risk assessment.

For Levine *et al.*, (2015) KCA 8.2.5.1/008; the data presented in the paper are relevant for use in risk assessment and the daphnia chronic and fish early life stage test endpoints are presented in the following risk assessment.

Gabriel U. U., 2010. CP 10.2.1/007; Toxicity of roundup (a glyphosate product) to fingerlings of *Clarias gariepinus*. The effects of Roundup were tested in an acute fish toxicity test with *C. gariepinus* fingerlings. The 96 h-LC_{50} was determined to be 15.88 mg prod./L. There is however insufficient information presented in the article to confirm the identity of the test substance used, therefore these data should be considered relevant but with restrictions over the uncertainty over the identity of the formulated product used. Based on the year the study was conducted and considering the Roundup products registered in the country at that time the study was conducted, it is highly probable that the formulation used contained a surfactant that is not used in the EU and is not relevant to the EU representative formulation. In the previous Annex I RAR (2015), the RMS (UBA) presented an extensive overview of acute fish toxicity endpoints achieved in studies performed with formulations containing POEA or related surfactants. The achieved endpoint in this study is within the range of endpoints achieved for POEA containing formulations. The results of the study would not affect the outcome of the presented fish acute risk assessment, with the PEC/RAC value still being < 1.0 based on the current PECsw values at FOCUS Step 1. However, given the uncertainty associated with the study and the test item identity, this endpoint should be considered with a degree of caution.

Rodrigues L. B. *et al.*, (2019) KCA 8.2.2.1/005; assessed the impact of the glyphosate-based commercial herbicide, its components and its metabolite AMPA on non-target aquatic organisms. The formulation tested contained POEA, which is not relevant to the EU renewal of glyphosate as the representative formulation does not contain POEA. Only technical data are considered in the following. An acute LC_{50} > 100 mg/L was determined. The FET data indicated some genotoxic damage from glyphosate at exposure concentrations beyond 10 mg/L. No other effects relevant to glyphosate were discussed. In this study, the acute toxicity of technical glyphosate, its metabolite aminomethylphosphonic acid (AMPA) and of a glyphosate based formulation (Antor 48) to zebrafish embryos was investigated. Glyphosate and AMPA caused no acute toxic effect (LC_{50}-96 h > 100 mg/L), while Antor 48 induced significant lethal effect in zebrafish embryo (LC_{50} 96 h = 76.50 mg/L). The study was stated to have been conducted according to OECD guideline 236, but there is no information on hatching rates in the treatment and control groups, so exposure of the embryo without a potential barrier function of the chorion cannot be confirmed. Concerning the validity of the study, four of the six validity criteria from the test guideline are mentioned in the paper (fertilization rate of embryo batches used was > 90 %, survival in the negative control group was > 90 %, temperature was maintained at 26 ±1 ºC and dissolved oxygen was at an acceptable level 8ppm). There is no information presented on the performance of the positive control group (3, 4-dichloroaniline) and no information provided on the hatching rates in the negative control group at 96 hours, which for the control group should exceed 80 %. As this information is not presented and the fact that there was no analytical verification of test concentrations reported, the reliability of the test and the achieved endpoints is considered questionable. Therefore, this study should be supportive information only.

The paper by Schweizer M. *et al.*, (2019) KCA 8.2.2.1/006; deals with how glyphosate and its associated acidity affect early development in zebrafish (*Danio rerio*). For Zebrafish (*Danio rerio*) embryos acutely exposed to glyphosate at concentrations between 1.69 and 1690.7 mg glyphosate/L (10 µM to 10 mM) for 96 h post fertilization (hpf) the LC_{10} and LC_{50} values (96 hpf) were calculated to be 65.1 mg a.s./L (385 µM) and 98.4 mg a.s./L (582 µM), respectively (in unbuffered glyphosate medium). Regarding heart rates the EC_{10} was 7.27 mg a.s./L (43 µM). Concerning hatching rate, 96 hpf -EC_{10} and EC_{50} values were 26.2 mg a.s./L (155 µM) and 37.9 (224 µM), respectively. For developmental delays at 24 hpf the EC_{10} was 21.3 mg a.s./L (126 µM). The test was conducted according to OECD 236 test guideline. Concerning the validity criteria in the OECD 236, despite the stated > 80% mortality in the positive control (>30% required) there are no details presented to confirm the level of mortality. The fertilisation rate of the batch of eggs used was not reported. Finally, acute endpoints based on developmental delay and heart rate are not relevant to an EU level risk assessment for Annex I renewal purposes. The test design is adequately described, however, there was no analytical verification of test concentrations reported in the study, thus the endpoints should be considered with some caution. Therefore, the study should be considered reliable with restrictions.

Then, of those papers considered relevant and reliable, Tian et al ., (2015) KCA 8.2.7/013, concerned the aquatic macrophyte 'Growth inhibition of two herbicides on *Spirodela polyrrhiza*, The effects of glyphosate to the aquatic macrophyte *Spirodela polyrhiza* was tested in a semi-static exposure of 7 days at concentrations between 8.4 and 20.902 mg/L. The 7 day-EC_{50} value was determined to be 12.817 mg/L. This species is closely related to *Lemna* sp. but does not present information that could influence the endpoint list used for the Annex 1 renewal. This study was conducted to guideline but not to GLP. The test concentrations were not analytically verified and thus the exact exposure concentrations of the aquatic macrophyte are unknown. Therefore, the derived endpoint is questionable and the study should be considered acceptable as supportive information only.

Endpoints of studies considered valid with the representative product MON 52276 are shown in the table below. In order to make a direct comparison of toxicity between studies conducted with MON 52276 and those conducted with IPA salt, glyphosate technical and glyphosate acid, the endpoints from all these studies have been converted to acid equivalents (a.e.). This conversion has been made by the acid equivalent purity of the test item stated in the reports.

Table 10.2-5: Endpoints and effect values of MON 52276 relevant for the risk assessment for aquatic organisms

Reference	Test item	Species	Test design	Endpoint based on	LC/EC$_{50}$ (mg a.e./L)
[redacted] 1992 CP 10.2.1/001	MON 52276	*Oncorhynchus mykiss*	Acute, 96 h, static	am	> 306
[redacted], 1992 CP 10.2.1/002	MON 52276	*Cyprinus carpio*	Acute, 96 h, static	am	> 277
[redacted] 1992 CP 10.2.1/003	MON 52276	*Daphnia magna*	Acute, 48 h flow-through	am	209
[redacted] 2012 CP 10.2.1/006	MON 52276	*Myriophyllum aquaticum*	14 d static	gm	relative increase: SL = 13.44 FW = 4.44 L DW = not determined RL = 5.84 growth rate: SL = 42.79 **FW= 10.33** DW = 143.34

a.e.: acid equivalents; nom: nominal; gm: geometric mean measured; am: arithmetic mean measured.
GR: growth rate; Y: yield; TSL: total shoot length; FW: fresh weight; DW: dry weight; RL: root length.
Endpoints in **bold** are used for risk assessment

The toxicity to aquatic plants from MON 52276 (E_rC_{50} = 10.33 mg a.e./L, fresh weight) is slightly higher compared to the toxicity shown by the active substance (E_rC_{50} = 23.4 mg a.e./L, fresh weight) but this is within a factor of 2.5 allowing for biological variability within the test systems and due to the impact of the additional components in the composition of the product that enhance the uptake of the active substance to the plant. Nevertheless the lower endpoint from the study with MON 52276 is used in the risk assessment as a worst case.

Risk assessment for aquatic organisms

The evaluation of the risk for aquatic organisms was performed in accordance with the recommendations of the Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009 (EF-SA Journal 2013; 11(7):3290); hereafter referred to as EFSA/2013/3290.

The table below summarises how the risk assessment for aquatic organisms considers all the proposed uses and the application rates presented in the GAP. The grey shaded cells indicate that a worst-case risk assessment for aquatic organisms for the proposed uses is provided below. The 'X" in the table indicates where PEC_{sw} values have been calculated and the risk assessment has been conducted. For completeness, all risk assessment is shown in Annex M-CP 10-04 to this document. PEC_{sw} values have been generated for glyphosate and the relevant metabolites; AMPA and HMPA. Where appropriate applications in spring and autumn have been considered and the maximum PEC_{sw} values from either application timing for each scenario has been used in risk assessment. Full details are provided in the environmental fate document M-CA Section 7.

Table 10.2-6: Risk assessment strategy for aquatic organisms

GAP number and summary of use	Maximum application rate, g/ha (28 day interval)							
	1 × 540	1 × 720	1 × 1440	3 × 720	2 × 1080	2 × 1440	1 × 1800	1 × 3600
Uses 1a-c: Applied to weeds; pre-sowing, pre-planting, pre emergence of **field crops.**		X	X					
Uses 2 a-c: Applied to weeds; post-harvest, pre-sowing, pre-planting of **field crops.**		X	X	X	X			
Use 3 a-b: Applied to cereal volunteers; post-harvest, pre-sowing, pre-planting of **field crops.**	X							
Use 4 a-c: Applied to weeds (post emergence) below trees in **orchards.**		X	X	X		X		
Use 5 a-c: Applied to weeds (post emergence) below vines in **vineyards**		X	X	X		X		
Use 6 a-b: Applied to weeds (post emergence) in **field crops BBCH < 20**		X	X					
Use 7 a-b: Applied to weeds (post emergence) around **railroad tracks**							X	X
Use 8 and 9: Applied to invasive species; 'Giant hogweed and Japanese knotweed' (post emergence) in **agricultural and non-agricultural areas**							X	
Uses 10 a-c: Applied to couch grass; post-harvest, pre-sowing, pre-planting of **field crops**		X	x					

X = this use is covered by the application rate indicated and PEC/RAC ratios are presented in Annex M-CP 10-04.
Grey shaded cells: worst case application scenario, risk assessment provided below.

In the following tables, the ratios between predicted environmental concentrations in surface water (PEC_{SW}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given for the worst-case use for each crop group as indicated below and for each organism group (risk assessment for all uses is presented in Annex M-CP 10-04).

- in **field crops** (covering GAP uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c); pre-sowing, pre-planting pre emergence, post-harvest. Field crops considered; root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables, sugar beets.
- in **orchards** (covering GAP uses 4 a-c) applied to weeds post emergence exposure below trees. Crops considered; pome/stone fruit, olives.
- in **vineyards** (covering GAP uses 5 a-c) applied to weeds post emergence exposure below vines. Crops considered; vines
- in **railroad tracks** (covering GAP uses 7 a-b). HardSPEC model used, non crop specific.
- in **agricultural and non-agricultural** areas to control invasive species (covering GAP uses 8 and 9) applied to weeds post emergence. Crops considered; Grass/alfalfa.

The relevant PEC_{SW} for risk assessments covering the proposed use pattern are taken from document M-CP Section 9.

The derivation of RAC values for the risk assessment is presented in the following tables. The most sensitive endpoint between the active substance (glyphosate, glyphosate acid or glyphosate salt) and the representative formulation MON 52276 is used to provide the representative RAC for each organism group and exposure (acute and chronic).

Table 10.2-7: Derivation of RAC values used in the risk assessment – glyphosate and relevant metabolites

Species	**Substance**	**Exposure**	**Results (µg/L)**	**Assessment Safety factor**	**RAC (µg/L)**
Glyphosate					
Lepomis macrochirus	Glyphosate acid	96 h	LC_{50} = 47000	100	470
Oncorhynchus mykiss	Glyphosate acid	85 d	NOEC ≥ 9630	10	963
Crassostrea gigas	Glyphosate acid	48h static	EC_{50} = 40000	100	400
Daphnia magna	Glyphosate acid	168 h	NOEC = 12500	10	1250
Skeletonema costatum	Glyphosate acid	72h static	E_rC_{50} = 13500	10	1350
Myriophyllum aquaticum	MON 52276	14 d static	E_rC_{50} = 10330	10	1033
AMPA					
Oncorhynchus mykiss	AMPA	96 h static	EC_{50} = 520000	100	5200
Pimephales promelas	AMPA	33 d flow through	NOEC = 12000	10	1200
Daphnia magna	AMPA	48 h static	EC_{50} = 690000	100	6900
Daphnia magna	AMPA	21 d semi static	EC_{50} = 15000	10	1500
Pseudokirchneriella subcapitata	AMPA	72 h	NOEC = 191000	10	19100
Myriophyllum aquaticum	AMPA	14 d	E_rC_{50} = 72000	10	7200
HMPA					
Daphnia magna	HMPA	48 h	EC_{50} > 100000	100	1000
Pseudokirchneriella subcapitata	HMPA	72 h	E_rC_{50} > 120000	10	12000
Lemna gibba	HMPA	14 d	EC_{50} > 123000	10	12300

In the following tables, the ratios between predicted environmental concentrations of glyphosate in surface water (PEC_{SW}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use (as described in Table 10.2-6) for each FOCUS scenario and for each organism group.

Please note that the PEC/RAC ratios in the following tables are rounded to 3 decimal places. For endpoints and the corresponding RAC value which are presented as ">" or "≥" the PEC/RAC ratios are presented without the symbol of '<'. This does not have any impact on the outcome of the risk assessment presented below.

Table 10.2-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in root vegetables (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	E_rC_{50}
(µg/L)		47000	≥ 9630	40000	12500	13500	10330
AF		100	10	100	10	10	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	128.016	0.272	0.133	0.320	0.102	0.095	0.124
Step 2							
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031
Step 3							
D3/ditch	6.756	0.014	0.007	0.017	0.005	0.005	0.007
D6/ditch	6.774	0.014	0.007	0.017	0.005	0.005	0.007
R1/pond	0.542	0.001	< 0.001	0.001	< 0.001	< 0.001	< 0.001
R1/stream	4.453	0.009	0.005	0.011	0.004	0.003	0.004
R2/stream	5.977	0.013	0.006	0.015	0.005	0.004	0.006
R2/stream 2nd	5.977	0.013	0.006	0.015	0.005	0.004	0.006
R3/stream	6.287	0.013	0.007	0.016	0.005	0.005	0.006
R4/stream	4.396	0.009	0.005	0.011	0.004	0.003	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in potatoes (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	E_rC_{50}
(µg/L)		47000	≥ 9630	40000	12500	13500	10330
AF		100	10	100	10	10	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	128.016	0.272	0.133	0.320	0.102	0.095	0.124
Step 2							
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031
Step 3							
D3/ditch	5.567	0.012	0.006	0.014	0.004	0.004	0.005
D4/pond	0.252	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
D4/stream	4.736	0.010	0.005	0.012	0.004	0.004	0.005
D6/ditch	5.605	0.012	0.006	0.014	0.004	0.004	0.005
D6/ditch 2nd	5.622	0.012	0.006	0.014	0.004	0.004	0.005
R1/pond	0.902	0.002	< 0.001	0.002	< 0.001	< 0.001	< 0.001
R1/stream	3.861	0.008	0.004	0.010	0.003	0.003	0.004
R2/stream	5.183	0.011	0.005	0.013	0.004	0.004	0.005
R3/stream	5.451	0.012	0.006	0.014	0.004	0.004	0.005

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in bulb vegetables (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330
AF		100	10	100	10	10	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	128.016	0.272	0.133	0.320	0.102	0.095	0.124
Step 2							
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031
Step 3							
D3/ditch	6.732	0.014	0.007	0.017	0.005	0.005	0.007
D4/pond	0.260	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
D4/stream	5.323	0.011	0.006	0.013	0.004	0.004	0.005
D6/ditch	6.803	0.014	0.007	0.017	0.005	0.005	0.007
D6/ditch 2nd	6.803	0.014	0.007	0.017	0.005	0.005	0.007
R1/pond	0.888	0.002	< 0.001	0.002	< 0.001	< 0.001	< 0.001
R1/stream	4.453	0.009	0.005	0.011	0.004	0.003	0.004
R2/stream	5.977	0.013	0.006	0.015	0.005	0.004	0.006
R3/stream	6.286	0.013	0.007	0.016	0.005	0.005	0.006
R4/stream	4.452	0.009	0.005	0.011	0.004	0.003	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in fruiting vegetables (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330
AF		100	10	100	10	10	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	128.016	0.272	0.133	0.320	0.102	0.095	0.124
Step 2							
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031
Step 3							
D6/ditch	6.789	0.014	0.007	0.017	0.005	0.005	0.007
R2/stream	5.977	0.013	0.006	0.015	0.005	0.004	0.006
R3/stream	6.287	0.013	0.007	0.016	0.005	0.005	0.006
R4/stream	4.452	0.009	0.005	0.011	0.004	0.003	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in leafy vegetables (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330
AF		100	10	100	10	10	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	128.016	0.272	0.133	0.320	0.102	0.095	0.124
Step 2							
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031
Step 3							
D3/ditch	6.755	0.014	0.007	0.017	0.005	0.005	0.007
D3/ditch 2nd	6.750	0.014	0.007	0.017	0.005	0.005	0.007
D4/pond	0.260	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
D4/stream	5.430	0.012	0.006	0.014	0.004	0.004	0.005
D6/ditch	6.803	0.014	0.007	0.017	0.005	0.005	0.007
R1/pond	0.451	< 0.001	< 0.001	0.001	< 0.001	< 0.001	< 0.001
R1/pond 2nd	1.201	0.003	0.001	0.003	< 0.001	< 0.001	0.001
R1/stream	4.451	0.009	0.005	0.011	0.004	0.003	0.004
R1/stream 2nd	4.448	0.009	0.005	0.011	0.004	0.003	0.004
R2/stream	5.977	0.013	0.006	0.015	0.005	0.004	0.006
R2/stream 2nd	5.977	0.013	0.006	0.015	0.005	0.004	0.006
R3/stream	6.287	0.013	0.007	0.016	0.005	0.005	0.006
R3/stream 2nd	6.287	0.013	0.007	0.016	0.005	0.005	0.006
R4/stream	4.452	0.009	0.005	0.011	0.004	0.003	0.004
R4/stream 2nd	4.452	0.009	0.005	0.011	0.004	0.003	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in sugar beets (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330
AF		100	10	100	10	10	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	128.016	0.272	0.133	0.320	0.102	0.095	0.124
Step 2							
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031
Step 3							
D3/ditch	5.567	0.012	0.006	0.014	0.004	0.004	0.005
D4/pond	0.256	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
D4/stream	4.880	0.010	0.005	0.012	0.004	0.004	0.005
R1/pond	1.165	0.002	0.001	0.003	< 0.001	< 0.001	0.001
R1/stream	3.861	0.008	0.004	0.010	0.003	0.003	0.004
R3/stream	5.451	0.012	0.006	0.014	0.004	0.004	0.005

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in pome/stone fruit (2 × 1440 g a.s./ha, with application interval of 28 days). ***Uses 4 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330
AF		100	10	100	10	10	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	170.688	0.363	0.177	0.427	0.137	0.126	0.165
Step 2							
N-Europe	52.829	0.112	0.055	0.132	0.042	0.039	0.051
S-Europe	43.176	0.092	0.045	0.108	0.035	0.032	0.042
Step 3							
D3/ditch	3.814	0.008	0.004	0.010	0.003	0.003	0.004
D4/pond	0.278	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
D4/stream	3.372	0.007	0.004	0.008	0.003	0.002	0.003
D5/pond	0.283	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
D5/stream	3.724	0.008	0.004	0.009	0.003	0.003	0.004
R1/pond	0.267	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
R1/stream	2.635	0.006	0.003	0.007	0.002	0.002	0.003
R2/stream	3.538	0.008	0.004	0.009	0.003	0.003	0.003
R3/stream	3.721	0.008	0.004	0.009	0.003	0.003	0.004
R4/stream	3.225	0.007	0.003	0.008	0.003	0.002	0.003

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in olives (2 × 1440 g a.s./ha, with application interval of 28 days). ***Uses 4 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330
AF		100	10	100	10	10	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	170.688	0.363	0.177	0.427	0.137	0.126	0.165
Step 2							
N-Europe	52.829	0.112	0.055	0.132	0.042	0.039	0.051
S-Europe	43.176	0.092	0.045	0.108	0.035	0.032	0.042
Step 3							
D6/ditch	3.830	0.008	0.004	0.010	0.003	0.003	0.004
R4/stream	4.511	0.010	0.005	0.011	0.004	0.003	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vines (2 × 1440 g a.s./ha, with application interval of 28 days). ***Uses 5 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330
AF		100	10	100	10	10	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	170.688	0.363	0.177	0.427	0.137	0.126	0.165
Step 2							
N-Europe	52.829	0.112	0.055	0.132	0.042	0.039	0.051
S-Europe	43.176	0.092	0.045	0.108	0.035	0.032	0.042
Step 3							
D6/ditch	3.830	0.008	0.004	0.010	0.003	0.003	0.004
R1/pond	0.267	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
R1/stream	2.635	0.006	0.003	0.007	0.002	0.002	0.003
R2/stream	3.538	0.008	0.004	0.009	0.003	0.003	0.003
R3/stream	3.721	0.008	0.004	0.009	0.003	0.003	0.004
R4/stream	4.363	0.009	0.005	0.011	0.003	0.003	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on HardSPEC calculations for the use of MON 52276 to railroad tracks, 1 x 3600 g a.s./ha. *Uses 7 a-b.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330
AF		100	10	100	10	10	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033
HardSPEC Scenario	**$PEC_{sw,max}$ (µg/L)**						
Railroad track ditch leaching	9.458	0.020	0.010	0.024	0.008	0.007	0.009
Railroad track ditch runoff	9.458	0.020	0.010	0.024	0.008	0.007	0.009

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in grass/alfalfa, (1 × 1800 g a.s./ha). ***Uses 8 and 9.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330
AF		100	10	100	10	10	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033
FOCUS Scenario	**PECsw,max (µg/L)**						
Step 1							
	106.680	0.227	0.111	0.267	0.085	0.079	0.103
Step 2							
N-Europe	44.120	0.094	0.046	0.110	0.035	0.033	0.043
S-Europe	35.993	0.077	0.037	0.090	0.029	0.027	0.035
Step 3							
D1/ditch	11.400	0.024	0.012	0.029	0.009	0.008	0.011
D1/stream	9.964	0.021	0.010	0.025	0.008	0.007	0.010
D2/ditch	11.410	0.024	0.012	0.029	0.009	0.008	0.011
D2/stream	10.150	0.022	0.011	0.025	0.008	0.008	0.010
D3/ditch	11.300	0.024	0.012	0.028	0.009	0.008	0.011
D4/pond	0.380	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
D4/stream	9.736	0.021	0.010	0.024	0.008	0.007	0.009
D5/pond	0.380	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
D5/stream	10.510	0.022	0.011	0.026	0.008	0.008	0.010
R2/stream	9.938	0.021	0.010	0.025	0.008	0.007	0.010
R3/stream	10.480	0.022	0.011	0.026	0.008	0.008	0.010

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Calculated PEC/RAC ratios for glyphosate based on maximum PEC_{SW} values are below 1 indicating an acceptable risk following use of MON 52276 according to the proposed use patterns in field crops, orchards, vineyards, railroad tracks and to control invasive species in agricultural and non-agricultural areas.

In the following tables, the ratios between predicted environmental concentrations of AMPA in surface water (PEC_{SW}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use (as described in Table 10.2-6) for each FOCUS scenario and for each organism group.

Please note that the PEC/RAC ratios in the following tables are rounded to 3 decimal places. For endpoints and the corresponding RAC value which are presented as ">" or "≥" the PEC/RAC ratios are presented without the symbol of '<'. This does not have any impact on the outcome of the risk assessment presented below.

Table 10.2-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	103.639	0.020	0.086	0.015	0.069	0.005	0.014
Step 2							
N-Europe	40.490	0.008	0.034	0.006	0.027	0.002	0.006
S-Europe	32.636	0.006	0.027	0.005	0.022	0.002	0.005

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**
[1] covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table 10.2-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in orchards[1] (2 × 1440 g a.s./ha, with application interval of 28 days). ***Uses 4 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	138.185	0.027	0.115	0.020	0.092	0.007	0.019
Step 2							
N-Europe	53.986	0.010	0.045	0.008	0.036	0.003	0.007
S-Europe	43.514	0.008	0.036	0.006	0.029	0.002	0.006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**
[1] covering all corresponding uses in pome/stone fruit and olives

Table 10.2-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in vines (2 × 1440 g a.s./ha, with application interval of 28 days). ***Uses 5 a–c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	138.185	0.027	0.115	0.020	0.092	0.007	0.019
Step 2							
N-Europe	53.986	0.010	0.045	0.008	0.036	0.003	0.007
S-Europe	43.514	0.008	0.036	0.006	0.029	0.002	0.006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on HardSPEC calculations for the use of MON 52276 to railroad tracks, 1 x 3600 g a.s./ha. ***Uses 7 a-b.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
HardSPEC Scenario	**$PEC_{sw,max}$ (µg/L)**						
Railroad track ditch leaching	3.913	0.001	0.003	0.001	0.003	< 0.001	0.001
Railroad track ditch runoff	3.913	0.001	0.003	0.001	0.003	< 0.001	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in grass/alfalfa, (1 × 1800 g a.s./ha). ***Uses 8 and 9.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	86.366	0.017	0.072	0.013	0.058	0.005	0.012
Step 2							
N-Europe	39.761	0.008	0.033	0.006	0.027	0.002	0.006
S-Europe	32.062	0.006	0.027	0.005	0.021	0.002	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Calculated PEC/RAC ratios for the metabolite AMPA based on maximum PEC_{SW} values are below 1 indicating an acceptable risk following use of MON 52276 according to the proposed use patterns in field crops, orchards, vineyards, railroad tracks and to control invasive species in agricultural and non-agricultural areas.

In the following tables, the ratios between predicted environmental concentrations of HMPA in surface water (PEC_{SW}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use (as described in Table 10.2-6) for each FOCUS scenario and for each organism group.

Please note that the PEC/RAC ratios in the following tables were rounded to 3 decimal places. For endpoints and the corresponding RAC value which are presented as ">" or "≥" the PEC/RAC ratios are presented without the symbol of '<'. This does not have any impact on the outcome of the risk assessment presented below.

Table 10.2-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a - c.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	> 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	48.385	0.048	0.004	0.004
Step 2				
N-Europe	16.892	0.017	0.001	0.001
S-Europe	13.741	0.014	0.001	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**
1 covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table 10.2-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in orchards[1] (2 × 1440 g a.s./ha, with application interval of 28 days). ***Uses 4 a-c.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	64.513	0.065	0.005	0.005
Step 2				
N-Europe	22.523	0.023	0.002	0.002
S-Europe	18.322	0.018	0.002	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**
[1] covering all corresponding uses in pome/stone fruit and olives

Table 10.2-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in vines (2 × 1440 g a.s./ha, with application interval of 28 days). ***Use 5 a-c.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	64.513	0.065	0.005	0.005
Step 2				
N-Europe	22.523	0.023	0.002	0.002
S-Europe	18.322	0.018	0.002	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on HardSPEC calculations for the use of MON 52276 to railroad tracks, 1 x 3600 g a.s./ha. ***Uses 7 a-b.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
HardSPEC Scenario	**$PEC_{sw,max}$ (µg/L)**			
Railroad track ditch leaching	0.627	0.001	< 0.001	< 0.001
Railroad track ditch runoff	0.627	0.001	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Table 10.2-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in grass/alfalfa, (1 × 1800 g a.s./ha). *Uses 8 and 9.*

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	40.321	0.040	0.003	0.003
Step 2				
N-Europe	18.768	0.019	0.002	0.002
S-Europe	15.232	0.015	0.001	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Calculated PEC/RAC ratios for the metabolite HMPA based on maximum PEC_{SW} values are below 1 indicating an acceptable risk following use of MON 52276 according to the proposed use patterns in field crops, orchards, vineyards, railroad tracks and to control invasive species in agricultural and non-agricultural areas.

Indirect Effects via Trophic Interactions

The available regulatory ecotoxicology data for glyphosate and its main metabolite AMPA includes a battery of acute and chronic aquatic guideline studies, across multiple trophic levels, that have been designed to assess the potential for direct and indirect effects through trophic interactions. Consideration of indirect effects through trophic interactions has been used to derive a SPG that is consistent with the current EFSA aquatic guidance (2013) and the Regulation ((EC) No 1107/2009). The SPG used for the biodiversity assessment states: "Negligible acute and long-term effects to aquatic plant and animal populations from direct and indirect effects through trophic interactions" (

Table 10.2-29). Negligible in the context of this assessment, and the EFSA aquatic guidance, means that there is a sufficient margin of safety to conclude there will be no unacceptable effects to aquatic ecosystems for the intended uses.

As previously discussed, glyphosate is an important tool to realize the benefits that conservation tillage has on biodiversity in agroecosystems. Low soil disturbance leaves the surface with adequate crop residue and organic matter that resists soil aggregate breakdown and soil crusting that contribute to runoff and erosion and consequently soil / particulate matter reaching aquatic systems resulting in sedimentation. The primary nutrient forms carried in runoff are ammonium, nitrate, and phosphate that contribute to degradation and eutrophication of aquatic ecosystems. Therefore, using glyphosate within conservation agriculture schemes can minimize impact to aquatic biodiversity.

The groups of aquatic organisms that were tested are well suited for direct and indirect effects assessment through trophic interactions because it contains the key components of the aquatic food chain as well as macrophytes that are an important structural component of aquatic waterbodies. Indeed, the test battery includes numerous representative species of primary producers (i.e., chronic studies with algae, diatoms, aquatic macrophytes), representative primary consumers (i.e., acute and chronic studies with pelagic invertebrates and sediment dwelling invertebrates) and acute and chronic studies with secondary consumers (i.e., fish development and reproduction and larval amphibian development) (Table 1, see document MCP Section 10.1 for details on the tested species).

The following assessment approach considers both direct effects and the potential for indirect effects via trophic interactions, based on the proposed Specific Protection Goals drawn from the existing EU guidance and working documents, and the 2016 EFSA Guidance on developing protection goals for ecological risk assessments (ERA) for pesticides. The SPGs based on direct effects assessment considering representative sensitive populations across the tested trophic levels. The biodiversity assessment, aimed to develop a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals, that includes considering indirect effects via trophic interaction. For example, reduced application rates relative to previous Annex I renewals, a reduced overall application volume of product on the land, and inclusion of no-spray buffer zones as a standard mitigation measure to protect edge of field surface waters. When defining SPGs for aquatic plants and animals, it is the responsibility of the risk assessors in the Member States to acknowledge existing protection goals and regulatory data requirements, to propose possible SPG options, and describe the possible environmental consequences of each option. The risk assessors within the Member States will need to propose realistic SPGs and exposure assessment goals and the interrelationships between them in a clear and transparent manner

The direct effects assessment covering a broad range of aquatic taxa groups, informs on the biodiversity assessment by highlighting an acceptable risk across multiple trophic layers of the aquatic food chain. Therefore, where an acceptable direct effects risk assessment is concluded upon after incorporation of standard mitigation measures to reduce off-target movement to surface waters (anyway required to support the NTTP assessment) coupled with the other standard mitigation measures that are applied, they are considered protective of indirect effects occurring outside of the target area.

However, for the purpose of this biodiversity assessment, the SPGs developed for aquatic systems is considered consistent with current EFSA guidance and what will likely be adopted in future EFSA guidance. The SPG is aimed at achieving negligible acute and long term direct and indirect effects on aquatic plant and animal populations.

Available study results and the risk assessment for direct effects presented in M-CP 10 show negligible risk from direct effects on the representative species for the various trophic levels. Moreover, glyphosate and its main metabolite AMPA, do not bioaccumulate (Log Pow less than 3 and a BCF = 1.1). Additionally, the basic principles that underlie an aquatic mixture assessment for glyphosate have been provided in [25]Appendix 1 of the biodiversity assessment document. In addition, based on predicted environmental concentrations, either from FOCUS surface water modelling or from surface water monitoring studies, the risk of additive effects of glyphosate in the presence of other plant protection products in surface waters is low to negligible.

Biodiversity Assessment

The assessment approach – as previously defined aims to assess the potential indirect effects via trophic interactions and the impact on biodiversity, by developing a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals. In the following table, the specific protection goals relevant to aquatic organisms are presented with the relationship between the SPGs, the direct effects study types, assessment and measurement endpoints. The assessment endpoint is an explicit expression of an environmental entity and the specific property of that entity to be protected. Measurement endpoints relates directly to the effects study endpoints.

A conclusion that a given data requirement has been satisfied, requires that an acceptable level of risk has been achieved (i.e. there is a protective margin of exposure or through a weight of evidence).

Based on the measurement endpoints from the study types, and the direct effects assessment presented above in this section, indirect effects from glyphosate on aquatic organisms are not anticipated.

The following table assessment illustrates that ecological function of aquatic organisms in off-field / off-target areas / edge of field surface water, will be sufficiently maintained to achieve the SPG for the aquatic organisms according to the protection goals as defined in the EFSA guidance (2016), that sustains habitat and food resources for other organisms whilst achieving negligible acute and chronic effects on aquatic plants and animals.

[25] [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

Table 10.2-29: The relationship between the Specific Protection Goal, assessment endpoints and measurement endpoints for aquatic systems (wetlands, rivers and lakes) exposed by runoff and/or spray drift.

Specific Protection Goal[1]	Assessment Endpoints	Measurement Endpoints	Glyphosate Study Types[2]
Negligible acute and long-term effects to aquatic plant and animal populations from direct and indirect effects through trophic interactions.	Survival, growth and reproduction of aquatic populations	Acute and chronic toxicity to aquatic plants and animals and bioaccumulation	Algal Vascular plants Acute Daphnia Daphnia life-cycle[3] Chironomid emergence[3] Acute fish Fish ELS[3] Fish repro screening [3] Fish Full Life-cycle[3] Amphibian metamorphosis [3] Fish bioconcentration
Biodiversity Assessment for Aquatic Ecosystems Based on the specific protection goal, inclusion of a 1 m buffer between the application area and the adjacent surface water body, for applications of MON 52276 made according to the proposed GAP, is considered protective of both direct and indirect effects on biodiversity in aquatic ecosystems through trophic interactions.			

[1] By accepting no population-level effects on representative sensitive populations in edge-of-field surface waters, these populations will be protected and propagation of effects to the community-, ecosystem- and landscape-level will not occur (Option 1: EFSA aquatic guidance, 2013).
[2] Acute and chronic aquatic studies for aquatic plants and animals are presented in the ecotoxicology section. Endpoints for AMPA are similar to endpoints for the same studies with glyphosate.
[3] Note these studies were performed to assess the potential for impacts to the endocrine pathways. No effects to the four endocrine pathways can be concluded based on the results of these studies and a weight of evidence evaluation (USEPA, 2015, EFSA, 2017, KCA 5.8.3/010, 2020)

As a conservative approach for finalizing the aquatic biodiversity assessment, the lower tier assessment option known as the Ecological Threshold Option (ETO) from the EFSA's tiered guidance for aquatic risk assessments (EFSA (2013). This option aims at ensuring that negligible effects only, may occur in aquatic populations (transient effects followed by recovery are not accepted with this option). Both direct and indirect effects on the food chain are covered within this option. When applied to the representative sensitive populations in edge-of-field surface water, this option allows to conclude that aquatic populations will be protected, and that propagation of effects to the community-, ecosystem-, and landscape level will not occur.

The current direct effects aquatic risk assessment in MCP10 shows that inclusion of a one-meter buffer between the applied area and the edge-of-field surface water for glyphosate applications is considered protective of both direct effects and indirect effects through trophic interactions on aquatic biodiversity for the intended uses.

Ecotoxicological relevance of the glyphosate surface water monitoring data

In addition to the predicted environmental concentrations from FOCUS modeling used for the standard aquatic assessment, there is an extensive amount of surface water monitoring data that can be used to further evaluate potential effects of glyphosate on biodiversity in aquatic ecosystems.

Horth (2012) provided a review that covers glyphosate and AMPA monitoring results for surface waters from all 27 Member States. The maximum concentrations of glyphosate found in surface water ranged from 1.3 to 370 µg acid equivalents (a.e.)/L and the maximum concentrations of AMPA ranged from 0.22 to > 200 µg/L. Glyphosate and AMPA concentrations in the monitoring data exceeded the predicted environmental concentration (PECsw), using the FOCUS (2000) surface water model for glyphosate and AMPA at an exceedingly small frequency. When calculating TER values with the concentrations monitored in the study by Horth, the outcome of the assessment demonstrates that the risk for direct and indirect effects to aquatic organisms from the intended uses of glyphosate is acceptable.

Based on a more recent analysis of the European Environment Agency water monitoring ([redacted], 2020) database, it can be concluded that 99.99 % of the measured glyphosate surface water concentrations are below a regulatory acceptable concentration (RAC). For surface water, there were > 250,000 analyses and exceedance rates of the RAC were 0.01 % for glyphosate and 0.001 % for AMPA ([redacted], 2020). The original RAC value (100 µg/L) concluded in the [redacted] report is considered highly conservative, as the underlying fish toxicity study on which the RAC had been based ([redacted], 2000; MCA 8.2.2.1/002) is not acceptable for use in risk assessment (KCA 8.2.2.1/002 and KCA 8.2.2.1/003). Based on the now proposed lowest RAC value (400 µg/L) from the available reliable ecotoxicology aquatic endpoints, evaluated against current validity criteria for the study types, a further 4-fold margin of safety may be applied to the evaluation of the surface water detects in the monitoring report.

Glyphosate aquatic risk assessment under the PPP regulation in the context of the Water Framework Directive (WFD)

The protection goal underlying the WFD refers to human and ecosystem health. Within the context of ecosystem health and setting Environmental Quality Standards (EQS) it is assumed that (1) ecosystem sensitivity depends on the most sensitive species population, and (2) protecting ecosystem structure protects community functioning. Aquatic risk assessments for the WFD focus on larger water bodies (e.g., river basins) and EQSs should be linked to an annual average concentration or the maximum of the measured concentrations (MAC-EQS). In contrast, the aquatic risk assessment for PPP Regulation focuses on concentrations that can be achieved in edge-of-field surface waters in agricultural landscapes and the exposure assessment uses harmonized exposure scenarios (FOCUS surface water scenarios). These scenarios, in combination with models that estimate the emissions and the fate and behavior of PPPs in surface waters, predict realistic worst-case exposure concentrations in edge-of-field surface waters.

In terms of effects endpoints, EQSs are derived on the basis of predicted no effect concentrations (PNECs) for all relevant populations of water organisms and is generally comparable to the ETO approach used for a PPP aquatic assessment. Overall, the general protection goal of the WFD and PPP Regulation do not differ substantially. EQS setting within the context of the WFD in principle is based on the Ecological Threshold Option approach (ETO, EFSA, aquatic guidance 2013), and glyphosate satisfies the ETO option as discussed above. Glyphosate was identified as "low risk" to the water compartment in the 2011 evaluation of candidate EU priority substances using a PNEC in water of 24 µg a.e./L. To put this value into perspective with the new surface water monitoring data, and including values identified as outliers, less than 0.042 % of samples exceed 24 µg a.e./L ([redacted], 2020). Moreover, considering the large margin of safety (>350-fold) between the endpoint driving the standard aquatic risk assessment, and measured levels of glyphosate from monitoring studies, risk of direct effects and indirect effects through trophic interactions on aquatic communities is negligible.

Relevance of the Drinking Water Threshold to Biodiversity Assessment

The Drinking Water Directive (DWD) sets the compliance limits at the tap of the consumer as 0.1 µg/L for individual pesticides and 0.5 µg/L for total pesticides. Only those pesticides which are likely to be present in a given supply need be monitored. From the environmental monitoring report ([redacted] 2020), the analysis of the dataset available for drinking water for glyphosate and AMPA indicates that compliance is to these requirements very high. Indeed, detections above 0.1 µg/L are very rare. When they do sporadically occur, they occur at low concentrations that are well below human health thresholds. The measured environmental concentrations available show that neither glyphosate nor AMPA pose a risk to human health via drinking water where the point of compliance is at the tap of the consumer. The drinking water threshold is not therefore considered relevant to the ecotoxicological risk assessment.

Scientific Literature that informs the aquatic biodiversity assessment

Baker *et al.* (2016) investigated the potential for indirect effects on natural communities of phytoplankton and zooplankton with a glyphosate-based formulation at concentrations up to 2.88 mg a.e./L, which represents a concentration resulting from an overspray application to a shallow waterbody (approximately 4.3 kg a.e./ha over-sprayed in to 15 cm water). Their co-application of herbicide and nutrients resulted in a transient decline in dietary quality of phytoplankton and zooplankton community similarity. However, direct and indirect effects were not evident in wetlands treated only with the formulation.

Rolando *et al.* (2017) conducted an extensive review of the available scientific literature for glyphosate-based herbicides used in forest management, at applications up to a rate of 4 kg a.e./ha and concluded that glyphosate use does not pose a significant long-term risk of direct and indirect effects in aquatic environments. Indirect effects of glyphosate to aquatic fauna were observed when high concentrations of the product were applied as overspray to the waterbodies. Effects on the aquatic fauna were associated with changes in aquatic plant community composition and habitat structure, cover, and food sources as a consequence of glyphosate's phytotoxic effects, rather than resulting from the toxicity of glyphosate on the aquatic fauna. To help put this observation of indirect effects into perspective, Edge *et al.* (2020) investigated the potential for indirect effects on aquatic animals from using a glyphosate-based formulation to control emergent aquatic vegetation. Results showed that control of the aquatic vegetation indirectly increased the abundance of benthic invertebrates and wood frog larvae. This study shows how glyphosate can be safely used to control aquatic vegetation and has benefits to aquatic biodiversity.

Edge *et al.* (2011, 212, 2013, 2014) conducted field studies to assess effects of a glyphosate-based formulation, commonly used in Canadian forestry, on larval tadpoles at concentrations representative of a direct overspray into shallow water (2.88 mg a.e./L). The results from these studies showed no impact on growth, development and survival and it was concluded that there was no unacceptable risk to larval amphibians. The absence of chronic effects was concluded to result from rapid dissipation of glyphosate and its adjuvant in the water column and showed the importance of testing under environmentally realistic conditions.

Conclusion

The current aquatic risk assessment for glyphosate, its environmental metabolites, and the representative formulation demonstrate that a 1 m no-spray buffer zone from edge-of-field is protective of aquatic biodiversity from direct effects and indirect effects through trophic interactions. By demonstrating negligible risk of population-level effects on representative sensitive populations in edge-of-field surface waters, aquatic populations will be protected and propagation of indirect effects to the community, ecosystem, and landscape levels will not occur. When performing our assessment using the measured levels of glyphosate and AMPA from aquatic monitoring programs, we come to the same conclusion that no direct or indirect effects to aquatic biodiversity are likely to occur.

Environmental risk mitigation measures are a key component in defining the conditions of use of pesticides in crop protection in Europe ((EC) No 1107/2009) and (EU) No 547/2011). These risk mitigation measures are derived directly from the evaluation of pesticide products and the risk assessment conducted for each use and are specific of the type of risk they are intended to mitigate. They therefore range from the adjustment of the conditions of use, to minimizing transfers to surface and groundwater, to the setting of buffer zones at the edge of the crop, and to requiring compensatory measures (e.g., field margins).

Examples of the standard mitigation measures considered applicable at the EU level (MAgPIE, 2017) are presented in the following table. Many of these have been considered in the current dossier submission.

Table 10.2-30: Types of standard risk mitigation measures described in MAgPIE across the various Member States to mitigate effects on biodiversity and how they could be applied to glyphosate products.

Type of Mitigation Measure	Risk Mitigation Measure	Benefits	Glyphosate renewal dossier (2020)
Restrictions or modifications of products' conditions of application	Application rate, Application frequency, application timing, and interval between applications	Lower transfers to groundwater and surface water; Reduces exposure of organisms in-crop and off-crop.	**Significant reductions (50 % in volume) in newly proposed application rates** compared with the representative use presented in the 2012 renewal dossier. See [26]**Appendix 2** of the biodiversity report that accompanies this submission. **Treated area restriction** 7. for the representative use GAPs: applying to only 50 % of the total area in orchard/vineyard area. 8. maximum of 50 % of the total area for broad acre vegetable inter-row 9. Invasive species control e.g., couch grass – maximum of 20 % of the cropland + extended application intervals. **Limited frequency and timing of application:** 28-day interval between applications and no pre-harvest applications
Application equipment with Spray Drift Reduction Technology (SDRT)	Spray drift reduction nozzles (SDRN), shields, Precision treatment, etc.	Reduces exposure of organisms in-crop (precision treatment) and off-crop	**Reduction of spray drift to the off-field**: 5. Use 75 % drift reducing nozzles for pre-sowing/pre-planting in arable crops. 6. Use of ground directed, shielded spray for band application in orchards / vineyards and broad-acre vegetable inter-row application.
Buffer zones	Non-sprayed zone at the edge of a crop	Reduces exposure of organisms and off-crop	**Establishment of buffer zones:** Buffer zones of varying size (depending on the type of SDRT) are required as protection for off-crop NTTP communities from spray drift.

For example in the current dossier;

- Reductions in maximum annual application rates of up to 50 % are considered in this dossier and are compared to the maximum rates applied for in the 2012 Annex I renewal dossier.
    - In 2012, the maximum annual application rate was 4.32 kg/ha.
    - In the current dossier submission, the maximum annual application rate is 2.16 kg/ha

- Reducing the total area being applied on a per hectare basis for certain uses, will reduce the total volume of product being applied to the landscape.
    - For example, controlling actively growing weeds in vineyards, orchards where a reduced area, up to a maximum of 50 % of the total application area is proposed e.g. using strip or band applications. Applications on target weeds around the base of trees within tree rows,

[26] [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

leaving the area between tree rows unsprayed, which is typically managed using mechanical methods.

- The use of shielded or hooded sprayers, hand-held sprayers and drift reducing technologies, e.g. 75 % drift reducing nozzles are recommended for all applications made for the control of actively growing weeds when applied to control invasive species. These measures will further reduce the off-target exposure risk.
- For weed control on railroad tracks, recommendations are made in the GAP table to use precision application equipment on spray trains, that detects and targets spray directly onto unwanted plants, thereby reducing the amount of product being applied, whilst maintaining an acceptable level of safety on the railroad tracks.

- No spray buffer areas in-field (such as compensation areas), are necessary to meet the specific protection goals for avoiding direct effects on non-target plants in off-target areas. This measure will in turn support non-target arthropod communities in off-field areas and reduces further, the potential for indirect effects on bees through trophic interaction.

In addition to the standard mitigation measures, ‘non-standard mitigation measures’ could also be considered where a local and specific mitigation need is identified. For example, in simplified landscapes or landscapes that are intensively managed, where typically there are limited refuge areas for insects, birds and mammals. Non-standard mitigation measures options could include for example, creation of off-target habitats, utilizing edge of field habitats and semi-field habitats that assist biodiversity by improving wildlife connectivity.

For further information on mitigation measures pleased refer to the supplementary information document[27] titled ‘Glyphosate: Indirect Effects via Trophic Interaction – A Practical Approach to Biodiversity Assessment.’ that accompanies this dossier submission.

CP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

[27] [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

1. Information on the study

Data point	CP 10.2.1/001
Report author	[redacted]
Report year	1992
Report title	MON 52276: Acute Toxicity To Rainbow Trout, *Oncorhynchus mykiss*, Under Flow-Through Test Conditions
Report No	J9108002b
Document No	[redacted]-91-296
Guidelines followed in study	US EPA FIFRA 72-1 (1982), OECD 203, and EEC Method C.1.
Deviations from current test guideline	Deviations from the current OECD 203 guideline (2019): Major: - Fish were acclimatised 48 hours prior to the test (7 days are required) Minor: - Observations occurred after 24h, 48h and 96h instead of twice/day - pH of the highest concentration (5.9) was slightly below the specified range of 6.0 – 8.5.
Previous evaluation	Yes, accepted in RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

The effects of MON 52276 (30.95 % glyphosate acid) on rainbow trout (*Oncorhynchus mykiss*) were evaluated in a 96-hour flow-through toxicity test. Two groups of ten fish each were exposed for 96 hours to nominal concentrations of MON 52276 at 0 (control), 130, 216, 360, 600 and 1000 mg/L. The test water was a blend of treated municipal water and treated well water. At 0, 48 and 96 hours, samples of test medium were taken for the analysis of glyphosate content.

Mortality and signs of toxicity were recorded at 24, 48, 72 and 96 hours after test initiation.

Mortality to one fish was observed at the lowest test concentration (119 mg/L), but it was judged to be not treatment-related. No mortality was observed at the higher test concentrations. No sublethal effects were observed at any test concentration. The present study is considered valid according to OECD guideline 203.

Based on mean measured concentrations, the 96-hour LC_{50} for rainbow trout (*Oncorhynchus mykiss*) exposed to MON 52276 in a flow-through test system was > 989 mg/L (> 306 mg glyphosate/L, arithmetic mean measured). The corresponding no observed effect concentration (NOEC) was ≥ 989 mg/L (≥ 306 mg glyphosate/L, arithmetic mean measured), based on the absence of mortality and abnormal sublethal effects at this concentration.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item:	MON 52276
Active substance:	Glyphosate
Description:	Amber liquid
Lot/Batch #:	LLN-9105-3135F
Purity:	30.95 %

2. Vehicle and/or positive control: none

3. Test organism:

Species:	Rainbow trout (*Oncorhynchus mykiss*)
Age:	Juveniles
Size:	Length: 3.1 – 4.1 cm
Loading:	10 test individual for 15 L test solution
Source:	[redacted]
Acclimation period:	48 hours prior to the test initiation
Body weight of the animals:	0.35 – 0.95 g (mean = 0.60 ± 0.16 g)
Food	live brine shrimp, nauplii and flake until 48h prior to test initiation

4. Environmental conditions:

Temperature:	11.5 – 13.8 °C
Photoperiod:	16 hours, 392 – 500 lux
pH:	8.1 (control); 5.9 – 7.4 (test item concentrations)
Dissolved oxygen:	≥ 7.1 mg/L (≥ 67 % of saturation)
Conductivity:	382 – 705 µmhos/cm
Hardness:	38 – 116 mg CaCO3/L
Alkalinity:	57 – 77 mg CaCO3/L
Dissolved oxygen saturation	10.8 mg/L at 12 °C

5. Dates of experimental work: October 7th to October 11th 1991

B. STUDY DESIGN

Experimental treatments: Two groups of ten fish each were exposed under flow-through conditions in a proportional diluter system 4.8 cycles/h (approx. 5.4 volume addition every 24h) for 96 hours to nominal concentrations of MON 52276 at 0 (controls), 130, 216, 360, 600 and 1000 mg/L. For flow-through system, the recommended maximum loading is 0.5 g wet weight fish/L per 24 hours. Taking into account a 15 L tank with a flow rate of 5.4 tank volumes per 24 hours, a total of 81 L passed through the tank in 24 hours. With 0.6 g fish and ten fish per tank (= 6 g), this was corresponding to 6 g in 81 L in 24 hours equivalent to 0,07 g/L in 24 hours.

The test water was a blend of treated municipal water and treated well water. During the 14-day holding period prior to test initiation, fish were fed daily and were in good health. There were two vessels per treatment, each containing ten fish (appr.24 L glass vessels containing 15 L test medium).

Observations: Mortality and signs of toxicity were recorded at 24, 48, 72 and 96 hours after test initiation. Water temperature in a control vessel was measured hourly throughout the test, and water pH and dissolved oxygen were measured daily in all test vessels. Hardness, total alkalinity and specific conductivity were measured at test initiation and test termination. At 0, 48 and 96 hours, samples of test medium were taken for quantification of glyphosate by HPLC.

Statistical calculations: LC_{50} values were calculated along with the 95 % confidence limits using non-linear interpolation.

II. RESULTS AND DISCUSSION

A. FINDINGS

Analytical data: The arithmetic mean measured concentrations during the 96-hour exposure ranged from 119 to 989 mg MON 52276/L and from 92 to 100 % of nominal. The results are provided based on mean measured concentrations.

Table 10.2.1-1: Analytical results

Nominal concentration [mg MON 52276/L]	Measured concentration [mg MON52276/L]			Mean (±SD) [mg MON 52276/L]	% of nominal
	0hr	48hr	96hr		
Control	ND	ND	ND	-	-
130	124 119	114 112	123 123	119 (5.1)	92
216	202 244	190 172	195 246	208 (30.2)	96
360	368 357	339 348	373 385	362 (16.9)	100
600	584 599	520 545	598 639	581 (42.4)	97
1000	1030 994	921 937	1010 1040	989 (49.1)	99

ND = not detection, limit of detection 2.6 mg/L

The LC_{50} and NOEC values are given below based on mean measured concentrations.

Table 10.2.1-2: Endpoints

Endpoints (96 h)	MON 52276 [mg/L]	Glyphosate [mg/L][1]
LC_{50} (95% C.I.)	> 989	> 306.1
NOEC	989	306.1

[1] MON 52276 is 30.95% glyphosate as active ingredient.

B. OBSERVATIONS

Mortality and signs of toxicity in control and treated groups are reported in the table below. Mortality to one fish was observed at the lowest test concentration (119 mg/L), but it was judged to be not treatment-related. No mortality was observed at the higher test concentrations. No sublethal effects were observed at any test concentration.

Table 10.2.1-3: Acute toxicity of MON 52276 to rainbow trout (*Oncorhynchus mykiss*) under flow-through conditions

MON 52276 [mg /L] [1]	Time point [h]	Abnormalities/ Sublethal Effects	Mortality[2]	Cumulative % mortality
0	24 48 72 96	None observed	0	0
119	24 48 72 96	None observed	1	5
208	24 48 72 96	None observed	0	0
362	24 48 72 96	None observed	0	0
581	24 48 72 96	None observed	0	0
989	24 48 72 96	None observed	0	0

[1] Mean measured values.
[2] Number of dead fish of 20 total.

All validity criteria according to OECD 203 were fulfilled, as no mortality was observed in control group, dissolved oxygen concentration was ≥ 60 % of air saturation and constant exposure conditions have been maintained.

The following points deviated from current guideline too:

- Fish were acclimatised 48 hours prior to the test instead of the 7 required
- Observations occurred after 24h, 48h, 72h and 96h. The requirements are the following a minimum of 2 observations within the first 24 hours of the study and on days 2 – 4 of the test, all vessels with living fish inspected twice per day (preferably early morning and late afternoon to best cover the 24-hour periods).
- The pH in the highest concentration outside of accepted range of 6.0 – 8.5 so the stock solution should have been adjusted to lie within this specified range.

These deviations are not considered to have a negative impact on the study.

III. CONCLUSIONS

Assessment and conclusion by applicant:

Based on mean measured concentrations, the 96-hour LC_{50} for rainbow trout (*Oncorhynchus mykiss*) exposed to MON 52276 in a flow-through test system was > 989 mg/L (> 306 mg glyphosate/L, arithmetic mean measured). The corresponding no observed effect concentration (NOEC) was ≥ 989 mg/L (≥ 306 mg glyphosate/L, arithmetic mean measured), based on the absence of mortality and abnormal sublethal effects at this concentration.

The study is considered to be valid and suitable for use in the risk assessment.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.2.1/002
Report author	[redacted]
Report year	1992
Report title	MON 52276: Acute Toxicity To The Common Carp, *Cyprinus carpio,* Under Flow-Through Test Conditions
Report No	J9108002c
Document No	[redacted]-91-298
Guidelines followed in study	OECD guideline 203
Deviations from current test guideline	Deviations from the current OECD 203 guideline (2019): Major: - Dissolved oxygen concentration dropped under 60% of saturation (from 8.7 mg/L to 2.5 mg/L = 28.7 %) Minor: - Temperature range should not vary more than ±1°C and should be within the range 20 – 24 °C (current values: 21.7 – 23.8 °C). - Observations occurred after 24h, 48h and 96h instead of twice/day - Fish length ranged from 2.7 – 5 cm, outside the recommended length of 2.0 – 4.0 cm. - pH of the highest concentration (5.7) was not in the specified range of 6.0 – 8.5. - The test concentrations were not maintained within 80 % of nominal concentrations at 96 h (current values from 52 to 84 %).
Previous evaluation	Yes, accepted in RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

The effects of MON 52276 (30.95 % glyphosate acid) on common carp (*Cyprinus carpio*) were evaluated in a 96-hour flow-through toxicity test. Two groups of ten fish each were exposed for 96 hours to nominal concentrations of MON 52276 at 0 (controls), 130, 216, 360, 600 and 1000 mg/L. The test water was a blend of treated municipal water and treated well water. At 0, 48 and 96 hours, samples of test medium were taken for the analysis of glyphosate content.

Mortality and signs of toxicity were recorded at 24, 48, 72 and 96 hours after test initiation.

No treatment related mortality or sublethal effects were observed in common carp at any test concentration.

The present study is considered valid according to OECD guideline 203 (even if the dissolved oxygen criterion is not met).

Based on arithmetic mean measured concentrations, the 96-hour LC_{50} for common carp (*Cyprinus carpio*) exposed to MON 52276 in a flow-through test system was > 895 mg/L (> 277 mg glyphosate/L). The corresponding no observed effect concentration (NOEC) was ≥ 895 mg/L (≥ 277 mg glyphosate/L, arithmetic mean measured).

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item:	MON 52276
Active substance	Glyphosate
Description:	Amber liquid
Lot/Batch #:	LLN-9105-3135F
Purity:	30.95 %

2. Vehicle and/or positive control: None

3. Test organism:

Species:	Common carp (*Cyprinus carpio*)
Age:	Juveniles
Size:	2.7 – 5.0 cm
Loading:	10 test individuals for 15 L test solution (0.93 g fish/L)
Source:	[redacted]
Acclimation period:	14 days prior to the test initiation
Body weight of the animals:	0.57 – 2.97 g (mean of 1.39 g)
Food	brine shrimp, nauplii and flake until 48h prior test initiation

4. Environmental conditions:

Temperature:	21.7 – 23.8 °C
Photoperiod:	16 hours light, 350 - 425 lux
pH:	8.1 (control); 7.1 to 5.7 (test item concentrations)
Dissolved oxygen:	6.7 – 8.7 mg/L (8.7 mg/L is 100 % saturation)
Conductivity:	1614 – 1688 µmhos/cm
Hardness:	184 – 192 mg $CaCO_3$/L
Alkalinity:	34 – 45 mg $CaCO_3$/L

5. Dates of experimental work: November 19th to November 23rd 1991

B. STUDY DESIGN

Experimental treatments: Two groups of ten fish each were exposed under flow-through conditions using a proportional diluter system (3.8 daily volume turnover) for 96 hours to nominal concentrations of MON 52276 at 0 (controls), 130, 216, 360, 600 and 1000 mg/L. The test water was a blend of treated municipal water and treated well water. During the 14-day holding period prior to test initiation, fish were fed daily and were in good health. There were two vessels per treatment, each containing ten fish (appr. 24 L glass vessels containing 15 L test medium).

Observations: Mortality and signs of toxicity were recorded at 24, 48, 72 and 96 hours after test initiation. Water temperature in a control chamber was measured hourly throughout the test, and water pH and dissolved oxygen were measured daily in all test chambers. Hardness, total alkalinity and specific conductivity were measured at test initiation and test termination. At 0, 48 and 96 hours, samples of test medium were taken for quantification of glyphosate by HPLC.

Statistical calculations: LC_{50} values were calculated along with the 95 % confidence limits using non-linear interpolation.

II. RESULTS AND DISCUSSION

A. FINDINGS

For an estimated period of 4 – 6 hours, beginning at 8 hours prior to test termination, only dilution water was delivered to test chambers due to a malfunction in the diluter system. Since there were no indications of stress or any other effects, it is unlikely that the reduction in exposure concentration for this short period had any effect on the outcome of the test.

Analytical data: The arithmetic mean measured concentrations during the 96 hour exposure ranged from 98 to 895 mg test item/L and from 75 to 90 % of nominal on the overall period. The results were determined based on mean measured concentrations.

Table 10.2.1-4: Analytical results

Nominal concentration [mg MON 52276/L]	Measured concentration [mg MON52276/L]			Mean (±SD) [mg MON 52276/L]	% of nominal
	0hr	48hr	96hr		
Control	ND	ND	ND	-	-
130	111	117	74	98 (21.7)	75
	112	107	67		
216	171	188	125	176 (48.4)	81
	235	219	116		
360	395	366	215	340 (69.6)	94
	371	390	302		
600	570	592	481	552 (92.8)	92
	619	649	403		
1000	1020	1002	677	895 (94.6)	90
	1047	1010	615		

ND = not detection, limit of detection 1.9 mg/L.

The LC_{50} and NOEC values are given below based on mean measured concentrations.

Table 10.2.1-5: Endpoints

Endpoints (96 h)	MON 52276 [mg/L]	Glyphosate [mg/L][1]
LC_{50} (95 % C.I.)	> 895	> 277
NOEC	≥ 895	≥ 277

[1] MON 52276 is 30.95 % glyphosate as active ingredient.

B. OBSERVATIONS

Mortality and signs of toxicity in control and treated groups are reported below. No mortality and no sublethal effects were observed at any test concentrations.

Table 10.2.1-6: Acute toxicity of MON 52276 to Common carp (*Cyprinus carpio*) under flow-through conditions

MON 52276 (mg/L)[1]	Time point (h)	Abnormalities/ Sublethal Effects	Mortality[2]	Cumulative % mortality
0	24 48 72 96	None observed	0	0
98	24 48 72 96	None observed	0	0
176	24 48 72 96	None observed	0	0
340	24 48 72 96	None observed	0	0
552	24 48 72 96	None observed	0	0
895	24 48 72 96	None observed	0	0

[1] Mean measured values.
[2] Number of dead fish of 20 total.

All validity criteria according to OECD 203 were fulfilled, as no mortality was observed in control group, dissolved oxygen concentration was ≥ 60 % of air saturation and constant exposure conditions have been maintained.
During the test period, the dissolved oxygen during the test fell below 60 % of the air saturation value in at least one replicate at every dose level and in both replicates at the two highest dose levels; the fish did not appear stressed as a result.

The following validity criteria according to the OECD 203 (2019) were fulfilled:

- The control mortality was lower than 10 % at the end of the study.
- Analytical measurement of the test concentrations was reported.

The following validity criterion according to the OECD 203 (2019) was not fulfilled:

- The dissolved oxygen concentration was below the trigger value of ≥ 60 % of the air saturation value (ranging from 8.7 mg/L to 2.5 mg/L = 28.7 % through the study).

The following points deviated from current guideline too:

- Observations occurred after 24 h, 48 h, 72 h and 96 h. The requirements are the following a minimum of 2 observations within the first 24 hours of the study and on days 2 – 4 of the test, all vessels with living fish inspected twice per day (preferably early morning and late afternoon to best cover the 24-hour periods).
- The pH in the highest concentration outside of accepted range of 6.0 – 8.5 so the stock solution should have been adjusted to lie within this specified range.
- Dissolved oxygen concentration dropped under 60 % of saturation (from 8.7 mg/L to 2.5 mg/L = 28.7 %)
- Temperature range should not vary more than ±1 °C and should be within the range 20 – 24 °C (current values: 21.7 – 23.8 °C).
- Fish length ranged from 2.7 – 5 cm, outside the recommended length of 2.0 – 4.0 cm.
- The test concentrations were not maintained within 80 % of nominal concentrations at 96 h (current values from 52 to 84 %). The endpoints have been based on the overall mean measured concentrations.

These deviations are not considered to have a negative impact on the study.

III. CONCLUSIONS

Assessment and conclusion by applicant:

Based on arithmetic mean measured concentrations, the 96-hour LC_{50} for common carp (*Cyprinus carpio*) exposed to MON 52276 in a flow-through test system was > 895 mg/L (> 277 mg glyphosate/L). The corresponding no observed effect concentration (NOEC) was ≥ 895 mg/L (≥ 277 mg glyphosate/L, arithmetic mean measured).

The study is considered to be valid and suitable for use in the risk assessment.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.2.1/003
Report author	[redacted]
Report year	1992
Report title	MON 52276: Acute toxicity to the water flea, *Daphnia magna*, under flow-through test conditions
Report No	J9108002a
Document No	TO-91-296
Guidelines followed in study	US EPA FIFRA 72-2 (1982), OECD 202 (1984), and EEC Method C.2 (1992).
Deviations from current test guideline	Deviations from current OECD 202 guideline (2004): Major: - none Minor: - The pH of the test system was correlated with MON 52276 concentration and varied by more than 1 unit across the 5 dose levels. - The temperature was slightly higher and ranged from 20.0 – 23.8 °C instead of 18.0 – 22.0 °C. This did not have a negative effect on the study and validity criteria are met.
Previous evaluation	Yes, accepted in RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

The effects of MON 52276 (30.95 % w/w glyphosate acid) on *Daphnia magna* were evaluated in a 48-hour flow-through toxicity test. Neonates of *Daphnia magna* were exposed to nominal concentrations of MON 52276 at 130, 216, 360, 600, and 1000 mg/L and a negative control consisting of dilution water. The test consisted of two replicates per treatment group and control. 10 Daphnids were exposed per replicate and were not fed during the test. Total number of *Daphnia magna* exhibiting immobility and other clinical signs of toxicity was recorded at 24 and 48 hours after test initiation.

Temperature, pH-values and dissolved oxygen concentrations were measured at the beginning, at approximately 24 hours during the test and at the end of the test. At 0 and 48 hours, samples of test medium were taken for quantification of glyphosate by HPLC. The analysed test concentrations ranged between 95 and 105 % of the nominal values.

No mortality to *Daphnia magna* from exposure to MON 52276 was observed at test concentrations ≤ 356 mg/L. At 580 mg/L, 20 % mortality was observed at 48 hours, with 100 % mortality observed at 948 mg/L. Sublethal effects were observed only at the 580 mg/L concentration.

Based on mean measured concentrations, the 48-hour EC_{50} for *Daphnia magna* exposed to MON 52276 in a flow-through test system was 676 mg/L (95 % confidence limits of 580 and 948 mg/L), (equivalent to 209 mg glyphosateL). The corresponding no observed effect concentration (NOEC) was 356 mg/L (107 mg glyphosate/L), based on the lack of mortality and sublethal effects at this concentration.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item::	MON 52276
Active substance:	Glyphosate
Purity:	30.95 %
Lot/Batch #:	LLN-9105-3135F
Appearance:	Amber liquid
2. Vehicle and/or positive control:	None
3. Test organism:	
Species:	*Daphnia magna* Straus
Age:	Neonates (< 24 h old)
Loading:	1 daphnid per 30 mL test medium
Source:	In-house culture (originally from: U.S. Environmental Protection Agency, Duluth, Minnesota)
Diet/Food:	none
Acclimation period:	Not stated
4. Environmental conditions:	
Temperature:	20.0 – 23.8 °C
Photoperiod:	16 hours light, 384 – 517 lux
pH:	5.9 – 8.3
Dissolved oxygen:	7.4 – 8.7 mg O_2/L
Conductivity:	436 – 644 µS/cm
Hardness:	60 – 96 mg $CaCO_3$/L
5.Dates of experimental work:	Oct 16th to Oct 18th 1991

B. STUDY DESIGN AND METHODS

1. Experimental treatments: The effects of MON 52276 (30.95 % w/w glyphosate acid) on neonates of *Daphnia magna* were evaluated in a 48-hour flow-through toxicity test using a proportional diluter system (1.6 cycles/h). Twenty Daphnids (2 replicates of 10 animals per test beaker) were exposed to nominal concentrations of MON 52276 at 130, 216, 360, 600, and 1000 mg/L dissolved in a blend of treated municipal water and treated well water (corresponding to 133, 227, 356, 580 and 948 mg/L of the measured concentrations). In addition, a control group was exposed to test water without test substance (blank control).

2. Observations: Total number of immobile *Daphnia magna* was recorded 24 h and 48 h after test initiation. In addition, specimens were observed for clinical signs of toxicity.
Water temperature was measured at 0 and 48 hours in each test chamber, as well as hourly in one negative control replicate. Water pH and dissolved oxygen were recorded at test start then every 24 hours. Hardness, alkalinity and specific conductance were measured once in the dilution water at test initiation.

At 0 and 48 hours, samples of test medium were taken for quantification of glyphosate by HPLC.

The validity criteria according to the current OECD 202 guideline are the following:

- In the control, not more than 10 percent of the daphnids should have been immobilised or show other signs of disease or stress.
- The dissolved oxygen concentration at the end of the test should be ≥ 3 mg/L in control and test vessels.

3. Statistical calculations: EC_{50} values including 95 % confidence limit were determined by non-linear interpolation.

II. RESULTS AND DISCUSSION

A. FINDINGS

The analysed test concentrations ranged between 95 and 105 % of the nominal values. The results were determined based on mean measured concentrations.

Table 10.2.1-7: Analytical results

Nominal concentration [mg MON 52276/L]	Measured concentration [mg MON 52276/L]			Mean (±SD) [mg MON 52276/L]	% of nominal
	0hr	24hr	48hr		
Control	ND	ND	ND	-	-
130	122 139	125 136	123 153	133 (12.1)	102
216	217 228	221 217	236 240	227 (9.9)	105
360	373 370	346 328	362 359	356 (16.8)	99
600	593 612	512 550	593 621	580 (41.4)	97
1000	969 961	911 870	985 994	948 (48.1)	95

ND = not detected, limit of detection 1.9 mg/L.

The LC_{50} and NOEC values are given below based on mean measured concentrations.

Table 10.2.1-8: Endpoints

Endpoints	MON 52276 [mg/L]	Glyphosate [mg/L][1]
EC_{50} (48 h)	676 mg/L (580 – 948 mg/L)	209 mg/L
NOEC (48 h)	356 mg/L	107 mg/L

[1] MON 52276 is 30.95 % glyphosate as active ingredient.

B. OBSERVATIONS

No mortality to *Daphnia magna* from exposure to MON 52276 was observed at test concentrations ≤ 356 mg/L. At 580 mg/L, 20 % mortality was observed at 48 hours, with 100 % mortality observed at 948 mg/L. Sublethal effects were observed only at the 580 mg/L concentration.

Table 10.2.1-9: Acute toxicity of MON 52276 to *Daphnia magna* under flow-through conditions

Measured concentration MON 52276 (mg/L) [1]	Time point (h)	Abnormalities/ Sublethal Effects	No. of *Daphnia* immobilised or dead[2]	Cumulative % mortality
0	24 48	None observed	0 0	0 0
133	24 48	None observed	0 0	0 0
227	24 48	None observed	0 0	0 0
356	24 48	None observed	0 0	0 0
580	24 48	None observed 3 lethargic	0 4	0 20
948	24 48	None observed --	11 20	55 100

[1] Mean measured values.
[2] Of 20 total *Daphnia* in group.

All validity criteria according to the OECD 202 were fulfilled, as no immobility of Daphnids was observed in control groups and dissolved oxygen concentration was ≥ 3 mg/L in all test vessels.
The following points deviated from current guideline:
- the pH of the test system was correlated with MON 52276 concentration and varied by more than 1 unit across the 5 dose levels. Within each test concentration, the pH variation was less than one unit.
- The temperature range during the test was 3.8 ºC, rather than the maximum range of 2 ºC specified in the guideline.

These deviations are not considered to have a negative impact on the study.

III. CONCLUSIONS

Assessment and conclusion by applicant:
Based on mean measured concentrations, the 48-hour EC_{50} for *Daphnia magna* exposed to MON 52276 in a flow-through test system was 676 mg/L (95% confidence limits of 580 and 948 mg/L), (equivalent to 209 mg glyphosate/L). The corresponding no observed effect concentration (NOEC) was 356 mg/L (107 mg glyphosate/L), based on the lack of mortality and sublethal effects at this concentration.

The study is considered to be valid and suitable for use in the risk assessment.

Assessment and conclusion by RMS:

1. Information on the study

Data point	CP 10.2.1/004
Report author	[redacted]
Report year	1992
Report title	Alga, growth inhibition test. Effect of MON 52276 on the growth of *Selenastrum capricornutum*
Report No	WE-06-057
Document No	TO-91-298
Guidelines followed in study	OECD Guideline 201 (1981) EU Directive 87/302/EEC, Part C (1987) NEN 6506, Delft (1984)
Deviations from current test guideline	Deviation from current OECD 201 guideline (2011): Major: - The test concentrations were not verified. Minor: - none
Previous evaluation	Yes, accepted in RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Supportive
Category study in AIR 5 dossier (L docs)	Category 2b

2. Full summary

Executive Summary

The effects of MON 52276 on *Selenastrum capricornutum* (currently known as *Raphidocelis subcapitata*) were evaluated in a 72-hour static toxicity test. Algal cells were exposed to five nominal MON 52276 concentrations of 50, 90, 160, 290 and 500 mg test item/L. In addition, a control group was prepared with algae added to test medium without test substance.

Six replicate vessels were prepared for the control and three replicates for each test concentration. Each vessel was inoculated with an initial algal cell density 1 x 10^4 cells/mL.

After 24, 48, and 72 hours, mean cell densities for each test concentration and control were determined based on spectrophotometrical measurements and cell counting. The concentration resulting in 50 % inhibition of cell growth (biomass) and reduction of cell growth rate (E_bC_{50} & E_rC_{50} values respectively) were then calculated. as well as the associated NOEC values.

The 72 hour E_bC_{50} for MON 52276 was calculated to be 150 mg/L and the 72 hour E_rC_{50} was calculated to be 393 mg/L, with a corresponding NOEC determined to be 90 mg/L.

I. MATERIALS AND METHODS

A. MATERIALS

Test Material:

Identification: MON 52276

Lot No.: LLN 260491 B

Chemical purity: 31 % glyphosate acid equivalent, as 41 % isopropylamine salt of glyphosate

Physical state: Light amber-brown liquid

Density: 1.16 mg/cm^3

Vehicle and/or positive control:

Vehicle:	None
Positive control:	None

Test organism:

Species:	*Selenastrum capricornutum* (currently known as *Raphidocelis subcapitata*)
Initial cell concentration:	1 x 10^4 cells/mL
Source:	Inoculum obtained from a 4 day incubated laboratory pre-culture, prepared at the performing laboratory (Original parent culture source is the Culture Centre for Amoeba and Protozoa in the UK. Strain No. CCAP 278/4)

Environmental conditions:

Temperature:	20.9 – 23.1 °C (Required: 21 to 25 ºC ± 2 ºC)
Photoperiod:	24 h light
Light intensity:	8875 ± 125 lux
pH:	8.31 – 8.97 (control), 6.38 – 8.89 at 50, 160 and 290 mg/L 7.32 – 8.99 at 90 mg/L- deviated by more than 1 pH unit (1984 guideline requirement, but within 1.5 pH units (current OECD 201 guideline requirement). 5.88 – 5.98 at 500 mg/L
Conductivity:	Not stated
Hardness:	Not stated

B. STUDY DESIGN

Experimental dates: 15 October – 18 October 1991

Experimental treatments

Based on a range finding test, the definitive algal growth inhibition test was performed with five concentrations (50, 90, 160, 290 and 500 mg test item/L) prepared by appropriate dilution of a 10 g/L stock solution. In addition, a control was also prepared where algae were exposed to algal medium only without test substance (blank control). OECD 201 recommended algal medium was used as the diluent. For each MON 52276 concentration, three replicate vessels were prepared, and six replicate vessels were prepared for the control group. (150 mL Erlenmeyer glass flasks with cotton wool bungs.) To each test or control vessel, 100 mL of the test medium was added, and all replicates vessels were then inoculated with algal cells, at an initial algal cell density of 1 × 10^4 cells/mL.

Observations

After 24, 48, and 72 hours, mean cell densities for each test concentration and control were determined based on spectrophotometrical measurements (absorbance measurement). In addition, the algal cell concentrations were also determined by microscopic counting at 48 hours and 72 hours. Inhibition of cell growth and reduction of cell growth rate were derived graphically, by plotting the average algal cell concentrations for each test concentration against time. Concentrations resulting in 50 % reduction of growth rate (E_rC_{50}) and 50 % inhibition of cell growth (E_bC_{50}) were determined, as well as the associated NOEC values. The endpoints were calculated for the absorbance and cell counting method. Temperature and the light intensity were recorded daily during the test, while the pH was measured in one replicate of each test concentration at the start and end of the test.

Statistical calculations
The median effect concentration is determined using the logit model of Chou and Chou (1985).

II. RESULTS AND DISCUSSION

A. FINDINGS

The E_rC_{50}, E_bC_{50} and NOEC values are given below based on nominal concentrations.

Table 10.2.1-10: Toxicity of MON 52276 to *Selenastrum capricornutum*

Endpoint	MON 52276 [mg test item/L]	
	absorbance	cell counting
0 - 72 h E_rC_{50}	393	284
0 - 72 h E_bC_{50}	150	178
NOEC	90	

B. OBSERVATIONS

Based on cell counting, reduction of algal growth rate increased with increasing concentration of MON 52276 from a nominal concentration of 160 mg test item/L upwards. For the two lowest test concentrations of 50 mg test item/L and 90 mg test item/L, increases of algal growth rate of 13.6 % and 8.4 %, respectively, were observed, with nearly 100 % inhibition in cell growth at the highest nominal concentration, compared to the control. Reduction of growth rate and cell growth results are below.

Table 10.2.1-11: Percentage reduction of growth rate and inhibition of cell growth of *Selenastrum capricornutum* exposed for 72 hours to MON 52276

	Control	MON 52276 [mg test item/L]				
Test parameters	-	50	90	160	290	500
Mean absorbance (0-72 h)	0.260	0.419	0.391	0.128	0.027	0.015
Cell growth rate reduction (0-72 h) [%] based on absorbance	-	-13.6	-8.4	10.9	42.8	58.2
Cell growth inhibition (0-72 h) [%] based on absorbance	-	-36.9	-27.7	50.3	81.5	89.6
Mean cell densities (0-72 h) (× 1000 cells/mL)	644	741	663	315	45	33
Cell growth rate reduction (0-72 h) [%] based on cell counting	-	-3.4	-0.7	17.5	64.8	72.5
Cell growth inhibition (0-72 h) [%] based on cell counting	-	-1.7	8.3	54.1	84.7	93.2

III. CONCLUSIONS

Based on absorbance, the 72 h E_rC_{50} and the 72 h E_bC_{50} for *Selenastrum capricornutum* exposed to MON 52276 were calculated to be 393 mg test item/L and 150 mg test item/L. The NOEC was determined to be 90 mg test item/L. For cell counting method, 72 h E_rC_{50} and 72 h E_bC_{50} for *Selenastrum capricornutum* exposed to MON 52276 were calculated to be 284 mg test item/L and 178 mg test item/L, respectively. The NOEC was determined to be 90 mg test item/L.

3. Assessment and conclusion

Assessment and conclusion by applicant:

Validity of the study was re-evaluated according to the current test guideline OECD 201 (2011) and EC_{10}, EC_{20}, and EC_{50}, NOEC and LOEC values were calculated to fulfil the data requirements according to regulation EU 283/2013.

Validity criteria

Validity criteria acc. to OECD 201 (2011)	Required (0 - 72 h)	Obtained (0 - 72 h)
The biomass in the control cultures should have increased exponentially by a factor of at least 16 within the 72-hour test period.	≥ 16	59
The mean coefficient of variation for section-by-section specific growth rates in the control cultures must not exceed 35 %.	≤ 35 %	20.4 %
The coefficient of variation of average specific growth rates during the whole test period in replicate solvent control cultures must not exceed 7 %.	≤ 7 %	4.1 %

The biomass in the control cultures increased by a factor of ≥ 16 (actual: 59), the coefficient of variance for section specific growth rates was ≤ 35 % (actual: 20.4 %) and the coefficient of variance for the whole test period it was ≤ 7 % (actual: 4.1 %).

This study was performed according to the valid test guideline at the time of conduct. In the last Annex I renewal, this study was evaluated and considered acceptable for use in risk assessment. In the current submission dossier, a re-evaluation of the study against the current test guideline validity criteria was conducted (at least a 16 fold increase in biomass, a mean coefficient of variation for section-by-section growth rates in the control being < 35 % and a coefficient of variation of the average specific growth rate over the test period in the controls being < 7 %) and against these criteria, the study was considered valid. Chemical analysis was not conducted during the study. However, glyphosate is very water soluble (> 10 g/L) and stable under conditions of exposure in laboratory algal studies is supported by more recent studies performed with alga. The principal route of degradation of glyphosate is via microbial action. Degradation of glyphosate over a short exposure period is not expected. Glyphosate is stable under conditions of continuous illumination (see results of the photolysis studies presented in the Environmental Fate section (see M-CA Section 7). Therefore, the losses of glyphosate from the test system following 72 or 96 hr exposure would not be expected. The study should therefore be considered strongly supportive of the risk assessment. The endpoints achieved in the MON 52276 algal study were 72 hr ErC50 = 284 mg test item/L; 72 hr EbC50 = 178 mg test item/L and NOEC = 90 mg test item/L.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.2.1/005
Report author	[redacted]
Report year	2002
Report title	Assessment of toxic effects of MON 52276 on aquatic plants using the duckweed *Lemna gibba*.
Report No	GA-2002-051
Document No	20021186/01-AALg
Guidelines followed in study	OECD 221 (draft of October 2000)
Deviations from current test guideline	Deviation from current OECD 221 guideline (2006): Major: - Bacterial contamination occurred in test concentrations 2.4 and 6.8 mg/L. Minor: - none
Previous evaluation	Yes, accepted in RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Supportive
Category study in AIR 5 dossier (L docs)	Category 2b

2. Full summary

Executive Summary

The effects on the growth of the aquatic plant *Lemna gibba* G3 exposed to MON 52276 (30.9 % w/w glyphosate acid) were determined in a seven-day semi-static study. For the main test, three replicates of 12 fronds in AAP Medium for *Lemna gibba* were exposed in glass beakers under continuous illumination to nominal MON 52276 concentrations of 0 (control), 0.9, 2.4, 6.8, 19.1, 53.6 and 150 mg/L, equivalent to 0.278; 0.742; 2.10; 5.90; 16.6; 46.4 mg glyphosate acid/L. Renewal of the test media was performed on day 3 and 5 after test initiation. Direct counts of number of fronds were conducted on day 3, 5 and 7. Observations of changes in plant development, frond size, appearance, necrosis or other abnormalities were also performed at those times. The effect on biomass production was evaluated by determining the final dry weights of the plants. The growth rate inhibition was determined by counting the number of fronds produced for each test concentration and control group. The effect on biomass production was evaluated by determining the final dry weights of the plants. Samples from all the test concentrations were collected for analysis of glyphosate by HPLC on Days 0, 3, 5 and 7.

Significant inhibitory effects of MON 52276 were observed at 53.6 and 150 mg/L (43 %) for frond numbers, growth rate and biomass increase. These were equivalent to 16.6 and 46.4 mg glyphosate acid/L respectively.

The EC_{50} for frond number, biomass and growth rates based on frond number and biomass for MON 52276 were determined to be 66.58, 118.16 and > 150 mg MON 52276/L, respectively. The overall NOEC was determined to be 19.1 mg MON 52276/L. Hence, The EC_{50} for frond number, biomass and growth rates based on frond number and biomass were determined to be 20.57, 36.51 and > 46.35 mg glyphosate acid/L, respectively. The overall NOEC was determined to be 5.9 mg glyphosate acid/L. The validity criteria according to guideline OECD 221 are fulfilled.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item::	MON 52276
Description:	Light amber-brown liquid formulation
Lot/Batch #:	A1C1204104
Purity:	30.9 % glyphosate acid equivalent, as 41.5 % isopropylamine salt of glyphosate
2. Vehicle and/or positive control:	None
3. Test organism:	
Species:	Young *Lemna gibba* G3, 2 – 5 fronds
Source:	Institut für Pflanzenökologie und Ökotoxikologie, University of Hohenheim, Stuttgart, Germany
4. Environmental conditions:	
Temperature:	22 – 25 °C
Light intensity:	Continuous illumination, 7000 lux
pH:	7.49 – 9.42 (adjusted to 7.5)
Conductivity:	not stated
Hardness:	Not stated
5. Dates of experimental work:	May 24th to June 15th 2002

B. STUDY DESIGN AND METHODS

1. Experimental treatments: On the basis of the results of a range finding test, the definitive test was performed with six concentration levels, 0.9, 2.4, 6.8, 19.1, 53.6 and 150 mg MON 52276/L, equivalent to 0.278; 0.742; 2.10; 5.90; 16.6; 46.4 mg glyphosate acid/L, with 3 replicates per test concentration. Three control replicates (without test substance) were tested under the same conditions. Colonies consisting of 2 – 5 fronds totalling 12 fronds per replicate were added to each replicate test chamber. The plants were placed in 100 mL test vessels containing 50 mL 20X-AAP test media. The pH of the test medium was adjusted at each test media renewal to 7.5, to avoid extreme pH values. The test was conducted under a 7-day static-renewal test conditions. The renewal of the test media was performed on day 3 and 5 after test initiation.

2. Observations:

<u>Biological data:</u> Observations were made on the number and the condition of the fronds on Days 3, 5 and 7. The growth rate inhibition was determined by counting the number of fronds produced for each test concentration and control group. The effect on biomass production was evaluated by determining the final dry weights of the plants.

<u>Physical data</u>: pH and temperature of the test vessels were measured on days 0, 3, 5 and 7. Samples from all the test concentrations were collected for analysis of glyphosate by HPLC on Days 0, 3, 5 and 7.

3. Statistical calculations: The 7-day EC_{50} value for frond counts and growth rates based on frond counts and biomass were determined by probit analysis and the calculation of statistical significance was determined by using one-way analysis of variance (ANOVA) and Dunnett's test ($\alpha = 0.05$).

II. RESULTS AND DISCUSSION

A. FINDINGS

Analytical data: The mean measured glyphosate concentrations were 82.9 % to 112 % of nominal over the test period. The test substance remained stable, therefore the results are based on the nominal concentrations.

Table 10.2.1-12: Analytical results

Nominal concentration [mg MON 52276/L]	Nominal concentration [mg glyphosate acid/L]	Mean measured [mg glyphosate acid/L]	% of nominal
Control		-	-
0.9	0.278	0.231	82.9
2.4	0.742	0.701	94.5
6.8	2.10	2.11	101
19.1	5.90	6.62	112
53.6	16.6	17.4	105
150	46.4	48.5	104

Results were based on nominal MON 52276 concentrations.

Table 10.2.1-13: Endpoints

Endpoint	Frond number [mg/L]	Growth rate based on frond number [mg/L]	Biomass [mg/L]
	Nominal concentration of MON 52276 [mg/L]		
EC_{50} (7 days)	66.58 (56.30 – 79.66)	> 150	118.16 (91.37 – 171.37)
NOEC (7 days)	19.1	19.1	19.1
	Nominal concentration of glyphosate a.e. [mg/L]		
EC_{50} (7 days)	20.57 (17.39 – 24.61)	> 46.35	36.51 (28.23 – 52.95)
NOEC (7 days)	5.9	5.9	5.9

B. OBSERVATIONS

Observations: Significant inhibitory effects were observed at 2.4 and 6.8 mg/L for frond numbers and growth rates, and at 6.8 mg/L for biomass. However, these effects were not dose-related and were considered to be due to a reduced uptake of nutrients following a root decay caused by a bacterial infection. Additional dose-related significant inhibitory effects were observed at 53.6 and 150.0 mg/L for frond numbers, growth rates and biomass increase.

Table 10.2.1-14: Toxicity of MON 52276 to *Lemna gibba* under semi-static conditions

MON 52276 concentration (mg/L) [1]	Mean frond number [2]			Mean dry weight (mg) [3]	Average specific growth rate (μ)	Mean biomass increase (based on dry weight)
	Day 3	Day 5	Day 7	Day 7	0 – 7 days	0 – 7 days
0 (control)	44	120	270	32.4	0.444	31.0
0.9	45	116	234	28.5	0.4233	27.2
2.4	43	100	204	27.8	0.4010	26.5
6.8	40	98	193	26.3	0.3961	25.0
19.1	49	119	242	28.3	0.4284	27.0
53.6	39	84	157	24.6	0.3668	23.3
150.0	27	48	71	14.1	0.2533	12.8

[1] Nominal values.
[2] Initial mean frond number: 12
[3] Initial mean dry weight: 1.3 mg

Based on nominal concentrations, the EC_{50} for frond count of *Lemna gibba* exposed to MON 52276 under semi-static test conditions for 7 days was 66.58 mg MON 52276/L (95 % confidence limits of 56.30 and 79.66 mg MON 52276/L), equivalent to 20.57 mg a.e./L. Since the percentage inhibition compared to control was only 43 % at the highest MON 52276 concentrations tested, the E_rC_{50} was estimated to be > 150 mg MON 52276/L, equivalent to 46.35 mg a.e./L. Based on nominal concentrations, the E_bC_{50} was 118.16 mg MON 52276/L (95 % confidence limits of 91.37 and 171.37mg MON 52276/L), equivalent to 36.51 mg a.e./L. The no-observed-effect-concentration (NOEC) was 19.1 mg MON 52276/L, equivalent to 5.90 mg a.e./L.

The doubling time of frond numbers in the control was less than 2.5 days (37.4 hours). The validity criteria according to the current guideline OECD 221 are therefore fulfilled.

III. CONCLUSION

Assessment and conclusion by applicant:

Based on nominal concentrations, the EC_{50} for frond count of *Lemna gibba* exposed to MON 52276 under semi-static test conditions for 7 days was calculated to be 66.58 mg/L (95 % confidence limits of 56.30 and 79.66 mg MON 52276/L), equivalent to 20.57 mg a.e./L. Since the percentage inhibition compared to control was only 43 % at the highest MON 52276 concentrations tested, the E_rC_{50} was estimated to be >150 mg MON 52276/L, equivalent to 46.35 mg a.e./L. Based on nominal concentrations, the E_bC_{50} was 118.16 mg MON 52276/L (95 % confidence limits of 91.37 and 171.37mg MON 52276/L), equivalent to 36.51 mg a.e./L. The no-observed-effect-concentration (NOEC) was 19.1 mg MON 52276/L, equivalent to 5.90 mg a.e./L.

This study was conducted according to the draft OECD 221 test guideline from October 2000. The currently adopted test guideline is largely unchanged from the draft guideline. In the last Annex I renewal, this study was evaluated and considered acceptable for use in risk assessment. For this submission, the study has been re-evaluated. The study was conducted at nominal rates of 0.9, 2.4, 6.8, 19.1, 53.6 and 150 mg MON 52276/L. Chemical analysis was conducted during the study with mean measured concentrations of product between 82.9 and 104 % of nominal achieved. The study was considered valid with a doubling time of < 48 hours compared to the required < 2.5 days in the test guideline. The report identifies bacterial infection in some test cultures, most notably in the two lowest exposure concentrations. Relative to the control group, there was no significant difference in the frond number inhibition (%) at the end of the study across the four lowest exposure concentrations. However, there was a significant inhibition in frond number at the highest exposure concentration (150 mg MON 52276/L), where there was 43 % inhibition. Despite the apparent bacterial infection which was not confirmed in the study report – only based on observation, the study should be considered supportive for use in risk assessment.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.2.1/006
Report author	[redacted]
Report year	2012
Report title	Effect of MON 52276 (Glyphosate formulation) on the Growth of *Myriophyllum aquaticum* in the Presence of Sediment, with a subsequent Recovery Period.
Report No	CHE-016/4-80/A
Document No	-
Guidelines followed in study	Maltby, L., *et al.* (2008): Aquatic Macrophyte Risk Assessment for Pesticides, SETAC AMRAP
Deviations from current test guideline	None according to Maltby *et al.* (2008)
Previous evaluation	Yes, accepted in RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

The toxicity of MON 52276 on growth of *Myriophyllum aquaticum* was evaluated in a 14 day static toxicity test, with subsequent 7 day recovery test, performed at concentrations of 0.78, 3.91, 19.6, 97.8, 489 and 2445 mg MON52276/L, equivalent to 0.24, 1.2, 6.0, 30, 150 and 750 mg glyphosate acid equivalent/L. A negative control (Smart & Bako medium) was prepared in parallel.

Two sets of vessels (exposure and recovery set) were prepared, with each set comprising three replicates for each test concentration and six replicates for the controls. Test vessels were 2 L beakers, each containing five individual plants potted in individual pots containing artificial sediment. Shoot length, fresh weight, dry weight and root length were determined in all vessels. Plant length was recorded at test start and after 3, 7, 10 and 14 days and after 21 days (recovery vessels). At test start and test end, fresh weight of each plant was determined. Dry weight was determined at test initiation using 25 additional plants and at test end on the tested plants. At the end of the test all plants were harvested and the root length was assessed semi-quantitatively in terms of length of the main root.

Test media were analysed for Glyphosate content at test start and end of exposure and recovery periods. The measured concentrations ranged from 83.9-145 % of nominal. Glyphosate was not detected in the control group.

Result showed a significant inhibition of fresh weight of 20.7 % at the lowest test concentration of 0.3 mg glyphosate acid equivalent/L. Shoot length increase and growth rate were unaffected at this concentration. Relative to the control group, at the highest treatment rate (723 mg test item/L) there was 93.8 % growth inhibition based on fresh weights, shoot length increase was inhibited by 94.1 growth rate by 90.2 %. The recovery period demonstrated that *Myriophyllum aquaticum* pre-exposed to up to 26.80 mg MON52276/L were able to recover to control levels of growth, in untreated culture medium within 7 days of transfer.
The study fulfilled the validity criteria of achieving at least 50 % increase in control plant growth in terms of length within 7 days of test initiation. The test was therefore considered to be valid.
MON 52276 significantly inhibited the fresh weight of *Myriophyllum aquaticum* after 14 days at a mean measured concentration of < 0.3 mg glyphosate acid equivalent/L. Shoot length was inhibited at or above mean measured concentrations of 5.16 mg glyphosate acid equivalent/L. The 14-d EC_{50} value for fresh weight inhibition was 4.4 mg glyphosate acid equivalent/L and for shoot length it was 13.44 mg glyphosate acid equivalent/L. *Myriophyllum aquaticum* pre-exposed for 14 days to up to 26.80 mg glyphosate acid equivalent/L were able to recover in untreated culture medium after a 7 day recovery period.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item:	Glyphosate SL formulation (MON 52276)
Description:	Clear, yellow, viscous liquid
Lot/Batch #:	A9K0106104
Purity:	358.8 ± 4.0 g glyphosate acid equivalent/L (30.68 % w/w)
2. Vehicle and/or positive control:	None
3. Test organism:	
Species:	*Myriophyllum aquaticum*
Source:	Institut für Gewässerschutz, MESOCOSM GmbH, Neu-Ulrichstein 5, D-35315 Homberg (Ohm), Germany
4. Environmental conditions:	
Growth medium:	Smart & Bako medium

Artificial sediment:	4 – 5 % peat 20% kaolin clay 75 – 76% quartz sand $CaCO_3$ (if needed to adjust pH to 7.0 ± 0.5) Based on artificial soil used in OECD guideline 219 Moistening of sediment up to 30 % with deionised water or nutrient medium (ammonium chloride and sodium phosphate)
Temperature:	20.0 °C
Photoperiod:	16 h light
Light intensity	7295 – 7518 lux
pH:	Values recorded at test start and end (in brackets) of 14 day exposure period: Controls = 7.97 (8.78 – 8.82) 0.3 mg/= 8.25 (8.82) 1.1 mg/L = 8.01 (8.82) 5.16 mg/L = 8.15 (8.82) 26.8 mg/L = 7.79 (8.81 – 8.82) 145 mg/L = 7.26 (6.11 – 8.82) 723 mg/L = 5.86 (6.09 – 6.82) Values at start and end of 7 day recovery period: Recovery period start = 6.0 – 9.2 Recovery period end = 8.3 – 9.8
Oxygen saturation	Values recorded at test start and end (in brackets) of 14 day exposure period: Controls = 96 % (102 – 108 %) 0.3 mg/L = 90 % (107 – 108 %) 1.1 mg/L = 96 % (107 – 111 %) 5.16 mg/L = 91 % (114 – 132 %) 26.8 mg/L = 95 % (100 – 104 %) 145 mg/L = 90 % (116 – 122 %) 723 mg/L = 96 % (4 – 9 %) Values at start and end of 7 day recovery period: Controls = 103 – 110 % (99 – 109 %) 0.3 mg/L not included in the recovery period 1.1 mg/L = 108 – 114 % (103 – 110 %) 5.16 mg/L = 111 – 113 % (115 – 121 %) 26.8 mg/L = 123 – 130 % (123 – 126 %) 145 mg/L = 127 – 137 % (104 – 143 %) 723 mg/L = 6 – 33 % (107 – 111 %)
5. Dates of experimental work:	Oct 28th to Nov 18th 2010

B. STUDY DESIGN AND METHODS

1. Experimental treatments: The toxicity test on *Myriophyllum aquaticum* was performed with six concentration levels of 0.24, 1.2, 6.0, 30, 150 and 750 mg glyphosate acid equivalent/L, equivalent to 0.78, 3.91, 19.6, 97.8, 489 and 2445 mg MON 52276/L, with 3 replicates per test concentration. Six control replicates (without test substance) were tested under the same conditions as the test groups. Two sets of vessels (exposure and recovery) were prepared at the start of the test.

The plants were planted in small plastic plant pots into sediment and placed in glass beakers (test vessels), containing 2 L Smart & Bako medium. The test was conducted under static conditions. Five plants were added to each test and control replicate.

After 14 days exposure another set of *Myriophyllum aquaticum* replicates, exposed to the same concentration levels, were transferred into freshly prepared test medium without test item to determine the potential recovery after an exposure event.

2. Observations: Plant length, fresh weight, dry weight and root length were determined in all vessels. Plant length was recorded at test start and after 5, 8, 11 and 14 days. At test start and test end, fresh weight of each plant was determined. Dry weight was determined at test initiation using 25 additional plants and at test end on the tested plants (dried at 105 °C for 24 h). At the end of the test all plants were harvested and the root length was assessed semi-quantitatively in terms of length of the main root. Temperature in the test chamber was recorded continuously. Oxygen content, pH and light intensity was recorded at test start and after 14 days.
Analytical control measurements of the actual concentration of the glyphosate were performed by means of LC/MS-MS analysis at test start, after 14 (after exposure phase) and 21 days (after recovery phase).

3. Statistical calculations: The EC_{10}, EC_{20} and EC_{50} and its 95 % confidence interval were calculated by probit analysis modified for continuous data. The NOEC values were determined by calculation of statistical significance using one-way analysis of variance (ANOVA), followed by Williams' t-test, Dunnett's t-test or Welch's t-test ($p = 0.05$).

II. RESULTS AND DISCUSSION

A. FINDINGS

Analytical data: Analytical control measurements of the actual concentration of the glyphosate were performed at test start, after 14 and 21 days (after recovery phase). The measured concentrations ranged from 83.9 – 145 % of nominal at test start and 88.1 to 110 % of nominal at test end. Except for the lowest treatment level the test item was stable during the test period. The results were evaluated using the geometric mean measured concentrations.

Table 10.2.1-15: Analytical results

Nominal concentration [mg glyphosate a.e./L]	Test start [mg glyphosate/L]		Test end [mg glyphosate/L]		Geometric mean [mg glyphosate/L]	
	Measured [mg/L]	% of nominal	Measured [mg/L]	% of nominal	Measured [mg/L]	% of nominal
Control	<LOQ	-	<LOQ	-	-	-
0.24	0.35	145.0	0.26	110.0	0.30	125.0
1.2	1.15	95.6	1.05	87.8	1.10	91.7
6.0	5.03	83.9	5.29	88.1	5.16	86.0
30	26.3	87.5	27.4	91.5	26.8	89.3
150	145.0	96.5	145.0	96.4	145.0	96.7
750	722.0	96.3	723.0	96.4	723.0	100.4

LOQ = 0.25 mg/L.

The EC_{50} and NOEC values after 14 day growth inhibition test are given below based on geometric mean measured concentrations.

Table 10.2.1-16: 14-day endpoints

Endpoint	Concentration in glyphosate a.e. [mg/L]			
	14 Day EC_{10} [1]	**14 Day EC_{20} [1]**	**14 Day EC_{50} [1]**	**14 Day NOEC**
Shoot length/relative increase	0.43 (0.1 – 1.06)	1.41 (0.48 – 2.8)	13.44 (7.72 – 23.74)	5.16
Shoot length/growth rate	1.07 (0.23 – 2.67)	3.81 (1.29 – 7.61)	42.79 (24.74 – 76.48)	5.16
Fresh weight/relative increase	0.11 (0.01 – 0.33)	0.39 (0.09 – 0.9)	4.44 (2.28 – 8.51)	< 0.30
Fresh weight/ growth rate	0.16 (0.03 – 0.46)	0.66 (0.19 – 1.48)	10.33 (5.59 – 19.21)	< 0.30
Dry weight/relative increase	n.d.	n.d.	n.d.	145
Dry weight/ growth rate	0.44 (n.d. – 7.50)	3.23 (n.d. – 30.52)	143.3 (10.06 – n.d.)	145
Root length/relative increase	1.05 (0.59 – 1.53)	1.89 (1.24 – 2.53)	5.84 (4.65 – 7.37)	1.10
Root length/growth rate	2.23 (1.10 – 3.75)	6.33 (3.77 – 9.39)	46.50 (34.75 – 62.52)	1.10
	Equivalence in concentration in MON52276 [mg/L]			
	14 Day EC_{10} [1]	**14 Day EC_{20} [1]**	**14 Day EC_{50} [1]**	**14 Day NOEC**
Shoot length/relative increase	1.39 (0.32 – 3.43)	4.60 (1.56 – 9.13)	43.81 (25.2 – 77.4)	16.82
Shoot length/growth rate	3.46 (0.74 – 8.64)	12.42 (4.20 – 24.8)	139.5 (80.6 – 249.3)	16.82
Fresh weight/relative increase	0.36 (0.03 – 1.07)	1.27 (0.29 – 2.93)	14.47 (7.43 – 27.7)	< 0.98
Fresh weight/ growth rate	0.518 (0.10 – 1.49)	2.15 (0.62 – 4.82)	33.67 (18.2 – 62.6)	< 0.98
Dry weight/relative increase	n.d.	n.d.	n.d.	473
Dry weight/ growth rate	1.42 (n.d. – 24.27)	10.52 (n.d. – 99.5)	467.1 (32.8 – n.d.)	473
Root length/relative increase	3.40 (1.91 – 4.95)	6.16 (4.04 – 8.25)	19.04 (15.2 – 24.0)	3.59
Root length/growth rate	7.22 (3.56 – 12.14)	20.63 (12.3 – 30.6)	151.6 (123.0 – 203.8)	3.59

[1] (CI) = 95% confidence interval
n.d.: not determined due to mathematical reasons or inappropriate data; highlighted value indicates most sensitive measured parameter

The EC_{50} and NOEC values after 7 day recovery period are given below based on geometric mean measured concentrations.

Table 10.2.1-17: 7-day recovery endpoints

Endpoint	**Concentrations in glyphosate a.e. [mg/L]**	
	7 Day Recovery EC_{50}	**7 Day Recovery NOEC**
Shoot length/relative increase	n.d.	26.80
Shoot length/growth rate	n.d.	26.80
Fresh weight/relative increase	n.d.	≥ 723
Fresh weight/ growth rate	n.d.	≥ 723
Dry weight/relative increase	n.d.	≥ 723
Dry weight/ growth rate	n.d.	≥ 723
Root length/relative increase	n.d.	≥ 723
Root length/growth rate	n.d.	≥ 723
	Equivalence in concentration in MON52276 [mg/L]	
Shoot length/relative increase	n.d.	87.35
Shoot length/growth rate	n.d.	87.35
Fresh weight/relative increase	n.d.	≥ 2357
Fresh weight/ growth rate	n.d.	≥ 2357
Dry weight/relative increase	n.d.	≥ 2357
Dry weight/ growth rate	n.d.	≥ 2357
Root length/relative increase	n.d.	≥ 2357
Root length/growth rate	n.d.	≥ 2357

n.d.: not determined due to mathematical reasons or inappropriate data

B. OBSERVATIONS

There was a concentration dependent effect on growth, root length, fresh and dry weight of *Myriophyllum aquaticum*. Growth was significantly reduced at 5.16 mg glyphosate acid equivalent /L, fresh weight at < 0.3 mg glyphosate acid equivalent/L, dry weight at 145 mg glyphosate acid equivalent/L and root length at 1.10 mg glyphosate acid equivalent L during the 14 day exposure test. In the subsequent recovery test it was shown that *Myriophyllum aquaticum*, pre-exposed to up to 26.80 mg glyphosate acid equivalent/L were able to recover to control levels of growth in untreated culture medium within 7 days of the exposure period.

Table 10.2.1-18: Percentage of inhibition of *Myriophyllum aquaticum* exposed for 14 days to MON 52276

Test parameters	Glyphosate a.e.[mg/L] (mean measured)					
	0.3	1.1	5.12	26.8	145	723
Inhibition of shoot length increase (%)	-3.5	5.1	30.5	74.1	70.3	94.1
Inhibition of shoot length growth rate (%)	-2.6	2.0	17.5	58.1	53.6	88.3
Inhibition of fresh weight increase (%)	20.7	19.2	61.2	80.1	77.6	93.8
Inhibition of fresh weight growth rate (%)	14.6	13.3	49.4	70.9	67.8	90.2
Inhibition of dry weight increase (%)	14.7	18.2	34.3	15.8	-6.9	106.6
Inhibition of dry weight growth rate (%)	11.1	14.4	29.6	19.6	-4.7	112.3
Inhibition of root length increase (%)	-6.8	-3.9	52.0	82.9	94.5	98.3
Inhibition of root length growth rate (%)	-1.7	-0.9	18.3	43.9	66.7	86.8

For *Myriophyllum aquaticum,* plant fresh weight measurements are relevant for risk assessment as lower variability is associated with individual plant measurement compared to procedure used for dry weights which attracts a greater variability - with all plants pooled according to treatment and then compared to dry weights established at test start using a separate set of plants. Furthermore, root length measurements are considered semi-quantitatively, as only the length of the longest roots have been measured. The number of side roots and total number have not been determined given the practical constraints associated with the sediment *Myriophyllum* test design. Effects on roots are considered to be reflected in fresh weight measurements.

The study fulfils the validity criteria as stated in the study plan which follows the criteria established by the AMRAP working group; with an increase of biomass (shoot length) in controls was > 50 %, indicating that continuous growth was supported throughout the test duration. Furthermore, constant maintenance of temperature (20 ± 2 °C) was also achieved.

III. CONCLUSIONS

Assessment and conclusion by applicant:

MON 52276 significantly inhibited the fresh weight of *Myriophyllum aquaticum* after 14 days. Based on geometric mean measured concentrations, the 14-d E_rC_{50} value for fresh weight inhibition was 10.33 mg glyphosate acid equivalent/L and for shoot length it was 42.79 mg glyphosate acid equivalent/L. *Myriophyllum aquaticum* pre-exposed for 14 days to up to 26.80 mg glyphosate acid equivalent/L were able to recover in untreated culture medium after a 7 day recovery period.

The study is considered to be valid and suitable for risk assessment purposes.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.2.1
Report author	Gabriel, U.U. *et al.*
Report year	2010

Report title	Toxicity of roundup (a glyphosate product) to fingerlings of *Clarias gariepinus*
Document No	ISSN: 159 – 3115
Guidelines followed in study	None
Deviations from current test guideline	Not applicable
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities (literature publication)
Acceptability/Reliability:	Yes/Reliable with restrictions

2. Full summary

Acute static renewal bioassays were conducted on fingerling and adult of *Clarias gariepinus* (mean weight, 1.22 ± 0.6 g; mean total length, 5.25 ± 1.25 cm) using the herbicide, Roundup (glyphosate). In the acute study, fingerlings were exposed in triplicate to 0.0, 14.0, 16.0, 18.0, 20.0, 22.0, and 24.0 mg/L of the herbicide for 96 hours to determine general behavioural responses.
The 96 hour LC_{50} of Roundup on the fish was 19.58 mg/L.

Materials and methods

The fingerlings of *C. gariepinus* (mean weight 1.22 ± 0.6 g; mean total length 5.25 ± 1.25 cm) were obtained from a private farm, Comsystem, Kpite, Rivers State and transported in 25 litre jerry can to the Wet Laboratory, Department of Fisheries and Aquatic Environment, Rivers State University of Science and Technology, where they were distributed 60 fish per aquarium in four rectangular aquaria filled with 20 litre borehole water (dissolved oxygen, 0.01 ± 0.05 mg/L, pH- 7.5 ± 1.3; conductivity, 410 ± 20.4 µS/cm; total dissolved solid 400 ± 10.25 ppm). They were fed at one percent biomass, half at 0900 and 1600 hours for a week. Cleaning of the tanks and water exchange were done daily. Mortality during acclimation period was less than one percent. Mucus accumulation on the skin as well as gills and skin pigmentation were recorded.
Range finding test and trial runs were done. Twenty litres of each of the following concentrations: 14, 16, 18, 20, 22 and 24 ppm of Roundup containing 360 g/l glyphosate (in the form of 480g/l isopropylamine salt) and a control were prepared in triplicate in glass aquaria. Ten fish was randomly distributed into each of the tanks. The general behaviours, opercular beat frequency, OBF, tail beat frequency, TBF and mortality (%) were recorded at 12, 24, 48, 72 and 96^{th} hour, respectively. The exposure lasted for 96 hours. Data obtained from the experiments were subjected to ANOVA using Statistical Package for the Social Sciences, SPSS version 15 and differences among means were separated by Duncan Multiple Range test at 0.05%. The dependent variables in the trials (OBF, TBF and cumulative mortality) were regressed on concentration of the toxicant to obtain the regression lines of best fit for predicting the values of the dependent variables with changes in that of the independent with Microsoft Excel®. Correlation analysis was used to determine the degree of association among the dependent and independent variables. Lethal concentrations (LC50) values for the 24, 48, 72 and 96 hour and the median lethal times (MLT50) for the various concentrations of herbicide were done with Probit Analysis. Safe concentration of the herbicide at the various time intervals were obtained by multiplying the lethal concentration by a factor, 0.1. The interaction effects of the behavioural responses (TBF and OBF) with exposure duration and concentrations of the herbicides were presented graphically.

Results

On introduction into the toxicant the fish showed initial hyper-excitability, stress responses such as increased opercular ventilatory rate, dash and erratic swimming and gasping for air within the first two hours. As exposure time increased before death occurred they "hung" on the surface of the solution gulping air, fell steadily to the aquaria bottom. This was usually followed by dash swimming. This sequence was repeated several times before the fish lost balance, lay flat on the bottom (exertion), tail beat stopped, followed by cessation of opercular movement and then death (non-response to tactile stimuli).

Table 10.2.1-19: Tail and opercular beat frequency (TBF and OBF) and cumulative mortality of fingerlings of *C. gariepinus* exposed to various concentrations of Roundup for 96 hours

Variable	Time of exposure (hours)				
	12	24	48	72	96
TBF/min.	5.45 ± 2.73^{b}	15.49 ± 4.41^{ab}	7.87 ± 4.41^{ab}	21.12 ± 5.22^{b}	4.49 ± 5.40^{b}
OBF/min.	113.50 ± 7.23^{a}	113.10 ±7.60^{a}	115.23 ±7.23^{a}	10.79 ± 8.99^{a}	65.15 ± 9.15^{b}
Cum. mortality	6.67 ± 6.86^{e}	37.227 ± 31.21^{d}	56.11 ± 36.16^{c}	63.89 ± 32.39^{b}	73.33 ±29.31^{a}

	Concentration of Roundup (mg/l)						
	0.0	4.0	16.0	18.0	20.0	22.0	24.0
TBF/min.	15.73 ±4.41^{a}	5.79 ±4.41^{a}	16.46 ±4.41^{a}	9.00 ±4.63^{a}	7.04 ±5.92^{a}	0.00 ±0.00	0.00 ±0.00
OBF/min.	96.71 ±7.60^{bc}	123.27 ±8.00^{ab}	108.58 ±8.00^{a-c}	100.93 ±8.00^{a-c}	73.42 ±10.19^{c}	124.72 ±16.99^{ab}	136.99 ±16.99^{a}
Cum. Mortality	0.00 ±0.00	22.67 ±12.80^{d}	24.00 ±24.43^{d}	32.67 ±19.81^{c}	50.67 ±37.70^{b}	77.33 ±36.15^{a}	77.33 ±37.89^{a}

Means with the same superscript in the row are not significantly different ($p > 0.05$)

Table 10.2.1-20: Regression lines of best fit for the prediction of the values of OBF/min., TBF/min. and cumulative mortality of *C. gariepinus* exposed to acute levels Roundup for 96 hours

Dependent Variable	Independent variable	Prediction equation	Curve type	r^2
TBF	Time	$Y=2.8415e^{0.221x}$	Exponential	0.9828
TBF	Concentration	$Y=0.0017x^2 +0.0192x$	Power	0.9442
OBF	Time	$Y=23.314Ln(x) +16.325$	Logarithmic	0.9186
OBF	Concentration	$Y=25.117Ln(x) +19.269$	Logarithmic	0.9812
Mortality	Time	$Y=0.513x$	Linear	0.9922
Mortality	Concentration	$Y=0.0021x^2 + 0.2451x +4.4278$	Polynomial	0.9722

Where x = independent variable, y= dependent variable

Cumulative mortality of exposed fish was very variable relative to the concentration of the herbicide (Figure 1).

The cumulative mortality differed with the time of exposure ($p < 0.01$), concentration of toxicant ($p < 0.001$) and interactions between exposure duration and herbicide concentration ($p < 0.01$, Figure 1). Exposed fish produced copious amount of mucus on the gill and skin which appeared to be concentration-dependent in exposed fish with minimal amount on the control group. Pigmentation of the skin of the fish was not noticed in any of the exposure concentrations.

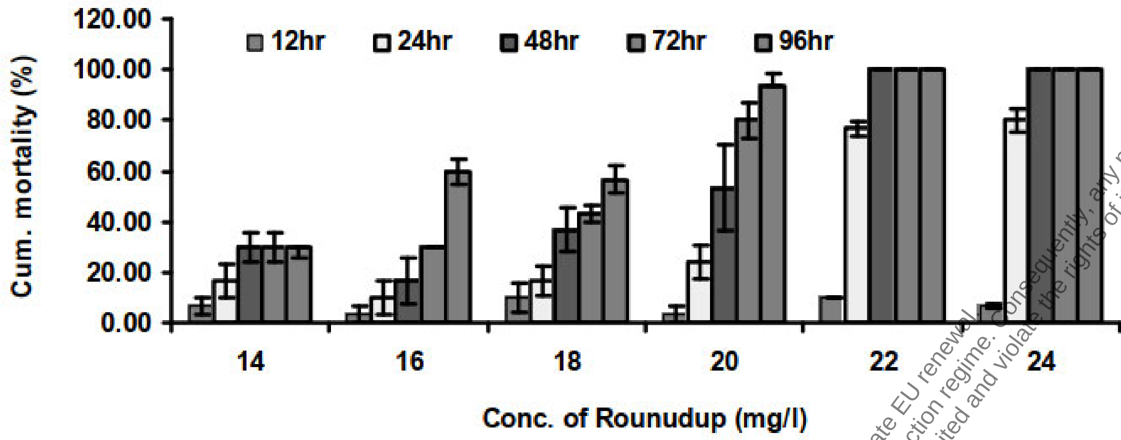

Figure 1: Percentage cumulative mortality of fingerlings of *C. gariepinus* exposed to various concentrations of Roundup for 96 hours

The 24, 48, 72 and 96 hour LC_{50} and associated 95 % confidence limits of the herbicide concentrations shown below indicated that the range of the values between the 24 hour and 96 hour LC_{50} (4.93 mg/L) as very narrow. Safe concentrations of Roundup to fingerlings of C. gariepinus were very low (2.08 mg/L for 24 hour and 1.59 mg/L for 96 hour). The time it took for half of the exposed fish to die at the various exposure concentrations decreased with time with the highest concentration (24 mg/L) killing half of the exposed fish at about one sixth the time it took for 14 mg/L of the herbicide.

Table 10.2.1-21: Lethal concentrations and associated 95 % confidence limits of Roundup to *C. gariepinus* fingerling exposure to Roundup for 96 hours

Time (hours)	Lethal Concentration	Safe concentration	Probit model estimation equation
24	LC_{50}- 20.81 (19.58-22.48)	2.08	y= -4.73+0.23x
24	LC_{90}- 26.44 (24.45-31.47)	2.64	
48	LC_{50}-18.50 (16.67-19.40)	1.85	y= -5.18+0.29x
48	LC_{90}-22.54 (20.88-26..09)	2.25	
72	LC_{50}-17.11 (16.30-17.84)	1.71	y= -5.30+0.31x
72	LC_{90}-21.44 (20.59-23.31)	2.14	
96	LC_{50}-15.88 (14.99-16.64)	1.59	y= -5.06+5.06x
96	LC_{90}-19.91 (18.97-21.42)	1.20	

Where y=dependent variable, x= independable variable

Discussion

The threshold concentration causing 100 % mortality in this study was 22 mg/L which is lower than that reported for other toxicants tested on any of the clariid species 7 suggesting that it may be more toxic than other tested toxicants. Half of the exposed fish (50 %) were killed by 15.88 mg/L of herbicide in 19.69 hours, hence the herbicide can be classified as being slightly toxic. Besides, in the wild where the agro-chemical is indiscriminately used the impact of the exposure stress caused by the herbicide, may be protracted, following the survivors throughout life and may affect various aspects of their lives.

Conclusion

The 24, 48, 72 and 96 hour LC_{50} and associated 95 % confidence limits indicated that the range of the values between the 24 hour and 96 hour LC_{50} (4.93 mg/L) as very narrow. Safe concentrations of Roundup to fingerlings of *C. gariepinus* were very low (2.08 mg/L for 24 hour and 1.59 mg/L for 96 hour). The 96 hour LC_{50} of Roundup on the fish was 19.58 mg/L.

3. Assessment and conclusion

Assessment and conclusion by applicant:

The effects of Roundup containing 360 g/l glyphosate (equivalent to 480 g/L isopropylamine salt) were tested in an acute test with *C. gariepinus* fingerlings. The 96 hour-LC_{90} was determined to be 19.91 mg product/L.

There is no analytical verification of test concentrations reported and thus the reliability of the endpoint is questionable. The appearance of mucus accumulation on the skin and gills and skin pigmentation recorded in fish in the holding / stock vessels is a clear indicator of stress. Therefore, the condition of the fish used in the test is questionable. The study was not conducted in accordance with a recognised test guideline and was not performed under conditions of GLP. Furthermore, the purity of the formulation roundup is not clearly given as the specification in the full text contains some typing errors. The study is considered reliable with restrictions.

CP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Available acute toxicity data on glyphosate acid and the representative product MON 52276 to fish, aquatic invertebrates, algae and aquatic macrophytes indicate no significantly enhanced toxicity of the formulated product MON 52276 in comparison to the active substance glyphosate. Therefore, based on the results of these studies the performance of any further study is not deemed necessary.

CP 10.2.3 Further testing on aquatic organisms

Further testing is not considered to be required, since the comparison of the RAC values for fish, aquatic invertebrates, algae, aquatic plants and aquatic macrophytes with the maximum PEC_{sw} values for glyphosate and the metabolites AMPA and HMPA, indicate an overall acceptable risk for aquatic organisms.

CP 10.3 Effects on Arthropods

CP 10.3.1 Effects on bees

Relevant and reliable studies for the risk assessment of honey bees, bumble bees and solitary bees, covering exposure to the different life stages of these *Apis* and non-*Apis* bee species from the active substance glyphosate are summarised in the tables below, presenting the most sensitive endpoints.

Details of these studies with the active substance are summarised in the Document M-CA, Section 8, point 8.3.1 and relevant endpoints for the risk assessment for honey bees are provided in the table below (**Table 10.3.1-1**) and for bumble bees and solitary bees in Table 10.3.1-29 and **Table 10.3.1-39**, respectively.

Table 10.3.1-1: Endpoints and effect values of glyphosate relevant for the risk assessment for honey bees

Acute toxicity					
Reference	Test item	Species	Test design/ GLP	LD_{50} (µg a.e./bee)	NOED (µg a.e./bee)
[redacted] 2003 CA 8.3.1.1.1/001	Glyphosate acid	*Apis mellifera*	Acute oral, 48 h	**> 104**	-
[redacted], 2003 CA 8.3.1.1.2/001	Glyphosate IPA salt	*Apis mellifera*	Acute contact, 48 h	**> 100**	-
Chronic toxicity					
Reference	Test item	Species	Test design/ GLP	LDD_{50} (µg a.e./bee/d)	NOEDD (µg a.e./bee/d)
[redacted] 2017 CA 8.3.1.2/001	Glyphosate IPA-salt	*Apis mellifera*	Chronic, Adult 10 days	> 179.9	**179.9**
Honey bee development and other honey bee life stages toxicity					
Reference	Test item	Species	Test design/ GLP	LD_{50} (µg a.e./larva)	NOED (µg a.e./larva)
[redacted] 2020 CA 8.3.1.3/001	Glyphosate IPA-salt	*Apis mellifera*	Chronic larvae, 22-day	-	**80**
Sub-lethal toxicity					
Reference	Test item	Species	Test design/GLP	LD_{50} (µg a.e./L)	NOAEL (µg a.e./L)
[redacted] 2012 CA 8.3.1.4/001	Glyphosate IPA-salt	*Apis mellifera*	Bee brood feeding test. Field study	-	**≥ 301000 (301 mg a.e./L)**

a.e.: glyphosate acid equivalents
Endpoints in **bold** are used for risk assessment

Studies on effects of the representative formulation MON 52276 on pollinators to fulfil the data requirements according to EU Regulation No 284/2013 are presented in the following. Studies considering the effects of MON 52276 on honey bees were assessed for their validity to current and relevant guidelines and are presented in the following table.

Table 10.3.1-2: Studies on the toxicity of MON 52276 to honey bees

Annex point	Study	Study type	Test species	Substance(s)	Status	Remark
CP 10.3.1.1.1/001	[redacted] 2001	Acute oral and contact	*Apis mellifera*	MON 52276	Valid	
CP 10.3.1.5/001	[redacted] 2011	Residues Semi-field	*Apis mellifera*	MON 52276	Valid	

Literature articles and peer-reviewed published data considered to be relevant and reliable or reliable with restrictions with regards to the impact on pollinators are summarised in the table below. Full literature evaluation is provided in document M-CA Section 9. A summary of previously evaluated peer reviewed literature from the RAR 2015 is also available in Annex M-CA 8-01 of the M-CA Section 8. Each literature article summary is presented below according to the respective annex point.

Table 10.3.1-3: Literature on toxicity of MON 52276 to pollinators

Annex point	Study	Study type	Substance(s)	Status	Remark
CP 10.3.1.5/002	Thompson *et al.* (2014) Evaluating Exposure and Potential Effects on Honeybee Brood (*Apis mellifera*) Development Using Glyphosate as an Example.	Colony feeding study	MON 52276 applied on phacelia for residues in bee matrices. Oomen study conducted with IPA salt.	Relevant	NOEC for effects at colony level was 301 mg a.e./L

Endpoints of studies considered valid with the representative product MON 52276 are shown in the table below. In order to make a direct comparison of toxicity between studies conducted with MON 52276 and those conducted with IPA salt, glyphosate technical and glyphosate acid, the endpoints from all these studies have been converted to acid equivalents (a.e.). This conversion has been made by the acid equivalent purity of the test item stated in the reports.

Table 10.3.1-4: Endpoints and effect values of MON 52276 relevant for the risk assessment for honey bees

Acute toxicity					
Reference	Test item	Species	Test design/GLP	LD_{50} (µg a.e./bee)	NOED (µg a.e./bee)
[redacted] 2001 CP 10.3.1.1.1/001	MON 52276	*Apis mellifera*	Acute oral, 48 h	> 77	-
[redacted], 2001 CP 10.3.1.1.1/001	MON 52276	*Apis mellifera*	Acute contact, 48 h	> 100	-
Cage and tunnel toxicity tests					
Reference	Test item	Species	Test design/GLP	Magnitude of residues in mg a.e./kg	
[redacted] 2011 CP 10.3.1.5/001	MON 52276	*Apis mellifera*	Residues in honeybee colony - Phacelia semi-field application at 8 L product/ha (2.88 g a.e./ha) during flowering and in the presence of foraging bees	**nectar: 2.78 – 31.3** **pollen: 87.2 – 629** **total daily intake based on mean residues over 1-3 d: 22**	

a.e.: glyphosate acid equivalents
Endpoints in **bold** are used for risk assessment

Consideration of metabolites

The primary metabolite of glyphosate is aminomethylphosphonic acid (AMPA). Most of the parent glyphosate is remained unchanged and only a small amount (less than 1 % of the applied dose) is transformed to aminomethylphosphonic acid (AMPA).

Following application to plant tissues, unchanged glyphosate was the only residue detected in significant amounts. In presence of soil as a substrate and rotational crops glyphosate degrades quickly and AMPA was found at rates comparable or even higher than the parent glyphosate. However, the uptake via roots and translocation in the plants was very low, resulting in not significant residue levels as confirmed by several plant metabolism and confined rotational crop studies (e.g. lettuce, cabbage, peas, barley, wheat, carrot, beets and radishes) involving application rates to bare soil equivalent to 3.87 – 6.5 kg ae/ha (exceeding the application rates according to the recent GAP). Neither glyphosate nor AMPA show a potential uptake into crops, as a major part of the glyphosate is degraded into CO_2. See M-CA Section 6, for details.

Therefore, studies with the metabolites are not considered necessary since the exposure to bees is covered by the assessment conducted with the parent glyphosate.

Risk assessment for bees

The table below indicates that the risk assessment for pollinators covers all the proposed uses presented in the GAP. There are some uses in the GAP that consider multiple applications, with a 28 day or 90 day interval, however the risk assessment presented here represents the maximum single application rates for relevant crop types for the proposed uses of MON 52276 according to available guidelines.

Table 10.3.1-5: Risk assessment strategy for Pollinators

GAP number and summary of use	Maximum single application rate (g a.e./ha)				
	1 x 540	1 x 720	1 x 1080	1 x 1440	1 x 1800
Uses 1 a-c: Applied to weeds; pre-sowing, pre-planting, pre emergence of **field crops**		X	X	X	
Uses 2 a-c: Applied to weeds; post-harvest, pre-sowing, pre-planting of **field crops**		X	X	X	
Use 3 a-b: Applied to cereal volunteers; post-harvest, pre-sowing, pre-planting of **field crops**	X				
Uses 4 a-c, 5a-c: Applied to weeds (post emergence) below trees in **orchards** and **vineyards**		X	X	X	
Use 6 a-b: Applied to weeds (post emergence) in **field crops BBCH < 20**		X	X		
Use 7 a-b: Applied to weeds (post emergence) around **rail tracks**					X
Use 8 and 9: Applied to invasive species (post emergence) in **agricultural and non-agricultural areas**					X
Uses 10 a-c: Applied to couch grass; post-harvest, pre-sowing, pre-planting of **field crops**		X	X	X	

X = this use is covered by the application rate indicated and a risk assessment in provided.

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). In addition, a risk assessment according to the “EFSA Guidance Document on the risk assessment of plant protection products on bees *(Apis mellifera*, *Bombus* spp. and solitary bee)” (2013) is presented to address the data requirements of the Regulation (EU) No. 284/2013, chronic risk to adult honey bees and honey bee brood. In consideration of the recommendations of the “Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology”[28] currently no risk assessment for bumble bees and solitary bees is required, given that the EFSA Bee Guidance has not yet been noted. Furthermore, EFSA stated that it is not recommended to routinely perform a risk assessment for bumble bees and solitary bees. Nevertheless, acute studies for bumble bees and solitary bees are available and the results are presented.

Although acute contact and oral data with MON 52276 are available, the endpoints are greater than values, indicating no enhanced toxicity of the formulated product in comparison to the active substance. Thus the LD_{50} values from the active substance acute studies have been used in the acute risk assessment. This assessment adequately represents also the risk from MON 52276.

Risk assessment according to SANCO/10329/2002 rev 2 final

The hazard quotients for oral and contact exposure of honey bees are based on the recommended field use rates and are presented in the table below.

[28] Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, provided by EFSA, published December 22, 2015

Table 10.3.1-6: Assessment of the risk of glyphosate for honey bees due to the use of MON 52276

Intended use	All uses (Uses: 1a-10c)		
Active substance	glyphosate		
Use pattern	1-2 x 1800 g a.e./ha, 1-2 x 1440 g a.e./ha, 1-3 x 1080 g a.e./ha, 1-3 x 720 g a.e./ha, 1 x 540 g a.e./ha		
Test design	**LD_{50} (lab.) (µg a.e./bee)**	**Single max. application rate (g a.e./ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	104	1800	17.3
		1440	14.0
		1080	10.4
		720	6.9
		540	5.2
Contact toxicity	> 100	1800	< 18.0
		1440	< 14.4
		1080	< 11.0
		720	< 7.2
		540	< 5.4

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure.

The oral and contact hazard quotients (Q_{HO}, Q_{HC}) are below the Regulation (EC) 549/2011 trigger value of 50. Low risk to honey bees is concluded for all intended use patterns and no further testing is required.

Further considerations regarding the risk to bees

A low acute contact and oral risk has been demonstrated in the risk assessment above for all uses. Studies to evaluate the chronic toxicity to adult honey bees and larval honey bee development are also provided along with additional information on the acute toxicity to non-*Apis* bees (see section on Bumble bees and Solitary bees below). Acute toxicity testing indicated that bumble bees (*Bombus terrestris*) and solitary bees (*Osmia bicornis*) are not more sensitive compared to the honey bee and hence the risk assessment for honey bees is considered to cover other types of bee.

Chronic toxicity

A 10-day chronic feeding study on adult honey bees has been conducted ([redacted], 2017, KCA 8.3.1.2/001). The findings of this study indicated that there were no delayed or cumulative toxicity effects when exposure to honey bees takes place chronically. Compared with acute testing, i.e. daily dosing with 179.9 µg a.e./bee over 10 days (total dose = 1799 µg a.e./bee) led to negligible mortality (3.3 %) and did not exhibit a higher mortality than after single acute oral exposure at 104 µg a.e./bee.

Larval toxicity/effects on brood

A 22-day repeated dose laboratory test has been conducted ([redacted], 2020, KCA 8.3.1.3/001). A NOED for honey bee larvae of 80 µg a.e./larva was recorded indicating similar sensitivity as adult honey bees.

There is currently no agreed chronic or larval risk assessment. However, as both endpoints are presented in terms of concentration in diet in addition to dose per honey bee and larva, respectively, it is possible to extrapolate the exposure to honey bees under natural conditions. [redacted] (2011, CP 10.3.1.5/001) provides measurements of the levels of exposure in nectar and honey following an application at 2.88 kg a.e./ha, which exceeds the maximum single application rate of the proposed uses in the GAP. Residues in nectar samples taken from forager bees at various time points after application ranged from 2.78 to 31.3 mg a.e./kg. Residues in pollen samples taken from the pollen trap (higher than from pollen taken from foragers) at various times after application ranged from 87.2 to 629 mg a.e./kg. Using this information, a risk assessment may be conducted in line with the recommendations of Reg (EU) No 283/2013 section 8(10) which states:

"*Pending the validation and adoption of new studies and of a new risk assessment scheme, existing protocols shall be used to address the acute and chronic risk to bees, including those on colony survival and development, and the identification and measurement of relevant sub-lethal effects in the risk assessment*".

Furthermore, under section 8.3.1. Effects on bees of the same Regulation it states that:

"[…] *risk assessment shall be based on a comparison of the relevant endpoint with those residue concentrations. If this comparison indicates that an exposure to toxic levels cannot be excluded, effects shall be investigated with higher tier tests.*"

A comparison can be made between the chronic and larval endpoint based on concentration in test diets and the maximum concentrations of glyphosate measured in nectar and pollen. In the chronic adult study the NOEC and NOEDD values (10 days) were 10000 mg a.e./kg feeding solution and 179.9 µg a.e./bee/day, respectively. As forager bees consume a diet which is virtually 100 % nectar this endpoint can be compared to the maximum measured residues in nectar of 31.3 mg a.e./kg demonstrating a margin of safety of 31.9.

In the larval toxicity study the NOEC and NOED values (over the larval development period) were 505 mg a.e./kg diet and 80 µg a.e./larva. Because larvae consume a mix of nectar and pollen it is necessary to consider the proportion of nectar and pollen in the diet and the contribution towards the exposure concentration. According to Rortais *et al.* (2015)[29] a single larva consumes 59.4 mg sugar and 2 mg pollen over 5 days. Assuming the nectar is foraged from treated weeds with a sugar content of 30 % (w/w) this means that the larval diet consists of 396 mg nectar and 2 mg of pollen, i.e. a ratio of 0.995:0.05 (nectar:pollen). As the maximum concentration in nectar was 31.3 mg a.e./kg and in pollen 629 mg a.e./kg the diet would have a concentration of:

Nectar: 0.995 x 31.3 mg a.e./kg = 31.1 mg a.e./kg + Pollen: 0.05 x 629 mg a.e./kg = 31.45 mg a.e./kg diet

Concentration of glyphosate in the larval diet = 62.6 mg a.e./kg (based on nectar and pollen)

Comparing the larval endpoint to the maximum measured residues in the larval diet of 62.6 mg a.e./kg a margin of safety of 8.1 is calculated. Note: This is considered a worst-case estimate of exposure as honey bee larvae are fed with royal jelly for the first two days of their development period.

Overall, a margin of safety between 31.9 and 8.1 is demonstrated for chronic exposure to adult honey bees and honey bee larvae. This approach indicates that the risk to honey bees is acceptable.

In addition, a honey bee brood feeding test ([redacted] 2012, KCA 8.3.1.4/001) was conducted to evaluate the potential risk to honey bee brood when they are directly exposed to glyphosate (tested as IPA salt). This study provides further information regarding the chronic risk to honey bees and honey bee brood. The dose levels of the test item were based on the residues characterised in the glasshouse study ([redacted] 2011, CP 10.3.1.5/001). The lowest test dose (75 mg glyphosate a.e./L) was based on the mean measured pollen and nectar concentration over the first 3 days following spray application, the mid-dose (150 mg a.e./L) was based on the highest residue concentration determined (in pollen and nectar following spray application) and the highest dose (301 mg a.e./L) was twice as high as the highest detected residue concentration. Mortality of adult honey bees as well as honey bee brood was assessed over a period of 7 days. Overall, no treatment related effects were observed. The NOAEL for adult mortality and brood development was the highest dose tested; 301 mg a.e./L.

[29] Rortais *et al.* (2015) Modes of honeybees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie 36 (2005) 71–83

Consequently, the presented risk assessment for honey bees according to SANCO10329/2002 and taking into account the provisions in Reg (EU) No 283/2013 demonstrate a low risk to honey bees for glyphosate and for all uses of MON 52276.

Risk assessment according to the EFSA GD on the Risk Assessment on Bees (2013)

In addition, the risk assessment for honey bees is performed in accordance with the recommendations of the "Guidance on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees)", as provided by the European Food Safety Authority (EFSA Journal 2013;11(7):3295 doi: 10.2903/j.efsa.2013.3295, July 04, 2014). All calculations are based on the EFSA Screening Step and 1st Tier calculator (BeeTool v3).

The risk assessment presented here considers also the consumption of contaminated water (guttation water, surface water and puddles).

The screening step was conducted considering all recommended application rates according to the proposed use pattern (downwards spray).

Table 10.3.1-7: Screening assessment of the risk of glyphosate for honey bees due to the use of MON 52276

Intended use	All uses (Uses: 1a-10c)				
Application method	downward spraying				
Active substance	Glyphosate				
Use pattern	1-2 x 1800 g a.e./ha, 1-2 x 1440 g a.e./ha, 1-3 x 1080 g a.e./ha, 1-3 x 720 g a.e./ha, 1 x 540 g a.e./ha				
Type design	**LD_{50} (µg a.e./bee)**	**Max. single application rate (g a.e./ha)**		**$HQ_{contact}$ criterion**	**Trigger**
Adult acute contact toxicity	> 100	1800		< 18.0	42
		1440		< 14.4	
		1080		< 10.8	
		720		< 7.2	
		540		< 5.4	
Type design	**Endpoint**	**Max. single application rate (kg a.e./ha)**	**E_f × SV**	**ETR**	**Trigger**
Adult acute oral toxicity	LD_{50} = 104 µg a.e./bee	1.80	7.6	0.13	≤ 0.2
		1.44		0.11	
		1.08		0.08	
		0.72		0.05	
		0.54		0.04	
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	1.80	7.6	**< 0.076**	≤ 0.03
		1.44		**< 0.06**	
		1.08		**< 0.04**	
		0.72		**< 0.0304**	
		0.54		< 0.023	
Larval toxicity	NOED = 80 µg a.e./larva	1.80	4.4	0.10	≤ 0.2

Table 10.3.1-7: Screening assessment of the risk of glyphosate for honey bees due to the use of MON 52276

		1.44		0.08	
		1.08		0.06	
		0.72		0.04	
		0.54		0.03	

Ef: exposure factor; SV: shortcut value; $HQ_{contact}$: Hazard quotient for contact exposure; ETR: Exposure toxicity ratio; ETR values shown in **bold** breach the relevant trigger.

The exposure toxicity ratio (ETR) for adult chronic toxicity is above the respective trigger value for application rates of 720 g a.e./ha, 1080 g a.e./ha, 1440 g a.e./ha and 1800 g a.e./ha. Therefore, a Tier 1 risk assessment is required for these use patterns. No risk is indicated at the screening step for the use rate of 540 g a.e./ha.

For the Tier 1 risk assessment calculations considering application of MON 52276 in crops planted in wide rows (i.e. orchards and vines) the "under crop application" scenario is used. The crop itself will not be over-sprayed as the application is done only to the area under the crop. Thus, no treated crop scenario is included in the following (**Table 10.3.1-8** to **Table 10.3.1-10**). Only weeds, field margin, adjacent crop and next crop scenarios are considered.

Table 10.3.1-8: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 in orchard crops and vines at 1440 g a.e./ha

Intended use		Orchard crops, vines (Uses: 4a, 5a)					
Application method		downward spraying					
Crop Category		under crop application[1]					
Active substance		glyphosate					
Use pattern		1-2 x 1440 g a.e./ha[2]					
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**E_f**	**SV**	**ETR**	**Trigger**
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	Weeds	weed < 10	1	0.27	< 0.01	0.03
			weed ≥ 10	1	2.9	< 0.02	
		field margin	weed < 10	0.0092	2.9	< 0.01	
			weed ≥ 10	0.0092	2.9	< 0.01	
		adjacent crop	weed < 10	0.0033	5.8	< 0.01	
			weed ≥ 10	0.0033	5.8	< 0.01	
		next crop	weed < 10	1	0.54	< 0.01	
			weed ≥ 10	1	0.54	< 0.01	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator
[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

Table 10.3.1-9: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 in orchard crops and vines at 1080 g a.e./ha

Intended use		Orchard crops, vines (Uses: 4a, 4b, 5a, 5b)					
Application method		downward spraying					
Crop category		under crop application[1]					
Active substance		glyphosate					
Use pattern		1-3 x 1080 g a.e./ha[2]					
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**E_f**	**SV**	**ETR**	**Trigger**
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	Weeds	weed < 10	1	0.27	< 0.001	0.03
			weed ≥ 10	1	2.9	< 0.013	
		field margin	weed < 10	0.0092	2.9	< 0.001	
			weed ≥ 10	0.0092	2.9	< 0.001	
		adjacent crop	weed < 10	0.0033	5.8	< 0.001	
			weed ≥ 10	0.0033	5.8	< 0.001	
		next crop	weed < 10	1	0.54	< 0.002	
			weed ≥ 10	1	0.54	< 0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator
[2] Max. single application rate of 1080 g a.e./ha considered for risk calculation

Table 10.3.1-10: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 in orchard crops and vines at 720 g a.e./ha

Intended use		Orchard crops, vines (Uses: 4b, 4c, 5b, 5c)					
Application method		downward spraying					
Crop Category		under crop application[1]					
Active substance		glyphosate					
Use pattern		1-3 x 720 g a.e./ha[2]					
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**E_f**	**SV**	**ETR**	**Trigger**
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	Weeds	weed < 10	1	0.27	< 0.001	0.03
			weed ≥ 10	1	2.9	< 0.008	
		field margin	weed < 10	0.0092	2.9	< 0.001	
			weed ≥ 10	0.0092	2.9	< 0.001	
		adjacent crop	weed < 10	0.0033	5.8	< 0.001	
			weed ≥ 10	0.0033	5.8	< 0.001	
		next crop	weed < 10	1	0.54	< 0.002	
			weed ≥ 10	1	0.54	< 0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator
[2] Max. single application rate of 720 g a.e./ha considered for risk calculation

All exposure toxicity ratios (ETRs) for adult chronic toxicity are below the respective trigger value, indicating acceptable risk to honey bees following application of MON 52276 in orchard crops and vines according to the proposed use pattern.

The recommended use pattern for MON 52276 includes also application on railroad tracks. Application is done by spray trains (spraying tanks, pumps and nozzles are mounted on special trains). Spray trains have an automatic plant detection system (infrared sensors and video cameras) to detect weeds using image processing. The automation system allows the nozzles to be opened or closed. So, MON 52276 is only sprayed on sections of the track that have weeds. The maximum application rate in any 12 months period is 3600 g a.e./ha (2 x 1800 g a.e./ha with a 90-day interval). Thus, the growth stage of weeds should not exceed BBCH 00 – 19. However, bees may possibly be exposed to MON 52276 by direct spraying while bees are foraging on flowers and weeds by oral uptake of contaminated pollen and nectar. As no definite crop scenario for railroad tracks is provided by EFSA, the under-crop application scenario was considered to address uses on railroad tracks.

Table 10.3.1-11: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 – railroad tracks at 1800 g a.e./ha

Intended use		Railroad tracks (Uses: 7a, 7b)					
Application method		downward spraying					
Crop Category		under crop application[1]					
Active substance		glyphosate					
Use pattern		1-2 x 1800 g a.e./ha[2]					
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**E_f**	**SV**	**ETR**	**Trigger**
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	Weeds	weed < 10	1	0.27	< 0.002	0.03
			weed ≥ 10	1	2.9	< 0.021	
		field margin	weed < 10	0.0092	2.9	< 0.001	
			weed ≥ 10	0.0092	2.9	< 0.001	
		adjacent crop	weed < 10	0.0033	5.8	< 0.001	
			weed ≥ 10	0.0033	5.8	< 0.001	
		next crop	weed < 10	1	0.54	< 0.004	
			weed ≥ 10	1	0.54	< 0.004	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] As no definite scenario for railroad tracks is provided by the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, the under crop application scenario was considered to address uses on railroad tracks
[2] Max. single application rate of 1800 g a.e./ha considered for risk calculation

All exposure toxicity ratios (ETRs) for adult chronic toxicity are below the respective trigger value, indicating acceptable risk to honey bees following application of MON 52276 on railroad tracks according to GAP.

Besides uses in agricultural areas and railroad tracks a proposed use of MON 52276 is also to control invasive weeds. It is important to control noxious, invasive weeds to help protect our diverse native plants, natural resources, and agriculture, as well as ensuring the safety of humans in the environment (e.g., Giant Hogweed). Although some noxious weeds may serve as forage for bees and other pollinators, e.g. invasive knotweed species are considered valuable to many beekeepers since they bloom later in the season than many other plants. However, the detrimental impacts of these invasive plants significantly outweigh their value as a pollen and nectar source.

MON 52276 is applied by spot application with a maximum single application rate of 1800 g a.s/ha in a 12 month period. Nevertheless, bees can be exposed while they are foraging by direct overspray or dried residues on plants and by oral uptake of contaminated pollen and nectar. Thus, an appropriate assessment is presented here to address risk from the use of MON 52276 on invasive weeds in agricultural and non-agricultural areas.

Table 10.3.1-12: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 – invasive plant species in agricultural and non-agricultural areas at 1800 g a.e./ha

Intended use	invasive plant species in agricultural and non-agricultural areas (Uses: 8, 9)
Application method	downward spraying
Crop Category	under crop application[1]
Active substance	glyphosate
Use pattern	1 x 1800 g a.e./ha

Test design	Endpoint (lab.)	Scenario	BBCH	E_f	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	Weeds	weed < 10	1	0.27	< 0.002	0.03
			weed > 10	1	2.9	< 0.021	
		field margin	weed < 10	0.0092	2.9	< 0.001	
			weed > 10	0.0092	2.9	< 0.001	
		adjacent crop	weed < 10	0.0033	5.8	< 0.001	
			weed > 10	0.0033	5.8	< 0.001	
		next crop	weed < 10	1	0.54	< 0.004	
			weed > 10	1	0.54	< 0.004	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.

[1] As no definite scenario for invasive weeds is provided by the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, under crop application: giant hogweed (*Heracleum* spp.) and Japanese knotweed (*Reynoutria japonica*)

All exposure toxicity ratios (ETRs) for adult chronic toxicity are below the respective trigger value, indicating acceptable risk to honey bees following application of MON 52276 on invasive species in agricultural and non-agricultural areas according to GAP.

For the Tier 1 risk assessment calculations considering the pre-sowing, pre-planting and post-harvest uses the “bare soil application” scenario is selected.

Table 10.3.1-13: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 – pre-sowing, pre-planting and post-harvest uses at 1440 g a.e./ha

Intended use	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet (Uses: 1a, 2a)
Application method	downward spraying
Crop category	bare soil application – crop attractive for pollen and nectar[1]
Active substance	glyphosate
Use pattern	1-2 x 1440 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	E_f	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.54	< 0.003	0.03
		Weeds	< 10	1	0.27	< 0.002	
		field margin	< 10	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.003	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.

[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator

[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

Table 10.3.1-14: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 - pre-sowing, pre-planting and post-harvest uses at 1080 g a.e./ha

Intended use	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet, Legume vegetables (Uses: 1b, 2a, 2b, 2c, 6a, 10a)
Application method	downward spraying
Crop category	bare soil application – crop attractive for pollen and nectar[1]
Active substance	Glyphosate
Use pattern	1-3 x 1080 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	E_f	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.54	< 0.002	0.03
		Weeds	< 10	1	0.27	< 0.001	
		field margin	< 10	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator
[2] Max. single application rate of 1080 g a.e./ha considered for risk calculation

Table 10.3.1-15: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 - pre-sowing, pre-planting and post-harvest uses at 720 g a.e./ha

Intended use	Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet, Legume vegetables (Uses: 1c, 2b, 6b, 10b, 10c)
Application method	downward spraying
Crop category	bare soil application – crop attractive for pollen and nectar[1]
Active substance	glyphosate
Use pattern	1-3 x 720 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	E_f	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.54	< 0.002	0.03
		Weeds	< 10	1	0.27	< 0.001	
		field margin	< 10	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category in the first tier oral assessment according to the EFSA GD on the Risk Assessment on Bees (2013)
[2] Max. single application rate of 720 g a.e./ha considered for risk calculation

All exposure toxicity ratios (ETRs) for adult chronic toxicity are below the respective trigger value, indicating acceptable risk to honey bees following application of MON 52276 pre-sowing, pre-planting and post-harvest.

For the Tier 1 risk assessment calculations, considering ground directed inter-row applications in vegetables the following crop categories are selected:

Crop according to GAP	Crop Category[1]
Root vegetables	Root vegetables
Tuber vegetables	Potatoes
Bulb vegetables	Bulb vegetables
Fruiting vegetables	Fruiting vegetables 1, fruiting vegetables 2
Brassica	Leafy vegetables
Leafy vegetables	Leafy vegetables, lettuce
Stem vegetables	Leafy vegetables
Sugar beet	Sugar beet
Legume vegetables	Pulses

[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator

Table 10.3.1-16: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 – fruiting, leafy and tuber vegetables at 1440 g a.s./ha

Intended use	Fruiting vegetables, Leafy vegetables, Tuber vegetables (Uses: 1a, 2a)
Application method	downward spraying
Crop category	fruiting vegetables 2, lettuce and potatoes[1]
Active substance	glyphosate
Use pattern	1-2 x 1440 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	E_f	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.012	< 0.001	0.03
			≥ 70	1	0	< 0.001	
		Weeds	< 10	1	2.9	< 0.017	
			≥ 70	0.3	2.9	< 0.005	
		field margin	< 10	0.0092	2.9	< 0.001	
			≥ 70	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
			≥ 70	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.003	
			≥ 70	1	0.54	< 0.003	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. fruiting vegetables 2 = tomatoes, eggplants
[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

Table 10.3.1-17: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 - fruiting, leafy and tuber vegetables at 1080 g a.e./ha

Intended use	Fruiting vegetables, Leafy vegetables, Tuber vegetables (Uses: 1b, 2a, 2b, 2c, 6a, 10a)
Application method	downward spraying
Crop category	fruiting vegetables 2, lettuce and potatoes[1]
Active substance	glyphosate
Use pattern	1-3 x 1080 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	Ef	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.012	< 0.001	0.03
			10 – 39[3]	1	0.92	< 0.004	
			10 – 49	1	0.92	< 0.004	
			≥ 70	1	0	< 0.001	
		Weeds	< 10	1	2.9	< 0.013	
			10 – 39[3]	1	2.9	< 0.013	
			10 – 49[3]	1	2.9	< 0.013	
			≥ 70	0.3	2.9	< 0.004	
		field margin	< 10	0.0092	2.9	< 0.001	
			10 – 39[3]	0.0092	2.9	< 0.001	
			10 – 49	0.0092	2.9	< 0.001	
			≥ 70	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
			10 – 39[3]	0.0033	5.8	< 0.001	
			10 – 49	0.0033	5.8	< 0.001	
			≥ 70	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.002	
			10 – 39[3]	1	0.54	< 0.002	
			10 – 49	1	0.54	< 0.002	
			≥ 70	1	0.54	< 0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. fruiting vegetables 2 = tomatoes, eggplants
[2] Max. single application rate of 1080 g a.e./ha considered for risk calculation
[3] BBCH stage 10-39 relevant for the crop category potatoes

Table 10.3.1-18: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 – fruiting, leafy and tuber vegetables at 720 g a.e./ha

Intended use	Fruiting vegetables, Leafy vegetables, Tuber vegetables (Uses: 1c, 2b, 6b, 10b, 10c)
Application method	downward spraying
Crop category	fruiting vegetables 2, lettuce and potatoes[1]
Active substance	glyphosate
Use pattern	1-3 x 720 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	Ef	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.012	< 0.001	0.03
			10 – 39[3]	1	0.92	< 0.003	
			10 – 49	1	0.92	< 0.003	
			≥ 70	1	0	< 0.001	
		Weeds	< 10	1	2.9	< 0.008	
			10 – 39[3]	1	2.9	< 0.008	
			10 – 49	1	2.9	< 0.008	
			≥ 70	0.3	2.9	< 0.003	
		field margin	< 10	0.0092	2.9	< 0.001	
			10 – 39	0.0092	2.9	< 0.001	
			10 – 49	0.0092	2.9	< 0.001	
			≥ 70	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
			10 – 39[3]	0.0033	5.8	< 0.001	
			10 – 49	0.0033	5.8	< 0.001	
			≥ 70	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.002	
			10 – 39[3]	1	0.54	< 0.002	
			10 – 49	1	0.54	< 0.002	
			≥ 70	1	0.54	< 0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. fruiting vegetables 2 = tomatoes, eggplants
[2] Max. single application rate of 720 g a.e./ha considered for risk calculation
[3] BBCH stage 10 – 39 relevant for the crop category potatoes

Table 10.3.1-19: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 – Brassica, leafy, stem, root, fruiting vegetables at 1440 g a.e./ha

Intended use	Root vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables (Uses: 1a, 2a)
Application method	downward spraying
Crop category	leafy vegetables, root vegetables and fruiting vegetables 1[1]
Active substance	glyphosate
Use pattern	1-2 x 1440 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	Ef	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.54	< 0.003	0.03
			≥ 70	1	0	< 0.001	
		Weeds	< 10	1	2.9	< 0.017	
			≥ 70	0.3	2.9	< 0.005	
		field margin	< 10	0.0092	2.9	< 0.001	
			≥ 70	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
			≥ 70	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.003	
			≥ 70	1	0.54	< 0.003	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.

[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. leafy vegetables: artichokes, asparagus, cabbages and other brassicas, cauliflowers and broccoli, chicory roots, spinach; root vegetables: anise, badian, fennel, corian, carrots, turnips for fodder, viper´s grass; fruiting vegetables 1: chillies, peppers, cucumbers, gherkins, pumpkins, squash, gourds, melon, watermelons

[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

Table 10.3.1-20: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 - Brassica, leafy, stem, root, fruiting and legume vegetables at 1080 g a.e./ha

Intended use	Root vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Legume vegetables (Use 1b, 2a, 2b, 2c, 6a, 10a)
Application method	downward spraying
Crop category	leafy vegetables, root vegetables, fruiting vegetables 1 and pulses[1]
Active substance	glyphosate
Use pattern	1-3 x 1080 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	Ef	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.54	< 0.002	0.03
			10 – 39[3]	1	5.8	< 0.025	
			10 – 49	1	5.8	< 0.025	
			≥ 70	1	0	< 0.001	
		Weeds	< 10	1	2.9	< 0.013	
			10 – 39[3]	1	2.9	< 0.013	
			10 – 49	1	2.9	< 0.013	
			≥ 70	0.3	2.9	< 0.004	
		field margin	< 10	0.0092	2.9	< 0.001	
			10 – 39[3]	0.0092	2.9	< 0.001	
			10 – 49	0.0092	2.9	< 0.001	
			≥ 70	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
			10 – 39[3]	0.0033	5.8	< 0.001	
			10 – 49	0.0033	5.8	< 0.001	
			≥ 70	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.002	
			10 – 39[3]	1	0.54	< 0.002	
			10 – 49	1	0.54	< 0.002	
			≥ 70	1	0.54	< 0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. leafy vegetables: artichokes, asparagus, cabbages and other brassicas, cauliflowers and broccoli, chicory roots, spinach; root vegetables: anise, badian, fennel, corian, carrots, turnips for fodder, viper´s grass; fruiting vegetables 1: chillies, peppers, cucumbers, gherkins, pumpkins, squash, gourds, melon, watermelons; pulses: beans, broad beans, horse beans, buckwheat, chick peas, cow peas, leguminous for silage, leguminous vegetables, lentis, lupins, peas, soybeans, vetches
[2] Max. single application rate of 1080 g a.e./ha considered for risk calculation
[3] BBCH stage 10-39 relevant for the crop category root vegetables

Table 10.3.1-21: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 - Brassica, leafy, stem, root, fruiting and legume vegetables at 720 g a.e./ha

Intended use	Root vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Legume vegetables (Uses: 1c, 2b, 6b, 10b, 10c)
Application method	downward spraying
Crop category	leafy vegetables, root vegetables, fruiting vegetables 1 and pulses[1]
Active substance	glyphosate
Use pattern	1-3 x 720 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	Ef	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.54	< 0.002	0.03
			10 – 39[3]	1	5.8	< 0.017	
			10 – 49	1	5.8	< 0.017	
			≥ 70	1	0	< 0.001	
		Weeds	< 10	1	2.9	< 0.008	
			10 – 39[3]	1	2.9	< 0.008	
			10 – 49	1	2.9	< 0.008	
			≥ 70	0.3	2.9	< 0.003	
		field margin	< 10	0.0092	2.9	< 0.001	
			10 – 39[3]	0.0092	2.9	< 0.001	
			10 – 49	0.0092	2.9	< 0.001	
			≥ 70	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
			10 – 39[3]	0.0033	5.8	< 0.001	
			10 – 49	0.0033	5.8	< 0.001	
			≥ 70	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.002	
			10 – 39[3]	1	0.54	< 0.002	
			10 – 49	1	0.54	< 0.002	
			≥ 70	1	0.54	< 0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. leafy vegetables: artichokes, asparagus, cabbages and other brassicas, cauliflowers and broccoli, chicory roots, spinach; root vegetables: anise, badian, fennel, corian, carrots, turnips for fodder, viper´s grass; fruiting vegetables 1: chillies, peppers, cucumbers, gherkins, pumpkins, squash, gourds, melon, watermelons, leguminous for silage, leguminous vegetables, lentis, lupins, peas, soybeans, vetches
[2] Max. single application rate of 720 g a.e./ha considered for risk calculation
[3] BBCH stage 10 – 39 relevant for the crop category root vegetables

Table 10.3.1-22: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 - bulb vegetables at 1440 g a.e./ha

Intended use	Bulb vegetables (Uses: 1a, 2a)
Application method	downward spraying
Crop category	bulb vegetables[1]
Active substance	glyphosate
Use pattern	1-2 x 1440 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	Ef	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.54	< 0.003	0.03
			≥ 70	1	0	< 0.001	
		weeds	< 10	1	2.9	< 0.017	
			≥ 70	0.6	2.9	< 0.010	
		field margin	< 10	0.0092	2.9	< 0.001	
			≥ 70	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
			≥ 70	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.003	
			≥ 70	1	0.54	< 0.003	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. bulb vegetables: garlic, leeks and other alliaceous vegetables, onions
[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

Table 10.3.1-23: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 - bulb vegetables at 1080 g a.e./ha

Intended use	Bulb vegetables (Uses: 1b, 2a, 2b, 2c, 6a, 10a)
Application method	downward spraying (bulb vegetables[1])
Crop category	bulb vegetables[1]
Active substance	glyphosate
Use pattern	1-3 x 1080 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	Ef	SV	ETR	Trigger
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	<10	1	0.54	<0.002	0.03
			10-39	1	5.8	<0.025	
			≥70	1	0	<0.001	
		weeds	<10	1	2.9	<0.013	
			10-39	1	2.9	<0.013	
			≥70	0.6	2.9	<0.008	
		field margin	<10	0.0092	2.9	<0.001	
			10-39	0.0092	2.9	<0.001	
			≥70	0.0092	2.9	<0.001	
		adjacent crop	<10	0.0033	5.8	<0.001	
			10-39	0.0033	5.8	<0.001	
			≥70	0.0033	5.8	<0.001	
		next crop	<10	1	0.54	<0.002	
			10-39	1	0.54	<0.002	
			≥70	1	0.54	<0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. bulb vegetables: garlic, leeks and other alliaceous vegetables, onions
[2] Max. single application rate of 1080 g a.e./ha considered for risk calculation

Table 10.3.1-24: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276- bulb vegetables at 720 g a.e./ha

Intended use	Bulb vegetables (Uses: 1c, 2b, 6b, 10b, 10c)						
Application method	downward spraying						
Crop category	bulb vegetables[1]						
Active substance	glyphosate						
Use pattern	1-3 x 720 g a.e./ha[2]						
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**Ef**	**SV**	**ETR**	**Trigger**
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.54	< 0.002	0.03
			10 – 39	1	5.8	< 0.017	
			≥ 70	1	0	< 0.001	
		weeds	< 10	1	2.9	< 0.008	
			10 – 39	1	2.9	< 0.008	
			≥ 70	0.6	2.9	< 0.005	
		field margin	< 10	0.0092	2.9	< 0.001	
			10 – 39	0.0092	2.9	< 0.001	
			≥ 70	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
			10 – 39	0.0033	5.8	< 0.001	
			≥ 70	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.002	
			10 – 39	1	0.54	< 0.002	
			≥ 70	1	0.54	< 0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. bulb vegetables: garlic, leeks and other alliaceous vegetables, onions
[2] Max. single application rate of 720 g a.e./ha considered for risk calculation

Table 10.3.1-25: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 - sugar beet at 1440 g a.e./ha

Intended use	Sugar beet (Uses: 1a, 2a)						
Application method	downward spraying						
Crop category	sugar beet[1]						
Active substance	glyphosate						
Use pattern	1-2 x 1440 g a.e./ha[2]						
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**Ef**	**SV**	**ETR**	**Trigger**
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.54	< 0.003	0.03
			≥ 70	1	0	< 0.001	
		weeds	< 10	1	2.9	< 0.017	
			≥ 70	0.25	2.9	< 0.004	
		field margin	< 10	0.0092	2.9	< 0.001	
			≥ 70	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
			≥ 70	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.003	
			≥ 70	1	0.54	< 0.003	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator
[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

Table 10.3.1-26: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 - sugar beet at 1080 g a.e./ha

Intended use	Sugar beet (Uses: 1b, 2a, 2b, 2c, 6a, 10a)						
Application method	downward spraying						
Crop category	sugar beet[1]						
Active substance	glyphosate						
Use pattern	1-3 x 1080 g a.e./ha[2]						
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**Ef**	**SV**	**ETR**	**Trigger**
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.54	< 0.002	0.03
			≥ 70	1	0	< 0.001	
			10 – 39	1	5.8	< 0.025	
		weeds	< 10	1	2.9	< 0.013	
			≥ 70	0.25	2.9	< 0.003	
			10 – 39	1	2.9	< 0.013	
		field margin	< 10	0.0092	2.9	< 0.001	
			≥ 70	0.0092	2.9	< 0.001	
			10 – 39	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
			≥ 70	0.0033	5.8	< 0.001	
			10 – 39	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.002	
			≥ 70	1	0.54	< 0.002	
			10 – 39	1	0.54	< 0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator
[2] Max. single application rate of 1080 g a.e./ha considered for risk calculation

Table 10.3.1-27: First-tier assessment (oral exposure) of the risk for honey bees due to the use of MON 52276 - sugar beet at 720 g a.e./ha

Intended use		Sugar beet (Use 1c, 2b, 6b, 10b, 10c)					
Application method		downward spraying					
Crop category		sugar beet[1]					
Active substance		glyphosate					
Use pattern		1-3 x 720 g a.e./ha					
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**Ef**	**SV**	**ETR**	**Trigger**
Adult chronic oral toxicity	LDD_{50} > 179.9 µg a.e./bee/day	treated crop	< 10	1	0.54	< 0.002	0.03
			≥ 70	1	0	< 0.001	
			10 – 39	1	5.8	< 0.017	
		weeds	< 10	1	2.9	< 0.008	
			≥ 70	0.25	2.9	< 0.002	
			10 – 39	1	2.9	< 0.008	
		field margin	< 10	0.0092	2.9	< 0.001	
			≥ 70	0.0092	2.9	< 0.001	
			10 – 39	0.0092	2.9	< 0.001	
		adjacent crop	< 10	0.0033	5.8	< 0.001	
			≥ 70	0.0033	5.8	< 0.001	
			10 – 39	0.0033	5.8	< 0.001	
		next crop	< 10	1	0.54	< 0.002	
			≥ 70	1	0.54	< 0.002	
			10 – 39	1	0.54	< 0.002	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator
[2] Max. single application rate of 720 g a.e./ha considered for risk calculation

All exposure toxicity ratios (ETRs) for adult chronic toxicity are below the respective trigger value, indicating acceptable risk to honey bees following application of MON 52276 in vegetables.

Overall, a low risk to honey bees has been demonstrated in the risk assessment above for all uses according to proposed GAP.

Assessment of risk according to EFSA GD on bees (2013) from exposure to contaminated water

An assessment of the risk to bees from contaminated water is provided in the table below. The risk assessment for contaminated water focuses on honey bees only based on the very high level of water fluxes in honey bee colonies. This should be also sufficiently protective for bumble bees and solitary bees.

Table 10.3.1-28: Assessment of the risk for bees due to the use of MON 52276 considering exposure to contaminated water

Intended use	All uses (Uses: 1a-10c)			
Application method	downward spraying			
Active substance	glyphosate			
Use pattern	1 x 1800 g a.e./ha 2 x 1440 g a.e./ha			
Water solubility	12000 mg/L			
PEC_{sw}[1]	0.01141 µg a.e./L (Step 3, grass/alfalfa, D2 ditch, early/late application)			
PEC_{puddle}[2]	0.032340 µg a.e./L (Step 3, pome/stone fruit, R4, early application)			
Surface water[1]				
Test design	**Endpoint (lab.)**	**water consumption (µl)**	**ETR[1]**	**Trigger**
Acute	104 µg a.e./bee	11.4	< 0.01	0.2
Chronic	> 179.9 µg a.e./bee/day	11.4	< 0.001	0.03
Larvae	80 µg a.e./larva	111	< 0.01	0.2
Puddle water[1,2]				
Test design	**Endpoint (lab.)**	**water consumption (µl)**	**ETR[2]**	**Trigger**
Acute	104 µg a.e./bee	11.4	< 0.01	0.2
Chronic	> 179.9 µg a.e./bee/day	11.4	< 0.001	0.03
Larvae	80 µg a.e./larva	111	< 0.01	0.2
Guttation water				
Test design	**Endpoint (lab.)**	**water consumption (µl)**	**ETR**	**Trigger**
Acute	104 µg a.e./bee	11.4	**1.32**	0.2
Chronic	> 179.9 µg a.e./bee/day	11.4	**0.411**	0.03
Larvae	80 µg a.e./larva	111	**11.99**	0.2

ETR: exposure toxicity ratio.
Values shown in **bold** breach the relevant trigger.
[1] Highest application rate of 1800 g a.e./ha considered for risk calculation, calculation based on FOCUS (2001) (for details refer to MCP Section 9)
[2] Application rate of 2 x 1440 g a.e./ha considered for risk calculation, PEC_{puddle} was calculated using a PRZM model (for details see MCP Section 9), which is independent from the PEC_{sw}

The calculated exposure toxicity ratios (ETRs) are below the relevant trigger values for surface and puddle water indicating no risk from exposure via contaminated water to honey bees. However, the calculated ETRs are above the trigger for guttation water. In EFSA (2013) the assumptions for the guttation risk assessment are for the crop to be the source of guttation and that this covers the risk to other sources of guttation fluid. The crop is a uniform stand of plants of a single species and at similar growth stages at any given time. In contrast MON 52276 applications are made to a potentially diverse assemblage of weeds to be controlled. Consequently, the conditions of EFSA 2013 regarding guttation do not relate to the use of the product. Therefore, several species of weed at different growth stages may be present and will not necessarily all be producing guttation fluid. Furthermore, it was observed in Thompson (2011 CP 10.3.1.5/001) that the treated plants start to wilt soon after treatment and honey bee foraging was greatly reduced after 4 – 5 days. Root pressure and cell turgor are required for a plant to produce guttation fluid and wilted plants will rapidly stop producing guttation fluid. The reduced bee activity will also limit exposure.

The assumption that guttation fluid will contain the active substance at its limit of solubility is a huge over estimate of exposure for substances of higher water solubility such as glyphosate. There are technical considerations regarding this point to consider in relation to the risk assessment. Assuming a guttation droplet contains glyphosate at the limit of water solubility, ca. 12000 mg/L, and the daily water intake of 11.4 µl/bee/day (EFSA bee GD 2013) this is equivalent to a forager daily intake of 136.8 µg a.e./bee. In the 10-day chronic study honey bees were observed to consume 179.9 µg a.e./bee/day without any observed mortality or other adverse effects. Given that the chronic risk assessment requires a trigger equivalent to approximately 34x the endpoint this would mean in order to pass the risk assessment the endpoint would need to be > 4651.2 µg a.e./bee/day which is almost 5 % of the average body weight of a honey bee of 100 mg. This level of consumption would not be achievable in a standard laboratory test with ad libitum feeding and is not likely to occur under field conditions. Currently it is not possible to gavage honey bees to achieve higher doses. Even so the 10-day chronic endpoint, which is a NOEDD, is higher than the worst-case unrealistic daily dose via guttation fluid which gives a good indication that there is an acceptable risk.

For larvae the exposure to water is considered a moot point. For the first 3 days they are fed exclusively on worker jelly which is a secretion from the glands of nurse bees. After that on days 4 and 5 they are still fed with jelly but also receive some pollen and nectar from hive stores. Larval water needs are met from the liquid food they receive but some dilution of stored honey may occur and fed to the larvae on days 4 and 5 of their development if these coincide with periods of cool wet weather and the colony needs to use some of the stored honey. Overall of the 111 µl water required by larval bees (EFSA bee GD 2013) only a minor proportion would come from extraneously collected water and of that only a fraction would be derived from guttation fluid. The real-life exposure of larvae to guttation water is probably negligible and the level of exposure to a low toxicity substances such as glyphosate arising from this is unlikely to pose a risk to honey bee brood.

The water exposure route and in particular via consumption of guttation fluid, is not considered as a major exposure route compared to nectar and pollen. The presented higher-tier assessment for honey bees based on the worst-case exposure via nectar and pollen should be sufficiently protective for the risk from exposure via contaminated water.

Additionally, it has to be considered that the bee guidance assumes that the whole water consumption is based on guttation, surface or puddle water. However, honey bees also use different sources and is most likely a mixture of available water resources.

Higher-tier assessment for exposure via contaminated water

A glasshouse study was conducted to determine worst-case field exposure of bees to glyphosate by quantifying residues in relevant bee matrices; pollen and nectar ([redacted] 2011, CP 10.3.1.5/001). Additionally, residues in honey bee larvae were measured. In total two large glasshouses with *Phacelia tanacetifolia* were set up, each glasshouse contained two honey bee colonies. Glasshouses were unheated and well ventilated but insect-proof during the exposure phase, each glasshouse comprised an area of 180 m^2. MON 52276 was applied once during full flowering at a rate of 2880 g a.e./ha.

Samples of pollen were collected from pollen traps. For nectar samples forager bees were collected and their stomachs were prepared. Pollen and nectar samples were collected on days -1 (control), 1, 2, 3, 4 and 7. Additionally, nectar samples were taken directly from the colonies on day 7. Also honey bee larvae were collected from the combs on days 4 and 7 in each hive.

Residue analysis indicated no residues in pollen and nectar before application of MON 52276 (samples on day -1, served as control; < 0.3 mg a.e./kg).
Residues in nectar samples from forager honey bees ranged from 2.78 to 31.3 mg a.e./kg. Residues in nectar samples from the colonies 7 days after application ranged from < LOQ (1.0 mg a.e./kg) to 1.30 mg a.e./kg.

Residues in pollen samples taken from the pollen traps ranged from 87.2 mg a.e./kg to 629 mg a.e./kg.
Residues in larvae samples at day 4 and day 7 ranged from 1.23 mg a.e./kg to 19.50 mg a.e./kg.
During the study also the foraging activity as well as the crop status was recorded. Thus, combined with the residue data the approximate daily exposure of a honey bee colony to glyphosate residues was calculated.

Results indicated a daily intake of glyphosate residues of 44.0 mg per colony (40.6 mg via nectar and 3.4 mg via pollen) considering the max. mean residues at day 1 at 22.0 mg per colony (20.1 mg via nectar and 1.9 mg via pollen) considering the mean residues over days 1-3.

Subsequently, a honey bee brood feeding test (according to Oomen *et al.* (1992)) was conducted to evaluate the potential risk to honey bee brood when they are directly exposed to glyphosate (tested as IPA salt) (Study No. V7H1001). The dose levels of the test item were based on the residues characterised in the glasshouse study (Study No. V7H1002, see below). The lowest dose (75 mg glyphosate a.e./L) was based on the mean pollen and nectar residue concentrations over the first 3 days following spray application, the mid-dose (150 mg a.e./L) was based on the highest residue concentration determined in pollen and nectar following spray application and the highest dose (301 mg a.e./L) was twice as high as the highest detected residue concentration.

Mortality of adult honey bees as well as honey bee brood was assessed over a period of 7 days. Overall, no treatment related effects were observed.
Considering the outcome of the Tier I calculation for contaminated water. The detected potential risk from contaminated water (guttation water) is sufficiently covered by the presented higher tier risk assessment considering exposure of honey bee via pollen and nectar. The NOAEL (301 mg a.e./L) is based on the measured residues after an application of 2880 g a.e./ha. The highest maximum single application rate according to proposed GAP is 1800 g a.e./ha on grasses and 1440 g a.e/ha on field crops, thus, there is no uncertainty left that the risk from contaminated water can be considered as negligible.

Bumble bees

In consideration of the recommendations of the "Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology"[30] currently no risk assessment for bumble bees is required, given that the EFSA Guidance Document on the risk assessment of plant protection products on bees has not yet been noted. Furthermore, EFSA stated that it cannot be recommended to routinely perform a risk assessment for bumble bees. Nevertheless, acute studies for bumble bees are available and a corresponding risk assessment is presented.

Details of the acute studies with *Bombus terrestris* and glyphosate are summarised in the Document M-CA, Section 8, point 8.3.1 and relevant endpoints for the risk assessment are provided in the table below.

Table 10.3.1-29: Endpoints and effect values of glyphosate relevant for the risk assessment for bees

Reference	Test item	Species	Test design/ GLP	LD_{50} (µg a.e./bee)	NOED (µg a.e./bee)
[redacted] 2017a CA 8.3.1.1.1/007	Glyphosate K-salt	*Bombus terrestris*	Acute oral, 48 h	**> 412**	≥ 412
[redacted] 2017a CA 8.3.1.1.2/008	Glyphosate IPA-salt	*Bombus terrestris*	Acute contact, 48 h	**> 461**	≥ 461

Further testing with the representative product MON 52276 and the toxicity to *Bombus terrestris* was not considered necessary and the risk assessment will be conducted on the active substance data.

Risk assessment for bumble bees

The risk assessment for the proposed uses of MON 52276 and the effects on bumble bees is provided below.

[30] Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, provided by EFSA, published December 22, 2015

Table 10.3.1-30: Screening assessment of the risk of glyphosate for bumble bees due to the use of MON 52276

Intended use	All uses (Uses: 1a to 10c)				
Application method	downward spraying				
Active substance	glyphosate				
Use pattern	1-2 x 1800 g a.e./ha, 1-2 x 1440 g a.e./ha, 1-3 x 1080 g a.e./ha, 1-3 x 720 g a.e./ha, 1 x 540 g a.e./ha				
Type design	**LD_{50} (µg a.e./bee)**	**Max. single application rate (g a.e./ha)**		**$HQ_{contact}$ criterion**	**Trigger**
Acute contact toxicity	> 461	1800		< 3.9	**7**
		1440		< 3.1	
		1080		< 2.3	
		720		< 1.6	
		540		< 1.2	
Type design	**LD_{50} (µg a.e./bee)**	**Max. single application rate (kg a.e./ha)**	**E_f × SV**	**ETR**	**Trigger**
Acute oral toxicity	> 412	1.80	11.2	**< 0.05**	0.036
		1.44		**< 0.04**	
		1.08		< 0.03	
		0.72		< 0.02	
		0.54		< 0.01	

Ef: exposure factor; SV: shortcut value; $HQ_{contact}$: Hazard quotient for contact exposure; ETR: Exposure toxicity ratio; ETR values shown in **bold** breach the relevant trigger.

The exposure toxicity ratio (ETR) for acute oral toxicity is above the respective trigger value for the application rates of 1440 g a.e./ha and 1800 g a.e./ha. Therefore, Tier 1 risk assessment is required for these use patterns. No risk is indicated at the screening step for the use rate of 540 g a.e./ha, 720 g a.e./ha and 1080 g a.e./ha.

For the Tier 1 risk assessment calculations considering application of MON 52276 in crops planted in wide rows (i.e. orchards and vines) the "under crop application" scenario is used. The crop itself will not be over-sprayed as the application is done only to the area under the crop. Thus, no treated crop scenario is included in the following assessment. Only weeds, field margin, adjacent crop and next crop scenarios are considered.

Table 10.3.1-31: First-tier assessment (oral exposure) of the risk for bumble bees due to the use of MON 52276 in orchard crops and vines at 1440 g a.e./ha

Intended use	Orchard crops, vines (Uses: 4a, 5a)						
Application method	downward spraying						
Crop Category	under crop application[1]						
Active substance	glyphosate						
Use pattern	1-2 x 1440 g a.e./ha[2]						
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**E_f**	**SV**	**ETR**	**Trigger**
Acute oral toxicity	LD_{50} > 412 µg a.e./bee	weeds	weed < 10	1	0.46	< 0.01	0.036
			weed ≥ 10	1	6.5	< 0.023	
		field margin	weed < 10	0.0092	6.5	< 0.01	
			weed ≥ 10	0.0092	6.5	< 0.01	
		adjacent crop	weed < 10	0.0033	11.2	< 0.01	
			weed ≥ 10	0.0033	11.2	< 0.01	
		next crop	weed < 10	1	0.9	< 0.01	
			weed ≥ 10	1	0.9	< 0.01	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator
[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

All exposure toxicity ratios (ETRs) for acute oral toxicity are below the respective trigger value, indicating acceptable risk to bumble bees following application of MON 52276 in orchard crops and vines according to the proposed use pattern.

The recommended use pattern for MON 52276 includes also application on railroad tracks. Application is done by spray trains (spraying tanks, pumps and nozzles are mounted on special trains). Spray trains have an automatic plant detection system (infrared sensors and video cameras) to detect weeds using image processing. The automation system allows the nozzles to be opened or closed. So, MON 52276 is only sprayed on sections of the track that have weeds. The maximum application rate in any 12 months period is 3600 g a.e./ha (2 × 1800 g a.e./ha with a 90-day interval). Thus, the growth stage of weeds should not exceed BBCH 00-19. However, bees may possibly be exposed to MON 52276 by direct spraying while bees are foraging on flowers and weeds by oral uptake of contaminated pollen and nectar. As no definite crop scenario for railroad tracks is provided by EFSA, the under crop application scenario was considered to address uses on railroad tracks as well.

Table 10.3.1-32: First-tier assessment (oral exposure) of the risk for bumble bees due to the use of MON 52276 – railroad tracks at 1800 g a.e./ha

Intended use		Railroad tracks (Uses: 7a, 7b)					
Application method		downward spraying					
Crop Category		under crop application[1]					
Active substance		glyphosate					
Use pattern		1-2 x 1800 g a.e./ha[2]					
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**E_f**	**SV**	**ETR**	**Trigger**
Acute oral toxicity	LD_{50} > 412 µg a.e./bee	weeds	weed < 10	1	0.46	< 0.002	0.036
			weed ≥ 10	1	6.5	< 0.028	
		field margin	weed < 10	0.0092	6.5	< 0.001	
			weed ≥ 10	0.0092	6.5	< 0.001	
		adjacent crop	weed < 10	0.0033	11.2	< 0.001	
			weed ≥ 10	0.0033	11.2	< 0.001	
		next crop	weed < 10	1	0.9	< 0.004	
			weed ≥ 10	1	0.9	< 0.004	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] As no definite scenario for railroad tracks is provided by the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, the under crop application was considered to address uses on railroad tracks
[2] Max. single application rate of 1800 g a.e./ha considered for risk calculation

All exposure toxicity ratios (ETRs) for acute oral toxicity are below the respective trigger value, indicating acceptable risk to bumble bees following application of MON 52276 on railroad tracks.

Besides uses in agricultural areas and railroad tracks MON 52276 is also used to control invasive weeds. It is important to control noxious, invasive weeds to help protect our diverse native plants, natural resources, and agriculture. Although some noxious weeds may serve as forage for bees and other pollinators, e.g. invasive knotweed species are considered valuable to many beekeepers since they bloom later in the season than many other plants. However, the detrimental impacts of these invasive plants significantly outweigh their value as a pollen and nectar source.

MON 52276 is applied by spot application with a maximum single application rate of 1800 g a.s/ha in a 12 month period. Nevertheless, bees can be exposed while they are foraging by direct overspray or dried residues on plants and by oral uptake of contaminated pollen and nectar. Thus, an appropriate risk assessment is presented in the following to address risk from the use of MON 52276 on invasive weeds.

Table 10.3.1-33: First-tier assessment (oral exposure) of the risk for bumble bees due to the use of MON 52276 – invasive plant species in agricultural and non-agricultural areas at 1800 g a.e./ha

Intended use		invasive plant species in agricultural and non-agricultural areas (Uses: 8, 9)					
Application method		downward spraying					
Crop Category		under crop application [1]					
Active substance		glyphosate					
Use pattern		1 x 1800 g a.e./ha[2]					
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**E_f**	**SV**	**ETR**	**Trigger**
Acute oral toxicity	LD_{50} > 412 µg a.e./bee	weeds	weed < 10	1	0.46	< 0.002	0.036
			weed > 10	1	6.5	< 0.028	
		field margin	weed < 10	0.0092	6.5	< 0.001	
			weed > 10	0.0092	6.5	< 0.001	
		adjacent crop	weed < 10	0.0033	11.2	< 0.001	
			weed > 10	0.0033	11.2	< 0.001	
		next crop	weed < 10	1	0.9	< 0.004	
			weed > 10	1	0.9	< 0.004	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] As no definite scenario for invasive weeds is provided by the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, under crop application: giant hogweed (*Heracleum* spp.), Japanese knotweed (*Reynoutria japonica*)
[2] Max. single application rate of 1800 g a.e./ha considered for risk calculation

All exposure toxicity ratios (ETRs) for adult chronic toxicity are below the respective trigger value, indicating acceptable risk to honey bees following application of MON 52276 on invasive species in agricultural and non-agricultural areas according to proposed GAP.

For the Tier 1 risk assessment calculations considering the pre-sowing, pre-planting and post-harvest uses the "bare soil application" scenario is selected.

Table 10.3.1-34: First-tier assessment (oral exposure) of the risk for bumble bees due to the use of MON 52276 –pre-sowing, pre-planting and post-harvest uses at 1440 g a.e./ha

Intended use		Root & tuber vegetables, Bulb vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables, Sugar beet (Uses: 1a, 2a)					
Application method		downward spraying					
Crop category		bare soil application – crop attractive for pollen and nectar[1]					
Active substance		glyphosate					
Use pattern		1-2 x 1440 g a.e./ha[2]					
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**E_f**	**SV**	**ETR**	**Trigger**
Acute oral toxicity	LD_{50} > 412 µg a.e./bee	treated crop	< 10	1	0.9	< 0.004	0.036
		weeds	< 10	1	0.46	< 0.002	
		field margin	< 10	0.0092	6.5	< 0.001	
		adjacent crop	< 10	0.0033	11.2	< 0.001	
		next crop	< 10	1	0.9	< 0.004	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator
[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

All exposure toxicity ratios (ETRs) for acute oral toxicity are below the respective trigger value, indicating acceptable risk to bumble bees following application of MON 52276 pre-sowing, pre-planting and post-harvest.

For the Tier 1 risk assessment calculations considering ground directed inter-row applications at a rate of 1440 g a.e./ha in vegetables the following crop categories are selected:

Crop according to GAP	**Crop Category[1]**
Root vegetables	Root vegetables
Tuber vegetables	Potatoes
Bulb vegetables	Bulb vegetables
Fruiting vegetables	Fruiting vegetables 1, fruiting vegetables 2
Brassica	Leafy vegetables
Leafy vegetables	Leafy vegetables, lettuce
Stem vegetables	Leafy vegetables
Sugar beet	Sugar beet

[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator

Table 10.3.1-35: First-tier assessment (oral exposure) of the risk for bumble bees due to the use of MON 52276 – fruiting, leafy and tuber vegetables at 1440 g a.e./ha

Intended use	Fruiting vegetables, Leafy vegetables, Tuber vegetables (Uses: 1a, 2a)						
Application method	downward spraying						
Crop category	fruiting vegetables 2, lettuce and potatoes[1]						
Active substance	glyphosate						
Use pattern	1-2 x 1440 g a.e./ha[2]						
Test design	**Endpoint (lab.)**	**Scenario**	**BBCH**	**E_f**	**SV**	**ETR**	**Trigger**
Acute oral toxicity	LD_{50} > 412 µg a.e./bee	treated crop	< 10	1	0.03	< 0.001	0.036
			≥ 70	1	0	< 0.001	
		weeds	< 10	1	6.5	< 0.023	
			≥ 70	0.3	6.5	< 0.007	
		field margin	< 10	0.0092	6.5	< 0.001	
			≥ 70	0.0092	6.5	< 0.001	
		adjacent crop	< 10	0.0033	11.2	< 0.001	
			≥ 70	0.0033	11.2	< 0.001	
		next crop	< 10	1	0.9	< 0.004	
			≥ 70	1	0.9	< 0.004	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. fruiting vegetables 2 = tomatoes, eggplants
[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

Table 10.3.1-36: First-tier assessment (oral exposure) of the risk for bumble bees due to the use of MON 52276 – Brassica, leafy, stem, root, fruiting vegetables at 1440 g a.e./ha

Intended use	Root vegetables, Fruiting vegetables, Brassica, Leafy vegetables, Stem vegetables (Uses: 1a, 2a)
Application method	downward spraying
Crop category	leafy vegetables, root vegetables and fruiting vegetables 1[1]
Active substance	glyphosate
Use pattern	1-2 x 1440 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	E_f	SV	ETR	Trigger
Acute oral toxicity	LD_{50} > 412 µg a.e./bee	treated crop	< 10	1	0.9	< 0.004	0.036
			≥ 70	1	0	< 0.001	
		weeds	< 10	1	6.5	< 0.023	
			≥ 70	0.3	6.5	< 0.007	
		field margin	< 10	0.0092	6.5	< 0.001	
			≥ 70	0.0092	6.5	< 0.001	
		adjacent crop	< 10	0.0033	11.2	< 0.001	
			≥ 70	0.0033	11.2	< 0.001	
		next crop	< 10	1	0.9	< 0.004	
			≥ 70	1	0.9	< 0.004	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. leafy vegetables: artichokes, asparagus, cabbages and other brassicas, cauliflowers and broccoli, chicory roots, spinach; root vegetables: anise, badian, fennel, corian, carrots, turnips for fodder, viper´s grass; fruiting vegetables 1: chillies, peppers, cucumbers, gherkins, pumpkins, squash, gourds, melon, watermelons
[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

Table 10.3.1-37: First-tier assessment (oral exposure) of the risk for bumble bees due to the use of MON 52276 - bulb vegetables at 1440 g a.e./ha

Intended use	Bulb vegetables (Uses: 1a, 2a)
Application method	downward spraying
Crop category	bulb vegetables[1]
Active substance	glyphosate
Use pattern	1-2 x 1440 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	E_f	SV	ETR	Trigger
Acute oral toxicity	LD_{50} > 412 µg a.e./bee	treated crop	< 10	1	0.9	< 0.004	0.036
			≥ 70	1	0	< 0.001	
		weeds	< 10	1	6.5	< 0.023	
			≥ 70	0.6	6.5	< 0.014	
		field margin	< 10	0.0092	6.5	< 0.001	
			≥ 70	0.0092	6.5	< 0.001	
		adjacent crop	< 10	0.0033	11.2	< 0.001	
			≥ 70	0.0033	11.2	< 0.001	
		next crop	< 10	1	0.9	< 0.004	
			≥ 70	1	0.9	< 0.004	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator, e.g. bulb vegetables: garlic, leeks and other alliaceous vegetables, onions
[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

Table 10.3.1-38: First-tier assessment (oral exposure) of the risk for bumble bees due to the use of MON 52276 - sugar beet at 1440 g a.e./ha

Intended use	Sugar beet (Uses: 1a, 2a)
Application method	downward spraying
Crop category	sugar beet[1]
Active substance	glyphosate
Use pattern	1-2 x 1440 g a.e./ha[2]

Test design	Endpoint (lab.)	Scenario	BBCH	E_f	SV	ETR	Trigger
Acute oral toxicity	LD_{50} > 412 µg a.e./bee	treated crop	< 10	1	0.9	< 0.004	0.036
			≥ 70	1	0	< 0.001	
		weeds	< 10	1	6.5	< 0.023	
			≥ 70	0.25	6.5	< 0.006	
		field margin	< 10	0.0092	6.5	< 0.001	
			≥ 70	0.0092	6.5	< 0.001	
		adjacent crop	< 10	0.0033	11.2	< 0.001	
			≥ 70	0.0033	11.2	< 0.001	
		next crop	< 10	1	0.9	< 0.004	
			≥ 70	1	0.9	< 0.004	

Ef: exposure factor; SV: shortcut value; ETR: exposure toxicity ratio.
[1] Crop category chosen according to the recommendations of the EFSA GD on the Risk Assessment on Bees (2013) and the EFSA Screening Step and 1st Tier Calculator
[2] Max. single application rate of 1440 g a.e./ha considered for risk calculation

All exposure toxicity ratios (ETRs) for acute oral toxicity are below the respective trigger value, indicating acceptable risk to bumble bees following application of MON 52276 in vegetables.

Solitary bees

In consideration of the recommendations of the "Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology"[31] currently no risk assessment for solitary bees is required, given that the EFSA Guidance Document on the risk assessment of plant protection products on bees has not yet been noted. Furthermore, EFSA stated that it cannot be recommended to routinely perform a risk assessment for solitary bees. Nevertheless, an acute contact study for solitary bees is available and a corresponding risk assessment is presented.

Details of the studies with *Osmia bicornis* and glyphosate are summarised in the Document M-CA, Section 8, point 8.3.1 and relevant endpoints for the risk assessment are provided in the table below.

Table 10.3.1-39: Endpoints and effect values of glyphosate relevant for the risk assessment for bees

Acute toxicity					
Reference	**Test item**	**Species**	**Test design/ GLP**	**LD_{50} (µg a.e./bee)**	**NOED (µg a.e./bee)**
[redacted], 2017b CA 8.3.1.1.2/009	Glyphosate K-salt	*Osmia bicornis*	Acute contact, 48 h	**> 461**	≥ 461

[31] Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, provided by EFSA, published December 22, 2015

Further testing with the representative product MON 52276 and the toxicity to *Osmia bicornis* was not considered necessary and the risk assessment will be conducted on the active substance data.

Risk assessment for solitary bees

The risk assessment for the proposed uses of MON 52276 and the effects on solitary bees is provided below.

Table 10.3.1-40: Screening assessment of the risk of glyphosate for solitary bees due to the use of MON 52276

Intended use	All uses (Uses: 1a-10c)			
Application method	downward spraying			
Active substance	glyphosate			
Use pattern	1-2 x 1800 g a.e./ha, 1-2 x 1440 g a.e./ha, 1-3 x 1080 g a.e./ha, 1-3 x 720 g a.e./ha, 1 x 540 g a.e./ha			
Type design	**LD_{50} (µg a.e./bee)**	**Max. single application rate (g a.e./ha)**	**$HQ_{contact}$ criterion**	**Trigger**
Adult acute contact toxicity	> 461	1800	< 3.9	8
		1440	< 3.1	
		1080	< 2.3	
		720	< 1.6	
		540	< 1.2	

$HQ_{contact}$: Hazard quotient for contact exposure

The hazard quotients (HQ) for acute contact toxicity are above the respective trigger value for the application rates of 540 g a.e./ha, 720 g a.e./ha, 1080 g a.e./ha, 1440 g a.e./ha and 1800 g a.e./ha. Therefore, no Tier 1 risk assessment is required.

Currently no official OECD test guideline considering oral toxicity to solitary bees is available. Thus, no study was conducted. However, comparison of the available acute contact data indicated that solitary bees did not show a higher sensitivity towards glyphosate. Therefore, the presented risk assessment considers that oral exposure of honey bees and bumble bees should be protective for solitary bees.

Indirect Effects on bees via Trophic Interactions

The ecotoxicology regulatory studies database for glyphosate includes a battery of acute and chronic guideline studies, designed to assess the potential for direct effects to bees, covering a range of life stages and different bee species.

The following approach has been taken to assess potential indirect effects via trophic interactions considers the proposed Specific Protection Goals drawn from the existing EU guidance and working documents, and the 2016 EFSA Guidance on developing protection goals for ecological risk assessments (ERA) for pesticides. The SPGs based on direct effects assessment considering representative sensitive populations across the tested trophic levels.

Currently, specific protection goals (SPGs) for bees have not been adopted. However, for the purpose of this biodiversity assessment, three SPGs have been developed (Table 10-41).

Concerning specifically potential impacts on biodiversity, there currently is no EU wide guidance on how this should be assessed at the taxa group level within the context of a single active substance renewal risk assessment.

The first SPG is derived from the Plant Protection Product (PPP) regulations to achieve no significant effect on honeybee colony survival and development. The second SPG is aimed at protection of pollination services and production of hive products. The third SPG is aimed at protecting bee biodiversity.

The submitted risk assessment for direct effects considering the proposed GAP, is based on the existing EPPO and EFSA approaches (section 10.3.1). This has concluded low to negligible acute and chronic risk to larval and adult bees from direct effects and no risk mitigation measures are considered necessary.

Further information on the biodiversity assessment for glyphosate may be found in the [doc number] accompanying this dossier submission.

Indirect effects assessment for Bees

Indirect effects to bees, resulting from reduction of off-crop pollen and nectar sources, may be mitigated through required no-spray buffer zones implemented to protect non-target terrestrial plant (NTTP) communities (Section 10.6).

Indirect effects to bees may potentially result from reducing pollen and nectar sources by control of in-crop flowering weeds. However, a recent analysis of the likelihood of indirect effects by reduction of in-crop flowering weeds shows that indirect effects are unlikely to occur because of the relatively low amount of flowering weeds in-crop (Last *et al.*, 2019). This data was derived from herbicide efficacy trial control data from a range of arable crops (sunflower, maize, oilseed rape, cereals, sugar beet, potatoes, peas and beans) as well as some permanent crops (orchards, citrus and grapes) and from a large data set on the presence of weed species within trial plots. Relevant information was extracted from the efficacy data with the intention of demonstrating that, for some crops, the occurrence of attractive flowering weeds in treated fields is relatively rare and constitutes < 10 % of the area of use, thereby highlighting that the presence of bee weeds in the treated field scenario, is not applicable for many commercially grown crops.

Ecotoxicological relevance of monitoring data for glyphosate residues in honey and pollen

The duration of exposure of honey bees to glyphosate in the environment will be transient and of limited duration. The reason for this is that only a small proportion of weeds in the field will be flowering at the time of application (Last *et al.*, 2019) and flowering weeds that are sprayed – for example in crop inter-row applications, in recently emerged crops, will rapidly wilt and their flowers will no longer be attractive to bees (Thompson *et al.*, 2014). In addition, levels of glyphosate in nectar and honey will rapidly decline with 50 % of initial levels after only 1 to 2 days (Thompson *et al.*, 2014).

Laberge *et al.*, (1997) measured glyphosate levels in nectar and pollen in a field study conducted in an agro-forestry environment. For this study, hives were placed within or at various distances from treated sites. Detectable residues of glyphosate were observed in approximately 50 % of the pollen samples and 3 of 9 honey samples, with maximal residues of 8.2 mg a.e./kg in pollen sampled 3 days post-treatment from a hive situated directly within the treated area. Based on their risk assessment, Laberge *et al.*, (1997) concluded that risks associated with glyphosate were negligible.

Data, on the frequency of detection and the level of glyphosate in honey, are summarized within the EFSA residue database. These data show a 10 % frequency of detection (42 out of 406 samples), with a maximum level detected of 0.61 ppm and an average of 0.09 ppm (minimum LOQ of 0.01 ppm and max LOQ of 0.14 ppm).

Another representative honey residue study was conducted by the US FDA with an LC-MS/MS assay (Chamkasem and Vargo, 2017). Their validated assay had an LOQ = 16 µg/kg, and 9 of 16 samples bought from a local market had glyphosate > LOQ. Of these, the median concentration of glyphosate was 0.026

ppm with a range of 0.017 to 0.121 ppm. Low levels of glyphosate in honey were likely as the outcome of processing of the nectar by the bee's, limited exposure to glyphosate in the environment, and/or dilution with untreated nectar in the hive.

Additional studies in the literature report similar residues in honey and have been summarized in Vicini *et al.*, (2020). The results of these monitoring studies demonstrate low environmental exposures to glyphosate and the conservative nature of the exposure values used for glyphosate exposure assessment for bees.

Scientific Literature that informs the bee assessment

The potential for adverse effects of glyphosate and Roundup to honey bees have been extensively tested in colony level feeding studies (Ferguson, 1987, 1988; Burgett and Fisher, 1990; Thompson et al, 2014). The first colony feeding study was performed in Australia and found no significant effects to larval and adult honey bees after six consecutive days of whole-hive exposure to 5 mg a.e./kg sucrose solution (Ferguson, 1987; Ferguson, 1988). Ferguson concluded from her study that glyphosate could be safely used around honey bee hives. Further, Ferguson reported that levels for a range of pesticides rapidly decline in nectar and pollen, with > 90 % dissipation in 3 to 4 days after spraying. Similar results, showing a rapid decline of glyphosate residues in nectar and pollen, were also reported by Thompson *et al.* (2014). This rapid decline of glyphosate residues in nectar and pollen greatly limits exposure of honey bee colonies to glyphosate.

These original findings by Ferguson were supported by colony feeding trials conducted by two well-established apicultural experts, Burgett and Fisher, from Oregon State University (Burgett and Fisher, 1990). In their first honey bee colony feeding study, colonies were fed Roundup in sucrose solution at a concentration that was 100 to 1000 times above worst-case glyphosate exposure levels reported by Thompson *et al.* (2014). No significant effects were observed to honey bee adults or brood production after 42 days of observation, which is an indicator of no effects to egg production, egg laying and brood maintenance. In their second whole-hive study, blooming bee-attractive vegetation adjacent to the hives were treated at 6.8 kg a.e./ha. As with the colony feeding study, there were no effects to adult honey bee or brood production over the 42-day post-application period. These earlier findings are supported by a more recently published colony feeding study followed international guidance for honey bee testing (OECD guidance document 75) and this study was found to be acceptable for risk assessment in the recent glyphosate Annex 1 renewal (Thompson et al, 2014). Thompson *et al.* demonstrated no effect to larval development, growth and survival and adult survival at glyphosate concentrations of 75, 150 and 300 mg a.e./L.

All of the other bee effect studies reviewed in the literature did not measure effects on survival, growth, development, or reproduction with the exception of one study that evaluated effects on survival after an extreme challenge with the opportunistic pathogen *Serratia marcescens* (Motta *et al.* 2018). The relevance of the laboratory study conducted by Motta *et al.* is questionable because of the relatively high exposure levels (10 mg a.e./L) and artificial nature of the study.

Assessment

After a through literature review and considering all recent guidance, the approach taken, aimed to assess potential indirect effects via trophic interactions and the impact on biodiversity for bees including *Apis* and non-*Apis* bee species, using a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals.

In the following table, the specific protection goals relevant to bees / pollinators are presented with the relationship between the SPGs, the direct effects study types, assessment and measurement endpoints. The assessment endpoint is an explicit expression of an environmental entity and the specific property of that entity to be protected. Measurement endpoints relates directly to the effects study endpoints. A conclusion that a given data requirement has been satisfied, requires that an acceptable level of risk has been achieved (i.e. there is a protective margin of exposure or through a weight of evidence) and if necessary through the application of standard mitigation measures as recognised at the EU level.

Based on the measurement endpoints from the study types, and the direct effects assessment presented above in this section, it is anticipated that for the proposed uses on the GAP table, that there will be no indirect effects on bee populations in terms of loss of foraging habitat that is not protected by the required in-field buffer distance required to support the non-target terrestrial plant – direct effects risk assessment, required to meet the specific protection goal for NTTPs which will also support bees, given the limited relevance to bees of weed species found in-field.

Table 10.3.1-41: The relationship between Specific Protection Goals, assessment and measurement endpoints for bees from contact and dietary exposure.

Specific Protection Goals	Assessment Endpoints	Measurement Endpoints	Study Types
No significant effect on honeybee colony survival and development.	Population size and stability of managed bees	Adult and larval survival and larval emergence	Adult honeybee acute Adult Bumble bee acute Adult solitary bee acute Adult honeybee chronic Larval honeybee emergence Honeybee semi-field brood study
Pollination services and production of hive products	Population size and stability of native and commercially managed bees and quantity and quality of honeybee hive products.	Adult and larval survival and larval emergence	
Bee Biodiversity	Species richness and abundance	Adult and larval survival and larval emergence	
Bee Biodiversity Assessment The direct effects assessment demonstrates negligible acute and chronic risk to adult and larval bees and is protective of effects at the population level. Indirect effects to bee populations from in-crop weed control is unlikely because in-crop flowering weeds are not a significant resource for nectar and honey and the off-crop NTTP community will be protected by in-crop no spray zones. Taken together, impacts on bee biodiversity from the intended uses of glyphosate and following the required risk mitigation measures, impacts to bee biodiversity are unlikely.			

Conclusion

Glyphosate is a critical tool to enable conservation tillage systems, which can greatly improve water quality in agroecosystems by reducing sediment and nutrient run-off. Negligible risk of direct effects to bee biodiversity is supported by measures of glyphosate residues in honey from monitoring programs. Indirect effects from in-crop weed control is unlikely to impact bee populations because in-crop flowering weeds are not a significant resource for nectar, pollen and honey. In addition, the off-crop NTTP community will be protected by in-crop no-spray zones as a required mitigation. Taken together, impacts on bee biodiversity from the intended uses of glyphosate and following the required risk mitigation measures, impacts to bee biodiversity are unlikely.

Examples of the standard mitigation measures considered applicable at the EU level are presented in the following table. Many of these have been considered in the current dossier submission.

Table 10.3.1-42: Examples of standard mitigation measures as described in MAgPIE (2017) across the various Member States to mitigate effects of glyphosate on biodiversity.

Type of Mitigation Measure	Risk Mitigation Measure	Benefits	Glyphosate renewal dossier (2020)
Restrictions or modifications of products' conditions of application	Application rate, Application frequency, application timing, and interval between applications	Lower transfers to groundwater and surface water; Reduces exposure of organisms in-crop and off-crop.	**Significant reductions (50 % in volume) in newly proposed application rates** compared with the representative use presented in the 2012 renewal dossier. See [32]**Appendix 2 of the biodiversity document accompanying this submission**. **Treated area restriction** 10. for the representative use GAPs: applying to only 50 % of the total area in orchard/vineyard area. 11. maximum of 50 % of the total area for broad acre vegetable inter-row 12. Invasive species control e.g., couch grass – maximum of 20 % of the cropland + extended application intervals. **Limited frequency and timing of application:** 28-day interval between applications and no pre-harvest applications
Application equipment with Spray Drift Reduction Technology (SDRT)	Spray drift reduction nozzles (SDRN), shields, Precision treatment, etc.	Reduces exposure of organisms in-crop (precision treatment) and off-crop	**Reduction of spray drift to the off-field**: 7. Use 75 % drift reducing nozzles for pre-sowing/pre-planting in arable crops. 8. Use of ground directed, shielded spray for band application in orchards / vineyards and broad-acre vegetable inter-row application.
Buffer zones	Non-sprayed zone at the edge of a crop	Reduces exposure of organisms and off-crop	**Establishment of buffer zones:** Buffer zones of varying size (depending on the type of SDRT) are required as protection for off-crop NTTP communities from spray drift.

For example;

- Reductions in maximum annual application rates of up to 50 % considered in this dossier are compared to the maximum rates applied for in the 2012 Annex I renewal dossier.
    - In 2012, the maximum annual application rate was 4.32 kg/ha.
    - In the current dossier submission, the maximum annual application rate is 2.16 kg/ha

32 [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

- Reducing the total area being applied on a per hectare basis for certain uses, will reduce the total volume of product being applied to the landscape.
  - For example, controlling actively growing weeds in vineyards, orchards where a reduced area, up to a maximum of 50 % of the total application area is proposed e.g. using strip or band applications. Applications on target weeds around the base of trees within tree rows, leaving the area between tree rows unsprayed, which is typically managed using mechanical methods.

- The use of shielded or hooded sprayers, hand-held sprayers and drift reducing technologies, e.g. 75 % drift reducing nozzles are recommended for all applications made for the control of actively growing weeds when applied to control invasive species. These measures will further reduce the off-target exposure risk.

- For weed control on rail tracks, recommendations are made in the GAP table to use precision application equipment on spray trains, that detect and targets spray directly onto unwanted plants, thereby reducing the amount of product being applied, whilst maintaining an acceptable level of safety on the railways.

- No spray-buffer areas in-field are considered necessary to meet the specific protection goals for avoiding direct effects on non-target plants in off-target areas. This measure will in turn support non-target arthropod communities, including beneficial insects such as the pollinators, in off-field areas and reduces further, the potential for indirect effects on bees through trophic interaction.

In addition to the standard mitigation measures, 'non-standard mitigation measures' could also be considered where a local and specific mitigation need is identified. For example, in simplified landscapes or landscapes that are intensively managed, where typically there are limited refuge areas for insects, birds and mammals. Non-standard mitigation measures options could include for example, creation of off-target habitats, utilizing edge of field habitats and semi-field habitats that assist biodiversity by improving wildlife connectivity.

For further information on mitigation measures pleased refer to the supplementary information document[33] titled 'Glyphosate: Indirect Effects via Trophic Interaction – A Practical Approach to Biodiversity Assessment.' (DOC No.) that accompanies this dossier submission.

References for the Indirect Effects via Trophic Interaction Section

Burgett M, Fisher G. 1990. A review of the Belizean honey bee industry: Final report prepared at the request of The Belize Honey Producers Federation. Department of Entomology, Oregon State University, Corvallis, Oregon.

Chamkasem N, JD Vargo. 2017. Development and independent laboratory validation of an analytical method for the direct determination of glyphosate, glufosinate, and aminomethylphosphonic acid in honey by liquid chromatography/tandem mass spectrometry. J Reg Sci 5:1-9.

Ferguson F. 1987. Interim report. Long term effects of systemic pesticides on honey bees. The Australian Beekeeper (September issue). Pages: 49-53.

Laberge L, Legris J, Couture G. 1997. Glyphosate residues in pollen and honey after applications in an agro-forest environment. Draft Report Ministere des Ressources naturelles du Quebec, Direction de lenvironement forestier Quebec.

[33] [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

Last G, Lewis G and G Pap. 2019. Regulatory report on the occurrence of flowering weeds in agricultural fields. Sponsored by the European Crop Protection Association. ERM report number (submitted upon request).

Motta Erick V S; Raymann Kasie; Moran Nancy A 2019 Glyphosate perturbs the gut microbiota of honey bees. Proceedings of the National Academy of Sciences of the United States of America, (20181009) Vol. 115, No. 41, pp. 10305-10310.

Thompson HM, Levine SL, Doering J, Norman S, Manson P, Sutton P, G von Mérey. 2016. Evaluating exposure and potential effects on honeybee brood (*Apis mellifera*) development using glyphosate as an example. Integr. Environ Assess Manag. 10(3):463-70.

CP 10.3.1.1 Acute toxicity to bees

CP 10.3.1.1.1 Acute oral toxicity to bees

1. Information on the study

Data point:	CP 10.3.1.1.1/001
Report author	[redacted]
Report year	2001
Report title	Laboratory bioassays to determine acute oral and contact toxicity of MON 52276 to the honeybee, *Apis mellifera*
Report No	MON-00-2 version 2
Document No	-
Guidelines followed in study	EPPO Guideline on test methods for evaluating the side-effects of plant protection products on honeybees. No. 170 (1992).
Deviations from current test guideline	Deviations from the current guideline OECD 213 (1998): Major: - none Minor: - 3 to 4 hours starvation instead of 1 to 2 hours recommended - Humidity was slightly outside the expected range: 46 – 83% instead of 50 – 70 % - 4 hours assessment was not carried out These deviations are not expected to have a negative impact on the validity of the study which was valid at the time of conduct.
Previous evaluation	Yes, accepted in RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

The acute oral toxicity of the formulated product MON 52276 to worker bees (*Apis mellifera* L.) was determined in a limit test at the nominal dose of 103 µg glyphosate isopropylamine/bee (a.s.), equivalent to 77 µg glyphosate acid equivalent/bee (a.e.) for oral exposure. Bees were also exposed to dimethoate at concentrations from 0.075 to 0.3 µg dimethoate/bee (reference toxicant group) or to an aqueous sucrose solution (negative control). The test comprised 5 replicate groups of 10 bees for the test treatments and the control group. Further 3 replicate cages containing each 10 bees were prepared for the reference group. Bee condition was assessed after 1, 3, 24 and 48 hours.

After 48 hours, there were no sub-lethal effects observed. Mortality did not reach or exceed 50 %. The control and treatment group mortality were both 4 %. All validity criteria according to OECD guideline 213 were fulfilled. In the oral test, the 48 h LD_{50} for honey bees exposed to MON 52276 was > 103 µg a.s./bee, equivalent to > 77 µg a.e./bee, the maximum amount consumed over a 5 h period.

I. MATERIALS AND METHODS

A. MATERIALS

Test material:

Test item:	MON 52276
Formulation type	Soluble concentrate (SL)
Description:	Dark yellow-coloured fluid
Active substance	glyphosate isopropylamine salt
Lot/Batch #:	100399
Purity:	41.5 % w/w glyphosate isopropylamine
	30.3 % w/w glyphosate acid equivalent (measured)
Density:	1.168 g/cm^3 (nominal)
Vehicle and/or positive control:	BASF Dimethoate 40 (400 g dimethoate/L)
Test organisms:	
Species:	Honey bee (*Apis mellifera* L.)
Age:	Adult worker bees
Source:	Roselea Apiaries, East Wellow, Hampshire, UK
Environmental conditions:	
Temperature:	24 – 26 °C
Humidity:	46 – 83 %
Photoperiod:	24 h dark
Experimental dates:	Not stated in the report

B. STUDY DESIGN

Experimental treatments

For the oral test, the test treatments and negative control group comprised five groups of 10 bees, maintained in stainless steel coated 2 – 2.5mm wire mesh cylinders measuring 140 mm deep × 40 mm in diameter, closed by polyurethane foam bungs at both ends. For the reference toxicant, 3 groups of 10 bees were held in mesh cages of the same design, for each of the treatment groups.

Worker honey bees were collected from a queen right hive on the morning of the tests. All bees were lightly anaesthetised using humidified carbon dioxide and added to cages in groups of ten and allowed to recover. Honeybees for the oral test remained unfed during recovery.

In the oral test, honeybees were exposed to MON 52276 dispersed in a 50 % sucrose solution delivered to the cages using a glass feeding tube inserted through one of the polyurethane bungs. A 200 µL volume of solution was provided and assumed that each bee would consume at least 20 µL of solution over a 5 h exposure period. After 5 h, the feeding tube was replaced with a tube containing 50 % sucrose solution only, which was replenished *ab libitum* for the 48 h duration of the test.

The reference item group was prepared in the same way as for the treatment groups. The reference item

group was evaluated in two stages, the highest application rate was tested alongside the treatment and control groups, with the lower two treatment rate evaluated five days later with an additional control group included for comparison.
All cages were maintained in the dark in an incubator for the duration of the test.

Observations
In the oral test, the feeding vials were weighed prior to treatment and again after 5 h to establish the actual dose per bee consumed. An assessment of the condition of the bees was made 1, 3, 24 and 48 hours after treatment. The bees were classified as being live, affected, moribund/dead.

Validity criteria
For a test to be valid the following conditions apply:

- The average mortality for the total number of controls must not exceed 10 % at the end of the test.
- The LD_{50} of the toxic standard meets the specified range.

Statistical calculations
Descriptive statistics only based on empirical observation. As the tests were conducted as limit tests, and not dose response tests, statistical analysis was not required.

II. RESULTS AND DISCUSSION

A. FINDINGS

The oral LD_{50} and NOEL values for honeybees exposed to MON 52276 are given below based on nominal concentrations.

Table 10.3.1.1.1-1: Toxicity of MON 52276 to honey bees (*Apis mellifera* L.) in an oral toxicity test

Endpoints (48 h)	MON 52276 glyphosate acid equivalent [µg a.e./bee]	MON 52276 glyphosate isopropylamine [µg a.s./bee]
LD_{50} oral	> 77	> 103
NOEL oral	> 77	> 103

B. OBSERVATIONS

The mortality in control and in the treatment groups was 4 % in the 48-hour exposure. There were no observations of treated bees being sick or behaving abnormally.

Table 10.3.1.1.1-2: Oral toxicity of MON 52276 to honey bees (*Apis mellifera* L.)

Exposure	Mortality [%]		Corrected mortality[2] [%]
	Control	MON 52276 103 µg a.s./bee[1] 77 µg a.e/bee[1]	
1 h	0	0	-
3 h	0	0	-
24 h	0	0	-
48 h	4	4	0

[1] Based on mean weight of test solution of 5 µg/µL consumed per cage of 10 bees, corrected for the density of the 50 % w/w sugar solution
[2] Corrected mortality according to Abbott (1925)
a.e = glyphosate acid equivalent, a.s.= glyphosate isopropylamine

For the reference group (BASF Dimethoate 40), 100 % and 33 % mortality were observed in 0.3 and 0.15 µg dimethoate/bee concentrations after 24 hours exposure, respectively. The LD_{50}-24h was in the range 0.10 – 0.35 µg a.s./bee requested in the guideline and was in line with published values (Gough *et al.*, 1994), indicating that the test insects were suitably sensitive.

The mortality in the control treatments did not exceed 10 %.
All the validity criteria according to guideline OECD 213 were therefore fulfilled.

The following points are deviated from the current guideline but are not expected to have any negative on the study validity:

- 3 to 4 hours starvation instead of 1 to 2 hours recommended.
- Humidity was slightly outside the expected range: 46 – 83 % instead of 50 –70 %.
- 1 and 3 hours assessments were carried out instead of the 4 hours requested.

III. CONCLUSION

Assessment and conclusion by applicant:

The LD_{50} (48 h) for honey bees exposed to MON 52276 was determined to be > 103 µg a.s./bee, equivalent to > 77 µg a.e./bee for oral exposure.

This study is considered valid and suitable for risk assessment purposes.

Assessment and conclusion by RMS:

CP 10.3.1.1.2 Acute contact toxicity to bees

1. Information on the study

Data point	CP 10.3.1.1.2/001
Report author	[redacted]
Report year	2001
Report title	Laboratory bioassays to determine acute oral and contact toxicity of MON 52276 to the honeybee, *Apis mellifera*
Report No	MON-00-2 version 2
Document No	-
Guidelines followed in study	EPPO Guideline on test methods for evaluating the side-effects of plant protection products on honeybees. No. 170. (1992).
Deviations from current test guideline	Deviations from the current guideline OECD 214 (1998): Major: - none Minor: - Humidity was slightly outside the expected range: 46 – 83 % instead of 50 – 70 % - 4 hours assessment was not carried out These deviations are not expected to have a negative impact on the validity of the study which was valid at the time of conduct.
Previous evaluation	Yes, accepted in RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Yes, Valid Study
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

The acute contact toxicity of the formulated product MON 52276, to young adult worker bees (*Apis mellifera* L.) was determined in a limit test at the equivalent of a single nominal dose of 134 µg glyphosate isopropylamine salt/bee, equivalent to 100 µg glyphosate acid equivalent (a.e.)/bee. Bees were also exposed to dimethoate at concentrations of 0.075 and 0.3 µg dimethoate/bee (reference toxicant group) or to an aqueous sucrose solution (negative control). The test comprised 5 replicate groups of 10 bees for the test treatments and the control group. Further 3 replicate cages containing each 10 bees were prepared for the reference group. Bee condition was assessed after 1, 3, 24 and 48 hours.

After 48 hours, there were no sub-lethal effects observed. Mortality did not reach or exceed 50 %. After 48 hours control and treatment group mortality were 2 % and 12 % respectively. All validity criteria according to OECD guideline 214 were fulfilled.

The 48 h LD_{50} for honeybees exposed to MON 52276 was > 134 µg a.s./bee, equivalent to > 100 µg a.e./bee for contact exposure.

I. MATERIALS AND METHODS

A. MATERIALS

Test material:

Test item:	MON 52276
Formulation type	Soluble concentrate (SL)
Description:	Dark yellow-coloured fluid
Active substance	glyphosate isopropylamine salt
Lot/Batch #:	100399
Purity:	41.5 % w/w glyphosate isopropylamine 30.3 % w/w glyphosate acid equivalent (measured)
Density:	1.168 g/cm^3 (nominal)
Vehicle and/or positive control:	BASF Dimethoate 40 (400 g dimethoate/L)
Test organisms:	
Species:	Honey bee (*Apis mellifera* L.)
Age:	Young adult worker bees
Source:	Roselea Apiaries, East Wellow, Hampshire, UK
Environmental conditions:	
Temperature:	24 – 26 °C
Humidity:	46 – 83 %
Photoperiod:	24 h dark

B. STUDY DESIGN

Experimental dates: No dates reported

Experimental treatments

For the contact tests, the test treatments and negative control group comprised five groups of 10 bees, maintained in stainless steel coated 2 × 2.5mm wire mesh cylinders measuring 140 mm deep × 40 mm in diameter, closed by polyurethane foam bungs at both ends. For the reference toxicant, 3 groups of 10 bees were held in mesh cages of the same design, for each of the treatment groups.

Worker honey bees were collected from a queen right hive on the morning of the tests. All bees were lightly anaesthetised using humidified carbon dioxide and added to cages in groups of ten and allowed to recover. Bees for the contact test were provided with sucrose solution during the recovery period.

For the contact test, the bees were again lightly anaesthetised with humidified carbon dioxide and then in groups of 10 were turned onto their back using lightweight forceps, and a 1 µL volume of test solution (MON 52276 dispersed in 0.01 % v/v Farmon blue – used to facilitate application to the hydrophobic hairs on the thorax) was applied to the ventral thorax using a micro-applicator and the bees were returned to the cages. The bees were fed 50 % sucrose solution *ad libitum* via a glass feeding tube inserted through one bung for the 48 h duration of the test

The reference item group was prepared in the same way as for the treatment groups. The reference item group was evaluated in two stages, the highest application rate was tested alongside the treatment and control groups, with the lower treatment rate evaluated five days later with an additional control group included for comparison.

All cages were maintained in the dark in an incubator for the duration of the test.

Observations
An assessment of the condition of the bees was made 1, 3, 24 and 48 hours after treatment. The bees were classified as being live, affected, moribund/dead.

Validity criteria
For a test to be valid the following conditions apply:
- The average mortality for the total number of controls must not exceed 10 % at the end of the test.
- The LD_{50} of the toxic standard meets the specified range.

Statistical calculations
Descriptive statistics only based on empirical observation. As the tests were conducted as limit tests, and not dose response tests, statistical analysis was not required.

II. RESULTS AND DISCUSSION

A. FINDINGS

The contact LD_{50} and NOEL values for honeybees exposed to MON 52276 are given below based on nominal concentrations.

Table 10.3.1.1.2-1: Endpoints

Endpoints (48 h)	MON 52276 glyphosate acid equivalent [µg a.e./bee]	MON 52276 glyphosate isopropylamine [µg a.s./bee]
LD_{50} contact	> 100	> 134
NOEL contact	≥ 100	≥ 134

B. OBSERVATIONS

After 48-hour exposure, the mortality was 2 % and 6 % in the control and treatment groups, respectively. The corrected mortality was 4 % after 48 hours of exposure. There were no observations of treated bees being sick or behaving abnormally.

Table 10.3.1.1.2-2: Contact toxicity of MON 52276 to honey bees (*Apis mellifera* L.)

Exposure	Mortality [%]		Corrected mortality[1] [%]
	Control	MON 52276 134 µg a.s/bee 100 µg a.e/bee	
1 h	0	0	-
3 h	0	0	-
24 h	0	0	-
48 h	2	6	0

[1] Corrected mortality according to Abbott (1925)
a.e = glyphosate acid equivalent, a.s.= glyphosate isopropylamine

For the reference group (BASF Dimethoate 40), 100 % and 22 % mortality were observed in 0.3 and 0.075 µg dimethoate/bee concentrations after 24 hours exposure, respectively. The LD_{50}-24h was in the range 0.10 – 0.35 µg a.s./bee requested in the guideline and was in line with published values (Gough *et al.*, 1994), indicating that the test insects were suitably sensitive.
The mortality in the control treatments did not exceed 10 %. The validity criteria according to guideline

OECD 214 were therefore fulfilled.

III. CONCLUSION

3. Assessment and conclusion

Assessment and conclusion by applicant:
The contact LD_{50} (48 h) for honey bees exposed to MON 52276 was determined to be > 134 µg a.s./bee, equivalent to > 100 µg a.e./bee. This study is considered valid and suitable for risk assessment purposes.

Assessment and conclusion by RMS:

CP 10.3.1.2 Chronic toxicity to bees

Further studies with honeybees are not considered required with representative product MON 52276 based on the low toxicity demonstrated by the risk assessments above.

CP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Further studies with honeybees are not considered required with representative product MON 52276 based on the low toxicity demonstrated by the risk assessments above.

CP 10.3.1.4 Sub-lethal effects

Further studies with honeybees are not considered required with representative product MON 52276 based on the low toxicity demonstrated by the risk assessments above.

CP 10.3.1.5 Cage and tunnel tests

Further studies with honeybees are not considered required with representative product MON 52276 based on the low toxicity demonstrated by the risk assessments above.

1. Information on the study

Data point	CP 10.3.1.5/001
Report author	[redacted]
Report year	2011
Report title	Glyphosate: Study to determine potential exposure of honeybee colonies to residues under semi-field conditions
Report No	V7YH1002
Document No	-
Guidelines followed in study	None; tailor made study
Deviations from current test guideline	Not applicable field study
Previous evaluation	Yes, accepted in RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

A semi-field study was undertaken to determine the potential exposure of honeybee colonies to glyphosate by quantifying residues in relevant food matrices, i.e. pollen and nectar, when the formulation MON 52276 was applied to flowering *Phacelia* grown in two large (180 m²) glasshouses. Following treatment of nominal 8 L/ha, equivalent to 2.88 kg a.e./ha, two honeybee colonies per glasshouse were exposed. Foraging activity in the crop and activity at each hive was assessed daily for 7 days. On days 0, 1, 2, 3, 4 and 7, forager bees were taken to get hold of the nectar from the honey stomach of the bees after foraging in the treated crop. On days -1, 1, 2, 3, 4 and 7, samples of pollen were collected from the pollen traps fitted to each hive. Samples of nectar were also collected from the combs in each hive on day 7. Furthermore, samples of larvae were collected from the combs in each hive on days 4 and 7. Daily assessments were made of the percentage of plants with wilted leaves or flowers.

Foraging assessment showed foraging activity on the crop from start of study throughout the exposure period in glasshouse 1 with a peak on day 4. The lowest foraging activity was observed on day 5 at 38 % of the mean pre-spray activity. In glasshouse 2 the activity declined throughout the assessment period to reach less than 10 % of mean spray activity on days 5 – 7. In line with the decreased foraging activity in glasshouse 2, the crop started to show significant effects of the treatment from day 4 onwards.

Residues in nectar samples taken from forager bees at various time points after application ranged from 2.78 to 31.3 mg a.e./kg; residues in nectar samples taken from the colonies ranged from below LOQ (1.0 mg a.e./kg) to 1.30 mg a.e./kg. Residues in pollen samples taken from the pollen trap at various time points after application ranged from 87.2 to 629 mg a.e./kg. Residues in larvae samples ranged from 1.23 to 19.50 mg a.e./kg.

The residue data can be used to assess the approximate exposure level of brood within colonies exposed under worst-case conditions.

The maximum pollen collected per colony was 2.9 g on day 0 and the traps are estimated to be about 50 % efficient so about 6 g of pollen per day was returned to the hive (the colony is using about 4.5 g of this based on the Rortais *et al.* 2005).

The nectar can be assessed using a mean of 18 foragers returning to the hive per 30 seconds and approximately 50 µL per load (max), which gives 18 trips/30 sec × 60 sec/min × 60 min/hour × 12 hours max foraging/day, equal to 25,920 trips/day × 0.050 mL, resulting in 1296 mL/day (of which the colony is using 135 g based on Rortais *et al.* 2005).

As a worst-case example considering the colony size of the present study, a honey bee colony collects 6 g pollen and 1296 mL nectar and of this the brood consumes 4.5 g pollen and 135 g nectar, which allows the excess to be stored for later consumption. As simulated in this study, for honeybee colonies foraging on the

model crop *Phacelia* treated with 8 L MON 52276/ha, a total daily intake of glyphosate residues of 44.0 mg a.e. (based on day 1 maximum mean residues) and of 22 mg a.e. (based on mean residues over days 1-3) can be estimated.

I. MATERIALS AND METHODS

A. MATERIALS

Test material:

Test item:	MON 52276 (Soluble concentrate)
Active substance:	Glyphosate acid 360 g glyphosate acid equivalents/L (nominal)
Active substance content:	358.8 g glyphosate acid equivalents/L (according to the Certificate of Analysis)
Proposed use:	Herbicide
Description:	Clear brown liquid
Lot/Batch #:	A9K0106104
Density:	1.1693 g/mL at 20 °C (according to the Certificate of Analysis)
Vehicle and/or positive control:	None
Test organism:	
Species:	*Apis mellifera* L. 4 honeybee colonies containing 4 – 6 frames of brood, containing 6000 – 12000 adult bees
Age:	Not stated
Source:	UK national Bee Unit
Acclimatisation:	3 days
Test system:	Two 180 m² glasshouses at Stockbridge Technology Centre, Selby, North Yorkshire, U.K.
Crop cultivated:	*Phacelia* (sown directly into soil of the glasshouse, no pesticide use during cultivation)
Replication:	2 glasshouses, each containing 2 bee colonies
Environmental conditions:	
Temperature:	Glasshouse 1: 7.7 – 39.9 °C, temperatures of > 35 °C were recorded on day 6 and 7 for 10 and 30 min. Glasshouse 2: 8.3 – 47.4 °C, temperatures of > 35 °C were recorded on days -1, 1, 2, 4, 6 and 7 for up to 30 min until day 4, for 1.5 h on day 4, 50 min on day 6 and 40 min on day 7. High temperatures occurred primarily between 11:30 and 14:00 and exhibited no obvious effects on crop or foraging bees
Humidity:	Glasshouse 1: 19.5 to 93.4 % Glasshouse 2: 13.9 to 100 %
Experimental dates:	12 May – 22 June 2011

B. STUDY DESIGN

Experimental treatments

Study site: The study was conducted in two 180 m² glasshouses situated at Stockbridge Technology Centre, Cawood, Selby, North Yorkshire. The glasshouses were well ventilated (but equipped with insect proof) to be as representative as possible of the outdoor situation but without direct precipitation. *Phacelia* was planted directly into the soil inside the glasshouse and no pesticides were applied during cultivation. The timing of the start of test i.e. transfer of colonies into the glasshouse was determined by the flowering of the crops. Temperature and humidity in the glasshouses were recorded continuously.

Experimental design: Four colonies of bees and brood comprising each of 4 to 6 frames of brood and containing 6000 to 12000 adult bees were used. Hives were fitted with a pollen trap. Three days prior to application two colonies each were located on opposite sides of each glasshouse and allowed to fly freely within the glasshouse. Colonies A and B were placed in glasshouse 1, colonies C and D were placed in glasshouse 2.

Test item application: The test item MON 52276 (nominal content: 360 g glyphosate acid equivalent/L) was applied onto the crop grown in the glasshouse on day 0 during a period when bees were actively foraging using a 3 nozzle lunch box sprayer unit with a hand-held boom fitted with Lurmark 03 F110 nozzles. The sprayer was pre-calibrated to deliver a known application rate of 400 L/ha. The colonies were protected from direct overspray and spray drift during the application.

Observations

Foraging assessments were performed each day during times peak foraging activity. The assessments were performed by counting the number of bees foraging in a marked area (5 m by 1 m transects) during a 1 minute period during peak activity. In addition, the number of bees returning to each hive and the number carrying pollen loads were counted during a 30 second period.

Visual assessment of the crop was performed daily by determination of the proportion of plants with wilted flowers and wilted leaves.

The contents of the pollen traps were collected on days -1, 1, 2, 3, 4 and 7 after application. Samples of forager bees were collected on days 0, 1, 2, 3, 4 and 7 after application. The nectar was collected from the bees honey stomachs. On days 4 and 7 samples of ten 4 – 5 day old larvae were taken from each colony, on day 7 an additional sample of nectar was collected from the combs of each colony.

Residues analysis

Analysis of glyphosate acid in samples was conducted following extraction with acetonitrile:water (1:4, v/v), clean up by solid phase extraction on C18 and derivatisation as FMOC-glyphosate and a second clean up (solid phase extraction on Oasis HLB, methanolic elution) by HPLC-MS/MS. Limit of quantification (LoQ) and limit of detection (LoD) were 1.0 and 0.3 mg/kg, respectively.

Data analysis

Considering residue levels determined in nectar and pollen after treatment of a model crop, possible exposure scenarios of honeybee brood are estimated based on information available from literature and the present study.

II. RESULTS AND DISCUSSION

A. FINDINGS

Verification of test item application: The actual application rates were 8.19 L MON 52276/ha (2.94 kg a.e./ha) in glasshouse 1 and , 8.30 L MON 52276/ha (2.98 kg a.e./ha) in glasshouse 2. The application rate was 102 – 104 % of the nominal application rate of 8 L MON 52276/ha and 102 – 103 % of the nominal application rate of 2.88 kg a.e./ha.

Residue analysis: Residues in nectar samples taken from forager bees at various time points after application ranged from 2.78 to 31.3 mg a.e./kg; residues in nectar samples taken from the colonies ranged from below LOQ (1.0 mg a.e./kg) to 1.30 mg a.e./kg. Residues in pollen samples taken from the pollen trap various times after application ranged from 87.2 to 629 mg a.e./kg. Residues in larvae samples ranged from 1.23 to 19.50 mg a.e./kg.

Table 10.3.1.5-1: Summary of residue analysis of pollen, nectar and larvae samples

		Days after treatment [mg glyphosate acid equivalent/kg]					
	Hive	**-1**	**1**	**2**	**3**	**4**	**7**
Nectar (honey stomachs)	A+B	n.d.	25.5	9.24	4.90 (samples combined DAT 3, 4, 7)		
	C+D	n.d.	31.3	15.2	7.18 (samples combined DAT 3, 4)		2.78
	Overall mean	**n.d.**	**28.4**	**12.2**	**6.0**		
Nectar (hive)	A	-	-	-	-	-	<LOQ
	B	-	-	-	-	-	1.30
	C	-	-	-	-	-	1.06
	D	-	-	-	-	-	1.00
Mean							**0.99**
Larvae (comb)	A	-	-	-	-	8.32	2.54
	B	-	-	-	-	16.70	10.6
	C	-	-	-	-	19.50	6.72
	D	-	-	-	-	2.88	1.23
Mean						**11.9**	**5.3**
Pollen (pollen trap)	A	n.d.	325	255	119 (samples combined)	134 (samples combined)	87.2 (samples combined)
	B	n.d.	405	213			
	Mean A&B	**n.d.**	**365**	**234**	**119**	**134**	**87.2**
	C	n.d.	518	333	181	176	130 (samples combined)
	D	n.d.	629	477	147	180	
	Mean C&D	**n.d.**	**574**	**405**	**164**	**178**	**130**
	Overall mean	**n.d.**	**470**	**320**	**142**	**156**	**109**

DAT day after treatment
n.d. not detected
< LOQ 0.6 mg/kg
LOD 0.3 mg/kg
LOQ 1.0 mg/kg

B. OBSERVATIONS

Foraging activity: Foraging assessment showed foraging activity on the crop from start of study throughout the exposure period in glasshouse 1 with a peak on day 4. The lowest foraging activity was observed on day 5 at 38 % of the mean pre-spray activity. In glasshouse 2 the activity declined throughout the assessment period to reach less than 10 % of mean spray activity on days 5 – 7. In line with the decreased foraging activity in glasshouse 2, the crop started to show significant effects of the treatment from day 4 onwards.

Data analysis: The residue data can be used to assess the approximate exposure level of brood within colonies exposed under worst-case conditions.

Table 10.3.1.5-2: Assessment of possible exposure of honey bee colonies to glyphosate residues under two scenarios is depicted below.

Scenario	Daily intake of glyphosate residues in nectar (1296 g nectar/d) [mg]	Daily intake of glyphosate residues in pollen (6 g pollen/d) [mg]	Total daily intake of glyphosate residues [mg a.e.]
Day 1 maximum mean residues (31.3 µg a.e./g in nectar, 574 µg a.e./g in pollen, glasshouse 2)	40.6	3.4	44.0
Mean residues over days 1-3 (15.5 µg a.e./g in nectar, 310 µg a.e./g in pollen, both glasshouses)	20.1	1.9	22.0

Two approaches can be made to assessing exposure - one based on generic published data on the requirements for nectar and pollen by larvae (generic data) and the other based on the observations made in this study (study data).

Generic data: The calculations are based on a daily brood requirement of 30 mg nectar (based on 40 % sugar in nectar) and 1 mg pollen for worker brood (Rortais *et al.* 2005). Based on a brood frame being 3600 cells and 25 % of the time is as unsealed brood (hatch day 3 to sealed day 8 with emergence day 21) then five frames of brood (4 – 6 were used in this study) is 18,000 brood cells therefore for 4500 larvae with a requirement of 135 g/day nectar and 4.5 g/day pollen for the colony.

Study data: The second approach is to assess the amount of pollen and nectar returning to the hive over the time course of exposure using the data on the numbers of returning foragers in the study and the amounts of pollen and nectar collected from bees by using the pollen trap and individual bee samples.
The maximum pollen collected per colony was 2.9 g on day 1 and the traps are estimated to be about 50 % efficient so about 6 g of pollen per day was returned to the hive (the colony is using about 4.5 g of this based on the Rortais *et al.* 2005).

The nectar can be assessed using a mean of 18 foragers returning to the hive per 30 seconds and approximately 50 µL per load (max), which gives 18 trips/30 sec × 60 sec/min × 60 min/hour × 12 hours max foraging/day, equal to 25,920 trips/day × 0.050 mL, resulting in 1296 mL/day (of which the colony is using 135 g based on Rortais *et al.* 2005).

III. CONCLUSION

3. Assessment and conclusion

Assessment and conclusion by applicant:

As a worst case example considering the colony size of the present study, a honey bee colony collects 6 g pollen and 1296 mL nectar and of this the brood consumes 4.5 g pollen and 135 g nectar, which allows the excess to be stored for later consumption. As simulated in this study, for honeybee colonies foraging on the model crop *Phacelia* treated with 8 L MON 52276/ha, a total daily intake of glyphosate residues of 44.0 mg a.e. (based on day 1 maximum mean residues) and of 22 mg a.e. (based on mean residues over days 1 – 3) can be estimated.

This study is considered valid and suitable for risk assessment purposes.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CA 8.3.1.3 / CP 10.3.1.5/002
Report author	Thompson *et al.*
Report year	2014
Report title	Evaluating Exposure and Potential Effects on Honeybee Brood (*Apis mellifera*) Development Using Glyphosate as an Example
Document No	DOI: 10.1002/ieam.1529 E-ISSN: 1551-3793
Guidelines followed in study	Oomen *et al.* 1992
Deviations from current test guideline	Not applicable
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities (literature publication)
Acceptability/Reliability:	Yes/Reliable

2. Full summary

Executive summary

This study aimed to develop an approach to evaluate potential effects of plant protection products on honeybee brood with colonies at realistic worst-case exposure rates. The approach comprised 2 stages. In the first stage, honeybee colonies were exposed to a commercial formulation of glyphosate applied to flowering *Phacelia tanacetifolia* with glyphosate residues quantified in relevant matrices (pollen and nectar) collected by foraging bees on days 1, 2, 3, 4, and 7 post-application and glyphosate levels in larvae were measured on days 4 and 7. Glyphosate levels in pollen were approximately 10 times higher than in nectar and glyphosate demonstrated rapid decline in both matrices. Residue data along with foraging rates and food requirements of the colony were then used to set dose rates in the effects study. In the second stage, the toxicity of technical glyphosate to developing honeybee larvae and pupae, and residues in larvae, were then determined by feeding treated sucrose directly to honeybee colonies at dose rates that reflect worst-case exposure scenarios. There were no significant effects from glyphosate observed in brood survival, development, and mean pupal weight. Additionally, there were no biologically significant levels of adult mortality observed in any glyphosate treatment group. Significant effects were observed only in the fenoxycarb toxic reference group and included increased brood mortality and a decline in the numbers of bees and brood. Mean glyphosate residues in larvae were comparable at 4 days after spray application in the exposure study and also following dosing at a level calculated from the mean measured levels in pollen and nectar, showing the applicability and robustness of the approach for dose setting with honeybee brood studies. This study has developed a versatile and predictive approach for use in higher tier honeybee toxicity studies. It can be used to realistically quantify exposure of colonies to pesticides to allow the appropriate dose rates to be determined, based on realistic worst-case residues in pollen and nectar and estimated intake by the colony, as shown by the residue analysis. Previous studies have used the standard methodology developed primarily to identify pesticides with insect-growth disrupting properties of pesticide formulations, which are less reliant on identifying realistic exposure scenarios. However, this adaptation of the method can be used to determine dose–response effects of colony level exposure to pesticides with a wide range of properties. This approach would limit the number of replicated tunnel or field-scale studies that need to be undertaken to assess effects on honeybee brood and may be of particular benefit where residues in pollen and nectar are crop- and/or formulation-specific, such as systemic seed treatments and granular applications.

Materials and methods

Technical grade glyphosate (62.27 % w/w glyphosate isopropylamine [IPA] salt corresponding to 46.14 % w/w glyphosate acid equivalent [a.e.]) and the soluble concentrate formulation of glyphosate (MON 52276) (30.68 % glyphosate a.e. as the IPA salt, batch no GLP-0810-19515-A), supplied by Monsanto (St. Louis, MO) were used in the study. All honeybee colonies were obtained from National Bee Unit, FERA, (York, UK) apiaries and were confirmed as having low incidence of adult bee diseases, viruses, and varroa with no clinical signs of brood diseases.

Exposure assessment

Two 180 m^2 well-ventilated but insect-proof glasshouses were used for the study so as to be as representative as possible of the outdoor situation (e.g., polytunnel) but without direct rainfall. *Phacelia* was planted directly into the soil in the glasshouses and no pesticides were used during its cultivation. Application was performed when *Phacelia* flowers were at 100 % of full bloom.

Three days before the application, 2 small honeybee colonies comprised of 4 to 6 frames of brood and 6000 to 12 000 adult bees were located on opposite sides of each glasshouse and allowed to fly freely. At the time of installation, each colony was fitted with a pollen trap and provided with a limited amount of stores to ensure that feeding on the crop was encouraged. This was done by removing as many frames as possible which contain only nectar or pollen, while ensuring survival and a maximum foraging activity. A supply of clean water, with provision to prevent bees from drowning, i.e., a sponge, was provided and replenished as required (it was removed during spray application).

To confirm that bees were foraging on the flowering *Phacelia*, foraging assessments were carried out each day during times when peak activity was expected. The assessments were performed by marking a 5 m × 1 m wide transect within the crop and counting the number of bees foraging within the marked area during a 1 min period once each day during the peak activity period (between 10.00 – 15.00 h in this study, based on previous experience). In addition, the number of bees returning to each hive and the number carrying pollen loads were counted during a 30 s period. These 2 counts provided information on the level of foraging activity of each hive within each glasshouse. Daily assessments of the crop were undertaken by visual assessment of the quality of the forage available, e.g., % plants with wilted flowers, wilted leaves.

The glyphosate formulation was applied at a rate equivalent to 8 L/ha (2.88 kg a.e./ha) in 400 L water/ha achieving an application efficiency of between 102 % to 104 % of the target rate, in both glasshouses. The application rate of 2.88 kg a.e./ha is the highest single application rate recommended for glyphosate, whereas the typical single application rate is 2.16 kg a.e./ha. The final treatment solution was prepared by adding the required quantities of test item—measured by weight, to measured volumes of tap water and thoroughly mixing in the field immediately before use to give the final treatment solution. The application was made during a period when the bees were actively foraging, using a 3 nozzle lunch box sprayer unit with a hand-held boom fitted with Lurmark 03 F110 nozzles. Direct spray drift onto the colonies was avoided by directing the spray away from the hives, and no direct overspray of the colonies occurred.

Pollen traps were activated 24 h before pollen collection, and the content of the pollen trap fitted to each hive was collected on days −1 (i.e., the day before application), 1, 2, 3, 4, and 7 after the application. The content of the traps was discarded on day 6 so as to only collect a sample from days 6 to 7. Each day and hive sample was kept separate unless they were too small for residue analysis, in which case samples from the same glasshouse were combined. All samples of pollen, nectar, and larvae were stored at −20 °C.

On days 0 (before application), 1, 2, 3, 4, and 7 after the application samples of approximately 40 returning forager bees were collected from each colony by blocking the entrance of the hives with a foam bung and collecting returning foraging bees directly into collection jars. The nectar was collected from the honey stomachs of individual honeybees by removal of the stomach by dissection and placed in a preweighed tube. Samples were combined to produce samples large enough for residue analysis (minimum 200 mg).

On days 4 and 7 after the application, samples of 10 4 – 5 day old larvae were taken from each colony using a forceps and stored at −20 °C. Each day and hive sample was kept separate. On day 7, an additional sample of nectar was taken from the combs using a syringe in each colony and each hive sample was kept separate.

Residue analysis

Residues of glyphosate were extracted from larvae, pollen, nectar, and sucrose solution samples with acetonitrile/water (1:4, v/v). Recovery samples were fortified by spiking blank samples after weighing. For larvae, pollen, and nectar, the whole sample was accurately weighed into a single-use centrifugation tube.

The sample was then homogenized, extracted with acetonitrile–water (1:4) with a high speed laboratory mixer, separated by centrifugation followed by solid-phase extraction of the supernate using a C18 column. All samples were then derivatized with fluorenylmethyl-chloroformate (FMOC-Cl). For derivatization, internal standard (1.0 µg/mL), borate buffer (0.2 mol/L sodium tetraborate decahydrate in water), and FMOC-Cl (5 g/L in acetonitrile) were added to the diluted extract. The samples were closed, mixed, and incubated at ambient temperature for at least 1 h. Finally, pH 3 water was added.
A second cleanup was carried out by applying the derivatized product to an Oasis HLB SPE column (equilibrated with dichloromethane followed by methanol and pH 3 water) and then rinsed with dichloromethane and the glyphosate-FMOC was eluted with methanol. The eluate was evaporated to dryness using a vacuum rotary evaporator. The residue was reconstituted in 5 % acetonitrile solution and transferred into a glass vial for high-performance liquid chromatography (HPLC)-tandem mass spectrometry (MS/MS) analysis.
The samples were analyzed using high-pressure liquid chromatography (Shimadzu LC-System) coupled with a triple quadrupole mass spectrometry detector (Sciex API4000). A Phenomenex Synergi column 2.5 µm Max-RP, 20 × 2.0 mm, 2.5 µm (No. 00M-4372-B0-CE) + 4 mm guard column was used. The column temperature was 40 °C and a 30 µL injection volume was used. The mobile phase comprised A: water + 0.1 % acetic acid (80 %), B: methanol + 0.1 % acetic acid (15 %), and C: 100 mM ammonium acetate solution in methanol (5 %) with a linear gradient over 5 min to comprise A: water + 0.1 % acetic acid (0 %); B: methanol + 0.1 % acetic acid (95 %) and C: 100 mM ammonium acetate solution in methanol (5 %). Glyphosate-FMOC was quantified using the transition 390.0 to 149.8 with an internal standard glyphosate 1,2-^{13}C2 15N-FMOC transition 393.0 to 152.8.
At the start of the analytical sequence, the detector linearity was confirmed over the calibration range of interest by constructing a calibration function of peak area versus concentration within the range from 2.0 ng/mL to 5000 ng/mL for larvae and nectar samples, 1.0 ng/mL to 3500 ng/mL for pollen samples, and from 2.0 ng/mL to 4000 ng/mL for sucrose solution samples. Injections of sample extracts were interspersed with injections of quality control standards after 2 to 4 samples to verify the detector response.
The methods were validated before use and showed 92 % – 102 % recovery with relative standard deviation (RSD) < 15 % with sucrose samples spiked at 1 and 400 mg a.e./kg, larval samples spiked at 1 and 200 mg a.e./kg, pollen samples spiked at 1, 500 and 700 mg a.e./kg and nectar samples spiked at 1 and 500 mg a.e./kg. Calibrations were linear within the range. Unless otherwise specified the limit of detection (LOD) was 0.3 mg a.e./kg, denoted as not detected (n.d.), and the limit of quantitation (LOQ) was 1.0 mg a.e./kg. Where data were used to generate mean values residues less than the LOQ were ascribed a value of 0.6 mg a.e./kg.

Effects assessment
Two approaches were made to assess exposure levels to be used in the effects study: one based on generic published data on the requirements for nectar and pollen by larvae (generic data) and the other based on the observations made in the exposure study (study data).
Generic data. The calculations were based on a daily brood requirement of 30 mg nectar (based on 40 % sugar in nectar) and 1 mg pollen per worker larva (Rortais *et al.* 2005). Based on a brood frame being 3600 cells (British Standard frame) and 5 frames of brood (4 – 6 were used in this study), there are 18000 brood cells. The brood is unsealed for 25 % of the time (hatch day 3 to sealed day 8 with emergence day 21, empirically determined in this study) therefore 4500 larvae have a requirement for 135 g/d nectar and 4.5 g/d pollen.

Study data
The second approach was to assess the amount of pollen and nectar returning to the hive over the time course of exposure using the data on the numbers of returning foragers in the study and the amounts of pollen and nectar collected from bees by using the pollen trap and individual bee samples.
The maximum pollen collected per colony was 2.9 g on day 1 and the traps were estimated to be approximately 50 % efficient based on calculated pollen collection (Levin and Loper 1984; Delaplane *et al.* 2013). Thus 6 g of pollen per day was returned to the hive (the colony was using approximately 4.5 g of this based on the study by Rortais *et al.* [2005]).
The nectar collection was more difficult to directly assess but with a mean of 18 foragers returning to the

hive per 30 s (observed in this study) and approximately 50 µL per load (max) this gives 18 trips/30 s × 60 s/min × 60 min/h × 12 h max foraging/d = 25 920 trips/d × 0.050 mL = 1296 mL/day (of which the colony was using 135 g, based on Rortais *et al.* [2005]). Because the assessment is brood exposure, the conservative collection estimate is justified. Therefore, as a worst case example considering the colony size used in the exposure study, the colony collected 6 g pollen and 1296 mL (i.e., 518 g sugar, assuming 40 % sugar content) nectar and of this the brood consumes 4.5 g pollen and 135 g nectar (Rortais *et al.* 2005) that allowed the excess to be stored for later consumption.

Considering that bee colonies used in the brood study were up to 50 % bigger than those used in the residue study, an additional calculation for the expected total daily intake of glyphosate residues was undertaken assuming that such colonies would collect 9 g pollen and 1944 mL nectar. Furthermore, the determined residue content based on a worst-case application rate of 2.88 kg a.e./ha for spot treatments in orchards and vines and was adjusted to reflect the more realistic maximum application rate of 2.16 kg a.e./ha for preplanting, preemergence of crops, and preharvest applications.

The brood feeding study was undertaken using glyphosate as the technical grade IPA salt. Three dose levels of the test item were used based on the residues identified in pollen and nectar in a glass house study performed before the initiation of the bee brood study. The lowest dose was based on the mean residue concentrations achieved over the first 3 days following the residue study spray application (75 mg glyphosate a.e./L). The mid-dose was based on the highest residue concentrations following the spray application (150 mg glyphosate a.e./L) and the highest dose was equivalent to twice this latter rate (301 mg glyphosate a.e./L). The test item was introduced into each hive in equivalent volumes of 50 % sucrose (w/v) solution (1 L) for each treatment group. Hence, the range could also be expressed in terms of concentration in the introduced dosing solution (mg glyphosate a.e./L and mg glyphosate a.e./kg). Control colonies were supplied with 50 % w/v sucrose solution in deionized water and the toxic reference, fenoxycarb, (750 mg a.s./L as the formulation Insegar WG 250 g a.s./kg, batch no SM01A406) reported to have significant adverse effects on honeybee brood, was used to ensure that the study had the ability to detect effects of the test substance if they occurred (de Ruijter and van der Steen 1987).

Twenty standardized honeybee colonies each consisting of a single wooden Smith hive with British Standard frames and a queen were used; each of the queens used in the study was of similar age and lineage. The colonies were divided into 5 groups of 4 colonies. Each colony had a dead bee trap fitted to the front and the contents were counted daily during the brood assessment period (Imdorf *et al.* 1987). The colonies contained a mean of 14 250 to 19 500 adult bees, 1.5 to 2.5 frames of brood, 1.0 to 1.9 frames of stores, and 0.2 to 0.7 frames of pollen. The test colonies were allowed to fly freely, there were no nearby flowering crops and few flowering weeds (clover). Colonies were assembled according to treatment and groups were placed at least 20 m apart from each other. Two colonies (one control colony and one of the highest exposure rate colonies) (301 mg glyphosate a.e./L) became queenless after dosing but were retained in the study as the marked brood was viable and this was therefore not considered to have a significant impact on the study. All colonies were generally assessed within 1 week before dosing and again within weeks 1, 2, and 3 after dosing (day 0). Each assessment was carried out on every frame within each colony, and included counts of the number of combs of adults, brood (sealed and unsealed), and stores (nectar and pollen) as well as any behavioral or physical abnormalities.

The processes during the study followed the method for honeybee brood feeding test with insect growth regulating compounds (Oomen *et al.* 1992). Up to 24 h before dosing, 100 brood cells containing eggs, 100 cells containing 1- to 2-day-old larvae and 100 cells containing 3- to 4-day-old larvae were selected in each colony and marked using the standard Oomen *et al.* (1992) acetate overlay sheet method.

On day 0, one group was an untreated control, i.e., fed 1 L 50 % sucrose solution, 3 groups were treated with glyphosate IPA salt (added to 1 L of 50 % sucrose to achieve doses of 301, 150 and 75 mg glyphosate a.e./L), and one group was treated with the toxic reference, fenoxycarb, dispersed in 1 L of 50 % w/v sucrose (750 mg a.s./L). Doses were administered by removing frames of stores from the colonies and placing a 1 L glass container containing the treated or control sucrose within the brood chamber. The container contained a cork float to allow access to the sucrose solution. Samples of each concentration of test item treated sucrose solution were retained for analysis by subsampling 5 mL from each of the prepared solutions and combining to a single sample (total 4 samples; control and 3 doses of glyphosate). The uptake of each sucrose solution was checked daily and the container removed when empty or after 5 days whichever was later.

On day 7, the marked brood cells (eggs, young, and old larvae) were assessed for mortality and appearance in each test colony. The final assessment for each larval was undertaken at day 13 for brood cells marked as containing old larvae, day 15 for cells containing young larvae, and day 16 for cells containing eggs. The cells were uncapped, the bee removed carefully with forceps, and the age of the bee assessed, weighed, and any deformities noted.

On days 4 and 7 (when the marked brood cells were assessed), samples of ten 4- to 5-day-old larvae were sampled from each treated colony (not from an area in which marked brood cells were located) for residue analysis. For the purpose of this study, mortality was defined as the total number of cells in any one group at any one observation period that were empty (other than recently emerged), contained dead larvae or pupae or contained larvae or pupae that were considered unhealthy (sick) and unlikely to survive. Brood mortality was statistically analyzed using a generalized linear model linked to a logit distribution for the brood mortality data and an analysis of variance for pupae weight data to determine the no observed effect concentration (NOEC) (equivalent to the no observed adverse effect level [NOAEL]) statistically, using the software Genstat v12 (VSN International). The study was considered valid if there were significant effects of the toxic reference (> 40 % effects on all stages) during the detailed brood assessment when compared to the control. The performance of the colonies in the control group were comparable with historical control data for the testing facility (10 % – 30 % larval mortality overall), and demonstrate that the control colonies had performed correctly.

Results

Exposure study

Daily assessments were made of the percentage of the plants that had wilted leaves or flowers. The crop started to show significant effects of the treatment from day 4 onward in both glasshouses and this coincided with the decreased foraging activity in glasshouse 2 although less pronounced effects on foraging were observed in glasshouse 1.

Foraging assessments showed foraging activity on the crop at the start of the study and this continued throughout the exposure period in glasshouse 1 with a peak on day 4; lowest foraging activity was on day 5 at 38 % of the mean prespray activity. In glasshouse 2, the foraging activity declined throughout the assessment period and reached < 10 % of the mean prespray activity on days 5 to 7. The weights of pollen collected from the traps fitted to each hive ranged from 0.37 to 1.8 g per colony per day.

Samples of honeybee products (nectar and pollen) and larvae were analyzed for residues of glyphosate acid equivalents. Glyphosate residues in nectar samples taken from forager bees before the application were not detectable (< 0.3 mg a.e./kg). Residues in nectar samples taken at various time points after the application and originating from forager honeybees ranged from 2.78 to 31.3 mg a.e./kg and declined over time (Figure 1A). Residues in nectar samples taken from the colonies 7 days after the application ranged from below the LOQ (1.0 mg a.e./kg) to 1.30 mg a.e./kg.

Residues in pollen samples taken from the pollen trap before the application were not detectable (< 0.3 mg a.e./kg). Residues in pollen samples taken at various time points after the application and originating from the trap ranged from 87.2 mg a.e./kg to 629 mg a.e./kg and declined over time (Figure 1B). Residues in larvae samples at 2 time points (day 4 and day 7) after the application ranged from 1.23 mg a.e./kg to 19.50 mg a.e./kg.

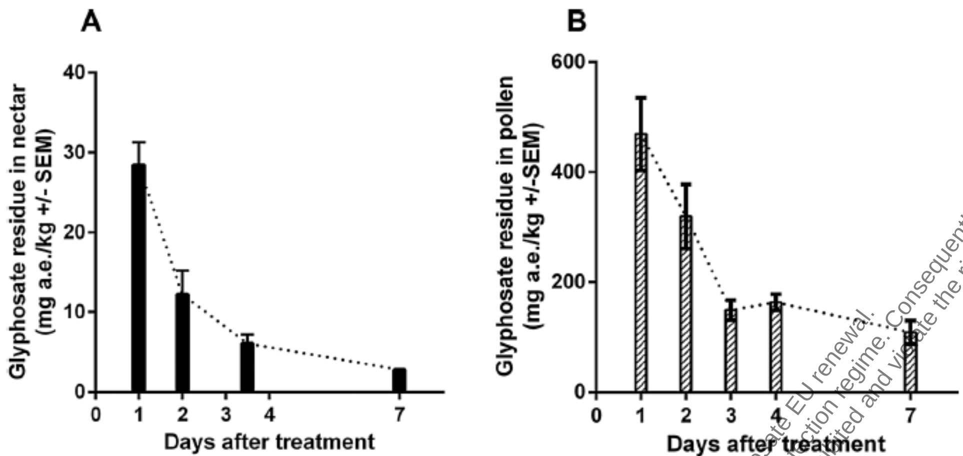

Fig. 1. Decline of glyphosate residues (mg a.e./kg ± SE). (A) Nectar collected from foragers. The nectar sample from days 3 and 4 were combined due to the small amount collected for analysis. (B) Pollen collected in pollen traps in mg a.e./kg matrix.

Effects study

Consumption of treated sucrose. Analysis of the dosing solutions showed they were within 11 % of the nominal doses. The control colonies consumed between 0.63 and 1.0 L of untreated sucrose. In the glyphosate-treated colonies, at least 3 of the 4 colonies in each group consumed the total volume of treated sucrose fed to each of them. There was no statistically significant difference in sucrose consumption in comparison to control for the 301 mg a.e./L group ($p = 0.438$), 150 mg a.i./L group ($p = 0.212$), the 75 mg a.i./L group ($p = 0.054$), which was slightly higher than the control, and the positive control fenoxycarb ($p = 0.151$).

In the 301 mg glyphosate a.e./L group, one colony consumed 0.39 L and the other 3 each consumed 1.0 L resulting in mean exposure to 255 ± 26 mg glyphosate a.e. In the 150 mg glyphosate a.e./L group, one colony consumed 0.67 L and the other 3 each consumed 1.0 L resulting in mean exposure to 130 ± 12 mg glyphosate a.e. In the 75 mg glyphosate a.e./L group one colony consumed 0.90 L and the other 3 each consumed 1.0 L resulting in mean exposure to 73 ± 2 mg glyphosate a.e. In the fenoxycarb treated colonies, consumption rates ranged from 0.45 to 0.88 L resulting in mean exposure to 510 ± 72 mg fenoxycarb. Exposure at the 150 mg a.i./L dose was significantly lower than at the 301 mg a.i./L dose ($p = 0.049$) and exposure at the 75 mg a.i./L dose was significantly lower than at 150 mg a.i./L dose ($p = 0.002$).

Brood mortality. Figure 2 summarizes the survival of marked brood stages at day 7 after dosing and just before emergence. There were no significant treatment-related effects except in the fenoxycarb toxic reference treated colonies, in which overall survival of marked cells was 20 % for marked eggs ($p < 0.001$), 0 % for marked young larvae ($p < 0.001$) and 12 % for marked old larvae ($p < 0.001$), meeting the established validity criterion for the toxic reference (> 40 % effects at all stages). This can be compared with overall survival of 85 % for marked eggs, 96 % for marked young larvae, and 96 % for marked old larvae in controls and 82 % – 87 % for marked eggs (300 mg a.i./L: $p = 0.435$, 150 mg a.i./L: $p = 0.310$, 75 mg a.i./L: $p = 0.250$), 87 % – 94 % for marked young larvae (300 mg a.i./L: $p = 0.185$, 150 mg a.i./L: $p = 0.060$, 75 mg a.i./L: $p = 0.254$), and 94 % – 95 % for marked old larvae (300 mg a.i./L: $p = 0.434$, 150 mg a.i./L: $p = 0.202$, 75 mg a.i./L: $p = 0.291$) in the glyphosate-treated colonies. The control mortality is similar to historical levels in studies conducted at the Food and Environmental Research Agency (FERA) (10 % – 30 %). Deformities were observed in the fenoxycarb-treated colonies where discolored heads, thorax, and abdomens were noted. No deformities were observed in of the control or any glyphosate-treated colonies. Additionally, there were no significant effects on the mean weight of the exposed pupae (Table 1) compared to controls in the 300 mg a.i./L group ($p = 0.424$), the 150 mg a.i./L ($p = 0.207$), or the 75 mg a.i./L ($p = 0.292$). The fenoxycarb-treated colonies showed significant effects on weight of surviving pupae marked as old larvae ($p = 0.003$). The only dead pupae observed in any significant number were those in the fenoxycarb treated group where a mean of up to 190 pupae/day was observed and a mean of 600 pupae were recovered from the colonies over the 17-day period after dosing compared with 2.0 pupae/d in the control and 1.3 to 1.8 pupae/d in the glyphosate-treated colonies. The only adverse effects on colony development were observed in the fenoxycarb-treated colonies where declines in the numbers of bees and brood were observed in the latter stages of the study compared to controls for the 300 mg a.i./L group (p = 0.401), the 150 mg a.i./L group ($p = 0.414$), the 75 mg a.i./L group (p = 0.360), or the positive control fenoxycarb ($p = 0.070$).

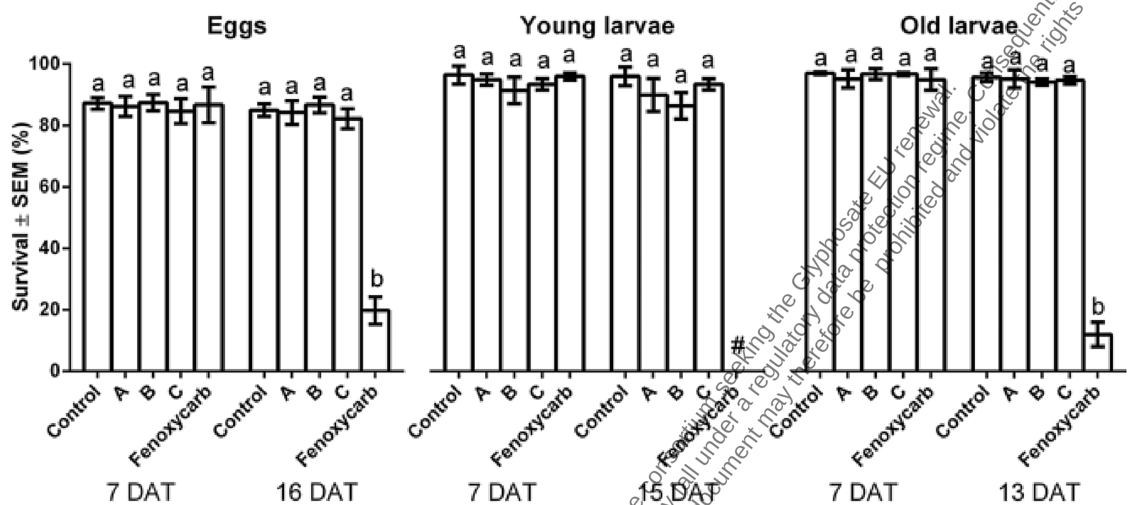

Fig. 2. Survival (% ± SE) of Eggs (7 and 16 Days After Treatment, DAT), Young Larvae (7 and 15 DAT) and Old Larvae (7 and 13 DAT) for treatment groups (mean consumption) Control (0 mg glyphosate a.e.), A (255 ± 46 mg glyphosate a.e.), B (138 ± 12 mg a.e.), C (73 ± 2 mg glyphosate a.e.), and Fenoxycarb (510 ± 72 mg). Different letters above the bars indicate statistical difference ($p < 0.05$) from the respective control. # no statistical analysis as no variance due to 100 % mortality.

Table 10.3.1.5-3 Mean pupae weight with SE at final assessment including dead and sick in the fenoxycarb treatment

Treatment	Dose rate mg/L	Mean dose consumed mg (SE)	Weight-surviving pupae marked as eggs (mg)	Weight-surviving pupae marked as young larvae (mg)	Weight-surviving pupae marked as old larvae (mg)
Control	0	0	127.5 ± 0.7	128.4 ± 0.6	128.9 ± 0.4
Glyphosate	301	255 ± 46	135.7 ± 0.6	125.4 ± 0.6	125.6 ± 0.4
Glyphosate	150	138 ± 12	126.7 ± 0.6	124.4 ± 0.8	122.6 ± 0.5
Glyphosate	75	73 ± 2	124.7 ± 0.8	128.3 ± 1.0	121.2 ± 0.5
Fenoxycarb	750	510 ± 72	125.9 ± 0.9	128.8 ± 1.3	115.4 ± 1.0[a]

SE = standard error
[a] Statistically different effect (p < 0.01)

Adult bee mortality. No biologically significant adult mortality was observed in any treatment group with a mean total of 73 to 25 dead adult workers were recovered from dead bee traps over the entire 17-day period after dosing.
Residue analysis. The residues in larvae sampled at 2 time points (day 4 and day 7) after dosing of the colonies (Figure 3) ranged from below the LOQ (1.0 mg a.e./kg) to 82.1 mg a.e./kg (at the highest dose

rate) confirming that larvae were exposed to test item provided in the sucrose solution and consumed it. There was a linear relationship between dose level and glyphosate levels in larvae on days 4 and 7. Levels of day 7 were considerably lower than on day 4 and are likely the result of larval growth and glyphosate exposure ending after 5 days of exposure. Notably, these residue levels are comparable with values from the exposure study which ranged from 2.9 to 19.5 mg a.e./kg with a mean of 11.5 mg a.e./kg on day 4 to 1.2 to 10.6 mg a.e./kg with a mean of 5.3 mg a.e./kg on day 7 after the glyphosate application.

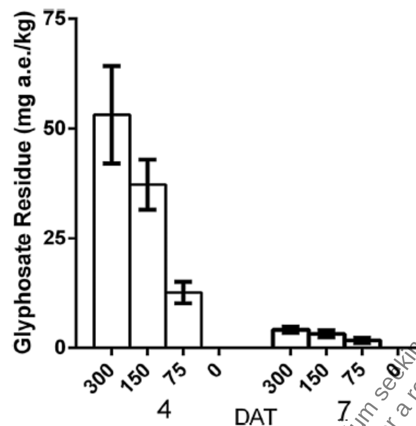

Fig. 3. Residues (mg a.e./kg ± SE) in larvae 4 and 7 days after treatment (DAT) for dose groups with dose rate of 300, 150, 75, and 0 mg a.e./kg sucrose solution.

Conclusion

There were no significant effects from glyphosate observed in brood survival, development, and mean pupal weight. Additionally, there were no biologically significant levels of adult mortality observed in any glyphosate treatment group. Significant effects were observed only in the fenoxycarb toxic reference group and included increased brood mortality and a decline in the numbers of bees and brood. Mean glyphosate residues in larvae were comparable at 4 days after spray application in the exposure study and also following dosing at a level calculated from the mean measured levels in pollen and nectar, showing the applicability and robustness of the approach for dose setting with honeybee brood studies.

3. Assessment and conclusion

Assessment and conclusion by applicant:

The Oomen *et al.* (1992) approach was used to quantify at residues in relevant matrices (pollen, nectar, and larvae) following application of glyphosate at 2.88 kg a.e./ha (400 L water/ha) to flowering *Phacelia tenacetifolia* in large glasshouses. Then brood feeding tests following the Oomen approach, were conducted by feeding 1 L treated sucrose solution at 75 / 150 and 301 mg glyphosate a.e./L directly to honeybee colonies.

The study is adequately described and all information to evaluate the study are available. At the time the study was conducted, there were no field level test guidelines adopted for use in the EU. The test did follow a recognised approach and is considered fit for purpose. The study is considered as reliable.

CP 10.3.1.6 Field tests with honeybees

Further studies with honeybees are not considered required with representative product MON 52276 based on the low toxicity demonstrated by the risk assessments above.

CP 10.3.2 Effects on non-target arthropods other than bees

Studies on effects of the representative formulation MON 52276 on non-target arthropods to fulfil the data requirements according to EU Regulation No 284/2013 are presented in the following.

Studies considering the toxicity of MON 52276 to non-target arthropods at Tier 1 and Tier 2 were assessed for validity against current and relevant guidelines and are presented in the following table. Studies previously evaluated in either the monograph 2001 or the RAR 2015 were also included in this assessment. Study summaries for all studies are presented in this section below.

Table 10.3.2-1: Studies on the toxicity of MON 52276 to non-target arthropods other than bees

Annex point	Study reference	Study type	Test species	Substance	Status	Remark
Tier 1 – laboratory studies						
CP 10.3.2.1/001	[redacted] 1995	Laboratory	*Aphidius rhopalosiphi*	MON 52276	supportive	Single rate tested 3.6 kg a.e/ha. 100 % mortality at 24 hrs, therefore no reproduction endpoints available.
CP 10.3.2.1/002	[redacted] 1995	Laboratory	*Typhlodromus pyri*	MON 52276	supportive	Single rate tested 3.6 kg a.e/ha. 100 % mortality at day 4, therefore no reproduction endpoints.
CP 10.3.2.1/003	[redacted] 1995	Laboratory	*Poecilus cupreus*	MON 52276	Valid	
CP 10.3.2.1/004	[redacted] 1995	Laboratory	*Pardosa sp.*	MON 52276	Valid	
Tier 2 – extended laboratory and aged residue						
CP 10.3.2.2/001	[redacted] 2010	Extended laboratory	*Typhlodromus pyri*	MON 52276	Valid	
CP 10.3.2.2/002	[redacted] 1999	Extended laboratory	*Typhlodromus pyri*	MON 52276	supportive	Several minor deviations to relevant guideline. A more recent study ([redacted] 2010) is available.
CP 10.3.2.2/003	[redacted] 1998	Extended laboratory	*Typhlodromus pyri*	MON 52276	supportive	Several minor deviations to relevant guideline. A more recent study ([redacted] 2010) is available.
CP 10.3.2.2/004	[redacted] 2010	Extended laboratory	*Aphidius rhopalosiphi*	MON 52276	Valid	
CP 10.3.2.2/005	[redacted] 1999	Extended laboratory	*Aphidius rhopalosiphi*	MON 52276	Valid	
CP 10.3.2.2/007	[redacted] 2010	Extended laboratory	*Aleochara bilineata*	MON 52276	Valid	
CP 10.3.2.2/008	[redacted] 1999	Extended laboratory	*Chrysoperla carnea*	MON 52276	supportive	Control eggs < 15. Mean No. eggs per female/day was 7.9.

Endpoints of studies considered valid with the representative product MON 52276 are shown in the table below. In order to make a direct comparison of toxicity between studies conducted with MON 52276 and those conducted with IPA salt, glyphosate technical and glyphosate acid, the endpoints from all these studies have been converted to acid equivalents (a.e.). Although no NTA studies with the active substance are available, the endpoints for MON 52276 have been converted to be consistent with the other organism groups. This conversion has been made by the acid equivalent purity of the test item stated in the reports.

Table 10.3.2-2: Endpoints: studies on toxicity of MON 52276 to non-target arthropods other than bees

Reference	Test item	Species	Test design	Mortality LR_{50}	Effects on reproduction
Tier 1 – laboratory studies					
[redacted], 1995 CP 10.3.2.1/003	MON 52276	*Poecilus cupreus*	Laboratory	> 10 L/ha (3600 g a.e./ha)	-
[redacted] 1995 CP 10.3.2.1/004	MON 52276	*Pardosa sp.*	Laboratory	> 10 L/ha (3600 g a.e./ha)	-
Tier 2 – extended laboratory and aged residue					
[redacted], 2010 CP 10.3.2.2/001	MON 52276	*Typhlodromus pyri*	Extended laboratory 2D	> 16.0 L/ha (5760 g a.e./ha)	**ER_{50} ≥ 12 L/ha (4320 g a.e./ha)** NOER = 8 L/ha (2880 g a.e./ha)
[redacted] 2010 CP 10.3.2.2/004	MON 52276	*Aphidius rhopalosiphi*	Extended laboratory 3D	> 16.0 L/ha (5760 g a.e./ha)	**ER_{50} > 16 L/ha (5760 g a.e./ha)** NOER ≥ 16 L/ha (5760 g a.e./ha)
[redacted] 1999 CP 10.3.2.2/005	MON 52276	*Aphidius rhopalosiphi*	Extended laboratory 3D	> 12.0 L/ha (4320 g a.e./ha)	ER_{50} > 12 L/ha (4320 g a.e./ha) NOER ≥ 12 L/ha (4320 g a.e./ha)
[redacted] 2010 CP 10.3.2.2/007	MON 52276	*Aleochara bilineata*	Extended laboratory	> 12.0 L/ha (4320 g a.e./ha)	ER_{50} > 12 L/ha (4320 g a.e./ha) NOER ≥ 12 L/ha (4320 g a.e./ha)

a.e. glyphosate acid equivalents
Endpoints in **bold** are used for risk assessment

There are no literature articles and peer-reviewed published data considered to be relevant and reliable or reliable with restrictions with regards to the impact of glyphosate or its relevant metabolites on non-target arthropods. Full literature evaluation is provided in document M-CA Section 9. A summary of previously evaluated peer reviewed literature from the RAR 2015 is also available in Annex M-CA 8-01 of the M-CA Section 8.

Risk assessment for other non-target arthropods

The table below summarises how the risk assessment for non-target arthropods considers all the proposed uses and the application rates presented in the GAP. The risk assessment presented here is shown by the grey shaded cells in the table, which represents the worst-case exposure to non-target arthropods and are selected based on the application rate, multiple application factor and the crop type for the proposed uses of MON 52276. Thus, the conclusions of the risk assessment here are protective of all uses indicated by "X".

Table 10.3.2-3: Risk assessment strategy for terrestrial non-target arthropods

GAP number and summary of use	Application rate of glyphosate considered g/ha (28 day interval unless otherwise stated)									
	1 × 540	1 × 720	1 × 1080	2 × 720	1 × 1440	3 × 720	1 × 1800	2 × 1080	2 × 1440	2 × 1800 (90 days apart)
Uses 1a-c: Applied to weeds; pre-sowing, pre-planting, pre-emergence of **field crops.**		X	X		X					
Uses 2 a-c: Applied to weeds; post-harvest, pre-sowing, pre-planting of **field crops.**		X	X	X	X	X		X		
Use 3 a-b: Applied to cereal volunteers; post-harvest, pre-sowing, pre-planting of **field crops.**	X									
Use 4 a-c: Applied to weeds (post-emergence) below trees in **orchards.**		X	X	X	X	X		X	X	
Use 5 a-c: Applied to weeds (post-emergence) below vines in **vineyards**			X	X	X	X		X	X	
Use 6 a-b: Applied to weeds (post-emergence) in **field crops BBCH < 20**		X	X							
Use 7 a-b: Applied to weeds (post-emergence) around **railroad tracks**							X			X
Use 8 and 9: Applied to invasive species (post-emergence) in **agricultural and non-agricultural areas**							X			
Uses 10 a-c: Applied to couch grass; post-harvest, pre-sowing, pre-planting of **field crops**		X	X							

X = this use is covered by the application rate indicated
Grey shaded cells: risk assessment presented.

For the non-target arthropod field assessment; crops that maybe present at time of application to target weeds and the relevant application rates shown in the table above are considered. The in-field and off field assessment results are presented below according to the uses described in the table above and grouped as follows:

- in **field crops**; covering GAP uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c.
- in **orchards/vineyards**; covering GAP uses 4 a-c, 5 a-c.
- around **railroad tracks**; covering GAP uses 7 a-b.
- in **agricultural and non-agricultural areas** to control invasive species; covering GAP uses 8 and 9.

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2 [34].

Where multiple applications per season are applicable, a multiple application factor is applied to the risk assessment, considering an application interval of 28 days. Therefore, the MAF is based on a DT_{50} of 2.8 days for decline of residues on leaf surfaces in a grass residues study, which is considered to cover decline on broadleaf plant foliage. This DT_{50} is supported by Ebeling & Wang (2018)[35], who evaluated the residue dissipation of 30 active substances (including glyphosate) on grasses / cereals (177 trials) and non-grass herbs (101 trials). No significant difference between residue dissipation on grasses / cereals and non-grass herbs was found. In addition, in the EFSA Conclusion for glyphosate (2015)[36] (EFSA Journal 2015;13(11):4302) the DT_{50} of 2.8 days was used to determine a calculated 21-day TWA of 0.19, that was applied to refine the risk to the medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*).

The principal route of non-target terrestrial plant exposure is via spray drift away from the applied areas. Currently, estimation of spray drift deposition is based on the values given by Rautmann (2001). These values apply to 90th percentile conditions. According to ESCORT 2 and Rautmann (2001) the estimated spray drift deposition for field crops (% of in-field target deposition) downwind of a sprayed (ground directed application) to a bare soil surface (without interception by vegetation) representing a field crop situation at distances of 1, 5 and 10 meters from the target area, are 2.77, 0.57 and 0.29 %.

Applications using high boom or blast sprayer applicators associated with for example, 'over the top' applications in perennial crops, are not a use on the proposed GAP table. The assessment does therefore only consider low boom – ground directed applications. The stated percentage drift values are for field crop drift values used for all crops according to recommendations of the Guidance Document on Terrestrial Ecotoxicology (2002) and are based on Rautmann (2001).

An assessment considering the Tier 2 extended laboratory studies for *T. pyri* and *A. rhopalosiphi* is provided below. The extended laboratory studies provide more realistic test conditions to assess the toxicity of MON 52276 on the indicator species using plant substrates in 2-dimentional (*T.pyri*) or 3-dimentional (*A. rhopalosiphi)* study designs.

The in-field risk assessment is presented below for the use of MON 52276 in field crops, orchards, vineyards, railroad tracks and agricultural/non-agricultural areas for the control of invasive species.

[34] Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet MC, Lewis G, Oomen PA, Schmuck R and Vogt H (eds) (2001): Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. From the ESCORT 2 workshop. SETAC, Pensacola, 46 p

[35] Ebeling, M., Wang, M. Dissipation of Plant Protection Products from Foliage. Environmental Toxicology and Chemistry (2018). Wiley Online Library.

[36] Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate (2015). European Food Safety Authority (EFSA), Parma, Italy.

Table 10.3.2-4: In-field HQs for non-target arthropods (*T. pyri* and *A. rhopalosiphi;* Tier 2) exposed to MON 52276 in field crops *(Uses: 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c)* – considering downward ground-directed spray

Crop scenario	Application pattern	Test species	ER_{50} [g a.e./ha]	MAF [1]	$PER_{in-field}$ [2] [g a.e./ha]	$PER_{in-field}$ below rate with ≤ 50% effect?
Field crops	1 × 540 g a.e./ha	*T. pyri*	> 4320	1 (foliar)/ 1 (soil)	540 (foliar)/ 540 (soil)	yes (foliar)/ yes (soil)
		A. rhopalosiphi	> 5760			yes (foliar)/ yes (soil)
	1 × 720 g a.e./ha	*T. pyri*	> 4320	1 (foliar)/ 1 (soil)	720 (foliar)/ 720 (soil)	yes (foliar)/ yes (soil)
		A. rhopalosiphi	> 5760			yes (foliar)/ yes (soil)
	3 × 720 g a.e./ha	*T. pyri*	> 4320	1 (foliar)/ 1 (soil)	720 (foliar)/ 720 (soil)	yes (foliar)/ yes (soil)
		A. rhopalosiphi	> 5760			yes (foliar)/ yes (soil)
	2 × 1080 g a.e./ha	*T. pyri*	> 4320	1 (foliar)/ 1 (soil)	1080 (foliar)/ 1080 (soil)	yes (foliar)/ yes (soil)
		A. rhopalosiphi	> 5760			yes (foliar)/ yes (soil)

a.e. glyphosate acid equivalents
PER: Predicted environmental rate
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) at 1 m from the application area considering downward ground directed spray

Table 10.3.2-5: In-field HQs for non-target arthropods (*T. pyri* and *A. rhopalosiphi;* Tier 2) exposed to MON 52276 in Orchards *(Uses: 4 a-c)* – considering downward ground-directed spray

Crop scenario	Application pattern	Test species	ER_{50} [g a.e./ha]	MAF [1]	$PER_{in-field}$ [2] [g a.e./ha]	$PER_{in-field}$ below rate with ≤ 50% effect?
Stone and pome fruit, Fruit crops	1 × 720 g a.e./ha	*T. pyri*	> 4320	1 (foliar)/ 1 (soil)	360 (foliar)/ 360 (soil)	yes (foliar)/ yes (soil)
		A. rhopalosiphi	> 5760			yes (foliar)/ yes (soil)
	2 × 1440 g a.e./ha	*T. pyri*	> 4320	1 (foliar)/ 1 (soil)	1440 (foliar)/ 1440 (soil)	yes (foliar)/ yes (soil)
		A. rhopalosiphi	> 5760			yes (foliar)/ yes (soil)

a.e. glyphosate acid equivalents
PER: Predicted environmental rate
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate of 2.77 % at 1 m from the application area considering downward ground directed spray

Table 10.3.2-6: In-field HQs for non-target arthropods (*T. pyri* and *A. rhopalosiphi;* Tier 2) exposed to MON 52276 in Vineyards *(Uses: 5 a-c)* – considering downward ground-directed spray

Crop scenario	Application pattern	Test species	ER_{50} [g a.e./ha]	MAF [1]	$PER_{in\text{-}field}$ [2] [g a.e./ha]	$PER_{in\text{-}field}$ below rate with ≤ 50% effect?
Table and wine grapes	1 × 1080 g a.e./ha	*T. pyri*	> 4320	1 (foliar)/ 1 (soil)	540 (foliar)/ 540 (soil)	yes (foliar)/ yes (soil)
		A. rhopalosiphi	> 5760			yes (foliar)/ yes (soil)
	2 × 1440 g a.e./ha	*T. pyri*	> 4320	1 (foliar)/ 1 (soil)	1440 (foliar)/ 1440 (soil)	yes (foliar)/ yes (soil)
		A. rhopalosiphi	> 5760			yes (foliar)/ yes (soil)

a.e. glyphosate acid equivalents
PER: Predicted environmental rate
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate of 2.77 % at 1 m from the application area considering downward ground directed spray

Table 10.3.2-7: In-field HQs for non-target arthropods (*T. pyri* and *A. rhopalosiphi;* Tier 2) exposed to MON 52276 in railroad tracks *(Uses: 7 a-c)* – considering downward ground-directed spray

Crop scenario	Application pattern	Test species	ER_{50} [g a.e./ha]	MAF [1]	$PER_{in\text{-}field}$ [2] [g a.e./ha]	$PER_{in\text{-}field}$ below rate with ≤ 50% effect?
Field crops (Railroad tracks)	1 × 1800 g a.e./ha	*T. pyri*	> 4320	1 (foliar)/ 1 (soil)	1800 (foliar)/ 1800 (soil)	yes (foliar)/ yes (soil)
		A. rhopalosiphi	> 5760			yes (foliar)/ yes (soil)
	2 × 1800 g a.e./ha	*T. pyri*	> 4320	1 (foliar)/ 1 (soil)	1800 (foliar)/ 1800 (soil)	yes (foliar)/ yes (soil)
		A. rhopalosiphi	> 5760			yes (foliar)/ yes (soil)

a.e. glyphosate acid equivalents
PER: Predicted environmental rate
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate of 2.77 % at 1 m from the application area considering downward ground directed spray

Table 10.3.2-8: In-field HQs for non-target arthropods (*T. pyri* and *A. rhopalosiphi;* Tier 2) exposed to MON 52276 for the control of invasive species *(Uses: 8 and 9)* – considering downward ground-directed spray

Crop scenario	Application pattern	Test species	ER_{50} [g a.e./ha]	MAF [1]	$PER_{in-field}$ [2] [g a.e./ha]	$PER_{in-field}$ below rate with ≤ 50% effect?
Field crops (Invasive species control)	1 × 1800 g a.e./ha	*T. pyri*	> 4320	1 (foliar)/ 1 (soil)	1800(foliar)/ 1800 (soil)	yes (foliar)/ yes (soil)
		A. rhopalosiphi	> 5760			yes (foliar)/ yes (soil)

a.e. glyphosate acid equivalents
PER: Predicted environmental rate
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate of 2.77 % at 1 m from the application area considering downward ground directed spray

The off-field risk assessment is presented below for the use of MON 52276 in field crops, orchards, vineyards, railroad tracks and agricultural/non-agricultural areas.

Table 10.3.2-9: Off-field HQs for non-target arthropods (*T. pyri* and *A. rhopalosiphi;* Tier 2) exposed to MON 52276 in field crops *(Uses: 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c)* – considering downward ground-directed spray

Crop scenario	Application pattern	Test species	ER_{50} [g a.e./ha]	MAF [1] (foliar)	vdf	$PER_{off-field}$ [2] [g a.e./ha]	CF	corr. $PER_{off-field}$ below rate with ≤ 50 % effect?
Field crops	1 × 540 g a.e./ha	*T. pyri*	> 4320	1	10	1.5	10	yes
		A. rhopalosiphi	> 5760		1	15		yes
	1 × 720 g a.e./ha	*T. pyri*	> 4320	1	10	1.99		yes
		A. rhopalosiphi	> 5760		1	19.9		yes
	3 × 720 g a.e./ha	*T. pyri*	> 4320	1	10	1.99		yes
		A. rhopalosiphi	> 5760		1	19.9		yes
	2 × 1080 g a.e./ha	*T. pyri*	> 4320	1	10	2.99		yes
		A. rhopalosiphi	> 5760		1	29.9		yes

a.e. glyphosate acid equivalents
PER: Predicted environmental rate, vdf: vegetation distribution factor; CF: correction factor
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate of 2.77 % at 1 m from the application area considering downward ground directed spray

Table 10.3.2-10: Off-field HQs for non-target arthropods (*T. pyri* and *A. rhopalosiphi;* Tier 2) exposed to MON 52276 in orchards *(Uses: 4 a-c)* – considering downward ground-directed spray

Crop scenario	Application pattern	Test species	ER_{50} [g a.e./ha]	MAF [1] (foliar)	vdf	$PER_{off\text{-}field}$ [2] [g a.e./ha]	CF	corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?
Stone and pome fruit, fruit crops	1 × 720 g a.e./ha	*T. pyri*	> 4320	1	10	1.99	10	yes
		A. rhopalosiphi	> 5760		1	19.9		yes
	2 × 1440 g a.e./ha	*T. pyri*	> 4320	1	10	3.98		yes
		A. rhopalosiphi	> 5760		1	39.8		yes

a.e. glyphosate acid equivalents
PER: Predicted environmental rate, vdf: vegetation distribution factor; CF: correction factor
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate of 2.77 % at 1 m from the application area considering downward ground directed spray

Table 10.3.2-11: Off-field HQs for non-target arthropods (*T. pyri* and *A. rhopalosiphi;* Tier 2) exposed to MON 52276 in vineyards *(Uses: 5 a-c)* – considering downward ground-directed spray

Crop scenario	Application pattern	Test species	ER_{50} [g a.e./ha]	MAF [1] (foliar)	vdf	$PER_{off\text{-}field}$ [2] [g a.e./ha]	CF	corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?
Table and wine grapes	1 × 1080 g a.e./ha	*T. pyri*	> 4320	1	10	8.66	10	yes
		A. rhopalosiphi	> 5760		1	86.6		yes
	2 × 1440 g a.e./ha	*T. pyri*	> 4320	1	10	3.98		yes
		A. rhopalosiphi	> 5760		1	39.8		yes

a.e. glyphosate acid equivalents
PER: Predicted environmental rate, vdf: vegetation distribution factor; CF: correction factor
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate of 2.77 % at 1 m from the application area considering downward ground directed spray

Table 10.3.2-12: Off-field HQs for non-target arthropods (*T. pyri* and *A. rhopalosiphi;* Tier 2) exposed to MON 52276 in railroad tracks *(Uses 7a-c)* – considering downward ground-directed spray

Crop scenario	Application pattern	Test species	ER_{50} [g a.e./ha]	MAF [1] (foliar)	vdf	$PER_{off\text{-}field}$ [2] [g a.e./ha]	CF	corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?
Field crops (Railroad tracks)	1 × 1800 g a.e./ha	*T. pyri*	> 4320	1	10	4.99	10	yes
		A. rhopalosiphi	> 5760		1	49.9		yes
	2 × 1800 g a.e./ha	*T. pyri*	> 4320	1	10	4.99		yes
		A. rhopalosiphi	> 5760		1	49.9		yes

a.e. glyphosate acid equivalents
PER: Predicted environmental rate, vdf: vegetation distribution factor; CF: correction factor
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate of 2.77 % at 1 m from the application area considering downward ground directed spray

Table 10.3.2-13: Off-field HQs for non-target arthropods (*T. pyri* and *A. rhopalosiphi;* Tier 2) exposed to MON 52276 for the control of invasive species *(Uses 8 and 9))* – considering downward ground-directed spray

Crop scenario	Application pattern	Test species	ER_{50} [g a.e./ha]	MAF [1] (foliar)	vdf	$PER_{off\text{-}field}$ [2] [g a.e./ha]	CF	corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?
Field crops (Invasive species control)	1 × 1800 g a.e./ha	*T. pyri*	> 4320	1	10	4.99	10	yes
		A. rhopalosiphi	> 5760		1	49.9		yes

a.e. glyphosate acid equivalents
PER: Predicted environmental rate, vdf: vegetation distribution factor; CF: correction factor
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate of 2.77 % at 1 m from the application area considering downward ground directed spray

For *Aphidius rhopalosiphi* and *Typhlodromus pyri*, the trigger value of HQ ≤ 1 demonstrates that no unacceptable effects are expected from the proposed uses of MON 52276 considering in-field or off-field habitats of field crops, orchards, vineyards, railroad tracks and agricultural/non-agricultural areas for the control of invasive species. No further testing is required.

Indirect Effects via trophic Interactions

The ecotoxicology regulatory study database for the representative formulation (MON 52276) includes guideline studies and risk assessment methodology that was designed to assess potential direct and indirect effects on beneficial insect communities (ESCORT 2, 2000). For the Tier 1 NTA assessment, studies were conducted using ecologically important and highly sensitive indicator species of adverse effects (Table **10.3.2-1**). Then at Tier II (extended studies) additional levels of realism were introduced into the exposure scenario, by intrudcing exposure on leaf-based substrates. Specific protection goals (SPGs) for non-target arthropods (NTAs) were developed at the ESCORT 2 and 3, (2000 and 2010) workshops, with separate SPGs developed for athropods occurring in the crop / in-field and off the crop / off-field. SCORT 3 saw further distinction between in-field and off-field scenarios. It was considered practical by the experts during the ESCORT 3 workshop to make distinctions and recognize trade-offs between in-crop and off-crop and in-field and off-field area, given the differences in the socio-economic and ecological functions of these two distinct areas. This is consistent with the recommendation of the EFSA problem formulation workshop that was convened to prepare guidance that would inform the development of SPGs (EFSA, 2010).

The first SPG from the ESCORT workshop addresses in-crop applications, where the goal is to maintain pest control (i.e., activity of parasitoids and predators) and to also provide a food source for wildlife - minimizing indirect effects through trophic interactions. In turn the aim here is to enable an in-crop NTA community to recover (Table 10.3.2-44 to Table 10.3.2-88).

The in-crop measurement endpoint and risk assessment procedures developed to achieve this SPG, allow for a maximum of a 50 % direct effect on individuals in-crop from a Tier 1 - 2 assessment approach. At the 1st tier lethality effects are considered, whilst at the second tier, impacts on reproduction are considered. The rationale for 50 % effect threshold for direct effects, is based on the principle that this level of effect would allow for in-field recovery via immigration of beneficial insects from the off-field areas to the in-field areas, or from in-field / off-crop areas, where for example, a no spray buffer in-field / off-crop buffer is included, thereby enhancing recovery.

The second SPG was derived to protect the off-crop NTA community, with the goal to maintain NTA biodiversity off-crop to facilitate in-field recovery of non-target arthropod species (Table 10.3.2-99 to Table 10.3.2-133).

Scientific Literature that informs the NTA assessment
The scientific literature review conducted for the last Annex I renewal (submitted in 2012) that appears in the RAR (2015) contains an extensive review of ecotoxicological papers considered relevant but supplementary to the Annex I renewal.

These papers presented information that could not be relatable to an EU level ecotoxicological risk assessment, but that were considered in the previous dossier, where they were also evaluated by the previous RMS (UBA). A further evaluation of these reviewed literature has not been conducted. The previous literature review has been submitted as part of the Literature review requirements and is presented in Annex M-CA 8-01 of the document M-CA Section 8.

Literature review for non-target arthropods from the previous Annex I (2012) submission.
In the area of arthropods other than bees, a total of 31 peer reviewed papers were submitted, with no paper considered relevant for use in risk assessment. The RMS (UBA) re-evaluated the submitted papers with 11 papers recognised as information having a low weight and a further 7 publications being considered as supportive information.

In the evaluation of the literature from the previous Annex I submission, the RMS (UBA) indicated that indirect effects on beneficial arthropod communities take place within treated areas and are principally due to vegetation changes subsequent to herbicide application. These vegetation changes, mainly decomposition / loss of plant cover, might result in a drastic reduction of the habitats of beneficial and other non-target arthropod communities and a loss of their refuges from predators. This would anyway be the case if a non-chemical means of weed control was applied.

The RMS (UBA) reviewed a multiyear study using pitfall trapping to collect mobile arthropod species on the soil surface, the combination of conservation tillage and herbicide treatment had less impact on biodiversity than conventional ploughing (Schier, 2006). The RMS (UBA) concluded that conservation tillage without the use of glyphosate is not practiced, due to the upcoming weed pressure on culture crops. Stating that it was not possible to identify the effects of glyphosate applications in the performed studies.

Arthropods in their natural environment can be exposed directly to pesticides after the application due to residues on food or due to contact with contaminated surfaces (such as plants, soil, surrounding substrate).

The RMS (UBA) also stated that risk analysis is currently based on beneficial arthropods important for biological control of agronomic pests, through predation or parasitism, including beetles, mites, wasps and spiders. They indicated that test species were selected for practical reasons because of their utility in agricultural production and feasibility in experimental setups than on the basis of their ecological relevance.

The Notifiers indicate that the species selected for these tests are the representative species selected for testing according to Annex I data requirements. These same species are considered in the current 'arthropods other than bees' risk assessment, that includes impacts on survival and reproduction, that is considered relevant to assess the recovery potential of such populations in transient habitats such a field row crops.

The RMS (UBA) highlighted that effects on different life stages and on other species, not considered in the traditional risk assessment, together with the indirect effects of herbicide treatment on the vegetation of their habitat, receive less attention even though they might have implications for the success of survival and reproduction.

In the current risk assessment – including the assessment of indirect effects via trophic interaction, the implications of the observed effects at the habitat and population level are considered. Notable from the previous RMS (UBA) review is the fact that there are few studies available on the indirect effects of glyphosate and also on conventional tillage weed control practices on terrestrial arthropod populations. This is still the case, but the assessment based on the direct effects' assessment is considered within the following indirect effects via trophic interaction assessment.

Glyphosate is considered a conservation tool that facilitates biodiversity. As stated by the previous RMS (UBA) following an assessment of a wide range of terrestrial invertebrate taxa showed variable responses in abundance and their diversity being largely a function of the degree of vegetation control (Guiseppe *et al.*, 2006; Sullivan and Sullivan, 2002). It was also identified that populations of arthropods in areas where conservation tillage is practiced - of which glyphosate is typically used to enable, often have more beneficial insects and consequently diversity of other wildlife (Warburton and Klimstra, 1984).

Concerning the current literature review, there were no literature articles considered relevant to the ecotoxicological risk assessment for Annex I renewal.

A number of relevant but supplementary papers were identified, that discuss the selectivity of glyphosate based herbicides on a range of non-target arthropods such as Culicidae (Bara *et al.*, 2014, Mohammed *et al.*, 2016)), *Chrysoperla externa* (Castilhos *et al.*, 2011, Pasini *et al.*, 2018), Colorado potato beetle (Rainio *et al.*, 2018), rose-grain aphids (Saska *et al.*, (2016), Hymenopterans (Stecca *et al.*, 2016), Bombyx mori (You *et al.*, 2010 and Zhang *et al.*, 2011) that all report impacts either directly in terms of mortality or indirectly via effects on reproduction or changes in life history traits. However, the observed findings are based on exposure of specific foliar predators following either an 'over the top application' under unrealistic exposure conditions, using glyphosate-based herbicides that are not the representative formulation for the Annex I renewal. The endpoints presented in these papers are not relatable to a test design that is used in EU level non-target arthropod risk assessment and were therefore considered supplementary to the assessment. Please refer to the literature review for further information on the supplementary nature of these articles.

Assessment

The following approach has been taken to assess potential indirect effects via trophic interactions, considers the proposed Specific Protection Goals drawn from the existing EU guidance and working documents, and the 2016 EFSA Guidance on developing protection goals for ecological risk assessments (ERA) for pesticides. The SPGs based on direct effects assessment considering representative sensitive populations across the tested trophic levels. The biodiversity assessment, aimed to develop a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals, that includes considering indirect effects via trophic interaction.

For example, reduced application rates relative to previous Annex I renewals, a reduced overall application volume of product on the land, and inclusion of no-spray buffer zones - a standard mitigation measure to protect non-target plant communities in off-target areas, which indirectly supports non-target arthropod biodiversity, by maintaining habitat and refuges for arthropods to reside in the off-field areas.

Although for example, for crop inter row applications and for applications made to control actively growing weeds in perennial row crops, herbicide application will result in habitat losses and non-target arthropods will be displaced as the directs effects assessment, indicates that there would be a limited direct effect on arthropod populations. The would be the case if an alternate herbicide was applied or if the weeds were removed mechanically. Populations in off-target areas would not be impacted and movement of non-target arthropods onto the developing crop or to areas adjacent to the application areas would occur.

Therefore, where an acceptable direct effects risk assessment is concluded upon after incorporation of standard mitigation measures to reduce off-target movement via drift to off-target areas, coupled with the standard mitigation measures, is considered protective of indirect effects occurring outside of the target area. When defining SPGs for arthropods that reflects both direct and indirect effects, it is the responsibility of the risk assessors in the Member States to acknowledge existing protection goals and regulatory data requirements, to propose possible SPG options, and describe the possible environmental consequences of each option. The risk assessors within the Member States will need to propose realistic SPGs and exposure assessment goals and the interrelationships between them in a clear and transparent manner.

The approach to the biodiversity assessment is to assess potential indirect effects via trophic interactions and their impact on biodiversity, by developing a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals.

In the following table, the specific protection goals relevant to non-target arthropods are presented with the relationship between the SPGs, the direct effects study types, assessment and measurement endpoints. The assessment endpoint is an explicit expression of an environmental entity and the specific property of that entity to be protected. Measurement endpoints relates directly to the effects study endpoints.

A conclusion that a given data requirement has been satisfied, requires that an acceptable level of risk has been achieved (i.e. there is a protective margin of exposure or through a weight of evidence).

Based on the measurement endpoints from the study types, and the direct effects assessment presented above in this section, for in-field exposure, direct effects from glyphosate on NTAs are not anticipated. Due to the mode of action of glyphosate, an indirect effect on habitat in the in-field areas cannot be avoided. It is important to remember that this would also be the case if a non-chemical means of weed removal was employed.

Where there is crop present in the field at the time of application such as inter-row applications for weed control – or for example, applications made in orchards and vineyards where the applications are made in strips around the base of trees, populations of non-target arthropods will still be maintained in the unsprayed areas between the tree rows. For in-crop inter-row weed control spray scenarios, NTAs will still be present on the crop.

The impact on NTA species in the off-crop / off-target areas will be supported by the required in-field no spray buffer area for the NTTPs, which will protect off-field populations of NTAs allowing for in-field recovery of populations either onto the developing crop or onto weed species developing from the seed bank.

The following table assessment illustrates that ecological function of beneficial NTAs both in-field / in crop and off-field / off-crop (off-target) will be sufficiently maintained to achieve the SPG for the non-target arthropods according to the protection goals as defined in the ESCORT 2 and 3, that sustains a food resource for other animals, primarily birds and mammals.

Table 10.3.2-14: The relationship between Specific Protection Goals and associated assessment and measurement endpoints for non-target arthropods (NTAs).

Specific Protection Goals[1]	Assessment Endpoints	Measurement Endpoints	Glyphosate Study Types
In-field Maintenance of ecological function of beneficial NTAs (i.e., pest control by parasitoids and predators), food source for wildlife, and effects not exceed the ability to recover. **Off-field** [1] Maintenance of NTA biodiversity and the ability to support in-field recovery	Tier 1, at the maximum use rate (MUR) achieve an assessment factor of ≥ 2 with mortality Tier 2, at the MUR no significant mortality and < 50 % effect on reproduction.	Survival (LR_{50}) and if appropriate, assess reproduction effects	Primary: *Typhlodromus pyri* (predatory mite) and *Aphidius rhopalosiphi* (parasitic wasp) Secondary: *O. laevigatus, C. carnea, C. septempunctata A. bilineata*
NTA Biodiversity Assessment Following ESCORT3 risk assessment guidance there is low to negligible risk of unacceptable direct and indirect effects to NTA communities for the representative formulation. Risk mitigation measures required for protecting the off-crop NTTP community (e.g., in-field buffers) will be protective of off-crop NTA biodiversity. However, if additional risk mitigation measures are determined to be required, to mitigate indirect effects resulting from in-crop weed control on NTA communities, options to be considered by risk assessors and risk managers within Member States are presented in Table 10.3.2-15.			

[1] The off-crop area is defined as the area in-field that is not the crop. For NTA RA, the off-crop area is a default 1 meter distance between the last sprayed row of the crop and the edge of the in-field area.

Conclusion

Following ESCORT3 risk assessment guidance there is negligible risk of unacceptable direct and indirect effects to NTA communities for the representative formulation. Risk mitigation measures required for protecting the off-crop NTTP community (e.g., in-field buffers) will be protective of off-crop NTA biodiversity. The existing SPG for the in-crop assessment has been designed to only allow for up to a transient 50 % effect on the NTA community and it allows for in-crop recovery to minimize the likelihood of indirect effects to birds and mammals through trophic interactions. The SPG for the off-crop assessment is protective of biodiversity based on spray-drift mitigations developed to protect the NTTP community. However, if additional risk mitigation measures are determined to be required, to mitigate indirect effects resulting from in-crop weed control on NTA communities, options to be considered by risk assessors and risk managers within Member States are presented in the following table.

Examples of the standard mitigation measures considered applicable at the EU level (MAgPIE, 2017) are presented in the following table. Many of these have been considered in the current dossier submission.

Table 10.3.2-15: Examples of standard mitigation measures as described in MAgPIE (2017) across the various Member States to mitigate effects of glyphosate on biodiversity.

Type of Mitigation Measure	Risk Mitigation Measure	Benefits	Glyphosate renewal dossier (2020)
Restrictions or modifications of products' conditions of application	Application rate, Application frequency, application timing, and interval between applications	Lower transfers to groundwater and surface water; Reduces exposure of organisms in-crop and off-crop.	**Significant reductions (50 % in volume) in newly proposed application rates** compared with the representative use presented in the 2012 renewal dossier. See [37]**Appendix 2 of the biodiversity document accompanying this submission**. **Treated area restriction** 13. for the representative use GAPs: applying to only 50 % of the total area in orchard/vineyard area. 14. maximum of 50 % of the total area for broad acre vegetable inter-row 15. Invasive species control e.g., couch grass – maximum of 20 % of the cropland + extended application intervals. **Limited frequency and timing of application:** 28-day interval between applications and no pre-harvest applications
Application equipment with Spray Drift Reduction Technology (SDRT)	Spray drift reduction nozzles (SDRN), shields, Precision treatment, etc.	Reduces exposure of organisms in-crop (precision treatment) and off-crop	**Reduction of spray drift to the off-field**: 9. Use 75 % drift reducing nozzles for pre-sowing/pre-planting in arable crops. 10. Use of ground directed, shielded spray for band application in orchards / vineyards and broad-acre vegetable inter-row application.
Buffer zones	Non-sprayed zone at the edge of a crop	Reduces exposure of organisms and off-crop	**Establishment of buffer zones:** Buffer zones of varying size (depending on the type of SDRT) are required as protection for off-crop NTTP communities from spray drift.

For example in the current dossier;

- Reductions in maximum annual application rates of up to 50 % considered in this dossier are compared to the maximum rates applied for in the 2012 Annex I renewal dossier.
    - In 2012, the maximum annual application rate was 4.32 kg/ha.
    - In the current dossier submission, the maximum annual application rate is 2.16 kg/ha

- Reducing the total area being applied on a per hectare basis for certain uses, will reduce the total volume of product being applied to the landscape.
    - For example, controlling actively growing weeds in vineyards, orchards where a reduced area, up to a maximum of 50 % of the total application area is proposed e.g. using strip or band applications. Applications on target weeds around the base of trees within tree rows, leaving the area between tree rows unsprayed, which is typically managed using mechanical methods.

[37] [redacted] 2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

- The use of shielded or hooded sprayers, hand-held sprayers and drift reducing technologies, e.g. 75 % drift reducing nozzles are recommended for all applications made for the control of actively growing weeds when applied to control invasive species. These measures will further reduce the off-target exposure risk.
- For weed control on rail tracks, recommendations are made in the GAP table to use precision application equipment on spray trains, that detect and target spray directly onto unwanted plants, thereby reducing the amount of product being applied, whilst maintaining an acceptable level of safety on the railroad tracks.

- No spray buffer areas in-field (as compensation areas), are necessary to meet the specific protection goals for avoiding direct effects on non-target plants in off-target areas. This measure will in turn support non-target arthropod communities in off-field areas and reduces further, the potential for indirect effects on bees through trophic interaction.

In addition to the standard mitigation measures, 'non-standard mitigation measures' could also be considered where a local and specific mitigation need is identified. For example, in simplified landscapes or landscapes that are intensively managed, where typically there are limited refuge areas for insects, birds and mammals. Non-standard mitigation measures options could include for example, creation of off-target habitats, utilizing edge of field habitats and semi-field habitats that assist biodiversity by improving wildlife connectivity.

For further information on mitigation measures pleased refer to the supplementary information document titled 'Glyphosate: Indirect Effects via Trophic Interaction – A Practical Approach to Biodiversity Assessment.' (DOC No.) that accompanies this dossier submission.

References relied upon in the Indirect Effects via Trophic Interaction Discussion

ESCORT2. 2000. Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. From the ESCORT 2 workshop (European Standard Characteristics Of non-target arthropod Regulatory Testing. Joint BART, EPPOCoE, OECD and IOBC workshop organised inn conjunction with Society of Environmental Toxicology and Chemistry (SETAC).and EC. Ed. Candolfi *et al.* (2000)

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Guiseppe KFL, Drummond FA, Stubbs C, Woods S. 2006. The Use of Glyphosate Herbicides in Managed Forest Ecosystems and their Effects on Non-Target Organisms with Particular Reference to Ants as Bioindicators; Maine Agricultural and Forest Experiment Station Technical Bulletin 192; Maine Agricultural and Forest Experiment Station, University of Maine: Orono, ME, USA, p. 51.

Sullivan DS, TP Sullivan. 2000. Non-target impacts of the herbicide glyphosate: A compendium of references and abstracts. 5th Edition. Applied Mammal Research Institute, Summerland, British Columbia, Canada.

Sullivan TP, Sullivan DS. 2003. Vegetation management and ecosystem disturbance: impact of glyphosate herbicides on plant and animal diversity in terrestrial systems. Env Rev 11:37-59.

Warburton DB, Klimstra WD. 1984. Wildlife use of no-till and conventionally tilled corn fields. Journal of Soil and Water Conservation. 39:327-330.

CP 10.3.2.1 Standard laboratory testing for non-target arthropods

1. Information on the study

Data point:	CP 10.3.2.1/001
Report author	[redacted]
Report year	1995
Report title	Testing toxicity to beneficial arthropods. Cereal aphid parasitoid - *Aphidius rhopalosiphi* (De Stefani-Perez) / Imagines according to IOBC Guideline (Mead-Briggs 1992). Roundup Ultra
Report No	95 10 48 054
Document No	-
Guidelines followed in study	IOBC Guideline (Mead-Briggs 1992)
Deviations from current test guideline	Deviations from current guideline IOBC (2000): Major: - For mortality phase, 3 replicates were used in test item treatment groups and 1 in reference item, instead of 4 Minor: - none
Previous evaluation	Yes, accepted in the RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Supportive
Category study in AIR 5 dossier (L docs)	Category 2b

2. Full summary

Executive Summary
The toxicity of MON 52276 to the parasitic wasp, *Aphidius rhopalosiphi* was tested with two day old wasps exposed to the equivalent of 10 L MON 52276/ha applied in 200 L/ha water on glass plates. A control was prepared in parallel (deionized water only) and dimethoate product was used as a reference item 0.2 L/ha in 200 L/ha water.
Three replicate cages, each containing 10 wasps, (30 wasps per treatment in total) were used for the test item treatment and the control group, with a single replicate used for the reference item. Mortality and sublethal effects were recorded at 0.5, 2, 24 and 48 hours after application, following application and then drying of the test substance onto glass plates.
After 24 hours, 100 % of the wasps died after treatment with MON 52276 after 24 h of exposure. Therefore, the parasitisation efficiency of the exposed wasps was not evaluated. All validity criteria were met. As there was 100 % mortality during the exposure phase, a full set of endpoints for the study could not be determined.

I. MATERIALS AND METHODS

A. MATERIALS

Test material:

Test item:	MON 52276 (Product name: Roundup Ultra)
Description:	Not stated
Lot/Batch #:	080694
Purity:	Glyphosate (isopropylamine salt) 360 g/L (31.0 % according to certificate)
Density:	1.1694 g/cm^3
Vehicle and/or positive control:	Reference item: Dimethoate product (dimethoate: 411.14 g/L)
Test organisms:	
Species:	Cereal aphid parasitoid (*Aphidius rhopalosiphi*)
Age:	Approximately 2 days
Source:	PK Nützlingszuchten, Welzheim, Germany
Diet/Food:	Honey + water (1 : 2)
Acclimatisation:	Not stated
Environmental conditions:	
Temperature:	20 – 23 °C
Relative humidity:	58 – 77 % in the testing room
Photoperiod:	16 hours light / 8 hours darkness
Experimental dates:	September 18th, 1995 to September 20th, 1995

B. STUDY DESIGN AND METHODS

Experimental treatments:

The test solutions were sprayed onto the surface of glass plates using an automatic application cabin, in water volumes equivalent to spraying 200 L/ha deionized water as control, 10 L MON 52276/ha in 200 L/ha water (equivalent to 3.6 kg a.e./ha) and 0.2 L Dimethoate product/ha in 200 L water/ha (reference substance). Plates were air dried in the laboratory for 2 - 3 hours and then with the sprayed surfaces inner-most, 2 plates were put together with a square aluminium frame. Then 5 females and 5 males *Aphidius* wasps were introduced into each cage through holes in the frame sides which were closed after insect insertion. The honey solution was offered to the parasitoids with at cotton wool stopper in one hole of the frame. The test cages were set up in a climatic test room and connected over a water bottle with an aquarian pump for ventilation with humid air.
In the test, three replicate cages, each containing 10 wasps, were used for the test item treatment and the control. The reference item was tested in one replicate. Because of high mortality (100 %) of the parasitoids in the treated variant the experiment was finished 48 h after application.

Observations: Mortality and sublethal effects were recorded 0.5, 2, 24 and 48 hours after application.

Statistical calculations: descriptive statistics.

II. RESULTS AND DISCUSSION

A. FINDINGS

Mortality:

Table 10.3.2.1-1: Toxicity of MON 52276 to parasitic wasps (*Aphidius rhopalosiphi*) in a 48 h laboratory test

Test solutions	Replicates	2 h	24 h		48 h	
		Surviving wasps	Surviving wasps	Mortality %	Surviving wasps	Mortality %
Control: 200 L/ha deionized	1	10	10	3.3	9	6.7
	2	10	9		9	
	3	10	10		10	
	Σ	30	29	-	28	-
Test substance: 10 L/ha MON 52276	1	3	0	100	-	-
	2	3	0		-	
	3	4	0		-	
	Σ	10	0	-	-	-
Reference substance: 0.2 L Dimethoate /ha	1	3	0	100	-	-
	Σ	3	0	-	-	-

B. OBSERVATIONS

No sublethal effects were observed. The mortality in the control treatments did not exceed 10 % for 48 hours, the corrected mortality in the reference treatment was > 50 %. The test was stopped after 24 hours for test item treatment and no evaluation of reproduction was conducted for the control treatments. Therefore, the study is not reliable to be used in risk assessment (as the study pre-dates the Mead-Briggs approach: the control was conducted using 30 instead of 40 wasps and no reproduction assessment was included).

III. CONCLUSIONS

Assessment and conclusion by applicant:

There was 100% mortality during the exposure phase at the rate tested (10 L MON 52276/ha) and therefore, no parasitisation efficiency data generated. Highly likely that the findings in the study may have been confounded by the wet sticky layer on the treated glass plates in the MON 52276 treatment group.

This study is therefore considered supportive and unreliable for use in the risk assessment.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.3.2.1/002
Report author	[redacted]
Report year	1995
Report title	Testing toxicity to beneficial arthropods. Predacious mite - *Typhlodromus pyri* (Scheuten) according to IOBC Guideline (Overmeer 1988 and Louis 1994). Roundup Ultra
Report No	95 10 48 056
Document No	-
Guidelines followed in study	IOBC Guideline (Overmeer 1988 and Louis 1994).
Deviations from current test guideline	Deviations compared to current IOBC guidelines (2000): Major: - 60 mites were used instead of 100 Minor: - none
Previous evaluation	Yes, accepted in the RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Supportive
Category study in AIR 5 dossier (L docs)	Category 2b

2. Full summary

Executive Summary

In the laboratory study the toxicity of MON 52276 to the predatory mites, *Typhlodromus pyri* was tested. Freshly hatched mites were exposed to 10 L MON 52276/ha in 200 L/ha water on dried glass plates. In addition, an undosed control was tested (200 L/ha deionized water). Kelthane 50 (480 g dicofol/L) was used as a reference item 0.1 L/ha in 200 L/ha water.

The test was conducted with 6 replicates per test concentration; control and reference control each containing 10 mites. Mortality was recorded 1 and 4 days after application.

100 % of the wasps died in treatment with MON 52276 after 4 days of exposure. Validity criteria were met. However due to 100 % mortality, endpoints could not be properly determined. Therefore, study does not provide relevant endpoints.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item:	MON 52276
Description:	Not stated
Lot/Batch #:	080694
Purity:	Glyphosate (isopropylamine salt) 360 g/L (31.0 % according to certificate)
Density:	1.1694 g/cm^3

2. Vehicle and/or positive control: Reference item: Kelthane 50 (dicofol: 480 g/L)

3. Test organisms:

Species:	Predacious mite (*Typhlodromus pyri*)
Age:	Approximately 1 day
Source:	PK Nützlingszuchten, Welzheim, Germany
Diet/Food:	spider mites (*Tetranychus urticae*) and during the test pollen
Acclimatisation:	Not stated

4. Environmental conditions:

Temperature:	25 – 27 °C
Relative humidity:	72 – 78 %
Photoperiod:	16 hours light / 8 hours darkness

5. Experimental dates: August 17th, 1995 to August 21st, 1995

B. STUDY DESIGN AND METHODS

1. Experimental treatments: Glass plates were sprayed with the deionised water, test substance or reference substance. Test concentrations used were 200 L/ha deionised water (control), 10 L MON 52276/ha in 200 L/ha water (test substance treatment) and 0.1 L Kelthane 50/ha in 200 L water/ha (reference substance). After air-drying at room temperature (about 60 minutes), glass plates were infested with young freshly hatched predacious mites together with pollen for food supply. The test was conducted with 6 replicates for control for each test item rates and reference item, each replicate containing 10 mites.

2. Observations: Mortality was recorded 1 and 4 days after application

3. Statistical calculations: No statistical calculations performed.

II. RESULTS AND DISCUSSION

A. FINDINGS

Table 10.3.2.1-2: Toxicity of MON 52276 to predatory mites (*Typhlodromus pyri*) in a 4 day laboratory test

Test concentration	Mortality [%]	
	1 d	4 d
Control: 200 L/ha deionised	5	10
Test substance: 10 L/ha MON 52276 in 200 L/ha water	90	100
Reference substance: 0.1 L Kelthane 50 /ha in 200 L water/ha	100	--

B. OBSERVATIONS

The final assessment was performed 4 days after the application, because of total mortality of the predacious mites in the test variant. No sublethal effects were observed.

III. CONCLUSIONS

Assessment and conclusion by applicant: Under the conditions of the present test, MON 52276 applied at 10 L/ha in 200 L/ha water resulted in 100 % mortality of the predatory mites after 4 days of exposure. The study is considered supportive and not sufficiently reliable to be used in risk assessment (as the study pre-dates the Blümel approach and the control was conducted using 60 instead of 100 mites and no reproduction assessment was included).

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.3.2.1/003
Report author	[redacted]
Report year	1995
Report title	Testing toxicity to beneficial arthropods - Carabid beetle - *Poecilus cupreus* L. according to BBA Guideline VI, 23-2.1.8 (1991) ROUNDUP ULTRA
Report No	95 10 48 055
Document No	-
Guidelines followed in study	BBA Guideline VI, 23-2.1.8 (1991)
Deviations from current test guideline	Deviations from current guideline Heimbach *et al.* (2000): Major: - none Minor: - Beetles should be kept at least 7 days before application in the lab (no indication). - One pupa per beetle and per feeding occasion is recommended (2 were provided in this study)
Previous evaluation	Yes, accepted RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

In the laboratory study, the toxicity of MON 52276 to the carabid beetle - *Poecilus cupreus* was tested. Adult carabid beetle were exposed to 10 L MON 52276/ha in 400 L/ha water on moistened quartz sand. In addition, an untreated control was tested (400 L/ha deionized water). Afugan was used as a toxic reference item (0.8 L/ha in 400 L/ha water).
In the test, five replicate cages, each containing 6 carabid beetles (3 females + 3 males) were used for each treatment group. Feeding, mortality and sublethal effects were recorded 2, 4 and 6 hours after application. Then 1, 2, 4, 7, 9, 11 and 14 days after application.
The mortalities in the control and in the MON 52276 treatments were 0 %. Consequently, the test fulfilled

the validity criterion (mortality in the control < 10 %). The feeding rate showed no differences in comparison with the control variant. No behavioural anomalies were observed.
The relative decrease of beneficial effectivity calculated according to OVERMEER & VAN ZON (1982) was E = 1 %.

I. MATERIALS AND METHODS

A. MATERIALS

Test material:

Test item:	MON 52276 (ROUNDUP ULTRA SL)
Active substance	Glyphosate
Lot/Batch #:	080694
Purity:	31 % (Glyphosate (isopropylamine salt) 360 g/L)
Density:	1.1694 g/cm^3
Toxic reference:	Afugan
Test organism:	
Species:	Carabid beetle - *Poecilus cupreus* L.
Age:	Adults (7 weeks old)
Source:	laboratory rearing of BBA Braunschweig
Food:	Onion fly (*Delia antiqua*)
Acclimatisation:	3 days under laboratory conditions without food
Environmental conditions:	
Temperature:	18 – 21 °C
Photoperiod:	16 h
Light intensity	approx. 1000 lux
Relative humidity:	Test units: 54 – 82 %
Experimental dates:	7 August - 21 August 1995

B. STUDY DESIGN AND METHODS

Experimental treatments

The test carabid beetles were kept for 3 days under laboratory conditions for acclimatisation. Three females and three males were placed into each test cage (cages of plastics: 18.3 cm × 13.6 cm × 6.4 cm) with moistened sand (250 g) covering the bottom without food. Immediately before the treatment the beetles were inspected, the ones which appear damaged were replaced by animals of the same sex. Then the sand was moistened with deionized water and fly pupae were added as food supply. The treatments were applied to the cages with the beetles in an automatic application cabin. The control treatment was sprayed with deionized untreated water, the test item treatment was sprayed with 10 L MON52276/ha solution and the toxic reference item was sprayed with 0.8 L Afungan/ha (equivalent to 235 g a.s./ha). After application the cages were incubated in an air condition room (20 °C, 16/8 h light/dark) for 14 days. After 1, 2, 4, 7 and 11 days food was changed (2 pupae/beetle) and sand was moistened.

Observations

The sex of the adults was determined before the beginning of the test. The number of dead beetles, the number of fed pupae and any behavioural effects were assessed after 2, 4 and 6 hours, as well as 1, 2, 4, 7, 11 and 14 days after application.

Calculations

The mortality of beetles was corrected following the formula of SCHNEIDER-ORELLI. The relative decrease of the beneficial effectivity was assessed by the formula of OVERMEER & VAN ZON. For evaluating the influence of the test substance on the test animals the results of the tests were rated according to the four categories selected by the IOBC Working Group "Pesticides and beneficial organisms":

- 1 = harmless: E < 30 % reduction of beneficial effectivity
- 2 = slightly harmful: E = 30 – 79 % reduction of beneficial effectivity
- 3 = moderately harmful: E = 80 – 99 % reduction of beneficial effectivity
- 4 = harmful: E > 99 % reduction of beneficial effectivity

II. RESULTS AND DISCUSSION

A. FINDINGS

The results of the test are given in the following tables.

Table 10.3.2.1-3: Effects of the MON 52276 on adult mortality

Time after application	Control (untreated deionized water)		Test item (10 L MON 52276/ha)		Toxic reference (0.8 L Afugan/ha)	
	No. of dead females	No. of dead males	No. of dead females	No. of dead males	No. of dead females	No. of dead males
2 hours	0	0	0	0	0	0
4 hours	0	0	0	0	0	0
6 hours	0	0	0	0	0	0
Day 1	0	0	0	0	0	0
Day 2	0	0	0	0	15	15
Day 4	0	0	0	0	0	0
Day 7	0	0	0	0	0	0
Day 11	0	0	0	0	0	0
Day 14	0	0	0	0	0	0
Total	0	0	0	0	15	15
Total in percentage	0		0		100	

Initial number of female and male beetles: 15

No behavioural effects were assessed in the control and test item groups. Stilted legs, troubles of locomotion and dorsal position symptoms were recorded in the toxic reference group.

Table 10.3.2.1-4: Effects of the MON52276 on the feeding rate

Time after application	Control (untreated deionized water)	Test item (10 L MON 52276/ha)	Toxic reference (0.8 L Afugan/ha)
	females + males	females + males	females + males
Day 1	50	50	25
Day 2	28	27	0
Day 4	33	32	0
Day 7	36	41	0
Day 11	47	49	0
Day 14	38	31	0
Total	232	230	25
Fed pupae/beetle	7.7	7.7	0.8
Fed pupae/group	232	230	25

Initial number of female and male beetles: 15

B. OBSERVATIONS

The mortality in the control was 0 %. The test item MON 52276 was tested at a dose of 10 L/ha in 400 L/ha of water and caused 0 % mortality.
The corrected mortality according to SCHNEIDER-ORELLI was 0 %. The feeding rate showed no differences in comparison with the control variant. No behavioural anomalies were observed.
The relative decrease of beneficial effectivity calculated according to OVERMEER & VAN ZON (1982) was E = 1 %.
According to the study protocol based on BBA Guideline VI, 23-2.1.8 (1991), for the study to be valid, mortality in the control group should not exceed 10 %. Consequently, the test accomplished the validity criterion (mortality in the control < 10 %).

The following validity criteria according to the current laboratory method to test effects of plant protection products on the carabid beetle *Poecilus cupreus* (Coleoptera: Carabidae) (Heimbach, 2000) were fulfilled:

- The control mortality must be < 6.7 % taking into account 5 replicates × 6 beetles (actual value: 0 %).
- The mortality in the toxic reference item should be 65 ± 35 % after 2 weeks (actual value: 100 %).

The following points deviated from the guideline:

- Beetles should be kept at least 7 days before application in the lab (no indication).
- One pupa per beetle and per feeding occasion is recommended (2 were provided in this study)

Taking into account 0 % mortality in the control and 100 % mortality in the toxic reference (test organisms sensitive), these deviations are not expected to have any impact on the study integrity. This study is therefore considered as valid.

III. CONCLUSIONS

Assessment and conclusion by applicant:
In a laboratory test to determine the effects of MON 52276 on the carabid beetles, *Poecilus cupreus* L., the LC_{50} was higher than 10 L MON 52276/ha. MON 52276, applied at the rate of 10 L/ha, had no adverse effects on the feeding performance. The study fulfilled the IOBC guideline validity criteria and is therefore considered valid and suitable to be used in the risk assessment.

Assessment and conclusion by RMS:

1. Information on the study

Data point	CP 10.3.2.1/004
Report author	[redacted]
Report year	1995
Report title	Testing toxicity to beneficial arthropods - Spider - *Pardosa spp.* According to BBA Guideline (Proposal 1994) ROUNDUP ULTRA
Report No	95 10 48 053
Document No	-
Guidelines followed in study	BBA Guideline (Proposal 1994)
Deviations from current test guideline	Deviations from current guideline Heimbach *et al.* (2000): Major: - none Minor: - Spiders should be kept at least 7 days before application in the lab (5 days in the study) - Spiders should be weighed before test start (no indication) - Minimum number of spider is 26 (20 in this study) - 5 flies per feeding occasion for each spider is recommended (1 or 2 were provided in this study) - Temperature rose above 20 ± 2 °C (23 °C in the study)
Previous evaluation	Yes, accepted RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

In the laboratory study, the toxicity of MON 52276 to the spider *Pardosa spp* was tested. Adult spiders were exposed to 10 L MON 52276/ha in 400 L/ha water on moistened quartz sand. In addition, an undosed control was tested (400 L/ha deionized water). Thiodan 35 EC was used as a reference item 0.085 L/ha in 400 L/ha water.

In the test, twenty replicate cages, each containing 1 spider (10 females + 10 males per treatment in total) were used for all the treatment groups. Feeding, mortality and sublethal effects were recorded 2, 4 and 6 hours after application. Then 1, 2, 3, 4, 7, 9, 11 and 14 days after application.
There was 0 % spider mortality in the control and in the test item treatments. Consequently, the test fulfilled the validity criterion (mortality in the control < 10 %). The feeding rate showed a low increase in comparison with the control variant. No behavioural anomalies were observed.
The relative decrease of beneficial effectivity calculated according to OVERMEER & VAN ZON (1982) was E = -4.5 %.

I. MATERIALS AND METHODS

A. MATERIALS

Test material:

Test item:	MON 52276 (ROUNDUP ULTRA SL)
Active substance	Glyphosate
Lot/Batch #:	080694
Purity:	31 % (Glyphosate (isopropylamine salt) 360 g/L)
Density:	1.1694 g/cm^3
Positive control:	Thiodan 35 EC (endosulfan 34.4 % w/w)
Test organism:	
Species:	Linyphiid spider - *Pardosa spp*
Age:	Adults
Source:	field population (Cunnersdorf/Paitzsch) - June 1995
Food:	Onion fly (*Delia antiqua*), reared in the laboratory
Acclimatisation:	5 days under laboratory conditions (20 ± 2 °C)
Environmental conditions:	
Temperature:	20 – 23 °C
Photoperiod:	16 h
Light intensity	approx. 1000 lux
Relative humidity:	Test units: 74 – 85 %
Experimental dates:	3 July – 17 July 1995

B. STUDY DESIGN AND METHODS

Experimental treatments
The test spiders were kept for 5 days under laboratory conditions at (20 ± 2 °C) for acclimatisation. Three days before treatment one female or one male was placed into each test cage (cages of plastics: 11.5 cm × 11.5 cm × 6.0 cm) with moistened sand (148 ± 2 g) covering the bottom without food. The following species have been collected and identified: *Pardosa Agricola, Pardosa agrestis and Pardosa lugubris*. Immediately before the treatment the spiders were inspected, the ones which appear damaged were replaced by animals of the same sex and the sand was moistened with deionized water. The treatments were applied to the cages with the spiders in an automatic application cabin. The control treatment was sprayed with deionized, the test item treatment was sprayed with 10 L MON 52276/ha solution and the toxic reference item was sprayed with 0.085 L Thiodan 35 EC/ha (equivalent to 30 g a.s./ha). Immediately after application two onion flies (*Delia antiqua*) were added as food supply to each spider and the cages were closed with gauze covers. After a waiting period of 2 hours the cages were incubated in an air condition room (20 °C, 16/8 h light/dark) for 14 days. Every 1, 2 or 3 days food was changed and every 3 or 4 days the sand was

moistened.

Observations
The sex of the adults was determined before the beginning of the test. The species of the collected spider was determined on ten females and ten males for each treatment group. The number of dead spiders, the number of fed flies and any behavioural effects were assessed after 2, 4 and 6 hours, as well as 1, 2, 3, 4, 7, 9, 11 and 14 days after application.

Calculations
The mortality of spiders was corrected following the formula of SCHNEIDER-ORELLI. The relative decrease of the beneficial effectivity was assessed by the formula of OVERMEER & VAN ZON. For evaluating the influence of the test substance on the test animals the results of the tests were rated according to the four categories selected by the IOBC Working Group "Pesticides and beneficial organisms":
- 1 = harmless: E < 30 % reduction of beneficial effectivity
- 2 = slightly harmful: E = 30 – 79 % reduction of beneficial effectivity
- 3 = moderately harmful: E = 80 – 99 % reduction of beneficial effectivity
- 4 = harmful: E > 99 % reduction of beneficial effectivity

II. RESULTS AND DISCUSSION

A. FINDINGS

The results of the test are given in the following tables.

Table 10.3.2.1-5: Effects of the MON 52276 on adult mortality

Time after application	Control (untreated deionized water)		Test item (10 L MON 52276/ha)		Toxic reference (0.085 L Thiodan 35 EC/ha)	
	No. of dead females	No. of dead males	No. of dead females	No. of dead males	No. of dead females	No. of dead males
2 hours	0	0	0	0	0	0
4 hours	0	0	0	0	2	0
6 hours	0	0	0	0	1	1
Day 1	0	0	0	0	3	9
Day 2	0	0	0	0	3	0
Day 3	0	0	0	0	0	0
Day 4	0	0	0	0	0	0
Day 7	0	0	0	0	0	0
Day 9	0	0	0	0	0	0
Day 11	0	0	0	0	0	0
Day 14	0	0	0	0	0	0
Total	0	0	0	0	9	10
Total in percentage	0		0		95	

Number of tested spiders: 10

No behavioural effects were assessed in the control and test item groups. Stilted legs, troubles of locomotion and dorsal position symptoms were recorded in toxic reference group.

Table 10.3.2.1-6: Effects of the MON 52276 on the feeding rate

Time after application	Control (untreated deionized water)		Test item (10 L MON 52276/ha)		Toxic reference (0.085 L Thiodan 35 EC/ha)	
	females	males	females	males	females	males
Day 1	16	12	17	15	1	0
Day 2	8	8	10	8	0	0
Day 3	7	7	10	9	0	0
Day 4	8	9	8	9	1	0
Day 7	11	16	11	10	2	0
Day 9	8	10	9	10	1	0
Day 11	10	9	10	9	1	0
Day 14	8	10	9	9	1	0
Total	75	81	84	79	7	0
Fed flies / spider	7.8		8.2		0.4	
Fed flies / group	156		163		7	

Number of tested spiders: 10

B. OBSERVATIONS

The mortality in the control was 0 %. The test item MON 52276 was tested at a dose of 10 L/ha in 400 L/ha of water and caused 0 % mortality.
The corrected mortality according to SCHNEIDER-ORELLI was 0 %. The feeding rate showed a low increase in comparison with the control variant. No behavioural anomalies were observed.
The relative decrease of beneficial effectivity calculated according to OVERMEER & VAN ZON (1982) was E = -4.5 %.
Consequently, the test accomplished the validity criterion (mortality in the control < 10 %).
According to the study protocol based on BBA Guideline (Proposal 1994), for the study to be valid, mortality in the control group should not exceed 10 %. This criterion was satisfied.

The following validity criteria according to the current laboratory method to test effects of plant protection products on spiders of the genus *Pardosa* (Aranea: Lycosidae) (Heimbach, 2000) were fulfilled:

- The control mortality must be < 3.9 % taking into account 20 replicates (actual value: 0 %),
- The mortality in the toxic reference item should be 65 ± 35 % after 2 weeks (actual value: 95 %)

The following points deviated from the guideline:

- Spiders should be kept at least 7 days before application in the lab (5 days in the study)
- Spiders should be weighed before test start (no indication)
- Minimum number of spiders is 26 in guideline (20 in this study)
- 5 flies per feeding occasion for each spider is recommended (1 or 2 were provided in this study)
- Temperature rose above 20 ± 2 °C (23 °C in the study)

Taking into account 0 % mortality in the control and 95 % mortality in the toxic reference (test organisms sensitive), these deviations are not expected to have any impact on the study integrity.
This study is therefore considered valid.

III. CONCLUSIONS

Assessment and conclusion by applicant: In a laboratory test to determine the effects of MON 52276 on the spiders, *Pardosa*, the LC_{50} was higher than 10 L MON 52276/ha. MON 52276, applied at the rate of 10 L/ha, had no adverse effects on the feeding performance. The study fulfilled the IOBC guideline validity criteria and is therefore considered valid and suitable to be used in the risk assessment.

Assessment and conclusion by RMS:

CP 10.3.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

1. Information on the study

Data point:	CP 10.3.2.2/001
Report author	[redacted]
Report year	2010
Report title	An extended laboratory bioassay of the effects of fresh residues of MON 52276 on the predatory mite, *Typhlodromus pyri* (Acari: Phytoseiidae)
Report No	MON-09-3
Document No	MT-2009-404
Guidelines followed in study	Blümel *et al.* (2000). Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) for regulatory testing of plant protection products
Deviations from current test guideline	Deviations from current guideline Blümel *et al.* (2000): Major: - None Minor: - None
Previous evaluation	Yes, accepted RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

The aim of this study was to determine the effects of fresh dry residues of MON 52276 on the predatory mite, *Typhlodromus pyri*, under extended laboratory test conditions. The test was conducted with 3 replicates per test concentration, control and reference control each containing 20 mites. The 60 mites were exposed to 3, 6, 8, 12 and 16 L product/ha in 200 L water/ha on leaf discs of French beans (equivalent to 5760, 4320, 2880, 2160 and 1080 g a.e./ha). Afterwards, their survival was assessed after a 7-day period.

A check was then made for sub-lethal effects on reproduction. For this, mites were left *in situ* and the numbers of eggs produced per female were recorded over a further 7 day period. The mean number of eggs produced per female between 7-14 days after treatment (DAT), and the overall mean number of eggs produced per female over the 7-day period of assessment was calculated for each treatment. In addition, a control and a toxic reference substance (Dimethoate) were tested.
The 7-day LR_{50} (median lethal rate) was higher than 16000 mL formulation/ha (nominally 5760 g a.e./ha). MON 52276 had no adverse effects on the reproductive performance of surviving mites up to and including a treatment rate of 8000 mL formulation/ha (nominally 2880 g a.e./ha).

I. MATERIALS AND METHODS

A. MATERIALS

Test material:

Test item:	MON 52276 (SL)
Description:	Yellow/amber fluid
Lot/Batch #:	A9B1207115
Purity:	360 g/L glyphosate acid equivalent, nominal 372.9 ± 2.1g/L glyphosate acid equivalent, measured
Vehicle and/or positive control:	BASF Perfektion EC (400 g/L dimethoate)
Test organisms:	
Species:	Predatory mite (*Typhlodromus pyri*)
Age:	less than 24 h old
Source:	In-house originally from PK. Niitzlingszuchten, Welzheim, Germany (pre-1995).
Diet/Food:	Mix of 3 pollen sources.
Acclimatisation:	culture maintained at 24 – 26 °C one week prior bioassay.
Environmental conditions:	
Temperature:	Mortality test: 25 – 26 °C Reproductive test: 25 – 27 °C
Relative humidity:	Mortality test 49.6 – 79 % Reproductive test: 63 – 79 %
Photoperiod:	16 hours light / 8 hours darkness
Light intensity	660 – 1230 lux
Experimental work dates:	19 October 2009 to 24 November 2009

B. STUDY DESIGN AND METHODS

Experimental treatments: Leaf discs of French beans were treated with 3, 8, 12 and 16 L product/ha in 200 L water/ha (equivalent to 1080, 2160, 2880, 4320 and 5760 g a.e./ha), a water control and toxic reference item. After the leaf discs had dried, they were placed into arenas with their treated surface facing upwards. Twenty proto-nymphal *T. pyri* were placed into each replicate arena, with three replicates (i.e. 60 mites) prepared per treatment. The mites were fed regularly with untreated pollen for food. Their survival was assessed after a 7-day period, by which time mites in the control treatment were adult. A check was then made for sub-lethal treatment effects on reproduction. For this, mites were left *in situ* and the numbers of eggs produced per female were recorded over a further 7-day period. Temperature and humidity measurements were taken at hourly intervals throughout the bioassay using an electronic data logger. Light

intensities were recorded at the start of assessments. Although the relative humidity fell below the intended range, this was for a period of less than two hours so was not therefore considered a deviation.
Observations: Mortality was recorded 1 and 7 days after application. The numbers of any *drowned, stuck* or *missing* mites were added to the number of dead mites found in each treatment to derive the overall mortality. Assessments of oviposition activities were carried out at 10, 13 and 14 DAT. Any eggs and nymphs present were recorded and then removed. The mean number of eggs produced per female between 7 – 14 days after treatment (DAT), and the overall mean number of eggs produced per female over the 7-day period of assessment was calculated for each treatment group.
During the mortality phase, the temperatures ranged between 25 and 26 °C and the relative humidity ranged from 49.6 to 79 %. During the reproduction phase, the temperatures ranged between 25 and 27 °C and the relative humidity ranged from 63 to 79 %. The photoperiod was 16 hours light per day between 600 and 1230 lux.
Statistical calculations: The percentage mortality was compared to the control using Fisher's Exact Test (error rate of $\alpha = 0.05$). For reproduction, the results were compared by one-way ANOVA and Dunnett's Test.
Validity criteria according to Candolfi *et al.* (2000):

- The mortality in control group should not exceed 20 % on day 7 after test start.
- The cumulative mean number of eggs per female from day 7 – 14 was ≥ 4 eggs/female
- The cumulative mortality of the reference item on day 7 should be between 50 and 100 %.

II. RESULTS AND DISCUSSION

A. FINDINGS

Mortality

Table 10.3.2.2-1: Toxicity of MON 52276 to predatory mites (*Typhlodromus pyri*) in a 7 d laboratory test

Test concentration [L/ha]	Mortality after 7 days[1] [%]	Abbott corrected mortality [%]	Mean number of eggs per female[2]	Effects on reproduction[3] [%]
Control	15	-	6.9	-
3	13	0	8.1	-17.4
6	18	4	4.2	39.1
8	23	9	5.9	14.5
12	32	20	3.8[4]	44.9
16	40[4]	29	3.0[4]	56.5

[1] Mortality in the individual test item treatments at 7 DAT was compared to that in the control using Fisher's Exact Test.
[2] Results for reproduction compared by one-way ANOVA and Dunnett's Test.
[3] Change in numbers of eggs per female, relative to control (after Blümel *et al.*, 2000). A positive value indicates a decrease and a negative value indicates an increase
[4] Significantly different from the control.

B. OBSERVATIONS

The 7-day LR_{50} is found to be higher than the maximum rate tested > 16 L MON 52276/ha (nominally 5760 g a.s./ha) and the surrogate endpoint for reproduction was set to be $ER_{50} \geq 12000$ mL MON 52276/ha. The mean number of eggs produced per female was calculated to be 6.9 in the control. There were no significant effects in reproduction, compared to the control, at treatment rates up to and including 8 L MON 52275/ha (ANOVA, P > 0.05).

Reference test: Treatment with the reference item BASF Perfektion resulted in significant effects on reproduction (85 % Abbott corrected mortality).

Validity criteria according to Candolfi *et al.* (2000) were fulfilled; as mortality in control group not exceeded 20 % on day 7 after test start (actual value: 15 %). The cumulative mean number of eggs per female from day 7 – 14 was ≥ 4 eggs/female (actual value: 6.9) and the cumulative mortality of the reference item on day 7 was between 50 and 100 % (actual value: 85 %).

The following points deviated from the guideline recommendations:

- The application for toxic reference was 30 mL product/ha instead of 9 - 15 mL/ ha recommended.
- The application substrate was plant instead of glass.

These deviations are due to the extended test design and are not expected to have any negative impact on the study validity.

III. CONCLUSIONS

Assessment and conclusion by applicant:

In an extended laboratory test to determine the effects of MON 52276 on the predatory mite, *Typhlodromus pyri*, the 7-day LR_{50} (median lethal rate) was higher than 16 L formulation/ha (nominally 5760 g a.e./ha) and the surrogate endpoint for reproduction was set to be ER_{50} ≥ 12 L MON 52276/ha. MON 52276 had no adverse effects on the reproductive performance of surviving mites up to and including a treatment rate of 8000 mL formulation/ha (nominally 2880 g a.e./ha).

The study is considered to be valid and suitable to be used for the risk assessment.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.3.2.2/002
Report author	[redacted]
Report year	1999
Report title	An extended laboratory test to determine the effects of MON 52276 on the predatory mite, *Typhlodromus pyri* (Phytoseiidae)
Report No	MON-99-2
Document No	US-99-092
Guidelines followed in study	Barrett *et al.* (1994): Guidance document on regulatory testing procedures for pesticides with non-target arthropods.
Deviations from current test guideline	Deviations compared to current guideline Blümel *et al.* (2000): Major: - Control mortality exceeded the trigger of 20 % (24 %) - Reproduction assessment conducted on untreated glass plates - Assessments of fecundity between 7 and 14 days have not been conducted (3 times) Minor: - none
Previous evaluation	Yes, accepted RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Supportive
Category study in AIR 5 dossier (L docs)	Category 2b

2. Full summary

Executive Summary

In the laboratory study the toxicity of MON 52276 to the predatory mites, *Typhlodromus pyri* was tested. 100 mites were exposed to 0.6, 3, 6 and 12 L product/ha in 200 L water/ha on leaves of potted French beans. Afterwards, the surviving females were put on untreated glass plates for the fecundity test, where the number of laid eggs was counted after another 7 days. In addition, a control and a toxic reference substance (Dimethoate 40) were tested.
The test was conducted with 5 replicates per test concentration, control and reference control each containing 20 mites. Mortality was recorded 7 days after application and the eggs counted 14 days after application.
At the concentration of 12 L test item/ha, 30 % and higher mortality was observed for lower concentration (6 L test item/ha), while no effects on fecundity were noticed.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item:	MON 52276 (EC)
Description:	Not stated
Lot/Batch #:	290598
Purity:	31 % w/w glyphosate acid, nominal 30.9 % w/w glyphosate acid, measured

2. Vehicle and/or positive control: BASF Dimethoate 40 (400 g/L dimethoate)

3. Test organisms:

Species:	Predacious mite (*Typhlodromus pyri*)
Age:	Approximately 4 days after eggs laying
Source:	In-house, originally from PK Nützlingszuchten, Welzheim, Germany (pre-1998).
Diet/Food:	Untreated broad bean pollen
Acclimatisation:	Not stated

4. Environmental conditions:

Temperature:	Mortality test: 21 – 26 °C Reproductive test: 22 – 26 °C
Relative humidity:	Mortality test 43 – 61% Reproductive test: 41 – 75 %
Photoperiod:	16 hours light / 8 hours darkness
Light intensity	Mortality test: 2600 – 3400 lux Reproductive test: ~2600 lux

5. Experimental dates: May 27th, 1999 to June 16th, 1999

B. STUDY DESIGN AND METHODS

1. Experimental treatments: 20 protonymphal mites (*Typhlodromus pyri*) were placed on leaves of potted French bean plants (*Phaseolus vulgaris*) which were treated with 0.6, 3, 6 and 12 L product/ha. The leaf petioles were surrounded with a sticky gel barrier to prevent the mites from escaping. Also, a control and a toxic reference were tested. The test was conducted with 5 replicates per test concentration, control and reference treatment each containing 20 mites. Surviving mites were transferred to untreated glass surfaces and the fecundity of these mites was assessed up to 14 days after treatment (thus, additional 7 days) by counting the produced eggs.

2. Observations: Mortality was recorded 7 days after application. Eggs were counted 14 days after treatment.

3. Statistical calculations: The mortality was corrected with the control mortality using Abbott's correction (1925).

I. RESULTS AND DISCUSSION

A. FINDINGS

Mortality

Table 10.3.2.2-2: Toxicity of MON 52267 to predatory mites (*Typhlodromus pyri*) in a 7 day laboratory test

Test concentration [L/ha]	Mortality after 7 days [%]	Abbott corrected mortality [%]
Control	24	-
0.6	19	0
3	40	21
6	51	36
12	47	30

Fecundity

Table 10.3.2.2-3: Toxicity of MON 52267 to predatory mites (*Typhlodromus pyri*) in the following 7 day fecundity test

Test concentration [L/ha]	Number females transferred 7 days after treatment	Number eggs/nymphs produced 14 days after treatment	Mean egg number/ female after 14 days
Control	42	174	4.1
0.6	52	246	4.7
3	41	194	4.7
6	33	136	4.1
12	28	136	4.9

B. OBSERVATIONS

The test item resulted in ≥ 30 % mortality of *Typhlodromus pyri* when applied at concentration of 6 L/ha and higher. In the fecundity assessment, no dose-response relationship was observed.

Reference test: Treatment with the reference item BASF Dimethoate 40 resulted in significant effects on reproduction (100 %).

Validity criteria according to Vogt *et al.* (2000) were not fulfilled; as mortality in control group slightly exceeded 20 % on day 7 after test start (24 %). The cumulative mean number of eggs per female from day 7 – 14 was ≥ 4 eggs/female and the cumulative mortality of the reference item on day 7 was between 50 and 100 %.

III. CONCLUSIONS

Assessment and conclusion by applicant:
Under the conditions of the present test, MON 52276 applied at concentrations of 6 L/ha in 200 L/ha water resulted in 30 % and more mortality of the predatory mites after 7 days of exposure. In the fecundity assessment, no dose-response relationship was observed.

The study is considered supportive and is not used in the risk assessment.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.3.2.2/003
Report author	[redacted]
Report year	1998
Report title	Testing toxicity to beneficial arthropods - Predatory mite – *Typhlodomus pyri* (SCHEUTEN) (extended laboratory test) according to IOBC Guideline (Oomen 1988)
Report No	95 10 48 065
Document No	-
Guidelines followed in study	IOBC Guideline (Oomen 1988), ESCORT Guidance Document (1994)
Deviations from current test guideline	Deviations from current guideline Blümel *et al.* (2000): Major: - none Minor: - Temperature and humidity in the test room were for short periods of time above the (25 ± 2 °C) range (21 – 28 °C) and the 60 – 80 % range (53 – 100 %), respectively. - 100 mites per treatment are recommended (60 were used) - Test lasted 18 days long (14 days is required) - Dimethoate rate recommended between 9 and 15 mL/ha (100 mL/ha was used).
Previous evaluation	Yes, accepted RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Supportive
Category study in AIR 5 dossier (L docs)	Category 2b

2. Full summary

Executive Summary

In the laboratory study, the toxicity of MON 52276 to the predatory mite *Typhlodromus pyri* (SCHEUTEN) was tested. MON 52276 was evaluated in a test with three spray application rates of 3, 6 and 12 L test item/ha. Leaves of potted vine plants, cultivated under field conditions without pesticide treatments were sprayed in an automatic application cabin once with untreated water, the test or reference substance at the stated concentrations. The test comprised 6 replicates per control, test item treatment and reference treatment with 10 predatory mites each. The number of living predatory mites were counted 1, 4, 8, 11, 13, 15 and 18 days after the application (from 8th day onward separated according to the sex), also behaviour recorded on days 8, 11, 13, 15 and 18. The number of laid eggs (with the exception of the 1st and 4th day) and the hatching rate of the mites as of day 10 were determined. The final assessment were performed 18 days after treatment. Three days later the last mites hatched were counted.

Exposure to dried spray deposits of MON 52276 on vine leaves resulted in low mortality at the dose of 3 L/ha and high mortality at 6 and 12 L/ha. There was no significant difference with controls in fecundity or fertility at 3 L/ha. At higher doses, the number of eggs produced by surviving female was either strongly reduced or not measured due to mortality. The test was considered valid as mortality in the control group was 17 % and thus did not exceed the 20 % and the toxic reference product resulted in substantial and unequivocal effects.

I. MATERIALS AND METHODS

A. MATERIALS

Test material:

Test item:	MON 52276
Active substance	Glyphosate
Lot/Batch #:	270198
Purity:	31 % (Glyphosate (isopropylamine salt)
Density:	1.166 g/cm^3

Positive control: Dimethoate EC 400

Test organism:

Species:	*Typhlodromus pyri* (SCHEUTEN)
Age:	Approx. 1 day old protonymphs
Source:	MITOX Consultants (Kruislaan 320, 1098 Amsterdam, Netherland) – July 1998
Food:	Pollen (pine, birch) at each assessment day or more often if required

Environmental conditions:

Temperature:	21 – 28 °C
Photoperiod:	16 h
Light intensity	approx. 1000 lux
Relative humidity:	Test units: 52 – 100 %

Experimental dates: 16 July – 6 August 1998

B. STUDY DESIGN AND METHODS

Experimental treatments

The test item MON 52276 was evaluated in a test with three spray application rates of 3, 6 and 12 L test item/ha. Leaves of potted vine plants, cultivated under field conditions without pesticide treatments were sprayed in an automatic application cabin once with untreated water, the test or reference substance at the stated concentrations. The test comprised 6 replicates per control, test item treatment and reference treatment with 10 predatory mites each. After air-drying of the spray deposits at room temperature (about 1 hour and 2 hours at 12 L/ha, respectively) leaf discs (Ø ~4 cm) of the treated leaves were placed with the treated surface upwards in petri dishes (Ø 9 cm) on moistened cotton wool. Each leaf disc was lined with insect glue and infested with 10 protonymphs. Pollen was added as food supply. The test units were then placed in a climatic test room.

Observations

The number of living predatory mites were counted 1, 4, 8, 11, 13, 15 and 18 days after the application (from 8th day onward separated according to the sex), also behaviour recorded on days 8, 11, 13, 15 and 18. The number of laid eggs (with the exception of the 1st and 4th day) and the hatching rate of the eggs as of day 10 were determined. The final assessment were performed 18 days after treatment. Three days later the last mites hatched were counted.

Statistical calculations

In order to detect any significant differences the STUDENT-t-test was used (RATTE 1998).

II. RESULTS AND DISCUSSION

A. FINDINGS

The effects of MON 52276 were tested at nominal rates equivalent to 3, 6 and 12 L/ha in 200 L/ha of water. The results are summarised in the following table.

Table 10.3.2.2-4: Findings *Typhlodromus pyri* (SCHEUTEN), extended laboratory test

	Typhlodromus pyri **(SCHEUTEN)**			
Exposure	**Spray treatment**			
Test formulation/reference	**MON 52276**			**Dimethoate EC 400**
Application	**3 L/ha**	**6 L/ha**	**12 L/ha**	**100 mL/ha**
Corrected mortality (%) until day 8 until day 18	 18 36	 84 86	 89 88	 100 100
Fecundity (% relative to controls)	113	10	0	-
Egg fertility (hatching rate) (% relative to controls)	97	(53)*	-	-
Total effect E (%) according to OVERMEER & VAN ZON	8	98	100	100

B. OBSERVATIONS

18 days after testing was started, 10 out of 60 predatory mites were recorded as dead in the control replicates (= 17 %). Thus, the test accomplished the validity criterion (in the control variant: ≤ 20 % mortality). The toxic reference (Dimethoate EC 400) produced substantial and unequivocal effects (100% mortality within

1 day). This demonstrates that the test strain used was susceptible to pesticide treatments. The effects of MON 52276 were tested at nominal doses equivalent to 3, 6 and 12 L/ha in 200 L/ha of water.

Table 10.3.2.2-5: Surviving predatory mites

	Number of surviving predatory mites																
Days after application	**1**	**4**	**8**			**11**			**13**			**15**			**18**		
	mites	mites	♀	♂	Σ	♀	♂	Σ	♀	♂	Σ	♀	♂	Σ	♀	♂	Σ
Control	60	58	37	18	55	36	18	54	35	17	52	34	17	51	33	17	50
MON 52276																	
3 L/ha	60	55	27	18	45	27	18	45	27	16	43	26	15	41	20	12	32
6 L/ha	60	18	6	3	9	5	2	7	5	2	7	5	2	7	5	2	7
12 L/ha	56	14	5	1	6	5	1	6	5	1	6	5	1	6	5	1	6
Dimethoate 400 EC																	
100 mL/ha	0																

Table 10.3.2.2-6: Egg production of surviving females

	Number of eggs				
Days after application	**11**	**13**	**15**	**18**	**total**
Control	32	49	81	45	207
MON 52276					
3 L/ha	35	54	63	23	175
6 L/ha	2	1	0	0	3

In the reference variant and the highest dose test substance variant (12 L/ha), no eggs were laid.

Table 10.3.2.2-7: Hatching rate of the eggs

	Number of larvae				
Days after application	**13**	**15**	**18**	**21**	**total**
Control	24	35	47	23	129
MON 52276					
3 L/ha	24	42	29	14	109
6 L/ha	1	0	0	0	1

Exposure to dried spray deposits of MON 52276 on vine leaves resulted in low mortality at the dose of 3 L/ha and high mortality at 6 and 12 L/ha. There was no significant difference with controls in fecundity or fertility at 3 L/ha. At higher doses, the number of eggs produced by surviving female was either strongly reduced or not measured due to mortality. The test was considered valid as mortality in the control group was 17 % and thus did not exceed the 20 % and the toxic reference product resulted in substantial and unequivocal effects.

The statistical calculation of the fecundity (number of eggs per female per day) on the basis of the student-test resulted in no statistically significant difference ($p \leq 0.05$) between the control and the MON 52276 treatment (3 L/ha) results.
In all treatments the vine leaves showed (since day 3) damages as a result of herbicide effects. The leaves

of the 12 L/ha treatment showed low damages at the leaf-edges already after 2 hours air-drying.

The following point deviated from the guideline:

- Temperature and humidity in the test room were for short periods of time above the (25 ± 2 °C) range (21 – 28 °C) and the 60 – 80 % range (53 – 100 %), respectively.
- Less than 100 mites per treatment were used (actual number: 60)
- Test lasted 18 days long (14 days is required)
- Dimethoate rate recommended between 9 and 15 mL/ha (100 mL/ha was used).

Taking into account these deviations, this study is therefore considered as supportive only.

The validity criteria of the current guideline were fulfilled as:

- The control mortality did not exceed 20 % after 7 days of exposure (actual values: 8 % after 8 days and 17 % after 18 days)
- The mean mortality in the toxic reference item ranged between 50 % and 100 % after 7 days of exposure (actual value: 100 % after 1 day). Nevertheless, the rate of toxic reference item was about 10 times the current recommended rate.
- The mean number of eggs per female at the end of the test is ≥ 4 eggs/female (actual value: 6.15)

From the recorded data the mortality (in % corrected according to ABBOTT 1925), the fecundity (number of eggs per female) and the hatching rate were calculated.

III. CONCLUSIONS

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

The laboratory test to determine the effects of MON 52276 on the predatory mite *Typhlodromus pyri*, resulted in low mortality at the dose of 3 L/ha and high mortality at 6 and 12 L/ha. There was no significant difference with controls in fecundity or fertility at 3 L/ha. All of the current validity criteria for this study design were satisfied in this test.

The study was considered supplemental in the 2015 RAR, due to the significant developments and changes in the risk assessment approach and strategy for terrestrial non-target arthropods since the evaluation of glyphosate in 2001. This study is no longer considered appropriate for a quantitative risk assessment according to current standards. Therefore, it is considered supportive.

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

1. Information on the study

Data point:	CP 10.3.2.2/004
Report author	[redacted]
Report year	2010
Report title	A rate-response extended laboratory test to determine the effects of MON 52276 on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae)
Report No	MON-09-2
Document No	MT-2009-405
Guidelines followed in study	Mead-Briggs *et al.* (in press). An extended laboratory test for evaluating the effects of plant protection product on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez) (Hymenoptera, Braconidae).
Deviations from current test guideline	Deviations compared to current Mead-Briggs *et al.* (in press): Major: - none Minor: - none
Previous evaluation	Yes, accepted RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

In the extended laboratory study the toxicity of MON 52276 to the parasitic wasp, *Aphidius rhopalosiphi* was tested. Adult parasitic wasps approximately 48 h old were exposed in a definitive rate-response test to 4000, 6000, 8000, 12000 and 16000 mL product/ha. In addition, a water control and a toxic reference (Perfekthion, 400 g/L dimethoate) were tested.

Five female wasps were exposed per replicate, with six replicates (i.e. a total of 30 wasps) prepared for each treatment. Mortality and repellence effects were recorded within the 3 first hours, 24 and 48 hours after application. The parasitisation efficiency of surviving insects in the control and in treatment groups with ≤ 60 % corrected mortality, by confining wasps individually over pots of untreated cereal plants, previously infested with cereal aphids. After 24 hours, wasps were removed and after a further 10 days, the number of mummies (parasitized aphids containing wasp pupae) that had developed was recorded. The validity criteria according to Mead-Briggs *et al.* (2010) are fulfilled.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item:	MON 52276
Appearance:	Yellow/amber fluid
Lot/Batch #:	A9B1207115
Purity:	Glyphosate (isopropylamine salt) 360 g/L
Density:	1.1683 g/cm^3 (at 20 °C ± 0.5 °C)
2. Vehicle and/or positive control:	Perfekthion – BAS 152 11 I (dimethoate: 400 g/L)
3. Test organisms:	
Species:	Parasitic wasp (*Aphidius rhopalosiphi*)
Age:	Adults approximately 48 h old
Source:	In-house culture originally obtained from PK Nützlingszuchten, Welzheim, Germany
Diet/Food:	Solution of honey in water (1 : 3 v/v)
4. Environmental conditions:	
Temperature:	Mortality phase: 20 °C Reproduction phase: 18 – 20 °C
Relative humidity:	69 – 72 %
Photoperiod:	16 hours light / 8 hours darkness
Light intensity:	Mortality phase: 2030 lux Reproduction phase: 4290 lux
5. Experimental work dates:	14 October 2009 to 09 November 2009

B. STUDY DESIGN AND METHODS

1. Experimental treatments: Following a preliminary range-finding test, MON 52276 was evaluated in a definitive rate-response test at five application rates, equivalent to 16000, 12000, 8000, 6000 and 4000 mL product/ha. These variants were compared to a control treatment of purified water and a toxic reference treatment of BASF Perfekthion (nominally 400 g/L dimethoate) applied at a rate of 10 mL product/ha (nominally 4 g a.s./ha). Treatments were applied at a volume rate equivalent to 400 L spray solution/ha to pots of seedling barley. Once dry, the barley plants were enclosed within cylindrical, ventilated collars (clear acrylic cylinders with fine gauge mesh netting secured over the open end. Five female wasps were then confined in each arena, with six replicates (i.e. a total of 30 wasps) prepared for each treatment. To determine any significant sub-lethal effects on wasp reproduction, assessments were then carried out using the surviving insects from the control and the three highest treatment rates of the test item that resulted in < 60 % corrected mortality. Fifteen wasps from each treatment were confined individually over pots of untreated barley plants that had previously been infested with cereal aphids (*Metopolophium dirhodum* and *Rhopalosiphum padi*). The wasps were then removed from the plants after 24 h and the aphids and plants left for a further 10 days before the number of 'mummies' (parasitized aphids containing wasp pupae) that had developed was recorded.

2. Observations: Mortality of the wasps was recorded approximately 2, 24 and 48 h after treatment. The behaviour of the wasps was assessed during the first 3 h after treatment and also at 24 and 48 h after treatment, to determine whether there was any apparent repellence from the treated plants. The percentage mortality of the test insects over 48 h was calculated. For the reproduction assessments, the number of

mummies produced per female found alive after the 24 h parasitisation period was determined.
The temperature and relative humidity were recorded at hourly intervals using an electronic data logger for mortality phase. For reproduction phase, the temperature in the room was recorded using a minimum-maximum mercury thermometer. Light levels were recorded at the start of each bioassay using an ELE Single Channel Light Measuring System. For the mortality-assessment phase of the definitive test, the room was maintained at 20 ºC and 69 – 72 % RH, with lighting of 2030 lux provided for a 16 h photoperiod. For the reproduction-assessment phase the pots of seedlings and parasitoids were maintained at 18 – 20 ºC, with a 16 h photoperiod (4290 lux).

The validity criteria according to this guideline are the following:

- The mortality in the control treatment should not exceed 10 %.
- The level of mortality expected in the toxic reference treatment should be specified in the study protocol and should be based on the previous experience of the test laboratory. The corrected mortality should, however, be > 50 %.
- For the reproduction assessments, there should be a minimum mean value of 5.0 mummies per female. Also, in the control treatment, no more than two of the surviving wasps should produce zero values.

3. Statistical calculations: ANOVA followed by Fisher's Exact test ($\alpha = 0.05$) for mortality. One-way ANOVA and Dunnett's Test as post hoc ($\alpha = 0.05$) for reproduction. Angularly transformation (square root arcsine), then ANOVA and Dunnett's test (Fowler & Cohen, 1990; SPSS, 2008) for repellence.

II. RESULTS AND DISCUSSION

A. FINDINGS

Table 10.3.2.2-8: Toxicity of MON 52276 to parasitic wasps (*Aphidius rhopalosiphi*) in a 48 h extended laboratory test

Test rate [mL/ha]	Mortality [%]	Corrected mortality [%] [1]
Control	0	--
4000	0	0
6000	0	0
8000	0	0
12000	3.3	3.3
16000	0	0

[1] Derived using Abbott's formula.

Reference test: Treatment with the reference item Perfekthion at a concentration of 10 mL/ha resulted in 90 % mortality after 48 h of exposure.

Table 10.3.2.2-9: Sublethal effects of MON 52276 to parasitic wasps (*Aphidius rhopalosiphi*) in a 48 h extended laboratory test (summary of wasp repellence assessments)

Test rate [mL/ha]	% observations where wasps recorded to be settled on the treated plants	
	Initial 3 h [1]	24 h & 48 h [2]
Control	32.7	40.0
4000	22.0	28.3
6000	24.7	28.3
8000	26.0	25.0
12000	20.7 *	27.5
16000	20.0 *	28.3

[1] Data from assessments made during the initial 3 h after wasp introduction. Results for the individual test item treatments were compared by one-way ANOVA and Dunnett's Test. Values marked with asterisks differed significantly from the control (* P < 0.05).
[2] Data from assessments made at 24 h and 48 h after wasp introduction. Results for the individual test item treatments were compared by one-way ANOVA (α = 0.05), but values for the test item treatments did not differ significantly from the control.

Reference test: Treatment with the reference item Perfekthion at a concentration of 10 mL/ha resulted in significant effects on reproduction after 48 h of exposure.

Table 10.3.2.2-10: Toxicity of MON 52276 to the parasitisation capacity of *Aphidius rhopalosiphi*

Test rate [mL/ha]	n [1]	Means number of mummies per female [2]	% change in reproduction, relative to control [3]
Control	14	21.4	-
8000	14	28.4*	-32.3
12000	14	30.6**	-43.0
16000	15	31.5**	-46.8

[1] n = number of female wasps successfully assessed for their reproductive capacity.
[2] The results for the test items treatments were compared to the control by one-way ANOVA and Dunnett's Test (α = 0.05). Results that differed significantly from the control are indicated with asterisks; however, these were due to a significant increase in the number of mummies produced (* P < 0.05; ** P < 0.01).
[3] Percentage effect on reproduction. A negative value indicates an increase, relative to the control

B. OBSERVATIONS

The following point deviated from the Mead-Briggs *et al.* (2010):

- Light intensity during mortality phase was 2030 lux, compared to 400 to 1200 lux requested by guideline. No impact on the mortality and fecundity phases as the validity criteria were met.

The mortality in the control treatments did not exceed 10 %, the corrected mortality in the reference treatment was > 50 %. In the control treatments, more than a minimum mean value of 5.0 mummies was produced per female. No more than two of the surviving wasps of the control treatments did not reproduce. Therefore, the test is considered valid according to Mead-Briggs *et al.* (2010).

III. CONCLUSIONS

Assessment and conclusion by applicant:
In an extended laboratory test to determine the effects of MON 52276 on the parasitic wasp, *Aphidius rhopalosiphi*, the 48-h LR_{50} was higher than 16000 mL product/ha. MON 52276 had no adverse effects on the reproductive performance of surviving wasps up to and including a treatment rate of 16000 mL product/ha.

This study is considered to be valid and relevant for use in risk assessment.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.3.2.2/005, CP 10.3.2.2/006 (Amendment)
Report author	[redacted]
Report year	1999
Report title	Testing toxicity to beneficial arthropods Cereal aphid parasitoid - *Aphidius rhopalosiphi* (DESTEFANI-PEREZ) (extended laboratory test) following the IOBC Guideline proposal (MEAD-BRIGGS 1994) MON 52276
Report No	98 10 48 066
Document No	-
Guidelines followed in study	IOBC Guideline (Proposal 1994). An extended laboratory test to evaluate the side-effects of pesticides applied to plant material on adults of the aphid parasitoid *Aphidius rhopalosiphi* (Hymenoptera: Braconidae).
Deviations from current test guideline	Deviations compared to current Mead-Briggs *et al.* (2010): Major: - none Minor: - For mortality phase, 4 replicates (5 wasps each) were used in test item treatment groups and 1 in reference item, instead of 6 replicates
Previous evaluation	Yes, accepted RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary
In the extended laboratory study the toxicity of MON 52276 to the parasitic wasps *Aphidius rhopalosiphi* was tested. Adult parasitic wasps approximately 48 h old were exposed to 3, 6 and 12 L test item/ha sprayed onto potted cereal plants and mortality and reproduction were assessed. In addition, a water control was tested and a toxic reference (Dimethoate EC 400 (0.85 mL/ha)) were tested.

Five female wasps were then confined in each of four arenas (i.e. a total of 20 wasps) prepared for each treatment. Mortality and sub-lethal effects were recorded 1, 2, 4, 24 and 48 hours after application. After 48 h, 14 surviving females from the control and the test item treated variants were confined in glass cylinders containing untreated potted wheat plants, infested with ~100 aphids (*Rhopalosiphum padi* L.) to assess the parasitisation capacity. The reduction of the beneficial effectivity of *Aphidius rhopalosiphi* was < 30 % in all variants. The behaviour of the wasps treated with the test item did not differ from the control. The number of mummies developed was recorded. All validity criteria according to Mead-Biggs *et al.* (2010) were fulfilled.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item:	MON 52276
Description:	Liquid, yellowish to brown
Lot/Batch #:	270198
Purity:	31 % Glyphosate acid
Density:	1.166 g/cm^3 (at 20 °C ± 0.5 °C)
2. Vehicle and/or positive control:	Positive control: Dimethoate EC 400 (0.85 mL/ha)

3. Test organisms:

Species:	*Aphidius rhopalosiphi* (DESTAFANI-PEREZ), cereal aphid parasitoid
Age:	Adults approximately 48 h old
Source:	PK Nützlingszuchten, 73642 Welzheim, Germany
Diet/Food:	Solution of honey in water (1:2 v/v), the wasps were not fed for 12 – 18 h prior to exposure.
Acclimatisation:	Not stated

4. Environmental conditions:

Temperature:	19 – 22 °C
Relative humidity:	65 – 84 %
Photoperiod:	16 hours light / 8 hours darkness
Light intensity:	~1000 lux

5. Experimental dates:

B. STUDY DESIGN AND METHODS

1. Experimental treatments: MON 52276 was evaluated in a test at three application rates of 3, 6 and 12 L test item/ha. These treatments were compared to a control treatment of deionised water and a toxic reference treatment of Dimethoate EC 400 applied at a rate of 0.85 mL product/ha. Potted wheat plants were sprayed with 25 % aqueous fructose and left to dry for 1 h, followed by application of the test items, applied in final water volumes equivalent to ~200 L spray solution/ha onto the plants surface. Once dry, the treated plants were put in glass cylinders and five female wasps were then confined in each arena, with 4 replicates (i.e. a total of 20 wasps) prepared for control and test item treatment. After 48 h, 14 surviving females from the control and the test item treated variants were confined in glass cylinders containing untreated potted wheat plants, infested with ~100 aphids (*Rhopalosiphum padi* L.) to assess the parasitisation capacity. The wasps were then removed from the plants after 24 h and the aphids and plants left for a further 10 days before the number of mummies (parasitized aphids containing wasp pupae) that had developed, was recorded.

2. Observations: Mortality and behaviour of the wasps were recorded 1, 2, 4, 24 and 48 h after treatment. The number of parasitized aphids (aphid mummies) was recorded 10 days after the wasps were able to lay eggs.

3. Statistics: The parasitisation rate was calculated using Mead-Briggs (1992). According to Overmeer & Van Zon (1982) the total effect "E" was calculated.

II. RESULTS AND DISCUSSION

A. FINDINGS

Mortality

Table 10.3.2.2-11: Toxicity of MON 52276 to parasitic wasps (*Aphidius rhopalosiphi*) in a 48 h extended laboratory test

Test rate [L/ha]	Mortality [%]		
	4 h	24 h	48 h
Control	0	0	0
3	0	0	15
6	0	0	15
12	0	0	25

Effects on parasitisation capacity

Table 10.3.2.2-12: Toxicity of MON 52276 to the parasitisation capacity of *Aphidius rhopalosiphi*

Test rate [L/ha]	∑ no. of females examined	Average no. of parasitized aphids per female after 11 days	Parasitisation rate relative to control [%]
Control	14	11.6	-
3	14	11.1	96
6	14	11.7	101
12	14	10.9	94

The total effect "E" is 18.7 % for 3 L test item/ha, 14.3 % for 6 L test item/ha and 29.5 % for 12 L test item/ha

Reference test: Treatment with the reference item Dimethoate EC 400 at a concentration of 0.85 mL product/ha resulted in 80 % mortality after 48 h of exposure.

B. OBSERVATIONS

The reduction of the beneficial effectivity of *Aphidius rhopalosiphi* was < 30 % in all variants. The behaviour of the wasps treated with the test item did not differ from the control.
Reference test: Treatment with the reference item Dimethoate EC 400 at a concentration of 0.85 mL product/ha resulted in significant effects on reproduction after 48 h of exposure.
All validity criteria according to Mead-Briggs *et al.* (2010): "An extended laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (*Hymenoptera*,

Braconidae) were fulfilled, as there was no mortality in control group and the mortality in the toxic reference was > 50 %, the number of mummies/female in the control was at least 5 and no more than 2 wasps produced no mummies.

III. CONCLUSIONS

Assessment and conclusion by applicant:
In conclusion, no significant mortality of *Aphidius rhopalosiphi* was observed after treatment with the maximum test rate of 12 L MON 52276/ha (< 30 %). The parasitisation rate showed no significant changes compared to the control and the total effect was between 14.3 and 29.5 %. This study is considered to be valid and relevant for use in risk assessment.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.3.2.2/007
Report author	[redacted]
Report year	2010
Report title	An extended laboratory test to determine the effects of MON 52276 on the ground-active beetle, *Aleochara bilineata* (Coleoptera, Staphylinidae)
Report No	MON-09-4
Document No	MT-2009-403
Guidelines followed in study	Grimm *et al.* A test for evaluating the chronic effects of plant protection products on the rove beetle, *Aleochara bilineata* Gyll. (Coleoptera: Staphylinidae), under laboratory and extended laboratory conditions
Deviations from current test guideline	Deviations compared to current guideline IOBC (2000): Major: - none Minor: - none
Previous evaluation	Yes, accepted RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

In the extended laboratory study the toxicity of MON 52276 to the rove beetle, *Aleochara bilineata* was tested. Adult rove beetles (3 – 4 days old) were exposed in the definitive rate-response test to 6000, 8000 and 12000 mL product/ha. In addition, a water control and a toxic reference (Cyren, 480 g/L chlorpyrifos)

were tested.
Ten female and ten male beetles (i.e. a total of 20 beetles) were introduced in each testing arena, with four replicates prepared for each treatment. Assessments of the condition of the beetles were made at 1, 7 and 28 days after treatment (DAT). The parasitic success of their larval offspring was assessed by the provision of ca. 500 onion fly pupae (*Delia antiqua*) in each replicate box on three weekly occasions, i.e. at 7, 14 and 21 DAT. The original adult beetles were removed from the arenas at 28 DAT and the number of new adults (F1 progeny) that subsequently developed from the parasitized fly pupae was recorded over a further 46-day period. The validity criteria according to Grimm *et al.* (2000) are fulfilled.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item:	MON 52276
Description:	Yellow/amber-coloured liquid appearance
Lot/Batch #:	A9B1207115
Purity:	Glyphosate (glyphosate acid equivalent) 360 g/L
Density:	1.1683 g/cm^3 (at 20 °C ± 0.5 °C)

2. Vehicle and/or positive control: Reference item: Cyren (chlorpyrifos: 480 g/L)

3. Test organisms:

Species:	Rove beetle (*Aleochara bilineata*)
Age:	Physiologically 3 – 4 days old
Source:	Commercial supplier (De Groene Vlieg, Nieuwe Tonge, The Netherlands)
Diet/Food:	Pellets (approximately 0.2 – 0.5 g) of raw minced beef for food every 1 – 3 days, until the adult beetles were removed 28 days after treatment (DAT)
Acclimatisation:	Not stated

4. Environmental conditions:

Temperature:	19 – 21 °C
Relative humidity:	51 – 86 %
Photoperiod:	16 hours light / 8 hours darkness
Light intensity:	340 – 700 lux

5. Experimental work dates: 02 October 2009 to 02 January 2010

B. STUDY DESIGN AND METHODS

1. Experimental treatments: MON 52276 was evaluated at three treatment rates, equivalent to 6000, 8000 and 12000 mL product/ha. These were compared to a water-treated control and a toxic reference treatment of chlorpyrifos (a 480 g/L EC formulation applied at a rate equivalent to 240 g a.s./ha). All treatments were applied to boxes (17.1 cm x 11.3 cm in area (= 193.2 cm surface area) by 6 cm deep) of a standard sandy soil (LUFA 2.1), using a track sprayer calibrated to deliver the equivalent of 400 L spray solution/ha. Applications were made to four replicate arenas per treatment and, immediately following spraying, twenty adult *Aleochara bilineata* (10 males: 10 females) were introduced into each replicate. Beetles were fed with pellets of raw minced beef one hour after treatment and then every 1 to 3 days thereafter. The parasitic success of their larval offspring was assessed by the provision of ca. 500 onion fly pupae (*Delia antiqua*) in each replicate box on three weekly occasions, i.e. at 7, 14 and 21 DAT. The original adult beetles were removed from the arenas at 28 DAT and the number of new adults (F1 progeny) that subsequently developed from the parasitized fly pupae was recorded over a further 46-day period.

2. Observations: Assessments of the condition of the beetles were made at 1, 7 and 28 days after treatment (DAT). Assessment of reproduction was conducted from 28 DAT for 46 days.
The temperature and relative humidity conditions were recorded at hourly intervals using an electronic data logger. Light intensities were recorded at the start of the assessments using an ELE Single Channel Light Measuring System. During the bioassay the temperature range recorded was 19 – 21 ºC and the relative humidity range recorded was 51 – 86 %, with a 16 h photoperiod of 340 – 700 lux.

3. Statistical calculations: Fisher's Exact test (α = 0.05) for mortality, ANOVA (α = 0.05) for reproduction.
The validity criteria according to IOBC guideline were the following:

- The average number of beetles emerging from parasitised fly pupae in the control treatment should be > 400 per replicate (nominally 26.7 % of those provided).
- The mean number of beetles emerging in the toxic reference treatment should be reduced by > 50 %, relative to the control.

II. RESULTS AND DISCUSSION

A. FINDINGS

Mortality

Table 10.3.2.2-13: Toxicity of MON 52276 to rove beetles (*Aleochara bilineata*) after 28 days in an extended laboratory test

Test rate [mL/ha]	Mortality [%]	Corrected mortality [%] [1]
Control	32.5	--
6000	38.8	9.3
8000	47.5	22.2
12000	35.0	37.0

[1] Derived using Abbott's formula

Reference test: Treatment with the reference item Cyren at a concentration of 240 g a.s./ha resulted in 100 % mortality after 28 d of exposure.

Reproduction effect

Table 10.3.2.2-14: Sublethal effects of MON 52276 to rove beetles (*Aleochara bilineata*) in an extended laboratory test (mean number of F_1 progeny)

Test rate [mL/ha]	Mean number of F_1 progeny per arena [1]	Standard deviation	Effect on reproduction [%] [2]
Control	862.5	66.8	--
6000	706.3	84.6	18.1
8000	846.0	109.5	1.9
12000	778.0	102.6	9.7

[1] The numbers of progeny emerging in the control and test item treatments were compared by ANOVA, but treatment means did not differ significantly (P > 0.05). For the toxic reference treatment (where all values were zero), no statistical comparisons were made.

[2] The percentage change in numbers of F1 progeny, relative to the control was calculated using the formula: R = (1-(Rt/Rc)) x 100, where Rt and Rc are the numbers of offspring observed in the treatment and control groups, respectively. Positive values indicate a decrease, relative to the control.

Reference test: Treatment with the reference item Cyren at a concentration of 240 g a.s./ha resulted in 100 % effects on reproduction.

B. OBSERVATIONS

The following point deviated from the IOBC guideline:

- Minor deviations to the required range of 60 – 90 % relative humidity (actual values: 51 – 86 %). No impact on the study validity

The average number of beetles emerging from parasitized fly pupae in the control treatment was > 400 per replicate, and a minimum reduction of 50 % reproductive capacity was achieved in the reference item treatment when compared to the control. The validity criteria according to Grimm *et al.* (2000) are therefore fulfilled.

III. CONCLUSIONS

Assessment and conclusion by applicant:

In an extended laboratory test to determine the effects of MON 52276 on the rove beetle (*Aleochara bilineata*), no significant effect on the parasitisation success of the beetles were observed up to and including the highest treatment rate of 12000 mL/ha.

This study is considered valid and relevant for use in the risk assessment.

Assessment and conclusion by RMS:

1. Information on the study

Data point:	CP 10.3.2.2/008
Report author	[redacted]
Report year	1999
Report title	A Laboratory Evaluation of the Effects of MON 52276 on the Green Lacewing, *Chrysoperla carne*a
Report No	MON-99-3
Document No	US-99-093
Guidelines followed in study	Bigler (1988)
Deviations from current test guideline	Deviation from the current guideline IOBC (2000): Major: - The mean number of eggs per female/day was 7.9 (guideline: > 15) - The toxic reference item was applied at 0.255 L product/ha (guideline: 0.04 L product /ha). Minor: - none
Previous evaluation	Yes, accepted RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Supportive
Category study in AIR 5 dossier (L docs)	Category 2b

2. Full summary

Executive Summary
The effects of MON 52276 (nominally 31% w/w glyphosate acid) on the development and fecundity of *Chrysoperla carnea* were evaluated. The toxicity test was performed using three concentrations, 0.6, 6 and 12 L MON 52276/ha. A negative control group (tap water only) and a positive control (dimethoate only) were included in the test design. Exposure arenas were 7.5 cm^2 glass plates, sprayed with product using a Potter tower applicator and left to air-dry for approximately 1 h, before a single larva (2 – 3 days old) was added to each plate, contained within a cylinder (44 mm internal diameter x approx. 25 mm tall) covered in a mesh netting to prevent escape of the developing larva. UV sterilised *Sitotroga* sp. eggs were added *ad libitum* each day until larval pupation. There were 50 test units per treatment. After pupation, pupae were transferred into ventilated plastic boxes. Once hatched, the adult lacewings were counted and transferred to oviposition boxes. Pre-imaginal mortality was recorded daily. For the following 21 days, the fecundity was assessed by observing the number of eggs laid, the viability of the eggs and the numbers of hatched juveniles.

During the larval development stage, there was no significant mortality of *Chrysoperla carnea* observed at rates up to 6 L MON 52275/ha. A significant pre-imaginal mortality was observed at 12 L MON 52275/ha. During the fecundity assessment no evidence of a dose-response relationship was found.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item:	MON 52276 (EC)
Active substance	Glyphosate acid
Active substance content	31.0 % w/w glyphosate acid (nominal) 30.9 % w/w glyphosate acid (measured)
Proposed use:	Herbicide
Lot/Batch #:	290598
2. Positive control:	BASF Dimethoate 40 (EC)
3. Test organism:	
Species:	*Chrysoperla carnea* Steph. (Neuoptera, Chrysopidae)
Age:	Larvae
Source:	Eggs: Bioplanet, Cesena, Italy (commercial supplier)
Egg treatment:	After delivery, the eggs were cooled to 0 – 4 °C to delay hatching. To encourage hatching, the eggs were placed for one day in warmer conditions (14 – 19 °C) with a 16 h photoperiod of 640 lux. Afterwards the temperature was brought to 22 – 24 °C with 16 h light of 3180 lux in ventilated plastic boxes lined with a fibrous tissue.
Diet/ Food:	Larvae: UV-killed eggs of *Sitotroga cerealella ad libitum* Adults: artificial diet (powdered yeast mixed 1:1 with honey and made into a paste with water, a 1:2 – 1:3 honey/water solution on a cotton wool pad, fresh water on a cotton wool pad
4. Environmental conditions:	
Temperature:	Test units: 21 – 25 °C Adult maturation: 22 – 24 °C Oviposition boxes: 20 – 26 °C
Photoperiod:	16 h
Light intensity	Test units: 3100 – 3140 lux Adult maturation: 6690 lux Oviposition boxes: 6690 lux
Relative humidity:	Test units: 63 – 75 % Adult maturation: 65 – 88 % Oviposition boxes: 57 – 99 %
5. Experimental dates:	May 25th, 1999 to July 22nd, 1999

B. STUDY DESIGN AND METHODS

1. Experimental treatments: The study encompassed three concentrations of 0.6, 6 and 12 L MON 52276/ha. In addition, *Chrysoperla carnea* were exposed to a toxic reference and a water control.
The test item, as well as the toxic reference and the water control, were applied to square glass plates using a Potter Laboratory Spray Tower with a delivery rate equivalent to 200 L/ha at a spray pressure of 0.7 bar. One 2-3-day-old larva was put into a test arena along with a sufficient amount of *Sitotroga* eggs. The test arena is a treated glass plates covered with a perspex sheet with a 50-mm-diameter hole and an exact fitting acrylic cylinder. The cylinder was treated with polytetrafluoroethylene. A mesh with 0.5 × 0.5 mm netting was placed over each cylinder.
After pupation they were transferred on the treated glass plate into ventilated plastic boxes. After hatching, the adult *Chrysoperla* were counted and transferred to oviposition boxes. Once a week a sheet of fibrous material was placed under the lid of each box as a site for oviposition. The egg sheets were removed after 24 h for a period of 21 days and put into ventilated plastic pots were the eggs were assessed for viability and number of emerged larvae. Emerging larvae were removed daily.

2. Observations: The larvae were assessed daily for mortality, sub-lethal effects and pupation. The emerging 2nd generation larvae were counted daily. The sex of the adults was determined on dead individuals and at test end.

3. Calculations: The mortality of larval insects was corrected with the losses in the control using Abbott's formula. The pre-imaginal mortality at each test concentration and the control were compared by Chi-square test.

II. RESULTS AND DISCUSSION

A. FINDINGS

The results of the test are depicted in the following tables.

Table 10.3.2.2-15: Mortality during the development of the test insects

Concentration [L MON 52276/ha]	Number of Larvae tested	Insects pupating [%]	Emerging as adults [%]	Pre-imaginal mortality [%]	Abbot-corrected pre-imaginal mortality [%]
0 (control)	48	83	81	19	-
0.6	50	76	72	28	11
6	50	66	64	36	21
12	48	35	33	67	59[1]
Dimethoate 40	48	0	0	100	100[1]

[1] significant difference compared to the blank control

Table 10.3.2.2-16: Egg production and viability assessment

Concentration [L MON 52276/ha]	Mean number eggs/ female/ day	Mean percentage viability	Mean no. viable eggs/ female/ day	Change relative to control [%]
0 (control)	7.9	89	7.0	-
0.6	6.3	84	5.3	-24
6	9.6	85	8.2	+17
12	6.3	89	5.6	-20
Dimethoate 40	-	-	-	-

B. OBSERVATIONS

During the development no significant mortality of *Chrysoperla carnea* was observed up to and including 6 L MON 52275/ha. A significant pre-imaginal mortality was noticed at 12 L MON 52275/ha. During the fecundity assessment no evidence of a dose-response relationship was found.

According to the study protocol based on the method by Bigler (1988), for the study to be valid, pre-imaginal mortality in the control group would not exceed 30 % and would be greater than 80 % in the positive control. These criteria were satisfied.

The validity criteria according to the current laboratory method to test effects of plant protection products on larvae of *Chrysoperla carnea* (Neuroptera:Chrysopidae) (Vogt, 2000) state that maximum cumulative mortality in the control group (dead larvae, pupae and adults) must be ≤ 20 %, fecundity (mean number of eggs per female per day) must be ≥ 15, fertility (mean hatching rate) must be ≥ 70 % and the mortality in the positive control group should be ≥ 50 %. Compared to these current criteria, three of the four criteria were satisfied. However, for control group fecundity, the mean number of eggs per female per day, was lower than 15 (7.9), with a mean percentage viability of eggs in the control being high (89 %). Despite the low level of control fecundity against the Vogt (2000) criteria, relatively, there was no significant reduction in fecundity at rates up to the 12 L/ha equivalent rate.

III. CONCLUSIONS

Assessment and conclusion by applicant:

MON 52276 did not affect the survival or fecundity of the green lacewing, *Chrysoperla carnea*, when applied at rates of 0.6 or 6 L MON 52276/ha. At the maximum rate of 12 L MON 52276/ha, corrected mortality was 59 %, which exceeds the threshold of 30 % currently accepted for indicating a harmful treatment effect. However, the fecundity of the surviving insects at this dose rate was only reduced by 20 %, relative to the control. There was no apparent dose-response effect on the fecundity of surviving lacewings, so it was considered unlikely that the slight reduction in fecundity seen in the 12 L MON 52276/ha treatment rate was of biological significance.

This study is therefore, considered to be supportive and unreliable for use in risk assessment.

Assessment and conclusion by RMS:

CP 10.3.2.3 Semi-field studies with non-target arthropods

The risk assessment presented for non-target arthropods indicates low risk for the proposed uses of MON 52276 when applied considering the GAP in field crops, orchards, vineyards and in agricultural/non-agricultural areas for control of invasive species. Therefore, no further studies are required.

CP 10.3.2.4 Field studies with non-target arthropods

The risk assessment presented for non-target arthropods indicates low risk for the proposed uses of MON 52276 when applied considering the GAP in field crops, orchards, vineyards and in agricultural/non-agricultural areas for control of invasive species. Therefore, no further studies are required.

CP 10.3.3 Other routes of exposure for non-target arthropods

The risk assessment presented for non-target arthropods indicates low risk for the proposed uses of MON 52276 when applied considering the GAP in field crops, orchards, vineyards and in agricultural/non-agricultural areas for control of invasive species. Therefore, no further studies are required.

CP 10.4 Effects on Non-Target Soil Meso- and Macrofauna

Studies on effects of the representative formulation MON 52276 on soil organisms to fulfil the data requirements according to EU Regulation No 284/2013 are presented in the following.
Studies considering the toxicity of glyphosate, relevant metabolites and MON 52276 to soil meso- and macrofauna were assessed for their validity to current and relevant guidelines. The results of these studies demonstrate that glyphosate, glyphosate salts, AMPA and MON 52276 are all of low toxicity to soil organisms.
Relevant and reliable studies for the risk assessment of glyphosate and relevant metabolites are summarised in the tables below. Details of the studies are summarised in the Document M-CA, Section 8, point 8.4.

Table 10.4-1: Endpoints and effect values for glyphosate relevant for the risk assessment for soil organisms

Reference	Test item	Species	Test design/ GLP	NOEC (mg a.e./kg dry soil)
[redacted] 2009 CA 8.4.1/001	Glyphosate IPA-salt	*Eisenia fetida andrei*	Mixed into substrate 56 d, chronic 10 % peat content	**≥ 473**
[redacted], 2009 CA 8.4.2.1/002	Glyphosate IPA-salt	*Hypoaspis aculeifer*	Mixed into substrate 14 d, chronic 5 % peat content	**≥ 473**
[redacted], 2010 CA 8.4.2.1/001	Glyphosate IPA-salt	*Folsomia candida*	Mixed into substrate 28 d, chronic 10 % peat content	**587**

a.e. glyphosate acid equivalents
Endpoints in **bold** are used for risk assessment

Table 10.4-2: Endpoints and effect values for AMPA relevant for the risk assessment for soil organisms

Reference	Test item	Species	Test design/ GLP	NOEC (mg/kg dry soil)
[redacted], 2003 CA 8.4.1/003	AMPA	*Eisenia fetida fetida*	Mixed into substrate 56 d, chronic 10 % peat content	**131.9**

Table 10.4-2: Endpoints and effect values for AMPA relevant for the risk assessment for soil organisms

Reference	Test item	Species	Test design/ GLP	NOEC (mg/kg dry soil)
[redacted], 2010 CA 8.4.2.1/004	AMPA	*Hypoaspis aculeifer*	Mixed into substrate 14 d, chronic 5 % peat content	**≥ 320**
[redacted] 2010 CA 8.4.2.1/003	AMPA	*Folsomia candida*	Mixed into substrate 28 d, chronic 5 % peat content	**≥ 315**

Endpoints in **bold** are used for risk assessment

A study with the representative product MON 52276 is available and has also been assessed for validity to current and relevant guidelines and is summarised in the following table.

Table 10.4-3: Studies on the toxicity of MON 52276 to soil organisms

Annex point	Study reference	Study type	Test species	Test design	Status
CP 10.4.1.1	[redacted] 2020	Chronic	*Eisenia andrei*	MON 52276	Valid

Endpoints of studies for MON 52276 considered valid are shown in the table below.

Table 10.4-4: Endpoints: studies on toxicity of MON 52276 to soil organisms

Reference	Test item	Species	Test design/ GLP	LC_{50} (mg a.e./kg dry soil)	NOEC (mg a.e./kg dry soil)
[redacted], 2020 CP 10.4.1.1/001	MON 52276	*Eisenia fetida*	Mixed into substrate 56 d, chronic 10 % peat content	-	≥ 38

a.e. glyphosate acid equivalents

The earthworm chronic study with MON 52276 shows a 'greater than' endpoint of ≥ 38 mg a.e./kg dw soil. The endpoint with the active substance glyphosate is also a 'greater than' endpoint ≥ 473 mg a.e./kg dw soil. Therefore, the risk assessment will be based on the higher endpoint for the active substance glyphosate of ≥ 473 mg a.e./kg dw soil, as there is no significant difference in the toxicity exhibited by the product compared to the active substance to earthworms.

Studies with the representative formulation MON 52276 are not currently available for soil organisms other than earthworms. However, additional data for the risk assessment evaluating the toxicity of MON 52276 to *Folsomia candida* and *Hypoaspis aculeifer* are currently being generated. Low toxicity is expected based on the observed effects of MON 52276 to earthworms and also the effect of glyphosate IPA salt on *Folsomia candida* and *Hypoaspis aculeifer.*

There are no literature articles and peer-reviewed published data considered to be relevant and reliable or reliable with restrictions with regards to the impact of glyphosate or its relevant metabolites on soil organisms. Full literature evaluation is provided in document M-CA Section 9. A summary of previously evaluated peer reviewed literature from the RAR 2015 is also available in Annex M-CA 8-01 of the document M-CA Section 8.

CP 10.4.1 Earthworms

Chronic earthworm toxicity studies have been conducted with glyphosate, the main metabolite AMPA and the product MON 52276 and are considered in the risk assessment.

Risk assessment for soil organisms

The evaluation of the risk is performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev. 2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

The PEC_{soil} calculations considered the lowest and highest application rates for each of the uses presented in the GAP, a 0 % foliar interception, a soil depth of 5 cm, and a bulk density of 1.5 g/cm^3. Where appropriate in addition to the worst case soil depth of 5 cm, a PEC_{soil} value was calculated for a 20 cm soil depth to account for tillage of the soil. A detailed description of PEC_{soil} calculations for glyphosate and its metabolite AMPA is provided in the Document M-CA, Section 7.

Due to slow degradation of glyphosate and its metabolite AMPA in soil (DT_{90} > 365 d, field data) the accumulation potential of both substances needs to be considered. The PEC_{soil} accumulation values for both glyphosate and AMPA are worst case at the 5 cm soil depth as expected due to lack of disturbance and dilution through tillage. Therefore, for this risk assessment, the TER values were determined for glyphosate and AMPA based on the ratio of the NOEC (chronic) values to the worst case accumulation $PEC_{soil,\ accu}$ at a soil depth of 5 cm.

The studies conducted with glyphosate, AMPA and MON 52276 were conducted in soils with 5 % or 10 % organic matter. However, as the log P_{ow} values for glyphosate and AMPA are < 2, there was no need to reduce the endpoints by a factor of 2 in order to account for the organic matter content of the artificial test soil.

The table below indicates how the risk assessment for soil organisms has covered all the proposed uses presented in the GAP. The risk assessment presented here is shown by the 'X' in the table, which represents the worst case PEC_{soil} values selected based on the maximum application to soil per year and the crop type for the proposed uses of MON 52276.

Table 10.4.1-1: Risk assessment strategy for soil organisms

GAP number and summary of use	Maximum application to soil g/ha (per year unless otherwise stated)								
	1 x 540	**1 x 720**	**1 x 1440**	**1 x 1800**	**1 x 2160**	**1 x 2880**	**1 x 3600**	**1 x 540 (every 3rd yr)**	**1 x 720 (every 3rd yr)**
Uses 1a-c: Applied to weeds; pre-sowing, pre-planting, pre-emergence of **field crops.**		X	X						
Uses 2 a-c: Applied to weeds; post-harvest, pre-sowing, pre-planting of **field crops.**		X	X		X				
Use 3 a-b: Applied to cereal volunteers; post-harvest, pre-sowing, pre-planting of **field crops.**	X							X	
Use 4 a-c: Applied to weeds (post emergence) below trees in **orchards.**		X	X			X			
Use 5 a-c: Applied to weeds (post emergence) below vines in **vineyards**		X	X			X			
Use 6 a-b: Applied to weeds (post emergence) in **field crops BBCH < 20**		X	X						
Use 7 a-b: Applied to weeds (post emergence) around **railroad tracks**				X			X		
Use 8 and 9: Applied to invasive species, Giant hogweed and Japanese knot weed (post emergence) in **agricultural and non-agricultural areas**				X					
Uses 10 a-c: Applied to couch grass; post-harvest, pre-sowing, pre-planting of **field crops**		X	X						X

X = this use is covered by the application rate given and PEC_{soil} values are available in the Document M-CA, Section 7.

The soil organisms risk assessment results are presented according to the uses described in the table above and grouped as follows:

- in **field crops**; covering GAP uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c.
- in **orchards**/vineyards; covering GAP uses 4 a-c, 5 a-c.
- around **railroad tracks;** covering GAP uses 7 a-b.
- in **agricultural and non-agricultural areas** to control of invasive species; covering GAP uses 8, 9.

The resulting TER values are shown in the tables below.

Table 10.4.1-2: First-tier assessment of the chronic risk for earthworms due to the use of MON 52276 – field crops *(Uses: 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c)*

Chronic effects on earthworms			
Intended use	Field crops (1 × 2160 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	4.236	111.7
AMPA	131.9	3.621	36.4
Intended use	Field crops (1 × 1440 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil. accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	2.824	167.5
AMPA	131.9	2.414	54.6
Intended use	Field crops (1 × 720 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	1.412	335.0
AMPA	131.9	1.207	109.3
Intended use	Field crops (1 × 540 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	1.059	446.6
AMPA	131.9	0.905	145.7
Intended use	Field crops (1 × 540 g/ha, every 3rd year)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	0.833	567.8
AMPA	131.9	0.500	263.8
Intended use	Field crops (1 × 720 g/ha, every 3rd year)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	1.111	425.7
AMPA	131.9	0.667	197.8

[1] TER: toxicity to exposure ratio = Endpoint / PEC_{soil} given in mg glyphosate acid equivalents/kg dw.

Table 10.4.1-3: First-tier assessment of the chronic risk for earthworms due to the use of MON 52276 – orchards and vineyards *(Uses: 4 a-c, 5 a-c)*

Chronic effects on earthworms			
Intended use	Orchards/vineyards (1 × 2880 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil,\ accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	5.648	83.7
AMPA	131.9	4.828	27.3
Intended use	Orchards/vineyards (1 × 1440 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil.\ accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	2.824	167.5
AMPA	131.9	2.414	54.6
Intended use	Orchards/vineyards (1 × 720 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil,\ accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	1.412	335.0
AMPA	131.9	1.207	109.3

[1] TER: toxicity to exposure ratio = Endpoint / PEC_{soil} given in mg glyphosate acid equivalents/kg dw.

Table 10.4.1-4: First-tier assessment of the chronic risk for earthworms due to the use of MON 52276 – post-emergence of weeds around railroad tracks *(Uses: 7 a-b)*

Chronic effects on earthworms			
Intended use	Railroad tracks (1 × 3600 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil,\ accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	7.06	67.0
AMPA	131.9	6.035	21.9
Intended use	Railroad tracks (1 × 1800 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil,\ accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	3.53	134.0
AMPA	131.9	3.017	43.7

[1] TER: toxicity to exposure ratio = Endpoint / PEC_{soil} given in mg glyphosate acid equivalents/kg dw.

Table 10.4.1-5: First-tier assessment of the chronic risk for earthworms due to the use of MON 52276 – control of invasive species in agricultural and non-agricultural areas *(Uses: 8 and 9)*

Chronic effects on earthworms			
Intended use	Control of invasive species (1 × 1800 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil,\ accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	3.53	134.0
AMPA	131.9	3.017	43.7

[1] TER: toxicity to exposure ratio = Endpoint / PEC_{soil} given in mg glyphosate acid equivalents/kg dw.

The TER values calculated using worst-case accumulation $PEC_{soil\ accu}$ values for glyphosate and its metabolite AMPA exceed the relevant trigger values (TER ≥ 5), indicating that the risk to earthworms is acceptable following the proposed uses of MON 52276.

CP 10.4.1.1 Earthworms – sub-lethal effects

1. Information on the study

Data point	CP 10.4.1.1/001
Report author	[redacted]
Report year	2020
Report title	MON 52276: Effects on survival, growth and reproduction of the earthworm *Eisenia andrei* tested in artificial soil
Report No	20 48 TEC 0028
Document No	BI-2019-0632
Guidelines followed in study	OECD 222 (2016), ISO 11268-2 (2012)
Deviations from current test guideline	Deviation from guideline OECD 222 (2016): Major: - none Minor: - none
Previous evaluation	No, not previously submitted
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 1

2. Full summary

Executive Summary

The effects of MON 52276 (360 g/L glyphosate acid equivalent) on *Eisenia andrei* were tested in a 56-days sublethal laboratory test (according to OECD 222) with regard to the parameters mortality, behavioural and pathological symptoms, body weight change and reproduction in OECD soil containing 10 % sphagnum peat. The test was conducted with nominal test concentrations of 11.7, 16.3, 22.9, 32.0, 44.8, 62.8, 87.9, 123 mg test item/kg soil dry weight, equivalent to 3.6, 5.0, 7.1, 9.9, 14, 19, 27, 38 mg a.e./kg soil dry weight, respectively. In addition, a control group was exposed to soil mixed with deionised water only.
After 56 days, the test item caused no mortality at any tested concentrations and control. No effects on behaviour (including feeding activity) of the worms were observed during the test. The test item caused no statistically significant change in biomass and in number of juveniles when compared to the control group. Therefore, No-Observed-Effect-Concentration (NOEC) for reproduction was determined to be ≥ 38 mg a.e./kg soil dry weight, and the Lowest-Observed-Effect-Concentration (LOEC) was determined to be > 38 mg a.e./kg soil dry weight. All validity criteria according to the OECD guideline 222 were fulfilled.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item:	MON 52276
Description:	Yellow liquid
Lot/Batch #:	11511167 (manufacturing lot AZE200810A)
Purity:	360 g/L glyphosate acid equivalent (nominal) 362 g/L glyphosate acid equivalent (analysed)
2. Vehicle and/or positive control:	Maypon Flow (carbendazim, SC 500), tested in a separate study
3. Test organism:	
Species:	Earthworm (*Eisenia andrei* (BOUCHE, 1972))
Age:	Adults, approx. 4 months old with clitellum
Weight:	270 – 423 mg/worm
Source:	In-house rearing (originally from W. Neudorff GmbH KG, An der Mühle 3, 31860 Emmerthal, Germany)
Food:	Air-dried and finely ground horse manure
Acclimation period:	Approx. 24 hours in the artificial substrate
4. Environmental conditions:	
Temperature:	19.9 – 21.8 °C
Photoperiod:	16 h light (630 Lux)/ 8 h dark
Soil pH:	5.99 – 6.06 (test start); 5.74 – 5.83 (test termination)
Soil moisture content:	test start: 34.9 – 35.0 (equivalent to 56.0 – 56.2 % of WHC) test end: 34.3 – 34.8 (equivalent to 55.1 – 55.9 % of WHC) (difference between start and end of the test: max. 2.0 %)
5. Experimental work dates:	2020-02-26 to 2020-04-22

B. STUDY DESIGN AND METHODS

1. Experimental treatments: A sublethal test was conducted with nominal test concentrations of 11.7, 16.3, 22.9, 32.0, 44.8, 62.8, 87.9, 123 mg test item/kg soil dry weight, equivalent to 3.6, 5.0, 7.1, 9.9, 14, 19, 27, 38 mg a.e./kg soil dry weight, respectively. In addition, a control group was exposed to soil mixed with deionised water only. The test concentrations were prepared by dispersing an exact weighed amount of the test item in deionised water (stock solutions) and thereafter diluted to obtain different test concentrations, which were thoroughly mixed with the artificial soil, achieving desired test concentrations with a final nominal water content of 40 – 60 % of WHC. The artificial soil substrate was composed of 10 % sphagnum peat, 20 % kaolin clay, 69.5 % industrial quartz sand and 0.5 % calcium carbonate. Four replicate test containers (test item) and 8 replicate test containers (control) with 675 g soil (wet weight) were prepared for each treatment group. 10 adult earthworms were exposed per replicate for 56 days.
As a toxic reference, earthworms were exposed in a separate study to Maypon Flow (carbendazim, SC 500). The results are in line with the OECD requirements (53 and 99 % of reduction in the number of juveniles at concentrations of 5 and 10 mg product/ kg dry soil respectively).

2. Observations: At test initiation, individual fresh weight, behavioural responses of earthworms and physico-chemical parameters of the artificial soil were recorded. Behavioural and pathological symptoms including feeding activity were observed on a weekly basis. Four weeks after test initiation, number of surviving adult earthworms and fresh weight of surviving adult earthworms per replicate were recorded. At test termination (8 weeks after test initiation), number of surviving juveniles per replicate, observation of behavioural/pathological symptoms and determination of physico-chemical parameters of the artificial soil were observed.

3. Statistical calculations: The Williams-t-test was used to compare the control with the independent test item groups. For statistical evaluation of the biomass change, the changed mean fresh weight of surviving worms per replicate was used. The statistical analysis was performed with the software ToxRat Professional 3.2.1 (Ratte 2015).

II. RESULTS AND DISCUSSION

A. FINDINGS

Table 10.4.1.1-1 Sublethal effects of MON 52276 on earthworms

MON 52276 [mg a.e./kg soil d.w.]	Control	3.6	5.0	7.1	9.9	14	19	27	38
Mortality of adult worms after 4 weeks (%)	0	0	0	0	0	0	0	0	0
Mean biomass change (%)	27.9	26.2	28.2	29.1	27.7	28.9	25.6	28.4	26.6
Mean number of juveniles per replicate after 8 weeks	222.9	225.5	218.5	232.3	223.5	214.5	211.3	227.3	221.0
CV %	12.8	26.8	17.0	8.3	18.0	13.0	20.0	16.7	23.5
Change of reproduction compared to control (%)	-	101.2	98.0	104.2	100.3	96.2	94.8	102.0	99.2
EC_{10} / EC_{20}	Not determined								
LOEC	> 38 mg a.e./kg soil d.w.								
NOEC	≥ 38 mg a.e./kg soil d.w.								

a.e.= acid equivalent

B. OBSERVATIONS

Mortality rates of 0 % were recorded in the test item treatment groups and in the control. No pathological symptoms and no effects on behaviour (including feeding activity) of the worms were observed during the test. The weight change of adult worms ranged between 25.6 and 29.1 % in the treated groups and 27.9 % in the control group. The test item caused no statistically significant change in biomass compared to the control groups at any concentration tested. No statistically significant effects on the number of juveniles compared to the control group were found at any concentration tested. Due to the lack of a concentration-response relationship no reliable EC_x-calculation is possible. Therefore, no EC_{10} / EC_{20}-value can be reported. Therefore, NOEC for reproduction was determined to be ≥ 38 mg a.e./kg soil dry weight, and LOEC was determined to be > 38 mg a.e./kg soil dry weight.

The validity criteria according to guideline OECD 222 are fulfilled as each replicate (containing 10 adults) has produced ≥ 30 juveniles by the end of the test in the control (actual value: 222.9 juveniles),the coefficient of variation of reproduction was ≤ 30 % in the control (actual value: 12.8 %) and adult mortality over the initial 4 weeks of the test was ≤ 10 % in the control (actual value: 0 %).

III. CONCLUSIONS

Assessment and conclusion by applicant:

The effects of glyphosate on mortality and reproduction of earthworms (*Eisenia andrei*) were assessed following application of MON 52276 under laboratory conditions and according to OECD 222.

The EC_{10} / EC_{20} of MON 52276 for earthworm reproduction could not be calculated due to lack of effects. The overall NOEC was determined to be ≥ 38 mg a.e./kg dry soil, equivalent to 123 mg test item/kg dry soil. The overall LOEC was determined to be > 38 mg a.e./kg soil d.w.

The study is considered valid and is suitable for risk assessment purposes.

Assessment and conclusion by RMS:

CP 10.4.1.2 Earthworms – field studies

The risk assessment presented for earthworms based on the technical material and the representative formulation, indicates a low-exposure risk to earthworms, for the proposed uses of MON 52276 when applied in accordance with the proposed GAP for uses in field crops, orchards, vineyards, railroad tracks and in agricultural/non-agricultural areas for the control of invasive species. Therefore, field studies with earthworms are not required.

CP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Chronic toxicity studies have been conducted with glyphosate and the main metabolite AMPA, to assess the toxicity to *Hypoaspis aculeifer* and *Folsomia candida.* The relevant and reliable endpoints for use in risk assessment are summarised in Table 10.4-1 and 10.4-2.

Risk assessment for soil meso- and macrofauna (other than earthworms)

The risk assessment is based on the approach as described for earthworms above in Section 10.4.1, using the $PEC_{soil,accu}$ values for glyphosate and its main metabolite AMPA, as provided in the Document M-CA, Section 7. The resulting TER values are presented below for the proposed uses of MON 52276 in field crops, orchards, vineyards, railroad tracks and agricultural and non-agricultural areas to control invasive species as detailed in Table 10.4.1-1 above.

Table 10.4.2-1: First-tier assessment of the chronic risk to *Hypoaspis aculeifer* from glyphosate and AMPA, considering uses in field crops *(Uses: 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c)*

Chronic effects on *Hypoaspis aculeifer*			
Intended use	Field crops (1 × 2160 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	4.236	111.7
AMPA	320	3.621	88.4
Intended use	Field crops (1 × 1440 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	2.824	167.5
AMPA	320	2.414	132.6

Table 10.4.2-1: First-tier assessment of the chronic risk to *Hypoaspis aculeifer* from glyphosate and AMPA, considering uses in field crops *(Uses: 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c)*

Chronic effects on *Hypoaspis aculeifer*			
Intended use	Field crops (1 × 720 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil, accu}$ (mg/kg)**	**TER$_{lt}$[1]**
Glyphosate	473	1.412	335.0
AMPA	320	1.207	265.1
Intended use	Field crops (1 × 540 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil, accu}$ (mg/kg)**	**TER$_{lt}$[1]**
Glyphosate	473	1.059	446.6
AMPA	320	0.905	353.6
Intended use	Field crops (1 × 540 g/ha, every 3rd year)		
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil, accu}$ (mg/kg)**	**TER$_{lt}$[1]**
Glyphosate	473	0.833	567.8
AMPA	320	0.500	640.0
Intended use	Field crops (1 × 720 g/ha, every 3rd year)		
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil, accu}$ (mg/kg)**	**TER$_{lt}$[1]**
Glyphosate	473	1.111	425.7
AMPA	320	0.667	479.8

[1] TER: toxicity to exposure ratio = Endpoint / PEC$_{soil}$ given in mg glyphosate acid equivalents/kg dw.

Table 10.4.2-2: First-tier assessment of the chronic risk to *Folsomia candida* from glyphosate and AMPA, considering uses field crops *(Uses: 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c)*

Chronic effects on *Folsomia candida*			
Intended use	Field crops (1 × 2160 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil. accu}$ (mg/kg)**	**TER$_{lt}$[1]**
Glyphosate	587	4.236	138.6
AMPA	315	3.621	87.0
Intended use	Field crops (1 × 1440 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil, accu}$ (mg/kg)**	**TER$_{lt}$[1]**
Glyphosate	587	2.824	207.9
AMPA	315	2.414	130.5
Intended use	Field crops (1 × 720 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil, accu}$ (mg/kg)**	**TER$_{lt}$[1]**
Glyphosate	587	1.412	415.7
AMPA	315	1.207	261.0
Intended use	Field crops (1 × 540 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil, accu}$ (mg/kg)**	**TER$_{lt}$[1]**
Glyphosate	587	1.059	554.3
AMPA	315	0.905	348.1
Intended use	Field crops (1 × 540 g/ha, every 3rd year)		
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil, accu}$ (mg/kg)**	**TER$_{lt}$[1]**
Glyphosate	587	0.833	704.7
AMPA	315	0.500	630.0

Table 10.4.2-2: First-tier assessment of the chronic risk to *Folsomia candida* from glyphosate and AMPA, considering uses field crops *(Uses: 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c)*

Chronic effects on *Folsomia candida*			
Intended use	Field crops (1 × 720 g/ha, every 3rd year)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	587	1.111	528.4
AMPA	315	0.667	472.3

[1] TER: toxicity to exposure ratio = Endpoint / PEC_{soil} given in mg glyphosate acid equivalents/kg dw.

Table 10.4.2-3: First-tier assessment of the chronic risk to *Hypoaspis aculeifer* from glyphosate and AMPA, considering uses orchards and vineyards *(Uses: 4 a-c and 5 a-c)*

Chronic effects on *Hypoaspis aculeifer*			
Intended use	Orchards/vinyards (1 × 2880 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	5.648	83.7
AMPA	320	4.828	66.3
Intended use	Orchards/vinyards (1 × 1440 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	2.824	167.5
AMPA	320	2.414	132.6
Intended use	Orchards/vinyards (1 × 720 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	1.412	335.0
AMPA	320	1.207	265.1

[1] TER: toxicity to exposure ratio = Endpoint / PEC_{soil} given in mg glyphosate acid equivalents/kg dw.

Table 10.4.2-4: First-tier assessment of the chronic risk to *Folsomia candida* from glyphosate and AMPA, considering uses orchards and vineyards *(Uses: 4 a-c and 5 a-c)*

Chronic effects on *Folsomia candida*			
Intended use	Orchards/vinyards (1 × 2880 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	587	5.648	103.9
AMPA	315	4.828	65.2
Intended use	Orchards/vinyards (1 × 1440 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	587	2.824	207.9
AMPA	315	2.414	130.5
Intended use	Orchards/vinyards (1 × 720 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	587	1.412	415.7
AMPA	315	1.207	261.0

[1] TER: toxicity to exposure ratio = Endpoint / PEC_{soil} given in mg glyphosate acid equivalents/kg dw.

Table 10.4.2-5: First-tier assessment of the chronic risk to *Hypoaspis aculeifer* from glyphosate and AMPA, considering uses post emergence of weeds around railroad tracks *(Uses: 7a-c)*

Chronic effects on *Hypoaspis aculeifer*			
Intended use	Railroad tracks (1 × 3600 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	7.06	67.0
AMPA	320	6.035	53.0
Intended use	Railroad tracks (1 × 1800 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	3.53	134.0
AMPA	320	3.017	106.1

[1] TER: toxicity to exposure ratio = Endpoint / PEC_{soil} given in mg glyphosate acid equivalents/kg dw.

Table 10.4.2-6: First-tier assessment of the chronic risk to *Folsomia candida* from glyphosate and AMPA, considering uses post emergence of weeds around railroad tracks *(Uses: 7a-c)*

Chronic effects on *Folsomia candida*			
Intended use	Railroad tracks (1 × 3600 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	587	7.06	83.1
AMPA	315	6.035	52.2
Intended use	Railroad tracks (1 × 1800 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	587	3.53	166.3
AMPA	315	3.017	104.4

[1] TER: toxicity to exposure ratio = Endpoint / PEC_{soil} given in mg glyphosate acid equivalents/kg dw.

Table 10.4.2-7: First-tier assessment of the chronic risk to *Hypoaspis aculeifer* from glyphosate and AMPA, considering uses control of invasive species in agricultural and non-agricultural areas *(Uses: 8 and 9)*

Chronic effects on *Hypoaspis aculeifer*			
Intended use	Control of invasive species (1 × 1800 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil, accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	473	3.53	134.0
AMPA	320.0	3.017	106.1

[1] TER: toxicity to exposure ratio = Endpoint / PEC_{soil} given in mg glyphosate acid equivalents/kg dw.

Table 10.4.2-8: First-tier assessment of the chronic risk to *Folsomia candida* from glyphosate and AMPA, considering uses control of invasive species in agricultural and non-agricultural areas *(Uses: 8 and 9)*

Chronic effects on *Folsomia candida*			
Intended use	Control of invasive species (1 × 1800 g/ha)		
Product/active substance	**NOEC (mg/kg dw)**	**$PEC_{soil,\ accu}$ (mg/kg)**	**TER_{lt}[1]**
Glyphosate	587	3.53	166.3
AMPA	315	3.017	104.4

[1] TER: toxicity to exposure ratio = Endpoint / PEC_{soil} given in mg glyphosate acid equivalents/kg dw.

The TER values calculated using worst-case $PEC_{soil,accu}$ values for glyphosate and its metabolite AMPA, exceed the relevant trigger value (TER ≥ 5), indicating that the risk to other non-target soil organisms is acceptable following the proposed uses of MON 52276.

Indirect effects via Trophic Interactions

The ecotoxicology regulatory study dataset for glyphosate and AMPA includes a battery of OECD test guideline studies, designed to assess the potential long-term effects on the structure and function of soil organism communities. For the Tier 1 assessment, studies were conducted using ecologically important indicators of soil organism community structure and function (see Table 10.4.2-9). These studies include long-term reproduction studies using a representative earthworm, a representative collembolan, and a representative predatory mite. Earthworms are tested because they play an important role as detritivores in soil communities. Collembola, which are the most abundant soil macro-organism, are also tested because they play an important role as detritivores and nutrient cycling in soil organism communities. Predatory mites are important to the battery in that they provide information on potential impacts to food chain interactions and biological control within soil organism communities.

Soil organisms contribute to a wide range of essential ecosystem services important for the function of terrestrial ecosystems, acting as the primary driving agents of nutrient cycling and regulating the dynamics of soil organic matter formation and decomposition, soil carbon sequestration, and greenhouse gas emission.

Soil macro-organisms modify soil physical structure and hydraulic properties that influence root growth, root function, and nutrient acquisition. Soil biodiversity is responsive to the management of cultivated systems (Schreck *et al.*, 2012; Trivino-Tarrades *et al.* 2019). Cultivation drastically affects the soil environment and hence the organisms present and their number (Trivino-Tarrades *et al.* 2019; Brussaard *et al.* 2007). Conservation tillage or minimal tillage generally have positive impacts on soil organism densities, diversity, and microbial content. No-till fields typically have significantly more beneficial insects, earthworms and earthworm diversity, higher organic matter and microbial content (Chan, 2001).

The following approach has been taken to assess potential indirect effects via trophic interactions, considers the proposed Specific Protection Goals drawn from the existing EU guidance and working documents, and the 2016 EFSA Guidance on developing protection goals for ecological risk assessments (ERA) for pesticides. The SPGs based on direct effects assessment considering representative sensitive populations across the tested trophic levels. The biodiversity assessment, aimed to develop a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals, that includes considering indirect effects via trophic interaction.

For example, reduced application rates relative to previous Annex I renewals, a reduced overall application volume of product on the land, and inclusion of no-spray buffer zones - a standard mitigation measure to protect non-target plant communities in off-target areas, which indirectly supports soil macro-organisms biodiversity, by maintaining soil structure and function in both in-field and off-field areas.

When defining SPGs for soil macro-organisms that reflects both direct and indirect effects, it is the responsibility of the risk assessors in the Member States to acknowledge existing protection goals and regulatory data requirements, to propose possible SPG options, and describe the possible environmental consequences of each option. The risk assessors within the Member States will need to propose realistic SPGs and exposure assessment goals and the interrelationships between them in a clear and transparent manner

Specific protection goal (SPGs) for soil organisms still need to be adopted. However, for the purpose of this biodiversity assessment, two SPGs have been developed that overall, are considered consistent with current [38]EFSA (2016) opinion on soil organisms and are likely be adopted in future EFSA guidance.

The first SPG is aimed at protecting the structure and function (e.g., detritivory) of soil macro-organism communities and the function of soil micro-organism communities. The second SPG is related to the first and is aimed at the protection of soil services (e.g., decomposition and cycling of organic matter and nutrients).

In the Annex 1 renewal, glyphosate and the representative formulation were shown to have low toxicity and an acceptably low long-term risk on the structure and function of soil macro-organisms, the functioning of soil micro-organism communities (– see next section for soil micro-organisms), and risk mitigations were required (EFSA, 2015a). This is further supported by the direct effects assessment for soil meso-organisms as presented in this section above.

Scientific Literature that informs the Soil Organism Risk Assessment

Literature review for non-target soil organisms from the previous Annex I (2012) submission.
The scientific literature review conducted for the last Annex I renewal (submitted in 2012) contains an extensive review of ecotoxicological papers considered relevant but supplementary to the Annex I renewal.

These papers presented information that could not be relatable to an EU level ecotoxicological risk assessment, but that were considered in the previous dossier as being supportive following re-evaluation by the previous RMS. A further evaluation of these literature papers according to the EFSA literature review approach used in this dossier has not been conducted. The previous literature review has been submitted as part of the Literature review requirements and is presented in Annex M-CA 8-01 of the M-CA Section 8.

The scientific literature review conducted for the last Annex I renewal (submitted in 2012) contains a review of ecotoxicological papers considered relevant to the area of soil macro-organisms and glyphosate. A total of 21 peer reviewed papers were submitted, with 5 citing studies focusing on earthworms and considered as supporting information for the risk assessment (Casabe *et al.*, 2007; . Correia *et al.*, 2012; Kaneda *et al.*, 2009; Verrel *et al.*, 2004 and Yasmin *et al.*, 2003). The full evaluation of these papers by the previous RMS (UBA) may be found in Annex M-CA 8-01 of the document M-CA Section 8.

The previous RMS (UBA) concluded on the submitted references, several points on acute exposure effects which are not considered relevant to the risk assessment as acute effects on soil organisms is now not a data requirement under Regulation (EC) No 1107/2009.

[38] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), Ockleford C, Adriaanse P, Berny P, Brock T, Duquesne S, Grilli S, Hernandez-Jerez AF, Bennekou SH, Klein M, Kuhl T, Laskowski R, Machera K, Pelkonen O, Pieper S, Stemmer M, Sundh I, Teodorovic I, Tiktak A, Topping CJ, Wolterink G, Craig P, de Jong F, Manachini B, Sousa P, Swarowsky K, Auteri D, Arena M and Rob S, 2017. Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms. EFSA Journal 2017;15(2):4690, 225 pp. doi:10.2903/j. efsa.2017.4690

There were effects on reproduction examined by Casabe *et al.*, (2007) and Yasmin *et al.*, (2003) that considered commercial formulations other than the representative formulation, but it was concluded that these effects were not relevant at the population level in nature.

In a reproduction test with *Eisenia fetida*, conducted with the active substance glyphosate (Correia *et al.*, 2012), earthworms were maintained in treated soil and classified as alive after the evaluation period, but with bodyweight effects across all test concentrations. Moreover - morphological abnormalities like elevating the body, coiling, and curling were observed in all specimens exposed to the highest concentrations of glyphosate (1000 mg/kg). Further behavioural abnormalities were described in terms of reduced casting production (Kaneda *et al.*, 2009), reduced cocoon viability, a reduction in the feeding activity (Casabé *et al.*, 2007) or reduced body weight (Yasmin *et al.*, 2006). However, the test rates were similar or above the one tested in the officially submitted studies, so that the outcome of the risk assessment for earthworm did not change.

In the current direct effects assessment, the results of a recent earthworm reproduction study were presented with worms exposed to the representative formulation (MON 52276) where there were no sub-lethal effects up to the maximum rate (1000 mg a.e./kg soil dw) tested, in either bodyweight effects at 28 days nor juvenile production at 56 days.

Concerning the current literature review, there were no literature articles that were considered relevant and reliable on soil meso-organisms, for use in the ecotoxicological risk assessment for Annex I renewal. There were 9 peer reviewed papers considered relevant but supplementary to the risk assessment for soil meso-organisms (Correia *et al.*, 2010, Dominguez *et al.*, 2016, Gaupp-Berghausen *et al.*, 2015, Jarmul-Pietraszczyk *et al.*, 2015, Nathan *et al.*, 2019, Pochron *et al.*, 2019, Santos *et al.*, 2012, Sihtmaee *et al.*, 2013 and Stellin *et al.*, 2017). An 11th paper was found relevant and reliable (Von Merey *et al.*, 2016). These data reviewed in this paper, exist in the regulatory list of endpoints. They will not be considered further in this review as data from this paper is used in the presented risk assessment for soil meso-organisms in this dossier.

Correia *et al.*, (2010), performed an earthworm reproduction study using a Brazilian soil at test concentrations between 1 and 1000 mg/kg soil dw. This study did not present any data that could be used in an EU level risk assessment for renewal purposes and was therefore considered to be supplementary. In studies by Dominguez *et al.*, 2016, Santoz *et al.*, 2012 and Santadino *et al.*, 2014 despite being conducted according to recognised test guidelines, the validity of the studies could not be confirmed due to lack of critical information in the papers.

Concerning indirect effects that may inform on trophic interactions, the biological availability of glyphosate and AMPA in soil is considered relevant. In a comprehensive study of 317 European agricultural soils, glyphosate and AMPA were found in 21 and 42 % of the samples, respectively (Silva *et al.* 2018). Concentrations of glyphosate or AMPA rarely exceeded 0.5 mg a.e./kg of soil, and the highest level detected was 2.05 mg a.e./kg. This maximum level of glyphosate detected is more than 2-times less than the predicted environmental soil concentration used for the standard glyphosate soil organism assessment, which considered a worst-case exposure scenario (i.e., the maximum use rate and maximum potential to build up in soil). See direct effects assessments for soil organisms above in this section.

Biodiversity Assessment

After a though literature search and considering all relevant guidance, the following approach is taken to assess potential indirect effects via trophic interactions and the impact on biodiversity, was to develop a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals. In the Table 10.4.2-9, the specific protection goals relevant to soil meso-fauna are presented with the relationship between the SPGs, the direct effects study types, assessment and measurement endpoints. The assessment endpoint is an explicit expression of an environmental entity and the specific property of that entity to be protected. Measurement endpoints relates directly to the effects study endpoints.

A conclusion that a given data requirement has been satisfied, requires that an acceptable level of risk has been achieved (i.e. there is a protective margin of exposure or through a weight of evidence).

Based on the measurement endpoints from the study types, and the direct effects assessment presented above in this section, it is anticipated that for the proposed uses on the GAP table, that there will be no impacts on soil meso-organisms population (e.g. earthworms, collembola and hypoaspis) survival, growth and reproduction, which in turn meets the specific protection goal for soil meso-organisms.

The Table 10.4.2-9 assessment illustrates that ecological diversity and function of soil meso-organisms within spray zones will be sufficiently maintained to achieve the SPG for this taxa group according to the protection goals as defined in the Terrestrial guidance document (SANCO/10329/2000) sustains a food resource for other animals, primarily birds and mammals within in -field areas, sustains soil structure and function that has a knock on effect of enabling soil function of soil microbial communities. This in turn helps to maintain the community structure within the soil.

Table 10.4.2-9. The relationship between Specific Protection Goals, assessment and measurement endpoints for soil macro- and micro-organisms from foliar applications.

Specific Protection Goals[1]	Assessment Endpoints	Measurement Endpoints	Glyphosate Study Types
Protection of structure (biodiversity) and function of soil macro-organism communities and function of soil micro-organism communities.	Structure and function of soil macro-organism communities Long-term effects on the function of soil micro-organism communities	Survival and reproduction N-transformation rate ≤ 25 % difference from control at ≥ 28 days.	Earthworm chronic Collembola chronic Predatory mite chronic N-transformation rate
Protection of soil services (e.g., decomposition and cycling of organic matter and nutrients)	Long-term effects on the function of soil micro-organism communities (i.e., Nitrogen cycling).	Survival and reproduction N-transformation rate ≤ 25 % difference from control at ≥ 28 days	
Soil Organism Biodiversity Assessment Based on the direct effects assessment, there is low to negligible risk to the structure and function of soil organism populations and communities (EFSA, 2015a) and the likelihood of indirect effects soil organism biodiversity is also considered to be negligible.			

[1] EFSA still needs to receive input from risk managers on the definition of specific protection goals being led by DG SANTE. In the draft Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms1, negligible effects are considered to be ≤ 10 % and small effects are considered to be ≤ 35 %.

Conclusion

Glyphosate is a critical tool to enable conservation tillage systems, which can greatly improve the abundance and biodiversity of soil organisms. There is negligible risk of direct effects to soil community biodiversity and supporting/regulating services related to soil processes. This conclusion is not changed after reviewing reported levels of glyphosate from soil monitoring studies (Silva *et al.* 2018). In addition, based on a review of the relevant and supportive literature, the likelihood of indirect effects soil organism biodiversity is also considered to be negligible.

However, if additional risk mitigation measures are determined to be required, to mitigate indirect effects resulting from in-crop weed control on soil meso-organism populations, there are standard mitigation measure options that may be considered by risk assessors and risk managers within Member States.

Examples of the standard mitigation measures considered applicable at the EU level (MAgPIE, 2017) are presented in the Table 10.4.2-10. Many of these have been considered in the current dossier submission.

Table 10.4.2-10: Examples of standard mitigation measures as described in MAgPIE (2017) across the various Member States to mitigate effects of glyphosate on biodiversity.

Type of Mitigation Measure	Risk Mitigation Measure	Benefits	Glyphosate renewal dossier (2020)
Restrictions or modifications of products' conditions of application	Application rate, Application frequency, application timing, and interval between applications	Lower transfers to groundwater and surface water; Reduces exposure of organisms in-crop and off-crop.	**Significant reductions (50 % in volume) in newly proposed application rates** compared with the representative use presented in the 2012 renewal dossier. See [39]**Appendix 2 of the biodiversity document accompanying this submission**. **Treated area restriction** 16. for the representative use GAPs: applying to only 50 % of the total area in orchard/vineyard area. 17. maximum of 50 % of the total area for broad acre vegetable inter-row 18. Invasive species control e.g., couch grass – maximum of 20 % of the cropland + extended application intervals. **Limited frequency and timing of application:** 28-day interval between applications and no pre-harvest applications
Application equipment with Spray Drift Reduction Technology (SDRT)	Spray drift reduction nozzles (SDRN), shields, Precision treatment, etc.	Reduces exposure of organisms in-crop (precision treatment) and off-crop	**Reduction of spray drift to the off-field**: 11. Use 75 % drift reducing nozzles for pre-sowing/pre-planting in arable crops. 12. Use of ground directed, shielded spray for band application in orchards / vineyards and broad-acre vegetable inter-row application.
Buffer zones	Non-sprayed zone at the edge of a crop	Reduces exposure of organisms and off-crop	**Establishment of buffer zones:** Buffer zones of varying size (depending on the type of SDRT) are required as protection for off-crop NTTP communities from spray drift.

[39] [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

For example, in the current dossier;

- Reductions in maximum annual application rates of up to 50 % considered in this dossier are compared to the maximum rates applied for in the 2012 Annex I renewal dossier.
  - o In 2012, the maximum annual application rate was 4.32 kg/ha.
  - o In the current dossier submission, the maximum annual application rate is 2.16 kg/ha.

- Reducing the total area being applied on a per hectare basis for certain uses, will reduce the total volume of product being applied to the landscape.
  - o For example, controlling actively growing weeds in vineyards, orchards where a reduced area, up to a maximum of 50 % of the total application area is proposed e.g. using strip or band applications. Applications on target weeds, around the base of trees within tree rows, leaving the area between tree rows unsprayed, which is typically managed using mechanical methods.

- The use of shielded or hooded sprayers, hand-held sprayers and drift reducing technologies, e.g. 75 % drift reducing nozzles are recommended for all applications made for the control of actively growing weeds when applied to control invasive species. These measures will further reduce the off-target exposure risk.
- For weed control on railroad tracks, recommendations are made in the GAP table to use precision application equipment on spray trains, that detects, and targets spray directly onto unwanted plants, thereby reducing the amount of product being applied, whilst maintaining an acceptable level of safety on the railroad tracks.

- No spray buffer areas in-field (or compensation areas), are necessary to meet the specific protection goals for avoiding direct effects on non-target plants in off-target areas. This measure will in turn support non-target arthropod communities in off-field areas and reduces further, the potential for indirect effects on bees through trophic interaction.

In addition to the standard mitigation measures, 'non-standard mitigation measures' could also be considered where a local and specific mitigation need is identified. For example, in simplified landscapes or landscapes that are intensively managed, where typically there are limited refuge areas for insects, birds and mammals. Non-standard mitigation measures options could include for example, creation of off-target habitats, utilizing edge of field habitats and semi-field habitats that assist biodiversity by improving wildlife connectivity.

For further information on mitigation measures pleased refer to the supplementary information document[40] titled 'Glyphosate: Indirect Effects via Trophic Interaction – A Practical Approach to Biodiversity Assessment.' that accompanies this dossier submission.

Reference relied upon in the Indirect Effects via Trophic Interaction discussion

Brussaard L, de Ruiter PC, GG Brown. 2007. Soil biodiversity for agricultural sustainability. Agric. Ecosyst. Environ. 121, 233–244.

Chan KY. 2001. An overview of some tillage impacts on earthworm population abundance and diversity - implications for functioning in soils. Soil and Tillage Research. 57:179–191.

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), Ockleford C, Adriaanse P, Berny P, Brock T, Duquesne S, Grilli S, Hernandez-Jerez AF, Bennekou SH, Klein M, Kuhl T, Laskowski R, Machera K, Pelkonen O, Pieper S, Stemmer M, Sundh I, Teodorovic I, Tiktak A, Topping CJ, Wolterink G, Craig P, de Jong F, Manachini B, Sousa P, Swarowsky K, Auteri D, Arena M and Rob

[40] [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

S, 2017. Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms. EFSA Journal 2017;15(2):4690, 225 pp. doi:10.2903/j. efsa.2017.4690

Trivino-Tarradas P, Gomez-Ariza MR, Basch G, EJ Gonzalez-Sanchez. 2019. Sustainability Assessment of Annual and Permanent Crops: The Inspia Model. Sustainability 11:738.

CP 10.4.2.1 Species level testing

Species level testing for the effects of MON 52276 on individual species other than those presented in the above assessment are not required, as an acceptable risk assessment - based on the soil organisms required according to the data requirements, has been presented. Additional species level testing is not therefore considered necessary for application of MON 52276 when applied in accordance with the proposed GAP, for use in field crops, orchards, vineyards, railroad tracks and in agricultural/non-agricultural areas for control of invasive species.

CP 10.4.2.2 Higher tier testing

The risk assessment presented for soil organisms indicates an acceptable risk from glyphosate and AMPA, considering the GAP for use in field crops, orchards, vineyards, railroad tracks and in agricultural/non-agricultural areas for control of invasive species, based on the soil organisms required according to the data requirements. Therefore, no further studies are required. Higher tier testing is not therefore considered necessary for application of MON 52276 when applied in accordance with the proposed GAP.

CP 10.5 Effects on Soil Nitrogen Transformation

Relevant and reliable studies for the risk assessment of soil microflora from the active substance glyphosate and relevant metabolites are summarised in the tables below, presenting the most sensitive endpoints. Details of the studies are summarised in the Document M-CA, Section 8, point 8.5.

Table 10.5-1: Endpoints and effect values for glyphosate relevant for the risk assessment for soil microflora

Reference	Test item	Species	Test design	NOEC (mg a.e./kg dry soil)
[redacted], 2014 CA 8.5/001	Glyphosate acid	N-mineralisation	28 d, aerobic	**≥ 33.1**

a.e. glyphosate acid equivalents
Endpoint in **bold** is used for risk assessment

Table 10.5-2: Endpoints and effect values for AMPA relevant for the risk assessment for soil microflora

Reference	Test item	Species	Test design	NOEC (mg/kg dry soil)
[redacted] 2010 CA 8.5/004	AMPA	N-mineralisation	56 d, aerobic	**≥ 160**

Endpoint in **bold** is used for risk assessment.

Studies on effects of the representative formulation MON 52276 on soil microflora to fulfil the data requirements according to EU Regulation No 284/2013 are presented in the following.

A study with the representative product MON 52276 is available and was also assessed for validity to current and relevant guidelines and is summarised in the following table. A study summary for the study is presented in this section below.

Table 10.5-3: Studies on the toxicity of MON 52276 to soil microflora

Annex point	Study reference	Study type	Substance	Status
CP 10.5	[redacted] 2012	Nitrogen cycle, Carbon cycle, 28 d	MON 52276	Valid

Endpoints of studies considered valid with the representative product MON 52276 are shown in the table below. In order to make a direct comparison of toxicity between studies conducted with MON 52276 and those conducted with IPA salt, glyphosate technical and glyphosate acid, the endpoints from all these studies have been converted to acid equivalents (a.e.). This conversion has been made by the acid equivalent purity of the test item stated in the reports.

Table 10.5-4: Endpoints: studies on toxicity of MON 52276 to soil microflora

Reference	Test item	Test design	NOEC (mg a.e./kg dry soil)	NOEC (kg a.e./ha)
[redacted] 2012 CP 10.5/001	MON 52276	N- mineralisation, 28 d	≥ 28.84	≥ 21.63

a.e. glyphosate acid equivalents

The study with MON 52276 shows a 'greater than' endpoint of ≥ 21.63 mg a.e./kg dry soil. The endpoint with the active substance glyphosate is also a 'greater than' endpoint of ≥ 33.1 mg a.e./kg dry soil. Therefore, the risk assessment will be based on the higher endpoint for the active substance glyphosate of ≥ 33.1 mg a.e./kg dry soil, as there is no significant difference in the toxicity exhibited by the product compared to the active substance to soil microflora.

There are no literature articles and peer-reviewed published data considered to be relevant and reliable or reliable with restrictions with regards to the impact of glyphosate or its relevant metabolites on soil microflora. Full literature evaluation is provided in document M-CA Section 9. A summary of previously evaluated peer reviewed literature from the RAR 2015 is also available in Annex M-CA 8-01 of the M-CA Section 8.

Risk assessment for Soil Nitrogen Transformation

The evaluation of the risk is performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev. 2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

The PEC_{soil} calculations considered the lowest and highest application rates for each of the uses presented in the GAP, a 0 % foliar interception, a soil depth of 5 cm, and a bulk density of 1.5 g/cm^3. Where appropriate in addition to the worst case soil depth of 5 cm, a PEC_{soil} value was calculated for a 20 cm soil depth to account for tillage of the soil. A detailed description of PEC_{soil} calculations for glyphosate and its metabolite AMPA is provided in the Document M-CA, Section 7.

Due to slow degradation of glyphosate and its metabolite AMPA in soil (DT_{90} > 365 d, field data) the accumulation potential of both substances needs to be considered. The PEC_{soil} accumulation values for both glyphosate and AMPA are worst case at the 5 cm soil depth as expected due to lack of disturbance and dilution through tillage. Therefore, the risk assessment was determined for glyphosate and AMPA based on the worst case accumulation $PEC_{soil,\ accu}$ at a soil depth of 5 cm compared with the maximum concentration where effects ≤ 25 % was observed in the study.

The table below indicates how the risk assessment for soil microflora has covered all the proposed uses presented in the GAP. The risk assessment presented here is shown by the 'X' in the table, which represents the worst case PEC_{soil} values selected based on the maximum application to soil per year and the crop type for the proposed uses of MON 52276.

Table 10.5-5: Risk assessment strategy for soil microflora

GAP number and summary of use	Maximum application to soil g/ha (per year unless otherwise stated)								
	1 x 540	1 x 720	1 x 1440	1 x 1800	1 x 2160	1 x 2880	1 x 3600	1 x 540 (every 3rd yr)	1 x 720 (every 3rd yr)
Uses 1a-c: Applied to weeds; pre-sowing, pre-planting, pre-emergence of **field crops.**		X	X						
Uses 2 a-c: Applied to weeds; post-harvest, pre-sowing, pre-planting of **field crops.**		X	X		X				
Use 3 a-b: Applied to cereal volunteers; post-harvest, pre-sowing, pre-planting of **field crops.**	X							X	
Use 4 a-c: Applied to weeds (post emergence) below trees in **orchards.**		X	X			X			
Use 5 a-c: Applied to weeds (post emergence) below vines in **vineyards**		X	X			X			
Use 6 a-b: Applied to weeds (post emergence) in **field crops BBCH < 20**		X	X						
Use 7 a-b: Applied to weeds (post emergence) around **railroad tracks**				X			X		
Use 8 and 9: Applied to invasive species, Giant hogweed and Japanese knot weed (post emergence) in **agricultural and non-agricultural areas**				X					
Uses 10 a-c: Applied to couch grass; post-harvest, pre-sowing, pre-planting of **field crops**		X	X						X

X = this use is covered by the application rate given and PEC_{soil} values are available in the Document M-CA, Section 7.

The soil microflora risk assessment results are presented according to the uses described in the table above and grouped as follows:

- in **field crops**; covering GAP uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c.
- in **orchards**/vineyards; covering GAP uses 4 a-c, 5 a-c.
- around **railroad tracks;** covering GAP uses 7 a-b.
- in **agricultural and non-agricultural areas** to control invasive species; covering GAP uses 8 and 9.

The resulting assessment of the risk for nitrogen transformation is shown in the tables below.

Table 10.5-6: Assessment of the risk for effects on nitrogen transformation due to the use of MON 52276 – field crops *(Uses: 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c)*

Nitrogen transformation			
Intended use	Field crops (1 × 2160 g/ha)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	4.236	yes
AMPA	≥ 160	3.621	yes
Intended use	Field crops (1 × 1440 g/ha)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	2.824	yes
AMPA	≥ 160	2.414	yes
Intended use	Field crops (1 × 720 g/ha)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	1.412	yes
AMPA	≥ 160	1.207	yes
Intended use	Field crops (1 × 540 g/ha)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	1.059	yes
AMPA	≥ 160	0.905	yes
Intended use	Field crops (1 × 540 g/ha, every 3rd year)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	0.833	yes
AMPA	≥ 160	0.500	yes
Intended use	Field crops (1 × 720 g/ha, every 3rd year)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	1.111	yes
AMPA	≥ 160	0.667	yes

Table 10.5-7: Assessment of the risk for effects on nitrogen transformation due to the use of MON 52276 – orchards and vineyards *(Uses: 4 a-c and 5 a-c)*

Nitrogen transformation			
Intended use	Orchards/vineyards (1 × 2880 g/ha)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	5.648	yes
AMPA	≥ 160	4.828	yes
Intended use	Orchards/vineyards (1 × 1440 g/ha)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	2.824	yes
AMPA	≥ 160	2.414	yes
Intended use	Orchards/vineyards (1 × 720 g/ha)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	1.412	yes
AMPA	≥ 160	1.207	yes

Table 10.5-8: Assessment of the risk for effects on nitrogen transformation due to the use of MON 52276 – post emergence of weeds around railroad tracks *(Uses: 7a-c)*

Nitrogen transformation			
Intended use	Railroad tracks (1 × 3600 g/ha)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	7.06	yes
AMPA	≥ 160	6.035	yes
Intended use	Railroad tracks (1 × 1800 g/ha)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	3.53	yes
AMPA	≥ 160	3.017	yes

Table 10.5-9: Assessment of the risk for effects on nitrogen transformation due to the use of MON 52276 – control of invasive species in agricultural and non-agricultural areas *(Uses: 8 and 9)*

Nitrogen transformation			
Intended use	Control of invasive species (1 × 1800 g/ha)		
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg)**	**$PEC_{soil, accu}$ (mg/kg)**	**Risk acceptable?**
Glyphosate	≥ 33.1	3.53	yes
AMPA	≥ 160	3.017	yes

No effects on nitrogen transformation were observed from the maximum expected concentrations of glyphosate and AMPA to the soil. It can be concluded that proposed uses of MON 52276 will not cause any detrimental effect to soil microflora.

Indirect Effects via Trophic Interactions

As stated in the EFSA 2017 Scientific opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms, general protection goals are stated in the European legislation, but are not precisely defined. A precise definition is considered crucial for designing appropriate risk assessment schemes. Different groups of soil organisms have been identified as providers of important ecosystem services in the soil ecosystem. In the biodiversity position paper submitted with this submission, specific protection goals have been developed that consider the six dimensions, namely ecological entity, attribute, magnitude of effects, temporal scale of effect, spatial scale of effect and degree of certainty. SPGs are proposed for both in-field and off-field areas. Due to the specific traits and short generation times, it has been possible to study internal recovery of microbial populations or communities after PPP exposure. It has been demonstrated that microbial communities do recover quickly from effects at both the structural and functional levels of the microbial community (EFSA (2017).

The ecotoxicology dataset for glyphosate and AMPA includes a battery of OECD guideline studies, designed to assess potential long-term effects on the structure and function of soil organism communities. The presented direct effects assessment in this section of the dossier, demonstrates that ecological function and therefore regulation of essential nutrients within the soil microbial community is not lost following exposure to glyphosate at application rates that are considerably higher than those proposed on the GAP table. With max application per annum also being substantially reduced compared to the previous Annex I renewal (2017), the overall burden of product on the land is also reduced, for both the in-field and off-field areas.

For soil microbes Tier 1 direct effects assessments, studies were conducted using ecologically important indicators of soil organism community function (see Table 10.5-10). Soil microbes in combination with other soil organisms contribute to a wide range of essential services that are important for the function of terrestrial ecosystems by acting as the primary driving agents of nutrient cycling, decomposition, soil carbon sequestration, and greenhouse gas emission. As stated for the soil meso-organisms, conservation tillage or minimal tillage generally have positive impacts on soil organism densities, diversity, and also microbial content. No-till fields typically have significantly higher organic matter and microbial content (Chan, 2001).

The following approach has been taken to assess potential indirect effects via trophic interactions, considers the proposed Specific Protection Goals drawn from the existing EU guidance and working documents, and the 2016 EFSA Guidance on developing protection goals for ecological risk assessments (ERA) for pesticides. The SPGs based on direct effects assessment considering representative sensitive populations across the tested trophic levels. The biodiversity assessment, aimed to develop a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals, that includes considering indirect effects via trophic interaction. For example, reduced application rates relative to previous Annex I renewals, a reduced overall application volume of product on the land, and inclusion of no-spray buffer zones as a standard mitigation measure to protect soil communities in off-target areas, which indirectly supports biodiversity by maintaining soil community function and structure, providing a substrate for habitat creation that provides refuge and food resource for other organisms in off-target areas. Therefore, where an acceptable direct effects risk assessment is concluded upon after incorporation of standard mitigation measures to reduce off-target movement via drift coupled with the other standard mitigation measures that are being applied, is considered protective of indirect effects occurring outside of the target area.

Specific protection goals (SPGs) for soil microbes still need to be adopted. However, for the purpose of this biodiversity assessment, two SPGs have been developed that overall are consistent with current EFSA guidance and what will likely be adopted in future EFSA guidance. The first SPG is aimed at protecting the function of soil micro-organism communities. The second SPG is related to the first and is aimed at the protection of soil services (e.g., decomposition and cycling of organic and nutrients) in which soil microbes play a critical role.

In the previous Annex 1 renewal, glyphosate and the representative formulation were shown to have low toxicity and negligible risk of long-term effects to the functioning of soil micro-organism communities, and no risk mitigations were required (EFSA, 2015a).

Scientific Literature that informs the soil organism assessment
Literature review for non-target soil organisms from the previous Annex I (2012) submission.
The scientific literature review conducted for the last Annex I renewal (submitted in 2012) contains a review of ecotoxicological papers considered relevant to the area of soil non-target micro-organisms. Out of 99 papers submitted, 21 papers were described in detail in the dossier. The RMS (UBA) re-evaluated the papers and mostly dealt with the rhizobia of glyphosate resistance crops and were therefore not relatable to an EU level ecotoxicological risk assessment. There were 28 papers considered to be informative with a low weight, with 18 papers considered to be supportive to the risk assessment and one publication considered critical with a high weight of evidence for use in risk assessment. The single study was conducted according to the recognised test guidelines (OECD 216 and 217) with glyphosate applied at the field rate of 4.5 mg/kg soil and also at a 5-fold factor higher (22.5 mg/kg soil). After 1, 7, 14 and 28 days incubation, soil respiration and nitrate formation rates did not significantly differ from the control soil.

The full evaluation of these papers by the previous RMS (UBA) may be found in Annex M-CA 8-01 of the document M-CA Section 8.

The conclusions of the previous RMS (UBA) literature review, included identifying effects on soil functional diversity (Liphadzi, *et al.* 2005).Where there were repeated applications, desiccation led to significant increases of microbial biomass (Ruzkova *et al.*, 2011) but reduced nitrate transformation rates. Some measured parameters were related as a function of time and site quality rather than pesticides application (Gomez *et al.*,2009), function of seasonality (Hart *et al.* ,2009), function of habitat and land use (Busse *et al.*, 2001), glyphosate as a source of P, C or N for soil bacteria (van Eerd *et al.*, 2003), that correlated with increases in soil respiration (Accinelli *et al.*, 2002), increased microbial biomass (Lupwayi, N.Z., *et al.*, 2004), increased rates of C- and N- mineralizations (Lancaster *et al.*, 2006; Haney *et al.*, 2000a, 2002b), which led to a shift in community structure (Ratcliff *et al.*, 2006) from fungal dominance to an equal ratio of fungal and bacteria communities. However, since no significant effects to the function of the fungal and bacterial communities have been observed, then no unacceptable indirect effects to the microorganisms' communities are anticipated.

The RMS (UBA) concluded in 2015, that the soil microorganisms play an important role in soil fertility, by assuming key ecological functions like matter decomposition and nutrient cycling. They indicated that plant biodiversity, productivity and variability are strongly dependant on the association with microorganisms and fungi in the soil. They also stated that the soil microbial diversity is extremely difficult to measure and therefore the risk assessment is restricted to the measurement of impact of pesticides on soil functional diversity. Currently, the data requirements for PPP registration in the EU require only studies on nitrogen transformation rates in artificial or field collected soils.

The RMS (UBA) indicated that there was a need to consider both microbial diversity and composition when considering the impact of plant protection products on soil non-target micro-organisms. However, the current test guidelines do not provide for such a study and based on the currently available test guideline considered relevant for risk assessment purposes, the direct effects assessment demonstrates an acceptable risk t considering the effects on soil function (nitrogen transformation).

Concerning the literature review for the current dossier: There were no public domain literature papers in the field of soil microbes that were classified as being both relevant and reliable for use in the ecotoxicological risk assessment for soil micro-organisms. There were 17 papers considered to be relevant but supplementary, which are presented in the literature review submitted in document M-CA Section 9.

Further to the discussion on diversity, a number of papers were considered relevant to the biodiversity assessment. In a comprehensive study of 317 European agricultural soils glyphosate and AMPA were found in 21 and 42 % of the samples, respectively (Silva *et al.* 2018). Concentrations of glyphosate or AMPA rarely exceeded 0.5 mg a.e./kg of soil, and the highest level detected was 2.05 mg a.e./kg of soil. This maximum level of glyphosate detected is more than 2-times less than the predicted environmental soil concentration used for the standard glyphosate soil organism risk assessment, which considered a worst-case exposure scenario (i.e., the maximum current use rate in the GAP and maximum potential to build up in soil).

Soil microbial populations and their associated biochemical processes are critical to maintain soil health and quality. Soil microbial communities are highly complex and are often characterized by high microbial diversity (Tiedje *et al.* 1999). The occurrence and abundance of soil microorganisms are affected by 1) soil characteristics like tilth, organic matter, nutrient content, and moisture capacity, 2) typical physico-chemical factors such as temperature, pH, and redox potential, and 3) soil management practices. Agricultural practices such as fertilization and cultivation may also have profound effects on soil microbial populations, species composition, colonization, and associated biochemical processes (Buckley and Schmidt, 2001, 2003). Consequently, significant variation in microbial populations is expected in agricultural fields. Minor changes in a single microbial species or group are difficult to measure in such a dynamic system and, moreover, the minor effects of such a change may be better assessed in more integrated measures such as soil fertility and carbon and nitrogen transformation.

The effects of glyphosate and glyphosate-based formulations on soil microorganisms have been extensively investigated (von Mérey *et al.*, 2016; Cerdeira and Duke, 2010; Duke *et al.* 2012; Sullivan and Sullivan, 2000). Results of standardized tests with glyphosate formulations performed for submission to regulatory agencies indicate no long-term effects on two key functional endpoints, carbon (not a current data requirement) and nitrogen transformation, in soil even at rates that greatly exceed maximum use rates. In addition, independent researchers have reviewed numerous laboratory and field studies, investigating the effects of glyphosate on soil bacteria and fungi (Felsot, 2001; Giesy *et al.*, 2000). Although some laboratory tests have shown effects on nitrogen-fixing bacteria and soil fungi, effects are typically observed only under laboratory conditions and at glyphosate concentrations well above normal field application rates. Several researchers have concluded that it is difficult to extrapolate results from some laboratory studies to the natural soil environment (Estok *et al.*, 1989; Wan *et al.*, 1998; Busse *et al.*, 2001).

Arbuscular mycorrhizal fungi are obligate symbionts that transfer mineral nutrients to their plant hosts (Harrison, 2005; Hata *et al.* 2010). The potential impact of glyphosate effects on arbuscular mycorrhizal fungi (AMF) colonization on glyphosate tolerant cultivars of cotton, corn and soybean grown in soil under greenhouse conditions has been evaluated (Savin *et al.* 2009; Knox *et al.* 2008; Lu *et al.* 2018). AMF colonization of roots was not affected by glyphosate, and neither were acid nor alkaline phosphatase soil enzyme activities. Additional research has shown that symbiosis of mycorrhiza, rhizobium, and soybean, no adverse effects of glyphosate was observed (Powell *et al.* 2009). Collectively, these studies indicate that effects of glyphosate on plants through effects on AMF are unlikely.

Biodiversity Assessment

After the thorough literature search and considering the relevant guidance, the following approach was taken to assess potential indirect effects via trophic interactions and the impact on biodiversity. This was achieved by developing a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals.

In the Table 10.5-10, the specific protection goals (as described above) relevant to soil microflora are presented with the relationship between the SPGs, the direct effects study types, assessment and measurement endpoints. The assessment endpoint is an explicit expression of an environmental entity and the specific property of that entity to be protected. Measurement endpoints relate directly to the effects study endpoints.

A conclusion that a given data requirement has been satisfied, requires that an acceptable level of risk has been achieved (i.e. there is a protective margin of exposure or through a weight of evidence).

Based on the measurement endpoints from the study types, and the direct effects assessment presented in this section, it is anticipated that for the proposed uses on the GAP table, that there will be no impacts on soil microbial populations in terms of nitrogen transformation and impacts on soil function, which based on the data requirements, meets the specific protection goal for soil micro-organisms.

The Table 10.5-10 assessment illustrates that ecological diversity and function of soil microbes within spray zones will be sufficiently maintained to achieve the SPG for this taxa group according to the protection goals as defined in the Terrestrial guidance document (SANCO/10329/2000).

Table 10.5-10. The relationship between Specific Protection Goals, assessment and measurement endpoints for soil micro-organisms from foliar applications.

Specific Protection Goals[1]	Assessment Endpoints	Measurement Endpoints	Glyphosate Study Types
Protection of function of soil micro-organism communities.	Long-term effects on the function of soil micro-organism communities	N-transformation rate ≤ 25 % difference from control at ≥ 28 days.	N-transformation rate
Protection of soil services (e.g., cycling of organic matter and nutrients)	Long-term effects on the function of soil micro-organism communities (i.e., Nitrogen cycling).	N-transformation rate ≤ 25 % difference from control at ≥ 28 days	
Soil micro-organism Biodiversity Assessment Based on the direct effects assessment, there is low risk to functioning of soil microbial populations and communities (EFSA, 2015a) and the likelihood of indirect effects on soil function due to effects on microbial or bacterial biodiversity is considered low to negligible.			

[1] EFSA still needs to receive input from risk managers on the definition of specific protection goals being led by DG SANTE. In the draft Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms, low to negligible effects are considered to be ≤ 10 % and small effects are considered to be ≤ 35 %.

Conclusion

Glyphosate is a critical tool to enable conservation tillage systems, which can greatly improve the abundance and biodiversity of soil organisms. There is low risk of direct effects to soil community biodiversity and supporting/regulating services related to soil processes. This conclusion is not changed after reviewing reported levels of glyphosate from soil monitoring studies. In addition, based on a review of the literature, the likelihood of indirect effects soil organism biodiversity is also considered to be low.

However, if additional risk mitigation measures are determined to be required, to mitigate indirect effects resulting from in-crop weed control on soil microbial populations, there are standard mitigation measure options that may be considered by risk assessors and risk managers within Member States.

Examples of the standard mitigation measures considered applicable at the EU level (MAgPIE, 2017) are presented in the following table. Many of these have been considered in the current dossier submission.

Table 10.5-11: Examples of standard mitigation measures as described in MAgPIE (2017) across the various Member States to mitigate effects of glyphosate on biodiversity.

Type of Mitigation Measure	Risk Mitigation Measure	Benefits	Glyphosate renewal dossier (2020)
Restrictions or modifications of products' conditions of application	Application rate, Application frequency, application timing, and interval between applications	Lower transfers to groundwater and surface water; Reduces exposure of organisms in-crop and off-crop.	**Significant reductions (50 % in volume) in newly proposed application rates** compared with the representative use presented in the 2012 renewal dossier. See [41] **Appendix 2 of the biodiversity document accompanying this submission.** **Treated area restriction** 19. for the representative use GAPs: applying to only 50 % of the total area in orchard/vineyard area. 20. maximum of 50 % of the total area for broad acre vegetable inter-row 21. Invasive species control e.g., couch grass – maximum of 20 % of the cropland + extended application intervals. **Limited frequency and timing of application:** 28-day interval between applications and no pre-harvest applications
Application equipment with Spray Drift Reduction Technology (SDRT)	Spray drift reduction nozzles (SDRN), shields, Precision treatment, etc.	Reduces exposure of organisms in-crop (precision treatment) and off-crop.	**Reduction of spray drift to the off-field**: 13. Use 75 % drift reducing nozzles for pre-sowing/pre-planting in arable crops. 14. Use of ground directed, shielded spray for band application in orchards / vineyards and broad-acre vegetable inter-row application.
Buffer zones	Non-sprayed zone at the edge of a crop	Reduces exposure of organisms and off-crop	**Establishment of buffer zones:** Buffer zones of varying size (depending on the type of SDRT) are required as protection for off-crop NTTP communities from spray drift.

For example, in the current dossier;

- Reductions in maximum annual application rates of up to 50 % considered in this dossier are compared to the maximum rates applied for in the 2012 Annex I renewal dossier.
  - In 2012, the maximum annual application rate was 4.32 kg/ha.
  - In the current dossier submission, the maximum annual application rate is 2.16 kg/ha
- Reducing the total area being applied on a per hectare basis for certain uses, will reduce the total volume of product being applied to the landscape.
  - For example, controlling actively growing weeds in vineyards, orchards where a reduced area, up to a maximum of 50 % of the total application area is proposed e.g. using strip or band applications. Applications on target weeds around the base of trees within tree rows,

[41] [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

leaving the area between tree rows unsprayed, which is typically managed using mechanical methods.

- The use of shielded or hooded sprayers, hand-held sprayers and drift reducing technologies, e.g. 75 % drift reducing nozzles are recommended for all applications made for the control of actively growing weeds when applied to control invasive species. These measures will further reduce the off-target exposure risk.
- For weed control on railroad tracks, recommendations are made in the GAP table to use precision application equipment on spray trains, that detects and targets spray directly onto unwanted plants, thereby reducing the amount of product being applied, whilst maintaining an acceptable level of safety on the railroad tracks.
- No spray buffer areas in-field (or compensation areas), are necessary to meet the specific protection goals for avoiding direct effects on non-target plants in off-target areas. This measure will in turn support non-target arthropod communities in off-field areas and reduce further, the potential for indirect effects on bees through trophic interaction.

In addition to the standard mitigation measures, 'non-standard mitigation measures' could also be considered where a local and specific mitigation need is identified by the respective member states. For example, additional biodiversity conservation measures could be considered in simplified landscapes or landscapes that are intensively managed, where typically there are limited refuge areas for insects, birds and mammals. These biodiversity conservation measures options could include for example, creation of habitats (in-field or off-field) and utilizing edge of field habitats and semi-field habitats that support biodiversity by improving wildlife connectivity.

For further information on mitigation measures please refer to the supplementary information document[42] titled 'Glyphosate: Indirect Effects via Trophic Interaction – A Practical Approach to Biodiversity Assessment.' that accompanies this dossier submission.

Reference relied upon in the Indirect Effects via Trophic Interactions section

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1. Information on the study

Data point:	CP 10.5/001
Report author	[redacted]
Report year	2012
Report title	MON 52276: Effect on Soil Microbial Activity, Carbon and Nitrogen Transformations
Report No	CEMR-5259
Document No	CE-2011-0537
Guidelines followed in study	OECD Guidelines 217 (2000) and 216 (2000)
Deviations from current test guideline	Deviations from the current guidelines OECD 216 (2000) and OECD 217 (2000): Major: - none Minor: - The changes in nitrate production was determined between each time point and not on the whole test from 0-28 days. - The temperature dropped under 18°C for 4 hours.
Previous evaluation	Yes, accepted in RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

The effects of MON 52276 on the carbon and nitrogen transformation pathways were assessed in a LUFA standard soil type 2.3. The transformation rates were determined in replicate soil samples treated with MON 52276 at rates of 18.8 and 94 mg MON 52276/kg dry soil (equivalent to 1 and 5 × the initial Predicted Environmental Concentration for a rate of 12 L MON 52276/ha) and compared to a control treatment of deionised water. The concentrations of 18.8 and 94 mg MON 52276/kg dry soil are equivalent to 5.768 and 28.84 mg glyphosate acid equivalent/kg dry soil. Substrate-induced (glucose) respiration measurements were made on Day 0, 7, 14 and 28 by measuring the carbon dioxide evolution over a 12-hour period. The products of the process of nitrification were extracted from the soil on Day 0, 7, 14 and 28 after treatment. As the difference in respiration rates between the treatment rates of MON 52276 (18.8 and 94 mg MON 52276/kg dry soil, equivalent to initial predicted environmental concentrations of 12 L/ha and 60 L/ha, respectively) and control is less than 25 % at Day 28, the test item can be evaluated as having no long-term influence on carbon transformation in soils. As the average rate of production of nitrate (mg/kg/day) from Day 14 to Day 28 between the treatment rates of MON 52276 (18.8 and 94 mg MON 52276/kg dry soil) and control is less than 25 % at Day 28, the test item can be evaluated as having no long term influence on nitrogen transformation in soils.

I. MATERIALS AND METHODS

A. MATERIALS

Test material:

Test item:	MON 52276
Formulation type:	Soluble concentrate (SL)
Description:	Not reported
Lot/Batch #:	A9K0106104
Purity:	30.68 % or 358.8 g/L a.e. glyphosate
Vehicle and/or positive control:	Deionised water control
Test system:	
Soil	Sandy loam soil "LUFA standard soil 2.3" (Batch number F2.34011)
Source:	LUFA-Speyer, Obere Langgasse 40, 67346 Speyer, Germany
Water holding capacity	35.6 % (g water/100 g dry soil)
pH:	7.5
Org. Carbon:	0.94 %
Microbial biomass:	1.91% to C_{org}.
Clay (< 0.002 mm):	8.7 %
Silt 0.002 – 0.050 mm):	27.6 %
Sand (0.050 – 2.0 mm):	63.7 %
Acclimation:	35 % (± 5 %) of MWHC at 20 ± 2 °C for 5 days
Environmental conditions:	
Temperature:	20 ± 2 °C (except during 4 hours dropping to 17.93 °C)
pH:	7.5 – 7.9
Water content:	40 % (± 5 %) of MWHC (actual achieved values: 38.9 %)
Photoperiod:	24 hours darkness
Experimental Dates:	November 11 – December 15, 2011

B. STUDY DESIGN AND METHODS

Experimental treatments

Soil samples were bulk dosed with MON 52276 at nominal rates equivalent to 1 and 5 × $PEC_{plateau}$ (18.8 and 94 mg MON 52276/kg dry soil, respectively). The concentrations of 18.8 and 94 mg MON 52276/kg dry soil are equivalent to 5.768 and 28.84 mg glyphosate acid equivalent/kg dry soil.

Five days before the start of the exposure phase, the soil moisture content was nominally adjusted to 35 % (± 5 %) of the MWHC. The soil was placed in the test cabinet in the dark at 20 ± 2 ºC. On the day of dosing, the moisture of the soil was adjusted to 40 % (± 5%) of the MWHC with deionised water with the appropriate dose of test item. Three replicates were prepared for the control treatment (deionised water) and the test item treatments. For the nitrogen test each replicate contained 500 g (dry weight equivalent) of soil. For the carbon test each replicate contained 1000 g (dry weight equivalent) of soil. Each replicate of soil was transferred to plastic test vessels (2 L). The test soil used in the carbon transformation test was amended with glucose at each sampling time point, to elicit a maximum respiratory response (8.0 mg glucose/g dry weight of soil). The test soil used in the nitrate transformation test was amended with lucerne (2.5 g of lucerne/500 g of soil) to the control and treatment groups on Day 0. The moisture content of soil samples was maintained during the test at 40 % of the maximum water holding capacity of the soil with a range of ± 5 %.

Observations
Soil microbial carbon respiration was measured for the individual respirometers from the Day 0 to Day 28. The mean concentrations of CO_2 (mg CO_2/kg/hour) were monitored over the 12-hour period and the mean respiration rates for the 12-hour period for each treatment at each time point were defined.
Concentrations of nitrate (as TON) and ammonium were measured (mg/kg dry soil) from Day 0 to Day 28. The nitrite values determined were not reported as the detected nitrite-N levels were all below 0.5 mg/L, and therefore considered not to have nitrite present in any of the extracted soil solutions. Changes in concentration of nitrate and nitrate transformation rates (mg/kg/day) over the duration of the study were measured. The changes in nitrate production from 0 – 7, 7 – 14 and 14 – 28 days were also determined.

Statistical calculations
Results were evaluated using Dunnett's two-tail test, $p \leq 0.05$.

II. RESULTS AND DISCUSSION

A. FINDINGS

Table 10.5-12: Effects of MON 52276 on soil nitrogen transformation

		Nitrogen concentration [mg/kg soil]		% deviation from control	
Concentration in MON 52276	**Control**	**18.8 mg/kg dws**	**94 mg/kg dws**	**18.8 mg/kg dws**	**94 mg/kg dws**
Concentrations in glyphosate a.e.	Control	5.768 mg/kg dws	28.84 mg/kg dws	5.768 mg/kg dws	28.84 mg/kg dws
Nitrate (NO_3^-)					
Day 0	22.4	24.4	25.1	+8.93	+12.05
Day 7	0	0	0	-	-
From Day 0-7	-3.20	-3.48	-3.59	+8.84	+12.24
Day 14	25.8	32.8	42.3	+27.13	+63.95
From Day 7 – 14	3.69	4.69	6.04	+27.14	+63.72
Day 28	75.3	84.5	95.7	+12.22	+27.09
From Day 14-28	3.54	3.69	3.81*	+4.31	+7.85
Ammonium (NH_4^+)					
Day 0	10.3	10.7	11.2	+3.88	+8.74
Day 7	3.0	2.9	2.8	-3.33	-6.67
Day 14	1.6	1.6	1.6	0	0
Day 28	1.1	1.1	1.0	0	-9.09

dws: dry weight soil
* = Significantly different from control ($\alpha = 0.05$)
- = inhibition, + = stimulation

Table 10.5-13: Effects of MON 52276 on soil microflora respiration (carbon cycle)

	CO_2 [mg CO_2/kg soil/h]			% deviation from control	
Concentration in MON 52276	**Control**	**18.8 mg/kg dws**	**94 mg/kg dws**	**18.8 mg/kg dws**	**94 mg/kg dws**
Concentrations in glyphosate a.e.	Control	5.768 mg/kg dws	28.84 mg/kg dws	5.768 mg/kg dws	28.84 mg/kg dws
Day 0	16.08	16.16	17.24	+0.47	+7.19
Day 7	15.42	16.64	18.73	+7.97	+21.52
Day 14	15.42	16.93	18.77	+9.78	+21.71
Day 28	16.49	17.15	18.90*	+3.96	+14.57

dws: dry weight soil
* = Significantly different from control ($\alpha = 0.05$)
- = inhibition, + = stimulation

B. OBSERVATIONS

Statistical analysis showed there was a significant difference ($p < 0.05$) between the treatment rate of 94 mg MON 52276/kg dry soil and the control treatment for nitrate production from Day 14 to 28.

As the average rate of production of nitrate (mg/kg/day) from Day 14 to Day 28 between the treatment rates of MON 52276 (18.8 and 94 mg MON 52276/kg dry soil, equivalent to 5.768 and 28.84 mg glyphosate acid equivalent/kg dry soil) and control is less than 25 % at Day 28, the test item can be evaluated as having no long term influence on nitrogen transformation in soils.
Statistical analysis showed there was a significant difference ($p < 0.05$) between the treatment rate of 94 mg MON 52276/kg dry soil and the control treatment for soil carbon transformations at Day 28.

As the difference in respiration rates between the treatment rates of MON 52276 (18.8 and 94 mg MON 52276/kg dry soil, equivalent to initial predicted environmental concentrations of 12 L/ha and 60 L/ha, respectively) and control is less than 25 % at Day 28, the test item can be evaluated as having no long-term influence on carbon transformation in soils.

Validity criteria

All validity criteria for the study were met for the study as the variation between replicate control treatments did not vary by more than ± 15 % at each sampling time point for nitrogen concentrations (actual values from -10.0 to 8.0 %) and for carbon transformation (actual values from -6.1 to 6.2 %).

III. CONCLUSIONS

Assessment and conclusion by applicant:

At soil concentrations of 18.8 and 94 mg MON 52276/kg dry soil (equivalent to 5.768 and 28.84 mg glyphosate acid equivalent/kg dry soil), there were < 25 % effect at Day 28 in nitrogen and carbon transformation, so MON 52276 is expected to have no long-term influence on the nitrogen and carbon transformation pathways in soils up to and including a test concentration 94 mg MON 52276 /kg dry soil.

The study is considered valid and is suitable for risk assessment purposes.

Assessment and conclusion by RMS:

CP 10.6 Effects on Terrestrial Non-Target Higher Plants

Studies considering the toxicity of glyphosate to terrestrial non-target plants were assessed for their validity to current and relevant guidelines for MON 52276 and are presented in the following table. Studies previously evaluated in either the monograph 2001 or the RAR 2015 were also included in this assessment. Study summaries for all valid studies are presented in this section below.

Table 10.6-1: Studies on toxicity of representative formulation to terrestrial non-target higher plants

Annex point	Study	Study type	Test species	Substance(s)	Status	Remark
CP 10.6.2/001	[redacted] 2019	Seedling emergence	*Cucumis sativus* *Brassica napus* *Raphanus sativus Glycine max Helianthus annuus* *Lycopersicon esculentum* *Zea mays* *Triticum aestivum* *Avena sativa* *Allium cepa*	MON 52276	Valid	
CP 10.6.2/002	[redacted] 2013	Vegetative vigour	*Zea mays* *Avena sativa* *Allium cepa* *Triticum aestivum* *Cucumis sativus* *Brassica napus* *Raphanus sativus* *Glycine max* *Helianthus annuus* *Lycopersicon esulentum*	MON 52276	Valid	with uncertainties
CP 10.6.2/003	[redacted], 2005	Vegetative vigour	*Beta vulgaris* *Raphanus rapistrum* *Lepidium sativum* *Pisum sativum* *Lolium perenne* *Triticum aestivum*	MON 52276	Invalid	
CP 10.6.2/004	[redacted] 2012	Comparison of Post-Emergence Phytotoxicity	*Echinochloa crus-galli* *Xanthium strumarium* *Zea mays* *Digitaria ischaemum* *Setaria veridis* *Chenopodium album* *Ipomoea sp.* *Panicum miliaceum* *Oryza sativa* *Polygonum pensylvanicum* *Sorghum bicolor* *Glycine max* *Beta vulgaris* *Abutilon theophrasti* *Triticum aestivum* *Polygonum convolvulus*	MON 52276 and AMPA	Supporti ve	

There are no literature articles and peer-reviewed published data considered to be relevant and reliable or reliable with restrictions with regards to the effects of glyphosate on non-target terrestrial plants. Full literature evaluation is provided in document M-CA Section 9. A summary of previously evaluated peer reviewed literature from the RAR 2015 is also available in Annex M-CA 8-01 of the M-CA Section 8.

Endpoints of studies for the representative formulation MON 52276 considered valid are shown in the table below. The active substance (glyphosate, glyphosate salt or glyphosate acid) is less toxic than the formulation and are therefore not presented below.

Table 10.6-2: Endpoint: Toxicity of representative formulation MON 52276 to terrestrial non-target higher plants

Reference	Test item	Species	Test design/ GLP	ER_{50} (g a.e./ha)	NOER (g a.e./ha)
CP 10.6.2/001 [redacted], 2019	MON 52276	*Cucumis sativus* *Brassica napus* *Raphanus sativus* *Glycine max* *Helianthus annuus* *Lycopersicon esculentum* *Zea mays* *Triticum aestivum* *Avena sativa* *Allium cepa*	Seedling emergence, 21 d	> 3610 (all tested species and all parameters)	≥ 3610 (all tested species and all parameters)
CP 10.6.2/002 [redacted], 2013	MON 52276	*Zea mays* *Avena sativa* *Allium cepa* *Triticum aestivum* *Cucumis sativus* *Brassica napus* *Raphanus sativus* *Glycine max* *Helianthus annuus* *Lycopersicon esulentum*	Vegetative vigour, 21 d	28.4 (cucumber, shoot length)	< 20 (cucumber: shoot length, shoot weight; sunflower, tomato: shoot weight)

a.e.: acid equivalents

Risk assessment for Terrestrial Non-Target Higher Plants

The table below summarises how the risk assessment for terrestrial non-target plants considers all the proposed uses and the application rates presented in the GAP. The risk assessment presented here is shown by the grey shaded cells in the table, which represents the worst case exposure to non-target plants and are selected based on the application rate, multiple application factor and the crop type for the proposed uses of MON 52276. Thus, the conclusions of the risk assessment here are protective of the other uses. However, the risk assessment calculations for all the other uses shown by the **X** in the table are also provided for completeness in Annex M-CP 10-05.

Table 10.6-3: Risk assessment strategy for terrestrial non-target plants

GAP number and summary of use	Application rate considered (28 day internal unless otherwise stated)									
	1 × 540 g/ha	1 × 720 g/ha	1 × 1080 g/ha	2 × 720 g/ha	1 × 1440 g/ha	3 × 720 g/ha	1 × 1800 g/ha	2 × 1080 g/ha[1]	2 × 1440 g/ha	2 × 1800 g/ha (90 days apart)
Uses 1 a-c: Applied to weeds; pre-sowing, pre-planting, pre-emergence of **field crops.**		X	X		X					
Uses 2 a-c: Applied to weeds; post-harvest, pre-sowing, pre-planting of **field crops.**		X	X	X	X	X		X		
Use 3 a-b: Applied to cereal volunteers; post-harvest, pre-sowing, pre-planting of **field crops.**	X									
Use 4 a-c: Applied to weeds (post-emergence) below trees in **orchards.**		X	X	X	X	X		X	X	
Use 5 a-c: Applied to weeds (post-emergence) below vines in **vineyards**		X	X	X	X	X		X	X	
Use 6 a-b: Applied to weeds (post-emergence) in **field crops BBCH < 20**		X	X							
Use 7 a-b: Applied to weeds (post-emergence) around **railroad tracks**							X			X
Use 8 and 9: Applied to invasive species (post-emergence) in **agricultural and non-agricultural areas**							X			
Uses 10 a-c: Applied to couch grass; post-harvest, pre-sowing, pre-planting of **field crops**		X	X							

X = this use is covered by the application rate indicated.
Grey shaded cells: risk assessment presented below, representing worst case exposure
[1] Due to the long spray interval of 28 days this use covers also the following possible application pattern: 2 × 1080 g a.s./ha plus 1 x 720 g a.s./ha (28 day interval between each application)

Risk of exposure from metabolites

The major metabolite of glyphosate is AMPA, which does not have a comparable target activity as the parent active compound as it does not contain the functional moiety to cause the herbicidal action that glyphosate does (Sanco/221/2000 – rev 10) and will not impact the Shikimic acid pathway.

To better estimate the mechanistic effects, the study by [redacted] (2012) [Section CA 9, [redacted] 2012] can be consulted. In this study, phytotoxic effects of glyphosate and AMPA to 17 crop and annual weed species were tested. Foliar applications of AMPA to post-emergent plants were unrealistically high and were only performed with the intent of comparing the relative potency of AMPA and glyphosate. The EC_{50} values of glyphosate and AMPA in the study were compared on molar basis and the factors of EC_{50} based on moles/ha of AMPA/glyphosate were in the range of 3.4 to 86.8. These factors > 2 indicate that AMPA has herbicidal activity versus glyphosate in the range of 1.2 to 29 %, with 29 % being the effect in the species hemp sesbania (*Sesbania exaltata*).

In conclusion, the herbicidal activity of AMPA is expected to be well below 50 % of the parent activity, therefore the potential for effects on non-target terrestrial plants from exposure to AMPA is considered covered by the risk assessment based on the parent molecule.

The risk assessment for non-target terrestrial plants are presented according to the uses described in the table above and grouped as follows:

- in **field crops**; covering GAP uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, 10 a-c.
- in **orchards**/vineyards; covering GAP uses 4 a-c, 5 a-c.
- around **railroad tracks;** covering GAP uses 7 a-b.
- in **agricultural and non-agricultural areas** to control invasive species; covering GAP uses 8 and 9.

The application rates that are considered as a worst-case and covering all other application rates in the first-tier risk assessments are presented in grey shaded cells in the table above.

For all other application rates, the deterministic and probabilistic risk assessments for both endpoints are presented in Annex M-CP 10-05 of this document for completeness.

Where multiple applications per season are applicable, a multiple application factor is applied to the risk assessment, considering an application interval of 28 days.

The risk assessment will be conducted based on FOCUS (2001), as stated in the currently adopted guidance SANCO/10329/2002 rev. 2, 'Directorate E. Food Safety: plant health, animal health and welfare, international questions. 2002. Guidance document on terrestrial Ecotoxicology under council directive 91/414/EEC.' 39 pp.

The principal route of non-target terrestrial plant exposure is via spray drift away from the applied areas. Currently, estimation of spray drift deposition is based on the values given by Rautmann (2001). These values apply to 90th percentile conditions. According to FOCUS (2001), the estimated spray drift deposition for field crops (% of in-field target deposition) downwind of a sprayed (ground directed application) to a bare soil surface (without interception by vegetation) representing a field crop situation at distances of 1, 5 and 10 meters from the target area, are 2.77, 0.57 and 0.29 %.

Applications using high boom or blast sprayer applicators associated with for example, 'over the top' applications in perennial crops, are not a use on the proposed GAP table. The assessment does therefore only consider low boom – ground directed applications. The stated percentage drift values are for field crop drift values used for all crops according to recommendations of the Guidance Document on Terrestrial Ecotoxicology (2002) and are based on Rautmann (2001).

The risk assessment for effects on non-target plants is performed in a step-wise approach, first using a deterministic approach and then a probabilistic approach.

The guidance[43] states "Probabilistic methods that make use of the species sensitivity distribution would be straightforward in this assessment step as data from 6 – 10 species are available. This approach requires that log-normal or another defined type of distribution has been shown to fit the data adequately. If the ER_{50} for less than 5 % of the species is above the highest predicted exposure level, the risk for terrestrial plants is assumed to be acceptable."

Deterministic Risk Assessment for Non-target Terrestrial Plants
The deterministic approach is performed using the most sensitive endpoint from the vegetative vigour and seedling emergence studies.

[43] Directorate E . Food Safety: plant health, animal health and welfare, international questions. 2002. Guidance document on terrestrial Ecotoxicology under council directive 91/414/EEC. 39 pp.

For vegetative vigour, the most sensitive endpoint is based on shoot fresh weight that achieved an ER_{50} = 28.5 g a.e./ha (soybean).

For seedling emergence, there were no effects observed across 10 species tested and all measured parameters. The endpoint ER_{50} was considered 'equal to or higher than' the highest application rate tested in the seedling emergence study ($ER_{50} \geq 3610$ g a.e./ha).

The MAF is based is based on a DT_{50} of 2.8 days for decline of residues on leaf surfaces in a grass residues study, which is considered to cover decline on broadleaf plant foliage, which is supported by Ebeling & Wang (2018)[44], who evaluated the residue dissipation of 30 active substances (including glyphosate) on grasses / cereals (177 trials) and non-grass herbs (101 trials). No significant difference between residue dissipation on grasses / cereals and non-grass herbs was found. In addition, in the EFSA Conclusion for glyphosate (2015)[45] (EFSA Journal 2015;13(11):4302) the DT50 of 2.8 days was used to determine a calculated 21-day TWA of 0.19, that was applied to refine the risk to the medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*).

Field Crops

Table 10.6-4: Deterministic assessment of the risk for non-target plants due to the use of MON 52276 – field crops considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 5)
Field Crops – GAP uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, & 10 a-c						
Vegetative vigour						
All uses considering downward ground directed spray	3 x 720	28.5	2.77	1.00	19.9	**1.43**
	2 x 1080			1.00	29.9	**0.95**
Seedling emergence						
All uses considering downward ground directed spray	3 x 720	3610	2.77	1.00	19.9	181
	2 x 1080			1.00	29.9	121

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 2.77 % at 1 m from the application area considering downward ground directed spray

[44] Ebeling, M., Wang, M. Dissipation of Plant Protection Products from Foliage. Environmental Toxicology and Chemistry (2018). Wiley Online Library.
[45] Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate (2015). European Food Safety Authority (EFSA), Parma, Italy.

Orchards

Table 10.6-5: Deterministic assessment of the risk for non-target plants due to the use of MON 52276 – orchards considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 5)
Orchards / vineyards – GAP uses 4 a-c & 5 a-c						
Vegetative vigour						
All uses considering downward ground directed spray	2 x 1440	28.5	2.77	1.00	39.9	**0.71**
Seedling emergence						
All uses considering downward ground directed spray	2 x 1440	3610	2.77	1.00	39.8	90.5

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 2.77 % at 1 m from the application area considering downward ground directed spray

Railroad tracks

Table 10.6-6: Deterministic assessment of the risk for non-target plants due to the use of MON 52276 – railroad tracks considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 5)
Railroad tracks GAP uses 7 a-b						
Vegetative vigour						
All uses considering downward ground directed spray	2 x 1800	28.5	2.77	1.00	49.86	**0.57**
Seedling emergence						
All uses considering downward ground directed spray	2 x 1800	3610	2.77	1.00	49.86	72.4

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 2.77 % at 1 m from the application area considering downward ground directed spray

Agricultural and non-agricultural area – Invasive species

Table 10.6-7: Deterministic assessment of the risk for non-target plants due to the use of MON 52276 – Agricultural and non-agricultural area – Invasive species considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 5)
Agricultural and non-agricultural area – Invasive species – uses 8 & 9						
Vegetative vigour						
All uses considering downward ground directed spray	2 x 1080	28.5	2.77	1.00	29.92	**0.95**
Seedling emergence						
All uses considering downward ground directed spray	2 x 1080	3610	2.77	1.00	29.92	121

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 2.77 % at 1 m from the application area considering downward ground directed spray

Vegetative vigour

Based on the vegetative vigour endpoint of 28.5 g a.e./ha, a further refinement of the non-target terrestrial plant risk assessment is required, as all achieved TER values in the deterministic approach are below the trigger value of 5, based on the PER achieved considering deposition via drift (2.77 %) at 1 m from the application area.

A refined deterministic risk assessment based on the vegetative vigour endpoint is presented below based on the PER (g a.e./ha) achieved considering drift rates (%) at 5 and 10 m from the application area.

Seedling emergence

Based on the seedling emergence endpoints, a further refinement of the non-target terrestrial plant risk assessment is not required, as all TER values in the deterministic approach exceed the trigger value of 5, based on the PER achieved considering deposition via drift at 1 m from the application area.

Field Crops

Table 10.6-8: Deterministic assessment of the risk for non-target plants due to the use of MON 52276 – field crops considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 5)
Field Crops – GAP uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, & 10 a-c						
Vegetative vigour						
All uses considering downward ground directed spray	3 x 720	28.5	0.57 – at 5 m	1.00	4.10	6.95
	2 x 1080			1.00	6.16	**4.63**
All uses considering downward ground directed spray	2 x 1080		0.29 – at 10 m	1.00	3.13	9.11

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 0.57 % at 5 m and 0.29 % at 10 m from the application area considering downward ground directed spray

Orchards

Table 10.6-9: Deterministic assessment of the risk for non-target plants due to the use of MON 52276 – orchards considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 5)
Orchards / vineyards – GAP uses 4 a-c & 5 a-c						
Vegetative vigour						
All uses considering downward ground directed spray	2 x 1440	28.5	0.57 – at 5 m	1.00	8.21	**3.47**
			0.29 – at 10 m	1.00	4.18	6.82

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 0.57 % at 5 m and 0.29 % at 10 m from the application area considering downward ground directed spray

Railroad tracks

Table 10.6-10: Deterministic assessment of the risk for non-target plants due to the use of MON 52276 – railroad tracks considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 5)
Railroad tracks – use 7 a-c						
Vegetative vigour						
All uses considering downward ground directed spray	2 x 1800	28.5	0.57 – at 5 m	1.00	10.26	**2.78**
			0.29 – at 10 m	1.00	5.22	5.46

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 0.57 % at 5 m and 0.29 % at 10 m from the application area considering downward ground directed spray

Agricultural and non-agricultural area – Invasive species

Table 10.6-11: Deterministic assessment of the risk for non-target plants due to the use of MON 52276 – Agricultural and non-agricultural area – Invasive species considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 5)
Agricultural and non-agricultural area – Invasive species – uses 8 & 9						
Vegetative vigour						
All uses considering downward ground directed spray	2 x 1080	28.5	0.57 – at 5 m	1.00	6.16	**4.63**
			0.29 – at 10 m	1.00	3.13	9.11

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 0.57 % at 5 m and 0.29 % at 10 m from the application area considering downward ground directed spray

Vegetative vigour

Considering the TERs achieved based on drift depositions at 5 meters from the application area, acceptable risk assessments may be achieved considering single applications of MON 52276 at rates up to 1080 g a.e./ha and for applying up to three applications of 720 g a.e./ha, the achieved TER values exceed the trigger value of 5.

For multiple applications made at 1080 g a.e./ha and higher, an acceptable risk assessment is not achieved as all TER values are below the trigger value of 5. Therefore, a further refinement of the risk assessment is required.

Based on the vegetative vigour endpoint of 28.4 g a.e./ha, and considering deposition via drift at 10 m from the application area, an acceptable risk assessment for all proposed uses may be achieved considering a drift distance off-target of at least 10 meters, as all TER values are either equal to or exceed the trigger value of 5.

Risk reduction
To reduce off-target terrestrial plant exposure risk, risk mitigation measures may be implemented at Member State level as – for example, in-field spray buffer strips and / or usage of drift reducing technologies such as drift reducing spray nozzles. The different combinations of drift reducing technology available at Member State level can reduce the size of the in-field spray buffer strip considerably, as it is explained below.

Concerning in-field spray drift buffers, the deterministic risk assessment demonstrates that including an in-field no-spray buffer of between 5 and 10 meters may achieve an acceptable risk assessment across all uses, if drift reducing technology is not available at Member State level.

If applying drift reducing technology, that may take the form of either an alternate nozzle type, that increases droplet size – thereby reducing off-target exposure risk, or the incorporation of shielded sprayers, which are stated on the GAP table, for applications made for the control of invasive species. Using shielded sprayers will substantially reduce the risk of non-target terrestrial plant exposure in off-target areas. Using alternate spray nozzle technology may also reduce the off-target drift deposition rates by 50 %, 75 % or even 90 %. For example, considering 2 x 1800 g a.e./ha, the corresponding PER value is 11.7 g a.e./ha, achieved at 5 meters from the application area (Table 10.6.2-6). An acceptable off-target risk to non-target terrestrial plants can be achieved using a 75 % drift reduction technology and would achieve an off-target PER value of 2.9 g a.e./ha, and a corresponding TER value of 9.8, that exceeds the trigger value of 5.

Refinement of Exposure Level Protective of 95 % of Species (HC_5 evaluation)
In addition to a deterministic approach to the risk assessment, as indicated above, the probabilistic approach is also a suitable approach to calculate the risk for non-target plants and to achieve the protection goal, as multiple plant species are tested under similar laboratory condictions, allowing for uncertainity when extrapolating between species to be accounted for in the risk assessment.

Probabilistic Risk Assessment for Non-target Terrestrial Plants
The hazardous concentration for 5 % of the population (HC_5) is derived by establishing a species sensitivity distribution (SSD), using ETX v2.2 software from RIVM. Biomass is the relevant endpoint for a plant community assessment because ecosystem function is related to biomass production and consumption, processing of organic detritus and mineralizing organic compounds (Suter and Bartell, 1993; Solomon and Takacs, 2002), and it is the most sensitive endpoint in 9 out of 10 tested plant species, the shoot weight endpoint was used to derive the HC_5.

The data used to prepare the SSD for the HC_5 derivation were the ER_{50} values for shoot weight for the 10 species tested in the vegetative vigor study. The goodness of fit of the SSD was acceptable, since all statistical tests indicated that the data is normally distributed, using three statistical tests (Anderson-Darling = 0.61, Kolmogorov-Smirnoff = 0.68, Cramer von Mises = 0.09). Correspondingly, the resulting HC_5 value was determined to be 21.6 g a.e./ha, based on biomass. Figure 10.6.2-1 shows a graph illustrating the species sensitivity distribution (SSD).

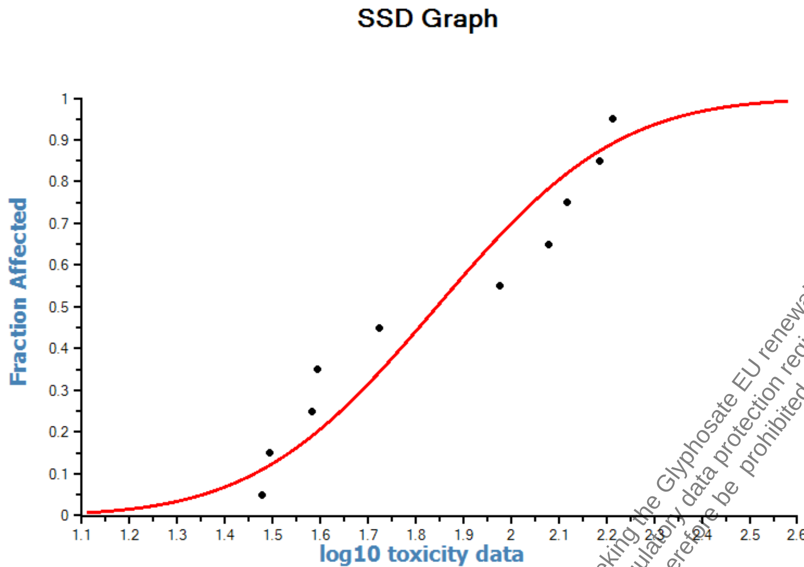

Figure 10.6.2-1: Species Sensitivity Distribution (SSD) for non-target plant biomass exposed to MON 52276.

Using the probabilistic approach (HC_5 = 21.6 g a.e./ha), the risk assessment is performed with a reduced TER trigger value of 1 considered appropriate as > 6 species were tested (10 in total), i.e. if the predicted exposure rate (PER) does not exceed the HC_5, the use of MON 52276 can be considered safe for non-target terrestrial plants in off-target areas.

The refined risk assessment based on the probabilistic approach, is presented below.

Field Crops

Table 10.6-12: Probabilistic assessment of the risk for non-target plants due to the use of MON 52276 – field crops considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 1)
Field Crops – GAP uses 1 a-c, 2 a-c, 3 a-b, 6 a-b, & 10 a-c						
Vegetative vigour						
All uses considering downward ground directed spray	3 x 720	21.6	2.77 – at 1 m	1.00	19.9	1.09
	2 x 1080			1.00	29.9	**0.72**
	3 x 720	21.6	0.57 – at 5 m	1.00	4.10	5.27
	2 x 1080			1.00	6.16	3.51

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 2.77 % at 1 m and 0.57 % at 5 m from the application area considering downward ground directed spray

Orchards

Table 10.6-13: Probabilistic assessment of the risk for non-target plants due to the use of MON 52276 – orchards considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 1)
Orchards / vineyards – GAP uses 4 a-c & 5 a-c						
Vegetative vigour						
All uses considering downward ground directed spray	2 x 1440	21.6	2.77 – at 1 m	1.00	39.9	**0.54**
			0.57 – at 5 m	1.00	8.21	2.63

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 2.77 % at 1 m and 0.57 % at 5 m from the application area considering downward ground directed spray

Railroad tracks

Table 10.6-14: Probabilistic assessment of the risk for non-target plants due to the use of MON 52276 – railroad tracks considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 1)
Railroad tracks GAP uses 7 a-b						
Vegetative vigour						
All uses considering downward ground directed spray	2 x 1800	21.6	2.77 – at 1 m	1.00	49.9	**0.43**
			0.57 – at 5 m	1.00	10.26	2.11

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 2.77 % at 1 m and 0.57 % at 5 m from the application area considering downward ground directed spray

Agricultural and non-agricultural area – Invasive species

Table 10.6-15: Probabilistic assessment of the risk for non-target plants due to the use of MON 52276 – Agricultural and non-agricultural area – Invasive species considering downward ground directed spray

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF [1]	PER [2] [g a.e./ha]	TER (criterion: TER ≥ 5)
Agricultural and non-agricultural area – Invasive species – uses 8 & 9						
Vegetative vigour						
All uses considering downward ground directed spray	2 x 1080	21.6	2.77 – at 1 m	1.00	29.9	**0.72**
			0.57 – at 5 m	1.00	6.16	4.63

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.
[1] MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)
[2] PER (g a.e./ha) based on drift rate (%) of 2.77 % at 1 m and 0.57 % at 5 m from the application area considering downward ground directed spray

Based on the probabilistic approach to the risk assessment, the achieved TER values based on deposition at 1 m from the application area (2.77 % drift) indicate an acceptable risk to non-target plants in off-field / target areas, for up to application rates of 3 × 720 g a.e./ha or lower.

Based on the deposition expected at 5 meters from the application area, based on the HC_5 value and a reduced trigger value, an acceptable risk assessment for all proposed uses is achievable.

Risk reduction

As described for the deterministic risk assessment above, to reduce terrestrial plant exposure risk in off-field areas, risk mitigation measures may be implemented at Member State level – for example, in-field spray buffer strips and / or usage of drift reducing technologies such as drift reducing spray nozzles. The different combinations of drift reducing technology available at Member State level can reduce the size of the in-field spray buffer strip considerably, as it is explained below.

Concerning in-field spray drift buffers, the deterministic risk assessment demonstrates that including an in-field no-spray buffer of between 5 and 10 meters may achieve an acceptable risk assessment across all uses, if drift reducing technology is not available at Member State level.

If applying drift reducing technology, that may take the form of either an alternate nozzle type, that increases droplet size – thereby reducing off-target exposure risk, or the incorporation of shielded sprayers, which are stated on the GAP table, for applications made for the control of invasive species. Using shielded sprayers will substantially reduce the risk of non-target terrestrial plant exposure in off-target areas.

Using alternate spray nozzle technology may also reduce the off-target drift deposition rates. For example, considering 2 × 1800 g a.e./ha, the corresponding PER value is 11.7 g a.e./ha, achieved at 5 meters from the application area (Table 10.6.2-8). An acceptable off-target risk to non-target terrestrial plants can be achieved using a 75 % drift reduction technology and would achieve an off-target PER value of 2.9 g a.e./ha, and a corresponding TER value of 1.5 based on the HC_5 value, that exceeds the proposed trigger value of 1.

Further refinement of the EU level risk assessment for non-target terrestrial plants occurring in off-target areas is not required.

Indirect effects via trophic interaction

The existing terrestrial ecotoxicology guidance[46] for NTTP assessments provides risk assessment methods for evaluating potential effects to NTTP communities outside the cropped area. Historically, protection of in-crop non-target plants / weeds has not been considered in ecological assessments for PPPs.

Therefore, a general protection goal, based on existing guidance, was derived to protect 95 % of the species 90 % of the time off-crop (Table 10.6.2-18). Based on the current assessment for the representative formulation, implementation of standard risk mitigation measures (e.g., in-field buffers, drift reduction technology nozzles, hooded / shielded sprayers) may be required to protect NTTP communities in off-target areas. (CP 10.6).

In the revision of the PPP data requirements (Annex to Commission Regulation (EC) No 284/2013), the former phrase "*Non-target plants are non-crop plants located outside the treatment area*" was deleted. As an outcome of this revision, an EFSA Scientific Opinion addressing the state of the science on risk assessment for NTTPs was developed that defined SPGs for off-field and in-field and linking them to biodiversity. In the EFSA Scientific Opinion (2014), NTTPs were newly defined as "*all plants growing outside fields, and those growing within fields that are not the intended pesticide target*". The proposed general protection goal for NTTPs in the Scientific Opinion is to maintain the biodiversity of plant species in the agricultural area, including both the above- and belowground (seed bank) diversity, and is linked to ecosystem services. Further, three Specific Protection Goals (SPGs) were defined: (1) protection of off-field NTTPs because they are drivers for nutrient cycling, water regulation, food web support, aesthetic values and genetic resources (biodiversity); (2) protection of in-field NTTPs because they are key drivers for food web support (primary production, provision of habitat and food for other non-target organisms, e.g. arthropods, birds), aesthetic values and genetic resources; and (3) protection of endangered plant species including rare arable weeds. However, the EFSA Scientific Opinion (2014) does not have the status of an official guidance document. The definition and selection of SPGs and exposure assessment goals (i.e., exposure in-crop versus off-crop) for NTTPs requires further discussion and decision making between risk assessors and risk managers (e.g., those of SCoPAFF, the Standing Committee on Plants, Animals, Food and Feed, in which risk managers of EU Member states are represented). When defining SPGs for arable weeds and NTTPs, it is the responsibility of the risk assessors in the Member States to acknowledge existing protection goals and regulatory data requirements, to propose possible SPG options, and describe the possible environmental consequences of each option. The risk assessors within the Member States will need to propose realistic SPGs and exposure assessment goals and the interrelationships between them in a clear and transparent manner.

Scientific Literature that informs the NTTP assessment

The scientific literature review conducted for the last Annex I renewal contains an extensive review of ecotoxicological papers considered relevant but supplementary to the Annex I renewal. The papers presented information that could not be relatable to an EU level ecotoxicological risk assessment, but that were considered in the previous dossier, where they were evaluated by previous RMS (UBA). A further evaluation of these literature papers according to the EFSA literature review approach used in this dossier has not been conducted. The previous literature review has been submitted as part of the Literature review requirements and is presented in Annex M-CA 8-01 of the document M-CA Section 8.

Literature review for non-target terrestrial plants from the previous Annex I (2012) submission.

In the area of non-target terrestrial plants, a total of 87 peer reviewed papers were submitted, from which a single paper (Boutin *et al.*, (2010) that measured variability in phytotoxicity testing using crop and wild plant species) was rated with the category 'Klimisch 2". All remaining papers were not considered relevant to risk assessment. The RMS (UBA) also evaluated the submitted papers, with 27 papers identified as being supportive. The RMS (UBA) identified that most of the cited studies used formulated products and not the active substance. An objective of the NTTP risk assessment by the UBA was to ensure that NTTPs will be harmed by unintended exposure via drift to the off-target / off-field area outside of the intended spray zones.

[46] Directorate E . Food Safety: plant health, animal health and welfare, international questions. 2002. Guidance document on terrestrial Ecotoxicology under council directive 91/414/EEC. 39 pp.

The full evaluations of all 87 non-target terrestrial plant papers submitted as part of the peer reviewed literature review for the previous Annex I renewal (2012) are presented in Annex M-CA 8-01 of the M-CA Section 8.

Current public domain literature review of published literature since the last dossier submission
Recently, Koning *et al.* (2019) investigated the effects of mold-board plowing, chisel plowing, and glyphosate herbicide application on weed species density and diversity in agricultural fields. Their results showed that in-crop weed communities evolved over the years depending on the type and timing of treatment. However, overall biodiversity of the weed community, which is at the basis for any consideration of potential trophic interaction within the field boundaries, was not more negatively affected by one method compared to another. <u>This is an important paper for the biodiversity assessment, because it demonstrates that conventional tillage weed control practices have a similar outcome as chemical weed control on in-crop plant biodiversity.</u>

A follow up to the EFSA Scientific Opinion (2014) on NTTPs, Arts *et al.*, (2017) developed a proposal for three possible SPGs for arable weeds: maximal weed reduction, moderate weed reduction, and beneficial weed protection. The "<u>maximal weed reduction</u>" option allows for trade-offs by allowing provisioning of the ecosystem service "crop production" as being of primary importance and considers all non-crop plants in the cropped area as weeds that are not protected. This option is consistent with the current NTTP guidance that only protects off-crop NTTP communities in line with the SANCO/10329/2002 rev 2 final 'Guidance document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC. Risk assessors and risk managers in the member states will need to consider the ecological consequences of this option in light of local properties of their agricultural landscapes. The "<u>moderate weed reduction</u>" option differs from the "maximal weed reduction option" in that it aims to support the presence of a moderate level of arable weeds in-crop to support ecosystem services provided by weeds in crop. These ecosystem services could provide supporting services such as provisioning habitat to invertebrates and food for farmland birds and cultural services such as protecting weeds of conservation concern. This option for "moderate weed control" would most practically be achieved by implementing non-spray crop areas along the field edges and/or at the corners of an agricultural field whilst the remaining in-crop area is maintained under 'maximal weed reduction'. The economic consequence of this option may be that the monetary value of the crop decreases due to competition of the crop with arable weed. In addition, where arable weeds are allowed to persist in-crop, it is important to consider potential seed returns, which may increase the seed burden in subsequent crops. Alternatively, the non-sprayed crop areas can be replaced by vegetation other than the crops. Finally, the "<u>beneficial weed protection</u>" option is challenging because it would be difficult to maintain effective in-crop control of problem weeds while sustaining beneficial species at economically acceptable levels. In addition, because of the broad-spectrum nature of glyphosate, this option would not be feasible without using advanced forms of precision agriculture.

The current NTTP assessment provided in section 10.6 is highly protective of off-crop NTTP populations and communities based on the effects data used, the exposure assessment, and the risk assessment procedures. However, because of the broad spectrum of weed control that glyphosate offers, many uses (e.g., pre-planting uses, range-land restorations) will result in loss of the in-field weeds prior to tillage. Nonetheless, there are specific scenarios with orchards / vineyards, spot treatments, control of invasive species, and directed applications where only a portion of the weed biomass will be left untreated, minimizing the impact to birds adapted to farmlands from indirect effects through trophic interactions.

It is unclear the extent to which indirect effects of broad-spectrum herbicides impact farmland birds across the different geographies in the EU, in addition to the unknown magnitude of affect that habitat modification / destruction, also has on these populations at a local and EU wide scale. In cases, where indirect effects from in-field weed control may be considered to pose an unacceptable risk in individual Member States, risk mitigation measures may be applied to mitigate effects from in-field weed control. Risk mitigation options or Member States to address direct effects and indirect effects from in-crop weed control are outlined in Table 10.6.2-18 after the conclusions below (insert cross reference) and are primarily derived from the risk mitigations discussed in the proceedings from the MAgPIE workshop (2013) and Arts *et al.* 2017.

Assessment

After a through literature review and considering all recent guidance, the following approach has been taken to assess potential indirect effects via trophic interactions considering the proposed Specific Protection Goals drawn from the existing EU guidance and working documents, and the 2016 EFSA Guidance on developing protection goals for ecological risk assessments (ERA) for pesticides. The SPGs were based on direct effects assessment considering representative sensitive populations across the tested trophic levels. The biodiversity assessment, aimed to develop a flexible framework that informs the development of risk mitigation options to achieve the specific protection goals, that includes mitigating against indirect effects via trophic interaction. For example, for NTTPs, the inclusion of no-spray buffer zones as a standard mitigation measure protects NTTP communities in off-target areas, which indirectly supports biodiversity by maintaining habitat as both a refuge and food source for other organisms in off-target areas. Therefore, where an acceptable direct effects risk assessment is concluded upon after incorporation of standard mitigation measures to reduce off-target movement via drift, this is considered protective of indirect effects occurring outside of the target area.

In the following table, the specific protection goals relevant to non-target terrestrial plants are presented with the relationship between the SPGs, the direct effects study types, assessment and measurement endpoints. The assessment endpoint is an explicit expression of an environmental entity and the specific property of that entity to be protected. Measurement endpoints relate directly to the effects study endpoints.

A conclusion that a given data requirement has been satisfied, requires that an acceptable level of risk has been achieved (i.e. there is a protective margin of exposure or through a weight of evidence). For NTTPs an acceptable direct effects assessment by including a standard mitigation measure e.g., no-spray buffer zone.

The direct effects assessment requires a no-spray buffer zone to reduce the possible exposure risk to plants occurring in off-target areas. This is considered to meet the proposed SPG. The relationship between study type, measured and assessed endpoints and the SPG are presented in Table 10.6.2-18.

Table 10.6-16: The relationship between specific protection goals and associated assessment and measurement endpoints for non-target terrestrial (NTTP) plants from off-crop spray drift.

Specific Protection Goals[1]	Assessment Endpoints	Measurement Endpoints	Glyphosate Study Types
Negligible risk to off-field NTTP communities to support nutrient cycling, water regulation, food web, aesthetic values and genetic resources (biodiversity)	Protect 95 % of the populations in 90 % of the cases.	EC_{50} values for plant survival, height and weight.	Vegetative vigor Seedling emergence
NTTP Biodiversity Assessment Based on the current direct effect assessment for the representative formulation, standard risk mitigation measures (e.g. in-field buffers, drift reduction technology nozzles, hooded sprayers) will be required on the label to protect NTTP communities outside the cropped area. However, if additional risk mitigation measures are considered to be required by risk managers at the Member States level, to mitigate indirect effects resulting from in-crop weed control, risk mitigation options that maybe considered are presented in Table 8 of the [redacted] (2020) Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment. (TRR0000305) presented with this document.			

[1] It is assumed that the biodiversity is maintained when most of the plant populations will not be affected using plant protection products. It is assumed that this goal can be reached when the plant populations are protected off-crop.

Conclusion

The existing terrestrial ecotoxicology guidance for NTTP assessments provides risk assessment methods for evaluating potential direct effects to NTTP communities outside the cropped area. Historically, protection of in-crop non-target plants / weeds has not been considered in ecological assessments for PPPs. However, in the revision of the PPP data requirements, the former phrase "*Non-target plants are non-crop plants located outside the treatment area*" was deleted. As an outcome of this revision, an EFSA Scientific Opinion (2014) was developed that defined SPGs for off-crop and in-crop NTTPs and linking them to biodiversity. In the Scientific Opinion (2014), NTTPs were newly defined as "*all plants growing outside fields, and those growing within fields that are not the intended pesticide target*"; though the Scientific Opinion (2014) does not have the status of an official guidance document. The derivation of SPGs for NTTPs requires further discussion and decision making between risk assessors and risk managers as well as risk mitigation options to address indirect effects. Holistically addressing potential indirect effects to birds and mammals by limiting in-crop weed control may be better handled through policies and programs outside the PPP framework.

Based on the current direct effect assessment for the representative formulation, standard risk mitigation measures (e.g., in-field buffers, drift reduction technology nozzles, hooded sprayers) will be required on the label to protect NTTP communities outside the target area . However, if additional risk mitigation measures are required by risk managers at the Member State level, standard risk mitigation options are available at the EU level and are presented in the following table. Many of these have been considered in the current dossier submission.

Table 10.6-17: Examples of standard mitigation measures as described in MAgPIE (2017) across the various Member States to mitigate effects of glyphosate on biodiversity.

Type of Mitigation Measure	Risk Mitigation Measure	Benefits	Glyphosate renewal dossier (2020)
Restrictions or modifications of products' conditions of application	Application rate, Application frequency, application timing, and interval between applications	Lower transfers to groundwater and surface water; Reduces exposure of organisms in-crop and off-crop.	**Significant reductions (50 % in volume) in newly proposed application rates** compared with the representative use presented in the 2012 renewal dossier. See [47]**Appendix 2 of the biodiversity document accompanying this submission**. **Treated area restriction** 22. for the representative use GAPs: applying to only 50 % of the total area in orchard/vineyard area. 23. maximum of 50 % of the total area for broad acre vegetable inter-row 24. Invasive species control e.g., couch grass – maximum of 20 % of the cropland + extended application intervals. **Limited frequency and timing of application:** 28-day interval between applications and no pre-harvest applications
Application equipment	Spray drift reduction nozzles (SDRN), shields,	Reduces exposure of organisms in-crop (precision treatment) and off-crop	**Reduction of spray drift to the off-field**: 15. Use 75 % drift reducing nozzles for pre-sowing/pre-planting in arable crops.

[47] [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

Table 10.6-17: Examples of standard mitigation measures as described in MAgPIE (2017) across the various Member States to mitigate effects of glyphosate on biodiversity.

Type of Mitigation Measure	Risk Mitigation Measure	Benefits	Glyphosate renewal dossier (2020)
with Spray Drift Reduction Technology (SDRT)	Precision treatment, etc.		16. Use of ground directed, shielded spray for band application in orchards / vineyards and broad-acre vegetable inter-row application.
Buffer zones	Non-sprayed zone at the edge of a crop	Reduces exposure of organisms and off-crop	**Establishment of buffer zones:** Buffer zones of varying size (depending on the type of SDRT) are required as protection for off-crop NTTP communities from spray drift.

References relied upon in Indirect effects via trophic interaction for Non-Target Terrestrial Plants discussion

Arts G, T Brock, I Roessink. 2017. Arable weeds and nontarget plants in prospective risk assessment for non-target plant: specific protection goals and exposure assessment goal options. Wageningen University.

Koning *et al.*, 2019: Effects of management by glyphosate or tillage on the weed vegetation in a field experiment. https://doi.org/10.1016/j.still.2018.10.012.

MAgPIE. 2013 Mitigating the Risks of Plant Protection Products in the Environment. Eds A Alix, C Brown, E Capri, G Goerlitz, B Golla, K Knauer, V Laabs, N Mackay, A Marchis, V Poulsen, EAlonso

CP 10.6.1 Summary of screening data

Screening data is not considered to be required, since toxicity of MON 52276 to terrestrial non-target plants is adequately addressed within the framework of vegetative vigour and seedling emergence tests with 10 different representative plant species. Summaries of these studies are presented below.

CP 10.6.2 Testing on non-target plants

Summaries are provided here for all the studies.

1. Information on the study

Data point	CP 10.6.2/001
Report author	[redacted]
Report year	2019
Report title	MON 52276: Effects on the Seedling Emergence and Growth of Ten Non-Target Terrestrial Plant Species under Greenhouse Conditions
Report No	S19-03634
Document No	EUR-2019-0233
Guidelines followed in study	OECD Guideline 208 (2006)
Deviations from current test guideline	Deviations from current test guideline OECD 208 (2006): Major: - none Minor: - No reference substance or historical data were mentioned in the report.
Previous evaluation	No, not previously submitted.
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 1

2. Full summary

Executive Summary

A seedling emergence study was conducted exposing six dicotyledonous (cucumber, oilseed rape, radish, soybean, sunflower and tomato) and four monocotyledonous (corn, oat, wheat and onion) plant species to five nominal test concentrations of 0.12, 0.37, 1.11, 3.33 and 10.00 L MON52276/ha (equivalent to 0.045, 0.134, 0.401, 1.203, and 3.610 kg glyphosate acid/ha). In addition, one negative control group (tap water) was tested. For each of the ten species, there were twenty seeds tested per treatment group.

Plants were assessed for seedling emergence, plant survival, growth stage, and phytotoxicity symptoms on days 7, 14 and 21 after 50 % of the seeds in the control had emerged in each species. The effects on plant shoot height and shoot dry weight were determined on day 21.

Compared to the control group, exposure of 10 plant species to MON 52276, resulted in no statistically significant differences in seedling emergence, mortality (survival), shoot heights and shoot dry weight, in any of the plant species tested. Therefore, the NOER is considered to be ≥ 10.00 L MON52276/ha (equivalent to ≥ 4.870 kg IPA salt/ha or to ≥ 3.610 kg glyphosate acid/ha), with the corresponding LOER, ER_{25} and ER_{50} for all parameters considered to be > 10.00 L MON52276/ha ≥ 4.870 kg IPA salt/ha or to ≥ 3.610 kg glyphosate acid/ha).

The validity of the present study according to OECD guideline 208 was achieved.

I. MATERIALS AND METHODS

A. MATERIALS

Test material:

Test item::	MON 52276 (formulated product)
Description:	Yellowish to brown liquid
Lot/Batch #:	AZE200810A
Purity:	Glyphosate acid (361 g/L); glyphosate IPA salt (487 g/L)
Vehicle and/or positive control:	No
Test organism:	
Species:	6 Dicotyledons: *Cucumis sativus* (cucumber), *Brassica napus* (oilseed rape), *Raphanus sativus* (radish), *Glycine max* (soybean), *Helianthus annuus* (sunflower), *Lycopersicon esculentum* (tomato) 4 Monocotyledons: *Zea mays* (maize), *Triticum aestivum* (wheat), *Avena sativa* (oat), *Allium cepa* (onion)
Source:	Battle: cucumber, maize, wheat and onion KWS: oilseed rape Hild: radish Baywa: soybean Bringenheimer: sunflower Monsanto: tomato Intersemillas: oat
Environmental conditions:	
Temperature:	17.5 – 36.2 °C
Relative humidity:	41 – 82 %
Photoperiod:	16 hours light/8 hours dark
Light intensity:	596 µEs/m^2
Soil textural class:	Sandy Loam (field collected) 67.28 % sand, 14.0 % silt, 18.72 % clay
Soil pH:	8.48
Soil organic content:	0.80 %
Soil conductivity:	0.351 mS/cm
Experimental work dates:	17 May – 22 August 2019

B. STUDY DESIGN

Experimental treatments

Twenty seeds per treatment group and per species were sown into plastic pots (diameter of 15 cm and capacity 1.5 L). Seeds of six dicotyledonous and four monocotyledonous species were sown into sandy-loam soil, with a pH of 8.48 and an organic carbon content of 0.80 %. For cucumber, oilseed rape, radish, soybean, sunflower, tomato and maize, ten replicates (including 2 seeds each) were set up. For wheat, oat and onion, five replicates (including 4 seeds each) were set up. MON 52276 was applied on the soil surface with a track-sprayer (Company Schachtner, Ludwigsburg, Germany) at the rates of control (0), 0.12, 0.37, 1.11, 3.33, and 10.00 L test item/ha (equivalent to 0.045, 0.134, 0.401, 1.203, and 3.610 kg glyphosate acid/ha). The track-sprayer was calibrated before the application to provide an output of 200 L with a tolerance of 10 % per ha.

Observations

Following the application, seedling emergence assessment was carried out daily (until no more emergence) and mortality, phytotoxicity and growth stage were assessed at 7, 14 and 21 days after 50 % of the seedlings in the control had emerged. At test termination, assessment of shoot height and dry weight were carried out. Results were compared to the tap water treated control. Analysis of the fortified and test item rate solution (10.00 L test item/ha) were analysed by HPLC. Phytotoxicity assessments were made with a gradual rating (ranging from 0 to 100 %) to describe necrosis, chlorosis and other characteristics that could be treatment related. Shoot heights of above-ground vegetation was measured for each surviving plant from the soil surface to the apical tip (oilseed rape, radish, maize, wheat, oat and onion), or highest aerial part (cucumber, soybean, sunflower and tomato). Surviving plants were clipped at soil level on the last assessment day and dried at 60 °C for at least 48 hours. The shoot dry weight was determined per replicate. Test solutions were analysed for the concentrations of glyphosate, the active ingredient in MON 52276 using a liquid chromatography tandem mass spectrometry (LC-MS/MS) system. The samples were collected from each test solution and control at application to the test systems for the definitive test.

Statistical calculations

Statistical analysis of data was performed using the ToxRat Solutions program (ToxRat® Professional Version 3.2.1). For determination of significant difference to the control, the significance level was set to α = 0.05 for all tests. For seedling emergence and mortality data, when the monotonic rate-response is not evident a Bonferroni-Fisher-Test was performed. Shoot height and shoot dry weight data was tested for normality of data with the Shapiro-Wilk's test and for homoscedasticity with the Levene's test before performing the appropriate statistical test. Comparison between each rate of the test item assayed, with at least three replicates with surviving individuals and the relative control, was performed for all the plant species. For shoot height and shoot dry weight data, when normal distribution and homogeneity of variance of the data was obtained, and a monotonic rate-response was evident, Williams test (α = 0.05) was performed. With the same conditions, where a monotonic rate-response was not evident, a Dunnett's test (α = 0.05) was performed. When normal distribution of the data was not obtained, Step-down Jonckheere-Tepstra (α = 0.05) or Multiple Sequentially Rejective U test after Bonferroni Holm (α = 0.05) was performed.

II. RESULTS AND DISCUSSION

A. FINDINGS

The highest test item application solution served as a stock solution. For all lower application rates aliquots were taken and diluted in water. The stock solution was analysed and details are given below:

Table 10.6.2-1: Analytical verification of the stock solution concentrations

	Nominal concentration [L test item/ha]	**Nominal concentration** [g glyphosate acid/ha]	**Nominal concentration** [g glyphosate acid/L]	**Determined concentration** [g glyphosate acid/L]	**% of the nominal**
Control	0	0	< LOD	< LOD	-
Stock solution	10	3610	18.05	15.3	85

LOD = 0.00300 g glyphosate/L = 30 % of the LOQ
LOQ = 0.0324 g test item/L (=0.0100 g glyphosate/L)

Table 10.6.2-2: Effects of MON 52276 after 21 days

Crops	MON 52276 [L test item/ha]					
	Control	0.12	0.37	1.11	3.33	10
	Glyphosate acid [kg a.s./ha]					
	Control	0.045	0.134	0.401	1.203	3.610
Mean seedling emergence [%]						
Cucumber	95	95	95	100	95	95
Oilseed rape	85	95	90	95	95	100
Radish	85	80	75	75	75	90
Soybean	75	90	80	80	80	80
Sunflower	85	85	85	85	90	85
Tomato	100	100	95	100	95	100
Maize	100	100	95	95	100	100
Wheat	95	95	85	85	95	100
Oat	100	100	95	100	95	100
Onion	85	85	100	95	100	90
Mean mortality						
Cucumber	0	0	0	0	0	0
Oilseed rape	0	0	0	0	0	0
Radish	0	0	0	0	0	0
Soybean	0	0	0	0	0	0
Sunflower	0	0	0	0	0	0
Tomato	0	0	0	0	0	0
Maize	0	0	0	0	0	0
Wheat	0	0	0	0	0	0
Oat	0	0	0	0	0	0
Onion	0	0	0	0	0	0
Phytotoxicity						
Cucumber	0	0	0	0	0	0
Oilseed rape	0	0	0	0	0	0
Radish	0	0	0	0	0	0
Soybean	0	0	0	0	0	0
Sunflower	0	0	0	0	0	0
Tomato	0	0	0	0	0	0
Maize	0	0	0	0	0	0
Wheat	0	0	0	0	0	0
Oat	0	0	0	0	0	0
Onion	0	0	0	0	0	0
Inhibition on shoot length [%][1]						
Cucumber	--	-9.04	-33.05	-35.31	-22.93	-26.96
Oilseed rape	--	9.77	-6.54	-0.56	-0.08	-2.50
Radish	--	-0.45	4.23	2.0	6.68	7.57

Table 10.6.2-2: Effects of MON 52276 after 21 days

Crops	MON 52276 [L test item/ha]					
	Control	**0.12**	**0.37**	**1.11**	**3.33**	**10**
	Glyphosate acid [kg a.s./ha]					
	Control	**0.045**	**0.134**	**0.401**	**1.203**	**3.610**
Soybean	--	-12.46	-1.15	-10.2	-13.46	-11.49
Sunflower	--	5.47	-1.56	0.7	-0.31	0.20
Tomato	--	-2.34	-10.23	-11.8	-6.68	14.14
Maize	--	3.45	1.67	0.11	-1.0	-1.02
Wheat	--	1.94	-5.69	1.75	0.79	4.4
Oat	--	9.38	7.21	4.38	0.02	-5.94
Onion	--	2.5	8.94	5.33	-11.01	12.55
Inhibition on dry weight [%][1]						
Cucumber	--	-0.78	-8.68	1.5	-12.91	-9.67
Oilseed rape	--	2.86	9.99	3.69	6.59	9.19
Radish	--	-2.3	-2.86	-9.33	4.13	10.75
Soybean	--	-17.05	-13.11	-34.62	-16.92	-5.30
Sunflower	--	-5.66	-13.15	-23.09	-28.28	-20.63
Tomato	--	13.54	12.52	13.43	-6.84	-1.51
Maize	--	3.14	-0.77	3.15	-2.63	3.91
Wheat	--	-1.91	-3.90	-7.32	9.14	10.38
Oat	--	13.26	1.11	15.08	8.12	-15.62
Onion	--	-13.54	-25.02	-21.70	-24.49	1.05

* = significantly different when compared to the control (α = 0.05)
NA = not applicable
[1] compare to the control

Table 10.6.2-3: 21-day NOER, LOER, ER_{25} and ER_{50} values for all parameter

Crop	Endpoints [L MON57226/ha]		
	Seedling emergence/Mortality/Phytoxicity/Length/Dry weight		
	NOER	LOER	EC_{25}/EC_{50}
Cucumber	≥ 10	> 10	> 10
Oilseed rape	≥ 10	> 10	> 10
Radish	≥ 10	> 10	> 10
Soybean	≥ 10	> 10	> 10
Sunflower	≥ 10	> 10	> 10
Tomato	≥ 10	> 10	> 10
Maize	≥ 10	> 10	> 10
Wheat	≥ 10	> 10	> 10
Oat	≥ 10	> 10	> 10
Onion	≥ 10	> 10	> 10

B. OBSERVATIONS

Analytical data: Correct rate preparation and application was confirmed both by analysis of the stock solution, with recoveries of 85 % of glyphosate and via calibration of the spray equipment.
Mortality results: None of the tested rates of the test item MON 52276 significantly affected the survivorship of the tested species.
Seedling emergence results: None of the tested rates of the test item MON 52276 significantly affected the emergence of the tested species.
Phytotoxicity results: None of the tested rates of the test item MON 52276 showed phytotoxicity symptoms for any of the tested species.
Growth stage results: No differences in growth stage could be detected between the test item groups and the control for the ten tested species at any of the rates tested.
Dry weight results: No statistically significant reductions on shoot dry weight were observed for the tested treatment rates of the test item MON 52276 for all tested species.
Shoot height results: No statistically significant reductions on shoot height were observed for the tested treatment rates of the test item MON 52276 for all tested species.

The following point deviated from the current guideline recommendations:

- No reference substance or historical data were mentioned in the report.

Validity criteria according to OECD 208 were fulfilled for all species tested:

- Seedling emergence: The control seedling emergence was ≥ 70 % (actually: 75 % to 100 %).
- Phytotoxicity: The control seedlings of each species did not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and control plants exhibited only normal variation in growth and morphology for that particular species.
- Mean survival: The mean survival of emerged control seedlings was ≥ 90 % (actually: 95 % to 100 %).
- Cultivation Conditions: The environmental conditions for each particular species were identical and growing media contained the same amount of soil matrix, support media, or substrate from the same source.

III. CONCLUSIONS

Assessment and conclusion by applicant:

Compared to the control group, exposure of 10 plant species to MON 52276, resulted in no statistically significant differences in seedling emergence, mortality (survival), shoot heights and shoot dry weight, in any of the plant species tested. Therefore, the NOER is considered to be ≥ 10.00 L MON52276/ha (equivalent to ≥ 3.610 kg glyphosate acid/ha), with the corresponding LOER, ER_{25} and ER_{50} for all parameters considered to be > 10.00 L MON52276/ha (> 3.610 kg glyphosate acid/ha).

Therefore, the study was classified as valid

Assessment and conclusion by RMS:

1. Information on the study

Data point	CP 10.6.2/002
Report author	[redacted]
Report year	2014
Report title	MON 52276: Effects on the Vegetative Vigor of Non-Target Terrestrial Plants (Tier II)
Report No	80477
Document No	-
Guidelines followed in study	OECD Guideline 227 (2006)
Deviations from current test guideline	Deviations from current test guideline OECD 227 (2006): Major: none Minor: - No reference substance or historical data were mentioned in the report. - Light intensity was lower than 350 $\mu E/m^2/s$ (mean values 170/173 $\mu Es^{-1}m^{-2}$)
Previous evaluation	Yes, accepted in RAR (2015)
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Valid
Category study in AIR 5 dossier (L docs)	Category 2a

2. Full summary

Executive Summary

A vegetative vigour study was conducted exposing six dicotyledonous (cucumber, oilseed rape, radish, soybean, sunflower and tomato) and four monocotyledonous (corn, oat, wheat and onion) plant species to seven nominal test concentrations of 20, 40, 80, 160, 320, 640, and 1280 g MON 52276 a.e./ha. In addition, one negative control group (deionized water) was tested. The test was replicated four times for all species. At test initiation, each pot contained five plants per pot, except for cucumber which contained three plants per pot.

Following the application, plant damage and phytotoxic effects were recorded weekly until the test termination at 21 days after application. At test termination, the numbers of live and dead plants were recorded along with the visual assessments. Shoots were composited by replicate and fresh weights were measured and recorded.

The most sensitive monocotyledonous plant species was wheat with an EC_{50} value of 38.2 g a.e./ha for shoot fresh weight. Cucumber was the most sensitive dicotyledonous plant species with an EC_{50} value of 28.4 g a.e./ha for shoot fresh weight.

The validity of the present study according to OECD guideline 227 was achieved.

I. MATERIALS AND METHODS

A. MATERIALS

Test material:

Test item::	MON 52276 (formulated product)
Description:	Amber liquid
Lot/Batch #:	GLP-1308-22862-F
Purity:	30.45 % glyphosate acid
Vehicle and/or positive control:	No
Test organism:	
Species:	6 Dicotyledons: (cucumber, oilseed rape, radish, soybean, sunflower and tomato) 4 Monocotyledons: (corn, oat, wheat and onion)
Source:	Syngenta Seed: corn, sunflower Ohio Foundation Seeds: oat Park Seed Co.: onion L.A. Hearne company: wheat NE Seed: cucumber, tomato Johnny's Selected Seeds: oilseed rape Sustainable Seed Company: radish Missouri Foundation Seeds: soybean
Environmental conditions:	
Temperature:	17.0 – 28.3 °C: corn, oat, onion, wheat, soybean, sunflower 21.4 – 29.4 °C: cucumber, oilseed rape, radish, tomato
Relative humidity:	32 – 92 %: corn, oat, onion, wheat, soybean, sunflower 27 – 73 %: cucumber, oilseed rape, radish, tomato
Photoperiod:	16 hours light/8 hours dark 170 µEs/m^2 (daily accumulated PAR was 10 E/m^2) for corn, oat, onion, wheat, soybean, sunflower 173 µEs/m^2 (daily accumulated PAR was 10 E/m^2) for cucumber, oilseed rape, radish, tomato
Soil textural class:	Sandy Loam (72 % sand; 18 % silt; 10 % clay)
Soil pH:	5.9
Soil organic content:	1.5 % (equivalent to 2.5 % organic matter)
Experimental work dates:	5 November – 26 November 2013

B. STUDY DESIGN

Experimental treatments

Prior to treatment, seedlings were grown (in 16.5 cm - diameter plastic pots containing 11.5 cm depth of soil) to the 2 to 3 – 4 true leaf stage from untreated seed in a sandy Loam soil (1.5 % organic matter, pH 5.9) in a greenhouse. The test was replicated four times for all species. Because the test species are different in their size and growth requirements, numbers of test plants per pot and pots per replicate were adjusted accordingly. Applications of the formulated product were made using a calibrated overhead track sprayer (De Vries Manufacturing). The single nozzle sprayer was equipped with a TeeJet 4001 E nozzle and operated at 40 psi. The target application volume was 100 L of water per hectare (L/ha). The application started with the controls and then progressed upward in treatment rates. The applications produced target application rates of 0 (control), 20, 40, 80, 160, 320, 640, and 1280 g a.e./ha.

Observations

Observations of survival (numbers of live plants present and cumulative mortality) and phytotoxicity ratings (i.e., visual injury assessments) were performed on a weekly basis for all species. Visual injury assessments were made on a scale of 0 to 100. The range and severity of effects as compared to the control plants are as follows: 0 to 10, no effect; 20 to 30, slight effect; 40 to 60, moderate effect; 70 to 90, severe effect; with 100 meaning all plants dead. Visually observed phytotoxic effects were stunting, chlorosis, wilting, leaf wrinkling, necrosis, and damping off, though not all manifested on all species.

Shoot lengths were measured from the base of the stem to the tip of the longest leaf for bulb or leaf rosette plants and from the base of the stem to the apical bud for other plants. The in-life phase was terminated 21 days after application of the test substance. At test termination, the numbers of live and dead plants were recorded along with the visual assessments. Plants were watered prior to taking fresh weights.

Test solutions were analysed for the concentrations of glyphosate, the active ingredient in MON 52276 using a liquid chromatography tandem mass spectrometry (LC-MS/MS) system. The samples were collected prior to and after application to the test systems for the definitive test.

Statistical calculations

All statistical computations were performed using SAS Version 9.3 software. Continuous data (length, weight) was analysed using analysis of variance (ANOVA) and Jonckheere-Terpstra test if monotonous. The NOEC for quantal data (survival) for species less than 100 % was determined by Cochran-Armitage. If monotonicity was not determined then pair-wise testing was performed using Dunnett's or Dunn's test for continuous data, after Shapiro-Wilk and Levene testing for normality and homogeneity of variance respectively, and Fisher's Exact test for quantal data. Estimates for continuous data (length, weight) were calculated by Bruce and Versteeg weighted Probit or other appropriate regression models, fit using the Marquardt method. Estimates for Quantal data (survival) were calculated using Probit when possible or Moving Average Angle or Binomial analysis when appropriate.

II. RESULTS AND DISCUSSION

A. FINDINGS

Table 10.6.2-4: Analytical verification of the concentrations

Parameter	Nominal concentration of glyphosate acid equivalent [g/ha]						
	0	320		640		1280	
	Nominal concentration of glyphosate acid equivalent [mg/L]						
	0	**3.20**		**6.40**		**12.8**	
	Measured concentration of glyphosate acid equivalent [mg/L]						
Pre-application concentration	< MQL[a]	3.10	3.08	6.0	5.88	12.8	13.3
Pre-application % of nominal	-	97	96	94	92	100	104
Post-application concentration	< MQL[a]	2.92	2.98	6.0	5.8	12.3	12.5
Post-application % of nominal	-	91	93	94	91	96	98

[a] MQL = 0.0200 mg/mL

Table 10.6.2-5: Effects of MON 52276 after 21 days

Crops	Glyphosate acid equivalent g/ha							
	Control	20	40	80	160	320	640	1280
Survival [%]								
Corn	100	100	100	100	100	95	50*	37*
Oat	100	100	100	100	92	22*	0*	0*
Onion	100	100	100	100	100	87*	67*	35*
Wheat	100	100	100	57*	2*	0*	0*	0*
Cucumber	100	100	100	42*	0*	0*	0*	0*
Oilseed rape	100	100	100	100	100	100	47*	0*
Radish	100	100	100	100	97	72*	20*	2*
Soybean	100	100	100	95	65*	7*	0*	0*
Sunflower	100	100	100	85*	20*	0*	0*	0*
Tomato	100	100	100	90	5*	0*	0*	0*
Phytotoxic Effects rating								
Corn	0	0	10	18	43	70	80	80
Oat	0	5	10	15	60	93	100	100
Onion	0	18	10	15	30	45	73	90
Wheat	0	0	25	45	98	100	100	100
Cucumber	0	10	28	63	100	100	100	100
Oilseed rape	0	0	3	8	38	60	85	100
Radish	0	5	10	23	43	65	90	98
Soybean	0	0	18	53	70	93	100	100
Sunflower	0	0	33	50	83	100	100	100
Tomato	0	0	33	55	95	100	100	100
Mean plant fresh weight [g/treatment replicate]								
Corn	74.329	69.113	68.585	60.905*	28.846*	2.448*	0.498*	0.454*
Oat	57.927	61.129	55.825	53.543	12.260*	0.814*	NA	NA
Onion	66.191	49.072	60.458	57.666	28.238*	8.926*	1.458*	0.218*
Wheat	31.373	27.120	14.170*	0.865*	0.059*	NA	NA	NA
Cucumber	157.47	122.01*	76.04*	10.298*	NA	NA	NA	NA
Oilseed rape	129.14	126.62	133.98	125.62	56.161*	17.283*	4.168*	NA
Radish	95.009	82.301	83.568	57.897*	19.982*	6.095*	0.919*	0.956*
Soybean	88.13	76.772	62.966*	20.617*	2.522*	2.175*	NA	NA
Sunflower	133.33	107.05*	42.117*	7.855*	1.017*	NA	NA	NA
Tomato	210.403	155.438*	60.455*	11.604*	0.291*	NA	NA	NA

Table 10.6.2-5: Effects of MON 52276 after 21 days

Crops	Glyphosate acid equivalent g/ha							
	Control	20	40	80	160	320	640	1280
Mean shoot length [mm]								
Corn	691	667	670	608*	361*	207*	188*	187*
Oat	720	690	687	709	367*	245*	NA	NA
Onion	417	398	386*	388*	298*	191*	157*	143*
Wheat	478	449	319*	260*	286*	NA	NA	NA
Cucumber	591	419*	151*	55*	NA	NA	NA	NA
Oilseed rape	264	261	266	268	189	175*	148*	NA
Radish	183	167	174	158*	134*	109*	94*	151*
Soybean	548	533	454*	226*	138*	146*	NA	NA
Sunflower	498	445	284*	146*	118*	NA	NA	NA
Tomato	302	314	158*	73*	71*	NA	NA	NA

* = significantly different when compared to the control determined by Cochran-Armitage test ($\alpha = 0.05$)
NA = not applicable

Table 10.6.2-6: 21-day NOER, ER_{25} and ER_{50} values

Crop	Endpoints [g acid equivalent/ha]		
	% Survival		
	NOEC	EC_{25} (95 % CI)	EC_{50} (95 % CI)
Corn	320	522 (414 – 626)	854 (714 – 1069)
Oat	160	204 (175 – 228)	252 (225 – 281)
Onion	160	536 (424 – 650)	916 (752 – 1194)
Wheat	40	70.2 (59.6 – 78.3)	85.9 (76.8 – 96.0)
Cucumber	40	NC	76.7 (65.1 – 92.7)
Oilseed rape	320	NC	632 (558 – 728)
Radish	160	305 (252 – 353)	431 (374 – 497)
Soybean	80	134 (112 – 153)	179 (157 – 204)
Sunflower	40	92.2 (78.3 – 104)	117 (104 – 132)
Tomato	80	92.4 (81.8 – 102)	108 (98.1 – 120)
Crop	**Fresh weight**		
	NOEC	EC_{25} (95 % CI)	EC_{50} (95 % CI)
Corn	40	87.1 (58.3 – 130)	131 (99.0 – 174)
Oat	80	91.7 (79.3 – 106)	120 (109 – 132)
Onion	80	103 (77.7 – 137)	163 (133 – 199)
Wheat	20	29.1 (24.6 – 34.5)	38.2 (33.9 – 43.1)
Cucumber	< 20	28.4 (22.6 – 35.7)	39.2 (33.7 – 45.7)
Oilseed rape	80	96.0 (81.7 – 113)	153 (137 – 171)
Radish	40	55.3 (42.0 – 72.9)	94.9 (78.1 – 115)
Soybean	20	34.7 (26.7 – 45.0)	52.9 (44.1 – 63.5)
Sunflower	< 20	21.9 (19.1 – 25.2)	31.1 (27.7 – 34.8)
Tomato	< 20	19.5 (15.7 – 23.3)	30.0 (26.2 – 33.8)
Crop	**Shoot length**		
	NOEC	EC_{25} (95 % CI)	EC_{50} (95 % CI)
Corn	40	55.8 (27.7 – 112)	207 (133 – 323)
Oat	80	112 (85.9 – 147)	204 (174 – 238)
Onion	20	99.7 (60.9 – 136)	387 (291 – 514)
Wheat	20	32.5 (16.7 – 63.2)	120 (73.4 – 197)
Cucumber	< 20	18.3 (14.0 – 22.5)	28.4 (24.1 – 32.7)
Oilseed rape	160	202 (131 – 313)	689 (525 – 902)
Radish	40	130 (42.8 – 392)	1144 (526 – 2487)
Soybean	20	33.0 (19.8 – 54.8)	75.3 (54.7 – 103)
Sunflower	20	21.4 (13.8 – 32.3)	50.9 (38.7 – 67.1)
Tomato	20	22.9 (12.7 – 41.0)	46.7 (32.1 – 67.9)

CI = confidence interval
NC= not calculated

B. OBSERVATIONS

Analytical data:
Chemical analyses were performed on samples of the three highest test solutions to quantify glyphosate in the test solution. The mean measured concentrations ranged from 92 to 104 % in the pre-application samples and ranged from 91 to 98 % to the post-application samples. The measured content of the test item always ranged between 80 and 120 % of nominal, so the ecotoxicological endpoints were evaluated using nominal concentrations of the test item.

Survival and phytotoxicity results:
There were no phytotoxic effects and the survival was 100 % in the control for all species. There was significant (p = 0.05) reduction in survival compared to the control in all species tested. After 21 days, treatment level mean phytotoxicity ratings ranged from 0 to 100 for all species and progressed toward moderate or severe with increasing test substance concentration. The lowest NOEC values was 40 g a.e./ha for wheat, cucumber and sunflower. The most sensitive species based on survival EC_{50} values was cucumber with an EC_{50} of 76.7 g a.e./ha.

Fresh weight results:
Shoot fresh weight was significantly reduced in all species. The most sensitive species based on shoot fresh weight EC_{50} values was tomato, with an EC_{50} of 30.0 g a.e./ha.

Shoot length results:
Shoot length was significantly reduced in all species. The most sensitive species based on shoot length EC_{50} values was cucumber with an EC_{50} of 28.4 g a.e./ha.

The most sensitive monocotyledonous plant species was wheat with an EC_{50} value of 38.2 g a.e./ha for shoot fresh weight. Cucumber was the most sensitive dicotyledonous plant species with an EC_{50} value of 28.4 g a.e./ha for shoot fresh weight.

The following points deviated from the current guideline recommendations:
- No reference substance or historical data were mentioned in the report.
- Light intensity was lower than 350 µE/m^2/s (means values 170/173 µEs^{-1} m^{-2})

However, there were no phytotoxic effects observed in the controls for any of the species tested, meaning that the growing conditions were appropriate for the species. In addition any competition for light was minimized considering that due to the test species being different in their size and growth requirements, numbers of test plants per pot and pots per replicate were adjusted accordingly.
The validity criteria according to the OECD 227 were fulfilled. The seedling emergence was at least 70 % (actual values from 85 to 99 %). In the control, the plants did not exhibit visible phytotoxic effects; the mean plant survival is at least 90 % for the duration of the study (actual value 100 %); environmental conditions for a particular species were identical and growing media contain the same amount of soil matrix, support media, or substrate from the same source.

III. CONCLUSIONS

Assessment and conclusion by applicant:

The lowest EC_{50} value for MON 52276 was observed with cucumber and was calculated to be 28.4 g acid equivalent/ha for shoot fresh weight. The lowest NOEC values were observed with cucumber, sunflower and tomato for fresh weight parameter and with cucumber for shoot length parameter and were calculated to be < 20 g acid equivalent/ha.

RMS conclusion in the RAR 2015:
Despite the assumption that the study was considered to be valid as criteria according to OECD 227 were fulfilled, RMS questioned the reliability of the endpoints from the study with half the recommended light intensity. RMS could not exclude the possibility that sensitivity of the test species was underestimated under the proposed environmental conditions and with the choice of the endpoint shoot length. RMS considered that uncertainties exist in terms of a reliable exposure of test plants and concerning the full potential of glyphosate action to affect a down regulated plastid localised pathway. Nevertheless, this study displayed the only dataset provided for the representative formulation MON 52276 and therefore, included information about the relevance of the formulants. In general, toxicity studies with the commercial product are more appropriate than studies with the active ingredient only for the assessment of the effects on non-target plants.

Assessment and conclusion by RMS:

1. Information on the study

Data point	CP 10.6.2/003
Report author	[redacted]
Report year	2005
Report title	Evaluation of the toxicity of glyphosate and paraquat to terrestrial non-target plants
Report No	CEA.104
Document No	-
Guidelines followed in study	OECD 208B (draft, 2000): Terrestrial non-target plant test; Vegetative Vigour Test.
GLP	No, no claims for GLP compliance were made for the study.
Previous evaluation	Yes, evaluated and not accepted: • RAR 2015
Short description of study design and observations	The vegetative vigour test assesses the potential damage to plants following exposure of Roundup (360 g glyphosate/L, EC) on non-target plants (*Beta vulgaris* (Sugar beet); *Raphanus rapistrum* (Rape); *Lepidium sativum* (Garden cress); *Pisum sativum* (Pea); *Lolium perenne* (Perennial ryegrass) and *Triticum aestivum* (Winter wheat)) following deposition on the leaves and above-ground portions of the plants. Seedlings were grown in pots filled with sterilised Kettering loam and Derby Quartz (mixture loam and grit: 5:1). Each treatment/crop combination was replicated four times. Prior to treatment, seedlings were grown to at least 2 – 4 true leaves. Roundup was applied indoors with a Mardrive pot sprayer at 225 L/ha. The plants were treated with

	seven nominal concentrations of 0.00004, 0.0004, 0.004, 0.04, 0.4, 2.0 and 4.0 L prod/ha. One negative control group was tested. After treatment plants were kept in a greenhouse at 12 to 18 °C. Phytotoxicity ratings, according to a nine point scoring system were recorded for the first 4 days and at approximately 7, 15 and 22 days after the application. All plots were harvested between 20 to 22 days after treatment to determine fresh shoot weight. The weights of plants in one pot were combined. Data for the No Observed Effect Rates (NOER) were analysed using one-way ANOVA and Dunnett's t-test was performed as post-hoc. The highest concentration not significantly different from the control was identified as the NOER.
Short description of results	*B. vulgaris* (Sugar beet) and *R. rapistrum* (Rape) responded most quickly to the application of glyphosate as Roundup, with both species showing significant differences in vegetative vigour from the controls at 50 % field application rate (2.0 L/ha) one day after application of the test item. The NOEC was 0.4 L/ha (10 % field application rate). There was no increase in the sensitivity of either *B. vulgaris* (Sugar beet) or *R. rapistrum* (Rape) for the duration of the study and the fresh shoot weight NOEC was also 0.4 L/ha. *L. sativum* (Garden cress) was the most sensitive species according to the vegetative vigour scores with a NOEC of 0.04 L/ha (1 % field rate) from day 2 to the end of the study. The fresh shoot weight was a less sensitive endpoint, with a NOEC of 0.4 L/ha. The NOEC for calculated for fresh shoot weight was the same for all test species.
Reasons for why the study is not considered relevant/reliable or not considered as key study	The study design is not in line with the current guideline OECD 227 requirements. The validity criteria according to the current guideline could not be fulfilled. Therefore, no consistent conclusions could be drawn from the study. Deviations from current guideline: • The mean plant survival was not evaluated • Seedling emergence rate for *Lepidum sativuma and Lolium pereme* is not known. • Analytical verification of the concentrations were not performed. • Soil characteristics were not provided (max: 1.5 % organic carbon acceptable). • Light intensity was not provided.
Reasons why the study report is not available for submission	The study is not considered as relevant because of the various shortcomings.
Category study in AIR 5 dossier (L docs)	Category 3b

1. Information on the study

Data point:	CP 10.6.2/004
Report author	[redacted]
Report year	2012
Report title	Comparative Post-Emergence Phytotoxicity of AMPA and Glyphosate to Crop and Annual Weed Species
Report No	MSL0024009
Document No	-
Guidelines followed in study	Not applicable.
GLP	No, this report do not contain any test material and any experimentation.
Previous evaluation	Yes, evaluated and accepted: • RAR 2015
Short description of study design and observations:	The purpose of this evaluation was to compare relative post-emergence phytotoxicity between glyphosate and aminomethylphosphonic acid (AMPA) with crop and annual weed species. At planting, containers were packed with sterilized silt loam soil. Seeds were planted between 5 and approximately 30 specimens. After planting, plants were moved to the greenhouse with supplementary lighting and sufficient tap water was provided. Nominal test concentrations for foliar applications were prepared from a 1 % stock solution for glyphosate acid equivalent and AMPA and applied as needed to achieve the desired rate of application to young plants. Low rates required further dilution of the 1 % stock solution to 0.1 % and 0.01 % stock solutions to ensure accuracy in pipetting. To complete the formulation prior to application 0.4 % of emulsifier-L (cyclo-L) was added to each spray bottle and then water was added in sufficient volume to provide a spray volume of 200 gallons/A. The plants were inspected approximately twice per week. Phytotoxicity was recorded as visual percent injury (chlorosis) relative to the untreated control and evaluated two weeks after test initiation. The percent injury observations were used as the phytotoxicity endpoint to calculate EC_{50} values in this analysis. Glyphosate Isopropylamine (IPA) and AMPA data from studies run in parallel were available from a studies conducted on 12 March and 15 August 1986. The glyphosate levels tested in March 1986 included 0.0625, 0.125, 0.25, 0.5, 1 and 5 lb a.e./A and the glyphosate levels tested on 15 August 1986 were 1, 5, 10 and 20 lb a.e./A. Statistical calculations: EC_{50} values were calculated using a 3-parameter logistic model with the software package GraphPad Prism version 5.04 (GraphPad Software, Inc.). The maximum asymptote was constrained in the logistic model to 100 % to reflect the maximum potential response based on percent injury observations.
Short description of results:	EC_{50} molar ratios were calculated as EC_{50} AMPA/EC_{50} glyphosate acid and ranged from 3.4 for hemp sesbania to 87 for common lambsquarters. All AMPA/EC_{50} glyphosate acid ratios were greater than 2, with an average ratio across the seventeen tested species of 22, indicating that AMPA has significantly lower herbicidal activity compared to glyphosate.

Table 1. Post-emergence EC_{50} values for AMPA and Glyphosate to Crop and Annual Weed Species based on units of kg/ha

Species Common name	Species Scientific Name	Glyphosate Acid EC_{50} (kg/ha)	AMPA EC_{50} (kg/ha)	EC_{50} Ratio [1]
BARNYARD GRASS	*Echinochloa crus-galli*	0.711	11.545	16.249
COCKLEBUR	*Xanthium strumarium*	0.697	2.883	4.135
CORN	*Zea mays*	0.289	4.702	16.260
CRABGRASS	*Digitaria ischaemum*	0.392	7.846	20.000
GREEN FOXTAIL	*Setaria veridis*	0.363	4.751	13.091
HEMP SESBANIA	*Sesbania exaltata*	1.003	2.238	2.231
LAMBSQUARTERS	*Chenopodium album*	0.389	22.193	56.978
MORNING GLORY	*Ipomoea sp.*	1.169	14.280	12.215
PROSO MILLET	*Panicum miliaceum*	0.330	4.849	14.709
RICE	*Oryza sativa*	0.936	9.732	10.395
SMARTWEED	*Polygonum pensylvanicum*	0.826	4.184	5.068
SORGHUM	*Sorghum bicolor*	0.560	10.844	19.373
SOYBEAN	*Glycine max*	0.950	10.291	10.832
SUGAR BEET	*Beta vulgaris*	0.557	4.357	7.829
VELVETLEAF	*Abutilon theophrasti*	0.880	15.815	17.972
WHEAT	*Triticum aestivum*	0.795	14.627	18.391
WILD BUCKWHEAT	*Polygonum convolvulus*	0.556	2.867	5.158
Average		**0.6701**	**8.706**	**14.758**

[1] EC_{50} ratio calculated as EC_{50} AMPA/EC_{50} glyphosate. Results were calculated with full precision mode in Excel and may differ slightly from hand calculated values.

Reasons for why the study is not considered relevant/reliable or not considered as key study:	This report is a comparison of post-emergence phytotoxicity between glyphosate and AMPA with crop and annual weed species, according to data generated from several screening studies previously performed. Nevertheless the results could be useful as supplemental data.
Reasons why the study report is not available for submission	The report is considered as supportive only.
Category study in AIR 5 dossier (L docs)	Category 3b

CP 10.6.3 Extended laboratory studies on non-target plants

Additional testing is not required, since toxicity of glyphosate and the representative product MON 52276 to terrestrial non-target plants is adequately addressed within the framework of vegetative vigour and seedling emergence tests with 10 different representative plant species and an acceptable risk assessment is concluded.

CP 10.6.4 Semi-field and field tests on non-target plants

Additional testing is not required.

CP 10.7 Effects on Other Terrestrial s (Flora and Fauna)

As acceptable risk has been shown for all standard test organisms, further testing on additional species is not considered necessary. In summary, acceptable acute or long-term risks were indicated for each of the indicator species including birds, mammals, aquatic organisms, bees and other terrestrial non-target arthropods, soil macro and meso-organisms, micro-organisms and terrestrial non-target plants, in consideration of the proposed uses for MON 52276. However, a report has been prepared to further address the impact on biodiversity, namely 'Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment[48]'. The purpose of this report is two-fold: (1) provide a biodiversity assessment that principally informs on indirect effects through trophic interactions and (2) to inform risk assessors and managers on risk mitigation options that are protective of aquatic and terrestrial biodiversity. The outcome of the present biodiversity assessment for glyphosate is summarized for the different environmental compartments and taxa where appropriate in the document M-CP Section 10.

CP 10.8 Monitoring Data

Available monitoring data for glyphosate and its metabolites in soil, water, sediment and air are presented and discussed in detail in MCA Section 7.5

[48] [redacted] (2020) Glyphosate: Indirect effects via trophic interaction - A Practical Approach to Biodiversity Assessment (TRR0000305).

Annex M-CP 10-01: Avian risk assessment

Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c

Table CP 10-01-1: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1440 g.a.s/ha)

Active substance		**Active substance:** Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		**Reprod. Toxicity (mg/kg bw/d):** 96.3					
TER criterion		**TER criterion**: 5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1440	Bulbs and onion like crops BBCH ≥ 40	Small granivorous bird "finch" Linnet (Carduelis cannabina)	6.9	1.0 × 0.53	4.34	22.2
		Cereals BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	2.52	38.2
		Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	2.59	37.1
		Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	2.52	38.2
		Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	7.40	13.0
		Leafy vegetables BBCH ≥ 50	Small granivorous bird "finch" Serin (*Serinus serinus*)	3.8	1.0 × 0.53	2.90	33.2
		Leafy vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	2.52	38.2
		Leafy vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	7.40	13.0
		Legume forage BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	2.59	37.1
		Legume forage BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	2.52	38.2

Table CP 10-01-1: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1440 g.a.s/ha)

Active substance		**Active substance:** Glyphosate					
Reprod. Toxicity (mg/kg bw/d) **TER criterion**		**Reprod. Toxicity (mg/kg bw/d):** 96.3 **TER criterion**: 5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV$_m$**	**MAF$_m$ × TWA**	**DDD$_m$ (mg/kg bw/d)**	**TER$_{lt}$**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1440	Legume forage BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	7.40	13.0
		Maize BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	1.0 × 0.53	2.06	46.7
		Maize BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	4.8	1.0 × 0.53	3.66	26.3
		Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	1.0 × 0.53	2.06	46.7
		Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	0.9	1.0 × 0.53	0.687	140
		Potatoes BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	2.52	38.2
		Potatoes BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	7.40	13.0
		Pulses BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	2.59	37.1
		Pulses BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	2.52	38.2
		Pulses BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	7.40	13.0
		Root & stem vegetables BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	2.59	37.1
		Root & stem vegetables BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula*	3.3	1.0 × 0.53	2.52	38.2

Table CP 10-01-1: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1440 g.a.s/ha)

Active substance		**Active substance:** Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		**Reprod. Toxicity (mg/kg bw/d):** 96.3					
TER criterion		**TER criterion**: 5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
			arborea)				
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1440	Root & stem vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	7.40	13.0
		Strawberries BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	4.4	1.0 × 0.53	3.36	28.7
		Strawberries BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	7.40	13.0

Table CP 10-01-2: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2 × 1080 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 1080	Bulbs and onion like crops BBCH ≥ 40	Small granivorous bird "finch" Linnet (Carduelis cannabina)	6.9	1.1 × 0.53	4.34	22.2
		Cereals BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	2.08	46.3
		Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.1 × 0.53	2.14	45.0
		Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	2.08	46.3
		Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	6.11	15.8

Table CP 10-01-2: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2 × 1080 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 1080	Leafy vegetables BBCH ≥ 50	Small granivorous bird "finch" Serin (*Serinus serinus*)	3.8	1.1 × 0.53	2.39	40.2
		Leafy vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	2.08	46.3
		Leafy vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	6.11	15.8
		Legume forage BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.1 × 0.53	2.14	45.0
		Legume forage BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	2.08	46.3
		Legume forage BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	6.11	15.8
		Maize BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	1.1 × 0.53	1.70	56.6
		Maize BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	4.8	1.1 × 0.53	3.02	31.9
		Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	1.1 × 0.53	1.70	56.6
		Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	0.9	1.1 × 0.53	0.567	170
		Potatoes BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	2.08	46.3
		Potatoes BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	6.11	15.8

Table CP 10-01-2: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2 × 1080 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 1080	Pulses BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.1 × 0.53	2.14	45.0
		Pulses BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	2.08	46.3
		Pulses BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	6.11	15.8
		Root & stem vegetables BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.1 × 0.53	2.14	45.0
		Root & stem vegetables BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	2.08	46.3
		Root & stem vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	6.11	15.8
		Strawberries BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	4.4	1.1 × 0.53	2.77	34.8
		Strawberries BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	6.11	15.8

Table CP 10-01-3: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 720 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 720	Bulbs and onion like crops BBCH ≥ 40	Small granivorous bird "finch" Linnet (Carduelis cannabina)	6.9	1.0 × 0.53	2.63	36.6
		Cereals BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.26	76.5
		Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	1.30	74.2
		Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.26	76.5
		Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	3.70	26.0
		Leafy vegetables BBCH ≥ 50	Small granivorous bird "finch" Serin (*Serinus serinus*)	3.8	1.0 × 0.53	1.45	66.4
		Leafy vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.26	76.5
		Leafy vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	3.70	26.0
		Legume forage BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	1.30	74.2
		Legume forage BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.26	76.5
		Legume forage BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	3.70	26.0
		Maize BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	1.0 × 0.53	1.03	93.5

Table CP 10-01-3: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 720 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 720	Maize BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	4.8	1.0 × 0.53	1.83	52.6
		Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	1.0 × 0.53	1.03	93.5
		Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	0.9	1.0 × 0.53	0.343	280
		Potatoes BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.26	76.5
		Potatoes BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	3.70	26.0
		Pulses BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	1.30	74.2
		Pulses BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.26	76.5
		Pulses BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	3.70	26.0
		Root & stem vegetables BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	1.30	74.2
		Root & stem vegetables BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.26	76.5

Table CP 10-01-3: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 720 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 720	Root & stem vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	3.70	26.0
		Strawberries BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	4.4	1.0 × 0.53	1.68	57.4
		Strawberries BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	3.70	26.0

Table CP 10-01-4: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2 × 720 g.a.s/ha)

Active substance		Active substance: Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 720	Bulbs and onion like crops BBCH ≥ 40	Small granivorous bird "finch" Linnet (Carduelis cannabina)	6.9	1.1 × 0.53	2.90	33.3
		Cereals BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	1.39	69.5
		Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.1 × 0.53	1.43	67.5
		Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	1.39	69.5
		Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	4.07	23.7

Table CP 10-01-4: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2 × 720 g.a.s/ha)

Active substance		Active substance: Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 720	Leafy vegetables BBCH ≥ 50	Small granivorous bird “finch” Serin (*Serinus serinus*)	3.8	1.1 × 0.53	1.60	60.4
		Leafy vegetables BBCH ≥ 50	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	1.39	69.5
		Leafy vegetables BBCH ≥ 20	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	4.07	23.7
		Legume forage BBCH ≥ 50	Small granivorous bird “finch” Linnet (*Carduelis cannabina*)	3.4	1.1 × 0.53	1.43	67.5
		Legume forage BBCH ≥ 50	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	1.39	69.5
		Legume forage BBCH ≥ 20	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	4.07	23.7
		Maize BBCH ≥ 40	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	2.7	1.1 × 0.53	1.13	85.0
		Maize BBCH ≥ 20	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	4.8	1.1 × 0.53	2.01	47.8
		Oilseed rape BBCH ≥ 40	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	2.7	1.1 × 0.53	1.13	85.0
		Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird “pigeon” Wood pigeon (*Columba palumbus*)	0.9	1.1 × 0.53	0.378	255
		Potatoes BBCH ≥ 40	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	1.39	69.5
		Potatoes BBCH ≥ 20	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	4.07	23.7

Table CP 10-01-4: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2 × 720 g.a.s/ha)

Active substance		Active substance: Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 720	Pulses BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.1 × 0.53	1.43	67.5
		Pulses BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	1.39	69.5
		Pulses BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	4.07	23.7
		Root & stem vegetables BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.1 × 0.53	1.43	67.5
		Root & stem vegetables BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.1 × 0.53	1.39	69.5
		Root & stem vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	4.07	23.7
		Strawberries BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	4.4	1.1 × 0.53	1.85	52.1
		Strawberries BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.1 × 0.53	4.07	23.7

Table CP 10-01-5: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1080 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1080	Cereals BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.89	51.0
		Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	1.95	49.5
		Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.89	51.0
		Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	5.55	17.3
		Leafy vegetables BBCH ≥ 50	Small granivorous bird "finch" Serin (*Serinus serinus*)	3.8	1.0 × 0.53	2.18	44.3
		Leafy vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.89	51.0
		Leafy vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	5.55	17.3
		Legume forage BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	1.95	49.5
		Legume forage BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.89	51.0
		Legume forage BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	5.55	17.3
		Maize BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	1.0 × 0.53	1.55	62.3

Table CP 10-01-5: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1080 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1080	Maize BBCH ≥ 20	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	4.8	1.0 × 0.53	2.75	35.0
		Oilseed rape BBCH ≥ 40	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	2.7	1.0 × 0.53	1.55	62.3
		Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird “pigeon” Wood pigeon (*Columba palumbus*)	0.9	1.0 × 0.53	0.515	187
		Potatoes BBCH ≥ 40	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.89	51.0
		Potatoes BBCH ≥ 20	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	5.55	17.3
		Pulses BBCH ≥ 50	Small granivorous bird “finch” Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	1.95	49.5
		Pulses BBCH ≥ 50	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.89	51.0
		Pulses BBCH ≥ 20	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	5.55	17.3
		Root & stem vegetables BBCH ≥ 40	Small granivorous bird “finch” Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	1.95	49.5
		Root & stem vegetables BBCH ≥ 40	Small omnivorous bird “lark” Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	1.89	51.0
		Root & stem vegetables BBCH ≥ 20	Small insectivorous bird “wagtail” Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	5.55	17.3
		Strawberries BBCH ≥ 40	Small omnivorous bird “lark” Woodlark (*Lullula*	4.4	1.0 × 0.53	2.52	38.2

Table CP 10-01-5: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1080 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
			arborea)				
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1080	Strawberries BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	5.55	17.3

Table CP 10-01-6: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (3 × 720 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	3 × 720	Cereals BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.2 × 0.53	1.51	63.7
		Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.2 × 0.53	1.56	61.9
		Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.2 × 0.53	1.51	63.7
		Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.2 × 0.53	4.44	21.7
		Leafy vegetables BBCH ≥ 50	Small granivorous bird "finch" Serin (*Serinus serinus*)	3.8	1.2 × 0.53	1.74	55.3
		Leafy vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.2 × 0.53	1.51	63.7
		Leafy vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.2 × 0.53	4.44	21.7

Table CP 10-01-6: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (3 × 720 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	3 × 720	Legume forage BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.2 × 0.53	1.56	61.9
		Legume forage BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.2 × 0.53	1.51	63.7
		Legume forage BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.2 × 0.53	4.44	21.7
		Maize BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	1.2 × 0.53	1.24	77.9
		Maize BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	4.8	1.2 × 0.53	2.20	43.8
		Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	1.2 × 0.53	1.24	77.9
		Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	0.9	1.2 × 0.53	0.412	234
		Potatoes BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.2 × 0.53	1.51	63.7
		Potatoes BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.2 × 0.53	4.44	21.7
		Pulses BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.2 × 0.53	1.56	61.9
		Pulses BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.2 × 0.53	1.51	63.7
		Pulses BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail	9.7	1.2 × 0.53	4.44	21.7

Table CP 10-01-6: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (3 × 720 g.a.s/ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
			(*Motacilla flava*)				
Field crops (Post-harvest, pre-sowing, pre-planting)	3 × 720	Root & stem vegetables BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.2 × 0.53	1.56	61.9
		Root & stem vegetables BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.2 × 0.53	1.51	63.7
		Root & stem vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.2 × 0.53	4.44	21.7
		Strawberries BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	4.4	1.2 × 0.53	2.01	47.8
		Strawberries BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.2 × 0.53	4.44	21.7

Field crops (Shielded ground directed inter-row application): Uses 6a, b

Table CP 10-01-7: Field crops (Shielded ground directed inter-row application): Uses 6a, b (1 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Shielded ground directed inter-row application)	1 × 1080	Bulbs and onion like crops BBCH 10 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	6.53	14.8
		Fruiting vegetables BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	6.53	14.8
Field crops (Shielded ground directed inter-row application)	1 × 1080	Fruiting vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	6.24	15.4
		Fruiting vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	6.47	14.9
		Leafy vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	6.24	15.4
		Leafy vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	6.47	14.9
		Legume forage BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	6.53	14.8
		Legume forage BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	6.24	15.4
		Legume forage BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	6.47	14.9
		Potatoes BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	6.24	15.4
		Potatoes BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	6.47	14.9
		Pulses BBCH 10 – 49	Small granivorous bird "finch"	11.4	1.0 × 0.53	6.53	14.8

Table CP 10-01-7: Field crops (Shielded ground directed inter-row application): Uses 6a, b (1 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
			Linnet (*Carduelis cannabina*)				
		Pulses BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	6.24	15.4
		Pulses Leaf development BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	13.0	7.41
Field crops (Shielded ground directed inter-row application)	1 × 1080	Pulses BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	6.47	14.9
		Root & stem vegetables BBCH 10 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	6.53	14.8
		Root & stem vegetables BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	6.24	15.4
		Root & stem vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	6.47	14.9
		Sugar beet Early (spring) (BBCH 10 – 19)	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	6.24	15.4
		Sugar beet BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	5.9	1.0 × 0.53	3.38	28.5

Table CP 10-01-8: Field crops (Shielded ground directed inter-row application): Uses 6a, b (1 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Shielded ground directed inter-row application)	1 × 720	Bulbs and onion like crops BBCH 10 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	4.35	22.1
		Fruiting vegetables BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	4.35	22.1
Field crops (Shielded ground directed inter-row application)	1 × 720	Fruiting vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	4.16	23.2
		Fruiting vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	4.31	22.3
		Leafy vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	4.16	23.2
		Leafy vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	4.31	22.3
		Legume forage BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	4.35	22.1
		Legume forage BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	4.16	23.2
		Legume forage BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	4.31	22.3
		Potatoes BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	4.16	23.2
		Potatoes BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	4.31	22.3
		Pulses BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	4.35	22.1

Table CP 10-01-8: Field crops (Shielded ground directed inter-row application): Uses 6a, b (1 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	Application rate (g a.s./ha)	Crop scenario Growth stage	Generic focal species	SV_m	$MAF_m \times TWA$	DDD_m (mg/kg bw/d)	TER_{lt}
		Pulses BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	4.16	23.2
		Pulses Leaf development BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	8.66	11.1
Field crops (Shielded ground directed inter-row application)	1 × 720	Pulses BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	4.31	22.3
		Root & stem vegetables BBCH 10 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	4.35	22.1
		Root & stem vegetables BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	4.16	23.2
		Root & stem vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	4.31	22.3
		Sugar beet Early (spring) (BBCH 10 – 19)	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	4.16	23.2
		Sugar beet BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	5.9	1.0 × 0.53	2.25	42.8

Control of invasive species: Uses 8, 9

Table CP 10-01-9: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Bulbs and onion like crops BBCH 10 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	10.9	8.85
		Bulb and onion like crops BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	6.9	1.0 × 0.53	6.58	14.6
		Bulb and onion like crops BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	6.5	1.0 × 0.53	6.20	15.5
		Bulb and onion like crops BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	9.25	10.4
		Cereals BBCH 10 – 29	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26
		Cereals BBCH 30 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	5.4	1.0 × 0.53	5.15	18.7
		Cereals BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	3.15	30.6
		Fruiting vegetables BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	10.9	8.85
		Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	3.24	29.7
		Fruiting vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26
		Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	3.15	30.6

Table CP 10-01-9: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Fruiting vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	10.8	8.93
		Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	9.25	10.4
		Hops BBCH ≥ 20	Small insectivorous bird "finch" Chaffinch (*Fringilla colebs*)	10.6	1.0 × 0.53	10.1	9.52
		Hops BBCH 10 – 19	Small granivorous bird "finch" Goldfinch (*Carduelis carduelis*)	11.4	1.0 × 0.53	10.9	8.85
		Hops BBCH 20 – 39	Small granivorous bird "finch" Goldfinch (*Carduelis carduelis*)	5.7	1.0 × 0.53	5.44	17.7
		Hops BBCH ≥ 40	Small granivorous bird "finch" Goldfinch (*Carduelis carduelis*)	3.4	1.0 × 0.53	3.24	29.7
		Leafy vegetables BBCH ≥ 50	Small granivorous bird "finch" Serin (*Serinus serinus*)	3.8	1.0 × 0.53	3.63	26.6
		Leafy vegetables BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26
		Leafy vegetables BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	3.15	30.6
		Leafy vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	10.8	8.93
		Leafy vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	9.25	10.4
		Legume forage BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	10.9	8.85

Table CP 10-01-9: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Legume forage BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	3.24	29.7
		Legume forage BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26
		Legume forage BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	3.15	30.6
		Legume forage Leaf development BBCH 21 – 49	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	21.7	4.45
		Legume forage BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	10.8	8.93
		Legume forage BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	9.25	10.4
		Maize BBCH 30 – 39	Medium granivorous bird "gamebird" Partridge (*Perdix perdix*)	1.5	1.0 × 0.53	1.43	67.3
		Maize BBCH ≥ 40	Medium granivorous bird "gamebird" Partridge (*Perdix perdix*)	0.8	1.0 × 0.53	0.763	126
		Maize BBCH 10 – 29	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26
		Maize BBCH 30 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	5.4	1.0 × 0.53	5.15	18.7
		Maize BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	1.0 × 0.53	2.58	37.4

Table CP 10-01-9: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Maize BBCH 10 – 29	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	21.7	4.45
		Maize BBCH 30 – 39	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	11.4	1.0 × 0.53	10.9	8.85
		Maize BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	5.7	1.0 × 0.53	5.44	17.7
		Maize BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	10.78	8.93
		Maize BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	4.8	1.0 × 0.53	4.58	21.0
		Oilseed rape Early (shoots) BBCH 10 – 19	Large herbivorous bird "goose" Greylag goose (*Anser anser*)	15.9	1.0 × 0.53	15.2	6.35
		Oilseed rape Late (with seeds) BBCH 80 – 99	Small granivorous bird "finch" Linnet (Carduelis cannabina	11.4	1.0 × 0.53	10.9	8.85
		Oilseed rape BBCH 10 – 29	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26
		Oilseed rape BBCH 30 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	3.15	30.6
		Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	2.7	1.0 × 0.53	2.58	37.4

Table CP 10-01-9: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Oilseed rape BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	21.7	4.45
		Oilseed rape BBCH 20 – 29	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	3.5	1.0 × 0.53	3.34	28.8
		Oilseed rape BBCH 30 – 39	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	1.1	1.0 × 0.53	1.05	91.8
		Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	0.9	1.0 × 0.53	0.859	112
		Oilseed rape BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	5.9	1.0 × 0.53	5.63	17.1
		Oilseed rape BBCH 20 – 29	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	2.8	1.0 × 0.53	2.67	36.1
		Orchard Not crop directed application all season	Small insectivorous/worm feeding species "thrush" Robin (*Erithacus rubecula*)	2.7	1.0 × 0.53	2.58	37.4
		Orchard Not crop directed application all season	Small granivorous bird "finch" Serin (*Serinus serinus*)	12.6	1.0 × 0.53	12.0	8.01
		Potatoes BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26
		Potatoes BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	3.15	30.6

Table CP 10-01-9: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Potatoes BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	10.8	8.93
		Potatoes BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	9.25	10.4
		Pulses BBCH 10 – 49	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	10.9	8.85
		Pulses BBCH ≥ 50	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	3.24	29.7
		Pulses BBCH 10 – 49	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26
		Pulses BBCH ≥ 50	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	3.15	30.6
		Pulses Leaf development BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon" Wood pigeon (*Columba palumbus*)	22.7	1.0 × 0.53	21.7	4.45
		Pulses BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	10.8	8.93
		Pulses BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motcailla flava*)	9.7	1.0 × 0.53	9.25	10.4
		Root & stem vegetables BBCH 10 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	10.9	8.85
		Root & stem vegetables BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	3.24	29.7
		Root & stem vegetables BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26

Table CP 10-01-9: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Root & stem vegetables BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	3.3	1.0 × 0.53	3.15	30.6
		Root & stem vegetables BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	10.8	8.93
		Root & stem vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	9.25	10.4
		Strawberries BBCH 10 – 39	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26
		Strawberries BBCH ≥ 40	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	4.4	1.0 × 0.53	4.20	22.9
		Strawberries BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	10.8	8.93
		Strawberries BBCH ≥ 20	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	9.7	1.0 × 0.53	9.25	10.4
		Sugar beet Late (summer / autumn)	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	11.4	1.0 × 0.53	10.9	8.85
		Sugar beet Early (spring) (BBCH 10 – 19)	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26
		Sugar beet BBCH 10 – 19	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	5.9	1.0 × 0.53	5.63	17.1
		Sugar beet BBCH 20 – 49	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	2.8	1.0 × 0.53	2.67	36.1
		Sugar beet BBCH 20 – 49	*Small insectivorous bird "wagtail" Yellow wagtail (Motacilla flava)*	9.7	1.0 × 0.53	9.25	10.4

Table CP 10-01-9: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		96.3					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Sunflower Early germination / Leaf development (BBCH 00 – 19)	Small omnivorous bird "lark" Woodlark (*Lullula arborea*)	10.9	1.0 × 0.53	10.4	9.26
		Sunflower Early germination / Leaf development (BBCH 00 – 19)	Small insectivorous bird "wagtail" Yellow wagtail (*Motacilla flava*)	11.3	1.0 × 0.53	10.8	8.93
		Vineyard BBCH ≥ 20	Small insectivorous species "redstart" Black redstart "*Phoenicurus ochruros*"	9.9	1.0 × 0.53	9.44	10.2
		Vineyard BBCH 10 – 19	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	6.9	1.0 × 0.53	6.58	14.6
		Vineyard BBCH 20 – 39	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	5.7	1.0 × 0.53	5.44	17.7
		Vineyard BBCH ≥ 40	Small granivorous bird "finch" Linnet (*Carduelis cannabina*)	3.4	1.0 × 0.53	3.24	29.7
		Vineyard BBCH 10 – 19	Small omnivorous bird "lark" Wood lark (*Lullula arborea*)	6.5	1.0 × 0.53	6.20	15.5
		Vineyard BBCH 20 – 39	Small omnivorous bird "lark" Wood lark (*Lullula arborea*)	5.4	1.0 × 0.53	5.15	18.7
		Vineyard BBCH ≥ 40	Small omnivorous bird "lark" Wood lark (*Lullula arborea*)	3.3	1.0 × 0.53	3.15	30.6

Annex M-CP 10-02: Calculations of the 21day time-weighted-average (twa) for glyphosate in grass foliage used in the avian and mammalian risk assessment

This information remains unchanged from the previous submission of glyphosate where this information was presented in the Renewal Assessment Report for Glyphosate, 29 January 2015, Volume 3, Annex B.9, B.9.13.

B.9.13 Calculation of the 21day time-weighted –average (twa) for glyphosate in grass foliage used in the mammalian risk assessment

The methodology used to calculate the TWA for glyphosate in grass foliage for the long-term mammalian risk assessment follows the procedure described in the Guidance Document on Terrestrial Ecotoxicology (1). With the approach outlined in the Guidance Document on Terrestrial Ecotoxicology, residues are assumed to follow the standard pattern of first order exponential decline.

The decline of glyphosate residue in grass was characterised using data from 22 residue trials each of which had a Day 0 value. Of these 22 trials, 18 of the trials were from 4 separate Monsanto reports (references 2 – 5) and 4 trials were from 2 separate Cheminova reports (references 6 and 7). MON 2139 and a comparable Cheminova formulation were used in these grass residue trials. The grass residue values from the Cheminova trials were taken directly from the Glyphosate Monograph (reference 8); the Cheminova reports themselves were not reviewed.

The dissipation of glyphosate in grass was estimated using the standard first-order dissipation model:

(1) $C_t = C_i \times e^{-kt}$

Where k is first order rate constant, Ci is the initial residue concentration, and Ct is the residue concentration at time t. Residue half-life time (DT_{50}) in days for these grass land trials was calculated with equation (2).

(2) $DT_{50} = \frac{-\ln 0.5}{k}$

In each Monsanto report, residual glyphosate in mg/kg dry matter in grass was normalised to 1 kg a.s./ha and these values were plotted against time in days. For the Monsanto residues trials, many of the later sampling intervals were taken after plant desiccation. Therefore, for the purpose of accurately characterising glyphosate dissipation kinetics in grass, the glyphosate resdiues in mg/kg normalised to 100 % dry matter content were used to eliminate the effect of sample weight losses during desiccation (Table II-1). However, since the final sampling day in Cheminova trials was on Day 5, when grass desiccation was negligible, correction for moisture content was not necessary (Table II-2).

The dissipation of glyphosate was modelled with equation I using nonlinear regression (9). For 20 of the 22 trials, the standard first-order dissipation model provided an adequate fit for glyphosate dissipation ($R2 > 0.8$). The standard first-order dissipation model inadequately fit one Monsanto trial and one Cheminova trial (coefficient of determination, $R2 < 0.600$). For these two trials, the DT_{50} was estimated by identifying the first day when a measured value had a greater than 50 % dissipation. Since the DT_{50} was estimated in this fashion for these two trials, the glyphosate residues in Table II-1 and Table II-2 are also expressed as a percentage of the initial concentration, which was set at 100 % for Day 0 after treatment. The average DT_{50} for the 22 trials was 2.8 days.

The linear first-order rate constant corresponding to a DT_{50} of 2.8 days was calculated using equation 3:

(3) $k = \frac{-ln0.5}{DT50}$

Which results in a rate constant k of 0.2476 days-1. The 21-days time-weighed average (TWA) was calculated using equation 4:

(4) $TWA = \frac{(1 - e^{-kt})}{kt}$

Where k is the first order rate constant calculated using equation (3), and t is the window of time over the TWA is calculated (i.e. 21 days). Using these parameters for k, and t, the 21-Day TWA is calculated to be 0.19 for active substance glyphosate acid.

Glyphosate residues in grass following a single treatment of Roundup® (MON 2139, SL/360). Source: Monsanto Field Residue Studies:

Country, Year Trial, ID	App. Rate (kg a.s./ha)[1]	NRG 100% of DM[2]	% of Day 0 a.s. residue	DAT[3]		R^2	k (days^{-1})	DT_{50} days	Glyphoaste Monograph reference; Monsanto Report No.
Great Britain, 1981									
SU 8125	1.08	101	100	1h		0.99	0.4106	1.7	RIP95-01242MLL 30.080
		27	26.7	3					
		12	11.9	7					
SU 8125	2.88	67	100	1h		0.997	0.3251	2.1	
		27	40.3	3					
		5	7.5	7					
SU 30117	1.08	247	100	1h		0.997	0.9587	0.72	
		14	5.7	3					
		8	3.2	7					
		7	2.8	9					
		6	2.4	10					
		3	1.2	14					
SU 30117	2.88	130	100	1h		0.976	0.7063	0.98	
		14	10.8	3					
		11	8.5	7					
		9	6.9	9					
		10	7.7	10					
		3	2.3	14					
SU 30119	1.08	193	100	1h		0.809	0.1456	4.8	
		175	90.7	4					
		38	19.3	9					
		9	4.7	11					
SU 30119	2.88	161	100	1h		0.901	0.155	4.5	
		123	76.4	4					
		30	18.6	9					
		13	8.1	11					
France, 1981									
811	0.72	168	100	0		0.976	0.4576	1.5	RIP95-01245MLL 30.082
		9	5.4	5					
		23	13.7	8					
		5	3	12					
811	1.08	134	100	0		0.95	0.3768	1.8	
		9	6.7	5					
		27	20.1	8					
		5	3.7	12					
Netherlands, 1982									
NL 8207	1.44	682	100	0		0.998	0.423	1.6	RIP95-01264MLL 30.101
		77	11.3	5					
		31.7	4.6	10					

Glyphosate residues in grass following a single treatment of Roundup® (MON 2139, SL/360). Source: Monsanto Field Residue Studies:

Country, Year Trial, ID	App. Rate (kg a.s./ha)[1]	NRG 100% of DM[2]	% of Day 0 a.s. residue	DAT[3]		R^2	k (days^{-1})	DT_{50} days	Glyphoaste Monograph reference; Monsanto Report No.
Danmark, 1981									
Villbach (GE)-1981-0181 Vi	1.8	162.9	100	0		0.844	0.1415	4.9	RIP95-01273MLL 30.132
		36	22.3	7					
		52.6	32.3	14					
Villbach (GE)-1981-0281 Vi	1.8	496.3	100	0		0.994	0.1537	4.5	
		184.4	37.2	7					
		37	7.5	14					
Lettgunbrunn (GE)-1981-0981LE	1.8	437.9	100	0		0.961	0.2616	2.6	
		51.2	11.7	7					
		69.4	15.8	14					
Villbach (GE)-1981-0481 Vi	1.8	190.7	100	0		0.937	0.1098	6.3	
		69	36.2	7					
		59	30.9	14					
Danmark, 1983									
Vogach (GE)-19B	1.44	158.9	100	0		0.995	0.9083	0.76	RIP95-01273MLL 30.132
		9.9	6.2	3					
		8.3	5.2	7					
		3.3	2.1	10					
		4.4	2.8	14					
Untermehlhausen (GE)-1983	1.44	169.6	100	0		0.99	0.2852	2.4	
		16.4	9.7	7					
		16.2	9.6	10					
		13	7.7	14					
Schoneberg	1.44	257.2	100	0		*	*	10[4]	
		155.8	60.6	3					
		144.6	56.2	7					
		123.9	48.2	10					
		151	58.7	14					
Utphe (GE)-1983	1.44	354.9	100	0		0.961	0.1718	4	
		78.7	22.2	7					
		62.7	17.7	14					
		39	11	21					
Meiling (GE)-1983	1.44	253.9	100	0		0.997	0.9014	0.77	
		16.6	6.5	3					
		6	2.4	7					
		6.3	2.5	10					
		8.3	3.3	14					

[1] a.s. = glyphosate acid.
[2] NRG 100 % of DM = residual glyphosate mg/kg normalized to 1 kg a s./ha and corrected to 100 % dry matter content. Values taken directly from Monsanto reports.
[3] DAT = Days After Treament.[4] Estimated DT_{50} value based on time when approximately 50 % dissipation was reached.
* Did not fit standard 1st order dissipation model.

Glyphosate residues in grass following a single treatment of CHE 3607 (SL/360).
Source: Cheminova Field Residue Studies (cited in Glyphosate Monograph):

App. Rate (kg a.s./ha)[1]	Residue (mg a.s./kg wet weight)	% of Day 0 a.s. Residue	DAT[2]	R^2	k (days^{-1})	DT_{50} (days)	Glyphoaste Monograph reference; Cheminova Report No.
Great Britain, 1992							
2.16	237.6	100	4h	0.987	1.9629	0.35	RIP95-01308 IF-93/04572-01
	45	18.9	1				
	19.6	8.2	3				
	9.6	4	5				
1.08	87.6	100	4h	0.937	2.0879	0.33	
	14.6	16.7	1				
	14.3	16.3	3				
	8.3	9.5	5				
2.16	252.3	100	4h	0.951	0.4885	1.4	RIP95-01312 IF-93/13842-01
	131	51.9	1				
	72.1	28.6	3				
	36.6	14.6	5				
1.08	90.4	100	4h	*	*	3[3]	
	142.8	158	1				
	39.8	44	3				
	17.3	19.1	5				

[1] a.s. = glyphosate acid.
[2] DAT = Days After Treament.
[3] Estimated DT_{50} value based on time when approximately 50 % dissipation was reached.
* Did not fit standard 1st order dissipation model.

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Annex M-CP 10-03: Mammalian risk assessment

Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c

Table CP 10-03-1: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1440 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1440	Bulbs and onion like crops BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	43.4	1.0 × 0.53	33.1	1.51
		Bulbs and onion like crops BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	4.7	1.0 × 0.53	3.59	13.9
		Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Cereals BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	16.6	3.02
		Cereals BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.76	28.5
		Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	16.6	3.02
		Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.76	28.5

Table CP 10-03-1: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1440 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1440	Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	16.6	3.02
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	10.9	4.58
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.76	28.5
		Legume forage BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Legume forage BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	16.6	3.02
		Legume forage BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.76	28.5
		Maize BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Maize BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	13.8	3.62
		Maize BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.45	34.5
		Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5

Table CP 10-03-1: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1440 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	13.8	3.62
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1440	Oilseed rape All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	10.9	4.58
		Oilseed rape BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.45	34.5
		Potatoes BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Potatoes BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	16.6	3.02
		Potatoes BBCH ≥ 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	4.3	1.0 × 0.53	3.28	15.2
		Potatoes BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.76	28.5
		Pulses BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Pulses BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	16.6	3.02
		Pulses BBCH ≥ 50	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	4.3	1.0 × 0.53	3.28	15.2
		Pulses BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.76	28.5
		Root and stem vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5

Table CP 10-03-1: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1440 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1440	Root and stem vegetables BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	16.6	3.02
		Root and stem vegetables BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.76	28.5
		Strawberries BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Strawberries BBCH ≥ 40	Small herbivorous mammal "vole Common vole (*Microtus arvalis*)	28.9	1.0 × 0.53	22.1	2.27
		Strawberries BBCH ≥ 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	5.7	1.0 × 0.53	4.35	11.5
		Strawberries BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	3.1	1.0 × 0.53	2.37	21.1
		Sugar beet BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Sugar beet BBCH ≥ 40	Small herbivorous mammal "vole Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	13.8	3.62
		Sugar beet BBCH ≥ 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	3.6	1.0 × 0.53	2.75	18.2
		Sugar beet BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.45	34.5
		Sunflower BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.45	34.5
		Sunflower BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	13.8	3.62

Table CP 10-03-1: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1440 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1440	Sunflower BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.0 × 0.53	2.75	18.2
		Sunflower BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.45	34.5

Table CP 10-03-2: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 1080	Bulbs and onion like crops BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	43.4	1.1 × 0.53	27.3	1.83
		Bulbs and onion like crops BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	4.7	1.1 × 0.53	2.96	16.9
		Cereals BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Cereals BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	13.7	3.66
		Cereals BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	1.45	34.5
		Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8

Table CP 10-03-2: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 1080	Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	13.7	3.66
		Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	1.45	34.5
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	13.7	3.66
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.1 × 0.53	9.00	5.55
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	1.45	34.5
		Legume forage BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Legume forage BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	13.7	3.66
		Legume forage BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	1.45	34.5
		Maize BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Maize BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.1 × 0.53	11.4	4.39

Table CP 10-03-2: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 1080	Maize BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.1 × 0.53	1.20	41.8
		Oilseed rape BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Oilseed rape BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.1 × 0.53	11.4	4.39
		Oilseed rape All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.1 × 0.53	9.00	5.55
		Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.1 × 0.53	1.20	41.8
		Potatoes BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Potatoes BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	13.7	3.66
		Potatoes BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	4.3	1.1 × 0.53	2.71	18.5
		Potatoes BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	1.45	34.5
		Pulses BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Pulses BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	13.7	3.66

Table CP 10-03-2: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV$_m$**	**MAF$_m$ × TWA**	**DDD$_m$ (mg/kg bw/d)**	**TER$_{lt}$**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 1080	Pulses BBCH ≥ 50	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	4.3	1.1 × 0.53	2.71	18.5
		Pulses BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	1.45	34.5
		Root and stem vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Root and stem vegetables BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	13.7	3.66
		Root and stem vegetables BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	1.45	34.5
		Strawberries BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Strawberries BBCH ≥ 40	Small herbivorous mammal “vole Common vole (*Microtus arvalis*)	28.9	1.1 × 0.53	18.2	2.75
		Strawberries BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	5.7	1.1 × 0.53	3.59	13.9
		Strawberries BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	3.1	1.1 × 0.53	1.95	25.6
		Sugar beet BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Sugar beet BBCH ≥ 40	Small herbivorous mammal “vole Common vole (*Microtus arvalis*)	18.1	1.1 × 0.53	11.4	4.39

Table CP 10-03-2: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 1080	Sugar beet BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.1 × 0.53	2.27	22.1
		Sugar beet BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.1 × 0.53	1.20	41.8
		Sunflower BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	1.20	41.8
		Sunflower BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.1 × 0.53	11.4	4.39
		Sunflower BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.1 × 0.53	2.27	22.1
		Sunflower BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.1 × 0.53	1.20	41.8

Table CP 10-03-3: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 540 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 540	Bulbs and onion like crops BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	43.4	1.0 × 0.53	12.4	4.03
		Bulbs and onion like crops BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	4.7	1.0 × 0.53	1.35	37.2

Table CP 10-03-3: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 540 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 540	Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Cereals BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	6.21	8.05
		Cereals BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.658	76.0
		Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	6.21	8.05
		Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.658	76.0
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	6.21	8.05
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	4.09	12.2
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.658	76.0
		Legume forage BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9

Table CP 10-03-3: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 540 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 540	Legume forage BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	6.21	8.05
		Legume forage BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.658	76.0
		Maize BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Maize BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	5.18	9.65
		Maize BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	0.544	91.9
		Oilseed rape BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Oilseed rape BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	5.18	9.65
		Oilseed rape All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	4.09	12.2
		Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	0.544	91.9
		Potatoes BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Potatoes BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	6.21	8.05

Table CP 10-03-3: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 540 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV$_m$**	**MAF$_m$ × TWA**	**DDD$_m$ (mg/kg bw/d)**	**TER$_{lt}$**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 540	Potatoes BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	4.3	1.0 × 0.53	1.23	40.6
		Potatoes BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.658	76.0
		Pulses BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Pulses BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	6.21	8.05
		Pulses BBCH ≥ 50	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	4.3	1.0 × 0.53	1.23	40.6
		Pulses BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.658	76.0
		Root and stem vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Root and stem vegetables BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	6.21	8.05
		Root and stem vegetables BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.658	76.0
		Strawberries BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Strawberries BBCH ≥ 40	Small herbivorous mammal “vole Common vole (*Microtus arvalis*)	28.9	1.0 × 0.53	8.27	6.05

Table CP 10-03-3: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 540 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 540	Strawberries BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	5.7	1.0 × 0.53	1.63	30.6
		Strawberries BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	3.1	1.0 × 0.53	0.887	56.4
		Sugar beet BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Sugar beet BBCH ≥ 40	Small herbivorous mammal “vole Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	5.18	9.65
		Sugar beet BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.0 × 0.53	1.03	48.5
		Sugar beet BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	0.544	91.9
		Sunflower BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.544	91.9
		Sunflower BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	5.18	9.65
		Sunflower BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.0 × 0.53	1.03	48.5
		Sunflower BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	0.544	91.9

Table CP 10-03-4: Field crops (Post harvest, pre-sowing, pre-planting): Use 2 a-c, 10 a-c (1 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 720	Bulbs and onion like crops BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	43.4	1.0 × 0.53	16.6	3.02
		Bulbs and onion like crops BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	4.7	1.0 × 0.53	1.79	27.9
		Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Cereals BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	8.28	6.04
		Cereals BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.878	57.0
		Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	8.28	6.04
		Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.878	57.0
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	8.28	6.04

Table CP 10-03-4: Field crops (Post harvest, pre-sowing, pre-planting): Use 2 a-c, 10 a-c (1 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 720	Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	5.46	9.16
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.878	57.0
		Legume forage BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Legume forage BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	8.28	6.04
		Legume forage BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.878	57.0
		Maize BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Maize BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	6.91	7.24
		Maize BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	0.725	69.0
		Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	6.91	7.24
		Oilseed rape All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	5.46	9.16

Table CP 10-03-4: Field crops (Post harvest, pre-sowing, pre-planting): Use 2 a-c, 10 a-c (1 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 720	Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	0.725	69.0
		Potatoes BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Potatoes BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	8.28	6.04
		Potatoes BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	4.3	1.0 × 0.53	1.64	30.5
		Potatoes BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.878	57.0
		Pulses BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Pulses BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	8.28	6.04
		Pulses BBCH ≥ 50	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	4.3	1.0 × 0.53	1.64	30.5
		Pulses BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.878	57.0
		Root and stem vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Root and stem vegetables BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	8.28	6.04

Table CP 10-03-4: Field crops (Post harvest, pre-sowing, pre-planting): Use 2 a-c, 10 a-c (1 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 720	Root and stem vegetables BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	0.878	57.0
		Strawberries BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Strawberries BBCH ≥ 40	Small herbivorous mammal "vole Common vole (*Microtus arvalis*)	28.9	1.0 × 0.53	11.0	4.53
		Strawberries BBCH ≥ 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	5.7	1.0 × 0.53	2.18	23.0
		Strawberries BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	3.1	1.0 × 0.53	1.18	42.3
		Sugar beet BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Sugar beet BBCH ≥ 40	Small herbivorous mammal "vole Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	6.91	7.24
		Sugar beet BBCH ≥ 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	3.6	1.0 × 0.53	1.37	36.4
		Sugar beet BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	0.725	69.0
		Sunflower BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	0.725	69.0
		Sunflower BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	6.91	7.24

Table CP 10-03-4: Field crops (Post harvest, pre-sowing, pre-planting): Use 2 a-c, 10 a-c (1 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 720	Sunflower BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.0 × 0.53	1.37	36.4
		Sunflower BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	0.725	69.0

Table CP 10-03-5: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2× 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 720	Bulbs and onion like crops BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	43.4	1.1 × 0.53	18.2	2.74
		Bulbs and onion like crops BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	4.7	1.1 × 0.53	1.97	25.3
		Cereals BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Cereals BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	9.11	5.49
		Cereals BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	0.965	51.8

Table CP 10-03-5: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2× 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 720	Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	9.11	5.49
		Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	0.965	51.8
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	9.11	5.49
		Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.1 × 0.53	6.00	8.33
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	0.965	51.8
		Legume forage BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Legume forage BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	9.11	5.49
		Legume forage BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	0.965	51.8
		Maize BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7

Table CP 10-03-5: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2× 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 720	Maize BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.1 × 0.53	7.60	6.58
		Maize BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.1 × 0.53	0.798	62.7
		Oilseed rape BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Oilseed rape BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.1 × 0.53	7.60	6.58
		Oilseed rape All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.1 × 0.53	6.00	8.33
		Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.1 × 0.53	0.798	62.7
		Potatoes BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Potatoes BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	9.11	5.49
		Potatoes BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	4.3	1.1 × 0.53	1.80	27.7
		Potatoes BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	0.965	51.8
		Pulses BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7

Table CP 10-03-5: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2× 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 720	Pulses BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	9.11	5.49
		Pulses BBCH ≥ 50	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	4.3	1.1 × 0.53	1.80	27.7
		Pulses BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	0.965	51.8
		Root and stem vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Root and stem vegetables BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.1 × 0.53	9.11	5.49
		Root and stem vegetables BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.1 × 0.53	0.965	51.8
		Strawberries BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Strawberries BBCH ≥ 40	Small herbivorous mammal “vole Common vole (*Microtus arvalis*)	28.9	1.1 × 0.53	12.1	4.12
		Strawberries BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	5.7	1.1 × 0.53	2.39	20.9
		Strawberries BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	3.1	1.1 × 0.53	1.30	38.4
		Sugar beet BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7

Table CP 10-03-5: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (2× 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	2 × 720	Sugar beet BBCH ≥ 40	Small herbivorous mammal “vole Common vole (*Microtus arvalis*)	18.1	1.1 × 0.53	7.60	6.58
		Sugar beet BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.1 × 0.53	1.51	33.1
		Sugar beet BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.1 × 0.53	0.798	62.7
		Sunflower BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.1 × 0.53	0.798	62.7
		Sunflower BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.1 × 0.53	7.60	6.58
		Sunflower BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.1 × 0.53	1.51	33.1
		Sunflower BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.1 × 0.53	0.798	62.7

Table CP 10-03-6: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1080	Bulbs and onion like crops BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	43.4	1.0 × 0.53	24.8	2.01
		Bulbs and onion like crops BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	4.7	1.0 × 0.53	2.69	18.6
		Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Cereals BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	12.4	4.03
		Cereals BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.32	38.0
		Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	12.4	4.03
		Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.32	38.0
		Grassland Late	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	12.4	4.03

Table CP 10-03-6: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1080	Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	8.19	6.11
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.32	38.0
		Legume forage BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Legume forage BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	12.4	4.03
		Legume forage BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.32	38.0
		Maize BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Maize BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	10.4	4.83
		Maize BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.09	46.0
		Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	10.4	4.83
		Oilseed rape All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	8.19	6.11
		Oilseed rape BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.09	46.0

Table CP 10-03-6: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1080	Potatoes BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Potatoes BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	12.4	4.03
		Potatoes BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	4.3	1.0 × 0.53	2.46	20.3
		Potatoes BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.32	38.0
		Pulses BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Pulses BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	12.4	4.03
		Pulses BBCH ≥ 50	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	4.3	1.0 × 0.53	2.46	20.3
		Pulses BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.32	38.0
		Root and stem vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Root and stem vegetables BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	12.4	4.03
		Root and stem vegetables BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	1.32	38.0

Table CP 10-03-6: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (1 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1080	Strawberries BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Strawberries BBCH ≥ 40	Small herbivorous mammal "vole Common vole (*Microtus arvalis*)	28.9	1.0 × 0.53	16.5	3.02
		Strawberries BBCH ≥ 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	5.7	1.0 × 0.53	3.26	15.3
		Strawberries BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	3.1	1.0 × 0.53	1.77	28.2
		Sugar beet BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Sugar beet BBCH ≥ 40	Small herbivorous mammal "vole Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	10.4	4.83
		Sugar beet BBCH ≥ 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	3.6	1.0 × 0.53	2.06	24.3
		Sugar beet BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.09	46.0
		Sunflower BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.09	46.0
		Sunflower BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	10.4	4.83
		Sunflower BBCH ≥ 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	3.6	1.0 × 0.53	2.06	24.3
Field crops (Post-harvest, pre-sowing, pre-planting)	1 × 1080	Sunflower BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.09	46.0

Table CP 10-03-7: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (3 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Post-harvest, pre-sowing, pre-planting)	3 × 720	Bulbs and onion like crops BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	43.4	1.2 × 0.53	19.9	2.52
		Bulbs and onion like crops BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	4.7	1.2 × 0.53	2.15	23.2
		Cereals BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
		Cereals BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.2 × 0.53	9.94	5.03
		Cereals BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.2 × 0.53	1.05	47.5
		Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
Field crops (Post-harvest, pre-sowing, pre-planting)	3 × 720	Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.2 × 0.53	9.94	5.03
		Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.2 × 0.53	1.05	47.5
		Grassland Late	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.2 × 0.53	9.94	5.03
		Leafy vegetables All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus*	14.3	1.2 × 0.53	6.55	7.64

Table CP 10-03-7: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (3 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
			cuniculus)				
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.2 × 0.53	1.05	47.5
		Legume forage BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
		Legume forage BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.2 × 0.53	9.94	5.03
		Legume forage BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.2 × 0.53	1.05	47.5
		Maize BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
		Maize BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.2 × 0.53	8.29	6.03
Field crops (Post-harvest, pre-sowing, pre-planting)	3 × 720	Maize BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.2 × 0.53	0.870	57.5
		Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
		Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	18.1	1.2 × 0.53	8.29	6.03
		Oilseed rape All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.2 × 0.53	6.55	7.64
		Oilseed rape BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.2 × 0.53	0.870	57.5
		Potatoes BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex	1.9	1.2 × 0.53	0.870	57.5

Table CP 10-03-7: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (3 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
			araneus)				
		Potatoes BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.2 × 0.53	9.94	5.03
		Potatoes BBCH ≥ 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	4.3	1.2 × 0.53	1.97	25.4
		Potatoes BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.2 × 0.53	1.05	47.5
		Pulses BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
		Pulses BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.2 × 0.53	9.94	5.03
Field crops (Post-harvest, pre-sowing, pre-planting)	3 × 720	Pulses BBCH ≥ 50	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	4.3	1.2 × 0.53	1.97	25.4
		Pulses BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.2 × 0.53	1.05	47.5
		Root and stem vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
		Root and stem vegetables BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.2 × 0.53	9.94	5.03
		Root and stem vegetables BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.2 × 0.53	1.05	47.5
		Strawberries BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
		Strawberries BBCH ≥ 40	Small herbivorous mammal "vole Common vole (*Microtus	28.9	1.2 × 0.53	13.2	3.78

Table CP 10-03-7: Field crops (Post harvest, pre-sowing, pre-planting): Uses 2 a-c, 10 a-c (3 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
			arvalis)				
		Strawberries BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	5.7	1.2 × 0.53	2.61	19.2
		Strawberries BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	3.1	1.2 × 0.53	1.42	35.2
		Sugar beet BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
		Sugar beet BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.2 × 0.53	8.29	6.03
Field crops (Post-harvest, pre-sowing, pre-planting)	3 × 720	Sugar beet BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.2 × 0.53	1.65	30.3
		Sugar beet BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.2 × 0.53	0.870	57.5
		Sunflower BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.2 × 0.53	0.870	57.5
		Sunflower BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.2 × 0.53	8.29	6.03
		Sunflower BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.2 × 0.53	1.65	30.3
		Sunflower BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.2 × 0.53	0.870	57.5

Field crops (Shielded ground directed inter-row application): Use 6a, b

Table CP 10-03-8: Field crops (Shielded ground directed inter-row application): Uses 6a, b (1 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Shielded ground directed inter-row application)	1 × 1080	Fruiting vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	2.40	20.8
		Fruiting vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	4.46	11.2
		Leafy vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	2.40	20.8
		Leafy vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	4.46	11.2
		Legume forage BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	2.40	20.8
		Legume forage BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	4.46	11.2
		Potatoes BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	2.40	20.8
		Potatoes BBCH 10 – 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	8.19	6.11
		Potatoes BBCH 10 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	4.46	11.2
		Pulses BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	2.40	20.8

Table CP 10-03-8: Field crops (Shielded ground directed inter-row application): Uses 6a, b (1 × 1080 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Shielded ground directed inter-row application)	1 × 1080	Pulses BBCH 10 – 49	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	8.19	6.11
		Pulses BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	4.46	11.2
		Root & stem vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	2.40	20.8
		Root & stem vegetables BBCH 10 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	4.46	11.2
		Sugar beet BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	2.40	20.8
		Sugar beet BBCH 10 – 39	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	8.19	6.11
		Sugar beet BBCH 10 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	4.46	11.2

Table CP 10-03-9: Field crops (Shielded ground directed inter-row application): Uses 6a, b (1 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Shielded ground directed inter-row application)	1 × 720	Fruiting vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	1.60	31.2
		Fruiting vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	2.98	16.8
		Leafy vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	1.60	31.2
		Leafy vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	2.98	16.8
		Legume forage BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	1.60	31.2
		Legume forage BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	2.98	16.8
		Potatoes BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	1.60	31.2
		Potatoes BBCH 10 – 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	5.46	9.16
		Potatoes BBCH 10 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	2.98	16.8
		Pulses BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	1.60	31.2
		Pulses BBCH 10 – 49	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	5.46	9.16

Table CP 10-03-9: Field crops (Shielded ground directed inter-row application): Uses 6a, b (1 × 720 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Field crops (Shielded ground directed inter-row application)	1 × 720	Pulses BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	2.98	16.8
		Root & stem vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	1.60	31.2
		Root & stem vegetables BBCH 10 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	2.98	16.8
		Sugar beet BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	1.60	31.2
		Sugar beet BBCH 10 – 39	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	5.46	9.16
		Sugar beet BBCH 10 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	2.98	16.8

Control of invasive species: Uses 8, 9

Table CP 10-03-10: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Bulbs & onion like crops BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Bulbs & onion like crops BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	43.4	1.0 × 0.53	41.4	1.21
		Bulbs & onion like crops BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	4.7	1.0 × 0.53	4.48	11.2
		Bush & cane fruit BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Bush & cane fruit BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Bush & cane fruit BBCH 10 – 19	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	43.4	1.0 × 0.53	41.4	1.21
		Bush & cane fruit BBCH 20 – 39	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	36.1	1.0 × 0.53	34.4	1.45
		Bush & cane fruit BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	20.7	2.42
		Bush & cane fruit BBCH 10 – 19	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	4.7	1.0 × 0.53	4.48	11.2
		Bush & cane fruit BBCH 20 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	3.9	1.0 × 0.53	3.72	13.4
		Bush & cane fruit BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8

Table CP 10-03-10: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Cereals BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Cereals BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Cereals BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	20.7	2.42
		Cereals BBCH 10 – 29	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Cereals BBCH 30 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	3.9	1.0 × 0.53	3.72	13.4
		Cereals BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8
		Fruiting vegetables BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	20.7	2.42
		Fruiting vegetables BBCH 10 – 49	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8
		Grassland All season	Large herbivorous mammal “lagomorph” Brown hare (*Lepus europaeus*)	17.3	1.0 × 0.53	16.5	3.03

Table CP 10-03-10: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Grassland Late	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Grassland All season	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	69.0	0.725
		Grassland Late season (seed heads)	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	6.6	1.0 × 0.53	6.30	7.94
		Hop BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Hop BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Hop BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	20.7	2.42
		Hop BBCH 10 – 19	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Hop BBCH 20 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	3.9	1.0 × 0.53	3.72	13.4
		Hop BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8
		Leafy vegetables BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Leafy vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Leafy vegetables BBCH 40 – 49	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	69.0	0.725

Table CP 10-03-10: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Leafy vegetables BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	20.7	2.42
Control of invasive species	1 × 1800	Leafy vegetables All season	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	13.6	3.67
		Leafy vegetables BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Leafy vegetables BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8
		Legume forage BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Legume forage BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Legume forage BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	69.0	0.725
		Legume forage BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	20.7	2.42
		Legume forage Leaf development BBCH 21 – 49	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	13.6	3.67
		Legume forage BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Legume forage BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8
		Maize BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5

Table CP 10-03-10: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Maize BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Maize BBCH 10 – 29	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	69.0	0.725
		Maize BBCH 30 – 39	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	36.1	1.0 × 0.53	34.4	1.45
		Maize BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	17.3	2.90
		Maize BBCH 10 – 29	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Maize BBCH 30 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	3.9	1.0 × 0.53	3.72	13.4
		Maize BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.81	27.6
		Oilseed rape BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Oilseed rape BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Oilseed rape BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	17.3	2.90
		Oilseed rape All season	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	13.6	3.67
		Oilseed rape BBCH 10 – 29	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72

Table CP 10-03-10: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Control of invasive species	1 × 1800	Oilseed rape BBCH 30 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8
		Oilseed rape BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.81	27.6
		Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	69.0	0.725
		Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	13.6	3.67
		Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Ornamentals/nursery BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	69.0	0.725
		Ornamentals/nursery BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	36.1	1.0 × 0.53	34.4	1.45
		Potatoes BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
Control of invasive species	1 × 1800	Potatoes BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Potatoes BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	20.7	2.42
		Potatoes BBCH 10 – 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	13.6	3.67

Table CP 10-03-10: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Potatoes BBCH ≥ 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	4.3	1.0 × 0.53	4.10	12.2
		Potatoes BBCH 10 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Potatoes BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8
		Pulses BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Pulses BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Pulses BBCH 40 – 49	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	69.0	0.725
		Pulses BBCH ≥ 50	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	20.7	2.42
		Pulses BBCH 10 – 49	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	13.6	3.67
Control of invasive species	1 × 1800	Pulses BBCH ≥ 50	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	4.3	1.0 × 0.53	4.10	12.2
		Pulses BBCH 10 – 49	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Pulses BBCH ≥ 50	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8
		Root & stem vegetables BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5

Table CP 10-03-10: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Root & stem vegetables BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Root & stem vegetables BBCH ≥ 40	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	21.7	1.0 × 0.53	20.7	2.42
		Root & stem vegetables BBCH 10 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Root & stem vegetables BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	2.3	1.0 × 0.53	2.19	22.8
		Strawberries BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Strawberries BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
Control of invasive species	1 × 1800	Strawberries BBCH ≥ 40	Small herbivorous mammal "vole Common vole (*Microtus arvalis*)	28.9	1.0 × 0.53	27.6	1.81
		Strawberries BBCH 10 – 39	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	13.6	3.67
		Strawberries BBCH ≥ 40	Large herbivorous mammal "lagomorph" Rabbit (*Oryctolagus cuniculus*)	5.7	1.0 × 0.53	5.44	9.19
		Strawberries BBCH 10 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Strawberries BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	3.1	1.0 × 0.53	2.96	16.9
		Sugar beet BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5

Table CP 10-03-10: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Sugar beet BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Sugar beet BBCH ≥ 40	Small herbivorous mammal “vole Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	17.3	2.90
		Sugar beet BBCH 10 – 39	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	13.6	3.67
		Sugar beet BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.0 × 0.53	3.43	14.6
		Sugar beet BBCH 10 – 39	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
Control of invasive species	1 × 1800	Sugar beet BBCH ≥ 40	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.81	27.6
		Sunflower BBCH 10 – 19	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Sunflower BBCH ≥ 20	Small insectivorous mammal “shrew” Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Sunflower BBCH ≥ 40	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	18.1	1.0 × 0.53	17.3	2.90
		Sunflower BBCH 10 – 19	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	14.3	1.0 × 0.53	13.6	3.67
		Sunflower BBCH 20 – 39	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	7.2	1.0 × 0.53	6.87	7.28
		Sunflower BBCH ≥ 40	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	3.6	1.0 × 0.53	3.43	14.6

Table CP 10-03-10: Control of invasive species: Uses 8, 9 (1 × 1800 g a.s./ha)

Active substance		Glyphosate					
Reprod. Toxicity (mg/kg bw/d)		50					
TER criterion		5					
GAP crop	**Application rate (g a.s./ha)**	**Crop scenario Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
		Sunflower BBCH 10 – 19	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72
		Sunflower BBCH 20 – 39	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	3.9	1.0 × 0.53	3.72	13.4
		Sunflower BBCH ≥ 40	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	1.9	1.0 × 0.53	1.81	27.6
		Vineyard Application ground directed	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	11.1	1.0 × 0.53	10.6	4.72
Control of invasive species	1 × 1800	Vineyard BBCH 10 – 19	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	6.7	1.0 × 0.53	6.39	7.82
		Vineyard BBCH 20 – 39	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	5.5	1.0 × 0.53	5.25	9.53
		Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph" Brown hare (*Lepus europaeus*)	3.3	1.0 × 0.53	3.15	15.9
		Vineyard BBCH 10 – 19	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	4.2	1.0 × 0.53	4.01	12.5
		Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew" Common shrew (*Sorex araneus*)	1.9	1.0 × 0.53	1.81	27.6
		Vineyard Application ground directed	Small herbivorous mammal "vole" Common vole (*Microtus arvalis*)	72.3	1.0 × 0.53	69.0	0.725
		Vineyard Application ground directed	Small omnivorous mammal "mouse" Wood mouse (*Apodemus sylvaticus*)	7.8	1.0 × 0.53	7.44	6.72

Annex M-CP 10-04: Aquatic risk assessment

Aquatic risk assessment for glyphosate, AMPA, HMPA for all proposed uses.

Table CP 10-04-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, root (1 × 720 g a.s./ha). ***Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	42.672	0.091	0.044	0.107	0.034	0.032	0.041	1560.000	0.016
Step 2									
N-Europe	17.648	0.038	0.018	0.044	0.014	0.013	0.017	727.897	0.007
S-Europe	14.397	0.031	0.015	0.036	0.012	0.011	0.014	590.246	0.006
Step 3									
D3/ditch	4.495	0.010	0.005	0.011	0.004	0.003	0.004	4.151	< 0.001
D6/ditch	4.507	0.010	0.005	0.011	0.004	0.003	0.004	6.978	< 0.001
R1/pond	0.152	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	6.540	< 0.001
R1/stream	2.962	0.006	0.003	0.007	0.002	0.002	0.003	68.110	< 0.001
R2/stream	3.976	0.008	0.004	0.010	0.003	0.003	0.004	513.500	0.005
R2/stream 2nd	3.976	0.008	0.004	0.010	0.003	0.003	0.004	396.100	0.004
R3/stream	4.183	0.009	0.004	0.010	0.003	0.003	0.004	14.380	< 0.001
R4/stream	2.924	0.006	0.003	0.007	0.002	0.002	0.003	17.380	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-2: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, root (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	30.607	0.065	0.032	0.077	0.024	0.023	0.030	1260.000	0.013
S-Europe	25.017	0.053	0.026	0.063	0.020	0.019	0.024	1020.000	0.010
Step 3									
D3/ditch	4.495	0.010	0.005	0.011	0.004	0.003	0.004	4.775	< 0.001
D6/ditch	4.507	0.010	0.005	0.011	0.004	0.003	0.004	21.890	< 0.001
R1/pond	0.705	0.002	< 0.001	0.002	< 0.001	< 0.001	< 0.001	30.830	< 0.001
R1/stream	2.962	0.006	0.003	0.007	0.002	0.002	0.003	271.200	0.003
R2/stream	3.976	0.008	0.004	0.010	0.003	0.003	0.004	1353.600	0.014
R2/stream 2nd	3.976	0.008	0.004	0.010	0.003	0.003	0.004	1370.300	0.014
R3/stream	4.183	0.009	0.004	0.010	0.003	0.003	0.004	296.300	0.003
R4/stream	3.495	0.007	0.004	0.009	0.003	0.003	0.003	173.000	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in potatoes (1 × 720 g a.s./ha). ***Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	42.672	0.091	0.044	0.107	0.034	0.032	0.041	1560.000	0.016
Step 2									
N-Europe	17.648	0.038	0.018	0.044	0.014	0.013	0.017	727.897	0.007
S-Europe	14.397	0.031	0.015	0.036	0.012	0.011	0.014	590.246	0.006
Step 3									
D3/ditch	3.704	0.008	0.004	0.009	0.003	0.003	0.004	2.559	< 0.001
D4/pond	0.146	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	2.375	< 0.001
D4/stream	3.151	0.007	0.003	0.008	0.003	0.002	0.003	0.197	< 0.001
D6/ditch	3.729	0.008	0.004	0.009	0.003	0.003	0.004	7.716	< 0.001
D6/ditch 2nd	3.741	0.008	0.004	0.009	0.003	0.003	0.004	13.680	< 0.001
R1/pond	0.160	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	10.110	< 0.001
R1/stream	2.568	0.005	0.003	0.006	0.002	0.002	0.002	107.400	0.001
R2/stream	3.448	0.007	0.004	0.009	0.003	0.003	0.003	613.100	0.006
R3/stream	3.626	0.008	0.004	0.009	0.003	0.003	0.004	200.500	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in potatoes (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	30.607	0.065	0.032	0.077	0.024	0.023	0.030	1260.000	0.013
S-Europe	25.017	0.053	0.026	0.063	0.020	0.019	0.024	1020.000	0.010
Step 3									
D3/ditch	3.704	0.008	0.004	0.009	0.003	0.003	0.004	3.823	< 0.001
D4/pond	0.162	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.458	< 0.001
D4/stream	3.151	0.007	0.003	0.008	0.003	0.002	0.003	0.412	< 0.001
D6/ditch	3.729	0.008	0.004	0.009	0.003	0.003	0.004	7.716	< 0.001
D6/ditch 2nd	3.741	0.008	0.004	0.009	0.003	0.003	0.004	13.680	< 0.001
R1/pond	1.017	0.002	0.001	0.003	< 0.001	< 0.001	< 0.001	41.600	< 0.001
R1/stream	2.568	0.005	0.003	0.006	0.002	0.002	0.002	365.700	0.004
R2/stream	3.448	0.007	0.004	0.009	0.003	0.003	0.003	1280.700	0.013
R3/stream	3.626	0.008	0.004	0.009	0.003	0.003	0.004	684.700	0.007

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, bulb (1 × 720 g a.s./ha). ***Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	42.672	0.091	0.044	0.107	0.034	0.032	0.041	1560.000	0.016
Step 2									
N-Europe	17.648	0.038	0.018	0.044	0.014	0.013	0.017	727.897	0.007
S-Europe	14.397	0.031	0.015	0.036	0.012	0.011	0.014	590.246	0.006
Step 3									
D3/ditch	4.479	0.010	0.005	0.011	0.004	0.003	0.004	2.921	< 0.001
D4/pond	0.150	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	2.431	< 0.001
D4/stream	3.541	0.008	0.004	0.009	0.003	0.003	0.003	0.169	< 0.001
D6/ditch	4.526	0.010	0.005	0.011	0.004	0.003	0.004	15.750	< 0.001
D6/ditch 2nd	4.526	0.010	0.005	0.011	0.004	0.003	0.004	15.930	< 0.001
R1/pond	0.156	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	9.841	< 0.001
R1/stream	2.962	0.006	0.003	0.007	0.002	0.002	0.003	106.800	0.001
R2/stream	3.976	0.008	0.004	0.010	0.003	0.003	0.004	513.400	0.005
R3/stream	4.182	0.009	0.004	0.010	0.003	0.003	0.004	9.843	< 0.001
R4/stream	2.961	0.006	0.003	0.007	0.002	0.002	0.003	17.420	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, bulb (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c*.**

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	30.607	0.065	0.032	0.077	0.024	0.023	0.030	1260.000	0.013
S-Europe	25.017	0.053	0.026	0.063	0.020	0.019	0.024	1020.000	0.010
Step 3									
D3/ditch	4.479	0.010	0.005	0.011	0.004	0.003	0.004	4.608	< 0.001
D4/pond	0.173	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.681	< 0.001
D4/stream	3.541	0.008	0.004	0.009	0.003	0.003	0.003	0.401	< 0.001
D6/ditch	4.526	0.010	0.005	0.011	0.004	0.003	0.004	20.250	< 0.001
D6/ditch 2nd	4.526	0.010	0.005	0.011	0.004	0.003	0.004	24.750	< 0.001
R1/pond	1.006	0.002	0.001	0.003	< 0.001	< 0.001	< 0.001	40.690	< 0.001
R1/stream	2.962	0.006	0.003	0.007	0.002	0.002	0.003	366.300	0.004
R2/stream	3.976	0.008	0.004	0.010	0.003	0.003	0.004	1352.800	0.014
R3/stream	4.182	0.009	0.004	0.010	0.003	0.003	0.004	317.000	0.003
R4/stream	3.503	0.007	0.004	0.009	0.003	0.003	0.003	102.500	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, fruiting (1 × 720 g a.s./ha). ***Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	42.672	0.091	0.044	0.107	0.034	0.032	0.041	1560.000	0.016
Step 2									
N-Europe	17.648	0.038	0.018	0.044	0.014	0.013	0.017	727.897	0.007
S-Europe	14.397	0.031	0.015	0.036	0.012	0.011	0.014	590.246	0.006
Step 3									
D6/ditch	4.517	0.010	0.005	0.011	0.004	0.003	0.004	11.910	< 0.001
R2/stream	3.976	0.008	0.004	0.010	0.003	0.003	0.004	613.800	0.006
R3/stream	4.183	0.009	0.004	0.010	0.003	0.003	0.004	201.100	0.002
R4/stream	2.961	0.006	0.003	0.007	0.002	0.002	0.003	50.180	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, fruiting (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	30.607	0.065	0.032	0.077	0.024	0.023	0.030	1260.000	0.013
S-Europe	25.017	0.053	0.026	0.063	0.020	0.019	0.024	1020.000	0.010
Step 3									
D6/ditch	4.517	0.010	0.005	0.011	0.004	0.003	0.004	20.410	< 0.001
R2/stream	3.976	0.008	0.004	0.010	0.003	0.003	0.004	1622.300	0.016
R3/stream	4.183	0.009	0.004	0.010	0.003	0.003	0.004	686.200	0.007
R4/stream	3.780	0.008	0.004	0.009	0.003	0.003	0.004	366.500	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, leafy (1 × 720 g a.s./ha). ***Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		*Lepomis macrochirus*	*Oncorhynchus mykiss*	*Crassostrea gigas*	*Daphnia magna*	*Skeletonema costatum*	*Myriophyllum aquaticum*		*Chironomus riparius*
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	42.672	0.091	0.044	0.107	0.034	0.032	0.041	1560.000	0.016
Step 2									
N-Europe	17.648	0.038	0.018	0.044	0.014	0.013	0.017	727.897	0.007
S-Europe	14.397	0.031	0.015	0.036	0.012	0.011	0.014	590.246	0.006
Step 3									
D3/ditch	4.494	0.010	0.005	0.011	0.004	0.003	0.004	4.072	< 0.001
D3/ditch 2nd	4.491	0.010	0.005	0.011	0.004	0.003	0.004	3.719	< 0.001
D4/pond	0.150	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	2.440	< 0.001
D4/stream	3.612	0.008	0.004	0.009	0.003	0.003	0.003	0.212	< 0.001
D6/ditch	4.526	0.010	0.005	0.011	0.004	0.003	0.004	16.430	< 0.001
R1/pond	0.152	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	5.981	< 0.001
R1/pond 2nd	0.321	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	16.570	< 0.001
R1/stream	2.960	0.006	0.003	0.007	0.002	0.002	0.003	67.390	< 0.001
R1/stream 2nd	2.959	0.006	0.003	0.007	0.002	0.002	0.003	357.400	0.004
R2/stream	3.976	0.008	0.004	0.010	0.003	0.003	0.004	513.600	0.005
R2/stream 2nd	3.976	0.008	0.004	0.010	0.003	0.003	0.004	548.900	0.005
R3/stream	4.183	0.009	0.004	0.010	0.003	0.003	0.004	208.400	0.002

Table CP 10-04-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, leafy (1 × 720 g a.s./ha). *Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
R3/stream 2nd	4.183	0.009	0.004	0.010	0.003	0.003	0.004	201.000	0.002
R4/stream	2.961	0.006	0.003	0.007	0.002	0.002	0.003	143.800	0.001
R4/stream 2nd	2.961	0.006	0.003	0.007	0.002	0.002	0.003	264.300	0.003

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, leafy (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophytes		Sed. dwell. prolonged
Test species		*Lepomis macrochirus*	*Oncorhynchus mykiss*	*Crassostrea gigas*	*Daphnia magna*	*Skeletonema costatum*	*Myriophyllum aquaticum*		*Chironomus riparius*
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	30.607	0.065	0.032	0.077	0.024	0.023	0.030	1260.000	0.013
S-Europe	25.017	0.053	0.026	0.063	0.020	0.019	0.024	1020.000	0.010
Step 3									
D3/ditch	4.494	0.010	0.005	0.011	0.004	0.003	0.004	4.962	< 0.001
D3/ditch 2nd	4.491	0.010	0.005	0.011	0.004	0.003	0.004	5.999	< 0.001
D4/pond	0.172	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.626	< 0.001
D4/stream	3.612	0.008	0.004	0.009	0.003	0.003	0.003	0.481	< 0.001
D6/ditch	4.526	0.010	0.005	0.011	0.004	0.003	0.004	20.770	< 0.001
R1/pond	0.492	0.001	< 0.001	0.001	< 0.001	< 0.001	< 0.001	27.790	< 0.001
R1/pond 2nd	1.243	0.003	0.001	0.003	< 0.001	< 0.001	0.001	48.270	< 0.001
R1/stream	2.960	0.006	0.003	0.007	0.002	0.002	0.003	267.100	0.003
R1/stream 2nd	2.959	0.006	0.003	0.007	0.002	0.002	0.003	486.800	0.005
R2/stream	3.976	0.008	0.004	0.010	0.003	0.003	0.004	1353.700	0.014
R2/stream 2nd	3.976	0.008	0.004	0.010	0.003	0.003	0.004	1300.300	0.013

Table CP 10-04-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, leafy (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
R3/stream	4.183	0.009	0.004	0.010	0.003	0.003	0.004	542.600	0.005
R3/stream 2nd	4.183	0.009	0.004	0.010	0.003	0.003	0.004	686.100	0.007
R4/stream	3.371	0.007	0.004	0.008	0.003	0.002	0.003	383.000	0.004
R4/stream 2nd	3.555	0.008	0.004	0.009	0.003	0.003	0.003	739.300	0.007

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in sugar beets, (1 × 720 g a.s./ha). *Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	42.672	0.091	0.044	0.107	0.034	0.032	0.041	1560.000	0.016
Step 2									
N-Europe	17.648	0.038	0.018	0.044	0.014	0.013	0.017	727.897	0.007
S-Europe	14.397	0.031	0.015	0.036	0.012	0.011	0.014	590.246	0.006
Step 3									
D3/ditch	3.704	0.008	0.004	0.009	0.003	0.003	0.004	2.538	< 0.001
D4/pond	0.146	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	2.306	< 0.001
D4/stream	3.246	0.007	0.003	0.008	0.003	0.002	0.003	0.314	< 0.001
R1/pond	0.235	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	13.340	< 0.001
R1/stream	2.568	0.005	0.003	0.006	0.002	0.002	0.002	156.200	0.002
R3/stream	3.626	0.008	0.004	0.009	0.003	0.003	0.004	200.500	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in sugar beets (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 2a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	30.607	0.065	0.032	0.077	0.024	0.023	0.030	1260.000	0.013
S-Europe	25.017	0.053	0.026	0.063	0.020	0.019	0.024	1020.000	0.010
Step 3									
D3/ditch	3.704	0.008	0.004	0.009	0.003	0.003	0.004	4.056	< 0.001
D4/pond	0.148	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.542	< 0.001
D4/stream	3.246	0.007	0.003	0.008	0.003	0.002	0.003	0.516	< 0.001
R1/pond	1.230	0.003	0.001	0.003	< 0.001	< 0.001	0.001	46.500	< 0.001
R1/stream	2.568	0.005	0.003	0.006	0.002	0.002	0.002	459.800	0.005
R3/stream	3.626	0.008	0.004	0.009	0.003	0.003	0.004	684.800	0.007

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in pome/stone fruit (1 × 720 g a.s./ha). *Uses 4 a–c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	42.672	0.091	0.044	0.107	0.034	0.032	0.041	1560.000	0.016
Step 2									
N-Europe	17.648	0.038	0.018	0.044	0.014	0.013	0.017	727.897	0.007
S-Europe	14.397	0.031	0.015	0.036	0.012	0.011	0.014	590.246	0.006
Step 3									
D3/ditch	1.899	0.004	0.002	0.005	0.002	0.001	0.002	2.537	< 0.001
D4/pond	0.120	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	2.037	< 0.001
D4/stream	1.679	0.004	0.002	0.004	0.001	0.001	0.002	0.203	< 0.001
D5/pond	0.120	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	2.081	< 0.001
D5/stream	1.854	0.004	0.002	0.005	0.001	0.001	0.002	0.541	< 0.001
R1/pond	0.120	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	2.024	< 0.001
R1/stream	1.312	0.003	0.001	0.003	0.001	< 0.001	0.001	1.358	< 0.001
R2/stream	1.762	0.004	0.002	0.004	0.001	0.001	0.002	13.100	< 0.001
R3/stream	1.853	0.004	0.002	0.005	0.001	0.001	0.002	23.140	< 0.001
R4/stream	1.311	0.003	0.001	0.003	0.001	< 0.001	0.001	7.161	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in pome/stone fruit (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 4 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	30.607	0.065	0.032	0.077	0.024	0.023	0.030	1260.000	0.013
S-Europe	25.017	0.053	0.026	0.063	0.020	0.019	0.024	1020.000	0.010
Step 3									
D3/ditch	1.899	0.004	0.002	0.005	0.002	0.001	0.002	3.362	< 0.001
D4/pond	0.138	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	3.778	< 0.001
D4/stream	1.679	0.004	0.002	0.004	0.001	0.001	0.002	0.337	< 0.001
D5/pond	0.140	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.165	< 0.001
D5/stream	1.854	0.004	0.002	0.005	0.001	0.001	0.002	1.010	< 0.001
R1/pond	0.134	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.958	< 0.001
R1/stream	1.388	0.003	0.001	0.003	0.001	0.001	0.001	4.428	< 0.001
R2/stream	1.762	0.004	0.002	0.004	0.001	0.001	0.002	46.210	< 0.001
R3/stream	1.853	0.004	0.002	0.005	0.001	0.001	0.002	29.010	< 0.001
R4/stream	2.397	0.005	0.002	0.006	0.002	0.002	0.002	23.020	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in olives (1 × 720 g a.s./ha). ***Uses 4 a –c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	42.672	0.091	0.044	0.107	0.034	0.032	0.041	1560.000	0.016
Step 2									
N-Europe	17.648	0.038	0.018	0.044	0.014	0.013	0.017	727.897	0.007
S-Europe	14.397	0.031	0.015	0.036	0.012	0.011	0.014	590.246	0.006
Step 3									
D6/ditch	1.907	0.004	0.002	0.005	0.002	0.001	0.002	6.973	< 0.001
R4/stream	1.311	0.003	0.001	0.003	0.001	< 0.001	0.001	9.064	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in olives (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 4 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	30.607	0.065	0.032	0.077	0.024	0.023	0.030	1260.000	0.013
S-Europe	25.017	0.053	0.026	0.063	0.020	0.019	0.024	1020.000	0.010
Step 3									
D6/ditch	1.907	0.004	0.002	0.005	0.002	0.001	0.002	12.080	< 0.001
R4/stream	2.733	0.006	0.003	0.007	0.002	0.002	0.003	27.420	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vines (1 × 720 g a.s./ha). ***Uses 5 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	42.672	0.091	0.044	0.107	0.034	0.032	0.041	1560.000	0.016
Step 2									
N-Europe	17.648	0.038	0.018	0.044	0.014	0.013	0.017	727.897	0.007
S-Europe	14.397	0.031	0.015	0.036	0.012	0.011	0.014	590.246	0.006
Step 3									
D6/ditch	1.907	0.004	0.002	0.005	0.002	0.001	0.002	6.973	< 0.001
R1/pond	0.120	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	2.017	< 0.001
R1/stream	1.312	0.003	0.001	0.003	0.001	< 0.001	0.001	1.343	< 0.001
R2/stream	1.762	0.004	0.002	0.004	0.001	0.001	0.002	13.070	< 0.001
R3/stream	1.853	0.004	0.002	0.005	0.001	0.001	0.002	22.850	< 0.001
R4/stream	1.311	0.003	0.001	0.003	0.001	< 0.001	0.001	8.137	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vines (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 5 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	30.607	0.065	0.032	0.077	0.024	0.023	0.030	1260.000	0.013
S-Europe	25.017	0.053	0.026	0.063	0.020	0.019	0.024	1020.000	0.010
Step 3									
D6/ditch	1.907	0.004	0.002	0.005	0.002	0.001	0.002	12.080	< 0.001
R1/pond	0.134	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.933	< 0.001
R1/stream	1.353	0.003	0.001	0.003	0.001	0.001	0.001	4.386	< 0.001
R2/stream	1.762	0.004	0.002	0.004	0.001	0.001	0.002	46.280	< 0.001
R3/stream	1.853	0.004	0.002	0.005	0.001	0.001	0.002	28.620	< 0.001
R4/stream	2.775	0.006	0.003	0.007	0.002	0.002	0.003	25.340	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, root (1 × 1440 g a.s./ha). ***Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.***

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophytes		Sed. dwell. prolonged
Test species		*Lepomis macrochirus*	*Oncorhynchus mykiss*	*Crassostrea gigas*	*Daphnia magna*	*Skeletonema costatum*	*Myriophyllum aquaticum*		*Chironomus riparius*
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	85.344	0.182	0.089	0.213	0.068	0.063	0.083	3130.000	0.031
Step 2									
N-Europe	35.296	0.075	0.037	0.088	0.028	0.026	0.034	1460.000	0.015
S-Europe	28.794	0.061	0.030	0.072	0.023	0.021	0.028	1180.000	0.012
Step 3									
D3/ditch	9.019	0.019	0.009	0.023	0.007	0.007	0.009	8.284	< 0.001
D6/ditch	9.043	0.019	0.009	0.023	0.007	0.007	0.009	13.850	< 0.001
R1/pond	0.307	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	13.290	< 0.001
R1/stream	5.945	0.013	0.006	0.015	0.005	0.004	0.006	114.900	0.001
R2/stream	7.979	0.017	0.008	0.020	0.006	0.006	0.008	973.300	0.010
R2/stream 2nd	7.979	0.017	0.008	0.020	0.006	0.006	0.008	736.800	0.007
R3/stream	8.393	0.018	0.009	0.021	0.007	0.006	0.008	25.250	< 0.001
R4/stream	5.870	0.012	0.006	0.015	0.005	0.004	0.006	29.270	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in potatoes (1 × 1440 g a.s./ha). ***Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	85.344	0.182	0.089	0.213	0.068	0.063	0.083	3130.000	0.031
Step 2									
N-Europe	35.296	0.075	0.037	0.088	0.028	0.026	0.034	1460.000	0.015
S-Europe	28.794	0.061	0.030	0.072	0.023	0.021	0.028	1180.000	0.012
Step 3									
D3/ditch	7.433	0.016	0.008	0.019	0.006	0.006	0.007	5.117	< 0.001
D4/pond	0.294	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.603	< 0.001
D4/stream	6.324	0.013	0.007	0.016	0.005	0.005	0.006	0.396	< 0.001
D6/ditch	7.484	0.016	0.008	0.019	0.006	0.006	0.007	15.270	< 0.001
D6/ditch 2nd	7.507	0.016	0.008	0.019	0.006	0.006	0.007	26.820	< 0.001
R1/pond	0.419	< 0.001	< 0.001	0.001	< 0.001	< 0.001	< 0.001	20.880	< 0.001
R1/stream	5.156	0.011	0.005	0.013	0.004	0.004	0.005	181.900	0.002
R2/stream	6.920	0.015	0.007	0.017	0.006	0.005	0.007	1185.300	0.012
R3/stream	7.277	0.015	0.008	0.018	0.006	0.005	0.007	346.200	0.003

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, bulb (1 × 1440 g a.s./ha). ***Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		*Lepomis macrochirus*	*Oncorhynchus mykiss*	*Crassostrea gigas*	*Daphnia magna*	*Skeletonema costatum*	*Myriophyllum aquaticum*		*Chironomus riparius*
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	85.344	0.182	0.089	0.213	0.068	0.063	0.083	3130.000	0.031
Step 2									
N-Europe	35.296	0.075	0.037	0.088	0.028	0.026	0.034	1460.000	0.015
S-Europe	28.794	0.061	0.030	0.072	0.023	0.021	0.028	1180.000	0.012
Step 3									
D3/ditch	8.987	0.019	0.009	0.022	0.007	0.007	0.009	5.840	< 0.001
D4/pond	0.303	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.709	< 0.001
D4/stream	7.106	0.015	0.007	0.018	0.006	0.005	0.007	0.339	< 0.001
D6/ditch	9.082	0.019	0.009	0.023	0.007	0.007	0.009	30.900	< 0.001
D6/ditch 2nd	9.082	0.019	0.009	0.023	0.007	0.007	0.009	31.250	< 0.001
R1/pond	0.408	< 0.001	< 0.001	0.001	< 0.001	< 0.001	< 0.001	20.320	< 0.001
R1/stream	5.945	0.013	0.006	0.015	0.005	0.004	0.006	181.000	0.002
R2/stream	7.979	0.017	0.008	0.020	0.006	0.006	0.008	972.900	0.010
R3/stream	8.391	0.018	0.009	0.021	0.007	0.006	0.008	17.410	< 0.001
R4/stream	5.944	0.013	0.006	0.015	0.005	0.004	0.006	29.180	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, fruiting (1 × 1440 g a.s./ha). ***Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	85.344	0.182	0.089	0.213	0.068	0.063	0.083	3130.000	0.031
Step 2									
N-Europe	35.296	0.075	0.037	0.088	0.028	0.026	0.034	1460.000	0.015
S-Europe	28.794	0.061	0.030	0.072	0.023	0.021	0.028	1180.000	0.012
Step 3									
D6/ditch	9.064	0.019	0.009	0.023	0.007	0.007	0.009	23.440	< 0.001
R2/stream	7.979	0.017	0.008	0.020	0.006	0.006	0.008	1186.900	0.012
R3/stream	8.393	0.018	0.009	0.021	0.007	0.006	0.008	347.100	0.003
R4/stream	5.944	0.013	0.006	0.015	0.005	0.004	0.006	85.970	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, leafy (1 × 1440 g a.s./ha). ***Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	85.344	0.182	0.089	0.213	0.068	0.063	0.083	3130.000	0.031
Step 2									
N-Europe	35.296	0.075	0.037	0.088	0.028	0.026	0.034	1460.000	0.015
S-Europe	28.794	0.061	0.030	0.072	0.023	0.021	0.028	1180.000	0.012
Step 3									
D3/ditch	9.017	0.019	0.009	0.023	0.007	0.007	0.009	8.127	< 0.001
D3/ditch 2nd	9.010	0.019	0.009	0.023	0.007	0.007	0.009	7.427	< 0.001
D4/pond	0.303	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.727	< 0.001
D4/stream	7.249	0.015	0.008	0.018	0.006	0.005	0.007	0.425	< 0.001
D6/ditch	9.082	0.019	0.009	0.023	0.007	0.007	0.009	32.200	< 0.001
R1/pond	0.308	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	12.140	< 0.001
R1/pond 2nd	0.801	0.002	< 0.001	0.002	< 0.001	< 0.001	< 0.001	33.560	< 0.001
R1/stream	5.942	0.013	0.006	0.015	0.005	0.004	0.006	117.100	0.001
R1/stream 2nd	5.939	0.013	0.006	0.015	0.005	0.004	0.006	672.800	0.007
R2/stream	7.979	0.017	0.008	0.020	0.006	0.006	0.008	973.500	0.010
R2/stream 2nd	7.979	0.017	0.008	0.020	0.006	0.006	0.008	1026.000	0.010
R3/stream	8.393	0.018	0.009	0.021	0.007	0.006	0.008	400.100	0.004

Table CP 10-04-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, leafy (1 × 1440 g a.s./ha). *Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
R3/stream 2nd	8.393	0.018	0.009	0.021	0.007	0.006	0.008	346.800	0.003
R4/stream	5.944	0.013	0.006	0.015	0.005	0.004	0.006	256.900	0.003
R4/stream 2nd	5.944	0.013	0.006	0.015	0.005	0.004	0.006	472.800	0.005

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in sugar beets (1 × 1440 g a.s./ha). ***Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	85.344	0.182	0.089	0.213	0.068	0.063	0.083	3130.000	0.031
Step 2									
N-Europe	35.296	0.075	0.037	0.088	0.028	0.026	0.034	1460.000	0.015
S-Europe	28.794	0.061	0.030	0.072	0.023	0.021	0.028	1180.000	0.012
Step 3									
D3/ditch	7.432	0.016	0.008	0.019	0.006	0.006	0.007	5.076	< 0.001
D4/pond	0.294	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.461	< 0.001
D4/stream	6.516	0.014	0.007	0.016	0.005	0.005	0.006	0.630	< 0.001
R1/pond	0.617	0.001	< 0.001	0.002	< 0.001	< 0.001	< 0.001	27.950	< 0.001
R1/stream	5.155	0.011	0.005	0.013	0.004	0.004	0.005	273.900	0.003
R3/stream	7.277	0.015	0.008	0.018	0.006	0.005	0.007	346.000	0.003

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in pome/stone fruit (1 × 1440 g a.s./ha). ***Uses 4 a-c.***

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophytes		Sed. dwell. prolonged
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	85.344	0.182	0.089	0.213	0.068	0.063	0.083	3130.000	0.031
Step 2									
N-Europe	35.296	0.075	0.037	0.088	0.028	0.026	0.034	1460.000	0.015
S-Europe	28.794	0.061	0.030	0.072	0.023	0.021	0.028	1180.000	0.012
Step 3									
D3/ditch	3.814	0.008	0.004	0.010	0.003	0.003	0.004	5.064	< 0.001
D4/pond	0.242	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	3.951	< 0.001
D4/stream	3.372	0.007	0.004	0.008	0.003	0.002	0.003	0.408	< 0.001
D5/pond	0.242	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.040	< 0.001
D5/stream	3.724	0.008	0.004	0.009	0.003	0.003	0.004	1.086	< 0.001
R1/pond	0.242	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	3.983	< 0.001
R1/stream	2.635	0.006	0.003	0.007	0.002	0.002	0.003	2.348	< 0.001
R2/stream	3.538	0.008	0.004	0.009	0.003	0.003	0.003	23.880	< 0.001
R3/stream	3.721	0.008	0.004	0.009	0.003	0.003	0.004	41.680	< 0.001
R4/stream	2.635	0.006	0.003	0.007	0.002	0.002	0.003	12.200	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in pome/stone fruit (2 × 1440 g a.s./ha, with application interval of 28 days). ***Uses 4 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	170.688	0.363	0.177	0.427	0.137	0.126	0.165	6260.000	0.063
Step 2									
N-Europe	52.829	0.112	0.055	0.132	0.042	0.039	0.051	2170.000	0.022
S-Europe	43.176	0.092	0.045	0.108	0.035	0.032	0.042	1770.000	0.018
Step 3									
D3/ditch	3.814	0.008	0.004	0.010	0.003	0.003	0.004	6.511	< 0.001
D4/pond	0.278	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	6.084	< 0.001
D4/stream	3.372	0.007	0.004	0.008	0.003	0.002	0.003	0.522	< 0.001
D5/pond	0.283	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	6.473	< 0.001
D5/stream	3.724	0.008	0.004	0.009	0.003	0.003	0.004	1.686	< 0.001
R1/pond	0.267	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	7.076	< 0.001
R1/stream	2.635	0.006	0.003	0.007	0.002	0.002	0.003	4.937	< 0.001
R2/stream	3.538	0.008	0.004	0.009	0.003	0.003	0.003	54.810	< 0.001
R3/stream	3.721	0.008	0.004	0.009	0.003	0.003	0.004	41.680	< 0.001
R4/stream	3.225	0.007	0.003	0.008	0.003	0.002	0.003	23.160	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in olives (1 × 1440 g a.s./ha). ***Uses 4 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	85.344	0.182	0.089	0.213	0.068	0.063	0.083	3130.000	0.031
Step 2									
N-Europe	35.296	0.075	0.037	0.088	0.028	0.026	0.034	1460.000	0.015
S-Europe	28.794	0.061	0.030	0.072	0.023	0.021	0.028	1180.000	0.012
Step 3									
D6/ditch	3.830	0.008	0.004	0.010	0.003	0.003	0.004	13.750	< 0.001
R4/stream	2.635	0.006	0.003	0.007	0.002	0.002	0.003	15.620	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in olives (2 × 1440 g a.s./ha, with application interval of 28 days). ***Uses 4 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	170.688	0.363	0.177	0.427	0.137	0.126	0.165	6260.000	0.063
Step 2									
N-Europe	52.829	0.112	0.055	0.132	0.042	0.039	0.051	2170.000	0.022
S-Europe	43.176	0.092	0.045	0.108	0.035	0.032	0.042	1770.000	0.018
Step 3									
D6/ditch	3.830	0.008	0.004	0.010	0.003	0.003	0.004	20.590	< 0.001
R4/stream	4.511	0.010	0.005	0.011	0.004	0.003	0.004	30.420	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vines (1 × 1440 g a.s./ha). ***Uses 5 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		*Lepomis macrochirus*	*Oncorhynchus mykiss*	*Crassostrea gigas*	*Daphnia magna*	*Skeletonema costatum*	*Myriophyllum aquaticum*		*Chironomus riparius*
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	85.344	0.182	0.089	0.213	0.068	0.063	0.083	3130.000	0.031
Step 2									
N-Europe	35.296	0.075	0.037	0.088	0.028	0.026	0.034	1460.000	0.015
S-Europe	28.794	0.061	0.030	0.072	0.023	0.021	0.028	1180.000	0.012
Step 3									
D6/ditch	3.830	0.008	0.004	0.010	0.003	0.003	0.004	13.750	< 0.001
R1/pond	0.242	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	3.967	< 0.001
R1/stream	2.635	0.006	0.003	0.007	0.002	0.002	0.003	2.318	< 0.001
R2/stream	3.538	0.008	0.004	0.009	0.003	0.003	0.003	23.830	< 0.001
R3/stream	3.721	0.008	0.004	0.009	0.003	0.003	0.004	41.180	< 0.001
R4/stream	2.635	0.006	0.003	0.007	0.002	0.002	0.003	14.000	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-30: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vines (2 × 1440 g a.s./ha, with application interval of 28 days). ***Uses 5 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	170.688	0.363	0.177	0.427	0.137	0.126	0.165	6260.000	0.063
Step 2									
N-Europe	52.829	0.112	0.055	0.132	0.042	0.039	0.051	2170.000	0.022
S-Europe	43.176	0.092	0.045	0.108	0.035	0.032	0.042	1770.000	0.018
Step 3									
D6/ditch	3.830	0.008	0.004	0.010	0.003	0.003	0.004	20.590	< 0.001
R1/pond	0.267	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	7.041	< 0.001
R1/stream	2.635	0.006	0.003	0.007	0.002	0.002	0.003	4.889	< 0.001
R2/stream	3.538	0.008	0.004	0.009	0.003	0.003	0.003	54.840	< 0.001
R3/stream	3.721	0.008	0.004	0.009	0.003	0.003	0.004	41.180	< 0.001
R4/stream	4.363	0.009	0.005	0.011	0.003	0.003	0.004	27.890	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-31: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, root (1 × 540 g a.s./ha). *Uses 3 a –c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	32.004	0.068	0.033	0.080	0.026	0.024	0.031	1170.000	0.012
Step 2									
N-Europe	13.236	0.028	0.014	0.033	0.011	0.010	0.013	545.923	0.005
S-Europe	10.798	0.023	0.011	0.027	0.009	0.008	0.010	442.684	0.004
Step 3									
D3/ditch	3.366	0.007	0.003	0.008	0.003	0.002	0.003	3.114	< 0.001
D6/ditch	3.375	0.007	0.004	0.008	0.003	0.003	0.003	5.245	< 0.001
R1/pond	0.113	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.885	< 0.001
R1/stream	2.218	0.005	0.002	0.006	0.002	0.002	0.002	54.310	< 0.001
R2/stream	2.978	0.006	0.003	0.007	0.002	0.002	0.003	392.400	0.004
R2/stream 2nd	2.978	0.006	0.003	0.007	0.002	0.002	0.003	304.700	0.003
R3/stream	3.132	0.007	0.003	0.008	0.003	0.002	0.003	11.300	< 0.001
R4/stream	2.189	0.005	0.002	0.005	0.002	0.002	0.002	13.950	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-32: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in potatoes (1 × 540 g a.s./ha). ***Uses 3 a –c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	32.004	0.068	0.033	0.080	0.026	0.024	0.031	1170.000	0.012
Step 2									
N-Europe	13.236	0.028	0.014	0.033	0.011	0.010	0.013	545.923	0.005
S-Europe	10.798	0.023	0.011	0.027	0.009	0.008	0.010	442.684	0.004
Step 3									
D3/ditch	2.773	0.006	0.003	0.007	0.002	0.002	0.003	1.918	< 0.001
D4/pond	0.109	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	1.802	< 0.001
D4/stream	2.359	0.005	0.002	0.006	0.002	0.002	0.002	0.148	< 0.001
D6/ditch	2.792	0.006	0.003	0.007	0.002	0.002	0.003	5.806	< 0.001
D6/ditch 2nd	2.801	0.006	0.003	0.007	0.002	0.002	0.003	10.330	< 0.001
R1/pond	0.110	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	7.503	< 0.001
R1/stream	1.922	0.004	0.002	0.005	0.002	0.001	0.002	85.520	< 0.001
R2/stream	2.582	0.005	0.003	0.006	0.002	0.002	0.002	465.200	0.005
R3/stream	2.715	0.006	0.003	0.007	0.002	0.002	0.003	158.600	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-33: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, bulb (1 × 540 g a.s./ha). ***Uses 3 a – c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	32.004	0.068	0.033	0.080	0.026	0.024	0.031	1170.000	0.012
Step 2									
N-Europe	13.236	0.028	0.014	0.033	0.011	0.010	0.013	545.923	0.005
S-Europe	10.798	0.023	0.011	0.027	0.009	0.008	0.010	442.684	0.004
Step 3									
D3/ditch	3.354	0.007	0.003	0.008	0.003	0.002	0.003	2.190	< 0.001
D4/pond	0.112	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	1.844	< 0.001
D4/stream	2.651	0.006	0.003	0.007	0.002	0.002	0.003	0.127	< 0.001
D6/ditch	3.390	0.007	0.004	0.008	0.003	0.003	0.003	11.890	< 0.001
D6/ditch 2nd	3.390	0.007	0.004	0.008	0.003	0.003	0.003	12.030	< 0.001
R1/pond	0.113	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	7.301	< 0.001
R1/stream	2.218	0.005	0.002	0.006	0.002	0.002	0.002	84.970	< 0.001
R2/stream	2.978	0.006	0.003	0.007	0.002	0.002	0.003	392.300	0.004
R3/stream	3.132	0.007	0.003	0.008	0.003	0.002	0.003	7.717	< 0.001
R4/stream	2.217	0.005	0.002	0.006	0.002	0.002	0.002	13.990	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-34: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, fruiting (1 × 540 g a.s./ha). ***Uses 3 a –c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	32.004	0.068	0.033	0.080	0.026	0.024	0.031	1170.000	0.012
Step 2									
N-Europe	13.236	0.028	0.014	0.033	0.011	0.010	0.013	545.923	0.005
S-Europe	10.798	0.023	0.011	0.027	0.009	0.008	0.010	442.684	0.004
Step 3									
D6/ditch	3.383	0.007	0.004	0.008	0.003	0.003	0.003	8.982	< 0.001
R2/stream	2.978	0.006	0.003	0.007	0.002	0.002	0.003	465.800	0.005
R3/stream	3.132	0.007	0.003	0.008	0.003	0.002	0.003	159.100	0.002
R4/stream	2.217	0.005	0.002	0.006	0.002	0.002	0.002	39.820	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-35: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, leafy (1 × 540 g a.s./ha). ***Uses 3 a – c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	32.004	0.068	0.033	0.080	0.026	0.024	0.031	1170.000	0.012
Step 2									
N-Europe	13.236	0.028	0.014	0.033	0.011	0.010	0.013	545.923	0.005
S-Europe	10.798	0.023	0.011	0.027	0.009	0.008	0.010	442.684	0.004
Step 3									
D3/ditch	3.366	0.007	0.003	0.008	0.003	0.002	0.003	3.055	< 0.001
D3/ditch 2nd	3.363	0.007	0.003	0.008	0.003	0.002	0.003	2.789	< 0.001
D4/pond	0.112	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	1.851	< 0.001
D4/stream	2.705	0.006	0.003	0.007	0.002	0.002	0.003	0.159	< 0.001
D6/ditch	3.390	0.007	0.004	0.008	0.003	0.003	0.003	12.400	< 0.001
R1/pond	0.113	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	4.468	< 0.001
R1/pond 2nd	0.221	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	12.370	< 0.001
R1/stream	2.216	0.005	0.002	0.006	0.002	0.002	0.002	53.170	< 0.001
R1/stream 2nd	2.215	0.005	0.002	0.006	0.002	0.002	0.002	273.800	0.003
R2/stream	2.978	0.006	0.003	0.007	0.002	0.002	0.003	392.400	0.004
R2/stream 2nd	2.978	0.006	0.003	0.007	0.002	0.002	0.003	421.600	0.004
R3/stream	3.132	0.007	0.003	0.008	0.003	0.002	0.003	158.600	0.002

Table CP 10-04-35: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, leafy (1 × 540 g a.s./ha). ***Uses 3 a – c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
R3/stream 2nd	3.132	0.007	0.003	0.008	0.003	0.002	0.003	159.000	0.002
R4/stream	2.217	0.005	0.002	0.006	0.002	0.002	0.002	112.300	0.001
R4/stream 2nd	2.217	0.005	0.002	0.006	0.002	0.002	0.002	206.300	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-36: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in sugar beets (1 × 540 g a.s./ha). ***Uses 3 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	32.004	0.068	0.033	0.080	0.026	0.024	0.031	1170.000	0.012
Step 2									
N-Europe	13.236	0.028	0.014	0.033	0.011	0.010	0.013	545.923	0.005
S-Europe	10.798	0.023	0.011	0.027	0.009	0.008	0.010	442.684	0.004
Step 3									
D3/ditch	2.773	0.006	0.003	0.007	0.002	0.002	0.003	1.903	< 0.001
D4/pond	0.109	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	1.751	< 0.001
D4/stream	2.431	0.005	0.003	0.006	0.002	0.002	0.002	0.235	< 0.001
R1/pond	0.157	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	9.834	< 0.001
R1/stream	1.922	0.004	0.002	0.005	0.002	0.001	0.002	122.800	0.001
R3/stream	2.715	0.006	0.003	0.007	0.002	0.002	0.003	158.600	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-37: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, root (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038	1630.000	0.016
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031	1330.000	0.013
Step 3									
D3/ditch	6.756	0.014	0.007	0.017	0.005	0.005	0.007	7.557	< 0.001
D6/ditch	6.774	0.014	0.007	0.017	0.005	0.005	0.007	26.450	< 0.001
R1/pond	0.542	0.001	< 0.001	0.001	< 0.001	< 0.001	< 0.001	25.090	< 0.001
R1/stream	4.453	0.009	0.005	0.011	0.004	0.003	0.004	203.100	0.002
R2/stream	5.977	0.013	0.006	0.015	0.005	0.004	0.006	1316.700	0.013
R2/stream 2nd	5.977	0.013	0.006	0.015	0.005	0.004	0.006	1275.000	0.013
R3/stream	6.287	0.013	0.007	0.016	0.005	0.005	0.006	77.270	< 0.001
R4/stream	4.396	0.009	0.005	0.011	0.004	0.003	0.004	97.080	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-38: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in potatoes (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038	1630.000	0.016
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031	1330.000	0.013
Step 3									
D3/ditch	5.567	0.012	0.006	0.014	0.004	0.004	0.005	5.402	< 0.001
D4/pond	0.252	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	5.458	< 0.001
D4/stream	4.736	0.010	0.005	0.012	0.004	0.004	0.005	0.440	< 0.001
D6/ditch	5.605	0.012	0.006	0.014	0.004	0.004	0.005	11.510	< 0.001
D6/ditch 2nd	5.622	0.012	0.006	0.014	0.004	0.004	0.005	20.290	< 0.001
R1/pond	0.902	0.002	< 0.001	0.002	< 0.001	< 0.001	< 0.001	38.010	< 0.001
R1/stream	3.861	0.008	0.004	0.010	0.003	0.003	0.004	320.200	0.003
R2/stream	5.183	0.011	0.005	0.013	0.004	0.004	0.005	1156.400	0.012
R3/stream	5.451	0.012	0.006	0.014	0.004	0.004	0.005	585.200	0.006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-39: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, bulb (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038	1630.000	0.016
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031	1330.000	0.013
Step 3									
D3/ditch	6.732	0.014	0.007	0.017	0.005	0.005	0.007	6.022	< 0.001
D4/pond	0.260	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	5.620	< 0.001
D4/stream	5.323	0.011	0.006	0.013	0.004	0.004	0.005	0.411	< 0.001
D6/ditch	6.803	0.014	0.007	0.017	0.005	0.005	0.007	34.230	< 0.001
D6/ditch 2nd	6.803	0.014	0.007	0.017	0.005	0.005	0.007	34.130	< 0.001
R1/pond	0.888	0.002	< 0.001	0.002	< 0.001	< 0.001	< 0.001	37.120	< 0.001
R1/stream	4.453	0.009	0.005	0.011	0.004	0.003	0.004	320.200	0.003
R2/stream	5.977	0.013	0.006	0.015	0.005	0.004	0.006	1316.200	0.013
R3/stream	6.286	0.013	0.007	0.016	0.005	0.005	0.006	70.680	< 0.001
R4/stream	4.452	0.009	0.005	0.011	0.004	0.003	0.004	46.370	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-40: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, fruiting (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038	1630.000	0.016
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031	1330.000	0.013
Step 3									
D6/ditch	6.789	0.014	0.007	0.017	0.005	0.005	0.007	35.550	< 0.001
R2/stream	5.977	0.013	0.006	0.015	0.005	0.004	0.006	1478.500	0.015
R3/stream	6.287	0.013	0.007	0.016	0.005	0.005	0.006	586.500	0.006
R4/stream	4.452	0.009	0.005	0.011	0.004	0.003	0.004	418.300	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-41: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, leafy (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038	1630.000	0.016
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031	1330.000	0.013
Step 3									
D3/ditch	6.755	0.014	0.007	0.017	0.005	0.005	0.007	6.211	< 0.001
D3/ditch 2nd	6.750	0.014	0.007	0.017	0.005	0.005	0.007	8.348	< 0.001
D4/pond	0.260	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	5.596	< 0.001
D4/stream	5.430	0.012	0.006	0.014	0.004	0.004	0.005	0.515	< 0.001
D6/ditch	6.803	0.014	0.007	0.017	0.005	0.005	0.007	32.370	< 0.001
R1/pond	0.451	< 0.001	< 0.001	0.001	< 0.001	< 0.001	< 0.001	24.620	< 0.001
R1/pond 2nd	1.201	0.003	0.001	0.003	< 0.001	< 0.001	0.001	47.090	< 0.001
R1/stream	4.451	0.009	0.005	0.011	0.004	0.003	0.004	233.300	0.002
R1/stream 2nd	4.448	0.009	0.005	0.011	0.004	0.003	0.004	655.200	0.007
R2/stream	5.977	0.013	0.006	0.015	0.005	0.004	0.006	1317.100	0.013
R2/stream 2nd	5.977	0.013	0.006	0.015	0.005	0.004	0.006	1501.400	0.015
R3/stream	6.287	0.013	0.007	0.016	0.005	0.005	0.006	599.200	0.006

Table CP 10-04-41: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in vegetables, leafy (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
R3/stream 2nd	6.287	0.013	0.007	0.016	0.005	0.005	0.006	586.400	0.006
R4/stream	4.452	0.009	0.005	0.011	0.004	0.003	0.004	374.800	0.004
R4/stream 2nd	4.452	0.009	0.005	0.011	0.004	0.003	0.004	670.800	0.007

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-42: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in sugar beets (2 × 1080 g a.s./ha, with application interval of 28 days)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	128.016	0.272	0.133	0.320	0.102	0.095	0.124	4690.000	0.047
Step 2									
N-Europe	39.622	0.084	0.041	0.099	0.032	0.029	0.038	1630.000	0.016
S-Europe	32.382	0.069	0.034	0.081	0.026	0.024	0.031	1330.000	0.013
Step 3									
D3/ditch	5.567	0.012	0.006	0.014	0.004	0.004	0.005	5.255	< 0.001
D4/pond	0.256	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	5.289	< 0.001
D4/stream	4.880	0.010	0.005	0.012	0.004	0.004	0.005	0.918	< 0.001
R1/pond	1.165	0.002	0.001	0.003	< 0.001	< 0.001	0.001	45.150	< 0.001
R1/stream	3.861	0.008	0.004	0.010	0.003	0.003	0.004	408.600	0.004
R3/stream	5.451	0.012	0.006	0.014	0.004	0.004	0.005	585.100	0.006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-43: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on HardSPEC calculations for the use of MON 52276 to railways, 1 x 1800 g a.s./ha. ***Uses 7a-b, 8 and 9.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
HardSPEC Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Railway ditch leaching	4.729	0.010	0.005	0.012	0.004	0.004	0.005	16.992	< 0.001
Railway ditch runoff	4.729	0.010	0.005	0.012	0.004	0.004	0.005	17.000	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-44: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on HardSPEC calculations for the use of MON 52276 to railways, 1 x 3600 g a.s./ha. *Uses 7a-b.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
HardSPEC Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Railway ditch leaching	9.458	0.020	0.010	0.024	0.008	0.007	0.009	33.984	< 0.001
Railway ditch runoff	9.458	0.020	0.010	0.024	0.008	0.007	0.009	34.000	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-45: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of MON 52276 in grass/alfalfa, (1 × 1800 g a.s./ha). ***Uses 7a-b, 8 and 9.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**		**Sed. dwell. prolonged**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Crassostrea gigas***	***Daphnia magna***	***Skeletonema costatum***	***Myriophyllum aquaticum***		***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 47000	NOEC ≥ 9630	EC_{50} 40000	NOEC 12500	E_rC_{50} 13500	E_rC_{50} 10330	**Endpoint (µg/kg)**	NOEC ≥ 1000000
AF		100	10	100	10	10	10	**AF**	10
RAC (µg/L)		470	≥ 963	400	1250	1350	1033	**RAC (µg/kg)**	≥ 100000
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**							**$PEC_{sed,max}$ (µg/kg)**	
Step 1									
	106.680	0.227	0.111	0.267	0.085	0.079	0.103	3910.000	0.039
Step 2									
N-Europe	44.120	0.094	0.046	0.110	0.035	0.033	0.043	1820.000	0.018
S-Europe	35.993	0.077	0.037	0.090	0.029	0.027	0.035	1480.000	0.015
Step 3									
D1/ditch	11.400	0.024	0.012	0.029	0.009	0.008	0.011	63.590	< 0.001
D1/stream	9.964	0.021	0.010	0.025	0.008	0.007	0.010	6.604	< 0.001
D2/ditch	11.410	0.024	0.012	0.029	0.009	0.008	0.011	61.080	< 0.001
D2/stream	10.150	0.022	0.011	0.025	0.008	0.008	0.010	47.820	< 0.001
D3/ditch	11.300	0.024	0.012	0.028	0.009	0.008	0.011	12.530	< 0.001
D4/pond	0.380	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	6.245	< 0.001
D4/stream	9.736	0.021	0.010	0.024	0.008	0.007	0.009	2.160	< 0.001
D5/pond	0.380	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	6.190	< 0.001
D5/stream	10.510	0.022	0.011	0.026	0.008	0.008	0.010	3.062	< 0.001
R2/stream	9.938	0.021	0.010	0.025	0.008	0.007	0.010	5.558	< 0.001
R3/stream	10.480	0.022	0.011	0.026	0.008	0.008	0.010	11.630	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Risk assessment for the metabolite AMPA

Table CP 10-04-46: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (1 × 720 g a.s./ha). *Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	34.546	0.007	0.029	0.005	0.023	0.002	0.005
Step 2							
N-Europe	15.904	0.003	0.013	0.002	0.011	< 0.001	0.002
S-Europe	12.825	0.002	0.011	0.002	0.009	< 0.001	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
[1] covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table CP 10-04-47: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (3 × 720 g a.s./ha, with application interval of 28 days). *Uses 2 a-c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	103.639	0.020	0.086	0.015	0.069	0.005	0.014
Step 2							
N-Europe	35.129	0.007	0.029	0.005	0.023	0.002	0.005
S-Europe	28.289	0.005	0.024	0.004	0.019	0.001	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
[1] covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table CP 10-04-48: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in orchards[1] (1 × 720 g a.s./ha). ***Uses 4 a-c.***

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophytes
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	34.546	0.007	0.029	0.005	0.023	0.002	0.005
Step 2							
N-Europe	15.904	0.003	0.013	0.002	0.011	< 0.001	0.002
S-Europe	12.825	0.002	0.011	0.002	0.009	< 0.001	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
[1] covering all corresponding uses in pome/stone fruit and olives

Table CP 10-04-49: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in orchards[1] (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 4 a-c.***

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophytes
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	103.639	0.020	0.086	0.015	0.069	0.005	0.014
Step 2							
N-Europe	35.129	0.007	0.029	0.005	0.023	0.002	0.005
S-Europe	28.289	0.005	0.024	0.004	0.019	0.001	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
[1] covering all corresponding uses in pome/stone fruit and olives

Table CP 10-04-50: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in vines (1 × 720 g a.s./ha). ***Uses 5 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	34.546	0.007	0.029	0.005	0.023	0.002	0.005
Step 2							
N-Europe	15.904	0.003	0.013	0.002	0.011	< 0.001	0.002
S-Europe	12.825	0.002	0.011	0.002	0.009	< 0.001	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-51: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in vines (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 5 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	103.639	0.020	0.086	0.015	0.069	0.005	0.014
Step 2							
N-Europe	35.129	0.007	0.029	0.005	0.023	0.002	0.005
S-Europe	28.289	0.005	0.024	0.004	0.019	0.001	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-52: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (1 × 1440 g a.s./ha). *Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	69.092	0.013	0.058	0.010	0.046	0.004	0.010
Step 2							
N-Europe	31.809	0.006	0.027	0.005	0.021	0.002	0.004
S-Europe	25.650	0.005	0.021	0.004	0.017	0.001	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

[1] covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table CP 10-04-53: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in orchards[1] (1 × 1440 g a.s./ha). *Uses 4 a-c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	69.092	0.013	0.058	0.010	0.046	0.004	0.010
Step 2							
N-Europe	31.809	0.006	0.027	0.005	0.021	0.002	0.004
S-Europe	25.650	0.005	0.021	0.004	0.017	0.001	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

[1] covering all corresponding uses in pome/stone fruit and olives

Table CP 10-04-54: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in orchards[1] (2 × 1440 g a.s./ha, with application interval of 28 days). *Uses 4 a-c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	138.185	0.027	0.115	0.020	0.092	0.007	0.019
Step 2							
N-Europe	53.986	0.010	0.045	0.008	0.036	0.003	0.007
S-Europe	43.514	0.008	0.036	0.006	0.029	0.002	0.006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

[1] covering all corresponding uses in pome/stone fruit and olives

Table CP 10-04-55: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in vines (1 × 1440 g a.s./ha). *Uses 5 a-c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	69.092	0.013	0.058	0.010	0.046	0.004	0.010
Step 2							
N-Europe	31.809	0.006	0.027	0.005	0.021	0.002	0.004
S-Europe	25.650	0.005	0.021	0.004	0.017	0.001	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-56: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in vines (2 × 1440 g a.s./ha, with application interval of 28 days). *Uses 5 a-c.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	138.185	0.027	0.115	0.020	0.092	0.007	0.019
Step 2							
N-Europe	53.986	0.010	0.045	0.008	0.036	0.003	0.007
S-Europe	43.514	0.008	0.036	0.006	0.029	0.002	0.006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-57: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (1 × 540 g a.s./ha). *Uses 3 a-b.*

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	25.910	0.005	0.022	0.004	0.017	0.001	0.004
Step 2							
N-Europe	11.928	0.002	0.010	0.002	0.008	< 0.001	0.002
S-Europe	9.619	0.002	0.008	0.001	0.006	< 0.001	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

[1] covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table CP 10-04-58: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	103.639	0.020	0.086	0.015	0.069	0.005	0.014
Step 2							
N-Europe	40.490	0.008	0.034	0.006	0.027	0.002	0.006
S-Europe	32.636	0.006	0.027	0.005	0.022	0.002	0.005

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

[1] covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table CP 10-04-59: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on HardSPEC calculations for the use of MON 52276 to railways, 1 x 1800 g a.s./ha. ***Uses 7 a-b, 8 and 9.***

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
HardSPEC Scenario	**$PEC_{sw,max}$ (µg/L)**						
Railway ditch leaching	1.956	< 0.001	0.002	< 0.001	0.001	< 0.001	< 0.001
Railway ditch runoff	1.956	< 0.001	0.002	< 0.001	0.001	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-60: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on HardSPEC calculations for the use of MON 52276 to railways, 1 x 3600 g a.s./ha. *Uses 7 a-b.*

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophytes
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
HardSPEC Scenario	**$PEC_{sw,max}$ (µg/L)**						
Railway ditch leaching	3.913	0.001	0.003	0.001	0.003	< 0.001	0.001
Railway ditch runoff	3.913	0.001	0.003	0.001	0.003	< 0.001	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-61: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in grass/alfalfa, (1 × 1800 g a.s./ha). *Uses 7 a-b, 8 and 9.*

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophytes
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50} 520000	NOEC ≥ 12000	EC_{50} 690000	NOEC 15000	E_rC_{50} 191000	E_rC_{50} 72000
AF		100	10	100	10	10	10
RAC (µg/L)		5200	≥ 1200	6900	1500	19100	7200
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**						
Step 1							
	86.366	0.017	0.072	0.013	0.058	0.005	0.012
Step 2							
N-Europe	39.761	0.008	0.033	0.006	0.027	0.002	0.006
S-Europe	32.062	0.006	0.027	0.005	0.021	0.002	0.004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Risk assessment for the metabolite HMPA

Table CP 10-04-62: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (1 × 720 g a.s./ha). *Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.*

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	16.128	0.016	0.001	0.001
Step 2				
N-Europe	7.507	0.008	< 0.001	< 0.001
S-Europe	6.093	0.006	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

[1] covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table CP 10-04-63: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (3 × 720 g a.s./ha, with application interval of 28 days). *Uses 2 a-c.*

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	48.385	0.048	0.004	0.004
Step 2				
N-Europe	13.101	0.013	0.001	0.001
S-Europe	10.668	0.011	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

[1] covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table CP 10-04-64: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in orchards[1] (1 × 720 g a.s./ha). ***Uses 4 a-c.***

Group		Inverteb. acute	Algae	Aquatic macrophytes
Test species		*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	$PEC_{sw,max}$ (µg/L)			
Step 1				
	16.128	0.016	0.001	0.001
Step 2				
N-Europe	7.507	0.008	< 0.001	< 0.001
S-Europe	6.093	0.006	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
[1] covering all corresponding uses in pome/stone fruit and olives

Table CP 10-04-65: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in orchards[1] (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 4 a-c.***

Group		Inverteb. acute	Algae	Aquatic macrophytes
Test species		*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	$PEC_{sw,max}$ (µg/L)			
Step 1				
	48.385	0.048	0.004	0.004
Step 2				
N-Europe	13.101	0.013	0.001	0.001
S-Europe	10.668	0.011	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
[1] covering all corresponding uses in pome/stone fruit and olives

Table CP 10-04-66: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in vines (1 × 720 g a.s./ha). ***Uses 5 a-c.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	16.128	0.016	0.001	0.001
Step 2				
N-Europe	7.507	0.008	< 0.001	< 0.001
S-Europe	6.093	0.006	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-67: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in vines (3 × 720 g a.s./ha, with application interval of 28 days). ***Uses 5 a-c.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	48.385	0.048	0.004	0.004
Step 2				
N-Europe	13.101	0.013	0.001	0.001
S-Europe	10.668	0.011	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-68: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (1 × 1440 g a.s./ha). *Covers uses 1 a-c, 2 a-c, 6 a-c, 10 a-c.*

Group		Inverteb. acute	Algae	Aquatic macrophytes
Test species		*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	$PEC_{sw,max}$ (µg/L)			
Step 1				
	32.256	0.032	0.003	0.003
Step 2				
N-Europe	15.015	0.015	0.001	0.001
S-Europe	12.185	0.012	0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
[1] covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table CP 10-04-69: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in orchards[1] (1 × 1440 g a.s./ha). *Uses 4 a-c.*

Group		Inverteb. acute	Algae	Aquatic macrophytes
Test species		*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Lemna gibba*
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	$PEC_{sw,max}$ (µg/L)			
Step 1				
	32.256	0.032	0.003	0.003
Step 2				
N-Europe	15.015	0.015	0.001	0.001
S-Europe	12.185	0.012	0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
[1] covering all corresponding uses in pome/stone fruit and olives

Table CP 10-04-70: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in orchards[1] (2 × 1440 g a.s./ha, with application interval of 28 days). ***Uses 4 a-c.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	64.513	0.065	0.005	0.005
Step 2				
N-Europe	22.523	0.023	0.002	0.002
S-Europe	18.322	0.018	0.002	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

[1] covering all corresponding uses in pome/stone fruit and olives

Table CP 10-04-71: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in vines (1 × 1440 g a.s./ha). ***Uses 5 a-c.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	32.256	0.032	0.003	0.003
Step 2				
N-Europe	15.015	0.015	0.001	0.001
S-Europe	12.185	0.012	0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-72: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in vines (2 × 1440 g a.s./ha, with application interval of 28 days). ***Uses 5 a-c.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	64.513	0.065	0.005	0.005
Step 2				
N-Europe	22.523	0.023	0.002	0.002
S-Europe	18.322	0.018	0.002	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-73: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (1 × 540 g a.s./ha). ***Uses 3 a-b.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} ≥ 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		≥ 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	12.096	0.012	0.001	< 0.001
Step 2				
N-Europe	5.631	0.006	< 0.001	< 0.001
S-Europe	4.569	0.005	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
[1] covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table CP 10-04-74: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in field crops[1] (2 × 1080 g a.s./ha, with application interval of 28 days). ***Uses 2 a-c.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	48.385	0.048	0.004	0.004
Step 2				
N-Europe	16.892	0.017	0.001	0.001
S-Europe	13.741	0.014	0.001	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
[1] covering all corresponding uses in root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables and sugar beets

Table CP 10-04-75: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on HardSPEC calculations for the use of MON 52276 to railways, 1 x 1800 g a.s./ha. ***Uses 7 a-b, 8 and 9.***

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
HardSPEC Scenario	**$PEC_{sw,max}$ (µg/L)**			
Railway ditch leaching	0.313	< 0.001	< 0.001	< 0.001
Railway ditch runoff	0.313	< 0.001	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-76: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on HardSPEC calculations for the use of MON 52276 to railways, 1 x 3600 g a.s./ha. *Uses 7 a-b.*

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
HardSPEC Scenario	**$PEC_{sw,max}$ (µg/L)**			
Railway ditch leaching	0.627	0.001	< 0.001	< 0.001
Railway ditch runoff	0.627	0.001	< 0.001	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table CP 10-04-77: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MON 52276 in grass/alfalfa, (1 × 1800 g a.s./ha). *Uses 7 a-b, 8 and 9*

Group		**Inverteb. acute**	**Algae**	**Aquatic macrophytes**
Test species		***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		EC_{50} > 100000	E_rC_{50} > 120000	E_rC_{50} > 123000
AF		100	10	10
RAC (µg/L)		> 1000	≥ 12000	> 12300
FOCUS Scenario	**$PEC_{sw,max}$ (µg/L)**			
Step 1				
	40.321	0.040	0.003	0.003
Step 2				
N-Europe	18.768	0.019	0.002	0.002
S-Europe	15.232	0.015	0.001	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Annex M-CP 10-05: Non-target terrestrial plant risk assessment

All uses – all rates covering deterministic and probabilistic assessments are presented below.

Table CP 10-05-1: Deterministic assessment of the risk for non-target plants due to the use of MON 52276. All rates covering all GAP table uses considering downward ground directed spray – PER (g a.e./ha) based on drift rate (%) at 1 m from application area = 2.77 %; MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF	PER [g a.e./ha]	TER (criterion: TER ≥ 5)
Vegetative vigour						
All uses considering downward ground directed spray	1 x 540	28.5	2.77	1	14.96	**1.91**
	1 x 720				19.94	**1.43**
	1 x 1080				29.92	**0.95**
	1 x 1440				39.89	**0.71**
	1 x 1800				49.86	**0.57**
	3 x 720				19.94	**1.43**
	2 x 1080				29.92	**0.95**
	2 x 1440				39.89	**0.71**
	2 x 1800				49.86	**1.91**
Seedling emergence						
All uses considering downward ground directed spray	1 x 540	3610	2.77	1	14.96	241.34
	1 x 720				19.94	181.01
	1 x 1080				29.92	120.67
	1 x 1440				39.89	90.50
	1 x 1800				49.86	72.40
	3 x 720				19.94	181.01
	2 x 1080				29.92	120.67
	2 x 1440				39.89	90.50
	2 x 1800				49.86	72.40

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Table CP 10-05-2: Deterministic assessment of the risk for non-target plants due to the use of MON 52276. All rates covering all GAP table uses considering downward ground directed spray – PER (g a.e./ha) based on drift rate (%) at 5 m from application area = 0.57 %; MAF = 1.00 (considering at least a 28 day interval and a DT50 of 2.8 days)

Crop scenario	Appl. Rate [g a.e./ha]	ER_{50} [g a.e./ha]	Drift [%]	MAF	PER [g a.e./ha]	TER (criterion: TER ≥ 5)
Vegetative vigour						
All uses considering downward ground directed spray	1 x 540	28.5	0.57	1	3.08	9.26
	1 x 720				4.10	6.94
	1 x 1080				6.16	**4.63**
	1 x 1440				8.21	**3.47**
	1 x 1800				10.26	**2.78**
	3 x 720				4.10	6.94
	2 x 1080				6.16	**4.63**
	2 x 1440				8.21	**3.47**
	2 x 1800				10.26	**2.78**

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Table CP 10-05-3: Probabilistic assessment of the risk for non-target plants due to the use of MON 52276. All rates covering all GAP table uses considering downward ground directed spray – PER (g a.e./ha) based on drift rate (%) at 1 m (= 2.77 %) and 5 m (= 0.57 %) from application area; MAF = 1.00 (considering at least a 28 day interval and a DT_{50} of 2.8 days)

Crop/Appl. Rate [g a.s./ha]	HC_5 [g a.s./ha]	Drift [%]	PER [g a.s./ha]	TER (criterion: TER ≥ 1)
Vegetative vigour				
1 x 540	21.6	2.77 % - at 1 m	14.96	1.44
1 x 720			19.94	1.08
1 x 1080			29.92	**0.72**
1 x 1440			39.89	**0.54**
1 x 1800			49.86	**0.43**
3 x 720			19.94	1.08
2 x 1080			29.92	**0.72**
2 x 1440			39.89	**0.54**
2 x 1800			49.86	**0.43**
1 x 540	21.6	0.57 % - at 5 m	3.08	7.02
1 x 720			4.10	5.26
1 x 1080			6.16	3.51
1 x 1440			8.21	2.63
1 x 1800			10.26	2.11
3 x 720			4.10	5.26
2 x 1080			6.16	3.51
2 x 1440			8.21	2.63
2 x 1800			10.26	2.11

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.