CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate[1]

European Food Safety Authority (EFSA)[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA), following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Germany, for the pesticide active substance glyphosate are reported. The context of the peer review was that required by Commission Regulation (EU) No 1141/2010 as amended by Commission Implementing Regulation (EU) No 380/2013. The conclusions were reached on the basis of the evaluation of the representative uses of glyphosate as a herbicide on emerged annual, perennial and biennial weeds in all crops [crops including but not restricted to root and tuber vegetables, bulb vegetables, stem vegetables, field vegetables (fruiting vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses, oil seeds, potatoes, cereals, and sugar- and fodder beet; orchard crops and vine, before planting fruit crops, ornamentals, trees, nursery plants etc.] and foliar spraying for desiccation in cereals and oilseeds (pre-harvest). The reliable endpoints, concluded as being appropriate for use in regulatory risk assessment and derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified. Following a second mandate from the European Commission to consider the findings from the International Agency for Research on Cancer (IARC) regarding the potential carcinogenicity of glyphosate or glyphosate-containing plant protection products in the on-going peer review of the active substance, EFSA concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008.

KEY WORDS

glyphosate, peer review, risk assessment, pesticide, herbicide

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[2] Correspondence: pesticides.peerreview@efsa.europa.eu

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SUMMARY

Commission Regulation (EU) No 1141/2010 (hereinafter referred to as 'the Regulation'), as amended by Commission Implementing Regulation (EU) No 380/2013, lays down the procedure for the renewal of the approval of a second group of active substances and establishes the list of those substances. Glyphosate is one of the active substances listed in the Regulation.

The rapporteur Member State (RMS) provided its initial evaluation of the dossier on glyphosate in the Renewal Assessment Report (RAR), which was received by EFSA on 20 December 2013. The peer review was initiated on 22 January 2014 by dispatching the RAR for consultation of the Member States and the applicants of the European Glyphosate Task Force, represented by Monsanto Europe S.A.

Following consideration of the comments received on the RAR, it was concluded that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology and EFSA should adopt a conclusion on whether glyphosate can be expected to meet the conditions provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and the Council. On 6 August 2014 EFSA received a mandate from the European Commission for the peer review of the active substance glyphosate.

On 30 April 2015 EFSA received another mandate from the European Commission to consider the findings by the International Agency for Research on Cancer (IARC) regarding the potential carcinogenicity of glyphosate or glyphosate-containing plant protection products in the ongoing peer review of the active substance. EFSA accepted the mandate on 19 May 2015 and has included its views in the conclusion of the peer review. After the IARC monograph 112 was published, EFSA asked the European Commission for an extension of the overall deadline to 30 October 2015, which was accepted, to take into account the findings of IARC as regards the potential carcinogenicity in line with the Commission's request.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of glyphosate as a herbicide on emerged annual, perennial and biennial weeds in all crops [crops including but not restricted to root and tuber vegetables, bulb vegetables, stem vegetables, field vegetables (fruiting vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses, oil seeds, potatoes, cereals, and sugar- and fodder beet; orchard crops and vine, before planting fruit crops, ornamentals, trees, nursery plants etc.] and foliar spraying for desiccation in cereals and oilseeds (pre-harvest), as proposed by the applicants. Full details of the representative uses can be found in Appendix A to this report.

A series of data gaps was identified in the section identity concerning additional validation data for the determination of impurities, batch data and updated specifications. Data gaps were also identified for further information on analytical methods of residues in order to get a complete database to enable an evaluation according to EU Guidance Document SANCO/825/00 rev. 8.1.

Data gaps were identified in the mammalian toxicology area to address the relevance of all individual impurities present in the technical specifications (except for the two already identified relevant impurities, formaldehyde and *N*-Nitroso-glyphosate), in particular impurities that elicited toxicological alerts according to quantitative structure-activity relationship (QSAR) assessments and the ones specified at higher level than the reference specification, in comparison with the toxicity profile of the parent compound. Regarding carcinogenicity, the EFSA assessment focused on the pesticide active substance and considered in a weight of evidence all available information. In contrast to the IARC evaluation, the EU peer review experts, with only one exception, concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP Regulation). Glyphosate is not classified or proposed to be classified as carcinogenic or toxic for reproduction category 2 in accordance with the provisions of Regulation

(EC) No 1272/2008 (harmonised classification supported by the present assessment), and therefore, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. To address the potential for endocrine-mediated mode of action, the full battery of Tier I screening assays according to the US Environmental Protection Agency Endocrine Disruptor Screening Program (EDSP), or Level 2 and 3 tests currently indicated in the OECD Conceptual Framework are needed. Toxicological data allowing a consumer risk assessment to be performed for the metabolites *N*-acetyl-glyphosate and *N*-acetyl-AMPA, which are relevant for uses on genetically modified (GM) glyphosate-tolerant plant varieties that are imported into the EU, are missing.

Based on the available information, residue definitions for monitoring and risk assessment were proposed for plant and animal commodities. These residue definitions were proposed considering the metabolism observed in conventional and in glyphosate-tolerant GM plants. Additional residue trials on olives and rapeseed were requested. Based on the representative uses, that were limited to conventional crops only, chronic or acute risks for the consumers have not been identified.

Regarding fate and behaviour in the environment, further information is needed to assess the contamination route through run off (especially in situations where application to hard surfaces might occur) and subsequent surface water contamination and bank infiltration to groundwater. In addition, degradation of the major soil metabolite AMPA needs to be investigated in acidic soils (pH = 5–6).

For the section on ecotoxicology, two data gaps were identified to provide an assessment to address the long-term risk for small herbivorous mammals and for insectivorous birds. For aquatic organisms, the risk was considered low, using the FOCUS step 2 PEC_{sw} values. The risk for bees, non-target arthropods, soil macro- and micro-organisms and biological methods for sewage treatment was considered low. The risk to non-target terrestrial plants was considered low, but only when mitigation measures are implemented.

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BACKGROUND

Commission Regulation (EU) No 1141/2010[3] (hereinafter referred to as 'the Regulation'), as amended by Commission Implementing Regulation (EU) No 380/2013[4] lays down the detailed rules for the procedure of the renewal of the approval of a second group of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and applicants for comments on the initial evaluation in the Renewal Assessment Report (RAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 16 of the Regulation, if mandated, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and the Council within 6 months from the end of the period provided for the submission of written comments, subject to an extension of up to 9 months where additional information is required to be submitted by the applicant(s) in accordance with Article 16(3).

In accordance with Article 9 of the Regulation, Germany (hereinafter referred to as the 'RMS') received an application from the applicants of the European Glyphosate Task Force for the renewal of approval of the active substance glyphosate. Complying with Article 11 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the Commission and the Authority about the admissibility.

The RMS provided its initial evaluation of the dossier on glyphosate in the RAR, which was received by EFSA on 20 December 2013 (Germany, 2013). The peer review was initiated on 22 January 2014 by dispatching the RAR to Member States and the applicants of the European Glyphosate Task Force for consultation and comments. In addition, EFSA conducted a public consultation on the RAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicants were invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicants' response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicants in accordance with Article 16(3) of the Regulation were considered in a telephone conference between EFSA, the RMS, and the European Commission on 5 August 2014. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicant and EFSA should organise an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology. In accordance with Art. 16(2) of the Regulation the European Commission decided to consult EFSA. The mandate was received on 6 August 2014

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation and the additional information to be submitted by the applicants, were compiled by EFSA in the format of an Evaluation Table.

[3] Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances. OJ L 322,8.12.2011, p. 10–19.
[4] Commission Implementing Regulation (EU) No 380/2013 of 25 April 2013 amending Regulation (EU) No 1141/2010 as regards the submission of the supplementary complete dossier to the Authority, the other Member States and the Commission. OJ L 116, 26.4.2013, p.4

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert consultation where this took place, were reported in the final column of the Evaluation Table.

On 30 April 2015 EFSA received another mandate from the European Commission to consider the findings by the International Agency for Research on Cancer (IARC) regarding the potential carcinogenicity of glyphosate or glyphosate containing plant protection products in the on-going peer review of the active substance. EFSA accepted the mandate on 19 May 2015 and included its views in the conclusion of the peer review.

A consultation on the conclusions arising from the peer review of the risk assessment excluding any consideration of the findings of IARC took place with Member States via a written procedure in July 2015. After the IARC monograph 112 was published EFSA asked the European Commission for an extension of the overall deadline to 30 October 2015, which was accepted to take into account the findings of IARC as regards the potential carcinogenicity in line with the Commission's request.

Following the publication of the IARC monograph 112, the RMS prepared an assessment thereof in the format of an addendum (Germany, 2015), which EFSA circulated for comments to all Member States. On the basis of the comments received EFSA organised an expert consultation in the section on mammalian toxicology in particular dedicated to carcinogenicity. The conclusion was updated accordingly and a final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States in October 2015.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a herbicide on emerged annual, perennial and biennial weeds in all crops [crops including but not restricted to root and tuber vegetables, bulb vegetables, stem vegetables, field vegetables (fruiting vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses, oil seeds, potatoes, cereals, and sugar- and fodder beet; orchard crops and vine, before planting fruit crops, ornamentals, trees, nursery plants etc.] and foliar spraying for desiccation in cereals and oilseeds (pre-harvest), as proposed by the applicants. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2015a) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the RAR,
- the Reporting Tables (6 August 2014),
- the Evaluation Table (21 October 2015),
- the report(s) of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on addendum 1 (RMS's assessment of the IARC monograph),
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR including its addendum (compiled version of October 2015 containing all individually submitted addenda (Germany, 2015)) and the Peer Review Report, both documents are considered respectively as background documents to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Glyphosate is the ISO common name for *N*-(phosphonomethyl)glycine (IUPAC).

It should be mentioned that the salts glyphosate-isopropylammonium, glyphosate-potassium, glyphosate-monoammonium, glyphosate-dimethylammonium are the modified ISO common names for isopropylammonium *N*-(phosphonomethyl)glycinate, potassium *N*-[(hydroxyphosphinato) methyl]glycine, ammonium *N*-[(hydroxyphosphinato)methyl]glycine and dimethylammonium *N*-(phosphonomethyl)glycinate (IUPAC), respectively. These salts are derivatives of the active substance glyphosate.

The representative formulated product for the evaluation was 'MON 52276', a soluble concentrate (SL) containing 360 g/L glyphosate as isopropylammonium salt (486 g/L).

The representative uses evaluated are spraying applications against emerged annual, perennial and biennial weeds in all crops [crops including but not restricted to root and tuber vegetables, bulb vegetables, stem vegetables, field vegetables (fruiting vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses, oil seeds, potatoes, cereals, and sugar- and fodder beet; orchard crops and vine, before planting fruit crops, ornamentals, trees, nursery plants etc.] and foliar spraying for desiccation in cereals and oilseeds (pre-harvest). Full details of the GAPs can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), SANCO /10597/2003 rev. 10.1 (European Commission, 2012), and SANCO/825/00 rev. 8.1 (European Commission, 2010).

The proposed minimum purity of the active substance as manufactured by the members of the European Glyphosate Task Force (GTF) comprising 24 applicants varied between 950 g/kg and 983 g/kg. The technical grade active ingredient is manufactured in the majority of cases as a TC but also as a TK. In 21 cases the proposed individual specifications of the technical active substances complied with the composition of the representative batches, in 3 cases they did not. The GTF proposed a common specification covering all sources. The RMS proposed certain changes to the reference specification proposed by the GTF based on toxicological considerations. The proposed minimum purity of the active substance as manufactured was 950 g/kg, meeting the requirements of the FAO specification 284/TC (2014), applicable to the materials of Monsanto, Cheminova, Syngenta and Helm. The RMS compared each individual specification to the new proposed reference specification and concluded that in 17 cases the proposed specification was regarded as equivalent according to the criteria given in Tier I of Guidance Document SANCO/10597/2003 rev 10.1.

N-nitroso-glyphosate and formaldehyde were considered relevant impurities at a maximum content of less than 1 mg/kg and 1 g/kg respectively (see Section 2).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of glyphosate or the representative formulation; however data gaps were identified for:

- an analytical method for formaldehyde with a sufficiently low LOQ and demonstrate that the technical material meets the proposed maximum content (relevant for Brokden S.L.)
- additional data/information regarding the validation of the analytical methods used for the quantification of the significant impurities and justification for the proposed limits of some impurities (relevant for Bro Spolka Jawna B.P. Miranowscy)
- new GLP 5 batch data (relevant for Excel Crop Care Europe NV)

- additional validation data for the determination of one of the impurities (relevant for Helm AG)
- an updated technical specification for the TC and TK based on batch data or QC data supporting the proposed limits for impurities, additional information concerning the methods for impurities and revised evaluation of the precision of one of the methods with respect to one impurity (relevant for Monsanto)
- an updated technical specification and validation data for the determination of the impurities (relevant for Sabero Europe B.V.)
- additional validation data for the determination of one impurity (relevant for Sinon Cooperation)
- additional validation data for the determination of one impurity (relevant for United Phosphorous)

The main data regarding the identity of glyphosate and its physical and chemical properties are given in Appendix A.

Appropriate methods of analysis are available for the determination of the active substance in the technical material and formulations and also for the determination of relevant impurities.

Considering additional analytical methods evaluated by the RMS which were not provided with the dossier of the GTF, residues of glyphosate and *N*-acetyl-glyphosate in food and feed of plant origin can be monitored by HPLC-MS/MS methods with LOQs of 0.05 mg/kg for both compounds in all representative commodity groups, however a data gap was identified for a confirmatory method for *N*-acetyl-glyphosate in dry plant materials and those with high water and high fat content. An HPLC-MS/MS method was available for the determination of residues of glyphosate and *N*-acetyl-glyphosate in all animal matrices with LOQs of 0.025 mg/kg in meat, milk and egg and 0.05 mg/kg in liver, kidney and fat respectively. Data gaps were identified for confirmatory method for glyphosate in animal fat and kidney/liver and a confirmatory method for *N*-acetyl-glyphosate in all animal matrices.

The residue definition for monitoring in soil was defined as glyphosate and AMPA. Compounds of the residue definition in soil can be monitored by GC-MS after derivatisation, with LOQs of 0.05 mg/kg for both compounds. A data gap was identified for a confirmatory method for glyphosate and AMPA in soil. An appropriate HPLC-MS/MS method is available for monitoring residues of glyphosate and AMPA in ground water and surface water with LOQs of 0.03 µg/l for both substances. Residues of glyphosate in air can be monitored by GC-MS with a LOQ of 5 µg/m^3.

The active substance is not classified as toxic according to Regulation (EC) No 1272/2008[5] (CLP Regulation), therefore a method of analysis is not required for body fluids and tissues.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 rev. 10 – final (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004) and SANCO/10597/2003 – rev. 10.1 (European Commission, 2012) and Guidance on Dermal Absorption (EFSA PPR Panel, 2012).

Glyphosate was discussed at the Pesticides Peer Review Experts' Meeting 125 in February 2015 and the carcinogenic potential of glyphosate was re-discussed at the Pesticides Peer Review Teleconference 117 in September 2015 after the publication of the Monograph 112 by the International Agency for Research on Cancer (IARC, 2015).

[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008 p.1–1355.

The new proposed reference specification as proposed by the RMS (Germany, 2015) is supported by the toxicological studies; however eight out of the 24 applicants presented specifications that were not supported by the toxicological assessment (Industrias Afrasa S.A., Arysta Lifescience SAS, Bros Spolka Jawna B.P. Miranowscy, Dow AgroScience S.r.l, three out of seven sources of Helm AG, Monsanto Europe, Société Financière de Pontarlier and one of the two Syngenta Limited manufacturing routes) which is a critical area of concern for the respective applicants/sources. In some cases, the applicants have to comply with the respective revised technical specification as proposed by the RMS to conclude on their equivalence to the new reference specification.

Two relevant impurities were identified, formaldehyde due to its harmonised classification in accordance with the provisions of Regulation (EC) No 1272/2008 (CLP Regulation) as Toxic, Carc 1B and Muta 2 and *N*-nitro-glyphosate (belonging to a group of impurities of particular concern as they can be activated to genotoxic carcinogens); at the specified levels these impurities are not of concern. The relevance of other impurities should be further assessed, in particular impurities that elicited toxicological alerts according to QSAR assessments and the ones specified at a higher level than in the reference specification; this was identified as a data gap.

The glyphosate dossier consists of an exceptionally large database, therefore the toxicological evaluation adopted by the RMS and agreed during the peer review rely on a magnitude of valid studies rather than on one 'key study' for each endpoint. Glyphosate is rapidly but incompletely absorbed after oral administration (around 20 % of the administered dose based on urinary excretion after 48 hours and comparison of kinetic behaviour after oral and iv administrations), being mostly eliminated unchanged via faeces. Absorbed glyphosate is poorly metabolised, widely distributed in the body, does not undergo enterohepatic circulation and is rapidly eliminated; showing no potential for bioaccumulation. Low **acute toxicity** was observed when glyphosate (as glyphosate acid or salts) was administered by the oral, dermal or inhalation routes; no skin irritation or potential for skin sensitisation were attributed to the active substance. Glyphosate acid was found to be severely irritant to the eyes (harmonised classification in Annex VI of CLP Regulation[6] as Eye Dam. 1, H318, 'Causes serious eye damage'), while salts of glyphosate do not need classification regarding eye irritation. The main target organs of glyphosate are the gastro-intestinal tract, salivary glands, liver and urinary bladder in rodents; furthermore, upon chronic exposure, rats developed cataracts. An overall **long term NOAEL** of 100 mg/kg bw per day was obtained considering a number of long term studies in rats. Dogs presented reduced body weight gain, gastrointestinal signs and liver toxicity upon short term exposure to glyphosate and a number of severe findings in one of the six studies investigating high doses of glyphosate (around 1000 mg/kg bw per day). Glyphosate did not present **genotoxic** potential and no evidence of **carcinogenicity** was observed in rats or mice. Out of five mice studies considered, one study with Swiss albino mice showed a statistically significant increased incidence of malignant lymphomas at the top dose of 1460 mg/kg bw per day. This study was discussed at length during the first Pesticides Peer Review Experts' Meeting (PPR 125). Although observed above the (limited) historical control data of this study, the increased incidence of malignant lymphomas occurred at a dose level exceeding the limit dose of 1000 mg/kg bw per day recommended for the oral route of exposure in chronic toxicity and carcinogenicity studies (OECD, 2012a) and was not reproduced in four other valid long term studies in mice. The large majority of the experts had considered it highly unlikely that glyphosate would present carcinogenic potential due to the generally recognised high background incidence of malignant lymphomas in this strain (confirmed by a post-meeting literature search made by the RMS that nevertheless did not include valid historical control data) and the high dose at which it occurred. The study was re-considered during the second experts' teleconference (TC 117) as not acceptable due to viral infections that could influence survival as well as tumour incidence – especially lymphomas.

[6] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1–1355.

After the PPR 125 expert meeting took place, the IARC released a summary of its evaluation in an article published by the Lancet (Guyton et al, 2015), classifying glyphosate as 'probably carcinogenic to humans' (group 2A). More detailed information is available in the IARC monograph 112 (IARC, 2015), which was published in July 2015. In order to address the European Commission mandate, EFSA asked the RMS to evaluate the IARC monograph 112, prepare an addendum (Germany, 2015) on the carcinogenicity potential addressing the IARC assessment to be examined in the peer review and support the discussion during the teleconference 117 with Member States experts and observers from international agencies including IARC.

There are several reasons explaining the diverging views between the different groups of experts. On one hand, the IARC did not only assess glyphosate but also glyphosate-based formulations, while the EU peer review is focused on the pure active substance; the peer review recognised that the issue of toxicity of the formulations should be considered further as some published genotoxicity studies (not according to GLP or to OECD guidelines) on formulations presented positive results *in vitro* and *in vivo*. In particular, it was considered that the genotoxic potential of formulations should be addressed; furthermore EFSA noted that other endpoints should be clarified, such as long-term toxicity and carcinogenicity, reproductive/developmental toxicity and endocrine disrupting potential of formulations (EFSA, 2015b). The assessment of the few epidemiological studies included in the IARC monograph, which were not reported in the original RAR (three out of ten cohort studies, six out of 19 case-control studies) was presented in the addendum of August 2015 to the RAR (Germany, 2015). With regard to the studies on experimental animals, three of the five mice studies used by the EU peer review and three of the nine studies in rats were not assessed by IARC. Importantly, there is a different interpretation of the statistical analysis used to assess the carcinogenic findings in the animal studies and on the use of historical control data; the EU peer review considered relevant historical control data from the performing laboratory. Additionally, referring to the unusually large data base available, it was considered appropriate by the EU peer review to adopt consistently a weight of evidence approach.

From the wealth of epidemiological studies, the majority of experts concluded that there is very limited evidence for an association between glyphosate-based formulations and non-Hodgkin lymphoma, overall inconclusive for a causal or clear associative relationship between glyphosate and cancer in human studies. Minority views nevertheless were expressed that there was either inadequate or limited evidence of an association. No evidence of carcinogenicity was confirmed by the large majority of the experts (with the exception of one minority view) in either rats or mice due to a lack of statistical significance in pair-wise comparison tests, lack of consistency in multiple animal studies and slightly increased incidences only at dose levels at or above the limit dose/MTD, lack of pre-neoplastic lesions and/or being within historical control range. The statistical significance found in trend analysis (but not in pair-wise comparison) *per se* was balanced against the former considerations. During the teleconference 117, the experts also agreed to the conclusion of the RMS, that for the active substance glyphosate no classification for mutagenicity is warranted. However, there were two minority views, that a Comet assay should be requested for confirmation.

In contrast to the IARC evaluation, the EU peer review experts, with only one exception, concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to the CLP Regulation.[7]

Reproductive and fertility parameters were not affected by glyphosate administration although a decrease in homogenisation on resistant spermatids (*cauda epididymis*) was observed in the parental generation (F_0) at the high dose level of 1000 mg/kg bw per day, not reproduced in the following generations, and a delay in preputial separation was seen at the same dose level in males of the filial generation F_1. Concomitant parental toxicity was observed at this dose level consisting of reduced

[7] It should be noted that the harmonised classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals for harmonised classification.

body weight gain, gastrointestinal signs and organ weight changes. Developmental effects (delayed ossification, increased incidence of skeletal anomalies) were observed in rats in the presence of maternal toxicity. Pregnant rabbits were found to be particularly vulnerable to glyphosate administration and developmental effects were linked to severe maternal toxicity, including maternal deaths. The occurrence of developmental anomalies (cardiac malformations) in one rabbit study was discussed by the experts. As the finding was associated with severe maternal toxicity and was not reproduced in the three newly submitted studies, the majority of the experts agreed that classification regarding developmental toxicity would not be required. The relevant overall maternal and developmental NOAEL were 50 mg/kg bw per day considering all developmental toxicity studies in rabbits.

Glyphosate is not classified or proposed to be classified as carcinogenic or toxic for the reproduction category 2 in accordance with the provisions of Regulation (EC) No 1272/2008 (harmonised classification supported by the present assessment), and therefore, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. Apical studies did not show adverse effects on the reproduction, however signs of endocrine activity, even if appearing at parental toxic doses, could not be completely ruled out regarding delay in preputial separation in F_1 males and decrease in homogenisation resistant spermatids (*cauda epididymis*) observed in the most recent multi-generation study. Glyphosate was selected by the US EPA Endocrine Disruptor Screening Program's (EDSP) to undergo a full battery of Tier I screening assays for evaluation of glyphosate's potential to interact with the oestrogen, androgen and thyroid endocrine pathways. The RMS mentions that the first published data revealed no effects on the androgenic and oestrogenic pathways (from the Hershberger and Uterotrophic assays), that glyphosate did not show evidence of endocrine disruption in male and female pubertal assays and no impact on steroidogenesis was observed in the *in vitro* assays. However these studies were not submitted for the renewal procedure and a data gap has been identified for the full battery of Tier I screening assays on the hazard assessment of endocrine disruptors in accordance with the EDSP, or the Level 2 and 3 tests currently indicated in the OECD Conceptual Framework (OECD, 2012b), and analysed in the EFSA Scientific Opinion (EFSA SC, 2013). Although the experts agreed that there is no evidence for endocrine-mediated effects for glyphosate, a firm conclusion cannot be reached now and a data gap was proposed. No potential for neurotoxicity or immunotoxicity was detected in glyphosate-administered rats.

Single and repeated administration of glyphosate in goats and cattle at high dose levels (1000 mg/kg bw) demonstrated that systemic intoxication in these animals was mainly characterised by gastrointestinal and neurological signs; the kidneys and GIT (mucosal irritation) were identified as target organs in ruminants by histopathological examination. Although these animals may be more sensitive than monogastric animals, urinary levels of glyphosate reported from farm animals, converted to the respective systemic dose levels, were estimated to remain well below the NOAEL for these animals in toxicological studies (with a margin of *ca.* 1:4200). A postulated adverse effect of glyphosate on quantitative composition of ruminal microflora or ruminal metabolism in ruminants could not be substantiated by means of the 'Rumen Simulation Technique', in particular, there was no evidence of *Clostridium botulinum* overgrowth. The gastro-intestinal signs that were observed after administration of high doses of glyphosate in mammals (laboratory and farm animals) were considered to be most likely due to the well-established irritating properties of glyphosate acid and could not be ascribed to alterations of the intestinal microflora.

A number of toxicological studies are available on the metabolite **AMPA** relevant to the environmental and plant/livestock residue assessments, but only found at trace levels in the rat metabolism studies. Overall it was concluded that AMPA presents a similar toxicological profile to glyphosate and the reference values of the latter apply to its metabolite AMPA. No toxicological data were provided on ***N*-acetyl-glyphosate** (NAG) and ***N*-acetyl-AMPA** which were identified as relevant compounds in plant/livestock residues where glyphosate tolerant genetically modified (GM) plant varieties are eaten by humans or farm animals. The need for information on this was identified as a data gap.

The acceptable daily intake (**ADI**) of glyphosate is 0.5 mg/kg bw per day, based on the maternal and developmental NOAEL of 50 mg/kg bw per day from the developmental toxicity study in rabbits and applying a standard uncertainty factor (UF) of 100. The previous EU evaluation had set an ADI of 0.3 mg/kg bw per day based on the four long term toxicity studies in rats that were available at that time. In line with the former regulatory practice, NOELs instead of NOAELs were used. An overall NOEL of 30 mg/kg bw per day was established. One of these studies has been found to no longer meet the current testing guideline criteria due to the low doses tested (the NOEL is the highest dose tested in this study) and in the current evaluation, an overall long term NOAEL of 100 mg/kg bw per day is based on six valid combined long term toxicity/carcinogenicity studies in rats.

The acute reference dose (**ARfD**) is 0.5 mg/kg bw, based on the same NOAEL of 50 mg/kg bw per day as the ADI (from the developmental toxicity in rabbits) due to the occurrence of severe toxicity including mortality observed in pregnant does and the increased incidences of post-implantation losses observed in two of the seven developmental toxicity studies in rabbits, applying an UF of 100. An ARfD had not been allocated in the previous EU evaluation.

The acceptable operator exposure level (**AOEL**) is 0.1 mg/kg bw per day on the same basis as the ADI and ARfD, applying a correction factor to account for the limited oral absorption of 20%. The previous EU evaluation had set an AOEL of 0.2 mg/kg bw per day based on a maternal NOEL (assumed to be a NOAEL) of 75 mg/kg bw per day from a rabbit developmental study, with an UF of 100 and 30% oral absorption.

Dermal absorption of the representative formulation 'MON 52276' (SL formulation containing 360 g glyphosate/L), was conservatively set at 1% for the concentrate and in-use spray dilutions to account for uncertainties and limitations identified in the *in vitro* dermal absorption study through human skin. Personal protective equipment (PPE) such as gloves during mixing and loading operations have to be considered to ensure that operator exposure does not exceed the AOEL according to the German model for hand-held applications, while estimated operator exposure was below the AOEL for tractor-mounted applications even when PPE is not worn. Worker exposure without PPE, bystander and residential exposure were estimated to be below the AOEL.

Human biomonitoring of urine samples from several publications did not give indications of health concern as the highest urine concentration value, converted for a systemic dose, was estimated to represent at most 8.4% of the AOEL, with the mean value of samples representing *ca.* 0.1% of the AOEL; generally lower values were obtained from urine samples assumed to result from dietary intake of glyphosate, representing 0.1-0.66 % of the ADI. Similarly, when AMPA was biomonitored, its maximum levels were estimated to remain below 0.1 % of the ADI however no direct correlation between glyphosate and AMPA could be established, indicating that AMPA's presence in urine may originate from other sources than from the metabolism of glyphosate in plants.

3. Residues

The assessment in the residue section is based on the guidance documents listed in the guideline 1607/VI/97 rev.2 and the guideline on extrapolation SANCO 7525/VI/95 rev. 9 (European Commission, 1999, 2011), the recommendations on livestock burden calculations stated in the JMPR reports (JMPR, 2004, 2007) and the OECD publication on MRL calculations (OECD, 2011).

Glyphosate was discussed at the Pesticides Peer Review Experts' Meeting 127 on residues in March 2015.

The metabolism of glyphosate in primary crops was investigated in numerous crop groups, including genetically modified plants containing the CP4-EPSPS,[8] GOX[9] or GAT[10] modifications.

In non-tolerant plants, metabolism was studied in the fruit, root, pulses/oilseeds, cereal and miscellaneous crop groups, using either soil, foliar, hydroponic or trunk application of ^{14}C-glyphosate and in some experiments, with ^{14}C-AMPA. Following soil application, the uptake of glyphosate was very low and amounted to mostly less than 1% of the applied radioactivity (AR) in plant matrices. Limited translocation was also observed after local foliar application, most of the applied radioactivity (80%) remaining in the treated parts of the plants. Hydroponic studies were therefore the key studies to identify the metabolic pattern of glyphosate in conventional plants. Globally without soil present as substrate, less than 5% AR was recovered in the aerial parts, up to 20% AR in the roots. No significant degradation was observed and unchanged glyphosate was observed as the major component of the residues in most of the samples (*ca.* 50% to 80% TRR) with low amounts of AMPA (4% to 10% TRR) and N-methyl-AMPA (0.3 to 5% TRR in root samples).

In genetically modified plants, the metabolic pattern of glyphosate is driven by the modifications introduced into the genome of the plant.

- In the metabolism studies conducted on GM soya bean, cotton and sugar beet containing the **CP4-EPSPS** modification, parent glyphosate was detected as the major component of the residues, accounting for 24% to 95% TRR in forage, hay, tops and roots and for 12% to 25% TRR in seeds. AMPA was present at much lower amounts (mostly 1% to 13% TRR) up to 49% TRR in soya bean seeds. Overall, the metabolic pattern was similar to that observed in conventional plants as the CP4-EPSPS modification does not affect the metabolism of glyphosate in genetically modified plants.
- The metabolism resulting from the introduction of the **GOX** modification was investigated in rape seed and maize in combination with the CP4-EPSPS modification. Following two foliar applications, glyphosate was observed in maize forage, silage and fodder (67% to 83% TRR), but almost not detected in seeds at harvest (7% TRR), where the main component of the residues was identified as AMPA, representing up to 8% TRR in rape seeds and 60% TRR in maize seeds.
- The impact of the **GAT** modification was investigated in three metabolism studies conducted on genetically modified rapeseed, soya bean and maize, following one pre-emergence application and three post emergence treatments, up to 7 or 14 days before harvest. Parent glyphosate was detected in the soya bean and maize forage and foliage (9% to 75% TRR) and in rape seeds (21%), but was almost absent in soya bean and maize seeds at harvest (0.1% to 3% TRR). In all plant matrices, the main component of the radioactive residues was identified as the *N*-acetyl-glyphosate metabolite formed by the action of the GAT enzyme, and accounting for 51% to 57% of the TRR in seeds and 18% to 93% TRR in the other plant parts. In addition *N*-acetyl-AMPA was also identified as a major metabolite in rape and soya bean seeds, representing 15 to 24% TRR.

Cultivation of glyphosate tolerant GM crops is not authorised in most of the EU member states, but since an import of glyphosate tolerant commodities is possible, the two following residue definitions were proposed for monitoring:

[8] CP4-EPSPS: In conventional plants, glyphosate inhibits the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein, a key enzyme in the biosynthesis of aromatic amino acids (e.g. tyrosine, phenylalanine…), leading to plant death. Tolerance to glyphosate is obtained by the introduction of a gene from *Rhizobium radiobacter* that codes for the expression of a modified EPSPS protein, insensitive towards glyphosate inhibition.

[9] GOX: Glyphosate oxidoreductase, protein obtained by the introduction of a gene from *Ochrobactrum anthrop* acting by breaking down glyphosate to AMPA and glyoxylate which have no herbicidal activity.

[10] GAT: Glyphosate N-acetyltransferase, protein obtained by the introduction of a gene from *Bacillus licheniformis*, giving rise to N-acetyl glyphosate which denotes no herbicidal activity.

- '*sum glyphosate and N-acetyl glyphosate expressed as glyphosate*' for plants with glyphosate tolerant GM varieties available on the market (mostly maize, oilseed rape and soya bean) and considering that glyphosate alone is not an appropriate maker for some GAT-modified plants,
- '*glyphosate*', for the other plant commodities.

For risk assessment the residue definition was proposed as:

- '*sum glyphosate, N-acetyl glyphosate, AMPA and N-acetyl-AMPA expressed as glyphosate*' and considering that the N-acetyl glyphosate and N-acetyl-AMPA metabolites are relevant for the GM crops containing the GAT modification.

In the framework of the renewal, representative uses were proposed for conventional crops only and residue trials on glyphosate tolerant GM crops were not provided. A very large number of residue trials were submitted where samples were almost all analysed for glyphosate and AMPA. AMPA residues were all below the LOQ values, except in the trials related to the pre-harvest uses on cereals and oilseeds. Since in conventional plants, the metabolism studies have shown AMPA to be present in very low amounts compared to glyphosate residues, it was agreed for risk assessment to consider the glyphosate LOQ value only, and not the sum of the glyphosate and AMPA LOQs as usually requested. Considering the low contribution of AMPA to the overall consumer intakes, conversion factors for risk assessment were not proposed for plant commodities from conventional crops. MRLs were derived for a large number of crops and extrapolated to all crop groups, having regard to the no-residues situations generally observed. Data gaps were identified for the clarification of the GAP and for additional residue trials for olives (oil production) and further trials on rape seed conducted according to the proposed GAPs were required.

The residue data were supported by storage stability studies showing that glyphosate and AMPA residues are stable for at least 2 years to more than 3 years in the different matrix types. *N*-acetyl-glyphosate was stable for at least 1 year in high acid, high water and dry/starch matrices and *N*-acetyl-AMPA is stable for at least 1 year in high water and dry/starch matrices and 1 month in high oil matrices. Glyphosate and N-acetyl-glyphosate were stable under standard hydrolysis conditions. Processing studies were submitted and processing factors were proposed for several crop commodities. Significant residues of glyphosate or AMPA are not expected in rotational crops.

Several livestock metabolism studies on goat and hen using ^{14}C-glyphosate and ^{14}C-AMPA labelled on the phosphonomethyl-moiety and conducted with glyphosate, glyphosate trimesium or a 9/1 glyphosate/AMPA mixture were submitted. Parent glyphosate was identified as the major component of the radioactive residues, accounting for 21% to 99% TRR in all animal matrices and AMPA was detected in significant proportions in liver (up to 36% TRR), muscle and fat (up to 19% TRR) and egg yolk (14% TRR). In addition, metabolism studies on goat and hen using ^{14}C-N-acetyl-glyphosate were provided. In these studies, N-acetyl-glyphosate was identified as the major component of the radioactive residues, accounting for 17% to 77% TRR. Degradation to N-acetyl-AMPA was observed in fat (10% to 15% TRR), to glyphosate in liver (15% TRR), poultry fat (37% TRR) and egg white (11% TRR) and to AMPA in poultry muscle and fat (11% to 17% TRR). Based on these studies and considering that it cannot be excluded that livestock are exposed to feed items from genetically GAT-modified crops imported from third countries, the residue definition for monitoring was proposed as '*sum of glyphosate and N-acetyl-glyphosate expressed as glyphosate*' for monitoring and as '*sum of glyphosate, N-acetyl glyphosate, AMPA and N-acetyl-AMPA expressed as glyphosate*' for risk assessment. Feeding studies conducted on dairy cows and laying hens fed with either glyphosate, glyphosate trimesium or a 9/1 glyphosate/AMPA mixture were submitted. A feeding study on pig using the glyphosate/AMPA mixture was also provided. Based on these studies and the estimated residue intakes by livestock, MRLs were proposed for animal matrices. However, it should be highlighted that these proposals are based on the representative uses limited to conventional crops only. Calculated intakes by livestock and therefore MRL proposals might be significantly changed if the nature and levels of residues present in feed commodities from glyphosate tolerant GM crops are taken into account.

The consumer risk assessment was performed using the EFSA PRIMo model and the STMR and HR values derived for plant and animal commodities. Based on the available data limited to only the uses on conventional crops, a risk for the consumer was not identified. The maximum chronic intake was calculated to be 3% of the ADI (IE, adult) and the highest acute intake 9% of the ARfD for barley (NL, adult).

4. Environmental fate and behaviour

Glyphosate was discussed in the Pesticides Peer Review Meeting 126 in February 2015.

The route of degradation in soil of glyphosate under aerobic conditions was investigated in two reliable experiments presented in the draft assessment report (DAR, Germany, 1998). Two other experiments were provided for information only on the rate of degradation of glyphosate. Additionally, two studies on the route of degradation of glyphosate-trimesium were submitted during the first EU review of glyphosate. The RMS re-evaluated the previously submitted studies and considered that the arguments presented in the DAR (Germany, 1998) for the non-acceptability of the study Kesterson & Atkins (1991, BVL no 1932061)/ Honegger (1992, BVL no 2325652) (Germany 2013) are no longer consistent with current evaluation practice. Therefore, these studies have now been considered acceptable regarding the results of the incubation of glyphosate in the silt loam soil Dupo. The Glyphosate Task Force (GTF) submitted a new soil metabolism study for the renewal process. Additionally four route of degradation studies under aerobic conditions in soil were available in the renewal dossier from the GTF. These studies were not considered during the first review of glyphosate. Results of an additional rate of degradation study submitted in the renewal dossier are also considered to provide route of degradation information. Therefore, the peer review considered that up to 12 experiments for aerobic degradation in soil at 20ºC were acceptable to characterise the route and rate of degradation of glyphosate. Three additional experiments were considered to provide only information on persistence or rate of degradation. From these twelve experiments, it is observed that glyphosate exhibits low to very high persistence in soil. The principal soil metabolite was aminomethylphosphonic acid (AMPA). The maximum amount of AMPA detected ranged from 13.3 to 50.1% AR. This metabolite exhibits moderate to high persistence in the nine laboratory experiments in which a reliable half-life was determined.

Glyphosate comprises of one alkaline amino functional group and three ionisable acidic sites; therefore, it is present, as multiple chemical species, at most pH values, although the di-anion predominates at the typical environmental pH range of 5-9. Furthermore, the molecule exists as a zwitterion at pH values < 10 due to protonation of the amino nitrogen. A moderate positive correlation between the pH of the soil and the mineralisation has been observed in the available studies (max. CO_2 23.6 % AR [pH 6.5] – 79.6 % AR [pH 7.5]). However, no robust correlation has been observed between pH of the soil and glyphosate half-lives (SFO DT_{50}). For AMPA the RMS proposed to exclude one soil due to the loss of microbial viability after 120 d. With this exclusion, the range of pH values in the soils tested with AMPA was 6.5–7.5 and a conclusion on the effect of the pH of soil on the degradation rate could not be reached. Reliable experiments on the pH range 5-6 were not available for AMPA, neither within the laboratory studies nor within the field dissipation studies. This range of pH values needs to be covered by experimental data according to the data requirements. Therefore, a data gap has been identified to investigate the degradation rate of the major metabolite AMPA in soils having pHs in the acidic range.

Degradation of glyphosate in soil under anaerobic conditions was investigated in three soils. Glyphosate exhibits high to very high persistence under these conditions ($DT_{50\ anaerobic}$ = 135 - > 1000 d). The same major metabolite AMPA, as identified under aerobic conditions, was also formed under anaerobic conditions.

Photolysis of glyphosate at the soil surface was investigated in four experiments with simulated and natural sun light at 20 ºC (three experiments submitted for the first authorisation and one experiment submitted for the renewal procedure). In these studies, irradiation does not significantly enhance degradation of glyphosate in soil. The main metabolite identified in the irradiated and dark samples was AMPA.

Field dissipation studies were available for glyphosate (eight sites) and the major metabolite AMPA (five sites). AMPA exhibited higher persistence in the field dissipation studies than in the laboratory aerobic degradation experiments. AMPA was also captured as being formed at a comparable (but numerically higher) proportion of the precursor glyphosate (53.8 % on a molar basis) to that which was observed in the available laboratory soil incubations.

Predicted environmental concentrations (PEC) soil values were calculated for the parent glyphosate and the metabolite AMPA for the representative uses in annual and permanent crops based on standard calculation approaches, the worst case field degradation pattern and the maximum application rate proposed for the representative uses. Plateau PEC soil values for glyphosate and the metabolite AMPA were calculated to be reached after 10 years of continuous application of glyphosate.

Batch soil adsorption / desorption studies were performed with glyphosate (24 soils were tested, 20 reliable experiments were identified and used to derive mean end points) and the metabolite AMPA (17 soils were tested, 16 reliable experiments were identified and used to derive mean end points). According to these studies glyphosate and AMPA may be considered to exhibit low mobility or be immobile in soil. Four column leaching studies in a total of 16 soils are available (three performed applying glyphosate trimesium salt). In addition, two aged (8 days and 30 days) column leaching studies in sandy soils were also available. These column leaching studies are considered to provide supplementary information on the leaching behaviour of glyphosate and its metabolite AMPA. No lysimeter studies have been submitted in the original and the supplementary EU dossiers.

Glyphosate is stable to hydrolysis in the range of environmentally relevant pH (pH 5–9) at 25 ºC and 40 ºC. Aqueous photolysis of glyphosate and glyphosate trimesium were investigated in buffered aqueous solutions (pH 5, pH 7 and pH 9 for glyphosate and pH 7 for the trimesium variant) under simulated sunlight. Aqueous photolysis could contribute to a limited extent to the degradation of glyphosate in aqueous environments. Glyphosate is not readily biodegradable according the available studies (OECD 301 F and OECD 302B; OECD 1992a and OECD 1992b). Degradation and dissipation of glyphosate in the aquatic environment under aerobic conditions was investigated in eight water/sediment systems. Glyphosate partitioned in the sediment to a substantial extent (max 61.4 % AR after 14 d). The persistence of glyphosate in these systems was relatively variable going from moderate to high persistence ($DT_{50\ \text{whole system (SFO)}}$ = 13.82 d to > 301 d). Two major metabolites were found in the water phase: AMPA (max. 15.7 % AR after 14 d) and HMPA (max. 10.0 % AR after 61 d). Only the metabolite AMPA exceeded 10 % AR in the sediment (max. 18.7 % AR after 58 d). Mineralisation ranged from 5.9 % AR to 47.9 % AR at the end of the studies. Un-extractable residue in the sediment increased to up to 49 % AR after 120 d, at study end. PEC_{SW} values were calculated up to step 3[11] for glyphosate and up to Step 2 for the major metabolites AMPA and HMPA with FOCUS SW tools using the FOCUS (2001) approach.

The potential for ground water exposure was assessed calculating the 80th percentile of 20 years annual average concentrations of glyphosate and AMPA at 1 m depth with FOCUS GW PELMO 4.4.3 model[12] for the representative uses in winter and spring cereals, potatoes and apples (FOCUS, 2009). The parametric drinking water limit of 0.1 µg/L was not exceeded by the parent or the metabolite AMPA for any of the uses and relevant scenarios. Simulations with a second model would be needed according to the EFSA PPR panel opinion (EFSA PPR, 2013). However, taking into account the low

[11] At Step 3, simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

[12] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

levels calculated in the available simulations (all < 0.001 µg/L) it was considered very unlikely that calculations with a second model would result in an exceedance of the parametric drinking water limit of 0.1 µg/L.

The applicant submitted several studies on groundwater monitoring. Glyphosate and AMPA have been detected in Europe above the parametric limit of 0.1 µg/L in a number of instances. Detailed groundwater monitoring studies demonstrating that glyphosate exceeded the limit of 0.1 µg/l were available from Italy, Germany, the Netherlands, Sweden, France and Spain. In some cases, the authors presented some clarifications of possible causes for glyphosate findings in groundwater aquifers at levels greater than 0.1µg/L. These were that they were not directly related to representative uses and other authorised good agricultural practices. However, it often remains unclear which findings above the parametric limit originate from an authorised use in agricultural areas and which from misuses. In considering these findings, it should be also taken into account that there are other sources of glyphosate than agricultural applications, e.g. the control of weeds in streams and drains, on railways, roads, sports fields and industrial areas. Nevertheless, due to the specific ionic characteristics of glyphosate and AMPA the chromatographic leaching mechanisms and routes simulated by FOCUS GW may not be the most relevant ones to assess the potential for groundwater contamination of these compounds. In particular, further information is needed to assess the contamination route through run off (especially in situations where application to hard surfaces might occur) and subsequent surface water contamination and bank infiltration to groundwater. This route was considered relevant for the representative uses on ‘all seeded or transplanted crops’ and ‘all seeded crops’ as horticultural practices can mean that containers or seed trays can be placed on hard surfaces. Therefore a data gap has been identified during the peer review (see section 7).

The criteria for active substances laid down in Art 4.3 (b) of Regulation No 1107/2009 have been appropriately addressed with respect to situations when water, potentially containing residues of glyphosate and AMPA, is abstracted for drinking water and treated by chlorination procedures.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b, 2002c), SETAC (2001), and EFSA (2009).

The new proposed reference specification as proposed by the RMS (Germany, 2015) is not supported by the specifications of all applicants. Therefore a critical area of concern was identified.

Some aspects of the risk assessment of glyphosate were discussed at the Pesticides Peer Review Meeting 128 (3–5 March 2015). The RMS raised concerns regarding the indirect effects (biodiversity) on non-target organisms via trophic interaction of extensively used herbicides such as glyphosate. At the meeting there was also an exchange of views on this issue. The experts considered this as an important risk management issue.

For the risk assessment to **birds and mammals**, it is acknowledged that no specific scenarios are available in the Guidance Document on Risk Assessment for Birds and Mammals (EFSA, 2009) for the spraying applications against emerged annual, perennial and biennial weeds for the representative use ‘all crops pre-planting and post planting’. The RMS used, as surrogate, the worst case scenarios related to the early stage of several crops for the representative uses ‘all crops’ (pre and post-planting). Although it is not clearly indicated in the guidance document (EFSA, 2009), likely the most suitable scenarios might have been those related to ‘not crop directed applications’, which were specifically developed for herbicides applied in orchards. However, the RMS’s approach covered both the latter scenarios and other more conservative ones. Therefore the RMS’s approach was considered acceptable.

It is noted that for all the representative uses, the maximum cumulative application rate per year was reported to be 4.32 kg a.s./ha. For the representative uses in orchards, the RMS considered a

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combination of possible use patterns, which included worst case situations. Furthermore, since the applications are made intra-row, it was assumed that the actual application rates per hectare of cropped areas were 50% of the rates per hectare of treated areas (i.e. 2.16 kg a.s. /ha of cropped areas).

The acute risk to **birds** via dietary exposure was assessed as low with the screening level for all the representative uses. The first tier long-term risk to birds was indicated as high for some of the scenarios for the representative uses 'all crops,' pre-planting (in particular for herbivorous birds) and for 'cereals, pre-harvest application' (in particular, for insectivorous birds), while the risk was low for the uses in 'all crops'(post-planting, oilseeds and orchards).

The acute risk to mammals was assessed as low at the first tier level for all the representative uses, except for the worst-case scenario 'small herbivorous mammals (e.g. common vole, *Microtus arvalis*)' for the uses in 'all crops' (pre-planting). No further risk assessment refinement was available for this scenario. The first tier long-term risk to mammals was indicated as high for all the representative uses.

The residue decline of glyphosate in grass was considered to refine the time weight average factor (f_{twa}) and the Multiple Application Factor (MAF) for herbivorous birds and mammals and for omnivorous mammals. Based on this refinement the long-term risk to herbivorous birds was indicated as low. The long-term risk to mammals was indicated as high for the representative uses 'all crops' pre-planting' and 'all crops' post-planting, in particular, to herbivorous mammals; the long-term risk to small herbivorous mammals was indicated high for the representative uses in orchards based on the application pattern of 1×2880 g a.s/ha reduced by 50% (see above). A low long-term risk to small herbivorous mammals was demonstrated for orchards only when the substance is applied 3 × max. 1440 g a.s./ha of treated area (i.e. 3 × max. 720 g a.s./ha of cropped area, which means half of the annual cumulative maximum application rate of 4.32 kg a.s./ha). The refined risk assessment indicated a low long-term risk for the uses on cereals and oilseeds.

Overall, a data gap was identified to further assess the risk to herbivorous mammals for the representative uses in orchards (long-term risk) and 'all crops', pre-planting (acute and long-term) and post planting (long-term). The risk refinement proposed by the RMS for insectivorous birds for the representative use in cereals (pre-harvest application) was based on unjustified assumptions (i.e. refinement of PD and consequently use of different RUD values for the generic indicator focal species) and thus it could not be considered acceptable. Therefore, a data gap was also identified to further address the risk to insectivorous birds for the representative use in cereals (pre-harvest application).

The risk to birds and mammals via consumption of contaminated water or via secondary poisoning was considered as low.

A number of studies were available to investigate the effects on aquatic organisms of glyphosate, the representative formulated product and the pertinent metabolites (AMPA, HMPA). The risk assessments indicated a low risk to aquatic organisms with the highest FOCUS step 2 PEC_{sw} values for all the representative uses.

A large dataset from the literature review was also available on amphibians. On the basis of these data, amphibians are less acutely and chronically sensitive than fish.

A low risk was concluded based on first tier risk assessments for bees, non-target arthropods earthworms, soil macro-organisms, soil micro-organisms and biological methods for sewage treatment.

For the risk assessment for non-target arthropods and for terrestrial non target plants, the use of modified drift values was proposed by the RMS for the pre-harvest applications (i.e. representative uses in cereals and oilseeds), because the scenario 'pre-harvest' is currently not considered by the FOCUS default drift values. This proposal was discussed at the experts' meeting. The experts considered more appropriate to use the FOCUS default drift values rather than the corrected values, but it was also agreed to highlight that the drift depositions might be underestimated with the default values for these particular uses of glyphosate.

For the risk assessment to terrestrial non target plants, the use of MAF values was discussed at the experts' meeting. The RMS proposed to consider the default MAF values reported in SETAC (2001) (i.e. 1.7 for 2 applications and 2.3 for 3 applications), which are recommended for the exposure assessment to non-target arthropods in the off-crop vegetated habitats, where dissipation time information is not available. The RMS explained that, considering the mode of action of glyphosate and the onset of the effect to plants is immediate, plants will be affected at each single application event and therefore, it would be not appropriate to consider any degradation of the substance. It was also acknowledged that further guidance would be needed on how to address effects to non-target plants of multiple exposure events. Overall, the RMS's proposal was agreed. The risk to terrestrial non-target plants was indicated as low when mitigation measures including drift reduction and/or in-field no-spray buffer zones were taken into account for all the representative uses.

On the basis of the available data in the area of ecotoxicology, there was no indication of endocrine disrupting adverse effects. However, pending on the outcome of the data gaps identified in section 2, further ecotoxicology data may be needed.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
glyphosate	Low to very high (DT_{50} = 2.8 – 500.3 d)	Low risk for earthworms
AMPA	Moderate to high (lab studies DT_{50} = 38.98 – 300.71 d) High to very high (field studies $DT_{SFO\ 50}$ = 288.4 – > 374.9 d) Data gap identified to investigate degradation rate in acidic soils (pH 5-6).	Low risk for earthworms

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter) [(a)]	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
glyphosate	Immobile to low mobility (K_{Foc} = 884 – 60000 mL / g)	FOCUS GW: No Lysimeter: not available Monitoring data: equivocal results. Exceedances are reported for which it is not possible to rule out that contamination was caused by uses following GAP	Yes	Yes	Low risk for organisms of surface water
AMPA	Immobile to low mobility (K_{Foc} = 1119 – 45900 mL / g)	FOCUS GW: No Lysimeter: not available Monitoring data: equivocal results. Exceedances are reported for which it is not possible to rule out that contamination was caused by uses following GAP	No	No Genotoxicity: consistently negative in Ames tests, mammalian cell gene mutation and UDS tests *in vitro* and in micronucleus assays *in vivo* AMPA and glyphosate elicit similar toxicological profile; reference values of glyphosate apply to AMPA	Low risk for organisms of surface water

(a): Note there is uncertainty in the assessment, as the standard FOCUSgw models, scenarios and approach do not account for the specific ionic characteristics of glyphosate and AMPA.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
glyphosate	Low risk
AMPA	Low risk
HMPA	Low risk

6.4. Air

Compound (name and/or code)	**Toxicology**
glyphosate	Rat LC_{50} inhalation > 5 mg/L air (4-h nose-only exposure); no classification required

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a list of data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to provisions of Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

- Analytical method for formaldehyde with a sufficiently low LOQ and demonstrate that the technical material meets the proposed maximum content (relevant for applicant Brokden, for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Additional data/information regarding the validation of the analytical methods used for the quantification of the significant impurities and justification for the proposed limits of some impurities (relevant for applicant Bros Spolka Jawna B.P. Miranowscy, for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)

- New GLP 5 batch data (relevant for applicant Excel Crop Care (Europe) NV, for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Additional validation data for the determination of one impurity (relevant for applicant Helm AG, for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Updated technical specification for the TC and TK based on batch data or QC data supporting the proposed limits for impurities (relevant for applicant Monsanto Europe N.V./S.A, for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Revised evaluation of the precision of one of the methods with respect to one impurity (see confidential Reporting Table) (relevant for applicant Monsanto Europe N.V./S.A., for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Updated technical specification and validation data for the determination of the impurities (relevant for applicant Sabero Europe B.V., for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Additional validation data for the determination of one impurity (see confidential RT) (relevant for applicant Sinon Cooperation, for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Additional validation data for the determination of one impurity (see confidential RT) (relevant for applicant United Phosphorous Ltd, for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Confirmatory method for N-acetyl-glyphosate in dry plant materials and those with high water and high fat content (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Confirmatory method for glyphosate in animal fat and kidney/liver (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Confirmatory method for *N*-acetyl-glyphosate in all animal matrices (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Confirmatory method for glyphosate and AMPA in soil (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)

- Relevance of all individual impurities present in the technical specification (except the two already identified relevant impurities, formaldehyde and N-Nitroso-glyphosate), in particular impurities that elicited toxicological alerts according to QSAR assessments and the ones specified at higher level than the reference specification, in comparison with the toxicity profile of the parent compound (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2)

- The full battery of Tier I screening assays according to the EDSP, or Level 2 and 3 tests currently indicated in the OECD Conceptual Framework, and analysed in the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors are needed to address the potential for endocrine-mediated mode of action regarding delay in preputial separation in F1 males and decrease in homogenisation resistant spermatids (*cauda epididymis*) observed in the most recent multigeneration study (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2 and 5)

- Toxicological data allowing a consumer risk assessment to be performed for metabolites *N*-acetyl-glyphosate and *N*-acetyl-AMPA (relevant for uses on glyphosate tolerant GM varieties; submission date proposed by the applicant: unknown; see Section 2 and 3)

- GAP for olives (ground picked) and additional trials conducted according to this GAP are required (relevant for representative use on olives (oil production); submission date proposed by the applicant: unknown; see section 3)

- Additional trials on rape-seed conducted according to the proposed GAP are required (relevant for representative use in rape seed; submission date proposed by the applicant: unknown; see Section 3)

- A data gap has been identified to investigate the degradation rate of major metabolite AMPA in soils with pHs in the acidic range (pH_{H2O} = 5-6; relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4)

- Further information is needed to assess the contamination route through run off (especially in situations where applications to hard surfaces might occur) and subsequent surface water contamination and bank infiltration to groundwater (relevant for all seeded or transplanted crops' and 'all seeded crops' representative uses; submission date proposed by the applicant: unknown; see Section 4)

- The risk to small herbivorous mammals for the representative uses in orchards (long-term risk) and to herbivorous mammals for the representative uses 'all crops', pre-planting (acute and long-term) and post planting (long-term) needs to be further addressed (relevant for orchards, 'all crops', pre-planting and post planting; submission date proposed by the applicant: unknown; see Section 5)

- Data gap to further assess the long-term risk assessment for insectivorous birds (relevant for pre-harvest application in cereals; submission date proposed by the applicant: unknown; see Section 5)

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- Personal protective equipment (PPE), such as gloves during mixing and loading operations have to be considered for hand-held applications to ensure that operator exposure does not exceed the AOEL (see Section 2).

- Mitigation measures including drift reduction and/or in-field no-spray buffer zone were needed to achieve a low risk to terrestrial non-target plants for all the representative uses.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[13] and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. Glyphosate is not classified or proposed to be classified as carcinogenic or toxic for the reproduction category 2 in accordance with the provisions of Regulation (EC) No. 1272/2008 (harmonised classification supported by the present assessment) and therefore the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. Apical studies did not show adverse effects on the reproduction, however as an endocrine-mediated mode of action could not be ruled out (see Section 2). Data gaps for the full battery of Tier I screening assays according to the EDSP, or the Level 2 and 3 tests currently indicated in the OECD Conceptual Framework, are identified and the assessment could not be finalised (see Sections 2 and 5).

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No. 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

2. Eight out of the 24 applicants presented specifications that were not supported by the toxicological assessment (Industrias Afrasa S.A., Arysta Lifescience SAS, Bros Spolka Jawna B.P. Miranowscy, Dow AgroScience S.r.l, three out of seven sources of Helm AG, Monsanto Europe, Société Financière de Pontarlier and one of the two Syngenta Limited manufacturing routes).

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

All columns are grey, as the technical material specification proposed was not comparable to the material used in the testing (Sections 2 and 5)

[13] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

Representative use		All seeded or transplanted crops - pre-planting	All seeded crops – post-planting - pre emergence	Cereals Pre-harvest	Oilseeds pre-harvest	Orchard crops and grapes
Operator risk	Risk identified					
	Assessment not finalised					
Worker risk	Risk identified					
	Assessment not finalised					
Bystander risk	Risk identified					
	Assessment not finalised					
Consumer risk	Risk identified					
	Assessment not finalised					
Risk to wild non target terrestrial vertebrates	Risk identified	X	X	X		X
	Assessment not finalised					
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified					
	Assessment not finalised					
Risk to aquatic organisms	Risk identified					
	Assessment not finalised					
Groundwater exposure active substance	Legal parametric value breached					
	Assessment not finalised					
Groundwater exposure metabolites	Legal parametric value breached					
	Parametric value of 10µg/L breached					
	Assessment not finalised					
Comments/Remarks						

The superscript numbers in this table relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Section 5 for further information.

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APPENDICES

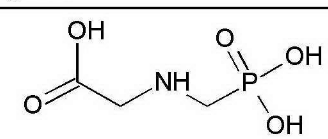
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name)	Glyphosate
Function (*e.g.* fungicide)	Herbicide

Rapporteur Member State	Germany
Co-rapporteur Member State	Slovakia

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	*N*-(phosphonomethyl)glycine
Chemical name (CA)	*N*-(phosphonomethyl)glycine
CIPAC No	284
CAS No	1071-83-6
EC No (EINECS or ELINCS)	213-997-4
FAO Specification (including year of publication)	284/TC (2014) applicable to material of Monsanto, Cheminova, Syngenta and Helm Glyphosate: ≥ 950 g/kg Formaldehyde: maximum 1.3 g/kg of the glyphosate acid content found *N*-Nitroso-glyphosate: maximum 1 mg/kg Insolubles in 1 M NaOH: maximum 0.2 g/kg
Minimum purity of the active substance as manufactured	950 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Formaldehyde < 1 g/kg *N*-Nitroso-glyphosate < 1 mg/kg
Molecular formula	$C_3H_8NO_5P$
Molar mass	169.1 g/mol
Structural formula	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity)	189 °C (99.9 %)
Boiling point (state purity)	Not applicable because glyphosate decomposes during melting.
Temperature of decomposition (state purity)	Pure glyphosate decomposes at about 200 °C (99.6 %)
Appearance (state purity)	White solid (99.6 %)
Vapour pressure (state temperature, state purity)	1.31 x 10^{-5} Pa at 25 °C (98.6%)
Henry's law constant	2.1 x 10^{-7} Pa m^3 mol^{-1} (25 °C)
Solubility in water (state temperature, state purity and pH)	10.5 g/L at 20 °C (pH 1.90 – 1.98) (99.5 %)
Solubility in organic solvents (state temperature, state purity)	Solubility at 20 °C in g/L (96.9 %) acetone < 0.6 mg/L 1,2-dichloroethane < 0.6 mg/L ethyl acetate < 0.6 mg/L heptane < 0.6 mg/L methanol 10 mg/L octan-1-ol < 0.6 mg/L xylenes < 0.6 mg/L acetonitrile 0.8 mg/L
Surface tension (state concentration and temperature, state purity)	72.2 mN/m (1 g/L H_2O solution, 20 °C) (96.9 %)
Partition co-efficient (state temperature, pH and purity)	log $P_{O/W}$ = - 3.2 at 25 °C (pH buffer 5–9) (99.9 %)
Dissociation constant (state purity)	pK_{a1} = 2.34 pK_{a2} = 5.73 all at 20 °C (99 %)
UV/VIS absorption (max.) incl. ε (state purity, pH)	No maximum in the range 200-340 nm ε at 290 nm < 10 L mol^{-1} cm^{-1}
Flammability (state purity)	Glyphosate is not highly flammable under the conditions of this test (98.7 %)
Explosive properties (state purity)	From the structural formula of glyphosate technical it can be concluded that the substance is not explosive. The substance does not contain any chemically instable or highly energetic groups that might lead to an explosion.
Oxidising properties (state purity)	Glyphosate technical material is not classified as an oxidising substance (96.9 %)

Summary of representative uses evaluated (*Glyphosate*)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation: Type (d-f)	Formulation: Conc. a.s. (i)	Application: method kind (f-h)	Application: growth stage & season (j)	Application: number min-max (k)	Application: interval between applications (min)	Application rate per treatment: L/ha product [1] min-max	Application rate per treatment: water L/ha min-max	Application rate per treatment: kg as/ha min-max	PHI (days) (l)	Remarks: (m)
All crops** (all seeded or transplanted crops)	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Pre planting of crop	1-2	21 d (see remark)	1-6	100-400	0.36-2.16		Spring & autumn after harvest (incl. stubble and/or seedbed prep.) For all crops: Max. application rate 4.32 kg/ha glyphosate in any 12 month period across use categories, equivalent to the sum of pre-plant, pre-harvest and post-harvest stubble applications. The interval between applications is dependent on new weed emergence after the first treatment, relative to the time of planting the crop.
All crops** (all seeded crops)	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Post planting/ pre emergence of crop	1		1-3	100-400	0.36-1.08		
Cereals (pre-harvest) wheat, rye, triticale,	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Crop maturity < 30 % grain moisture	1		2-6	100-400	0.72-2.16	7	Max. application rate 4.32 kg/ha glyphosate in any 12 month period across use categories, equivalent to the sum of pre-plant, pre-harvest and post-harvest stubble applications Pre-harvest uses in all crops include uses for weed control (higher doses) and harvest aid, sometimes referred to as desiccation (lower doses). The critical GAP is the high dose recommended used for weed control.
Cereals (pre-harvest) barley and oats	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Crop maturity < 30 % grain moisture	1		2-6	100-400	0.72-2.16	7	
Oilseeds (pre-harvest) rapeseed, mustard seed, linseed	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Crop maturity < 30 % grain moisture	1		2-6	100-400	0.72-2.16	14	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (min)	L/ha product [1] min-max	water L/ha min-max	kg as/ha min-max		
Orchard crops, vines, including citrus & tree nuts	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Post emergence of weeds	1-3	28 d	2-8	100-400	0.72-2.88	N/A	Stone & pome fruit, olives Applications to avoid contact with tree branches. Maximum cumulative application rate 4.32 kg/ha glyphosate in any 12 month period Note: Because applications are made to the intra-rows (inner strips between the trees within a row), application rates per ha are expressed per 'unit of treated surface area' the actual application rate per ha orchard or vineyard will roughly only be 33 %
Orchard crops, vines, including citrus & tree nuts	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	(ULV) Sprayer or Knapsack use (spot treatment)	Post emergence of weeds	1-3	28d	2-8	0-400	0.72-2.88		Stone & pome fruit, olives Applications made round base of trunk [0.0 L/ha water addresses ULV application of the undiluted product] Max. cumulative application rate 4.32 kg/ha glyphosate in any 12 month period Note: Because applications are made round base of trunk and to the intra-rows , (inner strips between two trees within a row), application rates per ha are expressed per 'unit of treated surface area' the actual application rate per ha orchard or vineyard will roughly only be 33 % - 50 %

* For uses where the column 'Remarks' is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

** Crops including but not restricted to: root & tuber vegetables, bulb vegetables, stem vegetables, field vegetables (fruiting vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses, oil seeds, potatoes, cereals, and sugar- & fodder beet; before planting fruit crops, ornamentals, trees, nursery plants etc.

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(j) Growth stage at 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

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained

(k) Indicate the minimum and maximum number of application possible under practical conditions of use
former information on kg a.s./hl replaced by RMS
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	AOAC/CIPAC; HPLC-UV
Impurities in technical as (analytical technique)	Formaldehyde & NNG (FAO), HPLC-colorimeter, HPLC-UV, Titration
Plant protection product (analytical technique)	AOAC/CIPAC; HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		For sweet corn, oilseed rape, soya beans and maize: sum of glyphosate and *N*-acetyl-glyphosate, expressed as glyphosate For other plant commodities: glyphosate
Food of animal origin		sum of glyphosate and *N*-acetyl-glyphosate, expressed as glyphosate
Soil		glyphosate and AMPA
Water	surface	glyphosate and AMPA
	drinking/ground	glyphosate and AMPA
Air		glyphosate

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS of underivatised analytes with phenyl-hexyl column; LOQ = 0.05 mg/kg for glyphosate and *N*-acetyl-glyphosate all commodity groups, ILV available For glyphosate confirmatory methods by HPLC with post-column derivatization or by GC-MS after derivatization with trifluoroacetic acid and heptafluorobutanol are available. A confirmatory method for *N*-acetyl-glyphosate is missing in crops of high water and high fat content.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS of underivatised analytes with phenyl-hexyl column; ILV available LOQ = 0.025 mg/kg in meat, milk and egg and 0.05 mg/kg in liver, kidney and fat for glyphosate and *N*-acetyl-glyphosate A confirmatory GC-MS method based on derivatization with a mixture of trifluoroacetic anhydride and trifluoroethanol is only available for glyphosate in milk, eggs and meat, but not for fat and kidney/liver. A confirmatory method for glyphosate in fat and liver/kidney as well as a confirmatory method for *N*-acetyl-glyphosate in all matrices are missing.

Soil (analytical technique and LOQ)	GC-MS after derivatization in a mixture of trifluoroacetic anhydride and trifluoroethanol, LOQ = 0.05 mg/kg for glyphosate and AMPA A confirmatory method is missing for glyphosate AMPA.
Water (analytical technique and LOQ)	LC-MS/MS after derivatization with 9-Fluorenylmethylchlorformate (FMOC), LOQ = 0.03 µg/L for glyphosate and AMPA in drinking, ground and surface water, confirmatory LC-MS/MS transition with LOQ = 0.03 µg/L validated, independent laboratory validation for drinking water successfully conducted
Air (analytical technique and LOQ)	GC-MS after derivatization in a mixture of trifluoroacetic anhydride and trifluoroethanol, LOQ = 5 µg/m^3 for glyphosate
Body fluids and tissues (analytical technique and LOQ)	Not required, not classified as toxic or very toxic

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	none

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption	Rapid but limited, about 20 %, based on urinary excretion and comparison of kinetic behaviour after oral and iv administrations
Distribution	Wide, highest residues after 7 d in bone, liver and kidney; C_{max} in plasma: 0,7-1,8 µg/mL (after 3-4 h), AUC: 18.6-23.1 µg h/mL, $t_{1/2}$: 6-12 h
Potential for accumulation	No evidence for accumulation (after 7 d total residues ≤ 1 % of the administered dose)
Rate and extent of excretion	Virtually complete within 7 d with major portion excreted within 48 h; absorbed amount eliminated via urine, unabsorbed via faeces; biliary excretion and exhalation negligible
Metabolism in animals	Poorly metabolised with the only biotransformation product aminomethylphosphonic acid (AMPA) accounting for up to 1 % of the total excreted amount (probably resulting from bacterial metabolism in the gut)
Toxicologically relevant compounds (animals and plants)	Glyphosate
Toxicologically relevant compounds (environment)	Glyphosate

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	> 2000 mg/kg bw (glyphosate acid & salts)	
Rat LD_{50} dermal	> 2000 mg/kg bw (glyphosate acid & salts)	
Rat LC_{50} inhalation	> 5 mg/L air (4-h nose only exposure) (glyphosate acid & salts)	
Skin irritation	Evidence of very slight irritation; classification and labelling not required (glyphosate acid & salts)	
Eye irritation	Irritant, classification needed for glyphosate acid but not for its salts	Cat. 1, H318
Skin sensitisation	Negative (M&K test, LLNA, Buehler) (glyphosate acid) Negative (M&K test) (IPA salt)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Rats & mice: GIT (irritation with diarrhoea and bw effects, caecum distension), urinary bladder (cystitis), liver (clinical chemistry findings), salivary glands (histology); Dogs: gastrointestinal signs, bw/bw gain↓ and evidence of weak liver toxicity with severe clinical signs and pathological lesions in different organs in a single 90-d dog study with capsule administration of 1000 mg/kg bw per day	
Relevant oral NOAEL	Rat, 90-d: 414 mg/kg bw per day Mouse, 90-d: 500 mg/kg bw per day Dog, 90-d & 1-yr: 300 mg/kg bw per day	
Relevant dermal NOAEL	Rat, 21/28-d: 1000 mg/kg bw per day (systemic), 500 mg/kg bw per day (local, irritation) Rabbit, 21/28-d: 5000 mg/kg bw per day (systemic), 1000 mg/kg bw per day (local, irritation)	
Relevant inhalation NOAEL	No valid data – not required	

Genotoxicity (Annex IIA, point 5.4)

	Not genotoxic	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect	Rat: Bw gain↓, salivary glands (wt↑, histological changes), liver (AP activity↑, wt↑), stomach (mucosal irritation) caecum (distension and wt↑), eye (cataracts), Mouse: Bw gain↓, food consumption/efficiency↓, liver (histological changes), caecum (distension and wt↑), prolapse and ulceration of anus, urinary bladder (histology)	
Relevant NOAEL	Rat, 2-yr: 100 mg/kg bw per day (overall NOAEL from a number of long-term studies) Mouse, 18-month/2-yr: 150 mg/kg bw per day (overall NOAEL)	
Carcinogenicity	Not carcinogenic in rats and mice; Very limited evidence for an association between glyphosate-based formulations and NHL in epidemiological studies. Overall inconclusive for a causal or clear associative relationship between glyphosate and cancer in human studies; classification and labelling not required	

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Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	<u>Adult:</u> bw gain↓, gastrointestinal signs, organ wt changes <u>Reproduction and fertility:</u> Homogenisation resistant spermatids↓ (in *Cauda epididymidis*) in F0 and delay in preputial separation in F1 males at very high dose of ca. 1000 mg/kg bw per day (15000 ppm) but no evidence for impairment of fertility and reproductive performance <u>Offspring:</u> bw gain↓, delayed preputial separation (in one study at 1000 mg/kg bw per day, 15000 ppm)	
Relevant parental NOAEL	overall 300 mg/kg bw per day	
Relevant reproductive NOAEL	351 mg/kg bw per day	
Relevant offspring NOAEL	overall 300 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect	<u>Maternal:</u> Rat: bw gain↓, gastrointestinal signs Rabbit: mortality, gastrointestinal signs, bw gain↓, abortions <u>Developmental:</u> Rat: ossification↓, skeletal anomalies; at excessive dose levels: post-implantation loss Rabbit: post-implantation loss, foetal wt & ossification↓; at excessive dose level: interventricular septal defects	
Relevant maternal NOAEL	Rat: 300 mg/kg bw per day Rabbit: 50 mg/kg bw per day	
Relevant developmental NOAEL	Rat: 300 mg/kg bw per day Rabbit: 50 mg/kg bw per day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity	Rat, no evidence up to highest dose of 2000 mg/kg bw causing some systemic effects (clinical signs and one death) Overall NOAEL 1000 mg/kg bw	
Repeated neurotoxicity	Rat, 90-day, no evidence up to highest dose of 20000 ppm (1546 mg/kg bw per day) causing lower bw (gain) and impaired food utilization Overall NOAEL 617 mg/kg bw per day	
Delayed neurotoxicity	Chicken, no evidence up to highest dose of 2000 mg/kg bw	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies	Severity of salivary gland findings is strain-specific in rats; effects are likely due to low pH in oral cavity but an adrenergic mechanism may be also involved; No evidence of immunotoxicity (humoral immune response, thymus and spleen weights) in mice Pharmacological effects: No haematological, electrocardiographic or behavioural/functional changes after oral administration; contractile response similar to that seen with known parasympatho-mimetic agents in isolated guinea pig ileum; no neuromuscular blocking activity on innervated rat gastrocnemius muscle Toxicity studies on farm animals: Goat LD_{50} oral = 3530 mg/kg bw (glyphosate acid) Goat LD_{50} oral = 5700 mg/kg bw (IPA salt) 7-day, cow: NOAEL 540 mg/kg bw per day, based on diarrhoea, decreased feed intake (IPA salt)
Studies performed on metabolites or impurities	Aminomethylphosphonic acid (AMPA, metabolite in glyphosate tolerant GM plants and in soil and water: Rat & mice LD_{50} oral > 5000 mg/kg bw, Rat LD_{50} dermal > 2000 mg/kg bw; Skin sensitisation: negative (M&K test); 90-day, rat: NOAEL: 400 mg/kg bw per day based on bw gain↓, urothelial hyperplasia (bladder) and gastro-intestinal clinical signs; 90-day, dog: NOAEL 263 mg/kg bw per day, the highest dose tested; Genotoxicity: consistently negative in Ames tests, mammalian cell gene mutation and UDS tests *in vitro* and in micronucleus assays *in vivo*; Rat developmental toxicity: No evidence of teratogenicity, maternal NOAEL 150 mg/kg bw per day, based on clinical signs, bw gain/food consumption↓, developmental NOAEL 400 mg/kg bw per day, based on mean foetal wt↓; AMPA presents a similar toxicological profile as glyphosate and the reference values of the latter apply to its metabolite AMPA. Data gaps were identified for toxicological data on the metabolites N-acetylglyphosate and N-acetyl-AMPA as they were included in the residue definition for plants with glyphosate tolerant GM plant varieties.

Medical data (Annex IIA, point 5.9)

No critical health effects reported from occupational health surveillance; no convincing evidence of carcinogenicity, neurotoxicity or effects on fertility and development in epidemiological studies; poisoning incidents after accidental or voluntary (suicidal) oral intake of large amounts of glyphosate-based herbicides; transient eye irritation as most frequent sign in operators following accidental exposure.

Summary (Annex IIA, point 5.10)**

	Value	Study	Uncertainty factor
ADI	0.5 mg/kg bw per day	Developmental toxicity, rabbit	100
AOEL	0.1 mg/kg bw per day	Developmental toxicity, rabbit	Overall 500* (100 + 20%*)
ARfD	0.5 mg/kg bw	Developmental toxicity, rabbit	100

* Correction for low oral absorption (20 %).
** The proposed reference values are different than those mentioned in the review report 6511/VI/99-final (European Commission, 2002)

Dermal absorption (Annex IIIA, point 7.3)

Formulation MON 52276 (360 g glyphosate/L SL)	1 % for concentrate and dilutions based on human skin *in vitro*

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Field crop tractor-mounted (application rate: 2.16 kg glyphosate/ha): <u>% of AOEL</u> **<u>German model</u>** Without PPE (T-shirt and shorts) 28 % **<u>UK POEM</u>** Without PPE (long sleeved shirt, long trousers) 261 % With PPE (gloves during mixing/loading and application): 49 % Hand-held spray applications (application rate: 2.88 kg glyphosate/ha) under high crops **<u>German model</u>** (high crop, which is a worst case) Without PPE (T-shirt and shorts) 115 % With PPE (gloves during mixing/loading): 32 % **<u>UK POEM</u>** Without PPE (long sleeved shirt, long trousers): 568 % PPE (gloves during mixing/loading and application and gloves, impermeable coverall during application)149 %
Workers	29 % of AOEL without PPE: worker wearing long sleeved shirt, long trousers (‘permeable’) but no gloves

Bystanders & Residents	Bystanders: Adults: 4.1 % of AOEL, children: 3.4 % of AOEL Residents: Adults: 5.5 % of AOEL, children: 20.8 % of AOEL (both for assumed applications on pasture, lawn or meadow, 'worst case')

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

Substance	glyphosate (acid)
Harmonised classification – Annex VI of Regulation (EC) No 1272/2008[14]	Danger GHS05 (corrosion) Eye Damage 1 H318 - Causes serious eye damage
RMS/peer review proposal[15]	the same as above

[14] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1–1355.

[15] It should be noted that proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals. Classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Non-tolerant crops Fruits - Mandarins (soil, foliar, hydroponic) - Almond, waltnut and pecan (soil, foliar) - Apples (soil, foliar, trunk) - Grapes (soil, foliar, trunk, hydroponic) - Avocado (foliar, direct fruit treatment) Root and tuber crops - Potato (soil, foliar) - Sugar beets (soil) Pulses and oilseeds - Cotton (soil, hydroponic) - Soya beans (soil, hydroponic) Cereal grains - Barley (soil, hydroponic) - Maize (soil, hydroponic) - Oats (soil, hydroponic) - Rice (soil, hydroponic) - Sorghum (soil, hydroponic) - Wheat (soil, hydroponic, foliar - dessication) Miscellaneous crops - Coffee (soil, foliar, stem, hydroponic) - Sugar cane (soil, foliar) Transgenic crops (all foliar sprayed) Oilseeds - Rape/canola (CP4-EPSPS & GOX, GAT) - Soya beans (CP4-EPSPS, GAT) - Cotton (CP4-EPSPS) Root and tubers - Sugarbeet (CP4-EPSPS) Cereal grains - Maize (CP4-EPSPS & GOX, GAT)
Rotational crops	- Beets, carrots, radish - Lettuce, cabbage - Peas - Soya beans - Barley, wheat
Metabolism in rotational crops similar to metabolism in primary crops?	yes, in rotational crops higher relative amounts of AMPA are expected due to its formation in soil
Processed commodities	Stable
Residue pattern in processed commodities similar to residue pattern in raw commodities?	yes
Plant residue definition for monitoring	Sweet corn, oilseed rape, soya beans and maize (non-tolerant and tolerant, all modifications): sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate Other plant commodities: glyphosate

Plant residue definition for risk assessment	Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, all expressed as glyphosate.
Conversion factor (monitoring to risk assessment)	For non-tolerant crops, the contribution of AMPA to the consumer exposure is minor, making a CF unnecessary. Residues in glyphosate tolerant GM crops and application type (pre-emergence/desiccation) should be considered to derive CF for plant commodities.

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Goats, chicken
Time needed to reach a plateau concentration in milk and eggs	Milk: <7 days Eggs: 14 days (based on 28 day feeding study, no plateau reached within 8 days in metabolism studies)
Animal residue definition for monitoring	Sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate
Animal residue definition for risk assessment	Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, all expressed as glyphosate
Conversion factor (monitoring to risk assessment)	Not proposed, since assessment based on conventional crops only while ratio of metabolites in animal matrices strongly depends on the ratio of metabolites in animal diet and therefore on the amount of GMO-feedstuff in diets. For non-tolerant feed crops, a conversion factor for animal commodities was considered unnecessary.
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

	Based on the supported uses, glyphosate and AMPA residues not expected in rotational crops

Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)

High acid content matrices	
Glyphosate	>14 to >31 months
AMPA	>14 to >31 months
N-acetyl-glyphosate	not investigated
N-acetyl-AMPA	not investigated
High water content matrices	
Glyphosate	>9 to 31 months
AMPA	6 to 24 months
N-acetyl-glyphosate	6 to >12 months
N-acetyl-AMPA	>1 to >12 months
High oil content matrices	
Glyphosate	>18 to >24 months
AMPA	>24 months
N-acetyl-glyphosate	>12 months
N-acetyl-AMPA	>1 month
High starch content matrices	
Glyphosate	18 to >48 months
AMPA	10 to >31 months
N-acetyl-glyphosate	>12 months
N-acetyl-AMPA	>12 months
High protein content matrices	
Glyphosate	>18 months
AMPA	not investigated
N-acetyl-glyphosate	not investigated
N-acetyl-AMPA	not investigated
Other plant matrices	
Glyphosate	18 to >45 months
AMPA	6 to >24 months
N-acetyl-glyphosate	>12 months
N-acetyl-AMPA	>1 months
Animal commodities	
Glyphosate	14 to >26 months
AMPA	14 to >26 months
N-acetyl-glyphosate	not investigated
N-acetyl-AMPA	not investigated

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes Dairy cattle: 1.58 mg/kg bw Beef cattle: 4.5 mg/kg bw	Yes 0.29 mg/kg bw	Yes 0.21 mg/kg bw
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	yes	yes	yes
	Feeding studies:		

	Ruminant:	Poultry:	Pig:
	Cattle study 1 (glyphosate:AMPA 9:1): 1.4/0.156; 4.0/0.48 and 12.8/1.4 mg eq/kg bw Cattle study 2 (glyphosate-trimesium): 0.012; 0.13; 1.44; 7.38 and 19.4 mg eq/kg bw Poulty: 0.24 and 2.2 mg/kg bw Pig: 1.08 mg/kg bw Estimated residue levels in animal matrices (mg/kg) at the expected intake levels:		
Muscle	<0.05	<0.05	<0.05
Liver	0.07	<0.05	<0.05
Kidney	1.6	0.08	0.12
Fat	0.06	<0.05	<0.05
Milk	<0.02		
Eggs		<0.01	

Summary of residues data according to the representative uses on raw agricultural commodities (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern/ Southern Region (a)	Trials results relevant to the representative uses (b)	Comments/remarks (c)	MRL (mg/kg)	HR (d)	STMR (e)
Unless otherwise stated, all samples were analysed for glyphosate and AMPA separately, achieving the same LOQ values. Since AMPA was never detected above the LOQs, residue levels measured in the trials listed below are reported for glyphosate only. In addition, since AMPA was always observed in much lower levels than glyphosate in the metabolism studies on conventional crops, when residue for glyphosate and AMPA were both <LOQ, the LOQ reported for glyphosate was considered for risk assessment (and not the sum of the LOQs as usually required)						
Hazelnut	SEU	4x <0.05	Based on the trials conducted on hazelnuts, apples, pears, cherries and peaches following soil application beneath trees, where residue levels were all <LOQ, a MRL of 0.05* mg/kg is proposed for the citrus, tree nuts, pome and stone fruits groups.	0.05*	0.05	0.05
Apples & pears	NEU	<0.02, 3x <0.05				
	SEU	17x <0.05				
Cherries	NEU	2x <0.05				
Peaches	SEU	2x <0.05				
Grapes	NEU	6x <0.05, 0.07, 0.30	Residue of 0.07 and 0.30 mg/kg measured in low hanging fruits (following application at a lower rate of 2x 720 g/ha) were considered to derived a MRL of 0.5 mg/kg for grapes; MRL_{OECD}: 0.43/0.5	0.5	0.3	0.05
Table Olives	SEU	tree-picked: 12x <0.05, 6x <0.05 ground-picked: 0.11, 0.14, 0.53, 0.93	Additional trials requested to derived MRL for olives (oil production) MRL_{OECD}: 2.0/2	2	0.93	0.335
Potato	NEU	2x <0.05	Based on pre-sowing application trials conducted on potato and carrots where residue levels were all <LOQ, a MRL of 0.05* mg/kg is proposed for the root and tuber vegetable group (including potato).	0.05*	0.05	0.05
	SEU	2x <0.05				
Carrots	NEU	2x <0.05				
	SEU	2x <0.05				
Onions (bulb)	NEU	6x <0.05	The MRL proposal of 0.05* mg/kg is extrapolated to the whole group 'bulb vegetables'	0.05*	0.05	0.05
	SEU	3x <0.05				
Tomato	NEU	2x <0.05	Based on pre-sowing application trials conducted	0.05*	0.05	0.05

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Crop	Northern/ Southern Region (a)	Trials results relevant to the representative uses (b)	Comments/remarks (c)	MRL (mg/kg)	HR (d)	STMR (e)
Cucumber	SEU	<0.05	on tomato, cucumber and courgette where residue levels were all <LOQ, a MRL of 0.05* mg/kg is proposed for the whole group. 'fruiting vegetables'			
Courgette (Zucchini)	NEU	<0.05				
	SEU	<0.05				
Cauliflower	NEU	2x <0.05	The MRL proposal of 0.05* mg/kg is extrapolated to the whole group 'brassica vegetables' (pre-emergence or pre-planting application)	0.05*	0.05	0.05
	SEU	2x <0.05				
Head cabbage	NEU	2x <0.05				
	SEU	2x <0.05				
Lettuce	NEU	2x <0.05	MRL proposal of 0.05* mg/kg extrapolated to the whole group 'leaf vegetables and fresh herbs'	0.05*	0.05	0.05
	SEU	2x <0.05				
Leek	NEU	2x <0.05	MRL proposal of 0.05 mg/kg extrapolated to the whole group 'stem vegetables'	0.05*	0.05	0.05
	SEU	2x <0.05				
Sugar beet (Roots)	NEU	6x <0.05	MRL proposal of 0.05 mg/kg extrapolated to the whole group 'Sugar plants'	0.05*	0.05	0.05
	SEU	2x <0.05				
Sugar beet (Tops)	NEU	6x <0.05		-	0.05	0.05
	SEU	2x <0.05				
All residue trails here below, were conducted on conventional crops and therefore samples were analysed for glyphosate and AMPA only. **Mo:** Residue level according to the residue definition for monitoring (conventional crops): glyphosate. **RA:** Residue level according to the residue definition for risk assessment (conventional crops): sum glyphosate + AMPA expressed as glyphosate STMR and HR values are expressed according to the residue definition for risk assessment (sum glyphosate + AMPA expressed as glyphosate)						
Rape seed	NEU	**Mo:** 1.4, 6.4, 9.0 **RA:** 1.7, 6.5, 9.0[(f)]	Data not sufficient to derive an MRL proposal	no proposal		

Crop	Northern/ Southern Region (a)	Trials results relevant to the representative uses (b)	Comments/remarks (c)	MRL (mg/kg)	HR (d)	STMR (e)
Barley, oats (grain)	NEU	**Mo:** 1.2, 1.5, 2.0, 2.1, 2.1, 2.2, 2.4, 2.5, 2.6, 2.6, 2.8, 3.95; 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2, 5.2, 5.2, 5.3, 5.4, 5.5, 5.5, 5.7, 5.9, 5.9, 6.2, 6.5, 6.7, 7.4, 7.7, 7.8, 8.0, 8.1, 8.4, 9.8, 10, 10.3, 12.4, 12.5, 14, 15.5, 16.5, 17, 17.5, 18.4, 21, 21.4 **RA:** 1.3, 1.5$^{(f)}$, 2.1, 2.2, 2.2, 2.3, 2.5, 2.5, 2.7, 2.9, 3.2, 4.2, 4.4, 4.6, 4.9, 5.0, 5.1$^{(f)}$, 5.2, 5.3, 5.3, 5.3$^{(f)}$, 5.5, 5.5$^{(f)}$, 5.6, 5.8, <u>5.8</u>, <u>5.9</u>, 6.2, 6.2$^{(f)}$, 6.6, 6.9, 7.5, 7.9, 8.0, 8.2, 8.3, 8.4$^{(f)}$, 10, 10.3, 10.4, 12.4$^{(f)}$, 12.8, 14.4, 16, 16.6, 17.2, 17.8, 18.4$^{(f)}$, 21.4$^{(f)}$, 21.6	Almost all values are the mean of replicates MRL_{OECD}: 28.3/30 (NEU) Having regard to the large number of residue trials in NEU and since levels in SEU tria ls are in the same order of magnitude, additional trials in SEU are not requested.	30	21.6	5.85
	SEU	**Mo:** 6.0, 7.8, 13.5, 19 **RA:** 6.0, 7.9, 13.7, 19.3				
Barley, oats (straw)	NEU	**Mo:** 4.6, 6.9, 9.6, 10.5, 11, 11.5, 12.8, 12.8, 14.5, 16, 17, 18, 22, 24, 26, 26.3, 26.5, 27, 27.3, 28.4, 32.2, 33.3, 36.9, 37, 41.5, 44, 49.7, 54, 56, 60.5, 69.6, 80.5, 86, 90.2, 109, 115, 117, 136, 140 **RA:** 4.7, 6.9$^{(f)}$, 10, 10.6, 11.3, 12.1, 13.1, 13.2, 14.6, 16.3, 17.7, 18$^{(f)}$, 22$^{(f)}$, 24.5, 26.7, 27.1, 27.6, 28.6, 28.7, 29.3, 29.6, 32.7, 33.9, 37.8, 38, 42.1, 44.4, 51.3, 56$^{(f)}$, 60.8, 61.9, 70.7, 83.6, 89.8, 92, 109$^{(f)}$, 115$^{(f)}$, 119, 140, 142	Almost all values are the mean of replicates	-	142	29.45
	SEU	**Mo:** 34, 49.5, 66, 102 **RA:** 34.9, 51, 68.1, 105				

Crop	Northern/ Southern Region (a)	Trials results relevant to the representative uses (b)	Comments/remarks (c)	MRL (mg/kg)	HR (d)	STMR (e)
Wheat, rye (grain)	NEU	**Mo:** 0.05, 0.11, 0.16, 0.19, 0.22, 0.23, 0.23, 0.26, 0.33, 0.5, 0.5, 0.6, 0.64, 0.67, 0.7, 0.7, 0.7(3), 0.71, 0.74, 0.75, 0.75, 0.77, 0.85, 1.3, 1.4, 1.5, 1.55, 1.6, 1.7, 1.7, 1.75, 2.2, 2.4, 2.9, 3.1, 3.45, 3.5, 3.7, 3.85, 4.7, 4.8, 4.85, 5.4, 9.5, 12.4, 17.5 **RA:** 0.125, 0.18, 0.24, 0.26, 0.27, 0.27, 0.28, 0.29, 0.36, 1.1, 0.58, 0.64[(f)], 0.7, 0.74, 0.74[(f)], 0.75, 0.77, 0.78, 0.78, 0.78, 0.78, 0.83, 0.83, 0.84, 0.93, 1.3[(f)], 1.5, 1.6, 1.6, 1.6[(f)], 1.7[(f)], 1.8, 1.9, 2.3, 2.4[(f)], 2.9[(f)], 3.1[(f)], 3.5, 3.6, 3.8, 3.9, 4.9, 5.0, 5.0, 5.4[(f)], 9.5[(f)], 13.3, 18.1	Almost all values are the mean of replicates MRL_{OECD}: 17.5/20 (NEU)	20	18.1	0.885
	SEU	**Mo:** 0.07, 0.38, 0.4, 0.4, 0.47, 0.6, 0.95, 1.2, 2.8 **RA:** 0.15, 0.45, 0.48, 0.48, 0.55, 0.68, 1.0, 1.3, 3.0				
Wheat, rye (straw)	NEU	**Mo:** 1.4, 5.3, 8.4, 9.5, 10.3, 10.6, 11.4, 14.7, 14.9, 17.3, 18.5, 19.1, 19.7, 21.5, 24.8, 26.9, 27.4, 27.5, 29.6, 31.4, 34.8, 42, 43.2, 43.8, 44.5, 46, 52.8, 63.3, 68, 70.5, 84.5, 85, 95.3, 95.5, 95.7, 96.5, 99, 175 **RA:** 1.5, 5.4, 9.3, 10.5, 10.9, 11, 12.6, 15.7, 15.7, 17.6, 19.2, 19.4, 19.9, 22.1, 25.5, 28, 28.2, 28.9, 29.6[(f)], 31.8, 35.9, 42.6, 43.2, 44.2, 45.4, 46(f), 52.8(f), 64.3, 68[(f)], 71.4, 87.5, 88.5, 96.5[(f)], 97.3, 97.6, 98, 103, 179	Almost all values are the mean of replicates	-	179	30.7
	SEU	**Mo:** 3.4, 15.5, 16, 20, 22, 28, 28.5, 55.5, 98 **RA:** 3.5, 16.9, 18.6, 20.9, 23.2, 29.6, 29.7, 56.5, 99				

(a) NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b) Individual residue levels considered for MRL calculation are reported in ascending order (2x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.10, 0.15, 0.17),
(c) Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values)
(d) HR: Highest residue level according to the residue definition for risk assessment.
(e) STMR: Median residue level according to residue definition for risk assessment
(f) AMPA not analysed for

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.5 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo model	not calculated
TMDI (% ADI) according (to be specified) diets	not calculated
IEDI according to EFSA PRIMo model	Highest IEDI: 3% ADI (IE, Adult)
NEDI (% ADI) according to German NVS II model	1.5% DE general population aged 14-80 yrs.
Factors included in IEDI and NEDI	STMR values, PFs if applicable
ARfD	0.5 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo model	Children: 5% for Oats (German children aged 2-4 y) Adults: 9% for barley (Netherland adults)
NESTI (% ARfD) according to German NVS II model	Children: 5% for Oats (German children aged 2-4 y) Adults: 6% for barley (General population aged 14-80 y)
Factors included in IESTI and NESTI	PF Rye: bran (1.5), flour (0.44), wholemeal flour (1.0) PF Wheat: bran (1.8), flour (0.57), wholemeal flour: (1.1)

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed product	Number of studies	Processing factors		Comments
		Glyphosate	AMPA	
Citrus				
juice	6	0.83	-	
peel	6	3	-	
feed meal	6	2.6	-	
press liquor	6	2	-	
Potato				
chips	3	-	1.3	
flakes	3	-	1.5	
wet peel	3	-	0.31	
dry peel	3	-	1.5	
granules	3	-	2.3	
Olives				
crude oil (vergine)	19	0.09	-	
refined oil	6	0.22	-	
Linseed				
oil	4	0.25	-	
press cake	4	1.6	-	
Rape seed				
crude oil	4	0.14	-	
refined oil	4	0.13	-	
press cake	4	1.4	-	
Soya beans				
fat free meal	2	0.98	0.95	
hulls	2	4.8	2.45	
crude oil	2	0.01	0.055	
soapstock	2	0.045	0.29	

Crop/processed product	Number of studies	Processing factors		Comments
		Glyphosate	AMPA	
Maize				
fat free meal	4 (2 AMPA)	1.1	0.64	
crude oil	4 (2 AMPA)	0.1	0.5	
refined oil	4 (2 AMPA)	0.1	0.5	
soapstock	4 (0 AMPA)	0.1	-	
small grits	2 (0 AMPA)	0.9	-	
medium grits	2 (0 AMPA)	0.75	-	
large grits	2 (0 AMPA)	0.75	-	
flour	2 (2 AMPA)	0.9	0.59	
Rye				
bran	4	1.5	0.76	
flour	4	0.44	1.3	
wholemeal flour	4	1	0.31	
wholemeal bread	4	0.63	0.61	
middlings	4	1.35	0.79	
Wheat				
bran	13 (1 AMPA)	1.8	1.2	
flour	13 (1 AMPA)	0.57	0.81	
wholemeal flour	2	1.1	-	
wholemeal bread	2	0.37	-	
middlings	2	0.61	-	
semolina	2	0.15	-	
semolina bran	2	1.8	-	

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Citrus, tree nuts, pome fruits, stone fruits Strawberries Root and tuber vegetables, bulb vegetables, Fruiting vegetables except sweet corn, Brassica vegetables, Leaf vegetables and fresh herbs Stem vegetables, Herbal infusions, Sugar plants		0.05* mg/kg
Pulses Oilseeds Buckwheat, maize, millet, rice, sorghum, other cereals,		0.05* mg/kg Trials were not provided, but having regard to the no residue situation (all values <0.05 mg/kg) observed when glyphosate is used before sowing/emergence of annual crops and since metabolism studies suggest a negligible uptake from roots, a MRL of 0.05* mg/kg is proposed to cover the pre-sowing/emergence uses of the active substances on these crops.
Grapes		0.5 mg/kg
Table Olives		2 mg/kg
Barley, oats		30 mg/kg
Wheat, rye		20 mg/kg
Swine	Muscle Fat Liver Kidney	0.05* mg/kg 0.05* mg/kg 0.05* mg/kg 0.2 mg/kg
Bovine	Muscle Fat Liver Kidney Milk	0.05* mg/kg 0.1 mg/kg 0.1 mg/kg 2.0 mg/kg 0.05* mg/kg
Poultry	Muscle Fat Liver Kidney Eggs	0.05* mg/kg 0.05* mg/kg 0.05* mg/kg 0.1 mg/kg 0.025* mg/kg

When the MRL is proposed at the LOQ, this should be annotated by an asterisk (*) after the figure.

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralisation after 100 days	16.9 - 79.6 % after 60 – 366 d (n = 12)
Non-extractable residues after 100 days	2.5 - 43.2 % after 60 – 366 d (n = 12)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	AMPA: 13.3 - 50.1 % max. at 7- 120 d (n = 12) Field: AMPA: 19.65 - 53.8 % max. after 56 - 271 d (n = 10)

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	
Mineralisation after 100 days	0.87 - 45.42 % after 66 - 120 d (n = 3)
Non-extractable residues after 100 days	20.88 - 24.6 % 66 - 120 d (n = 3)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	AMPA: max. 30.2 % after 84 days (n = 3)
DT_{50}	DT_{50} = 142 d (n = 1), no significant degradation (n = 1), no DT_{50} calculated (n = 1)
Soil photolysis	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	1st study: DT_{50} in d (experimental): 90 d (irradiated), 96 d (dark) AMPA: max. 13.0 % max. (irradiated), 9.6% max. (dark) 2nd study: DT_{50} in d (experimental): 101 d (irradiated), 1236 d (dark) AMPA: max.8.2% (irradiated), 6.1 % (dark) 3rd study: DT_{50} in d: 5.5 d (at 50°N) AMPA: max.24 %

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies

Glyphosate	Aerobic conditions						
Persistence endpoints at 20 and 25°C							
Soil type	pH (H_2O)	T (°C) / soil moisture	DT_{50} (d)	DT_{90} (d)	Kinetic parameters	Fit χ2 error (%)	Method of calculation
Gartenacker, loam	7.1	20/ pF2.5	7.86	56.29	k_1: 0.2474 k_2: 0.0304 g: 0.4459	3.0	DFOP
Arrow, sandy loam	6.5[a]	20/ 40% MWHC	37.75	1661	α: 0.45389 β: 10.47275	2.31	FOMC
Soil B, sandy loam	6.7	25/ 75% of 1/3 bar	1.2	20.8	α: 0.6565 β: 0.6406	6.9	FOMC
Les Evouettes, Silt Loam	6.1[b]	20/ 40% MWHC	8.55	83.92	k_1: 0.23497 k_2: 0.00826 g: 0.541289	5.93	DFOP
Maasdjik, sandy loam	7.5[a]	20/ 1/3 bar	4.61	62.00	k_1: 0.2638 k_2: 0.0192 g: 0.6715	0.84	DFOP
Drusenheim, loam	7.4	20/ pF2.5	2.06	15.38	k_1: 1.2566 k_2: 0.1161 g: 0.4038	2.4	DFOP
Pappelacker, loamy sand	7.0	20/ pF2.5	3.94	43.45	α: 0.8550 β: 3.1539	4.1	FOMC
18-Acres, clay loam	5.7	20/ pF2.5	67.72	471.4	k_1: 0.1129 k_2: 0.0040 g: 0.3453	2.9	DFOP
Speyer 2.3, Loamy Sand	6.9	20/40% MWHC	5.78	21.99	k_1: 0.1277 k_2: 2.3e-014 g: 0.9578	2.41	DFOP
Speyer 2.1, sand	6.5[a]	20/ 45% MWHC	8.3	51.3	k_1: 0.4736 k_2: 0.0372 g: 0.3278	2.45	DFOP
Speyer 2.2, loamy sand	6.2[a]	20/ 45% MWHC	18.7	428	α: 0.5770 β: 8.0642	4.04	FOMC
Speyer 2.3, loamy sand	6.9[a]	20/ 45% MWHC	2.70	13.03	k_1: 0.3162 k_2: 0.0494 g: 0.8355	7.45	DFOP
Dupo, silt loam	7.3[b]	25/ 75% FC	1.01	9.31	α: 1.01 β: 9.31	3.8	FOMC
Speyer 2.2, loamy sand	6.0	20/ 40% MWHC	43.53	144.61	k: 0.0159	6.95	SFO
Speyer 2.1, sand	6.9[b]	20/ 40% MWHC	11.11$	144.25$	α: 0.7683 β: 7.5833	3.91	FOMC$

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Maximum* (n = 15)	37.75	1661	α: 0.45389 β: 10.47275	Arrow FOMC

[a] converted from given pH in $CaCl_2$ or KCl
[b] buffer solution unknown
$ labelled in the phosphonomethyl-glycine anion of glyphosate-trimesium
* maximum, which would result to the highest PECsoil

Glyphosate	Aerobic conditions						
Persistence endpoints at 10°C							
Soil type	pH (H_2O)	T (°C) / soil moisture	DT_{50} (d)	DT_{90} (d)	Kinetic parameters	Fit χ2 error (%)	Method of calculation
Speyer 2.3, loamy sand	6.9[a]	10/ 45% MWHC	8.07	50.79	k_1: 0.300 k_2: 0.0361 g: 0.3756	2.31	DFOP

[a] converted from given pH in $CaCl_2$ or KCl

Laboratory studies

Glyphosate	Aerobic conditions						
Endpoint in regard to P-criterion							
Soil type	pH (H_2O)	T (°C) / soil moisture	recalculated SFO DT_{50} (days) actual	Normalised SFO DT_{50}(days) 20 °C, pF2		Fit χ2 error (%)	Method of calculation
Gartenacker, loam	7.1	20/ pF2.5	16.95	15.2		3.0	DFOP, DT_{90}/3.32
Arrow, sandy loam	6.5[a]	20/ 40% MWHC	500.3	427.8		2.31	FOMC DT_{90}/3.32
Soil B, sandy loam	6.7	25/ 75% of 1/3 bar	6.27	6.7		6.9	FOMC DT_{90}/3.32
Les Evouettes, Silt Loam	6.1[b]	20/ 40% MWHC	25.28	22.6		5.93	DFOP, DT_{90}/3.32
Maasdjik, sandy loam	7.5[a]	20/ 1/3 bar	18.7	14.1		0.84	DFOP, DT_{90}/3.32
Drusenheim, loam	7.4	20/ pF2.5	4.63	3.6		2.4	DFOP, DT_{90}/3.32
Pappelacker, loamy sand	7.0	20/ pF2.5	13.09	12.0		4.1	FOMC DT_{90}/3.32
18-Acres, clay loam	5.7	20/ pF2.5	141.9	133.8		2.9	DFOP, DT_{90}/3.32
Speyer 2.3, Loamy Sand	6.9	20/40% MWHC	6.6	6.6		2.41	DFOP, DT_{90}/3.32
Speyer 2.1, sand	6.5[a]	20/ 45% MWHC	15.45	15.45		2.45	DFOP, DT_{90}/3.32
Speyer 2.2, loamy sand	6.2[a]	20/ 45% MWHC	129	129		4.04	FOMC DT_{90}/3.32
Speyer 2.3, loamy sand	6.9[a]	20/ 45% MWHC	3.93	3.93		7.45	DFOP, DT_{90}/3.32
Dupo, silt loam	7.3[b]	25/ 75% FC	2.80	3.70		3.8	FOMC DT_{90}/3.32
Speyer 2.2, loamy sand	6.0	20/ 40% MWHC	43.53	40.6		6.95	SFO

Speyer 2.1, sand	6.9[b]	20/ 40% MWHC	43.06$	43.06		3.91	FOMC DT_{90}/3.32 $
Maximum (n = 15)				427.8	according to EFSA DG SANCO working document on evidence needed to identify POP, PBT and vPvB properties for pesticides from 25.09.2012- rev.3		
Geometric mean (n = 15)				19.74			

[a] converted from given pH in $CaCl_2$ or KCl in order to allow pH dependency tests of the degradation
[b] buffer solution unknown
$ labelled in the phosphonomethyl-glycine anion of glyphosate-trimesium

Glyphosate	Aerobic conditions				
Modelling endpoints					
Soil type	pH (H_2O)	T (°C) / % soil moisture	DT_{50} (d) 20 °C pF2	Fit $\chi 2$ error (%)	Method of calculation
Gartenacker, loam	7.1	20/ pF2.5	16.0	4.6	DT_{90} FOMC/ 3.32
Arrow, sandy loam	6.5[a]	20/ 40% MWHC	159.6	3.52	DFOP slow phase
Soil B, sandy loam	6.7	25/ 75% of 1/3 bar	6.6	6.92	DT_{90} FOMC/ 3.32
Les Evouettes, Silt Loam	6.1[b]	20/ 40% MWHC	93.3	6.17	DT_{90} FOMC/ 3.32
Maasdjik, sandy loam	7.5[a]	20/ 1/3 bar	15.2	3.79	DT_{90} FOMC/ 3.32
Drusenheim, loam	7.4	20/ pF2.5	4.2	3.5	DT_{90} FOMC/ 3.32
Pappelacker, loamy sand	7.0	20/ pF2.5	12.0	4.1	DT_{90} FOMC/ 3.32
18-Acres, clay loam	5.7	20/ pF2.5	160.5	2.9	DFOP slow phase
Speyer 2.3, Lomay Sand	6.9	20/40% MWHC	7.2	3.84	DT_{90} FOMC/ 3.32
Speyer 2.1, sand	6.5[a]	20/ 45% MWHC	19.5	5.72	DT_{90} FOMC/ 3.32
Speyer 2.2, loamy sand	6.2[a]	20/ 45% MWHC	72.2	4.97	DFOP slow phase
Speyer 2.3, loamy sand	6.9[a]	20/ 45% MWHC	3.76	7.67	DT_{90} FOMC/ 3.32
Dupo, silt loam	7.3[b]	25/ 75% FC	3.70	3.80	DT_{90} FOMC/ 3.32
Speyer 2.2, loamy sand	6.0	20/ 40% MWHC	40.6	6.95	SFO
Speyer 2.1, sand	6.9[b]	20/ 40% MWHC	43.06$	3.91$	DT_{90} FOMC/ 3.32
Geometric mean (n = 15)			20.51	-	Endpoint for modelling of PEC_{GW} and PEC_{SW}/ PEC_{Sed}
pH dependency			No		

[a] converted from given pH in $CaCl_2$ or KCl
[b] buffer solution unknown
$ labelled in the phosphonomethyl-glycine anion of glyphosate-trimesium

Metabolite AMPA	Aerobic conditions					
Persistence endpoints at 20 and 25°C						
Soil type	pH (H_2O)	T (°C) / % soil moisture	DT_{50} (d)	DT_{90} (d)	Fit χ2 error (%)	Method of calculation
Gartenacker, loam	7.1	20/ pF2.5	120.07	398.9	9.2	DFOP (par) – SFO (met)
Soil B, sandy loam	6.7	25/ 75% of 1/3 bar	99.1	329	6.98	FOMC (par) – SFO (met)
Les Evouettes, Silt Loam	6.1[b]	20/ 40% MWHC	300.71	998.9	16.06	DFOP (par) – SFO (met)
Drusenheim, loam	7.4	20/ pF2.5	38.98	129.5	3.3	DFOP (par) – SFO (met)
Pappelacker, loamy sand	7.0	20/ pF2.5	126.57	420.5	6.2	FOMC (par) – SFO (met)
Speyer 2.3, loamy sand	6.9	20/ 40% MWHC	77.50	257.43	10.18	DFOP (par) – SFO (met)
Speyer 2.3, loamy sand	6.9[a]	20/ 45% MWHC	41.87	139.10	16.23	DFOP (par) – SFO (met)
Dupo, silt loam	7.3[b]	25/ 75% FC	48.32	160.5	7.57	FOMC (par) – SFO (met)
Speyer 2.1, sand	6.9[b]	20/ 40% MWHC	230.7	766	4.29	FOMC (par) – SFO (met)
Maximum (n = 9)			300.71	998.9		SFO

[a] converted from given pH in $CaCl_2$ or KCl
[b] buffer solution unknown

Metabolite AMPA	Aerobic conditions					
Modelling endpoints						
Soil type	pH (H_2O)	T (°C) / % soil moisture	f. f. ($k_{par} \rightarrow k_{met}$)	DT_{50} (d) 20 °C pF2/10kPa	Fit χ2 error (%)	Method of calculation
Gartenacker, loam	7.1	20/ pF2.5	0.1817	119.9	8.9	FOMC (par) – SFO (met)
Soil B, sandy loam	6.7	25/ 75% of 1/3 bar	0.2646	106.2	6.98	FOMC (par) – SFO (met)
Les Evouettes, Silt Loam	6.1[b]	20/ 40% MWHC	0.3618	300.9	14.00	FOMC (par) – SFO (met)
Drusenheim, loam	7.4	20/ pF2.5	0.2578	36.8	2.1	FOMC (par) – SFO (met)

Metabolite AMPA	Aerobic conditions					
Modelling endpoints						
Soil type	pH (H_2O)	T (°C) / % soil moisture	f. f. ($k_{par} \rightarrow k_{met}$)	DT_{50} (d) 20 °C pF2/10kPa	Fit χ2 error (%)	Method of calculation
Pappelacker, loamy sand	7.0	20/ pF2.5	0.1835	116.3	6.2	FOMC (par) – SFO (met)
18-Acres, clay loam	5.7	20/ pF2.5	0.2169[1)]	-[1)]	-[1)]	FOMC (par) – SFO (met)
Speyer 2.3, loamy sand	6.9	20/ 40% MWHC	0.3435	70.92	11.41	FOMC (par) – SFO (met)
Speyer 2.1, sand	6.5[a]	20/ 45% MWHC	0.520[1)]	-[1)]	-[1)]	DFOP (par) – SFO (met)
Speyer 2.2, loamy sand	6.2[a]	20/ 45% MWHC	0.6076[1)]	-[1)]	-[1)]	FOMC (par) – SFO (met)
Speyer 2.3, loamy sand	6.9[a]	20/ 45% MWHC	0.4283	42.14	16.48	FOMC (par) – SFO (met)
Dupo, silt loam	7.3[b]	25/ 75% FC	0.3637	30.5	7.57	FOMC (par) – SFO (met)
Speyer 2.1, sand	6.9[b]	20/ 40% MWHC	0.5851	230.7	4.29	FOMC (par) – SFO (met)
Geometric mean (n = 9)			-	88.84		
pH dependency			-	No		
Arithmetic mean (n = 12)			0.3595			

[a] converted from given pH in $CaCl_2$ or KCl

[b] buffer solution unknown

1) Acceptable visual fit for formation phase of AMPA, however no statistically acceptable fit for AMPA could be obtained in this pathway

Field studies

Persistence endpoints

Parent glyphosate	Aerobic conditions								
Soil type	Location	Application rate (kg a.s/ha)	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	Kinetic parameters	Fit χ2 error (%)	Method of calculation
Sandy clay	Diegten Switzerland	3.53	7.1	0-30	6.1	116.1	k1 0.1437 k2 0.0033 g 0.854	4.96	DFOP
Sandy loam	Menslage Germany	3.67	4.7	0-30	5.7	200.8	k1 0.1786 k2 0.0041 g 0.771	9.4	DFOP
Loamy sand	Buchen Germany	5.20*	6.4	0-30	40.9	187.3	k1 0.019 k2 2.3E-14 g 0.927	6.6	DFOP
Sandy loam	Kleinzecher Germany	5.7*	7.0	0-30	38.3	386.6	k1 0.0384 k2 0.0037 g 0.575	11.7	DFOP

Field studies

Persistence endpoints

Parent glyphosate	Aerobic conditions								
Soil type	Location	Application rate (kg a.s/ha)	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	Kinetic parameters	Fit χ2 error (%)	Method of calculation
Loam	Unzhurst, Germany	4.8*	6.7	0-30	27.7	122.3	k1 0.0280 k2 8.9E-4 g 0.922	8.4	DFOP
Silt loam	Rohrbach Germany	5.0*	8.5	0-30	20.1	66.9	k 0.0344	3.8	SFO Top down
Clay loam	Herrngiers-dorf Germany	4.6*	8.0	0-30	33.7	111.9	k 0.0206	10.6	SFO
Silt loam	Wang-Inzkofen Germany	4.8*	7.2	0-30	17.8	165.5	alpha 0.975 beta 17.207	8.7	FOMC
Worst case kinetics for PEC_{Soil} and as trigger for higher tier studies (n = 8)					38.3	386.6	k1 0.0384 k2 0.0037 g 0.575	DFOP Kleinzecher, Germany	
Maximum with regard to P-criterion (n = 8)					116.4	386.6	maximum overall DT_{90} (DFOP)/3.32** trial Kleinzecher		
Geomean with regard to P-criterion (n = 8)					45.2	149.96	based on overall DT90/3.32**		

* Glyphosat-trimesium as test substance

** according to EFSA DG SANCO working document on evidence needed to identify POP, PBT and vPvB properties for pesticides from 25.09.2012- rev.3

Metabolite AMPA	Aerobic conditions							
Soil type	Location	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	formation fraction (ff)	Fit χ2 error (%).	Method of calculation
Sandy loam	Kleinzecher, Germany	7.0	0-30	514.9	>1000	0.508	15.9	DFOP-SFO
Loam	Unzhurst, Germany	6.7	0-30	633.1	>1000	0.332	13.3	DFOP-SFO
Silt loam	Rohrbach, Germany	8.5	0-30	374.9	>1000	n.d.	8.6	SFO Top down
Clay loam	Herrngiers-dorf, Germany	8.0	0-30	288.4	958.1	n.d.	10.9	SFO Top down
Silt loam	Wang-Inzkofen, Germany	7.2	0-30	283.6	942.3	0.547	15.6	FOMC-SFO
Maximum (n = 5)				633.1	>1000		SFO Unzhorst, Germany	
Arithmetic mean (n = 3)						0.462		

Soil accumulation and plateau concentration	no experimental data calculation of plateau concentration see PEC_{Soil}

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent glyphosate							
Soil Type	OC %	Soil pH (H_2O)	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc}/K_{doc} (mL/g)	1/n
Drummer, silty clay loam	1.45	6.5			324.0	22300	0.92
Dupo, silt loam	0.87	7.4			33.0	3800	0.80
Spinks, loamy sand	1.10	5.2			660.0	60000	1.16
Greenan sand, sand	0.80	5.7	263	32838	-	32838	1.00
Auchincruive, sand loam	1.60	7.1	811	50660	-	50660	1.00
Headley Hall, sandy clay loam	1.40	7.8	50	3598	-	3598	1.00
Californian sandy soil, loamy sand	0.60	8.3	5	884	-	884	1.00
Les Evouettes II, silt loam	1.40	6.1	48	3404	-	3404	1.00
Darnconner sediment, loam (Sediment)	3.00	7.1	510	17010	-	17010	1.00
Lilly Field, sand	0.29	5.7			64.0	22000	0.75
Visalia, sandy loam	0.58	8.4			9.4	1600	0.72
Wisborough Green, silty clay loam	2.26	5.7			470.0	21000	0.93
Champaign, silty clay loam	2.15	6.2			700.0	33000	0.94
18 Acres, sandy loam	1.80	7.4			90.0	5000	0.76
Speyer 2.1, sand	0.62	6.5			29.5	4762	0.84
Speyer 2.2, loamy sand	2.32	6.2			71.7	3091	0.84
Speyer 2.3, loamy sand	1.22	6.9			37.7	3092	0.84
Soil 2.1, sand	0.70	5.9	66.4	9486	-	9486	1.00
Soil 2.3, loamy sand	1.34	6.3	76.5	5709	-	5709	1.00
Soil F3, sandy loam	1.20	7.3	54.4	4533	-	4533	1.00
Arithmetic mean (n = 20)						15388	0.93
pH dependency						No	-

Metabolite AMPA							
Soil Type	OC %	Soil pH (H_2O)	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
SLI Soil #1, clay loam	2.09	7.7			77.1	3640	0.79
SLI Soil #2, sand	18.68[1)]	4.7[1)]			1570.0[1)]	8310[1)]	0.9[1)]
SLI Soil #4, sand	1.33	7.4			15.7	1160	0.75
SLI Soil #5, clay loam	0.93	7.6			53.9	5650	0.79
SLI Soil #9, loamy sand	1.57	6.3			110.0	6920	0.77
SLI Soil #11, sand	0.29	4.6			73.0	24800	0.79
Lilly Field, sand	0.29	5.7			133.0	45900	0.86

Visalia, sandy loam	0.58	8.4			10.0	1720	0.78
Wisborough Green, silty clay loam	2.26	5.7			509.0	22500	0.91
Champaign, silty clay loam	2.15	6.2			237.0	11100	0.86
18 Acres, sandy loam	1.80	7.4			74.2	4130	0.84
Schwalbach, silt loam	1.59	6.1			137.4	8642	0.98
Hofheim, silt loam	1.24	6.1			87.9	7089	0.92
Bergen-Enkheim, silty clay	2.25	8.3			33.9	1507	0.91
Soil 2.1, sand	0.90	5.8			16.7	1861	0.6650
Soil 2.2, loamy sand	2.30	6.2			189.7	8248	0.5506
Soil 3A, sandy silty loam	2.60	7.6			29.1	1119	0.67109
Arithmetic mean (n = 16)						9749	0.81
pH dependency						No	-

1) Not included for calculation of statistics (mean values, correlations) due to high OC - content

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching	1st study (glyphosate): 7 soils, Eluation : 508 mm water Leachate: 0.03 - 6.56% of applied radioactivity in leachate 2nd study (glyphosate): 3 soils, Eluation: 200 mm water Leachate: 0.12 - 1.45% of applied radioactivity in leachate 3rd study (glyphosate): 3 soils Leachate: <1 µg/L - 2.6 µg/L glyphosate derivatives 4th study (glyphosate trimesium): 3 soils, Eluation: 200 mm water Leachate: <2% of applied glyphosate-trimesium
Aged residues leaching	1st study (glyphosate): 1 sand soil Aged for (d): 8 days Eluation (mm): 380mm over 48 h ^{14}C distribution after 8 days: Glyphosate: 48.6% of applied radioactivity, AMPA: 21.45% of applied radioactivity, non-extractable: 1.65% of applied radioactivity, CO_2: 2.35% of applied radioactivity 2nd study (glyphosate-trimesium): 1 sand soil Aged for (d): 30 d Eluation (mm): 200 mm water over 48 h ^{14}C distribution after 30 days: Glyphosate-^{14}C: 52 % extractable (AMPA 26 %), 12 % unextractable, 33 % CO_2; TMS-^{14}C: 10 % extractable, 21 % unextractable, 57 % CO2 0.1% / 0.5% (Glyphosate /TMS) of applied radioactivity in leachate

Lysimeter/ field leaching studies	No lysimeter or field leaching studies submitted

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	ESCAPE 2.0: input parameters k1 0.0384 ($DT_{50\ fast}$ (d): 18.05 days) k2 0.0037 ($DT_{50\ slow}$ (d): 187.34 days) g 0.575 Kinetics: DFOP (best fit, trial Kleinzecher/ Germany) Field: worst case kinetics (best fit) from field studies (not normalized)
Application data	Crop: all crops Depth of soil layer: 5 cm for $PEC_{initial}$ 20 cm for $PEC_{plateau}$ concentration for annual crops 5 cm for $PEC_{plateau}$ concentration for permanent crops Soil bulk density: 1.5 g/cm^3 % plant interception: 0 Number of applications: 1 Application rate: 4320 g as/ha (maximum application rate per ha/year for all crops as worst case approach))

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		5.7600		-	
Short term	24 h	5.6262	5.6931	-	-
	2 d	5.4971	5.6274	-	-
	4 d	5.2524	5.5005	-	-
Long term	7 d	4.9167	5.3211	-	-
	28 d	3.3372	4.3549	-	-
	50 d	2.5201	3.7072	-	-
	100 d	1.7621	2.8902	-	-

Plateau concentration	annual crops (tillage depth 20 cm): 0.2140 mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration) = 5.974 mg/kg
	permanent crops (tillage depth 5 cm): 0.8562 mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration.) = 6.6162 mg/kg

Application data	Crop: all crops Depth of soil layer: 5 cm for $PEC_{initial}$ 20 cm for $PEC_{plateau}$ concentration for annual crops 5 cm for $PEC_{plateau}$ concentration for permanent crops Soil bulk density: 1.5 g/cm^3 % plant interception: 0 Number of applications: 1 Application rate: 2 x 2160 g as/ha , interval 21 days

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		4.7514		-	
Short term	24 h	4.6524	4.7019	-	-
	2 d	4.5568	4.6533	-	-
	4 d	4.3755	4.5593	-	-
Long term	7 d	4.1263	4.4263	-	-
	28 d	2.9408	3.7186	-	-
	50 d	2.3084	3.2353	-	-
	100 d	1.6779	2.7075	-	-

Plateau concentration	annual crops (tillage depth 20 cm): 0.2058 mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration) = 4.957 mg/kg
	permanent crops (tillage depth 5 cm): 0.8232mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration.) = 5.5746 mg/kg

Application data	Crop: all crops Depth of soil layer: 5 cm for PEC initial 20 cm for $PEC_{plateau}$ concentration for annual crops 5 cm for $PEC_{plateau}$ concentration for permanent crops Soil bulk density: 1.5 g/cm^3 % plant interception: 0 Number of applications: 1 Application rate: 1 x 1080 g as/ha

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		1.440		-	
Short term	24 h	1.4065	1.4233	-	-
	2 d	1.3742	1.4068	-	-

PEC(s) (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
	4 d	1.3131	1.3751	-	-
Long term	7 d	1.2291	1.3302	-	-
	28 d	0.8340	1.0886	-	-
	50 d	0.6297	0.9266	-	-
	100 d	0.4402	0.7223	-	-

Plateau concentration	annual crops (tillage depth 20 cm): 0.0535 mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration) = 1.4935 mg/kg
	permanent crops (tillage depth 5 cm): 0.2138 mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration.) = 1.6538 mg/kg

Application data	Crop: cereals Depth of soil layer: 5 cm for $PEC_{initial}$ 20 cm for $PEC_{plateau}$ concentration for annual crops Soil bulk density: 1.5 g/cm^3 % plant interception: 90 Number of applications: 1 Application rate: 1 x 2160 g as/ha , pre-harvest

PEC(s) (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.2880		-	
Short term	24 h	0.2813	0.2847	-	-
	2 d	0.2748	0.2814	-	-
	4 d	0.2626	0.2750	-	-
Long term	7 d	0.2458	0.2660	-	-
	28 d	0.1668	0.2177	-	-
	50 d	0.1259	0.1853	-	-
	100 d	0.0880	0.1445	-	-

Plateau concentration	annual crops (tillage depth 20 cm): 0.0107 mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration) = 0.2987 mg/kg

Application data	Crop: oil seed rape Depth of soil layer: 5 cm for $PEC_{initial}$ 20 cm for $PEC_{plateau}$ concentration for annual crops Soil bulk density: 1.5 g/cm^3 % plant interception: 80 Number of applications: 1 Application rate: 1 x 2160 g as/ha , pre-harvest

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.576		-	
Short term	24 h	0.5626	0.5693	-	-
	2 d	0.5497	0.5627	-	-
	4 d	0.5252	0.5500	-	-
Long term	7 d	0.4916	0.5321	-	-
	28 d	0.3336	0.4354	-	-
	50 d	0.2519	0.3706	-	-
	100 d	0.1761	0.2889	-	-

Plateau concentration	annual crops (tillage depth 20 cm): 0.0214 mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration) = 0.5974 mg/kg

Application data	Crop: orchard crop, vines, citrus & tree nuts Depth of soil layer: 5 cm for $PEC_{initial}$ 5 cm for $PEC_{plateau}$ concentration for permanent crops Soil bulk density: 1.5 g/cm^3 % plant interception: 0 Number of applications: 3 Application rate: 3 x 2880 g as/ha , interval 28 days Soil relevant application rate*: 3 x 960 g as/ha *Because applications are made to the intra-rows (inner strips between the trees within a row) application rates per ha are expressed per 'unit of treated surface area' the actual application rate per ha orchard or vineyard will roughly only be 33 %

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		2.5490		-	
Short term	24 h	2.5031	2.5260	-	-

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
	2 d	2.4587	2.5035	-	-
	4 d	2.3744	2.4599	-	-
Long term	7 d	2.2582	2.3980	-	-
	28 d	1.6966	2.0670	-	-
	50 d	1.3837	1.8440	-	-
	100 d	1.0422	1.6473	-	-

Plateau concentration	permanent crops (tillage depth 5 cm): 0.5159 mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration) = 3.0648 mg/kg

Application data	Crop: orchard crop, vines, citrus & tree nuts Depth of soil layer: 5 cm for $PEC_{initial}$ 5 cm for $PEC_{plateau}$ concentration for permanent crops Soil bulk density: 1.5 g/cm^3 % plant interception: 0 Number of applications: 3 Application rate: 3 x 2880 g as/ha , interval 28 days Soil relevant application rate*: 3 x 1440 g as/ha *Because applications are made round base of trunk and to the intra-rows (inner strips between the trees within a row) application rates per ha are expressed per 'unit of treated surface area' the actual application rate per ha orchard or vineyard will roughly only be 33 % - 50 %)

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	3.8235		-	
Short term 24 h	3.7546	3.7890	-	-
2 d	3.6881	3.7552	-	-
4 d	3.5617	3.6898	-	-
Long term 7 d	3.3873	3.5970	-	-
28 d	2.5449	3.1005	-	-
50 d	2.0755	2.7661	-	-
100 d	1.5633	2.4709	-	-

Plateau concentration	permanent crops (tillage depth 5 cm): 0.7738 mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration) = 4.5973 mg/kg

Metabolite AMPA Method of calculation	Molecular weight relative to the parent: 0.657 DT_{50} (d): 633 days (k 0.0013) Kinetics: SFO (best fit, trial Unzhorst/ Germany) Field: Maximum value from field studies (not normalized)
Application data	Application rate assumed: 1527 g as/ha (assumed AMPA is formed at a maximum of 53.8 % of the applied dose

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		2.0360		-	
Short term	24 h	2.0338	2.0349	-	-
	2 d	2.0315	2.0338	-	-
	4 d	2.0271	2.0315	-	-
Long term	7 d	2.0205	2.0282	-	-
	28 d	1.9745	2.0051	-	-
	50 d	1.9275	1.9813	-	-
	100 d	1.8248	1.9285	-	-

Plateau concentration	annual crops (tillage depth 20 cm): 1.0359 mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration) = 3.0719 mg/kg
	permanent crops (tillage depth 5 cm): 4.1437 mg/kg after 10 years PEC_{accu} ($PEC_{initial}$ + plateau concentration) = 6.1797 mg/kg

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 %	Glyphosate: pH 5: stable (25°C) pH 7: stable (25°C) pH 9: stable (25°C) Glyphosate trimesium: pH 5: stable (25°C and 40°C) pH 7: stable (25°C and 40°C) pH 9: stable (25°C and 40°C) AMPA: no data
Photolytic degradation of active substance and metabolites above 10 %	Glyphosate: DT_{50} (experimental): 33 d (at pH 5), 69 d (at pH 7), 77 d (at pH 9) Metabolite AMPA: 16% max (at pH5), 11.6% max. (at pH 7), 6.5% max. (at pH 9) Glyphosate trimesium: DT_{50} (37°N): 81 d (at pH 7), TMS cation: stable
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not determined

Readily biodegradable (yes/no)	No OECD 301F : < 60 % after 28 days) OECD 302B : 0 - 2 % after 28 days

Degradation in water / sediment

Parent Glyphosate	Distribution: max. 61.4 % in sediment after 14 days						
Study	System	Persistence endpoints at Level P-I				Modelling endpoints at Level P-I	
		Model	DT_{50} [4] (days)	DT_{90} [4] (days)	SFO DT_{50} [4] (days)	Model	SFO DT_{50} [4] (days)
Glyphosate (total system)							
Bowler & Johnson (1999)	Cache	FOMC	8.47	45.89	13.82[5)]	FOMC	13.82[1)]
	Putah	DFOP	210.66	976.54	294.14[5)]	DFOP	329.85[2)]
Möllerfeld & Römbke (1993)	Loamy Sediment	FOMC	70.48	∞	-[6)]	-[3)]	-[3)]
	Sandy Sediment	HS	16.03	346.81	104.46[5)]	HS	154.19[2)]
Heintze (1996)	Creek	SFO	16.78	55.74	16.78	SFO	16.78
	Pond	HS	67.45	281.39	84.76[5)]	HS	92.42[2)]
Muttzall (1993)	TNO	FOMC	93.06	> 1000	>301.20[5)]	-[3)]	-[3)]
	Kromme Rijn	DFOP	28.86	232.92	70.16[5)]	DFOP	88.67[2)]
Minimum			-	-	13.82		13.82
Maximum			-	-	301.20		329.85
Geometric mean (n = 7/6[8)])			-	-	74.52		67.74
Glyphosate (water phase)							
Bowler & Johnson (1999)	Cache	HS	4.98	26.84	8.08[5)]	SFO	6.94
	Putah	FOMC	8.25	72.40	21.81[5)]	FOMC	21.81[1)]
Möllerfeld & Römbke (1993)	Loamy Sediment	FOMC	1.06	24.11	7.26[5)]	FOMC	7.26[1)]
	Sandy Sediment	DFOP	2.03	22.63	6.82[5)]	DFOP	6.82[1)]
Heintze (1996)	Creek	SFO	13.15	43.67	13.15	SFO	13.15
	Pond	HS	1.00	26.89	8.10[5)]	HS	8.10[1)]
Muttzall (1993)	TNO	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]
	Kromme Rijn	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]
Minimum			-	-	6.82		6.82
Maximum			-	-	21.81		21.81
Geometric mean (n = 6)			-	-	9.88		9.63

Glyphosate (sediment phase):							
Bowler & Johnson (1999)	Cache	SFO	34.05	113.10	34.05	SFO	34.05
	Putah	-3)	-3)	-3)	-3)	-3)	-3)
Möllerfeld & Römbke (1993)	Loamy Sediment	-3)	-3)	-3)	-3)	-3)	-3)
	Sandy Sediment	FOMC	383.86	∞	-6)	-3)	-3)
Heintze (1996)	Creek	-3)	-3)	-3)	-3)	-3)	-3)
	Pond	-3)	-3)	-3)	-3)	-3)	-3)
Muttzall (1993)	TNO	-3)	-3)	-3)	-3)	-3)	-3)
	Kromme Rijn	SFO	75.61	251.16	75.61	SFO	75.61
Minimum			-	-	34.05		34.05
Maximum			-	-	75.61		75.61
Geometric mean (n = 2)			-	-	-7)		-7)

1) Back-calculated from DT90 of bi-phasic model (DT90/3.32)
2) Calculated from slower k-rate
3) no reliable fit achieved
4) DT50 = degradation DT50 for total system, Dissipation DT50 for water and sediment phase
5) Back-calculated SFO to derive endpoints for P criteria (SFO DT50 = DT90/3.32)
6) Back-calculation of SFO DT50 not possible
7) Not calculated, since a sufficient number of DT50 values were not available
8) Number of values for deriving persistence endpoint (SFO DT50) and the modelling endpoint

Metabolite AMPA	Distribution: max. 15.7 % AR in water after 14 d, max. 18.7 % AR in sediment after 58 d						
Study	System	Persistence endpoints at Level P-I				Modelling endpoints at Level P-I	
		Model	DT_{50} 4) (days)	DT_{90} 4) (days)	SFO DT_{50} 4) (days)	Model	SFO DT_{50} 4) (days)
AMPA (total system)							
Feser-Zügner (2002)	Rückhaltebecken	FOMC	13.80	1513.00	455.72 5)	DFOP	102.87 2)
	Schäphysen	-3)	-3)	-3)	-3)	-3)	-3)
Knoch (2003)	Bickenbach	HS	10.54	191.25	57.61 5)	HS	77.83 2)
	Unter-Widdersheim	HS	77.36	307.19	92.53 5)	HS	98.98 2)
Knoch & Spirlet (1999)	Bickenbach	HS	44.53	205.21	61.81 5)	HS	69.31 2)
	Unter-Widdersheim	FOMC	20.13	885.03	266.58 5)	-3)	-3)
McEwen (2004b)	A	-3)	-3)	-3)	-3)	-3)	-3)
	B	-6)	-6)	-6)	-6)	-6)	-6)
Minimum			-	-	57.61		69.31
Maximum			-	-	455.72		102.87
Geometric mean (n = 5/4 7))			-	-	131.97		86.09
AMPA (water phase)							

Feser-Zügner (2002)	Rückhaltebecken	FOMC	2.20	22.50	6.78[5)]	FOMC	6.78[1)]
	Schäphysen	FOMC	1.00	7.80	2.35[5)]	FOMC	2.35[1)]
Knoch (2003)	Bickenbach	DFOP	2.54	47.57	14.33[5)]	DFOP	14.33[1)]
	Unter-Widdersheim	FOMC	2.13	26.31	7.92[5)]	FOMC	7.92[1)]
Knoch & Spirlet (1999)	Bickenbach	DFOP	6.59	51.47	15.50[5)]	DFOP	15.50[1)]
	Unter-Widdersheim	HS	2.02	17.15	5.17[5)]	HS	5.17[1)]
McEwen (2004b)	A	FOMC	0.69	8.87	2.67[5)]	FOMC	2.67[1)]
	B	DFOP	1.28	6.87	2.07[5)]	DFOP	2.07[1)]
Minimum			-	-	2.07		2.07
Maximum			-	-	15.50		15.50
Geometric mean (n = 8)			-	-	5.47		5.47
AMPA (sediment phase)							
Feser-Zügner (2002)	Rückhaltebecken	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]
	Schäphysen	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]
Knoch (2003)	Bickenbach	-[8)]	-[8)]	-[8)]	-[8)]	-[8)]	-[8)]
	Unter-Widdersheim	-[8)]	-[8)]	-[8)]	-[8)]	-[8)]	-[8)]
Knoch & Spirlet (1999)	Bickenbach	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]
	Unter-Widdersheim	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]
McEwen (2004b)	A	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]
	B	-[6)]	-[6)]	-[6)]	-[6)]	-[6)]	-[6)]

1) Back-calculated from DT90 of bi-phasic model (DT90/3.32)
2) Calculated from slower k-rate
3) no reliable fit achieved
4) DT50 = DegT50 for total system but DT50 for water and sediment phase
5) Back-calculated SFO to derive endpoints for P criteria (SFO DT50 = DT90/3.32)
6) excluded from kinetic evaluation due to analytical problems
7) Number of values for deriving persistence endpoint (SFO DT50) and the modelling endpoint
8) excluded from kinetic evaluation due to different amounts of AMPA in the sediment reported in the study

Metabolite HMPA	Distribution: 10.0 % & 7.5 % max. in water after 61 & 100 d (consecutive data points)

Mineralisation and non extractable residues

Water / sediment system	**pH water phase**	**pH sed.**	**Mineralisation x % after n d (end of the study)**	**Non-extractable residues in sed. max x % after n d**	**Non-extractable residues in sed. max x % after n d (end of the study)**
Cache	8.2	8.1	47.9 (100 d)	13.5 (100 d)	13.5 (100 d)
Putah	8,4	7,5	5.9 (100 d)	20.3 (58 d)	16.7 (100 d)
Bickenbach	8.6	7.8	23.5 (100 d)	22.0 (100 d)	22.0 (100 d)
Unter Widdersheim	8.6	7.7	17.8 (100 d)	13.6 (100 d)	13.6 (100 d)
Creek	-	6.64	14.77 (120 d)	17.15 (120 d)	17.15 (120 d)
Pond	-	7.85	30.08 (120 d)	49 (120 d)	.49 (120 d)

TNO	7,6	--	5.8 (91 d)	35.1 (91 d)	35.1 (91 d)
Kromme Rijn	7,2	--	25.7% (91 d)	30.5 (91 d)	30.5 (91 d)

PEC surface water and PEC sediment (Annex IIIA, point 9.2.3)

Parent Parameters used in $FOCUS_{sw}$ step 1 and 2	Version control no. of FOCUS calculator: Step1-2 (version 2.1) Molecular weight (g/mol): 169.07 Water solubility (mg/L): 10500 (pH2, 20 °C) K_{oc} (L/kg): 15844 DT_{50} soil (d): 20.51days (Laboratory, geometric mean, SFO at 20°C and pF 2) DT_{50} water/sediment system (d): 67.74 d (SFO, geometric mean at 20°C) DT_{50} water (d): 67.74 d (DT_{50} value of total system) DT_{50} sediment (d): 67.74 d (DT_{50} value of total system)
Parameters used in $FOCUS_{sw}$ step 3	Version control no.'s of FOCUS software: SWASH (version 3.1) Vapour pressure: $1.31 \cdot 10^{-5}$ Pa (calculated at 25°C) K_{oc} (L/kg): 15844 (arithmetic mean) [1)] 1/n: 0.91 (arithmetic mean) [1)] DT_{50} soil (d): 20.51 (Laboratory, geometric mean, SFO at 20°C and pF 2) DT_{50} water (d): 1000 d (default) DT_{50} sediment : 67.74 d (DT_{50} value of total system, geometric mean at 20°C) DT_{50} crop: 10 days (default) [1)] As an outcome of the discussions in the Pesticides Peer Review Meeting 126 the arithmetic mean Kfoc and 1/n values for glyphosate have been amended. The experts agreed that for the EU approval no additional exposure calculations were necessary, due to the limited effect on the mean endpoints. The correct values to be used in future PEC simulations are Kfoc:15388 and 1/n: 0.93
Application rate	Step 1: 1. Crop: Not crop specific, crops interception: no interception number of applications: 1 Application rates: 4.32 kg a.s./ha Interval (d): - Step 2: 1. Crop: Field crops (= Spring & winter cereals, field beans, maize, spring & winter oil-seed rape, sugar beets, vegetables (bulb, fruiting, leafy), grass& alfalfa & legumes) Crop interception: no interception Number of applications: 2 Application rates: 2.16 kg a.s./ha Interval (d): 21 2. Crop: Appl. Hand (crop < 50 cm) for perennials Crop interception: no interception

	Number of applications: 1 Application rates: 4.32 kg a.s./ha Interval (d): - Step 3: 1. Crop: Various Field Crops (= winter cereals, winter rape, spring cereals, potatos, spring oilseed, maize legumes) Crop interception: Calculated internally by MACRO or PRZM (Step 3 & 4) Number of applications: 1 & 2 Application rate: 2.16 kg a.s./ha Interval (d): 21 Application windows: August - November (1 application) and July - December (2 applications) for autumn applications; February - May (1 application) and Jan - May (2 applications) for spring applications - The actual dates are set by the PAT within MACRO and PRZM (Step 3 & 4) Crop: pome/ stone fruit with manually set drift rates for application to soil and trunks Crop interception: Calculated internally by MACRO or PRZM (Step 3 & 4) Number of applications:1 & 3 application rate:1 x 2.88 kg a.s./ha & 1 x 2.88 kg a.s./ha + 2 x 0.72 kg a.s./ha Application window: February - April (1 application) and February - May (3 applications)
Main routes of entry	Spray drift

FOCUS STEP 1 Scenario	Day after overall maximum	1 x 4.32 kg a.s./ha, not crop-specific	
		global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
		Actual	Actual
	0 h	104.81	10300

FOCUS STEP 2 Scenario	Day after overall maximum	2 x 2.16 kg/ha to Field crops	
		global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
		Actual	Actual
Northern EU, Oct-Feb	0 h	23.38	3570
Northern EU, Mar- May	0 h	18.49	1560
Northern EU, Jun-Sep	0 h	18.49	1560
Southern EU, Oct-Feb	0 h	19.14	2900
Southern EU, Mar- May	0 h	19.14	2900
Southern EU, Jun-Sep	0 h	18.49	2230

FOCUS STEP 2 Scenario	Day after overall maximum	1 x 4.32 kg a.s./ha to the trunks of pome/stone fruit (Appl. Hand (crop < 50 cm))	
		global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
		Actual	Actual
Northern EU, Oct-Feb	0 h	39.73	4770
Northern EU, Mar- May	0 h	39.73	2070
Northern EU, Jun-Sep	0 h	39.73	2070
Southern EU, Oct-Feb	0 h	39.73	3870
Southern EU, Mar- May	0 h	39.73	3870
Southern EU, Jun-Sep	0 h	39.73	2970

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	1 x 2.16 kg/ha to winter cereals		2 x 2.16 kg/ha to winter cereals	
			global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)	global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
D1	ditch	0 h	13.608	71.425	14.170	117.576
D1	stream	0 h	11.899	7.722	10.293	10.531
D2	ditch	0 h	13.622	57.576	12.765	85.108
D2	stream	0 h	12.116	51.082	11.182	73.995
D3	ditch	0 h	13.394	6.991	11.777	12.344
D4	pond	0 h	0.461	5.694	0.582	9.389
D4	stream	0 h	11.627	2.557	10.054	3.582
D5	pond	0 h	0.461	6.024	0.591	9.878
D5	stream	0 h	12.546	4.798	10.849	5.128
D6	ditch	0 h	13.566	45.680	12.184	67.199
R1	pond	0 h	0.461	7.989	0.592	13.831
R1	stream	0 h	8.850	25.962	7.687	47.807
R3	stream	0 h	12.277	815.228	10.841	1696.174
R4	stream	0 h	8.355	468.878	7.694	214.027

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	1 x 2.16 kg/ha to spring cereals		2 x 2.16 kg/ha to spring cereals	
			global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)	global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
D1	ditch	0 h	13.546	28.478	11.857	31.442
D1	stream	0 h	11.161	0.975	9.650	1.039
D3	ditch	0 h	13.404	7.557	11.751	12.097
D4	pond	0 h	0.461	5.319	0.531	8.505
D4	stream	0 h	10.447	0.434	9.033	0.535
D5	pond	0 h	0.460	5.224	0.541	8.360
D5	stream	0 h	8.591	0.107	8.977	0.316

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	1 x 2.16 kg/ha to spring cereals		2 x 2.16 kg/ha to spring cereals	
			global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)	global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
R4	stream	0 h	8.809	63.360	7.686	105.090

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	1 x 2.16 kg/ha to winter oil seed rape		2 x 2.16 kg/ha to winter oil seed rape	
			global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)	global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
D2	ditch	0 h	13.622	57.427	12.345	78.794
D2	stream	0 h	12.116	50.942	10.660	58.093
D3	ditch	0 h	13.538	28.639	11.940	40.701
D4	pond	0 h	0.461	5.694	0.522	8.657
D4	stream	0 h	11.627	2.557	10.054	3.134
D5	pond	0 h	0.461	5.541	0.581	8.693
D5	stream	0 h	12.546	3.617	10.849	4.919
R1	pond	0 h	0.462	5.193	0.568	8.198
R1	stream	0 h	8.887	7.750	7.684	11.546
R3	stream	0 h	12.490	160.896	10.801	227.865

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	1 x 2.16 kg/ha to spring oilseed rape		2 x 2.16 kg/ha to spring oilseed rape	
			global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)	global max PEC_{SW} (µg/L)	global max PEC_{Sed}(µg/kg)
D1	ditch	0 h	13.546	28.478	11.857	31.442
D1	stream	0 h	11.161	0.975	9.650	1.039
D3	ditch	0 h	13.427	9.793	11.738	12.996
D4	pond	0 h	0.461	5.323	0.531	8.509
D4	stream	0 h	10.447	0.434	9.033	0.535
D5	pond	0 h	0.460	5.225	0.541	8.362
D5	stream	0 h	8.591	0.107	8.977	0.316
R1	pond	0 h	0.463	9.748	0.777	28.795
R1	stream	0 h	8.616	76.161	7.591	366.862

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	1 x 2.16 kg/ha to potatoes		2 x 2.16 kg/ha to potatoes	
			global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)	global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
D3	ditch	0 h	11.115	7.604	9.649	10.454
D4	pond	0 h	0.446	4.828	0.526	7.871
D4	stream	0 h	9.298	0.485	8.001	0.615
D6, early app.	ditch	0 h	11.205	32.899	9.518	4.286

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	1 x 2.16 kg/ha to potatoes		2 x 2.16 kg/ha to potatoes	
			global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)	global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
D6, late app.	ditch	0 h	11.205	32.899	9.743	31.731
R1	pond	0 h	0.447	6.964	0.569	14.265
R1	stream	0 h	7.685	35.792	6.634	110.556
R2	stream	0 h	10.115	46.144	8.742	1730.618
R3	stream	0 h	10.824	26.095	9.360	54.887

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	1 x 2.16 kg/ha to maize		2 x 2.16 kg/ha to maize	
			global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)	global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
D3	ditch	0 h	11.102	7.605	9.644	10.945
D4	pond	0 h	0.446	5.156	0.517	8.237
D4	stream	0 h	9.064	0.376	7.800	0.469
D5	pond	0 h	0.446	5.022	0.551	7.891
D5	stream	0 h	9.802	0.423	8.443	0.507
D6	ditch	0 h	11.110	8.379	9.646	10.476
R1	pond	0 h	0.447	6.931	0.569	14.217
R1	stream	0 h	7.685	35.102	6.634	109.876
R2	stream	0 h	10.223	24.159	8.810	678.650
R3	stream	0 h	10.825	244.954	9.392	244.742
R4	stream	0 h	7.682	60.609	6.621	393.570

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	1 x 2.16 kg/ha to legumes		2 x 2.16 kg/ha to legumes	
			global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)	global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
D3	ditch	0 h	11.103	7.575	9.640	9.281
D4	pond	0 h	0.446	5.149	0.479	8.234
D4	stream	0 h	9.064	0.376	8.154	0.585
D5	pond	0 h	0.446	5.062	0.523	8.088
D5	stream	0 h	7.453	0.0929	7.751	0.273
D6	ditch	0 h	11.110	8379	9.646	10.476
R1	pond	0 h	0.446	8.786	0.648	14.159
R1	stream	0 h	7.710	73.485	6.502	100.506
R2	stream	0 h	10.198	678.046	8.765	196.543
R3	stream	0 h	10.828	244.935	9.330	505.314
R4	stream	0 h	7.678	208.671	6.611	344.072

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	2.88 kg/ha to pome/stone fruit		2.88 + 0.72 + 0.72 kg/ha to pome/stone fruit	
			global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)	global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
D3	ditch	0 h	6.209	4.161	4.537	6.484
D4	pond	0 h	0.213	2.500	0.238	4.802
D4	stream	0 h	4.594	0.137	3.748	0.446
D5	pond	0 h	0.213	2.459	0.245	4.764
D5	stream	0 h	3.971	0.0495	3.811	0.242
R1	pond	0 h	0.213	2.531	0.252	4.820
R1	stream	0 h	6.505	1.605	2.978	3.179
R2	stream	0 h	5.358	3.725	3.937	5.612
R3	stream	0 h	5.794	2.117	4.203	4.378
R4	stream	0 h	4.063	17.616	2981	25.323

Metabolite AMPA Parameters used in $FOCUS_{sw}$ step 1 and 2	Molecular weight (g/mol): 111 Water solubility (mg/L): 10500 (pH 2, 20°C) - water solubility of parent Max. occurrence in soil & water/sediment system: Soil: max. 50.1 % Water/sediment: max. 27.1 % K_{oc} (L/kg): 9749 DT_{50} soil (d): 88.84 days ((Laboratory, geometric mean, SFO at 20°C and pF 2) DT_{50} water/sediment system (d): 86.09 days (SFO, geometric mean, n = 5) DT_{50} water (d): 86.09 days (DT_{50} value of total system) DT_{50} sediment (d): 86.09 days (DT_{50} value of total system)
Parameters used in $FOCUS_{sw}$ step 3	not performed

Application rate	Step 1: 1. Crop: Not crop specific, crops interception: no interception number of applications: 1 Application rates: 4.32 kg a.s./ha Interval (d): - Step 2: 1. Crop: Field crops (= Spring & winter cereals, field beans, maize, spring & winter oil-seed rape, sugar beets, vegetables (bulb, fruiting, leafy), grass& alfalfa & legumes) Crop interception: no interception Number of applications: 2 Application rates: 2.16 kg a.s./ha Interval (d): 21 2. Crop: Appl. Hand (crop > 50 cm) for perennials Crop interception: no interception Number of applications: 1 Application rates: 4.32 kg a.s./ha Interval (d): -
Main routes of entry	Spray drift

FOCUS STEP 1 Scenario	Day after overall maximum	1 x 4.32 kg a.s./ha, not crop-specific	
		global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
		Actual	Actual
	0 h	40.90	3300

FOCUS STEP 2 Scenario	Day after overall maximum	2 x 2.16 kg/ha to Field crops	
		global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
		Actual	Actual
Northern EU, Oct-Feb	0 h	15.76	1520
Northern EU, Mar- May	0 h	6.67	628.4
Northern EU, Jun-Sep	0 h	6.67	628.4
Southern EU, Oct-Feb	0 h	12.73	1220
Southern EU, Mar- May	0 h	12.73	1220
Southern EU, Jun-Sep	0 h	9.70	924.0

FOCUS STEP 2 Scenario	Day after overall maximum	1 x 4.32 kg/ha to to the trunks of pome/stone fruit (Appl. Hand (crop < 50 cm))	
		global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
		Actual	Actual
Northern EU, Oct-Feb	0 h	17.16	1640
Northern EU, Mar- May	0 h	7.32	685.1
Northern EU, Jun-Sep	0 h	7.32	685.1
Southern EU, Oct-Feb	0 h	13.88	1320

FOCUS STEP 2 Scenario	Day after overall maximum	1 x 4.32 kg/ha to to the trunks of pome/stone fruit (Appl. Hand (crop < 50 cm))	
		global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
		Actual	Actual
Southern EU, Mar- May	0 h	13.88	1320
Southern EU, Jun-Sep	0 h	10.60	1000

Metabolite HMPA Parameters used in $FOCUS_{sw}$ step 1 and 2	Molecular weight (g/mol): 112 Water solubility (mg/L): not relevant, only maximum values were determined Max. occurrence in soil & water/sediment system: Soil: 0% Water phase: max. 10.0 % K_{oc} (L/kg): not relevant, only maximum values were determined DT_{50} soil (d): not relevant DT_{50} water/sediment system (d): not relevant, only maximum values were determined DT_{50} water (d): not relevant, only maximum values were determined DT_{50} sediment (d): not relevant, only maximum values were determined
Parameters used in $FOCUS_{sw}$ step 3	not performed
Application rate	Step 1: 1. Crop: Not crop specific, crops interception: no interception number of applications: 1 Application rates: 4.32 kg a.s./ha Interval (d): - Step 2: 1. Crop: Field crops (= Spring & winter cereals, field beans, maize, spring & winter oil-seed rape, sugar beets, vegetables (bulb, fruiting, leafy), grass& alfalfa & legumes) Crop interception: no interception Number of applications: 2 Application rates: 2.16 kg a.s./ha Interval (d): 21 2. Crop: Appl. Hand (crop > 50 cm) for perennials Crop interception: no interception Number of applications: 1 Application rates: 4.32 kg a.s./ha Interval (d): -
Main routes of entry	Formation in water

FOCUS STEP 1 Scenario	Day after overall maximum	1 x 4.32 kg a.s./ha, not crop-specific	
		global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
		Actual	Actual
	0 h	6.71	696

FOCUS STEP 2 Scenario	Day after overall maximum	2 x 2.16 kg/ha to Field crops	
		global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
		Actual	Actual
Northern EU, Oct-Feb	0 h	1.22	196
Northern EU, Mar- May	0 h	1.22	86.8
Northern EU, Jun-Sep	0 h	1.22	86.8
Southern EU, Oct-Feb	0 h	1.22	160
Southern EU, Mar- May	0 h	1.22	160
Southern EU, Jun-Sep	0 h	1.22	123

FOCUS STEP 2 Scenario	Day after overall maximum	1 x 4.32 kg/ha to the trunks of pome/stone fruit (Appl. Hand (crop < 50 cm))	
		global max PEC_{SW} (µg/L)	global max PEC_{Sed} (µg/kg)
		Actual	Actual
Northern EU, Oct-Feb	0 h	2.63	294
Northern EU, Mar- May	0 h	2.63	128
Northern EU, Jun-Sep	0 h	2.63	128
Southern EU, Oct-Feb	0 h	2.63	238
Southern EU, Mar- May	0 h	2.63	238
Southern EU, Jun-Sep	0 h	2.63	183

PEC groundwater (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model with appropriate $FOCUS_{GW}$ scenarios according to FOCUS guidance: Model: FOCUS PELMO 4.4.3 Scenarios: Châteaudun, Hamburg , Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva Crops: Winter cereals, spring cereals, potatoes, pome fruit (apples) Input parameters for glyphosate: DT_{50}: Geometric mean of the DT_{50} values of all soils: 20.51d (normalisation to 20 °C and pF2 with Q10 = 2.58) K_{oc}: Arithmetic mean of the Koc values of all soils: 15844 ml/g[1)] Freundlich exponent (1/n): Arithmetic mean of the 1/n values of all soils: 0.914[1)] Plant uptake factor: 0 (worst case assumption) [1)] As an outcome of the discussions in the Pesticides Peer Review Meeting 126 the arithmetic mean Kfoc and 1/n values for glyphosate have been amended. The experts agreed that for the EU approval no additional exposure calculations were necessary, due to the limited effect on the mean endpoints. The correct values to be used in future PEC simulations are Kfoc:15388 and 1/n: 0.93 Input parameters for the metabolite AMPA: DT_{50}: Geometric mean of the DT_{50} values of all soils: 88.84 d (normalisation to 20 °C and pF2 with Q10 = 2.58) K_{oc}: Arithmetic mean of the Koc values of all soils: 9749 ml/g Freundlich exponent (1/n): Arithmetic mean of the 1/n values of all soils: 0.853[2)] Formation fraction: 0.36 Plant uptake factor: 0 (worst case assumption) [2)] As an outcome of the discussions in the Pesticides Peer Review Meeting 126 the arithmetic mean 1/n value for AMPA has been amended. The experts agreed that for the EU approval no additional exposure calculations were necessary, due to the limited effect on the mean endpoints. The correct arithmetic mean 1/n value to be used in future PEC simulations is 0.81
Application rate	Application rate (maximum yearly for all crops): 4320 g/ha

Crop	$FOCUS_{GW}$-crop	Appli-cation rate (g /ha)	No. of appl.	Min. interval (d)	Application period
Various crops (autumn appl.)	Winter cereals	2160	2	21	Pre-planting /pre-emergence
Various crops (spring + autumn appl.)	Spring cereals	2160	2	21	Pre-planting /pre-emergence
Various crops (spring appl.)	Potatoes	2160	2	21	Pre-planting /pre-emergence
Orchards, citrus, vines, tree nuts	Pome fruit (apples)	2880/ 720/ 720	3	28	Post-emergence of weeds

PEC_{GW} - FOCUS modelling results (80th percentile annual average concentration at 1 m)

	Scenario	Parent (µg/L)	Metabolite (µg/L)
		Glyphosate	AMPA
FOCUS PELMO 4.4.3/ winter cereals	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	Jokioinen	<0.001	<0.001
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
FOCUS PELMO 4.4.3/ spring cereals	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	Jokioinen	<0.001	<0.001
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Porto	<0.001	<0.001
FOCUS PELMO 4.4.3/ potatoes	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	Jokioinen	<0.001	<0.001
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
FOCUS PELMO 4.4.3/ apples	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	Jokioinen	<0.001	<0.001
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	Not determined
Photochemical oxidative degradation in air	DT_{50} of 1.6 hours derived by the Atkinson model (version 1.92). OH (12h) concentration assumed = $1.5 \times 10^6 cm^{-3}$
Volatilisation	Volatilization from plants and soil surfaces (BBA guideline): not detectable after 24 hours (n = 2)

PEC_{air}

Method of calculation	Glyphosate: vapour pressure: 1.31 x 10^{-5} Pa at 25°C; Henry's Law Constant: 2.1 × 10^{-7} Pa m³ mol^{-1} (25 °C) Glyphosate trimesium: < 1 · 10^{-11} Pa (20 °C), Henry's Law Constant: < 2 · 10^{-9} Pa m^3 mol^{-1} → No volatilisation expected from soil and plants The calculated atmospheric life time of glyphosate is < 2 days, thus long range transport via air can be excluded

$PEC_{(a)}$

Maximum concentration	negligible

Residues requiring further assessment

Environmental occurring residues requiring assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	Soil: Glyphosate, AMPA Surface Water: Glyphosate, AMPA, HMPA Sediment: Glyphosate, AMPA Groundwater: Glyphosate, AMPA Air: Glyphosate

Monitoring data, if available (Annex IIA, point 7.4)

Soil	no data
Surface water	One study (Member states of European Union plus Norway and Switzerland, 2012): Review of surface water monitoring results throughout Europe; Glyphosate has been analyzed in 75000 surface water samples from about 4000 sites (from 1993-2011) and was detected in 33% of samples, with 23% above 0.1µg/L. The maximum concentrations of glyphosate acid found in surface water reached from 1.3 to 370 µg/L. The highest glyphosate values in surface water were detected in Sweden (370 µg/L), Ireland (186 µg/L) and Belgium (139 µg/L). The main metabolite AMPA has been analysed in about 56700 samples from nearly 3000 sites (1997-2011) and was detected in 54% of samples, with 46% above 0.1 µg/L and maximum concentrations reaching from 0.22 to > 200 µg/L
Groundwater	1st study (Italy, 2012): Investigation of glyphosate concentrations > 0.1 µg/L in 5 groundwater wells in Italy in 2007 and again in four of these wells in 2010/ 2011, glyphosate concentrations of 4 wells allocated to surface water inflow or point source contamination; for 1 well investigations still ongoing 2nd study (Germany, 2006): Officially requested investigation of glyphosate findings in concentrations > 0.1 µg/L in 5 wells and and AMPA findings in concentrations > 0.1 µg/L in 21 wells in Germany from 2005 - 2003; Five wells showed inflow of surface water or bank filtrate; one well was affected

	by a waste deposit; one well was located inside a sewage plant and showed influence of waste water; in one well the sample was contaminated since it serves as processing water well for a tank filling place. 16 findings were due to an analysis which was obviously deficient 3rd study (The Netherlands, 2010): two reports on groundwater monitoring in The Netherlands: in 6 out of 189 wells (report of 2008) and in 4 out of 169 wells (report of 2007) glyphosate concentrations were > 0.1 µg/L; some wells were not fully protected and contact with surface water may have occurred; Uncertainty was identified regarding the data processing; for 6 wells, no explanation could be found during this investigation 4th study (Sweden, 2005): investigation on glyphosate findings in concentrations of 0.045 µg/L (1st well) and 0.18 plus 0.035 µg/L (2nd well) of a groundwater catchment between August 2004 and February 2005; potential reason is a direct hydrological connectivity between surface water and shallow groundwater via an artificial drainage systems 5th study (France, 2012): Glyphosate and AMPA were detected in concentrations > 0.1 µg/L at several groundwater sampling sites throughout France; 27wells were investigated further; two sites were not further investigated due to their low vulnerability; from the 25 sites, in 19 cases, the detections in concentrations > 0.1 µg/L were sporadic (one sample of several analysis), demonstrating that the contamination was not widespread in the aquifer; in 2 wells used as drinking water supply the contaminations only occurred in one year; at four sites not used as drinking water supply, the contaminations occurred over several years, potential causes were not further investigated 6th study (Member states of European Union plus Norway and Switzerland, 2012): Review of groundwater monitoring results throughout Europe; Glyphosate has been analyzed in 66662 samples from about 675 sites (1993-2010) and detected in 1 % of samples, with 0.64 % above 0.1 µg/L; AMPA has been analyzed in 51652 samples from 1345 sites (1993 - 2011) and detected in 2.6 % of samples, with 0.77 % above 0.1 µg/L. The glyphosate detections have been reported from Denmark (4.7 µg/L) and France (24 µg/L). Findings > 0.1 µg/l have also been measured in Austria, Ireland, The Netherlands and the UK: - Austria: the findings of glyphosate were only in isolated cases , findings from AMPA were more frequent; AMPA in 2 spring water samples might also be related to aminophosphonates from detergents - France: early contaminations before 2001 most likely due to sample contamination or analytical problems; findings from 2001-2003 and more recent may warrant further investigation. From a recent study to analyze the potential contamination of groundwater with glyphosate (and AMPA) at 27 sites from 2007-

	2010, it is clear that none of the glyphosate detections could be attributed to long-term contamination of typical groundwater; majority of detections occurred once only and the small number of multiple detections occurred in shallow groundwater (spring water) or wells unsuitable for groundwater monitoring, suggesting superficial short-term contamination - Ireland: no clarification for the glyphosate groundwater findings > 0.1 µg/L presented - Switzerland: detection of glyphosate attributable to short-term contamination of shallow groundwater or spring water - The Netherlands: glyphosate and AMPA were detected once each in 10 different wells; 5 of the results were uncertain (high margins of error of measured concentration), all sampling points with positive detections were in cultivation areas with sandy or highly sandy soils, samples were taken mainly from shallow groundwater - UK: a number of positive samples and high maximum concentrations were found in Wales , which may warrant further investigation 7th study (Spain, 2012): 129 groundwater samples were collected from wells located in 11 different sampling sites in Catalonia, Spain, in an area with intensive agriculture between May and September in 2007, 2008, 2009 and 2011; the concentrations of glyphosate range from MLQQ to 2.6 µg/L, average: 202 ng/L; the pathways of glyphosate into groundwater are not investigated by the authors, several possible pathways like preferential flow or bank infiltration, etc. were suggested. Regular Federal groundwater monitoring program in Germany (1997-2009 & 2011): 89 to 430 samples taken from 1997-2007, >1500 samples taken from 2008-2009 & 2011): glyphosate was not detected in groundwater in concentrations > 0.1 µg/l for many years (1997-2001, 2003, 2006-2007). In 1996 2 samples (1.4 %), in 2002 1 sample (0.4 %), in 2004 1 sample (0.5 %) and in 2005 5 samples (2.1 %) contained glyphosate in concentrations > 0.1 µg/L; In 2008 glyphosate concentrations > 0.1 µg/L were detected in 7 samples (0.5 %), in 2009 in 6 samples (0.4 %) and in 2011 in 7 samples (0.4 %)
Drinking water	One study (2008, selected European countries): - Belgium, Germany and Ireland: no exceedances > 0.1 µg/l of glyphosate - France, The Netherlands and UK: some sporadic exceedances > 0.1 µg/l of glyphosate reported; some were attributed to problems with the analysis, once raw water was analyzed instead of rather than finished drinking water, some exceedances remain unclear but there seem to be no indication of a persistent presence in drinking water. - France and Sweden: some exceedances > 0.1 µg/l of AMPA

	- Denmark: no exceedances > 0.1 µg/l in public supplies but some in small private supplies affected by shallow groundwater with was rapid infiltration of surface water - Sweden: some glyphosate and AMPA exceedances > 0.1 µg/l were found in drinking water; no further sample details were available
Air	no data

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Candidate for Chronic (long-term) aquatic hazard. (as it is 'not readily biodegradable')

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds				
Bobwhite quail	Glyphosate acid.	Acute	4334 (extrapolated with factor 2.167)	-
Bobwhite quail	AMPA	Acute	> 2250	-
Bobwhite quail	Glyphosate acid	Short-term	>5200	-
Bobwhite quail	AMPA	Short-term	>5620	-
Bobwhite quail	Glyphosate acid	Long-term	96.3	1000
Mallard duck	Glyphosate acid	Long-term	125.3	1000
Mammals				
Rat	Glyphosate acid	Acute	> 2000	-
Rat	Glyphosate acid	Long-term	197	-
Rabbit	Glyphosate acid	Long-term	50	-
Additional higher tier studies				
- /-				

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Crop and application rate

<table>
<tr><th>Indicator species/Category[2]</th><th>Time scale</th><th>DDD (mg/kg)</th><th>TER[1, 4]</th><th>Annex VI Trigger[3]</th></tr>
<tr><td colspan="5">Screening – uptake via diet (Birds)</td></tr>
<tr><td>All crops (all seeded or transplanted crops)/
Pre-planting of crop,
Max. 2 × 2160 g a.s./ha , Min. 21 d interval
Worst case scenario: Small omnivorous bird</td><td rowspan="4">Acute</td><td>411.60</td><td>11</td><td rowspan="4">10</td></tr>
<tr><td>All crops (all seeded crops)/
Post planting/pre emergence of crop,
Max. 1 × 1080 g a.s./ha
Worst case scenario: Small omnivorous bird</td><td>171.5</td><td>25</td></tr>
<tr><td>Cereals pre harvest /crop maturity,
Max. 1 × 2160 g a.s./ha
Small omnivorous bird</td><td>343.0</td><td>13</td></tr>
<tr><td>Oilseed (pre harvest) /Crop maturity
Max. 1 × 2160 g a.s./ha
Small omnivorous bird</td><td>343.0</td><td>13</td></tr>
</table>

Indicator species/Category[2]	Time scale	DDD (mg/kg)	TER[1, 4]	Annex VI Trigger[3]
Orchard crops (vines, including citrus & and tree nuts) Post emergence of weeds Worst case use pattern and worst case scenario 1 × max. 2880 g a.s./ha 3 × max. 1440 g a.s./ha (Interval 28d) Small omnivorous bird		137.2[5] /89.2[5]	32 /49	
Tier1 – uptake via diet **(Birds)**				
All crops (all seeded or transplanted crops)/ Pre-planting of crop, Max. 2 × 2160 g a.s./ha [6], Min. 21 d interval Worst case scenarios: Medium herbiv.graniv. bird 'pigeon' Wood pidgeon (*Columba palumbus*) Shortcut value: 22.7, MAF: 1.23, fwa: 0.53/ Large herbiv. bird 'goose' Pink-foot goose (*Anser brachyrhynchus*) Shortcut value: 16.2, MAF: 1.23, fwa: 0.53	Long-term	31.96 22.81	**3** **4.2**	5
All crops (all seeded crops)/ Post planting/pre emergence of crop, Max. 1 × 1080 g a.s./ha Worst case scenarios: Med. herbiv./ graniv. bird 'pigeon' Wood pidgeon *(Columba palumbus)* Shortcut value: 22.7, fwa 0.53		13	7.41	
Cereals pre harvest /crop maturity, Max. 1 × 2160 g a.s./ha Worst case scenario: Small insectivorous bird 'passerine' (*Cisticola juncidis*) Shortcut value: 22.4, fwa 0.53		25.64	**3.8**	
Oilseed (pre harvest) /Crop maturity Max. 1 × 2160 g a.s./ha Worst case scenario: Small granivorous bird 'finch' *(Carduelis cannabina)* Shortcut value: 11.4, fwa 0.53		13.05	7.38	
Orchard crops (vines including citrus & and tree nuts) Post emergence of weeds Worst case use pattern and worst case scenario 1 × max. 2880 g a.s./ha 3 × max. 1440 g a.s./ha, interval 28d (MAF 1.16) Worst case scenario Small graniv. bird 'finch' Serin *(Serinus serinus)* Shortcut value: 12.6, fwa 0.53		9.6[5] /5.6[5]	10 /17	
Higher tier refinement – uptake via diet (Birds)				
The decline of glyphosate residue in grass was characterised using data from 22 residue trials. The average DT_{50} for the 22 trials was 2.8 days. The 21-day time weighted average (twa) for glyphosate in grass foliage has been used to calculate a refined f_{twa}. The 21-day twa is calculated to be 0.19 and the refined MAF is 1.				

Indicator species/Category[2]	**Time scale**	**DDD (mg/kg)**	**TER**[1, 4]	**Annex VI Trigger**[3]
All crops (all seeded or transplanted crops)/ Pre-planting of crop, Max. 2 × 2160 g a.s./ha , Min. 21 d interval Worst case scenarios: Medium herbiv.graniv. bird 'pigeon' Wood pidgeon (*Columba palumbus*), shortcut value 22.7, MAF: 1, fwa: 0.19/ Large herbiv. bird 'goose' Pink-foot goose (*Anser brachyrhynchus*), shortcut value 16.2, MAF: 1, fwa: 0.19	Long-term	6.65 9.32	14.48 10.34	5
Cereals pre harvest /crop maturity, Max. 1 × 2160 g a.s./ha Small insectivorous bird 'passerine' (*Cisticola juncidis*) DATA GAP				
Tier 1– uptake via drinking water (Birds)				
Not required	Acute			10
Tier 1 – secondary poisoning (Birds)				
Not required	Long-term			5
Tier 1 – uptake via diet **(Mammals)**				
All crops (all seeded or transplanted crops)/ Pre-planting of crop, Max. 2 × 2160 g a.s./ha , Min. 21 d interval (MAF 1.14) Worst case scenarios: Small herbivorous mammal 'vole' (*Microtus arvalis*), Shortcut value 136.4 Large herbivorous mammal lagomorph (rabbit, *Oryctolagus cuniculus*), Shortcut value 42.1	Acute	335.9 /103.67	**>6** />19.2	10
All crops (all seeded crops)/ Post planting/pre emergence of crop, Max. 1 × 1080 g a.s./ha Worst case scenarios: Small herbivorous mammal 'vole' (*Microtus arvalis*) Shortcut value 136.4		147.3	>13.6	
Cereals (pre harvest) wheat, rye, triticale, barley and oats/ Crop maturity Max. 1 × 2160 g a.s./ha Small herbivorous mammal 'vole' (*Microtus arvalis*) Shortcut value 40.9		88.34	>23	
Oilseed (pre harvest) rapeseed, mustard seed, linseed/ Crop maturity Max. 1 × 2160 g a.s./ha Small herbivorous mammal 'vole' (*Microtus arvalis*) Shortcut value 34.1		73.66	> 27	

Indicator species/Category[2]	**Time scale**	**DDD (mg/kg)**	**TER[1, 4]**	**Annex VI Trigger[3]**
Orchard crops (vines including citrus & tree nuts) Post emergence of weeds 28 d.interval bet.applic. Worst case use pattern and worst case scenario 1 × max. 2880 g a.s./ha 3 × max. 1440 g a.s./ha ((MAF 1.1) Small herbivorous mammal 'vole' (*Microtus arvalis*) Shortcut value 136.4		196.42[5] /108.03[5]	> 10 >18.5	
All crops (all seeded or transplanted crops)/ Pre-planting of crop, Max. 2 × 2160 g a.s./ha , Min. 21 d interval (MAF 1.23) <u>Worst case scenarios</u> Small herbivorous mammal 'vole' (*Microtus arvalis*), Shortcut value 72.3, ftwa 0.53 Small omnivorous mammals, wood mouse (*Apodemus sylvaticus*), Shortcut value 7.8, ftwa 0.53 Large herbivorous mammal lagomorph (rabbit, *Oryctolagus cuniculus),* Shortcut value 22.3 ftwa 0.53		101.8 /10.98 /31.4	**0.49** **/4.55** **/1.6**	
All crops (all seeded crops)/ Post planting/pre emergence of crop, Max. 1 × 1080 g a.s./ha <u>Worst case scenarios</u>: Small herbivorous mammal 'vole' (*Microtus arvalis*), Shortcut value 72.3, ftwa 0.53 Small omnivorous mammals Wood mouse (*Apodemus sylvaticus*), Shortcut value 7.8, ftwa 0.53 Large herbivorous mammal lagomorph (rabbit, *Oryctolagus cuniculus),* Shortcut value 22.3 ftwa 0.53	Long-term	41.48 /5.49 /15.7	**1.21** /9.1 **/3.2**	5
Cereals (pre harvest) wheat, rye, triticale, barley and oats/ Crop maturity Max. 1 × 2160g a.s./ha Small herbivorous mammal 'vole' (*Microtus arvalis*) Shortcut value 21.7 ftwa 0.53		24.69	**2.0**	
Oilseed (pre harvest) rapeseed, mustard seed, linseed/ Crop maturity Max. 1 × 2160 g a.s./ha Small herbivorous mammal 'vole' (*Microtus arvalis*) Shortcut value 18.1 ftwa 0.53		20.72	**2.4**	

Indicator species/Category[2]	Time scale	DDD (mg/kg)	TER[1, 4]	Annex VI Trigger[3]
Orchard crops (vines including citrus & tree nuts) Post emergence of weeds 28 d.interval bet.applic. Worst case use pattern and worst case scenario 1 × max. 2880 g a.s./ha 3 × max. 1440 g a.s./ha (MAF 1.16) Small herbivorous mammal 'vole' (*Microtus arvalis*), Shortcut value 72.3 ftwa 0.53		55.17 /32	**0.9** **/1.6**	
Higher tier refinement – uptake via diet (Mammals) The decline of glyphosate residue in grass was characterised using data from 22 residue trials. The average DT_{50} for the 22 trials was 2.8 days. The 21-day time weighted average (twa) for glyphosate in grass foliage has been used to calculate a refined f_{twa}. The 21-day twa is calculated to be 0.19. Also the MAF values were refined				
All crops (all seeded or transplanted crops)/ Pre-planting of crop, Max. 2 × 2160 g a.s./ha , Min. 21 d interval Small herbivorous mammal 'vole' (*Microtus arvalis*), shortcut value 72.3, MAF 1, ftwa 0.19 Small omnivorous mammals, wood (*Apodemus sylvaticus*), shortcut value 7.8, MAF 1, ftwa 0.19 Large herbivorous mammal lagomorph (rabbit, *Oryctolagus cuniculus),* Shortcut value 22.3 ftwa 0.53		29.67 /3.2 /9.15	**1.69** /15.6 /5.5	
All crops (all seeded crops)/ Post planting/pre emergence of crop, Max. 1 × 1080 g a.s./ha Worst case scenarios: Small herbivorous mammal 'vole' (*Microtus arvalis*), shortcut value 72.3, MAF 1, ftwa 0.19 Large herbivorous mammal lagomorph (rabbit, *Oryctolagus cuniculus*), Shortcut value 22.3 ftwa 0.19	Long-term	14.84 /4.6	**3.37** /11	5
Cereals (pre harvest) wheat, rye, triticale, barley and oats/ Crop maturity Max. 1 × 2160g a.s./ha Small herbivorous mammal 'vole' (*Microtus arvalis*), Shortcut value 21.7 ftwa 0.19		8.9	5.6	
Oilseed (pre harvest) rapeseed, mustard seed, linseed/ Crop maturity Max. 1 × 2160 g a.s./ha Small herbivorous mammal 'vole' (*Microtus arvalis*), Shortcut value 18.1 ftwa 0.19		7.43	6.7	

Indicator species/Category[2]	Time scale	DDD (mg/kg)	TER[1, 4]	Annex VI Trigger[3]
Orchard crops (vines including citrus & tree nuts) Post emergence of weeds 28 d.interval bet.applic. Worst case use pattern and worst case scenario 1 × max. 2880 g a.s./ha 3 × max. 1440 g a.s./ha (MAF 1) Small herbivorous mammal 'vole' (*Microtus arvalis*) Shortcut value 72.3 ftwa 0.19		19.78[5] /9.89[5]	**2.53** /5.06	
Tier 1– uptake via drinking water (Mammals)				
Not required	Acute			10
Tier 1 – secondary poisoning (Mammals)				
Not required	Long-term			5

[1] in higher tier refinement provide brief details of any refinements used (e.g. residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column
[4] TER in bold do not meet the acceptability criteria.
[5] Because applications are made round base of trunk and to the intra-rows, (inner strips between two trees within a row), application rates per ha are expressed per 'unit of treated surface area' the actual application rate per ha orchard or vineyard will only be 50%. Exposure estimations took into account the 50 % of the total application rate.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests				
Fish				
Oncorhynchus mykiss	Glyphosate acid	96 hr (static)	Mortality, EC_{50}	38 (nom.)
Lepomis macrochirus	Glyphosate acid	96 hr (static)	Mortality, EC_{50}	47 (nom.)
Danio rerio	Glyphosate acid	96 hr (semi-static)	Mortality, EC_{50}	123 (nom.)
Cyprinus carpio	Glyphosate acid	96 hr (semi-static)	Mortality, EC_{50}	> 100 (nom.)
Oncorhynchus mykiss	MON 52276	96 hr (static)	Mortality, EC_{50}	> 989 (mm.) > 306 a.e. [2]
Cyprinus carpio	MON 52276	96 hr (static)	Mortality, EC_{50}	> 895 (mm.) > 277 a.e. [2]
Oncorhynchus mykiss	AMPA	96 hr (static)	Mortality, EC_{50}	520 (mm.)
Pimephales promelas	Glyphosate acid	255days	Growth NOEC	25.7 (mm.)
Brachydanio rerio	Glyphosate acid	168 hr	Growth NOEC	1 (nom.)
Oncorhynchus mykiss	Glyphosate acid	85 days	Growth NOEC	9.6 (mm.)
Pimephales promelas	AMPA	33 days	Growth NOEC	12 (mm.)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Aquatic invertebrate				
Daphnia magna	Glyphosate acid	48 h (static)	Mortality, EC_{50}	40 (nom.)
Daphnia magna	AMPA	48 h (static)	Mortality, EC_{50}	690 (nom.)
Daphnia magna	HMPA	48 h (static)	Mortality, EC_{50}	> 100 (nom.)
Daphnia magna	MON 52276	48 h (static)	Mortality, EC_{50}	676 (nom.) 209 a.e.
Daphnia magna	Glyphosate acid	21 d (semi-static)	Reproduction, NOEC	12.5 (nom.)
Daphnia magna	AMPA	21 d (semi-static)	Reproduction, NOEC	15 (nom.)
Sediment dwelling organisms				
Chironomus riparius	Glyphosate acid	28 d (static)	NOEC	-
Algae				
Anabaena flos-aquae	Glyphosate acid	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} NOErC	8.5 (nom.) 22 (nom.) 12 (nom.)
Skeletonema costatum	Glyphosate acid	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} NOErC	11 (nom.) 18 (nom.) 1.82 (nom.)
Pseudokirchneriella subcapitata	Glyphosate acid	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} NOErC	18 (nom.) 19 (nom.) 10 (nom.)
Desmodesmus subspicatus	AMPA	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} NOErC NOEC	89.8 (nom.) 452 (nom.) 0.96(nom.) 24(nom.)
Pseudokirchneriella subcapitata	AMPA	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} NOErC	110 (nom.) 200 (nom.) 46 (nom.)
Pseudokirchneriella subcapitata	HMPA	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} NOAEC	> 115 (nom.) > 115 (nom.) 60 (nom.)
Pseudokirchneriella subcapitata	MON 52276	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} NOEC	178 (55 a.e.)[2] (nom.) 284 (88 a.e.) (nom.) 90 (28 a.e.)
Higher plant				
Lemna gibba	Glyphosate acid	14 d (semi-static)	Fronds, EC_{50} $NOEC_{empiric}$	12 (nom.) 1.5 (nom.)

Group	**Test substance**	**Time-scale (Test type)**	**End point**	**Toxicity[1] (mg/L)**
Lemna gibba	HMPA	7 d (semi-static)	Fronds, EC_{50} NOEC	> 123 (nom.) 123 (nom.)
Lemna gibba	MON 52276	7 d (semi-static)	Fronds, EC_{50} NOEC	67 (nom.) 21(a.e.) 0.9(nom.) 0.3(a.e.)
Myriophyllum aquaticum	Glyphosate acid (MON 77973)	14 d (static)	Fresh weight, relative increase, EC_{50} NOEC	12.3(nom.) << 5(nom.)
Myriophyllum aquaticum	AMPA	14 d (static)	Fresh weight, relative increase, EC_{50} dry weight, relative increase, EC_{50} for root length NOEC	70.8 (mm.) 63.2 (mm.) 31.1(mm) << 5.4 (nom.)
Myriophyllum aquaticum	MON 52276	14 d (static)	Fresh weight, relative increase, EC_{50} NOEC	4.44 a.e.[2] (mm.) < 0.3 a.e.[2] (mm.)

Microcosm or mesocosm tests - /-

Indicate if not required - /-

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

[2] a.e.: acid equivalents

Defendant's Exhibit 2323_0094

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Maximum PEC_{SW} values and TER values for Glyphosate acid – not crop specific application for all crops with maximum application rate 4.32 kg/ha glyphosate in any 12 month period across use categories, equivalent to the sum of pre-plant, pre-harvest and post-harvest stubble applications (**Focus Step 1**) and for field crops (spring & winter cereals, field beans, maize, spring & winter oil-seed rape, sugar beets, vegetables (bulb, fruiting, leafy), grass & alfalfa & legumes) with maximum application rate 2 x 2.16 kg/ha glyphosate (**Focus Step2**)

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	Fish acute	Fish prolonged	Fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Aquatic plants	Sed. dweller prolonged
			O. mykiss	*B. rerio*	*P. promelas*	*D. magna*	*D. magna*	*A. flosaquae*	*M. aquaticum*	-
			LC_{50}	NOEC	NOEC	EC_{50}	NOEC	E_bC_{50}	$\mathbf{E_bC_{50}}$	NOEC
			38000 µg/L	1000 µg/L	25700 µg/L	40000 µg/L	12500 µg/L	8500 µg/L	4400 µg/L	µg/L
FOCUS Step 1	104.81		363	9.5	245	382	119	81	42	-
FOCUS Step 2										-
North Europe (Oct-Feb)	23.38		1625	43	1099	1711	535	364	188	-
North Europe (Mar – May) and (Jun-Sep)	18.49		2055	54	1390	2163	676	460	240	-
South Europe (Oct – Feb) and (Mar - May)	19.14		1985	52	1343	2090	653	444	230	-
Annex VI Trigger			100	10	10	100	10	10	10	-

Maximum PECsw values and TER values for AMPA, Focus Step 1

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	Fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Aquatic plants	Sed. dweller prolonged
			O. mykiss	***P. promelas***	***D. magna***	***D. magna***	***D. subspicatus***	***M. aquaticum***	-
			LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	$\mathbf{E_bC_{50}}$	NOEC
			520000 µg/L	12000 µg/L	690000 µg/L	15000 µg/L	89900µg/L	31100µg/L	µg/L
FOCUS Step 1	40.93		12705	293	16858	366	2196	760	
Annex VI Trigger			100	10	100	10	10	10	-

Maximum PECsw values and TER values for HMPA, Focus Step 1

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	Fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Aquatic plants	Sed. dweller prolonged
			-	-	***D. magna***	-	***D. subspicatus***	***M. aquaticum***	-
			LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	$\mathbf{E_bC_{50}}$	NOEC
			-	-	>100000 µg/L	-	>115000 µg/L	>123000 µg/L	µg/L
FOCUS Step 1	6.71		-	-	14903	-	17139	18331	-
Annex VI Trigger			100	10	100	10	10	10	-

Bioconcentration

	Active substance			
log $P_{O/W}$	log P_{ow} of glyphosate acid and its metabolites was < 3, accumulation potential in aquatic non-target organisms is hence considered to be low			
Bioconcentration factor (BCF)[1]	BCF = 1.1 ± 0.61; steady state after 120 ± 59 d (56 d bio-concentration flow-through; *Lepomis macrochirus*)			
Annex VI Trigger for the BCF	1000			
Clearance time (days) (CT_{50})	Not relevant			
(CT_{90})	Not relevant			
Level and nature of residues (%) in organisms after the 14 day depuration phase				

[1] only required if log PO/W > 3.

* based on total 14C or on specific compounds

Effects on honeybees (Annex IIA, point 8.7, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
as	100	> 100
Preparation[1]	> 77	> 100
Metabolite 1		
Field or semi-field tests		
A field study (Thompson, 2012) was undertaken to determine the potential for toxicity to developing honey bee larvae and pupae to glyphosate (tested as the IPA salt) when fed directly to honey bee colonies. In this study the overall NOAEL (No Observed Adverse Effect Level) for brood development of honey bee colonies was 301 mg glyphosate a.e./L sucrose solution, the highest dose tested.		

[1] for preparations indicate whether endpoint is expressed in units of as or preparation

Hazard quotients for honey bees (Annex IIIA, point 10.4)

2880 g a.s. /ha; all crops*

Test substance	Route	Hazard quotient	Annex VI Trigger
as	contact	< 29	50
as	oral	29	50
Preparation	contact	< 29	50
Preparation	oral	< 38	50

*the HQs calculated with this application rate covered all the representative uses

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	Endpoint	Effect (LR_{50} g/ha[1])
Aphidius rhopalosiphi	MON 52276	Mortality (Extended laboratory (whole plant), 3D)	LR_{50} > 16.0 L product/ha (5760 g a.s./ha)
Typhlodromus pyri	MON 52276	Mortality (Extended laboratory (leaf discs), 2D)	ER_{50} ≥ 12.0 L product /ha (4320 g a.s./ha)
Aleochara bilineata	MON 52276	Mortality (Extended Laboratory (soil))	ER_{50} > 12.0 L product /ha (4320 g a.s./ha)

1 for preparations indicate whether endpoint is expressed in units of as or preparation

Crop and application rate 'All crops' 2x 2160 g a.s./ha*

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
MON 52276	*Aphidius rhopalosiphi*	> 5760	< 0.6	< 0.1	2
MON 52276	*Typhlodromus pyri*	> 4320	≤ 0.9	< 0.1	2

*the HQs calculated with this application rate covered all the representative uses

Further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	Endpoint	% effect[3]	Trigger value
Aphidius rhopalosiphi	Adults approx. 48 h old	MON 52276 Extended laboratory (barley plants, 3D)	5760, 4320, 2880, 2160, 1080 g a.s./ha	Mortality Repro-duction	LR_{50} >5760 g a.s./ha Increase in no. of mummies /female of 46.8%, 43.0% and 32.3% at 5760, 4320, 2880 g a.s./ha	50 %
Typhlodromus pyri	< 24 h	MON 52276 Extended laboratory (leaf discs, bean plants, 2D)	5760, 4320, 2880, 2160, 1080 g a.s./ha	Mortality Repro-duction	LR_{50} >5760 g a.s./ha 5760 g a.s./ha > ER_{50} ≥ 4320 g a.s./ha (reduction in no. of egg/female 45 % at 4320 g a.s./ha)	50 %
Aleochara bilineata	3 - 4 days	MON 52276 (Extended Laboratory soil, LUFA 2.1)	4320, 2880, 2160 g a.s./ha	Mortality Repro-duction	LR_{50} > 4320 g a.s./ha) ER_{50} > 4320 g a.s./ha) (effects between 1.9-18.1% on reproduction)	50 %
Field or semi-field tests - /-						
Indicate if not required - /-						

1 indicate whether initial or aged residues
2 for preparations indicate whether dose is expressed in units of as or preparation
3 indicate if positive percentages relate to adverse effects or not

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA, points 8.4 and 8.5, Annex IIIA, points 10.6 and 10.7)

Test organism	Test substance	Time scale	Endpoint[1]
Earthworms			
Eisenia fetida	Glyphosate acid	Acute 14 days	LC_{50}=5600 mg as/kg d.w.soil (mg as/ha)
Eisenia fetida	MON 52276	Acute 14 days	LC_{50} > 1250 mg/kg dry soil equivalent to LC_{50} > 388 mg a.e./kg dry soil
Eisenia andrei	AMPA	Acute 14 days	LC_{50} > 1000 mg AMPA/kg dry
Eisenia fetida	MON 0139 (63.81% w/w Glyphosate IPA salt)	Chronic 56 days	NOEC > 1000 mg /kg dry soil equivalent to NOEC > 473 mg a.e. /kg dry soil.
Eisenia fetida	AMPA	Chronic 56 days	NOEC = 131.90 mg/kg dry soil
Soil mesofauna			
Hypoaspis aculeifer	Glyphosate IPA-salt	14 d chronic	NOEC=1000 mg/kg 472.8 mg a.e./kg
Hypoaspis aculeifer	AMPA	14 d chronic	NOEC=320 mg/kg dry soil
Folsomia candida	Glyphosate IPA salt	28 d chronic	NOEC= 1000 mg/kg 587 mg a.e./kg
Folsomia candida	AMPA	28 d chronic	NOEC= 315 mg/kg
Soil micro-organisms			
Nitrogen mineralisation	Glyphosate acid (MON 77973)	28-day study	6 % effect at day 28 when applied at 33.1 mg a.e./kg dry soil (23 kg/ha)
	AMPA	28/56-day study	21% effect at day 28 at 160 mg /kg d.w.soil (120kg /ha)
	MON 52276	28-day study	8% effect at day 28 at 94 mg /kg d.w.soil (60L/ha)
Carbon mineralisation	Glyphosate acid		9.3% effect at day 28 at 6.4 mg /kg d.w.soil (4.8kg /ha)
	AMPA	28/56-day study	18% effect at day 28 at 160 mg /kg d.w.soil (120kg /ha)
	MON 52276	28-day study	15% effect at day 28 at 94 mg /kg d.w.soil (60L/ha)
Field studies[2] -/-			
Indicate if not required -/-			

[1] indicate where endpoint has been corrected due to log Po/w > 2.0 (e.g. LC50corr)
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above and earthworm field studies

Toxicity/exposure ratios for soil organisms

Maximum application rate per ha/year for all crops as worst case approach

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia fetida	Glyphosate acid	Acute, 14 d	6.6162	846	10
Eisenia fetida	MON 52276 (rec. acid equivalent)	Acute, 14 d	6.6162	59	10
Eisenia andrei	AMPA	Acute, 14 d	6.1797	59	10
Eisenia fetida	MON0139 (rec. acid equivalent)	Chronic, 56 d	6.6162	72	5
Eisenia fetida	AMPA	Chronic, 56 d	6.1797	21	5
Other soil macro-organisms					
Hypoaspis aculeifer	Glyphosate IPA-salt	Chronic, 14 d	6.6162	71	5
Hypoaspis aculeifer	AMPA	Chronic, 14 d	6.1797	52	5
Folsomia candida	Glyphosate IPA salt	Chronic, 28 d	6.6162	89	5
Folsomia candida	AMPA	Chronic ,28 d	6.1797	51	5

[1] to be completed where first Tier triggers are breached

[2] PECaccu = PECinitial + plateau concentration. a tillage depth of 5 cm was considered for calculating the background concentration

Effects on non-target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Scenario	ER_{50} (g a.s./ha)	PERin-field (g a.s./ha)	Distance (m)	PERoff-field (g a.s./ha)	TER	TER with 50 % drift reduction	TER with 75 % drift reduction	TER with 90 % drift reduction
All crops (all seeded and transplanted crops)	28.4	2 x 2160 (MAF 1.7)	1	87.4	**0.3**	**0.6**	**1.3**	**3.2**
			5	17.3	**1.6**	**3.3**	6.6	16.4
			10	9.9	**2.9**	5.7	11.5	28.7

Scenario	ER_{50} (g a.s./ha)	PERin-field (g a.s./ha)	Distance (m)	PERoff-field (g a.s./ha)	TER	TER with 50 % drift reduction	TER with 75 % drift reduction	TER with 90 % drift reduction
All crops (all seeded post planted crops)		1 x 1080	1	29.9	**0.9**	**1.9**	**3.8**	9.5
			5	6.2	**4.6**	9.2	18	46
			10	3.1	9.2	18	37	92
Orchard crops, vines including citrus & tree nuts Intra-row & Spot treatment (50% applic. rate) [4]		1 x 2880	1	79.8 x 0.5 *	**0.7**	**1.4**	**2.8**	7.1
			5	16.4 x 0.5*	**3.5**	6.9	14	35
			10	8.4 x 0.5*	6.7	14	27	68
Orchard crops, vines including citrus & tree nuts		3 x 1440 (MAF 2.3)	1	66.6 x 0.5*	**0.9**	**1.7**	**3.4**	8.6
			5	13.6 x 0.5*	**4.2**	8.4	17	42
			10	6.6 x 0.5*	8.6	17	34	86
		1 x 2880	1	79.8	**0.4**	**0.7**	**1.4**	**3.6**
			5	16.4	**1.7**	**3.5**	6.9	17
			10	8.4	**3.4**	6.8	14	34
			10	5.2	5.4	11	22	55
		3 x 1440	1	66.6	**0.4**	**0.9**	**1.7**	**4.3**
			5	13.6	**2.1**	**4.2**	8.4	21
			10	6.6	**4.3**	8.6	17	43
Cereals, Oilseeds (pre-harvest)		1 x 2160	1	59.83	**0.5**	**0.9**	**1.9**	**4.7**
			5	12.31	**2.3**	**4.6**	9.2	23.1
			10	6.32	**4.5**	9.0	18	45
TER in bold are below the relevant trigger of 5.								

* Because applications are made round base of trunk and to the intra-rows, (inner strips between two trees within a row), application rates per ha are expressed per 'unit of treated surface area' the actual application rate per ha orchard or vineyard will only be 50 % of the reported rate

Additional studies (e.g. semi-field or field studies)

-/-

Effects on biological methods for sewage treatment (Annex IIA, point 8.7)

Test type/organism	endpoint
Inhibition of respiration rate of the activated sludge	EC_{50} > 1000 mg /L

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Parent (glyphosate), Metabolite (AMPA)
water	Parent (glyphosate), Metabolite (AMPA*)
sediment	Parent (glyphosate), Metabolite (AMPA*)
groundwater	Parent (glyphosate), Metabolite (AMPA*)

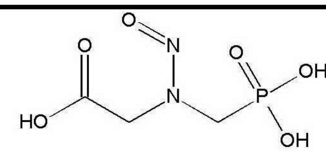
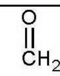
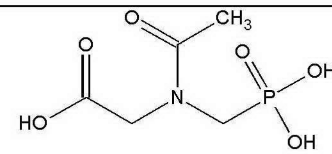
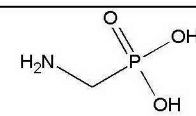
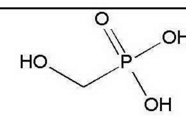
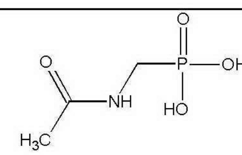
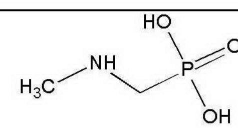
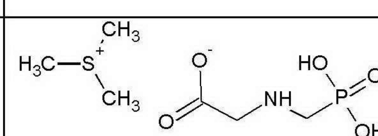
* AMPA is not ecotoxicologically relevant for the compartments water, sediment and groundwater. For precautionary reasons AMPA is proposed as relevant residue due to the frequent detections in surface waters and groundwater and the widespread intended uses of glyphosate in almost all crops.

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	Chronic 2, H411, GHS09 P273 P391 P501

Defendant's Exhibit 2323_0102

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name/SMILES notation**	Structural formula**
***N*-nitroso-glyphosate (NNG)**	[nitroso(phosphonomethyl)amino]acetic acid O=NN(CC(=O)O)CP(=O)(O)O	
formaldehyde	formaldehyde C=O	
***N*-acetyl-glyphosate**	*N*-acetyl-*N*-(phosphonomethyl)glycine OC(=O)CN(CP(=O)(O)O)C(C)=O	
AMPA	(aminomethyl)phosphonic acid NCP(=O)(O)O	
HMPA	(hydroxymethyl)phosphonic acid OCP(=O)(O)O	
***N*-acetyl-AMPA**	(acetamidomethyl)phosphonic acid CC(=O)NCP(=O)(O)O	
***N*-methyl-AMPA**	[(methylamino)methyl]phosphonic acid CNCP(=O)(O)O	
Glyphosate-trimesium	trimethylsulfonium *N*-[(hydroxyphosphinato)methyl]glycine O=C([O-])CNCP(=O)(O)O.C[S+](C)C	

* The metabolite name in bold is the name used in the conclusion.
** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOAC	AOAC international
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AUC	area under the blood concentration/time curve
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
ca.	*circa* (about)
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
CLP	classification, labelling and packaging
cm	centimetre
Cmax	concentration achieved at peak blood level
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
ED	endocrine disruption
EDSP	(US Environmental Protection Agency) Endocrine Disruptor Screening Program
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union

EUROPOEM	European Predictive Operator Exposure Model
F_0	parental generation
F_1	filial generation
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionisation detector
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GHS	globally harmonized system
GHS05	hazard pictogram (corrosion) according to GHS
GIT	gastro-intestinal tract
GM	genetically modified
GMO	genetically modified organism
GS	growth stage
GSH	Glutathione
GTF	Glyphosate Task Force
h	hour(s)
H318	hazard statement for serious eye damage according to Reg. (EC) No. 1272/2008
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IARC	International Agency for Research on Cancer
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
IPA	isopropylamine
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LLNA	local lymph node assay
LOAEL	lowest observable adverse effect level
LOD	limit of detection

LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
M&K	Maximisation test of Magnusson & Kligman
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEL	no observed effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen phosphorous detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
POEM	Predictive Operator Exposure Model
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QC	quality control
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RAR	renewal assessment report
REACH	Registration, Evaluation, Authorisation of CHemicals
RMS	rapporteur Member State
RPE	respiratory protective equipment
RUD	residue per unit dose

SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SL	soluble concentrate
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TC	technical material
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organization
wk	week
wt	weight
yr	year
↓	decrease
↑	increase