Setting of an import tolerance for glyphosate in soyabeans

EFSA (European Food Safety Authority)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Corteva submitted a request to the competent national authority in Germany to set an import tolerance for the active substance glyphosate in genetically modified (GM) soyabeans imported from the USA. The genetic modification confers tolerance to the herbicide glyphosate. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposals for soyabeans. When the MRL is calculated according to the existing residue definition for enforcement in soyabeans (glyphosate only), there is no indication that the existing MRL of 20 mg/kg needs to be modified. However, an MRL of 50 mg/kg was also calculated in line with the residue definition for enforcement which has been proposed during the MRL review for glyphosate-tolerant (CP4-EPSPS) soybeans (sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate). A risk management decision needs to be taken on the possible implementation of the residue definition for enforcement derived by the MRL review and therefore on the need to change the existing MRL for soyabeans. Adequate analytical methods for enforcement are available to control the residues of glyphosate, AMPA and N-acetyl-glyphosate in the commodity under consideration, at the validated limit of quantification (LOQ) of 0.05 mg/kg (for each compound). However, confirmatory methods for N-acetyl-glyphosate (in high water and high fat content matrices and dry commodities) and for AMPA (in all matrices) are still missing. EFSA concluded that the short-term and long-term intake of residues resulting from the existing uses of glyphosate and the import tolerance on soyabeans is unlikely to present a risk to consumer health. The chronic exposure calculation, however, is affected by uncertainties related to the data gaps identified during the MRL review and is based on the assumption that MRLs for the existing uses of glyphosate will be amended as recommended in the recent MRL review.

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Keywords: glyphosate, genetically modified tolerant crop, soyabeans, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Corteva submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to set an import tolerance for the active substance glyphosate in glyphosate-tolerant soybeans. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 19 July 2020. The EMS proposed to maintain the maximum residue level (MRL) for soybeans imported from the United States at the current level of 20 mg/kg, based on the existing residue definition according to Reg. (EU) No 396/2005 (glyphosate only); or alternatively, to raise the existing MRL to 50 mg/kg if the residue definition as proposed by the MRL review for glyphosate-tolerant (CP4-EPSPS) soybeans is implemented (‘sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate’).

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements which needed further clarification, which were requested from the EMS. On 27 May 2021, the EMS submitted the requested information in a revised evaluation report.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of glyphosate in conventional and genetically modified crops (containing EPSPS, GOX and GAT modifications) was assessed in the framework of the EU pesticides peer review and in the MRL review. All available key studies (including studies performed on EPSPS genetically modified soybeans, cotton and maize) were considered. In genetically modified plants containing the EPSPS gene expression (as relevant for the soybeans under consideration), parent glyphosate was detected as the major component of residues. Metabolite AMPA was present in lower amounts, except in soybean seeds, where glyphosate and AMPA were present at the same level. Overall, the metabolic pattern in GM crops containing EPSPS gene was similar to that observed in conventional plants. In conventional crops, the main residue is parent glyphosate, whereas in crops containing GAT modification, the main component of the radioactive residues is N-acetyl-glyphosate, and, in addition, N-acetyl-AMPA. As the proposed use of glyphosate is on imported crops investigations of residues in rotational crops were not required.

Studies investigating the effect of processing on the nature of glyphosate (hydrolysis studies) demonstrated that glyphosate and N-acetyl glyphosate are stable under the standard conditions. The effect of processing on the nature of AMPA was not investigated. However, considering the extremely simple structure of AMPA without structural elements capable of hydrolysis, AMPA is expected to be stable following processing and no additional studies were required.

Based on the metabolic pattern identified in metabolism studies with conventional and genetically modified crops, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products and the capabilities of enforcement analytical methods, two different options were proposed by the MRL review for the residue definition for enforcement: Option 1: for plants with glyphosate-tolerant genetically modified varieties currently available on the market (sweet corn, cotton seeds, sugar beets, rapeseeds, maize and soybeans): ‘sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate’; for all commodities other than sweet corn, cotton seeds, sugar beets, rapeseeds, maize and soybeans: ‘glyphosate’. Option 2: ‘sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate’ (for all commodities). The proposed enforcement residue definitions have not been yet implemented in the MRL legislation. The existing enforcement residue definition according to Regulation (EC) No 396/2005 is currently set as ‘glyphosate’ for all plant commodities. For risk assessment, the following residue definition was concluded: ‘sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, expressed as glyphosate’.

EFSA concluded that for the use under assessment on genetically modified ‘CP4-EPSPS’ soybeans, the metabolic behaviour in primary crops is sufficiently addressed and that the residue definitions proposed in the MRL review are applicable. Validated analytical methods based on high-performance liquid chromatography (HPLC) are available to control the residues of glyphosate, AMPA and N-acetyl-glyphosate in the commodity under consideration, at the validated LOQ of 0.05 mg/kg (for each compound). However, confirmatory methods for N-acetyl-glyphosate (in high water and high fat content matrices and dry commodities) and for AMPA (in all matrices) are still required (data gap relevant for the use on soybeans).
The available residue trials are sufficient to derive MRL proposals for soyabeans according to both the existing and the proposed enforcement residue definitions. According to the existing residue definition for enforcement, an MRL of 20 mg/kg is derived, which is equal to the existing MRL. According to the residue definition for enforcement (in glyphosate tolerant crops) which has been proposed during the MRL review an MRL of 50 mg/kg was also calculated. It is also noted that the MRL currently set for soyabeans in the United States is 20 mg/kg (with only glyphosate in the residue definition for enforcement). Should the proposed residue definition be implemented in the future, further risk managers considerations are required as regards the current EU MRL for soyabeans.

Processing factors (PF) for soyabeans-based processed products were derived from processing studies provided and are recommended to be included in Annex VI of Regulation (EC) No 396/2005. When considering the existing residue definition of enforcement, the PF are calculated as follows:

- Soyabeans/hulls: 6.9
- Soyabeans/presscake: 1.0
- Soyabeans/toasted meal: 0.87

When considering the residue definition of enforcement proposed during the MRL review for soyabeans, the PF are calculated as follows:

- Soyabeans/hulls: 3.8
- Soyabeans/presscake: 1.0
- Soyabeans/toasted meal: 1.0

As soybean seed and by-products from soybean oil production (soybean hulls, soybean meal) may be used for feed purposes, a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species. However, the relative contribution of glyphosate residues from the crop under consideration in this MRL application to the total livestock exposure was insignificant, and therefore, a modification of the existing MRLs for commodities of animal origin was considered unnecessary.

The toxicological profile of glyphosate was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.5 mg/kg bw per day and an acute reference dose (ARfD) of 0.5 mg/kg bw. The metabolites included in the residue definition were considered to be of similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). In accordance with the internationally agreed methodology, the short-term exposure assessment was performed only for residues in soyabeans using the median residue levels (STMR) as derived from the supervised residue field trials submitted in support of the import tolerance application. The short-term exposure did not exceed the ARfD for soybeans.

The comprehensive long-term exposure assessment performed in the MRL review (using PRIMo rev.2) was updated considering the revision 3.1 of the EFSA PRIMo and considering the new risk assessment value derived for soyabeans. Only the most critical scenario assessed during the MRL review was updated: i.e. the risk assessment with consideration of the Codex MRL (CXLs), scenario 2 (considering the optional enforcement residue definition). The contributions of commodities where no GAP or safe CXL was reported to EFSA were not included in the calculations, except for the intended uses on GAT rapeseed, GAT soyabeans and GAT maize which were evaluated by EFSA in the framework of previous MRL applications but not legally implemented so far.

Under the assumption that for the existing uses of glyphosate, the MRLs will be amended as proposed in the MRL review, the estimated long-term dietary intake was in the range of 0.4–16% of the ADI (GEMS/Food G11 diet). The maximal contribution from residues expected in soyabeans to the overall long-term exposure is 10.5% of the ADI (GEMS/Food G11 diet).

EFSA concluded that the short-term and long-term intake of residues resulting from the existing uses of glyphosate and the import tolerance on soybeans is unlikely to present a risk to consumer health. The chronic exposure calculation, however, is affected by uncertainties related to the data gaps identified during the MRL review and is based on the assumption that MRLs for the existing uses of glyphosate will be amended as recommended in the MRL review.

The peer review for the renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing, and therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.
A risk management decision needs to be taken regarding the need to amend the existing MRL for soyabeans, as explained in the summary table below. Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|-------------------------|-------------------------|-----------------------|
| 0401070 | Soyabeans | 20                      | No change               | The submitted data are sufficient to derive an import tolerance (US GAP) in soyabeans. Risk for consumers unlikely. The available data confirm the existing MRL for glyphosate and do not provide evidence that the existing MRL has to be modified. |

**Enforcement residue definition (proposed during MRL review):** sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|-------------------------|-------------------------|-----------------------|
| 0401070 | Soyabeans | –                       | Further risk management considerations required | The submitted data are sufficient to derive an import tolerance (US GAP) in soyabeans; in accordance with the enforcement residue definition proposed in the MRL review an MRL of 50 mg/kg would be derived. Risk for consumers unlikely. A risk management decision needs to be taken on the possible implementation of the residue definition for enforcement derived for soyabeans during the MRL review (EFSA, 2019b) and therefore on the need to change the existing MRL for soyabeans (to 50 mg/kg), noting that in the country of origin (US), the current MRL is 20 mg/kg (with only glyphosate in the residue definition for enforcement). |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice. (a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Setting of an import tolerance for glyphosate in soybeans
Assessment

The European Food Safety Authority (EFSA) received an application to set an import tolerance for the active substance glyphosate in glyphosate-tolerant soyabeans. The detailed description of the intended use of glyphosate in the United States in soyabeans, which is the basis for the current MRL application, is reported in Appendix A.

Glyphosate is the ISO common name for N-(phosphonomethyl)glycine (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Glyphosate was first evaluated in the framework of 91/414/EEC¹ and included in Annex I of this Directive, by Directive 2001/99/EC², which entered into force on 1 July 2002 for use as herbicide.

The active substance (including glyphosate-trimesium) was then re-evaluated for renewal of the approval in 2015 (EFSA, 2015) in the framework of Commission Regulation (EU) No 1141/2010³ as amended by Commission Implementing Regulation (EU) No 380/2013⁴, with Germany designated as RMS. The representative uses considered were spraying applications against emerged annual, perennial and biennial weeds in all crops and foliar spraying for desiccation in cereals and oilseeds (preharvest). A 5-year approval of glyphosate was granted by Commission Implementing Regulation (EU) 2017/2324⁵ of 12 December 2017 Regulation (EC) No 1107/2009⁶. Glyphosate is approved for use as herbicide only. The approval of glyphosate is due to expire in December 2022. The peer review for renewal of the approval is currently ongoing and in August 2021 the Assessment Group on Glyphosate (AGG) submitted updated versions of the renewal assessment report (RAR) and the report for harmonised labelling and classification (CLH) to EFSA and ECHA, respectively, for parallel assessment of the active substance.

The EU MRLs for glyphosate and for trimethyl-sulfonium (TMS) cation, resulting from the use of glyphosate (including glyphosate-trimesium) are established in Annexes II and IIIB of Regulation (EC) No 396/2005⁷. The review of existing glyphosate MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2019b), but the proposed modifications have not yet been implemented in the EU MRL legislation. Codex maximum residue limits (CXLs) for glyphosate have also been established by the Codex Alimentarius Commission (CAC)⁸ and a CXL of 20 mg/kg is currently set in soyabeans for the residue definition 'sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate.' In accordance with Article 6 of Regulation (EC) No 396/2005, Corteva submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to set an import tolerance for the active substance in glyphosate tolerant (EPSPS) soyabeans. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 19 July 2020. The EMS proposed to maintain the maximum residue level (MRLs) for soyabeans imported from the United States at the current level of 20 mg/kg based on the existing residue definition according to Reg. (EU) No 396/2005 (glyphosate only); or alternatively, to raise the existing MRL to 50 mg/kg if the residue definition as proposed by the MRL review for glyphosate-tolerant (CP4-EPSPS) soyabeans is implemented ('sum of glyphosate, N-acetyl-glyphosate, and express as glyphosate')

1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Directive 2001/99/EC of 20 November 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include glyphosate and thifensulfuron-methyl as active substances. OJ L 304, 21.11.2001, p. 14–16.
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/EC and establishing the list of those substances. OJ L 322, 8.12.2010, 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. 4–4.
5 Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.C/2017/8419. OJ L 333, 15.12.2017, p. 10–16.
6 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
7 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
8 For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as
AMPA and $N$-acetyl-glyphosate, expressed as glyphosate\textsuperscript{)}). EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2020), the renewal assessment report (RAR) (and its addendum) (Germany, 2013, 2015) prepared under Regulation (EC) 1107/2009, the Commission review report on glyphosate (European Commission, 2017a), the conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate (EFSA, 2015), as well as the conclusions from the reasoned opinions (EFSA, 2009, 2013) including the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2018b, 2019b).

For this application, the data requirements established in Regulation (EU) No 544/2011\textsuperscript{9} and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2017b; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011\textsuperscript{10}.

As the EU pesticides peer review for the renewal of the approval of the active substance in accordance with Regulation (EC) No 1107/2009 is currently ongoing, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer review.

A list of end points of relevant studies assessed previously is presented in Appendix B; additional end points from the studies submitted and assessed in the framework of this MRL application are also reported.

The evaluation report submitted by the EMS (Germany, 2020) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of glyphosate in conventional and genetically modified crops (containing EPSPS, GOX and GAT modifications) was assessed in the framework of the EU pesticides peer review and in the MRL review. All available key studies (including studies performed on EPSPS genetically modified soya beans (relevant for the present MRL application), cotton and maize) were considered in the MRL review (EFSA, 2019b).

The metabolism was investigated in conventional plants belonging to the fruit, root, pulses/oilseeds, cereal and miscellaneous crop groups, using either soil, foliar, hydroponic or local direct (on stem, trunk or into fruit peduncle) application of $^{14}$C-glyphosate and, in some experiments, with $^{14}$C-AMPA. No significant degradation was observed, and unchanged glyphosate was observed as the major component of the residues in most of the samples (ca. 50–80\% total radioactive residue (TRR)) with low amounts of AMPA (4–10\% TRR) and $N$-methyl-AMPA (0.3–5\% TRR in root samples). The same metabolic pattern was observed in studies representative for the use of glyphosate as desiccant and performed on wheat with foliar application.

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 beans, cotton, maize and sugar beet containing the EPSPS modification (which is also the modification of the soybeans under assessment in the present application), parent glyphosate was detected as the major component of the residues. It accounted for 24–99\% TRR in forage, hay, tops and roots of the investigated crops and for 70\% of the TRR in cotton seeds, 37\% of the TRR in maize grain and 45\% of the TRR in soybean seeds. AMPA was present in lower amounts (mostly 1–13\% TRR), except in soybeans seeds, where glyphosate and AMPA were present at the same level representing 45\% and 48\% of the TRR, respectively. Overall, the metabolic pattern was similar to that observed in conventional plants as the EPSPS modification does not affect the metabolism of glyphosate in genetically modified plants.

\textsuperscript{9} Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

\textsuperscript{10} 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.
The metabolism resulting from the introduction of the GOX modification was investigated in rapeseed and maize in combination with the EPSPS modification. Following two foliar applications, glyphosate was observed in maize forage, silage and fodder (67–83% 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, soyabeans 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 soyabean and maize forage and foliage (9–75% TRR) and in rape seeds (21%) but was almost absent in soyabean and maize seeds at harvest (0.1–3% TRR). In all plant matrices, the main component of the radioactive residues was identified as the N-acetyl-glyphosate, a metabolite formed by the action of the GAT enzyme, and accounting for 51–57% of the TRR in seeds and 18–93% TRR in the other plant parts. In addition, N-acetyl-AMPA was also identified as a major metabolite in rape and soyabean seeds, representing 15–24% TRR.

For the use under assessment on genetically modified ‘CP4-EPSPS’ soyabeans, the metabolic behaviour in primary crops is sufficiently addressed; the main residues in soyabean seeds following the intended use pattern will be glyphosate and its metabolite AMPA.

1.1.2. Nature of residues in rotational crops

Investigations of residues in rotational crops are not required for imported crops. It is however noted that the metabolism of glyphosate was investigated in rotational crops (leafy vegetables, root and tuber vegetables and cereals) (EFSA, 2019b). According to the results from the confined rotational crop studies it was concluded that the metabolism in rotational crops is similar to the metabolism in primary crops with higher relative amounts of AMPA expected due to its formation in soil. Glyphosate and AMPA were the only compounds identified in the rotated crops accounting for up to 33% TRR (wheat chaff) and 29% TRR (wheat grain), respectively.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of glyphosate was investigated in the framework of the EU pesticides peer review (EFSA, 2015) by means of standard hydrolysis studies performed with glyphosate and with N-acetyl glyphosate. Based on the results of these studies, it was possible to conclude that glyphosate and N-acetyl-glyphosate are hydrolytically stable under the standard conditions.

The effect of processing on the nature of AMPA was not investigated. However, considering the extremely simple structure of AMPA without structural elements capable of hydrolysis, AMPA is expected to be stable following processing and no additional studies are required.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of glyphosate residues in plant commodities were assessed during the peer review for the renewal of approval which concluded that glyphosate and N-acetyl-glyphosate can be enforced at the limit of quantification (LOQ) of 0.05 mg/kg for each compound in high water and high oil content, acidic and dry commodities (EFSA, 2015). The same method has also been sufficiently validated for AMPA in high water and high oil content, acidic and dry matrices. However, a confirmatory method for AMPA is not available and this has been identified as a data gap during the MRL review (EFSA, 2019b). A confirmatory method for N-acetyl-glyphosate in high water and high fat content matrices and dry commodities was also identified as a data gap during the peer review and no additional data were received so far (EFSA, 2019b).

According to the information provided by the European Union Reference Laboratories (EURLs), the following LOQs can be achieved in the different matrices: 0.02 mg/kg (for glyphosate, AMPA and N-acetyl-AMPA) and 0.01 mg/kg (for N-acetyl-glyphosate) in high water, high acid content and dry commodities; 0.1 mg/kg (for glyphosate, AMPA and N-acetyl-AMPA) and 0.05 mg/kg (for N-acetyl-glyphosate) in high oil content commodities (EFSA, 2018b). Nevertheless, analytical methods currently in place for the routine analyses could not be assessed in the MRL review since they had not been provided for the assessment. According to the validation data available from the EURLs, analytical standards for glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA are commercially available (EFSA, 2018b).
Analytical methods for the enforcement of trimethyl-sulfonium cation in plant commodities were not assessed during the peer review for renewal or in the MRL review. Nevertheless, according to the information provided by the EURLs, during routine analyses, an LOQ of 0.01 mg/kg can be achieved for the enforcement of trimethyl-sulfonium cation in the four main matrices (EFSA, 2018b).

It is concluded that sufficiently validated analytical methods are available for the enforcement of glyphosate (existing residue definition), with a limit of quantification (LOQ) of 0.05 mg/kg in high water, high oil, acidic and dry matrices. Basic validation data indicate that AMPA and N-acetyl-glyphosate can be enforced with an LOQ of 0.05 mg/kg each. Therefore, the sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate (proposed residue definition for soyabeans; see Section 1.1.6) can be enforced at the combined LOQ of 0.2 mg/kg in all matrices. Nevertheless, confirmatory methods for N-acetyl-glyphosate (in high water and high fat content matrices and dry commodities) and for AMPA (in all matrices) are still required (data gap relevant for the use on soyabeans).

1.1.5. Storage stability of residues in plants

The storage stability of glyphosate and AMPA in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2015). Residues of glyphosate and AMPA were found to be stable at −18/20°C for at least 24 months in all matrices; except for high protein content commodities where the storage stability of AMPA was not investigated. Nevertheless, considering that the storage stability of AMPA has been demonstrated for at least 24 months in the main matrices including dry commodities, this was not identified as a data gap (EFSA, 2019b).

The storage stability of N-acetyl-glyphosate and N-acetyl-AMPA in plants stored under frozen conditions was investigated in the framework of the MRL review (EFSA, 2019b). According to the results from these studies, at storage temperature of −20°C, metabolite N-acetyl-glyphosate is stable for at least 1 year in high oil, high water and dry/starch matrices and N-acetyl-AMPA is stable for at least 1 year, 18 months and 23 months in high water, high oil and dry/starch matrices, respectively.

For the crop assessed in the framework of this application (Genetically modified ‘CP4-EPSPS’ soyabeans), storage stability of residues was sufficiently investigated.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies with conventional and genetically modified crops, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products and the capabilities of enforcement analytical methods, the following residue definitions were proposed during the MRL review (EFSA, 2019b):

- residue definition for risk assessment: sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, expressed as glyphosate. This residue definition is meant to cover both conventional and genetically modified crops.
- residue definition for enforcement:

Option 1:
- for sweet corn, cotton seeds, sugar beets, rapeseeds, maize and soyabeans: sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate
- for all commodities other than sweet corn, cotton seeds, sugar beets, rapeseeds, maize and soyabeans: glyphosate

Option 2:
- for all commodities: sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate

EFSA is of the opinion that glyphosate is a sufficient marker for enforcement in conventional crops while AMPA and N-acetyl-glyphosate are only necessary for the enforcement in glyphosate tolerant crops.

11 The combined LOQ was calculated considering the sum of LOQs and molecular factors of 1.5 to convert AMPA to glyphosate and 0.8 to convert N-acetyl-AMPA to glyphosate (combined LOQ = 0.05 × 1.5 × 0.05 + 0.8 × 0.05 = 0.165, rounded up to 0.2 mg/kg).
12 Plants with glyphosate-tolerant genetically modified varieties currently available on the market.
13 Plants without glyphosate-tolerant genetically modified varieties currently available on the market.
genetically modified crop varieties (option 1). However, during the MRL review, EFSA also carried out an assessment reflecting the option 2: a general residue definition for enforcement for all plant commodities as ‘sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate’. The respective assessments of option 1 and option 2 were performed in the MRL review (EFSA, 2019b).

As regards the crop under assessment in the present opinion (i.e. genetically modified ‘CP4-EPSPS’ soyabean), the relevant residue definition for enforcement as proposed by the MRL review is the ‘sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate’. This residue definition, however, has not been yet implemented in the MRL legislation. The existing residue definition for enforcement in Regulation (EC) No 396/2005 is set as glyphosate alone. In order to accommodate the existing residue definition (glyphosate) and to anticipate the possible implementation of the enforcement residue definition as derived by the MRL review (sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate), EFSA derived two MRL proposals for soyabean in the present assessment (See Appendix B.4).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of this MRL application, the applicant submitted several residue trials performed in glyphosate-tolerant soybeans containing the 5-Enolpyruvylshikimate-3-Phosphate Synthase (2mepsps) gene.

In all available studies, the samples of soybean seeds, forage and hay were analysed for glyphosate and for metabolite AMPA. The molecular weight conversion factor of 1.52 was used to express the residues of AMPA as glyphosate equivalents. The trials do not provide results for metabolites N-acetyl-glyphosate and N-acetyl-AMPA, which are also in the residue definition for risk assessment. However, the N-acetyl compounds are not expected to occur in EPSPS-tolerant crops because they are specific to GAT-tolerant crops (See Section 1.1.1). Therefore, considering that the use under assessment is on EPSPS-tolerant soybeans, the available results for glyphosate and AMPA are sufficient to derive MRL and risk assessment values, in line with the residue definitions for monitoring (existing and proposed) and with the residue definition for risk assessment.

According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Germany, 2020). The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The description of the critical GAP parameters to be considered for this import tolerance (existing GAP on glyphosate-tolerant genetically modified EPSPS soybeans in the United States) was provided by the applicant and reported by the EMS in the evaluation report. According to the original label of the authorised US GAP, the following application patterns are defined:

- Before or at planting of soybean plants: 1 ‘pre-emergence’ application at the maximum rate of 4.20 kg a.s./ha;

Once the pre-emergence treatment is done, the remaining amount of glyphosate (max 2.52 kg/ha) can be applied on soybeans according to two different application modes:

- After emergence of the crop until end of flowering (BBCH 65): application(s) at maximum 1.68 kg a.s./ha can be performed on the crops (also called ‘in-crops’ application). This application can be split or repeated, provided that the total application from emergence to harvest does not exceed 2.52 kg a.s./ha. Furthermore, the total amount applied during flowering should not exceed 1.68 kg a.s./ha.
- Until 14 days before harvest: 1 application at max 0.84 kg a.s./ha can be performed provided that the total combined application from emergence to harvest does not exceed 2.52 kg a.s./ha.

Consequently, two different critical treatment regimes, both with an application of 1.68 kg as/ha during flowering and a total application rate from emergence to harvest not exceeding 2.52 kg a.s./ha, are identified. These two patterns differ on the timing of application of the additional 0.84 kg as/ha (i.e. before flowering or preharvest). The two critical treatment regimes have been tested in the available side-by-side residue trials:

1) 'In-crop’ only: 0.84 kg as/ha before flowering followed by 1.68 kg as/ha during flowering (2.52 kg as/ha total)
Ten independent trials were performed according to this application pattern. In these trials, one pre-emergence application was performed at ca. 4 kg a.s./ha and two ‘in-crops’ applications were performed before BBCH 65 (first at 0.80–0.91 kg as/ha before flowering and second at 1.5–1.8 kg as/ha during flowering). These trials were therefore all considered appropriate to support the authorised GAP on genetically modified (EPSPS) soyabean in the United States (scenario with ‘in crops’ applications).

2) ‘In-crop’ plus pre-harvest: 1.68 kg as/ha during flowering combined with 0.84 kg as/ha pre-harvest (2.52 kg as/ha total)

Ten independent trials were performed according to this application pattern. In these trials, one pre-emergence application was performed at ca. 4 kg a.s./ha and one ‘in-crops’ application was performed at ca. 1.7–1.8 kg a.s./ha (during flowering and before BBCH 65). The last application ranged between 0.84 and 0.88 kg a.s./ha and was always performed within 13–15 days PHI, in accordance with the GAP. These trials were therefore all considered appropriate to support the authorised GAP on genetically modified (EPSPS) soyabean in the United States (scenario with ‘in crops’ and preharvest applications).

The respective residue data sets according to both options of the label are reported in Appendix B.1.2.1. The two sets of trials indicated that both treatment regimes result in similar residue concentrations in harvested seeds. It is concluded that using the maximum annual in-crop rate either before BBCH 65 (two subsequent sprayings; pre-flowering and during flowering) or in combination with a preharvest treatment (one spraying at BBCH 65 in combination with the maximum preharvest rate) does not have an impact on the final residues. The same MRLs would be derived from both data sets.

The available data were used to derive MRL and risk assessment values according to the existing residue definition for enforcement (glyphosate) (an MRL proposal of 20 mg/kg) and according to the proposed residue definition for enforcement (sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate) (an MRL proposal of 50 mg/kg).

The data also allowed to derive a median conversion factor of 2.8 to convert data from the existing residue definition for enforcement (glyphosate) to the residue definition for risk assessment (sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, expressed as glyphosate).

1.2.2. Magnitude of residues in rotational crops

Investigations of residues in rotational crops are not required for imported crops.

1.2.3. Magnitude of residues in processed commodities

One processing trial performed with soyabean was submitted in the present application (Germany, 2020). The study investigates the effect of the processing of soyabean oil production on the magnitude of glyphosate and AMPA residues in oil (crude and refined) and its by-products (hulls, aspirated grains, toasted and untoasted meal). In this trial (performed at two locations in the USA), glyphosate was applied on tolerant variety of soyabeans (containing the 2mepsps gene), representative of the GAP under assessment. In the raw agricultural commodity (RAC) samples, concentration of glyphosate and AMPA was above the LOQ. Therefore, all trials could be used to assess the effect of processing on the magnitude of the relevant residues.

It is noted that processing factors (PFs) have also been previously derived in the framework of the MRL review based on processing studies performed on conventional soyabean and on GAT-modified soyabean (EFSA, 2019b). However, considering the importance of metabolite AMPA and the irrelevance of N-acetyl-compounds in the total residues found in EPSPS modified soyabean, it is not deemed relevant to merge these previous data with the new trial performed on EPSPS-tolerant soyabean. Therefore, for the present assessment, only the new trials were considered to derive PFs.

The new trials indicated that oil processing leads to a clear reduction of the residues (<LOD) in crude oil and refined oil. On the opposite, a concentration of total residues (sum of glyphosate and AMPA) is observed in soyabean hulls. As regards meal (untoasted presscake and toasted), the residue concentrations were comparable to concentrations observed in RAC, leading to PF of 1 in those matrices.

Different PFs were derived according to the proposed residue definition for enforcement in RAC and processed commodities for tolerant crops (sum of glyphosate, AMPA, N-acetyl-glyphosate, expressed as glyphosate) and according to the existing residue definition for enforcement in all RAC and processed commodities (glyphosate). As the samples were not obtained from GAT-tolerant crops, the level of N-acetyl glyphosate can be considered as zero. The overview of the derived processing factors is provided in Appendix B.1.2.3.
When considering the proposed residue definition for enforcement, conversion factors (CF) are not necessary (CF = 1) because AMPA is considered in both enforcement and risk assessment residue definitions and N-acetyl-glyphosate is not present in RAC and processed commodities for EPSPS tolerant crops. When considering the existing residue definition for enforcement, CFs from enforcement to risk assessment were derived to consider the presence of AMPA in the residue definition for risk assessment, since this compound is not part of the existing residue definition for enforcement.

The number and quality of the processing studies are acceptable and are sufficient to derive robust processing factors which can be recommended for inclusion in Annex VI of Regulation (EC) No 396/2005, except for aspirated grains, where a tentative PF was derived from two trials, with a difference of more than 50% between the two results. EFSA acknowledges that according to the data requirements applicable for the assessment of this MRL application, at least one additional trial would be required. However, the submitted studies are fully valid and compliant with the data requirements of Regulation (EU) No 283/2013, therefore, the lack of additional trial is considered a minor data gap.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodity under evaluation (soyabeans) based on the GAP reported in Appendix A, noting that both treatment regimes (using the maximum annual in-crop rate either before BBCH 65 or in combination with a preharvest treatment) result in similar residue concentrations in harvested seeds. The same MRLs would be derived from both treatment regimes. In Section 3, EFSA assessed whether residues on soyabeans and its by-products resulting from the authorised use in USA are likely to pose a consumer health risk.

According to the existing residue definition for enforcement (glyphosate), an MRL of 20 mg/kg is derived, which is equal to the existing MRL. It is noted that this MRL was not derived during the MRL review because no import tolerances for EPSPS modified soyabeans were reported during the GAP collection phase of the MRL review (EFSA, 2019b).

Furthermore, an MRL of 50 mg/kg is also calculated in order to consider the residue definition for enforcement in glyphosate-tolerant crops – sum of glyphosate, AMPA, N-acetyl glyphosate, expressed as glyphosate – which has been proposed for this crop during the MRL review. This higher MRL is due to the importance of metabolite AMPA in the total residues found in EPSPS modified soyabeans. It is noted that the MRL in the country of origin is set at 20 mg/kg, with only glyphosate in the residue definition for enforcement.

2. Residues in livestock

Soyabean seed and by-products from soyabean oil production (soyabean hulls, soyabean meal) may be used for feed purposes. Hence, it was necessary to estimate whether the residues in soyabeans from the import tolerance under evaluation would have an impact on the residues expected in food of animal origin.

EFSA updated the calculations performed in the MRL review (EFSA, 2019b) where livestock dietary burden calculations were performed for different groups of livestock according to OECD guidance (OECD, 2013), reflecting to two different scenarios:

- Scenario 1: all existing uses of glyphosate (see Appendix D.1 in EFSA, 2019b)
- Scenario 2: all existing uses of glyphosate plus the intended uses on GAT-tolerant crops assessed in previous MRL applications (rapeseed, soyabeans and maize) (see Appendix G in EFSA, 2019b).

In the present opinion, an update of the scenario 2 (the most comprehensive one) was performed by adding the input values for soyabean seeds, soyabean hulls and soyabean meal as derived from the submitted residue trials and processing studies. The authorised use on soyabeans in the United States results in more critical residue values than those used for soyabean in the MRL review. The risk assessment values derived from the GAP under assessment and the PFs and CFs derived from the

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14 Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, p. 1-84.

15 https://www.ecfr.gov/cgi-bin/text-idx?SID=a3b6495316cc17c31211db2edd81f789&mce=true&node=pt40.24.180&rgn=div5#se40.26.180_1364
processing trials submitted in the present application were used. The default processing factors for the by-products were not considered. Input values used for the dietary burden assessment are presented in Appendix D.1.

The results of the livestock dietary burden calculation are presented in Section B.2. The calculated dietary burden resulted to be the same as in the MRL review for cattle (13.1 mg/kg bw per day) and sheep (17.7 mg/kg bw per day). A negligible increase is observed for the maximum dietary burdens of swine (2.92 vs. 2.83 mg/kg bw per day) and for poultry (2.20 vs. 2.15 mg/kg bw per day). Based on these results, it is concluded that the import tolerance of glyphosate-tolerant soyabeans (expressing EPSPS gene) is not expected to alter the overall dietary burden (for glyphosate and AMPA). This is mainly due to the major contribution of residues from the existing uses of glyphosate on grass forage and wheat (straw). Consequently, the outcome of the MRL review (EFSA, 2019b) remains valid. The MRL and risk assessment values previously derived in the MRL review for commodities of animal origin are unchanged, noting that in the absence of confirmatory methods for glyphosate in fat, liver and kidney, and for AMPA and N-acetyl-glyphosate in all matrices, all derived MRLs should still be considered tentative only (EFSA, 2019b).

As regards the N-acetyl compounds, the import tolerance on glyphosate tolerance soyabeans (EPSPS) is not expected to have any impact on the dietary burden previously calculated for N-acetyl-glyphosate and N-acetyl-AMPA because these compounds are not formed in EPSPS-tolerant crops. Consequently, the calculations previously derived for the N-acetyl compounds (see Appendix G in EFSA, 2019b) also remain unchanged.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019a). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference value (TRV) for glyphosate used in the risk assessment (acceptable daily intake (ADI) value of 0.5 mg/kg bw per day and acute reference dose (ARfD) of 0.5 mg/kg bw) were derived in the framework of the EU pesticides peer review (European Commission, 2017a,b). The metabolites included in the current risk assessment residue definition were considered to be of a similar toxicity as the parent compound. It should be noted that in the framework of the renewal of the approval of glyphosate, which is currently ongoing, a reassessment of the toxicological properties of glyphosate and its metabolites will be carried out. However, the current application is assessed with the endpoints as set by European Commission (European Commission, 2017a,b).

The short-term exposure assessment was performed only for soyabeans, the commodity under consideration in this application. Commodities of animal origin were not considered since addition of soyabeans to the livestock diet did not affect the magnitude of residues in animal commodities. For soyabeans, the calculations were based on the median residue levels (STMR) derived from supervised field trials supporting the import tolerance under assessment. The complete list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for soyabeans (see Appendix B.3).

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed (using PRIMO rev.2; EFSA, 2007), taking into account the existing uses at EU level and the CXLs taken over in EU legislation (EFSA, 2019b). In addition, a second risk assessment has also been carried out during the MRL review, including all existing uses and CXLs, plus intended uses on GAT-tolerant rapeseed, soyabeans and maize, which were evaluated by EFSA in the framework of previous MRL applications (EFSA, 2009, 2013) but not legally implemented so far (see Appendix G in EFSA, 2019b).

These previous calculations are now updated using the revision 3.1 of the EFSA PRIMo and considering the new risk assessment values derived for soyabeans (STMRRA = 14.1 mg/kg) based on the import tolerance under assessment. It is noted that two scenarios were assessed during the MRL review according to the two possible options16 for monitoring residue definitions (see list of endpoints Appendix B.1.1.1). Although the residue definition for risk assessment was the same in both cases, the MRLs derived according to the optional definition can be higher than the MRLs derived according to the mandatory definition. A negligible increase is observed for the maximum dietary burdens of swine (2.92 vs. 2.83 mg/kg bw per day) and for poultry (2.20 vs. 2.15 mg/kg bw per day). Based on these results, it is concluded that the import tolerance of glyphosate-tolerant soyabeans (expressing EPSPS gene) is not expected to alter the overall dietary burden (for glyphosate and AMPA). This is mainly due to the major contribution of residues from the existing uses of glyphosate on grass forage and wheat (straw). Consequently, the outcome of the MRL review (EFSA, 2019b) remains valid. The MRL and risk assessment values previously derived in the MRL review for commodities of animal origin are unchanged, noting that in the absence of confirmatory methods for glyphosate in fat, liver and kidney, and for AMPA and N-acetyl-glyphosate in all matrices, all derived MRLs should still be considered tentative only (EFSA, 2019b).

As regards the N-acetyl compounds, the import tolerance on glyphosate tolerance soyabeans (EPSPS) is not expected to have any impact on the dietary burden previously calculated for N-acetyl-glyphosate and N-acetyl-AMPA because these compounds are not formed in EPSPS-tolerant crops. Consequently, the calculations previously derived for the N-acetyl compounds (see Appendix G in EFSA, 2019b) also remain unchanged.

16 Option 1 (main residue definition): For glyphosate-tolerant genetically modified plant varieties currently available on the market (sweet corn, cotton seeds, sugar beets, rapeseed, maize and soyabeans): sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate; For all other plant commodities: glyphosate. Option 2 (optional residue definition): For all plant commodities (including plants with glyphosate-tolerant genetically modified varieties currently available on the market): sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate.
the main residue definition, because with the optional residue definition, a higher LOQ applies to all commodities for which a no residue situation can be anticipated (0.2 mg/kg instead of 0.05 mg/kg). For this reason, the scenario of the optional residue definition (scenario 2) was more critical and was updated in the framework of the present assessment. The contributions of commodities where no GAP or Codex MRL (CXL) was reported to EFSA were not included in the calculations, except for the intended uses on GAT rapeseed, GAT soyabeans and GAT maize which were evaluated by EFSA in the framework of previous MRL applications (EFSA, 2009, 2013) but not legally implemented so far. The input values used in the exposure calculations are summarised in Appendix D.2.

Under the assumption that for the existing uses of glyphosate, the MRLs will be amended as proposed in the MRL review, the estimated long-term dietary intake was in the range of 0.4–16% of the ADI. The maximal contribution from residues expected in soyabeans (assessed in this application) to the overall long-term exposure is 10.5% ADI (GEMS/Food G11 diet) and presented in more detail in Appendix B.3.

Although uncertainties remain due to the data gaps identified during the MRL review (see data gaps in EFSA, 2019b), this indicative exposure calculation did not indicate a risk to consumer health. EFSA concluded that the long-term intake of residues of glyphosate resulting from the existing uses and the authorised use of glyphosate on soyabeans in the USA is unlikely to present a risk to consumer health.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for soyabeans. According to the existing residue definition for enforcement (glyphosate), an MRL of 20 mg/kg is derived, which is equal to the existing MRL. It is noted that this MRL was not derived during the MRL review because no import tolerances on EPSPS-modified soyabeans were reported during the GAP collection phase of the MRL review. However, as long as the residue definition for enforcement proposed during the MRL review for soyabeans and other glyphosate tolerant crops (sum of glyphosate, AMPA, N-acetyl glyphosate, expressed as glyphosate) is not implemented in the legislation, a change of the existing MRL value (20 mg/kg) is not needed for soyabeans.

Furthermore, an MRL of 50 mg/kg was also calculated in order to consider the residue definition for enforcement in glyphosate-tolerant crops (sum of glyphosate, AMPA, N-acetyl glyphosate, expressed as glyphosate) which has been proposed during the MRL review. So far this residue definition has not been implemented in the MRL legislation. It is also noted that the MRL currently set for soyabeans in the United States is 20 mg/kg (with only glyphosate in the residue definition for enforcement). Should the proposed residue definition be implemented in the future, further risk management considerations are required as regards the current EU MRL for soyabeans. Furthermore, it is highlighted that data gaps linked to the enforcement of the sum of glyphosate, AMPA, N-acetyl glyphosate, expressed as glyphosate were identified during the MRL review (confirmatory methods for N-acetyl-glyphosate (in high water and high fat content matrices and dry commodities) and confirmatory methods for AMPA (in all matrices)) are missing.

Based on the assumption that residue definitions and MRL proposals derived by the MRL review for the existing glyphosate uses will be implemented, EFSA concluded that the existing uses and the authorised use of glyphosate on soyabeans will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health. The consumer risk assessment shall be regarded as indicative since affected by uncertainties related to the data gaps identified in the MRL review.

The MRL recommendations are summarised in Appendix B.4.

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**Abbreviations**

- **a.s.** active substance
- **ADI** acceptable daily intake
- **ARfD** acute reference dose
- **BBCH** growth stages of mono- and dicotyledonous plants
- **bw** body weight
- **CAC** Codex Alimentarius Commission
- **CAS** Chemical Abstract Service
- **CF** conversion factor for enforcement to risk assessment residue definition
- **CIRCA** (EU) Communication & Information Resource Centre Administrator
- **CS** capsule suspension
- **CV** coefficient of variation (relative standard deviation)
- **CXL** Codex maximum residue limit
- **DALA** days after last application
- **DAR** draft assessment report
- **DAT** days after treatment
- **DM** dry matter
- **DS** powder for dry seed treatment
- **EDI** estimated daily intake
- **EMS** evaluating Member State
- **FAO** Food and Agriculture Organization of the United Nations
- **FID** flame ionisation detector
- **GAP** Good Agricultural Practice
- **GC** gas chromatography
- **GC-FID** gas chromatography with flame ionisation detector
- **GC-MS** gas chromatography with mass spectrometry
- **GC-MS/MS** gas chromatography with tandem mass spectrometry
- **GS** growth stage
- **HPLC** high-performance liquid chromatography
- **HPLC-MS** high-performance liquid chromatography with mass spectrometry
- **HPLC-MS/MS** high-performance liquid chromatography with tandem mass spectrometry
- **HR** highest residue
- **IEDI** international estimated daily intake
- **IESTI** international estimated short-term intake
- **ILV** independent laboratory validation
- **ISO** International Organisation for Standardisation
- **IUPAC** International Union of Pure and Applied Chemistry
- **LC** liquid chromatography
- **LOD** limit of detection
- **LOQ** limit of quantification
- **MRL** maximum residue level
- **MS** Member States
- **MS** mass spectrometry detector
- **MS/MS** tandem mass spectrometry detector
- **MW** molecular weight
- **NEU** northern Europe
- **OECD** Organisation for Economic Co-operation and Development
- **PBI** plant back interval
- **PF** processing factor
- **PHI** preharvest interval
- **PRIMo** (EFSA) Pesticide Residues Intake Model
- **QuEChERS** Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
- **RA** risk assessment
- **RAC** raw agricultural commodity
RD  residue definition
SANCO  Directorate-General for Health and Consumers
SC  suspension concentrate
SEU  southern Europe
SL  soluble concentrate
SP  water-soluble powder
STMR  supervised trials median residue
TAR  total applied radioactivity
TRR  total radioactive residue
UV  ultraviolet (detector)
WHO  World Health Organization
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|-----------------------------------|-------------|-------------|--------------------------------|
| Soyabeans (tolerant with 2mepsps gene) | USA F | Weeds | SL 479 g/L | Spraying 1\(^{(a)}\) (pre-emergence): before or at planting 2nd (‘in-crops’): during flowering (up to BBCH 65) 3rd (preharvest) | Pre-emergence: 1 ‘in crops’: variable (see remarks) Preharvest: 1 | Up to 4.8% 38 minimum | 1st: 4.20 kg a.s./ha 2nd: 1.68 3rd: 0.84 kg a.s./ha | 14 | Ground air application. In-crop application (after emergence up to BBCH 65) can be split and/or repeated. During flowering stage (‘R2 stage’, BBCH 65), the maximum total rate (either single treatment or sum of split treatment rates) is limited to 1.68 kg a.s./ha. The total combined rate of applications between emergence and harvest should not exceed 2.52 kg a.s./ha. |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SL: formulation type, soluble (liquid) concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to 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.
(d): PHI – minimum preharvest interval.
### Appendix B – List of end points

#### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

#### B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crops       | Applications                                                                                     | Sampling (DAT) | Comment/ Source |
|----------------------------------|-------------|-------------|------------------------------------------------------------------------------------------------|---------------|-----------------|
| Conventional crops               | Fruit crops | Mandarins   | Soil or foliar, 1 × 2.24 kg/ha                                                                  | 119           | EFSA (2019b)    |
|                                  |             |             | Hydroponic, 10 mg/L solution                                                                   | 7, 14         | EFSA (2019b)    |
|                                  |             |             | Foliar, 1 × 4 mg/leaf                                                                          | 7-56          | EFSA (2019b)    |
|                                  | Almonds     | Soils, 1 × 5.1 kg/ha                                                                          | 112           | EFSA (2019b)    |
|                                  | Walnuts     | Foliar, 1 × 0.1 mg/leaf                                                                        | 14, 35        | EFSA (2019b)    |
|                                  | Pecans      |                                                        |               |                 |
|                                  | Apples      | Soil, 1 × 3.4 kg/ha glyphosate or 1.7 kg/ha AMPA                                               | 42, 84        | EFSA (2019b)    |
|                                  |             | Trunk, 1 × 0.09 mg/plant                                                                       | 8, 42         | EFSA (2019b)    |
|                                  |             | Foliar, 1 × 0.005 mg/4-5 leaves                                                                | 7 to 70       | EFSA (2019b)    |
|                                  | Grapes      | Soil spraying, 8 kg/ha split in 2 applications (glyphosate-trimesium)                          | 14, 365       | EFSA (2019b)    |
|                                  |             | Foliar, 0.03 g/plant split in 2 applications                                                    | 14            | EFSA (2019b)    |
|                                  |             | Soil drench, 1 × 8 kg/ha (glyphosate-trimesium)                                                | 7             | EFSA (2019b)    |
|                                  |             | Soil, 1 × 3.4 kg/ha (glyphosate) or 1.7 kg/ha AMPA                                             | 42, 84        | EFSA (2019b)    |
|                                  |             | Trunk, 1 × 0.04 mg/plant                                                                       | 42, 84        | EFSA (2019b)    |
|                                  |             | Hydroponic, 5, 10, 20 or 40 mg/L solution                                                      | 10, 21, 42    | EFSA (2019b)    |
|                                  |             | Foliar, 1 × 0.01, 0.06 or 0.12 mg/plant                                                       | 7-70          | EFSA (2019b)    |
|                                  | Avocados    | Onto the leaf, rate not reported                                                               | 10            | EFSA (2019b)    |
|                                  |             | Into fruit peduncle, a 453000 cpm solution                                                     | Not reported  | EFSA (2019b)    |
|                                  | Root crops  | Potatoes    | Soil, 1 × 5.75 × 10⁸ dpm                                                                      | 9-128         | EFSA (2019b)    |
|                                  |             | Foliar, 1 × 0.1 mg/plant                                                                       | 1-34          | EFSA (2019b)    |
|                                  | Sugar beet  | Soil, 1 × 4.5 kg/ha                                                                           | 28, 49, 56    | EFSA (2019b)    |
|                                  | Cereals/grass crops | Barley, Oat, Rice, Sorghum | Soil, 1 × 4.5 kg/ha | 28, 49, 56 | EFSA (2019b) |
|                                  |             | Hydroponic, 0.183 mg/L solution                                                                | 7, 14, 28     | EFSA (2019b)    |
|                                  |             | Maize, Wheat | Soil, 1 × 4.5 kg/ha glyphosate or 1.7 kg/ha AMPA                                             | 28, 49, 56    | EFSA (2019b)    |
|                                  |             | Hydroponic (solution or substrate), equivalent to 2.24 kg/ha                                   | 4, 10, 18     | EFSA (2019b)    |
|                                  |             | Hydroponic, 0.6-2.4 mg/L solutions                                                             | 6-28          | EFSA (2019b)    |
|                                  | Wheat       | Foliar, 1 × 6 kg/ha (glyphosate-trimesium)                                                     | 7             | EFSA (2019b)    |
| Crop groups                  | Crops                          | Applications                                    | Sampling (DAT) | Comment/Source |
|-----------------------------|--------------------------------|-------------------------------------------------|----------------|----------------|
| Primary crops (available studies) |                                |                                                 |                |                |
| Maize                       | Soil, 1 × 5.1 kg/ha (glyphosate-trimesium) | Study informative only.                         | 33, 48, 154    | EFSA (2019b)   |
| Rice                        | Soil, 1 × 2.5 kg/ha            |                                                 | 31, 47, 73, 122| EFSA (2019b)   |
| Pulses/oilseeds             | Cotton, Soyabeans             | 1 × 4.5 kg/ha (glyphosate) or 1.7 kg/ha (AMPA)  |                | EFSA (2019b)   |
|                             | Hydroponic (solution or substrate), equivalent to 2.24 kg/ha |                  | 4, 10, 18      | EFSA (2019b)   |
|                             | Hydroponic, 2.4 to 2.65 mg/L solutions |                                             | 6–28           | EFSA (2019b)   |
| Soyabeans                   | Soil drench, 1 × 8.4 kg/ha (glyphosate-trimesium) |            | 31, 97         | EFSA (2019b)   |
|                             | Foliar, not reported. Study informative only. |                                | 0–14           | EFSA (2019b)   |
|                             | Soil, 1 × 4.35 kg/ha. Study informative only. |                                    |                | EFSA (2019b)   |
|                             | Hydroponic, 4.4 mg/L solution. Study informative only. |                            | 9              | EFSA (2019b)   |
| Miscellaneous               | Coffee                        | Soil, 1 × 4.5 kg/ha (glyphosate) or 4.5 kg/ha (AMPA) |                | EFSA (2019b)   |
|                             | Hydroponic, 1.1, 3.6 or 11.1 mg/L solution |                                            | 21             | EFSA (2019b)   |
|                             | Stem application, 700 g solution |                                              | 35             | EFSA (2019b)   |
|                             | Foliar, 7.7 × 10^6 to 1.5 × 10^9 dpm |                                       | 21–35          | EFSA (2019b)   |
| Sugar cane                  | Soil, 1 × 11.2 kg/ha, pre-planting |                                               | 195, 354       | EFSA (2019b)   |
|                             | Soil, 1 × 3.4 or 6.7 kg/ha, post-planting |                                       | 0, 91, 83      | EFSA (2019b)   |
|                             | Foliar, 1 × 5.6 or 11.2 kg/ha, post-emergence |                                    | 40, 42, 44, 47 | EFSA (2019b)   |
| Pasture                     | Soil, 1 × 4.5 kg/ha. Study informative only. |                                    | 42, 84, 126, 168 and 224 | EFSA (2019b) |
|                             | Pre-planting weed spraying, 1.7 kg/ha. Study informative only. |                       | 42, 84, 126 168 | EFSA (2019b)   |
|                             | Foliar, 1.1 kg/ha. Study informative only. |                                                  | 63, 105 and 161 | EFSA (2019b)   |
|                             | Foliar, 1.1 kg/ha. Study informative only. |                                                  | 7              | EFSA (2019b)   |
| EPSPS and GOX tolerant crops |                                |                                                 |                |                |
| Pulses/oilseeds             | Oilseed rape (EPSPS and GOX)   | Foliar, 1 × 0.455 kg/ha, BBCH 14                 | 87             | EFSA (2019b)   |
|                             | Foliar, 2 × 0.9 kg/ha, 14 and 22 days after planting |                                           | 79             | EFSA (2019b)   |
|                             | Soyabeans (EPSPS)              | Soil, 1 × 5.4 kg/ha                           |                | EFSA (2019b)   |
|                             | Foliar, 1 × 0.84 kg/ha (BBCH 23) |                                      | 56, 84, 104    | EFSA (2019b)   |
|                             | Foliar, 0.84 kg/ha (BBCH 23) + 1.68 kg/ha (BBCH 51) |          | 35, 63, 83     | EFSA (2019b)   |
|                             | 4.2 kg/ha (pre-sowing) + 1.26 kg/ha (BBCH 13) |                          | 13, 41, 61     | EFSA (2019b)   |
|                             | 4.2 kg/ha (pre-sowing) + 1.26 kg/ha (BBCH 65) |                                   | 0, 60          | EFSA (2019b)   |
|                             | Foliar, 1.1 kg/ha. Study informative only. |                                                  |                | EFSA (2019b)   |
| Primary crops (available studies) | Crop groups | Crops | Applications | Sampling (DAT) | Comment/Source |
|----------------------------------|-------------|-------|--------------|----------------|----------------|
| Cotton (EPSPS)                   | Foliar, 930 g/ha (BBCH 14) + 1260 g/ha, (BBCH 16) | 27, 158 | EFSA (2019b) |
|                                  | 2.5 kg/ha (pre-emergence) + 2 × 1.7 kg/ha (BBCH 15 and 19) + 0.84 kg/ha (7 days preharvest) | 168 | EFSA (2019b) |
| Root crops                       | Sugar beet (EPSPS) | 1 × 0.9 kg/ha (pre-emergence) + 1.08 kg/ha (BBCH 19) | 160 | EFSA (2019b) |
|                                  | Foliar, 1 × 1.08 kg/ha (BBCH 14) + 1.08 kg/ha (BBCH 19) | 92 | EFSA (2019b) |
| Cereals                          | Maize (EPSPS and GOX) | Foliar, 1 × 0.9 kg/ha (BBCH 16) + 0.8 kg/ha (BBCH 19) | 3, 49–53, 83 | EFSA (2019b) |
|                                  | Maize (EPSPS) | 1 × 4.2 kg/ha (after sowing) + 3 × 0.84 kg/ha | 65, 96, 131 | EFSA (2019b) |

| GAT-tolerant crops               | Crop groups | Crops | Applications | Sampling |
|----------------------------------|-------------|-------|--------------|----------|
| Pulses/oilseeds                  | Oilseed rape | 4.5 kg/ha (pre-emergence) + 3 × 1.9 kg/ha (BBCH 12 and 15 and 7 days preharvest) | At BBCH 69, 87, 89 (7 DALA) | EFSA (2019b) |
| Soyabeanse                        | 3.4 kg/ha (pre-emergence) + 1.5 (BBCH 61) + 2.4 (BBCH 65) + 0.9 kg/ha (14 days preharvest) | 36 DATsoil, 82 DAT₂, 14 DALA | EFSA (2019b) |
| Cereals                          | Maize       | 4.3 kg/ha (pre-emergence) + 3 × 1.1 kg/ha (at BBCH 31, 39 and 87) | 48 DATsoil, 59 DAT₂, 7 DALA | EFSA (2019b) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|-------------------------------------|-------------|---------|----------------|-----------|
| Root/tuber crops                    | Beets       | Soil before sowing soyabeanos or wheat (primary), 4.5 kg/ha | 120 | EFSA (2019b) |
|                                    |             | Soil before sowing cabbages (primary), 4.5 kg/ha | 360 | EFSA (2019b) |
|                                    |             | Soil before sowing soyabeanos (primary), 2 × 4.5 kg/ha | 30 | EFSA (2019b) |
| Carrots                            | Foliar on rye grass, 4.2 kg/ha | 30, 120, 365 | EFSA (2019b) |
|                                    | Foliar on peas (primary), 4.5 kg/ha | 1–23 | EFSA (2019b) |
|                                    | Foliar on cabbages (primary), 4.5 kg/ha | 1–23 | EFSA (2019b) |
| Radishes                           | Bare soil, 6.5 kg a.s./ha | 30, 120, 365 | EFSA (2019b) |
|                                    | Foliar on soyabean (primary), 4.4 kg/ha + bare soil 1.4 kg/ha + 0.75 kg ha (glyphosate-trimesium) | 63, 308 | EFSA (2019b) |
|                                    | Foliar on soyabean (primary), 1 × 3.87 kg/ha (glyphosate-trimesium) | 35 | EFSA (2019b) |
| Leafy crops                        | Cabbages    | Foliar on peas (primary), 4.5 kg/ha | 1–23 | EFSA (2019b) |
|                                    |             | Foliar on carrots (primary), 4.5 kg/ha | 1–23 | EFSA (2019b) |
|                                    | Soil before sowing beets (primary), 4.5 kg/ha | 120 | EFSA (2019b) |
| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s)                                                                 | PBI (DAT) |
|--------------------------------------|-------------|---------|--------------------------------------------------------------------------------|-----------|
|                                      |             |         | Soil before sowing soyabeans (primary), 4.5 kg/ha                              | 360       |
|                                      |             |         | Soil before sowing cabbages (primary), 2 × 4.5 kg/ha                         | 30        |
| Lettuces                             |             |         | Foliar on rye grass, 4.2 kg/ha.                                              | 30, 120, 365 |
|                                      |             |         | Bare soil, 6.5 kg a.s./ha                                                     | 30, 120, 365 |
|                                      |             |         | Foliar on soyabeans (primary), 4.4 kg/ha + bare soil 1.4 kg/ha + 0.75 kg ha (glyphosate-trimesium) | 63, 308   |
|                                      |             |         | Foliar on soyabeans (primary), 1 × 3.87 kg/ha (glyphosate-trimesium)          | 35        |
| Cereals (small grain)                | Barley      |         | Foliar on rye grass, 4.2 kg/ha.                                              | 30, 120, 365 |
|                                      | Maize       |         | Foliar on beans (primary), 4.5 kg/ha                                          | 1–23      |
|                                      | Wheat       |         | Bare soil, 6.5 kg a.s./ha                                                     | 30, 120, 365 |
|                                      |             |         | Soil before sowing cabbages (primary), 4.5 kg/ha                             | 360       |
|                                      |             |         | Soil before sowing beets (primary), 4.5 kg/ha                                | 30        |
|                                      |             |         | Soil before sowing wheat (primary), 2 × 4.5 kg/ha                            | 120       |
|                                      |             |         | Foliar on soyabeans (primary), 4.4 kg/ha + bare soil 1.4 kg/ha + 0.75 kg ha (glyphosate-trimesium) | 63, 308   |
|                                      |             |         | Foliar on soyabeans (primary), 1 × 3.87 kg/ha (glyphosate-trimesium)          | 35        |
| Others                               | Legumes beans and legumes peas | Foliar on carrots (primary), 4.5 kg/ha                                       | 1–23      |
|                                      |             |         | Foliar on cabbages (primary), 4.5 kg/ha                                       | 1–23      |
| Processed commodities (hydrolysis study) | Conditions   | Investigated? | Pasteurisation (20 min, 90°C, pH 4)                                        | Yes       |
|                                      | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes |
|                                      | Sterilisation (20 min, 120°C, pH 6) | Yes |

Parent and N-acetyl-glyphosate were found to be stable. AMPA was not investigated but considering the simple structure of AMPA without structural elements capable of hydrolysis, AMPA is expected to be stable following processing and additional studies are not required EFSA (2019b).
### Plant residue definition for monitoring (RD-Mo)

**Option 1 (main residue definition):**
- For plants with glyphosate tolerant genetically modified varieties currently available on the market (sweet corn, cotton seeds, sugar beets, rapeseeds, maize and soyabeans): sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate.
- For all other plant commodities: glyphosate.

**Option 2 (optional residue definition):**
- For all plant commodities (including plants with glyphosate tolerant genetically modified varieties currently available on the market): sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate.

[EFSA notes that the proposed residue definitions reported under Option 1 and Option 2 have not been implemented in the MRL legislation. In the present assessment, the MRL proposals for soyabeans were derived for the existing residue definition (glyphosate) and for the proposed residue definition (sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate)].

### Plant residue definition for risk assessment (RD-RA)

- Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, expressed as glyphosate.

### Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

- HPLC-MS/MS; high water and high oil content, acidic and dry commodities; LOQ = 0.05 mg/kg each for glyphosate, AMPA and N-acetyl-glyphosate; ILV available for glyphosate (EFSA, 2019b).
- Confirmatory methods for AMPA (in all matrices) and N-acetyl-glyphosate (in high water and high fat content matrices and dry commodities) not available. A fully validated analytical method in complex matrices is not available.

### Stability of residues in plants

| Plant products (available studies) | Category | Commodity       | T (°C) | Stability (Months) | Source          |
|-----------------------------------|----------|-----------------|--------|-------------------|-----------------|
| **Glyphosate**                    | High water content | **Tomatoes**       | –18    | 31 months         | EFSA (2019b)    |
|                                  | High oil content    | **Soyabeans**      | –20    | 24 months         | EFSA (2019b)    |
|                                  | Dry/high protein    | **Dry beans**      | –18    | 18 months         | EFSA (2019b)    |
|                                  | Dry/high starch     | **Sorghum grain**  | –20    | 48 months         | EFSA (2019b)    |

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; GC-MS: gas chromatography with mass spectrometry; LC-MS/MS: liquid chromatography with tandem mass spectrometry; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

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**B.1.1.2. Stability of residues in plants**
| Plant products (available studies) | Category | Commodity | T (°C) | Stability (Months) | Source       |
|-----------------------------------|----------|-----------|--------|--------------------|--------------|
|                                   | High acid content | Oranges   | –18    | 24 months         | EFSA (2019b) |
|                                   | Other     | Rye straw | –20    | 45 months         | EFSA (2019b) |
| **AMPA**                          | High water content | Soyabean forage | –18    | 24 months         | EFSA (2019b) |
|                                   | High oil content | Soyabean   | –20    | 24 months         | EFSA (2019b) |
|                                   | Dry/high protein | –         | –      | –                 | –            |
|                                   | Dry/high starch | Maize grain | –18    | 31 months         | EFSA (2019b) |
|                                   | High acid content | Oranges   | –18    | 24 months         | EFSA (2019b) |
|                                   | Other     | Soyabeans straw | –20    | 24 months         | EFSA (2019b) |
| **N-acetyl-glyphosate**           | High water content | Soyabean forage, maize green plant and forage | –20    | 12 months         | EFSA (2019b) |
|                                   | High oil content | Soyabean seeds | –20    | 12 months         | EFSA (2019b) |
|                                   | Dry/high protein | –         | –      | –                 | –            |
|                                   | Dry/high starch | Maize grain | –20    | 12 months         | EFSA (2019b) |
|                                   | High acid content | –         | –      | –                 | –            |
|                                   | Other     | Soyabeans straw, maize stover | –20    | 12 months         | EFSA (2019b) |
| **N-acetyl-AMPA**                 | High water content | Maize stover, Soyabean forage, maize green plant and forage | –20    | 12 months         | EFSA (2019b) |
|                                   | High oil content | Soyabean seeds | –20    | 18 months         | EFSA (2019b) |
|                                   | Dry/high protein | –         | –      | –                 | –            |
|                                   | Dry/high starch | Maize grain | –20    | 23 months         | EFSA (2019b) |
|                                   | High acid content | –         | –      | –                 | –            |
|                                   | Other     | Soyabeans straw, maize stover | –20    | 12 months         | EFSA (2019b) |
## B.1.2. Magnitude of residues in plants

### B.1.2.1. Summary of residues data from the supervised residue trials

| Commodity                      | Region | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR(a) (mg/kg) | STMR(b) (mg/kg) | CF(c) |
|--------------------------------|--------|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| *Soyabeans (GAP 'in crop')*   | US     | **Mo:** 0.84; 0.90; 1.7; 2.2; 4.6; 4.9; 7.4; 7.5; 8.0; 12 Ra:** 2.6; 2.1; 4.5; 6.1; 14.8; 13.4; 21; 18; 19; 28 | Residue trials on glyphosate-tolerant genetically modified soybean (containing a 2mepsps gene) compliant with GAP. Trials compliant with GAP 'in-crop': 4.2 kg as/ha pre-emergence + 0.84 kg as/ha pre-flowering + 1.68 kg as/ha at flowering. The existing EU MRL and the current MRL in the country of origin is 20 mg/kg. | 20                     | Mo: 12       | RA: 28         | 2.6   |
| *Soyabeans (GAP 'pre-harvest')* | US     | **Mo:** 0.8; 1.2; 1.8; 3.4; 4.2; 4.6; 6.1; 6.6; 8.1; 9.8 Ra:** 3.0; 3.2; 5.2; 5.5; 12; 13.6; 18; 16; 19; 24 | Residue trials on glyphosate-tolerant genetically modified soybean (containing a 2mepsps gene) compliant with GAP. Trials compliant with GAP 'pre-harvest': 4.2 kg as/ha pre-emergence + 1.68 kg as/ha at flowering + 0.84 preharvest, PHI: 14 days. The existing EU MRL and the current MRL in the country of origin are 20 mg/kg. | 20                     | Mo: 9.8      | RA: 24         | 2.8   |

Proposed residue definition for enforcement according to MRL review (EFSA, 2019b): **sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate**

Risk assessment residue definition (RA): sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, expressed as glyphosate(d) [Only glyphosate and AMPA metabolite were analyzed in the available trials. However, as N-acetyl-glyphosate and N-acetyl-AMPA are not expected to occur in EPSPS tolerant crops, results corresponding to the 'sum of glyphosate and AMPA, expressed as glyphosate' are in line with the residue definition for risk assessment.

| Commodity                      | Region | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR(a) (mg/kg) | STMR(b) (mg/kg) | CF(c) |
|--------------------------------|--------|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| *Soyabeans (GAP 'in crop')*   | US     | **Mo:** 2.1; 2.6; 4.5; 6.1; 14.8; 18; 19; 21; 28 Ra:** 2.1; 2.6; 4.5; 6.1; 14.8; 18; 19; 21; 28 | Residue trials on glyphosate-tolerant genetically modified soybean (containing a 2mepsps gene) compliant with GAP. Trials compliant with GAP 'in-crop': 4.2 kg as/ha pre-emergence + 0.84 kg as/ha pre-flowering + 1.68 kg as/ha at flowering. | 50                     | Mo: 28       | RA: 28         | 14.1  |

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| Commodity                  | Region | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR(a) (mg/kg) | STMR(b) (mg/kg) | CF(c) |
|----------------------------|--------|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|----------------|--------|
| Soyabean (GAP 'pre-harvest') | US     | **Mo**: 3.0; 3.2; 5.2; 5.5; 12; 13.6; 16; 18; 19; 24 **RA**: 3.0; 3.2; 5.2; 5.5; 12; 13.6; 16; 18; 19; 24 | Residue trials on glyphosate-tolerant genetically modified soyabean (containing a 2mepsps gene) compliant with GAP. Trials compliant with GAP 'pre-harvest': 4.2 kg as/ha pre-emergence + 1.68 kg as/ha at flowering + 0.84 pre harvest, PHI: 14 days. | 50                     | **Mo**: 24    | **RA**: 24     | n.r.   |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
(a): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(b): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(d): The molecular weight conversion factor of 1.52 was used to express the residues of AMPA as glyphosate equivalents.
B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?

| Not triggered | Investigations of residues in rotational crops are not required for imported crops. |
|---------------|----------------------------------------------------------------------------------|

Residues in rotational and succeeding crops expected based on field rotational crop study?

| Not triggered | Investigations of residues in rotational crops are not required for imported crops. |
|---------------|----------------------------------------------------------------------------------|

B.1.2.3. Processing factors

| Processed commodity                      | Number of valid studies | Processing Factor (PF) | CFp<sup>(a)</sup> | Comment/Source |
|------------------------------------------|-------------------------|------------------------|-------------------|----------------|
| | | Individual values | Median PF | |
| Soyabeans, hulls                       | 2                       | 3.6; 4.1               | 3.8               | 1              |
| Soyabeans, aspirated grains              | 2                       | 0.24; 0.55             | 0.39              | 1              |
| Soyabeans, untoasted meal (presscake)   | 2                       | 1.00; 1.04             | 1.0               | 1              |
| Soyabeans, toasted meal                  | 2                       | 0.98; 1.01             | 1.0               | 1              |
| Soyabeans, crude oil                     | 2                       | < 0.02; < 0.13         | < 0.1<sup>(b)</sup> | 1              |
| Soyabeans, refined oil                   | 2                       | < 0.02; < 0.13         | < 0.1<sup>(b)</sup> | 1              |
| Soyabeans, hulls crude oil               | 2                       | 6.11; 7.62             | 6.9               | 1              |
| Soyabeans, aspirated grains              | 2                       | 0.40; 1.32             | 0.86              | 1.7            |
| Soyabeans, untoasted meal (presscake)   | 2                       | 0.99; 1.08             | 1.0               | 3.4            |
| Soyabeans, toasted meal                  | 2                       | 0.92; 0.83             | 0.87              | 3.9            |
| Soyabeans, crude oil                     | 2                       | < 0.04; < 0.22         | < 0.13<sup>(b)</sup> | 2              |
| Soyabeans, refined oil                   | 2                       | < 0.04; < 0.22         | < 0.13<sup>(b)</sup> | 2              |

PF: processing factor; RAC: raw agricultural commodity; CFp: conversion factor in processed commodity.

(a): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial, noting that N-acetyl-compounds are not expected to occur in EPSPS-tolerant crops.

(b): PF is derived based on the results < LOD for both glyphosate and AMPA in crude and refined oil while significant residues are found in RAC.

(c): Tentative PF because derived from two trials, with a difference of more than 50% between the two results.

B.2. Residues in livestock

Dietary burden calculation according to OECD, 2013.
### Relevant groups (subgroups)

| Relevant groups (subgroups) | Dietary burden expressed in (mg/kg bw per day) | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | Previous assessment (EFSA, 2019b) |
|-----------------------------|---------------------------------------------|---------------------------|----------------------------|------------------------|----------------------------------|
|                             | Median | Maximum | Median | Maximum |                        |                                   |
|-----------------------------|--------|---------|--------|---------|------------------------|----------------------------------|
| Cattle (all)                | 1.72   | 13.1    | 44.8   | 340.2   | Dairy cattle            | Grass forage (fresh)             | Y                                | 13.1                              |
| Cattle (dairy only)         | 1.72   | 13.1    | 44.8   | 340.2   | Dairy cattle            | Grass forage (fresh)             | Y                                | 13.1                              |
| Sheep (all)                 | 2.37   | 17.7    | 65.0   | 531.7   | Ram/Ewe                | Grass forage (fresh)             | Y                                | 17.7                              |
| Sheep (ewe only)            | 2.17   | 17.7    | 65.0   | 531.7   | Ram/Ewe                | Grass forage (fresh)             | Y                                | 17.7                              |
| Swine (all)                 | 0.65   | 2.92    | 28.1   | 126.5   | Swine (breeding)        | Grass forage (fresh)             | Y                                | 2.83                              |
| Poultry (all)               | 1.08   | 2.20    | 15.8   | 32.1    | Poultry layer          | Wheat straw                      | Y                                | 2.15                              |
| Poultry (layer only)        | 1.08   | 2.20    | 15.8   | 32.1    | Poultry layer          | Wheat straw                      | Y                                | 2.15                              |
| Fish                        | n.a.   | n.a.    | n.a.   | n.a.    | n.a.                   | n.a.                             | n.a.                             | n.a.                              |

bw: body weight; DM: dry matter; n.a.: not applicable.
(a): When one group of livestock includes several subgroups (e.g., poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

### B.2.1. Nature of residues and methods of analysis in livestock

#### B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal       | Dose (mg/kg bw per day) | Duration (days) | Comment/Source                        |
|-------------------------------|--------------|-------------------------|----------------|---------------------------------------|
|                               | Laying hen   | 18.2                    | 5–7            | EFSA (2019b)                          |
|                               | Laying hen   | 0.067–7.1               | 4              | Informative only because residues were not sufficiently identified (EFSA, 2019b) |
|                               | Lactating goat | 7.1–8.0               | 5              | EFSA (2019b)                          |
|                               | Laying hen   | 9.7 glyphosate + 1.03 AMPA | 7            | EFSA (2019b)                          |
|                               | Laying hen   | 32.2 glyphosate + 3.4 AMPA | 7            | EFSA (2019b)                          |
|                               | Lactating goat | 4.1 glyphosate + 0.45 AMPA | 5            | EFSA (2019b)                          |
|                               | Laying hen   | 4.1                     | 10             | EFSA (2019b)                          |
|                               | Lactating goat | 2.6                    | 7              | EFSA (2019b)                          |
|                               | Lactating goat | 2.0(a)                 | 4              | Informative only because residues were not sufficiently identified (EFSA, 2019b) |
|                               | Laying hen   | 4.5                     | 7              | EFSA (2019b)                          |
|                               | Lactating goat | 6.8                    | 5              | EFSA (2019b)                          |

(a): Reported in the study as 70 mg/kg in the feed and recalculated assuming a body weight of 70 kg and maximum daily intake of 2 kg feed.
Time needed to reach a plateau concentration in milk and eggs (days)  

|                | Milk: <7 |                | Eggs: 14 | Based on 28 day feeding study, no plateau reached within 8 days in metabolism studies |
|----------------|---------|----------------|----------|-------------------------------------------------------------------------------------|

Metabolism in rat and ruminant similar:  
Yes

Can a general residue definition be proposed for animals?  
Yes

Animal residue definition for monitoring (RD-Mo)  
Sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate

Animal residue definition for risk assessment (RD-RA)  
Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, expressed as glyphosate

Fat soluble residues:  
No

Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)  
HPLC-MS/MS; ILV available; LOQ for glyphosate, AMPA and N-acetyl-glyphosate: 0.025 mg/kg each in meat, milk and egg and 0.05 mg/kg each in liver, kidney and fat. A confirmatory GC-MS method is only available for glyphosate in milk, eggs and meat. A confirmatory method for glyphosate in fat and in liver/kidney as well as a confirmatory method for AMPA and N-acetyl-glyphosate in all matrices is missing (EFSA, 2019b)

B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|--------|-----------|--------|-----------------|-------------------|----------------|
|                                   |        |           |        | Value | Unit     |                    |                |
| Swine Fat                         | -20    | 26 Months | Glyphosate | EFSA (2019b) |
| Swine Muscle                      | -20    | 26 Months | Glyphosate | EFSA (2019b) |
| Swine Liver                       | -20    | 26 Months | Glyphosate | EFSA (2019b) |
| Swine Kidney                      | -20    | 26 Months | Glyphosate | EFSA (2019b) |
| Cow Milk                          | -20    | 16 Months | Glyphosate | EFSA (2019b) |
| Chicken Egg                       | -20    | < 14 Months | Glyphosate | EFSA (2019b) |
| Swine Fat                         | -20    | 26 Months | AMPA    | EFSA (2019b) |
| Swine Muscle                      | -20    | 26 Months | AMPA    | EFSA (2019b) |
| Swine Liver                       | -20    | 26 Months | AMPA    | EFSA (2019b) |
| Swine Kidney                      | -20    | 26 Months | AMPA    | EFSA (2019b) |
| Cow Milk                          | -20    | 16 Months | AMPA    | EFSA (2019b) |
| Chicken Egg                       | -20    | < 14 Months | AMPA    | EFSA (2019b) |

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

Not needed. The calculated dietary burden is the same as calculated in the MRL review (EFSA, 2019b). The outcome of the MRL review remains valid. The MRL and risk assessment values previously derived in the MRL review for food of animal origin remain unchanged.
B.3. Consumer risk assessment

| ARfD | 0.5 mg/kg bw (European Commission, 2017) |
|------|----------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Soyabean: 16% of ARfD (adults)  
Soyabean: 7% of ARfD (children) |
| Assumptions made for the calculations | The calculation is based on the median residue level (STMR) expected in soyabean (RAC) according to the submitted residue trials performed in GM soyabean. A CF for risk assessment was not needed because the STMR was directly expressed according to the residue definition for risk assessment (noting that the N-acetyl compounds are not expected to occur in glyphosate tolerant crops, containing EPSPS gene modification). |
| | Calculations performed with PRIMo revision 3.1. |

| ADI | 0.5 mg/kg bw per day (European Commission, 2017) |
|-----|-----------------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 16% ADI (GEMS/Food G11 diet)  
Maximal contribution of crop assessed:  
Soyabean: 10.46% of ADI (GEMS/Food G11 diet) |
| Assumptions made for the calculations | The calculation is based on the median residue levels (STMR) as derived for soybean from the residue trials submitted in support of the import tolerance request for GM soyabean.  
For remaining commodity, the STMR values were as derived for raw agricultural commodity all uses on conventional and genetically modified crops reported during the MRL review (EFSA, 2019b). For citrus juices, maize oil, wheat and rye milled (wholemeal) and wheat flour, processing factors were also applied.  
The most critical scenario calculated during the MRL review was updated (i.e. risk assessment with consideration of the CXLs, scenario 2 (considering the optional enforcement residue definition)) (see MRL review: EFSA, 2019b).  
For MRLs which during the MRL review were proposed at the LOQ, risk assessment was performed considering a combined LOQ (summing up individual LOQs of glyphosate, AMPA and N-acetyl-glyphosate). For those commodities where data were insufficient to derive an MRL in the framework of the MRL review, EFSA considered the existing EU MRL as an input value.  
CFs for risk assessment were not needed because the STMRs were directly expressed according to the residue definition for risk assessment (noting that the N-acetyl compounds are not expected to occur in EPSPS tolerant crops).  
The crops on which no GAP was reported in the framework of the MRL review were not included in the calculation, except for the intended uses on GAT rapeseed, GAT soyabauens and GAT maize which were
The chronic risk assessment calculation is based on the assumption that MRLs for existing uses of glyphosate will be amended as recommended in the MRL review and is affected by the uncertainties related to the data gaps identified during the MRL review (EFSA, 2019b).

Calculations performed with PRIMO revision 3.1.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMO: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit.

### B.4. Recommended MRLs

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------|-----------|------------------------|-------------------------|-----------------------|
| 0401070    | Soyabeans | 20                     | No change               | The submitted data are sufficient to derive an import tolerance (US GAP) in soyabeans. Risk for consumers unlikely. The available data confirm the existing MRL for glyphosate and do not provide evidence that the existing MRL has to be modified. |

### Enforcement residue definition (proposed during MRL review): sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------|-----------|------------------------|-------------------------|-----------------------|
| 0401070    | Soyabeans | –                      | Further risk management considerations required | The submitted data are sufficient to derive an import tolerance (US GAP) in soyabeans; in accordance with the enforcement residue definition proposed in the MRL review an MRL of 50 mg/kg would be derived. Risk for consumers unlikely. A risk management decision needs to be taken on the possible implementation of the residue definition for enforcement derived for soyabeans during the MRL review (EFSA, 2019b) and therefore on the need to change the existing MRL for soyabeans (to 50 mg/kg), noting that in the country of origin (US), the current MRL is 20 mg/kg (with only glyphosate in the residue definition for enforcement). |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.

\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
# Appendix C – Pesticide Residue Intake Model (PRIMo)

## Glyphosate

| Source of ADI | ADI (mg/kg bw per day) | Source of ARfD | ARfD (mg/kg bw) |
|--------------|------------------------|----------------|---------------|
| EFSA PRIMo revision 3.1; 2021/01/06 | 0.5 | EFSA | 0.5 |

LOQs (mg/kg) range from: 0.1 to: 0.20

### Calculated exposure (% of ADI)

| Commodity/group of commodities | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) |
|-------------------------------|---------------------------------------------|-----------------------------------------|-----------------------------------------|
| Barley                        | 16%                                        | 10%                                     | 3%                                      |
| Barley                        | 15%                                        | 14%                                     | 3%                                      |
| Maize/corn                    | 13%                                        | 3%                                      | 3%                                      |
| Cotton seeds                  | 12%                                        | 5%                                      | 3%                                      |
| Barley                        | 12%                                        | 5%                                      | 1%                                      |
| Barley                        | 11%                                        | 5%                                      | 1.0%                                    |
| Soyabeans                     | 11%                                        | 6%                                      | 3%                                      |
| Barley                        | 11%                                        | 6%                                      | 0.6%                                    |
| Oat                           | 9%                                         | 4%                                      | 3%                                      |
| Milk: Cattle                  | 7%                                         | 3%                                      | 2%                                      |
| Milk: Cattle                  | 6%                                         | 3%                                      | 1%                                      |
| Milk: Cattle                  | 6%                                         | 3%                                      | 0.8%                                    |
| Milk: Cattle                  | 6%                                         | 3%                                      | 0.5%                                    |
| Barley                        | 6%                                         | 3%                                      | 0.8%                                    |
| Milk: Cattle                  | 6%                                         | 3%                                      | 0.7%                                    |
| Milk: Cattle                  | 6%                                         | 2%                                      | 0.6%                                    |
| Milk: Cattle                  | 6%                                         | 2%                                      | 0.4%                                    |
| Barley                        | 5%                                         | 5%                                      | 0.1%                                    |
| Barley                        | 5%                                         | 2%                                      | 1%                                      |
| Barley                        | 5%                                         | 2%                                      | 0.5%                                    |
| Sugar beet roots              | 5%                                         | 2%                                      | 0.5%                                    |
| Potatoes                      | 5%                                         | 2%                                      | 0.9%                                    |
| Sugar beet roots              | 4%                                         | 2%                                      | 0.9%                                    |
| Sugar beet roots              | 4%                                         | 2%                                      | 0.6%                                    |
| Walnuts                       | 3%                                         | 3%                                      | 0.1%                                    |
| Barley                        | 3%                                         | 2%                                      | 0.8%                                    |
| Rye                           | 3%                                         | 2%                                      | 0.5%                                    |
| Barley                        | 2%                                         | 2%                                      | 0.6%                                    |
| Soyabeans                     | 2%                                         | 2%                                      | 0.4%                                    |
| Sugar beet roots              | 2%                                         | 2%                                      | 0.3%                                    |
| Sugar beet roots              | 2%                                         | 2%                                      | 0.2%                                    |
| Sugar beet roots              | 1%                                         | 3%                                      | 0.2%                                    |
| Barley                        | 1%                                         | 3%                                      | 0.1%                                    |
| Barley                        | 1%                                         | 3%                                      | 0.0%                                    |
| Rye                           | 1%                                         | 3%                                      | 0.0%                                    |
| Oat                           | 0.4%                                       | 0.1%                                    | 0.0%                                    |

### Supplementary results – chronic risk assessment

- **Input values**
  - Refined calculation mode
  - Chronic risk assessment: JMPR methodology (IEDI/TMDI)

### Conclusion

- The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
- The long-term intake of residues of glyphosate is unlikely to present a public health concern.

**DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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### Results for all crops

#### Unprocessed commodities

| Commodity                  | MRL/input (mg/kg) | Exposure (µg/kg bw) | Commodity | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|----------------------------|-------------------|---------------------|------------|-------------------|---------------------|
| 22% Potatoes               | 0.71              | 106                 | 13% Sweet corn | 1.45              | 63                  |
| 10% Wheat                  | 30.361            | 52                  | 8% Barley   | 30.8              | 45                  |
| 7% Snap peas               | 50.141            | 33                  | 6% Sweet corn | 3.145             | 23                  |
| 6% Melon                   | 0.2/0.2           | 30                  | 6% Ryie     | 30.361            | 17                  |
| 5% Oranges                 | 0.2/0.2           | 27                  | 5% Barley   | 7.679             | 14                  |
| 5% Barley                  | 7.679             | 26                  | 5% Sweet corn | 0.2/0.2           | 24                  |
| 5% Watermelons             | 30.361            | 23                  | 5% Watermelons | 0.2/0.2           | 22                  |
| 4% Apples                  | 0.2/0.2           | 22                  | 4% Barley   | 30/8              | 29                  |
| 4% Bananas                 | 0.2/0.2           | 19                  | 4% Wheat    | 30/3.61           | 22                  |
| 4% Peaches                 | 0.2/0.2           | 18                  | 4% Broccoli | 30/3.61           | 18                  |

### Results for processed commodities

| Commodity                  | MRL/input (mg/kg) | Exposure (µg/kg bw) | Commodity | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|----------------------------|-------------------|---------------------|------------|-------------------|---------------------|
| 73% Sugar beets (root)     | 15/39.6           | 364                 | 29% Sugar beets (root) | 15/39.6           | 145                 |
| 13% Potatoes fried         | 1/0.71            | 66                  | 12% Barley/ beer | 30.1.6            | 58                  |
| 12% Snap peas              | 50.141            | 33                  | 3% Wheat/ bread/pizza | 30.361           | 16                  |
| 6% Cereal                  | 30.8              | 29                  | 3% Wheat/ pasta | 30.361            | 14                  |
| 6% Barley/ cooked          | 30.8              | 29                  | 3% Wheat/ bread (wholemeal) | 30.361        | 13                  |
| 5% Wheat/ milling (flour)  | 30.8              | 24                  | 2% Oat/ boiled | 30.8              | 12                  |
| 5% Oat/ milling (flakes)   | 30.8              | 24                  | 2% Oat/ boiled | 30.8              | 12                  |
| 4% Soyabeans/ soya drink  | 50/5.64           | 20                  | 2% Cereal/ flake | 0.2/0.2           | 3.2                 |
| 4% Milk/ milk              | 30.361            | 20                  | 2% Milk/ milk | 30.361            | 14                  |
| 4% Oat/ milling (flakes)   | 30.8              | 24                  | 2% Milk/ milk | 30.361            | 14                  |
| 3% Barley/ boiled          | 30/3.61           | 18                  | 1% Apples/ juice | 0.2/0.2           | 0.6                 |
| 3% Broccoli/ boiled        | 30/3.61           | 18                  | 1% Apples/ juice | 0.2/0.2           | 0.6                 |

### Conclusion

No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of glyphosate is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

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**Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation):**

- **Results for children:**
  - No of processed commodities for which ARfD/ADI is exceeded (IESTI): [details]
  - Results for unprocessed commodities for which ARfD/ADI is exceeded (IESTI): [details]

- **Results for adults:**
  - No of processed commodities for which ARfD/ADI is exceeded (IESTI): [details]
  - Results for unprocessed commodities for which ARfD/ADI is exceeded (IESTI): [details]
### Appendix D – Input values for the exposure calculations

#### D.1. Livestock dietary burden calculations

| Feed commodity       | Median dietary burden | Maximum dietary burden |
|----------------------|-----------------------|------------------------|
|                      | Input value (mg/kg)   | Comment                |
|                      |                       | Comment                |
| Alfalfa, forage (green) | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* HR × CF (1) (tentative) (EFSA, 2019b) |
| Alfalfa, hay (fodder)  | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* HR × CF (1) (tentative) (EFSA, 2019b) |
| Alfalfa, meal       | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) |
| Alfalfa, silage     | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) |
| Barley, straw       | 57.8 STMR × CF (1) (tentative) (EFSA, 2019b) | 140 HR × CF (1) (tentative) (EFSA, 2019b) |
| Beet, mangel, fodder | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* HR × CF (1) (tentative) (EFSA, 2019b) |
| Beet, sugar, tops   | 0.2* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.2* HR × CF (1) (tentative) (EFSA, 2019b) |
| Cabbage, heads, leaves | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* HR × CF (1) (tentative) (EFSA, 2019b) |
| Clover, forage      | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* HR × CF (1) (tentative) (EFSA, 2019b) |
| Clover, hay         | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) |
| Clover, silage      | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) |
| Grass, forage (fresh) | 16 STMR × CF (1) (tentative) (EFSA, 2019b) | 139 HR × CF (1) (tentative) (EFSA, 2019b) |
| Grass, hay          | 17.6 STMR × CF (1) × PF (1.1) (tentative) (EFSA, 2019b) | 153 HR × CF (1) × PF (1.1) (tentative) (EFSA, 2019b) |
| Grass, silage       | 14.4 STMR × CF (1) × PF (0.9) (tentative) (EFSA, 2019b) | 125 HR × CF (1) × PF (0.9) (tentative) (EFSA, 2019b) |
| Kale, leaves (forage) | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* HR × CF (1) (tentative) (EFSA, 2019b) |
| Oat, straw          | 57.8 STMR × CF (1) (tentative) (EFSA, 2019b) | 140 HR × CF (1) (tentative) (EFSA, 2019b) |
| Rye, straw          | 31.4 STMR × CF (1) (tentative) (EFSA, 2019b) | 175 HR × CF (1) (tentative) (EFSA, 2019b) |
| Triticale, straw    | 31.4 STMR × CF (1) (tentative) (EFSA, 2019b) | 175 HR × CF (1) (tentative) (EFSA, 2019b) |
| Turnip, tops (leaves) | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* HR × CF (1) (tentative) (EFSA, 2019b) |
| Wheat, straw        | 31.4 STMR × CF (1) (tentative) (EFSA, 2019b) | 175 HR × CF (1) (tentative) (EFSA, 2019b) |
| Carrot, culls       | 0.05* STMR × CF (1) (EFSA, 2019b) | 0.05* HR × CF (1) (EFSA, 2019b) |
| Cassava/tapioca     | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* HR × CF (1) (tentative) (EFSA, 2019b) |
| Potato, culls       | 0.07 STMR × CF (1) (tentative) (EFSA, 2019b) | 0.59 HR × CF (1) (tentative) (EFSA, 2019b) |

**Risk assessment residue definition:** sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl AMPA, expressed as glyphosate.
| Feed commodity | Median dietary burden | Maximum dietary burden |
|----------------|-----------------------|------------------------|
|                | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Swede, roots   | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* HR × CF (1) (tentative) (EFSA, 2019b) |
| Turnip, roots  | 0.05* STMR × CF (1) (tentative) (EFSA, 2019b) | 0.05* HR × CF (1) (tentative) (EFSA, 2019b) |
| Barley, grain  | 7.85 STMR × CF (1) (EFSA, 2019b) | 7.85 STMR × CF (1) (EFSA, 2019b) |
| Bean, seed (dry) | 0.91 STMR × CF (2) (tentative) (EFSA, 2019b) | 0.91 STMR × CF (2) (tentative) (EFSA, 2019b) |
| Corn, field (Maize), grain | 0.93 STMR × CF (1) (tentative) (EFSA, 2019b) | 0.93 STMR × CF (1) (tentative) (EFSA, 2019b) |
| Cotton, undelinted seed | 17.7 STMR × CF (1) (EPSPS, tentative) (EFSA, 2019b) | 17.7 STMR × CF (1) (EPSPS, tentative) (EFSA, 2019b) |
| Cowpea, seed | 0.91 STMR × CF (2) (tentative) (EFSA, 2019b) | 0.91 STMR × CF (2) (tentative) (EFSA, 2019b) |
| Lupin, seed | 0.22 STMR × CF (2) (tentative) (EFSA, 2019b) | 0.22 STMR × CF (2) (tentative) (EFSA, 2019b) |
| Millet, grain | 0.89 STMR × CF (2.3) (EFSA, 2019b) | 0.89 STMR × CF (2.3) (EFSA, 2019b) |
| Oat, grain | 7.85 STMR × CF (1) (EFSA, 2019b) | 7.85 STMR × CF (1) (EFSA, 2019b) |
| Pea (Field pea), seed (dry) | 0.91 STMR × CF (2) (tentative) (EFSA, 2019b) | 0.91 STMR × CF (2) (tentative) (EFSA, 2019b) |
| Rye, grain | 0.85 STMR × CF (1) (EFSA, 2019b) | 0.85 STMR × CF (1) (EFSA, 2019b) |
| Sorghum, grain | 10.35 STMR × CF (2.3) (tentative) (EFSA, 2019b) | 10.35 STMR × CF (2.3) (tentative) (EFSA, 2019b) |
| Soyabean, seed | 13.30 STMR (4.75)(d) × CF (2.8)(d) (see Section B.1.2.1) | 13.30 STMR (4.75)(d) × CF (2.8)(d) (see Section B.1.2.1) |
| Triticale, grain | 0.85 STMR × CF (1) (EFSA, 2019b) | 0.85 STMR × CF (1) (EFSA, 2019b) |
| Wheat, grain | 0.85 STMR × CF (1) (EFSA, 2019b) | 0.85 STMR × CF (1) (EFSA, 2019b) |
| Apple pomace, wet | 0.05* STMR × CF (1) (EFSA, 2019b) | 0.05* STMR × CF (1) (EFSA, 2019b) |
| Beet, sugar, dried pulp | 0.2* STMR × CF (1) (EFSA, 2019b) | 0.2* STMR × CF (1) (EFSA, 2019b) |
| Beet, sugar, ensiled pulp | 0.2* STMR × CF (1) (EFSA, 2019b) | 0.2* STMR × CF (1) (EFSA, 2019b) |
| Beet, sugar, molasses | 0.2* STMR × CF (1) (EFSA, 2019b) | 0.2* STMR × CF (1) (EFSA, 2019b) |
| Barley, brewer’s grain (dried) | 25.91 STMR × CF (1) × default PF (3.3)(b) (EFSA, 2019b) | 25.91 STMR × CF (1) × default PF (3.3)(b) (EFSA, 2019b) |
| Canola (Rape seed), meal | 4.65 STMR × CF (1) × PF (1.5)(c) (tentative) (EFSA, 2019b) | 4.65 STMR × CF (1) × PF (1.5)(c) (tentative) (EFSA, 2019b) |
| Citrus fruits, dried pulp | 0.13 STMR × CF (1) × F (2.6) (EFSA, 2019b) | 0.13 STMR × CF (1) × F (2.6) (EFSA, 2019b) |
| Coconut, meal | 0.05* STMR × CF (1) (EFSA, 2019b) | 0.05* STMR × CF (1) (EFSA, 2019b) |
| Corn, field, milled by-products | 0.84 STMR × CF (1) × PF (0.9)(e) (tentative) (EFSA, 2019b) | 0.84 STMR × CF (1) × PF (0.9)(e) (tentative) (EFSA, 2019b) |
### Feed commodity

| Feed commodity               | Input value (mg/kg) | Comment | Maximum dietary burden |
|-----------------------------|---------------------|---------|------------------------|
| Corn, field, hominy meal    | 5.58                | STMR × CF (1) × default PF (6)(b) (tentative) (EFSA, 2019b) | 5.58 STMR × CF (1) × default PF (6)(b) (tentative) (EFSA, 2019b) |
| Corn, field, gluten feed    | 2.33                | STMR × CF (1) × default PF (2.5)(b) (tentative) (EFSA, 2019b) | 2.33 STMR × CF (1) × default PF (2.5)(b) (tentative) (EFSA, 2019b) |
| Corn, field, gluten meal    | 0.93                | STMR × CF (1) × default PF (1)(b) (tentative) (EFSA, 2019b) | 0.93 STMR × CF (1) × default PF (1)(b) (tentative) (EFSA, 2019b) |
| Cotton, meal                | 22.1                | STMR × CF (1) × default PF (1.3)(b) (tentative) (EFSA, 2019b) | 22.1 STMR × CF (1) × default PF (1.3)(b) (tentative) (EFSA, 2019b) |
| Wheat/Corn, distiller’s grain (dried) | 3.07                | STMR (maize)x CF (1) × default PF (3.3)(b) (tentative) (EFSA, 2019b) | 3.07 STMR (maize)x CF (1) × default PF (3.3)(b) (tentative) (EFSA, 2019b) |
| Flaxseed/Linseed, meal      | 1.86                | STMR × CF (1) × PF (1.6) (EFSA, 2019b) | 1.86 STMR × CF (1) × PF (1.6) (EFSA, 2019b) |
| Lupin seed, meal            | 0.24                | STMR × CF (2) × default PF (1.1)(b) (tentative) (EFSA, 2019b) | 0.24 STMR × CF (2) × default PF (1.1)(b) (tentative) (EFSA, 2019b) |
| Palm, kernel meal           | 0.05*               | STMR × CF (1.0)(a) (tentative) (EFSA, 2019b) | 0.05* STMR × CF (1.0)(a) (tentative) (EFSA, 2019b) |
| Peanut, meal                | 0.05*               | STMR × CF (1.0)(a) (tentative) (EFSA, 2019b) | 0.05* STMR × CF (1.0)(a) (tentative) (EFSA, 2019b) |
| Potato, process waste       | 1.4                 | STMR × CF (1) × default PF (20)(b) (tentative) (EFSA, 2019b) | 1.4 STMR × CF (1) × default PF (20)(b) (tentative) (EFSA, 2019b) |
| Potato, dried pulp          | 2.66                | STMR × CF (1) × default PF (38)(b) (tentative) (EFSA, 2019b) | 2.66 STMR × CF (1) × default PF (38)(b) (tentative) (EFSA, 2019b) |
| Rape seed, meal             | 4.65                | STMR × CF (1) × PF (1.5) (tentative) (EFSA, 2019b)(c) | 4.65 STMR × CF (1) × PF (1.5) (tentative) (EFSA, 2019b)(c) |
| Safflower, meal             | 0.05*               | STMR × CF (1.0)(a) (tentative) (EFSA, 2019b) | 0.05* STMR × CF (1.0)(a) (tentative) (EFSA, 2019b) |
| **Soyabean, meal**          | **16.2**            | STMR (4.75)(d) × CF (3.4) × PF (1) (see Sections B.1.2.1 and B.1.2.3) | **16.2** STMR (4.75)(d) × CF (3.4) × PF (1) (see Sections B.1.2.1 and B.1.2.3) |
| **Soyabean, hulls**         | **62.3**            | STMR (4.75)(d) × CF (1.9) × PF (6.9) (see Sections B.1.2.1 and B.1.2.3) | **62.3** STMR (4.75)(d) × CF (1.9) × PF (6.9) (see Sections B.1.2.1 and B.1.2.3) |
| Sugarcane, molasses         | 0.39                | STMR × CF (1) × PF (7.8) (tentative) (EFSA, 2019b) | 0.39 STMR × CF (1) × PF (7.8) (tentative) (EFSA, 2019b) |
| Sunflower, meal             | 2.52                | STMR × CF (1.1) × default PF (2)(b) (tentative) (EFSA, 2019b) | 2.52 STMR × CF (1.1) × default PF (2)(b) (tentative) (EFSA, 2019b) |
| Wheat gluten, meal          | 1.53                | STMR × CF (1) × default PF (1.8)(b) (EFSA, 2019b) | 1.53 STMR × CF (1) × default PF (1.8)(b) (EFSA, 2019b) |
| Wheat, milled by-products   | 1.53                | STMR × CF (1) × PF (1.8) (EFSA, 2019b) | 1.53 STMR × CF (1) × PF (1.8) (EFSA, 2019b) |

**STMR**: supervised trials median residue; **HR**: highest residue; **PF**: processing factor.

(a): For alfalfa and clover hay, meal and silage, apples pomace, sugar beet dried pulp, ensiled pulp and molasses, coconuts meal, palm hearts kernel meal, peanut meal and safflower meal, no default processing factor was applied because residues in the raw commodities are proposed at the LOQ. Concentration of residues in these commodities is therefore not expected.

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In the absence of processing factors supported by data, default processing factors (in bracket) were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

For rapeseed meal and canola meal, the critical risk assessment values and processing factors were derived from uses on genetically modified GAT rapeseed, which were derived in previous MRL assessments (see Appendix G.3.1 in EFSA, 2019b).

Highest values (STMR and CF) from the two treatment regimes ('in-crop' GAP and 'pre-harvest' GAP) were used for the risk assessment.

D.2. Consumer risk assessment

| Commodity       | Proposed MRL (mg/kg) (option 1)(a) | Proposed MRL (mg/kg) (option 2)(b) | Source          | Chronic risk assessment | Acute risk assessment |
|-----------------|------------------------------------|------------------------------------|-----------------|-------------------------|-----------------------|
|                 | Proposed MRL (mg/kg) (option 1)(a) | Proposed MRL (mg/kg) (option 2)(b) | Source          | Input value(c)(mg/kg)   | Comment               |
|                 |                                    |                                    |                 | Comment                 |                       |
|                 |                                    |                                    |                 | (mg/kg)                 | Comment               |
| Grapefruits     | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Oranges         | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Lemons          | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Limes           | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Mandarins       | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Almonds         | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Brazil nuts     | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Cashew nuts     | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Chestnuts       | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Coconuts        | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Hazelnuts/ cobnuts | 0.05*                              | 0.2*                              | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Macadamias      | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Pecans          | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Pine nut kernels | 0.05*                              | 0.2*                              | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Pistachios      | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Walnuts         | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Apples          | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Pears           | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Quinces         | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |
| Medlars         | 0.05*                              | 0.2*                               | EFSA (2019b)    | 0.2*                    | STMR-RAC x CF (1)     |
|                 |                                    |                                    |                 |                         |                       |

Risk assessment residue definition: sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl AMPA, expressed as glyphosate.
| Commodity                          | Proposed MRL (mg/kg) (option 1) | Proposed MRL (mg/kg) (option 2) | Source          | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|---------------------------------|---------------------------------|----------------|-------------------------|-----------------------|
|                                  | (a)                             | (b)                             |                 | Input value (mg/kg)     | Comment (mg/kg)       |
| Loquats/ Japanese medlars         | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Apricots                          | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Cherries (sweet)                  | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Peaches                           | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Plums                             | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Table grapes                      | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Wine grapes                       | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Strawberries                      | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Blueberries                       | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Cranberries                       | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Currants (black, red and white)   | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Gooseberries (green, red and yellow) | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Rose hips                         | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Mulberries (black and white)      | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Azaroles/ Mediterranean medlars    | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Elderberries                      | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Figs                              | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Table olives                      | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Kumquats                          | 0.05*                           | 0.2*                            | EFSA (2019b)    | 0.2*                    | 0.2*                  |
| Commodity                          | Proposed MRL (mg/kg) (option 1) | Proposed MRL (mg/kg) (option 2) | Source                          | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|--------------------------------|--------------------------------|--------------------------------|-------------------------|-----------------------|
|                                   | (a)                            | (b)                            |                                | Input value (mg/kg)     | Comment               |
| Kaki/Japanese persimmons          | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Kiwi fruits (green, red, yellow)  | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Litchis/lychees                   | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Passionfruits/maracujas           | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Avocados                          | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Bananas                           | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Mangoes                           | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Papayas                           | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Granate apples/pomegranates       | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Cherimoyas                         | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Potatoes                          | 1                              | 1                              | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Cassava roots/manioc              | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Sweet potatoes                    | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Yams                              | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Arrowroots                        | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Beetroots                         | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Carrots                           | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Celeriacs/turnip-rooted celeries  | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Horseradishes                     | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Jerusalem artichokes              | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Parsnips                          | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Parsley roots/Hamburg roots parsley| 0.05*                         | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Radishes                          | 0.05*                          | 0.2*                           | EFSA (2019b)                   | 0.2*                    | STMR-RAC × CF (1)     |
| Commodity                              | Proposed MRL (mg/kg) (option 1) | Proposed MRL (mg/kg) (option 2) | Source                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------------|---------------------------------|---------------------------------|-------------------------------|-------------------------|-----------------------|
|                                        | (a)                             | (b)                             |                               | Input value (c) (mg/kg) | Comment               |
|                                        |                                 |                                 |                               | Comment (d) (mg/kg)     |                       |
| Salsifies                              | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Swedes/rutabagas                       | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Turnips                                | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Garlic                                 | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Onions                                 | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Shallots                               | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Spring onions/green onions and Welsh onions | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Tomatoes                               | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Sweet peppers/bell peppers             | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Aubergines/eggplants                   | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Okra/lady's fingers                    | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Cucumbers                              | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Gherkins                               | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Courgettes                             | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Melons                                 | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Pumpkins                               | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Watermelons                            | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Sweet corn                             | 3                               | 3                               | EFSA (2019b)                  | 0.51                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Broccoli                               | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Cauliflowers                           | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Brussels sprouts                       | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Head cabbages                          | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Chinese cabbages/pe-tsai               | 0.05*                           | 0.2*                            | EFSA (2019b)                  | 0.2*                    | STMR-RAC × CF (1)     |
|                                        |                                 |                                 |                               |                         |                       |
| Commodity                        | Proposed MRL (mg/kg) (option 1)(a) | Proposed MRL (mg/kg) (option 2)(b) | Source                | Chronic risk assessment | Acute risk assessment |
|---------------------------------|-----------------------------------|------------------------------------|-----------------------|-------------------------|-----------------------|
|                                 | Input value(c) (mg/kg)            | Comment                            | Input value(c) (mg/kg)| Comment                 |                        |
|                                 | Comment                            |                                    |                       |                         |                        |
| Kales                           | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Kohlrabies                      | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Lamb’s lettuces/corn salads     | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Lettuces                        | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Escaroles/broad-leaved endives  | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Cresses and other sprouts and   | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| shoots                          |                                    |                                    |                       |                         |                        |
| Land cresses                    | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Roman rocket/rucola             | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Red mustards                    | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Baby leaf crops                 | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| (including brassica species)    |                                    |                                    |                       |                         |                        |
| Spinaches                       | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Purslanes                       | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Chards/beet leaves              | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Grape leaves and similar species| 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Watercresses                    | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Witloofs/Belgian endives        | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Chervil                         | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Chives                          | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Celery leaves                   | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Parsley                         | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Sage                            | 0.05*                              | 0.2*                               | EFSA (2019b)          | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Commodity                  | Proposed MRL (mg/kg) (option 1) | Proposed MRL (mg/kg) (option 2) | Source                   | Chronic risk assessment | Acute risk assessment |
|---------------------------|---------------------------------|---------------------------------|--------------------------|-------------------------|-----------------------|
|                           | (a)                             | (b)                             |                          | (c)                     | (d)                   |
| Rosemary                  | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Thyme                     | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Laurel/bay leave          | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Tarragon                  | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Beans (with pods)         | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Beans (without pods)      | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Peas (with pods)          | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Peas (without pods)       | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Lentils (fresh)           | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Asparagus                 | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Cardoons                  | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Celeries                  | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Florence fennels          | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Globe artichokes          | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Leeks                     | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Rhubarbs                  | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Bamboo shoots             | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Palm hearts               | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Cultivated fungi          | 0.1                             | 0.2*                            | EFSA (2019b)             | 0.2*                    | Existing MRL with LOQ |
|                           |                                 |                                 |                          |                         | 0.2* existing MRL     |
| Wild fungi                | 0.05*                           | 0.2*                            | EFSA (2019b)             | 0.2*                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Beans (dry)               | 15                              | 30                              | EFSA (2019b)             | 0.91                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Lentils (dry)             | 10                              | 20                              | EFSA (2019b)             | 1.46                    | STMR-RAC × CF (1)     |
|                           |                                 |                                 |                          |                         |                      |
| Peas (dry)                | 15                              | 30                              | EFSA (2019b)             | 0.91                    | STMR-RAC × CF (1)     |
| Commodity                          | Proposed MRL (mg/kg) (option 1)\(^{(a)}\) | Proposed MRL (mg/kg) (option 2)\(^{(b)}\) | Source                     | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|------------------------------------------|------------------------------------------|---------------------------|------------------------|-----------------------|
|                                   | Input value\(^{(c)}\) (mg/kg) | Comment | Input value\(^{(c)}\) (mg/kg) | Comment |
| Lupins/lupini beans (dry)         | 10                                       | 20                           | EFSA (2019b)             | 0.22                  | STMR-RAC \times CF (1) |
| Linseeds                          | 15                                       | 15                           | EFSA (2019b)             | 1.28                  | STMR-RAC \times CF (1) |
| Peanuts/groundnuts                | 0.05\(^{*}\)                             | 0.2\(^{*}\)                 | EFSA (2019b)             | 0.2\(^{*}\)          | STMR-RAC \times CF (1) |
| Poppy seeds                       | 0.05\(^{*}\)                             | 0.2\(^{*}\)                 | EFSA (2019b)             | 0.2\(^{*}\)          | HR-RAC \times CF (1) |
| Sesame seeds                      | 0.05\(^{*}\)                             | 0.2\(^{*}\)                 | EFSA (2019b)             | 0.2\(^{*}\)          | HR-RAC \times CF (1) |
| Sunflower seeds                   | 30                                       | 30                           | EFSA (2019b)             | 1.27                  | STMR-RAC \times CF (1) |
| Rapeseeds/canola seeds            | 30                                       | 30                           | EFSA (2019b)             | 2.98                  | STMR-RAC \times CF (1.01) |
| **Soyabeans**                     | **50\(^{(e)}\)**                        | **50\(^{(e)}\)**          | **Import tolerance request** | **14.1** | **STMR-RAC\(^{(f)}\) \times CF (1)\(^{(g)}\)** |
| Mustard seeds                     | 10                                       | 10                           | EFSA (2019b)             | 10                    | Existing MRL \times CF (1) |
| Cotton seeds                      | 60                                       | 60                           | EFSA (2019b)             | 17.7                  | STMR-RAC \times CF (1) |
| Pumpkin seeds                     | 0.05\(^{*}\)                             | 0.2\(^{*}\)                 | EFSA (2019b)             | 0.2\(^{*}\)          | STMR-RAC \times CF (1) |
| Safflower seeds                   | 0.05\(^{*}\)                             | 0.2\(^{*}\)                 | EFSA (2019b)             | 0.2\(^{*}\)          | STMR-RAC \times CF (1) |
| Borage seeds                      | 10                                       | 10                           | EFSA (2019b)             | 0.7                   | STMR-RAC \times CF (1) |
| Gold of pleasure seeds            | 0.05\(^{*}\)                             | 0.2\(^{*}\)                 | EFSA (2019b)             | 0.2\(^{*}\)          | STMR-RAC \times CF (1) |
| Hemp seeds                        | 0.05\(^{*}\)                             | 0.2\(^{*}\)                 | EFSA (2019b)             | 0.2\(^{*}\)          | STMR-RAC \times CF (1) |
| Castor beans                      | 0.05\(^{*}\)                             | 0.2\(^{*}\)                 | EFSA (2019b)             | 0.2\(^{*}\)          | STMR-RAC \times CF (1) |
| Olives for oil production         | 30                                       | 30                           | EFSA (2019b)             | 0.53                  | STMR-RAC \times CF (1) |
| Oil palms kernels                 | 0.05\(^{*}\)                             | 0.2\(^{*}\)                 | EFSA (2019b)             | 0.2\(^{*}\)          | HR-RAC \times CF (1) |
| Oil palms fruits                  | 0.05\(^{*}\)                             | 0.2\(^{*}\)                 | EFSA (2019b)             | 0.2\(^{*}\)          | HR-RAC \times CF (1) |
| Kapok                             | 0.05\(^{*}\)                             | 0.2\(^{*}\)                 | EFSA (2019b)             | 0.2\(^{*}\)          | HR-RAC \times CF (1) |
| Barley grains                     | 30                                       | 30                           | EFSA (2019b)             | 8                     | STMR-RAC \times CF (1) |
| Buckwheat and other pseudo-cereal grains | 30                                       | 30                           | EFSA (2019b)             | 3.61                  | STMR-RAC \times CF (1.03) |
| Maize/corn grains                 | 4                                        | 4                            | EFSA (2019b)             | 0.93                  | STMR-RAC \times CF (1) |
| Commodity                                  | Proposed MRL (mg/kg) (option 1)(a) | Proposed MRL (mg/kg) (option 2)(b) | Source                  | Chronic risk assessment | Acute risk assessment |
|--------------------------------------------|------------------------------------|------------------------------------|-------------------------|-------------------------|------------------------|
| Common millet/proso millet grains          | 30                                 | 30                                 | EFSA (2019b)            | 3.61 STMR-RAC × CF (1.03) | 3.61 STMR-RAC × CF (1.03) |
| Oat grains                                 | 30                                 | 30                                 | EFSA (2019b)            | 8 STMR-RAC × CF (1)      | 8 STMR-RAC × CF (1)    |
| Rice grains                                | 0.1                                | 0.2*                               | EFSA (2019b)            | 0.2 STMR-RAC × CF (1)    | 0.2 STMR-RAC × CF (1)  |
| Rye grain                                  | 30                                 | 30                                 | EFSA (2019b)            | 3.61 STMR-RAC × CF (1.03) | 3.61 STMR-RAC × CF (1.03) |
| Sorghum grains                             | 30                                 | 30                                 | EFSA (2019b)            | 3.61 STMR-RAC × CF (1.03) | 3.61 STMR-RAC × CF (1.03) |
| Wheat grains                               | 30                                 | 30                                 | EFSA (2019b)            | 3.61 STMR-RAC × CF (1.03) | 3.61 STMR-RAC × CF (1.03) |
| Teas                                       | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Coffee beans                               | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Herbal infusions from flowers              | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Herbal infusions from leaves and herbs     | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Herbal infusions from roots                | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Carobs/Saint John’s breads                | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Hops                                       | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Seed spices                                | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Fruit spices                               | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Bark spices                                | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Root and rhizome spices                    | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Bud spices                                 | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Flower pistil spices                       | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Aril spices                                | 0.05*                              | 0.2*                               | EFSA (2019b)            | 0.2* STMR-RAC × CF (1)   | 0.2* HR-RAC × CF (1)   |
| Sugar beet roots                           | 15                                 | 15                                 | EFSA (2019b)            | 3.3 STMR-RAC × CF (1)    | 7.1 HR-RAC × CF (1)    |
| Commodity          | Proposed MRL (mg/kg) (option 1) | Proposed MRL (mg/kg) (option 2) | Source               | Chronic risk assessment | Acute risk assessment |
|--------------------|---------------------------------|---------------------------------|----------------------|-------------------------|------------------------|
|                    |                                |                                 |                      | Input value(c) (mg/kg)  | Comment                | Input value(c) (mg/kg) | Comment                |
| Sugar canes        | 2                               | 0.2*                            | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Chicory roots      | 0.05*                           | 0.2*                            | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Swine meat         | 0.2                             | 0.2                             | EFSA (2019b)         | 0.17 STMR-RAC × CF (1)  | 0.17 HR-RAC × CF (1)   |
| Swine fat tissue   | 0.2*                            | 0.2*                            | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Swine liver        | 0.4                             | 0.4                             | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.35 HR-RAC × CF (1)   |
| Swine kidney       | 3                               | 3                               | EFSA (2019b)         | 0.21 STMR-RAC × CF (1)  | 2.43 HR-RAC × CF (1)   |
| Bovine meat        | 0.2                             | 0.2                             | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.18 HR-RAC × CF (1)   |
| Bovine fat tissue  | 0.2*                            | 0.2*                            | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Bovine liver       | 0.7                             | 0.7                             | EFSA (2019b)         | 0.54 STMR-RAC × CF (1)  | 0.69 HR-RAC × CF (1)   |
| Bovine kidney      | 7                               | 7                               | EFSA (2019b)         | 0.66 STMR-RAC × CF (1)  | 6.79 HR-RAC × CF (1)   |
| Sheep meat         | 0.2                             | 0.2                             | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.19 HR-RAC × CF (1)   |
| Sheep fat tissue   | 0.3                             | 0.3                             | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.21 HR-RAC × CF (1)   |
| Sheep liver        | 0.9                             | 0.9                             | EFSA (2019b)         | 0.54 STMR-RAC × CF (1)  | 0.81 HR-RAC × CF (1)   |
| Sheep kidney       | 10                              | 10                              | EFSA (2019b)         | 0.80 STMR-RAC × CF (1)  | 9.27 HR-RAC × CF (1)   |
| Goat meat          | 0.2                             | 0.2                             | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.19 HR-RAC × CF (1)   |
| Goat fat tissue    | 0.3                             | 0.3                             | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.21 HR-RAC × CF (1)   |
| Goat liver         | 0.9                             | 0.9                             | EFSA (2019b)         | 0.54 STMR-RAC × CF (1)  | 0.81 HR-RAC × CF (1)   |
| Goat kidney        | 10                              | 10                              | EFSA (2019b)         | 0.80 STMR-RAC × CF (1)  | 9.27 HR-RAC × CF (1)   |
| Equine meat        | 0.2                             | 0.2                             | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.18 HR-RAC × CF (1)   |
| Equine fat tissue  | 0.2*                            | 0.2*                            | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Equine liver       | 0.7                             | 0.7                             | EFSA (2019b)         | 0.54 STMR-RAC × CF (1)  | 0.69 HR-RAC × CF (1)   |
| Equine kidney      | 10                              | 10                              | EFSA (2019b)         | 0.66 STMR-RAC × CF (1)  | 6.79 HR-RAC × CF (1)   |
| Poultry meat       | 0.2                             | 0.2                             | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Poultry fat tissue | 0.2*                            | 0.2*                            | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Poultry liver      | 0.2*                            | 0.2*                            | EFSA (2019b)         | 0.2* STMR-RAC × CF (1)  | 0.2* HR-RAC × CF (1)   |
| Commodity     | Proposed MRL (mg/kg) (option 1)(a) | Proposed MRL (mg/kg) (option 2)(b) | Source                  | Chronic risk assessment | Acute risk assessment |
|---------------|------------------------------------|------------------------------------|-------------------------|-------------------------|-----------------------|
|               | Input value(c) (mg/kg)              | Comment                            | Input value(c) (mg/kg)  | Comment(d)              |
| Cattle milk   | 0.1*                               | EFSA (2019b)                       | 0.1*                    | STMR-RAC × CF (1)       | 0.1*                  | HR-RAC × CF (1)       |
| Sheep milk    | 0.1*                               | EFSA (2019b)                       | 0.1*                    | STMR-RAC × CF (1)       | 0.1*                  | HR-RAC × CF (1)       |
| Goat milk     | 0.1*                               | EFSA (2019b)                       | 0.1*                    | STMR-RAC × CF (1)       | 0.1*                  | HR-RAC × CF (1)       |
| Horse milk    | 0.1*                               | EFSA (2019b)                       | 0.1*                    | STMR-RAC × CF (1)       | 0.1*                  | HR-RAC × CF (1)       |
| Birds eggs    | 0.1*                               | EFSA (2019b)                       | 0.1*                    | STMR-RAC × CF (1)       | 0.1*                  | HR-RAC × CF (1)       |

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.

(a): 'Proposed MRLs' come from the MRLs derived during the MRL review (EFSA, 2019b), according to the main RD for enforcement (option 1), i.e. for all plant commodities other than sweet corn, cotton seeds, sugar beets, rapeseeds, maize and soyabean, RD-Mo is glyphosate; for sweet corn, cotton seeds, sugar beets, rapeseeds, maize and soyabean, RD-Mo is sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate.

(b): 'Proposed MRLs' come from the MRLs review (EFSA, 2019b) according to the optional RD for enforcement (option 2), i.e. sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate (for all plant commodities).

(c): Input values were derived using the worst-case scenario of the MRL review, i.e. considering the optional RD for enforcement and a combined LOQ of 0.2* mg/kg (EFSA, 2019b). Since the RA values are directly derived for the inclusive residue definition for all crops (i.e. including glyphosate and AMPA), a CF of 1 is used for all commodities except for some CXLs.

(d): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

(e): For soyabean, the MRL derived for proposed residue definitions (option 1 or option 2) is 50 mg/kg because for this crop, RD-Mo is the sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate in both cases. When derived according to the existing RD-Mo (glyphosate), the MRL value would be 20 mg/kg. It is noted that the MRL in the country of origin is set at 20 mg/kg, with only glyphosate in the residue definition for enforcement.

(f): The highest STMR from the two treatment regimes (‘in-crop’ GAP and ‘pre-harvest’ GAP) was used for the risk assessment.

(g): For soyabean, the STMR was derived for the sum of glyphosate and AMPA, expressed as glyphosate. A CF of 1 is considered because N-acetyl-glyphosate and N-acetyl-AMPA are not expected to occur under the conditions of use (GAP on EPSPS glyphosate-tolerant soyabean).
## Appendix E – Used compound codes

| Code/trivial name         | Chemical name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|---------------------------|------------------------------------------------------|----------------------------------|
| glyphosate                | \(N\)-(phosphonomethyl)glycine \(\text{OC}(-\text{O})\text{CNCP}(-\text{O})(\text{O})\text{O}\) | ![Glyphosate Structural Formula](attachment:Glyphosate.png) |
| glyphosate-trimesium      | \(N\)-[giyphosphinato)methyl]glycine \([\text{O}]\text{P}(-\text{O})(\text{O})\text{CNCC}(-\text{O})\text{O.C}[\text{S}^+](\text{C})\text{C}\) | ![Glyphosate Trimesium Structural Formula](attachment:GlyphosateTrimesium.png) |
| trimethyl-sulfonium       | trimethylsulfanium \(\text{C}[\text{S}^+](\text{C})\text{C}\) | ![Trimethylsulfonium Structural Formula](attachment:Trimethylsulfonium.png) |
| AMPA                      | \(\text{O}(-\text{O})\text{CN}(\text{C})\text{OP}(-\text{O})(\text{O})\text{O}\text{C}(-\text{O})\text{O}\text{H}\) | ![AMPA Structural Formula](attachment:AMPA.png) |
| N-acetyl-AMPa             | \([(\text{carboxyamino})\text{methyl}]\text{phosphonic acid} \(\text{O}(-\text{C})(\text{O})\text{NCP}(-\text{O})(\text{O})\text{O}\) | ![N-acetyl-AMPa Structural Formula](attachment:N-acetyl-AMPa.png) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

<sup>(a)</sup> AC/Name 2020.2.1 AC/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

<sup>(b)</sup> AC/ChemSketch 2020.2.1 AC/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).