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Board for the Authorisation of Plant Protection Products and Biocides
 PO Box 8030
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Brussels, July 31, 2018

Subject : EFSA Reasoned Opinion: Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005 – Monsanto comments

Dear Sir, Madam,

On April 17, 2018, the EFSA issued a Reasoned Opinion (RO) on the 'Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005' (EFSA Journal 2018;16(5):5263).

After a careful reading, Monsanto identified some major concerns that we would like to formally raise before the Commission and Member States consider the next steps in the finalization of this Article 12 review. These concerns relate to the following elements: the considered residue definitions, the relevance of certain uses listed in the critical GAP and the allegedly missing but available data resulting in 'tentative' MRLs and 'indicative' risk assessments in the final RO.

Monsanto would have raised these concerns before finalization of this RO if we would have been given the opportunity to comment on a more advanced draft RO. Indeed, this final RO differs substantially from the draft version we were asked to comment on in 2014. Although we realize this is not a procedural requirement, it is in retrospect a missed opportunity.

We hope that the comments outlined in the document attached to this letter are still helpful and will be considered. At all time we remain at your disposal for any further clarification.

Sincerely yours

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 Monsanto Europe S.A./N.V.

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Date: July 25, 2018

Author: 5.1.2.e Woo – Monsanto Europe S.A./N.V.

On April 17, 2018, the EFSA issued a Reasoned Opinion (RO) on the '*Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005.*' (EFSA Journal 2018;16(5):5263), further referred to as 2018-RO.

After reviewing this 2018-RO, Monsanto identified some major concerns, and would strongly urge the Commission and the Member States to keep the finalization of the Article 12 review for glyphosate on hold and request the Authority to amend its Opinion with consideration of our comments and concerns.

In Summary:

First, in this 2018-RO, EFSA proposes two (2) options for an amended residue definition for enforcement purposes. These proposed options are consistent with the recommendations issued in the Standing Committee on Plants Animals Food and Feed (SCoPAFF) meeting of September 22-23, 2016, during which the Commission and Member States discussed on which bases EFSA should review the MRLs for glyphosate under Art 12 of Regulation (EC) 396/2005. Agreement was reached that EFSA should consider two options, alternative to the current residue definition for enforcement purposes, but SCoPAFF confirmed the current residue definition for risk assessment purposes.

Monsanto urges the Commission and the Member States to consider a refined residue definition proposal for enforcement purposes that. This refined residue definition would not impact significantly impact the MRL proposals and would limit the impact on analytical enforcement complexity.

Secondly, we have identified a substantial amount of uses that should be critically re-assessed for their relevance. These uses drive the critical GAP and therefore the MRL proposal but are of no agronomic or commercial relevance.

Thirdly, in this 2018-RO, the Authority concludes that based on the assessment of the available data, no apparent risk to consumers was identified but outlined an extensive list of "missing" information, rendering the consumer risk assessment 'indicative' and resulting in a substantial amount of 'tentative' MRLs. In this context, Monsanto would like to highlight that most of the alleged missing information is available. What's more, the lion share has been previously submitted and has must have been overlooked. Had we been given the opportunity to comment on an advanced draft version of this Reasoned opinion, the availability of this information could have been flagged, and the information resubmitted if needed.

Especially the fact that a substantial amount of available information has been overlooked should trigger the Commission and the Member States to mandate EFSA to reconsider its reasoned opinion this time taking all available information into account and consider the refined residue definition proposal.

Below, the refined residue definition proposal is further elaborated and the concern regarding the allegedly missing but available data is further substantiated.

1. Refined residue Definition proposal for enforcement purposes

With regards to the proposals for and amended residue definition for enforcement purposes, Monsanto invites the Commission and the member States to consider a refined residue definition based on the following:

Reference is made to a conclusion reached earlier in the Standing Committee on Food Chain and Animal Health (SCoPAFF) – meeting of February 3-4 of 2011.

During this meeting a RO from EFSA with regards to a “*modification of the residue definition of glyphosate in genetically modified grain and soybeans and in products of animal origin*” (EFSA Journal 2009; 7(9):1310, was discussed (further referred to as 2009-RO).

In this 2009-RO, EFSA proposed the residue definition for risk assessment as the **Sum of glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl AMPA, calculated as glyphosate**. SCoPAFF agreed with this proposal.

In addition, in this 2009-RO, EFSA proposed for Maize and Soybeans, three (3) options for the residue definition for enforcement purposes were considered:

- Option 1: Glyphosate;
- Option 2: Sum of Glyphosate and N-acetyl-glyphosate expressed as glyphosate
- Option 3: N-acetyl glyphosate

For other plant commodities and animal commodities EFSA did not propose changes (it is residue definition for enforcement = **glyphosate**).

The SCoPAFF concluded that the residue definition for enforcement should not change (i.e. **Option 1 for Maize and Soybeans**). These SCoPAFF conclusions are the basis of the glyphosate residue definitions (risk assessment and enforcement) that are in force today.

For conventional commodities, Monsanto agrees that ‘glyphosate’ is to be considered a sufficient marker for enforcement purposes.

For EPSPS - GM tolerant crop commodities Monsanto would like to point out that ‘glyphosate’ is a sufficient marker for enforcement purposes and therefore no amended residue definition for enforcement purposes should be necessary. The latter was, clearly indicated by the conclusions of the February 2011 SCoPAFF and is also confirmed in EFSA’s 2018-RO. Indeed, EFSA concluded in the 2018 RO as follows: “*Overall the metabolic pattern was similar to that in genetically modified plants as the EPSPS modification does not affect the metabolism of glyphosate in genetically modified plants*”.

In order to take into account GAT GM tolerant crop commodities, we refer to the **2013 JMPR** residue definitions:

- For Maize, Rape seed and soy bean: **glyphosate and N-acetyl glyphosate** expressed as glyphosate
- For other plant commodities: **glyphosate**

In order to take into account, the GOX GM tolerant crop commodities, 5.1.2.f Woo, , we agree with and refer to the 2018-RO conclusion that AMPA is the main residue component detected at harvest.

Given the above Monsanto proposes the following refined residue definitions for enforcement purposes:

- For Maize and soy bean: **glyphosate and N-acetyl glyphosate expressed as glyphosate**
- For OSR and canola: **glyphosate, N-acetyl glyphosate and AMPA expressed as glyphosate**
- For other plant commodities including plants with glyphosate tolerant genetically modified varieties currently available on the market: **glyphosate**

Taking into account the above enforcement residue definitions, one can conclude that glyphosate and N-acetyl glyphosate are adequate markers in conventional and GM glyphosate tolerant crops relevant for use in animal feed (EPSPS and GAT). In addition, the 2018-RO EFSA concluded that glyphosate and N-acetyl glyphosate are not significantly metabolized in animals. This allows to conclude that also in animal commodities glyphosate and N-acetyl glyphosate are sufficient markers for enforcement purposes. The latter was acknowledged by JMPR in 2011 in its enforcement residue definition for animal commodities and confirmed again by JMPR in 2013. Given the above Monsanto's proposes the following residue definition for enforcement purposes:

- For all animal commodities: **glyphosate and N-acetyl glyphosate expressed as glyphosate**

For risk assessment purposes, the residue definition is the **sum of glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl AMPA, calculated as glyphosate.**

2. General comments on the GAP table for conventional crops (Appendix 1 to the 2018-RO)

Monsanto would urge for this GAP table to be substantially rationalized and for the relevance of certain crops and uses to be critically re-assessed. For instance, crops such as grapefruits, oranges, lemons, mandarins, almonds, brazil nuts, cashew nuts, chestnuts, coconuts, macadamia, pecans, pine nuts kernels, pistachios, table olives, olives for oil productions, bamboo Shoots, palm hearts, peanuts...are, but should not have been listed in critical outdoor GAP for Northern Europe. Cultivated fungi, which are also part of the Northern European GAP, grow in the dark and don't need weed control.

The critical GAP for many of the listed crops (mainly vegetables and herbs) is based on a L&G formulation (7.2 g/L) and involves a soil treatment or weed wiping up to 7 days before harvest, with a application rate of maximum 1.44 kg/ha. According to the comment in the table, up to 3 applications/year are authorized.

This GAP is to our knowledge nowhere registered and affects the critical GAP of the following crops: strawberries, blackberries, dewberries, raspberries, cranberries, currants, gooseberries, rose hips, mulberries, elderberries, table olives, beetroots, carrots, celeriac, horse radishes, jerusalem artichokes, parsnips, parsley roots, radishes, salsifies, garlic, onions, shallots, spring onions, tomatoes, sweet peppers, aubergines, cucumbers, gherkins, courgettes, melons, pumpkins, brussels Sprouts, head cabbages, chinese cabbage, kohlrabies, lamb's lettuces, lettuces, escaroles, cresses, land cresses, roman rocket, red mustard, baby leaf crops, spinaches, purslanes, chards, water cresses, witloofs, chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil, laurel, tarragon, asparagus, cardoons, celeries, florence fennels, globe artichokes, leeks, rhubarbs, bamboo shoots, palm hearts, cultivated fungi, peanuts, poppy seeds, sesame seeds, cotton seeds, pumpkin seeds, safflower seeds, gold of pleasure seeds, castor beans, herbal infusions from flowers, herbal infusions from leaves and herbs, herbal infusions from roots, hops, seed spices, fruit spices, root and rhizome spices.

What's more, this GAP is totally unrealistic and a Lawn and garden label should not drive the MRL setting. There is no agronomic need or benefit to treat the weeds in vegetable fields up to 7 days before harvest. In addition, these uses are not covered by residue trials and, as mentioned by EFSA, may lead to exposure of the crop to glyphosate. Removing the unsustainable GAP related to those uses would significantly simplify the GAP table and allow to focus on realistic uses (as was the case with the draft EFSA RO of 2014). In addition, professional weed wiper uses have not been registered for these crops nor the crop groups they are part off. Data gaps for all these crops have been identified in the 2018-RO but, given the above, not relevant.

In the draft EFSA RO of 2014 the GAP for many vegetables and for berries was inter-row shielded application. In this 2014 draft RO, EFSA commented that the GAP needed to be clarified, as no PHI was proposed in most cases. As a follow-up, Monsanto did conduct a set for field trials on different vegetable groups. These data were provided in 2016 (see Appendix 3), but apparently overlooked, since the GAP changed (now driven by the above mentioned Lawn & Garden formulation).

3. Data indicated as 'missing' but available and not considered

With regards to the missing information, which resulted in 'tentative' MRLs and 'indicative risk assessment, Monsanto would like to comment that a lot of available information has not been considered and it is totally unclear what information (residue data and GAP information) was considered and how, for instance, conversion factors (CF) were derived. To illustrate these concerns, we provide the following two examples: (1) the residue data supporting the Cotton Seed MRL (p 169 of the 2018-RO) belongs to Monsanto and does not correspond with the data Monsanto submitted; (2) Sufficient metabolism and residue data on dry pulses is available to refine the proposed AMPA conversion factor (CF=2). We are not sure what data was available to the Authority and how it was considered.

Appendix 1 to this document provides an overview of allegedly missing information that should have been considered (and was in most cases available or could have been provided) to the RMS and EFSA.

Monsanto regrets that no opportunity was offered to comment on a more final draft of this reasoned opinion. Indeed, only on May 28, 2014, The German BVL requested Monsanto to comment on a draft of the Reasoned Opinion. In its request BVL clearly asked us not to submit any additional data. On March 18, 2016 EFSA wrote a letter to relevant stakeholders requesting data (by April 15, 2016) in the context of EFSA's mandated assessment of the impact of glyphosate residues in feed of animal health (mainly metabolism and toxicology information) and included a reminder with regards to the ongoing glyphosate MRL review, urging Stakeholders to make sure that relevant data were made available to Rapporteur Member State Germany. Germany confirmed to Monsanto that only documents that appeared later than the commenting period for the EFSA Draft RO (issued May 28, 2014) should be submitted. On October 06, 2016, the BVL asked Monsanto to provide "only" GAPs authorized in third countries and the residue data supporting the import MRLs.

No further opportunity was offered to review a draft of the reasoned opinion (that dramatically changed since the 2014 version) or to submit additional information.

Given the fact that relevant and readily available information has not been considered, Monsanto urges the Commission and the Member States to (1) keep the finalization of the Article 12 review for glyphosate on hold and (2) to request the Authority to revise its Opinion with consideration of all available relevant information. Indeed, referring to Article 14 of Regulation 369/2005, a Regulation on the setting, modification or deletion of the glyphosate MRLs shall be prepared by the Commission. This Regulation should, according to point 2a of that article, consider the scientific and technical knowledge available. This condition has not been met since a lot of available data was overlooked.

APPENDIX 1 Data reported as missing but available

Additional information is indeed available. The Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate (EFSA Journal 2015;13(11):4302), provides a “*list of studies to be generated, still ongoing or available but not peer reviewed*”. This List indicated the same missing analytical methods (primary, confirmatory and ILVs) compared to the missing analytical methods highlighted in the 2018-RO. Also, the need for an AMPA degradation study under acidic conditions was identified in the EFSA opinion on glyphosate.

The Glyphosate Task Force (Monsanto immediately initiated the studies needed to fill these requirements and Monsanto submitted these methods as part of the Art 43 glyphosate product renewal submissions. A reference list of these methods is presented below. If Monsanto would have been asked to comment on a more advanced version of the draft reasoned opinion, the availability of this information could have been flagged and subsequently formally been submitted at the request of the Authority under the timeline provisions of article 11.2 of Regulation 396/2005.

Author	Year	Title
5.1.2.e Woo	2016a	Analytical method for the determination of Glyphosate and AMPA in matrices of plant origin. MSL0027298, Non-GLP
5.1.2.e Woo	2015	Independent laboratory validation of an analytical method for the determination of glyphosate and AMPA in different matrices of plant origin. Unpublished study No S14-05172/GAB-1434V. GLP
5.1.2.e Woo 5.1.2.e Woo 5.1.2.e v	2015	Validation of an Analytical Method for the Determination of Glyphosate and AMPA in Tobacco Using LC/MS/MS. MSL0027204, GLP
5.1.2.e Woo	2016	Independent Laboratory Validation of an Analytical Method for the Determination of Glyphosate and AMPA in Tobacco. MSL0027761, GLP
5.1.2.e Woo	2016b	Analytical method for the determination of N-Acetyl glyphosate in matrices of plant origin MSL0027300, Non-GLP
5.1.2.e Woo 5.1.2.e Woo	2016a	Independent Laboratory Validation of an Analytical Method for the Determination of N-Acetyl glyphosate in Matrices of Plant Origin. MSL0027695, GLP

5.1.2.e Woo	2016c	Analytical Method for the Determination of Glyphosate and AMPA in Matrices of Animal Origin. MSL0027299, non-GLP
5.1.2.e Woo	2016d	Analytical Method for the Determination of N-Acetyl Glyphosate in Matrices of Animal Origin. MSL0027301, non-GLP
5.1.2.e Woo 5.1.2.e Woo	2016b	Independent Laboratory Validation of Analytical Methods for the determination of Glyphosate and its Metabolites N-Acetyl Glyphosate and AMPA in matrices of animal origin. MSL0027696, GLP
5.1.2.e Woo 5.1.2.e Woo	2016	Aminomethylphosphonic Acid (AMPA): Rate of Degradation of AMPA in one Acidic Soil Incubated under Aerobic Conditions, GTF Study No. EPS-2016-0309, Eurofins Agroscience Services Report No. S16-04460 / EPS-2016-0309

In the 2018-RO, EFSA also flagged many residue data gaps in the section “Magnitude of residues in plants”. These data gaps clearly show that the data in the monograph has been overlooked and that data submitted to the RMS over the last couple of years have not been considered. All data available to the RMS in 2005 have been summarized by the RMS in an overview document (Appendix 2 to this document). All additional data submitted to the RMS in 2016 has been listed in Appendix 3.

A subset of the alleged missing but available or irrelevant missing trials is outlined below:

- **EFSA:** *“the application rates assessed during the peer review for the early treatments (BBCH 00-09), were significantly lower (2.16 kg/ha) compared to the most critical uses currently authorized and considered in this review. Moreover, representative uses were supported by residue trials confirming a no-residue situation while no residue trials, reflecting the most critical application rate authorised, are available.”*

Monsanto response: Residue trials following pre-emergent application rates as high as 8.64 kg/ha have been summarized and evaluated in the 2001 Monograph. (B6 Residues Table B 6.6.7-1 to 6)

- **EFSA:** *“Similarly, also for soil application done at pre-emergence or before sowing, planting and after harvest, EFSA is of the opinion that at least two residue trials confirming the no-residue situation at the critical GAP considered in this review are still required. This approach is aligned to the current guidance document on MRL setting and extrapolation.”*

Monsanto response: Pre-emergence residue data from the monograph have been overlooked (B6 Residues Table B 6.6.7-1 to 6)

- **EFSA:** *“Sunflower: only two trials are available to support the northern GAP for desiccation. Moreover, in these trials, residues were analysed for glyphosate only. According to the RMS, additional trials are available. However, since study reports for these trials were not reported to the RMS, they could not be evaluated by the RMS. Therefore, eight trials compliant with the northern outdoor GAP, eight trials compliant with the southern outdoor GAP and eight trials compliant with the import tolerance are required;”*

Monsanto response: Data from 8 trials are available supporting the proposed GAP, and the results were used to set the current EU MRL (See Appendix 2). It is thus surprising that the RMS mentions that they hadn’t received the reports. Nevertheless, the reports can be provided upon request. Data from 4 additional trials (South Europe) were submitted to the RMS in 2016 (See Appendix 3)

- **EFSA:** *"Soybeans: eight trials compliant with the northern outdoor GAP, eight trials compliant with the southern outdoor GAP and eight trials compliant with the import tolerance are required;"*

Monsanto response: Soybeans are not cultivated at commercial level in the North so it's unclear what GAP has been submitted by the member States and considered by the Authority. Data supporting the import MRL were submitted to the RMS in 2016. (See Appendix 3)

- **EFSA:** *" Mustard seeds: four trials compliant with the northern outdoor GAP and four trials compliant with the southern outdoor GAP are required;"*

Monsanto response: 4 trials covering the Northern GAP are available in the monograph. These 4 trials were considered for the current MRL setting (See Appendix 2) and conducted at 1.44 kg/ha (thus within 25% of current GAP) so should be suitable. The GAP for the South is not commercially relevant.

- **EFSA:** *" Grass forage: although MRL and risk assessment values can be derived from the northern outdoor GAP, two residue trials compliant with the southern outdoor GAP are still required."*

Monsanto response: 4 Southern European trials were submitted to the RMS in 2016 (See Appendix 3)

- **EFSA:** regarding EPSPS genetically modified plants: *" No residue data were available for sugar beet roots. Therefore, the following data gap was identified: Eight residue trials compliant with the import tolerance GAP for EPSPS-modified sugar beets"*

Monsanto response: This data was submitted to the RMS in 2016 (See Appendix 3)

- **EFSA:** *Maize and Soybeans: GAP details and supporting residue trials for the currently authorised import tolerance on EPSPS soybeans.*

Monsanto response: For both crops, the Codex MRL is driven by a pre-harvest application. These data was submitted to the RMS in 2016 (See Appendix 3)

- **EFSA:** *"Eight residue trials compliant with the import tolerance GAP for GOX-modified rapeseeds."*

Monsanto response: Data was submitted to the RMS in 2016 (See Appendix 3)

- **EFSA:** *"All available trials supporting the GAP on conventional maize were performed on EPSPS modified maize."*

Monsanto response: This is not correct. The data supporting the Codex MRL on maize was submitted to the RMS in 2016 (See Appendix 3) and were conducted on conventional maize.

EFSA also identified the need to confirm the calculated plateau concentrations for AMPA with a soil degradation study in acidic soils. This study is available and has been submitted to RMS Germany earlier this year.

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
1. Fruit				
1.1 Citrus fruit	none	0.1*		cGAP: S-EU: 4.32 kg as/ha, ground treatment, PHI: -. N-EU: No GAP.
Grapefruits			0.1*	US: 17 trials, 1-2 x 4.48 - 3 x 8.97 kg as/ha, PHI: 1 - 21 d; Glyphosate: 16 x <0.05, 0.06 mg/kg AMPA: 14 x <0.05 mg/kg
Lemons			0.1*	US: 17 trials, 1-3 x 4.48 - 3 x 8.97 kg as/ha, PHI: 1 - 21 d; Glyphosate: 25 x <0.05, 2 x <0.06, 2 x 0.08 mg/kg AMPA: 24 x <0.05 mg/kg
Mandarines			0.1*	ES: 3 trials, 1 x 4.8 kg as/ha, PHI: 6, 7 d; Glyphosate: all <0.05 mg/kg
Oranges			0.5	Glyphosate: grapefruit, lemon and mandarin: $R_{max} = 0.07$ mg/kg, $R_{ber} = 0.10$ mg/kg, STMR = 0.05 mg/kg US: 39 trials, 1-3 x 4.48 - 3 x 8.97 kg as/ha, PHI: 0 - 28 d; Glyphosate: 25 x <0.05, 2 x <0.1, <0.13, 0.08, 0.14, 0.2, 0.25, 0.26, 0.32, 2 x <0.5, 0.46, 0.47, 0.68 mg/kg AMPA: 27 x <0.05, 6 x <0.1, 0.13 mg/kg
Tangerines			0.5	GR: 2 trials, 4.8, 9.6 kg as/ha, PHI: 7, 14, 21 d; Glyphosate: 2 x <0.05 mg/kg PT: 4 trials, 1 x 3.5 - 3.75 kg as/ha, PHI: 28 d; Glyphosate: all <0.05 mg/kg US: 1 trial, 1 x 8.97 kg as/ha, PHI: 7 d; Glyphosate: 0.16 mg/kg AMPA: <0.05 mg/kg Glyphosate: orange and tangerine: $R_{max} = 0.45$ mg/kg, $R_{ber} = 0.27$ mg/kg, STMR = 0.05 mg/kg

Only US reports

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Others			0.1*	
1.2 Tree nuts				
Almonds	none	0.1*	0.1*	cGAP: ES, IT; 4.32 kg as/ha, ground treatment, PHI: -; US: 12 trials, 2 x 4.48 - 1 x 8.96 kg as/ha, PHI: 20 d; Glyphosate: all <0.05 mg/kg
Haselnuts				IT: 8 trials, 1 x 0.72 - 8.64 kg as/ha, PHI: 20, 21, 67, 90 d; Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg
Pecans				US: 10 trials, 2 x 4.48 - 1 x 8.96 kg as/ha, PHI: 20 d; Glyphosate: all <0.05 mg/kg
Walnuts				US: 8 trials, 2 x 4.48 - 1 x 8.96 kg as/ha, PHI: 20 d; Glyphosate: all <0.05 mg/kg
1.3. Pome fruit				
Apples	none	0.1*	0.1*	cGAP: N-EU and S-EU; 4.32 kg as/ha, ground treatment, PHI: 7 d. DE: 12 trials, 1.8 or 3.6 kg as/ha, PHI: 50, 56 d 7 trials, 2.4 kg as/ha, PHI: 0 - 42 d Glyphosate: all <0.05 mg/kg AMPA: 12 x <0.05 mg/kg DK: 2 trials, 1.8 - 2.88 kg as/ha, PHI: 0, 47 d Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg FR: 6 trials, 4.32 - 9.0 kg as/ha, PHI: 35 - 51 d Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg NL: 1 trial, 1.44 + 2.16 kg as/ha, PHI: 40 d Glyphosate: <0.05 mg/kg AMPA: <0.05 mg/kg

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Pears				<p>N-FR: 1 trial, 3.6 kg as/ha, PHI: 26 d Glyphosate: <0.05 mg/kg AMPA: <0.05 mg/kg</p> <p>S-FR: 8 trials, 4.32 - 9.0 kg as/ha, PHI: 26 - 47d Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg</p> <p>PT: 4 trials, 3.4 - 3.7 kg as/ha, PHI: 28, 45 d Glyphosate: all <0.03 mg/kg</p> <p>US: 18 trials, 2 x 4.48 - 1 x 8.96 kg as/ha, PHI: 13d Glyphosate: all <0.05 mg/kg AMPA: -</p> <p>DE: 2 trials, 2.4 kg as/ha, PHI: 0 - 42 d Glyphosate: all <0.05 mg/kg AMPA: -</p> <p>S-FR: 3 trials, 4.32 - 11.7 kg as/ha, PHI: 32, 40 d Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg</p> <p>US: 12 trials, 2 x 4.48 or 1 x 8.96 kg as/ha, PHI: 13d Glyphosate: all <0.05 mg/kg AMPA: -</p>
1.4. Stone fruit Apricots	none	0.1*	0.1*	<p>cGAP: N-EU andS-EU; 4.32 kg as/ha, ground treatment, PHI: 7 d.</p> <p>US: 1 trial, 4.48 kg as/ha, PHI: 30 d Glyphosate: <0.05 mg/kg AMPA: <0.05 mg/kg</p> <p>DE: 2 trials, 4.2 - 4.4 kg as/ha, PHI: 13 - 14 d Glyphosate: all <0.05 mg/kg</p>
Cherries				

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Peaches				<p>AMPA: all <0.05 mg/kg</p> <p>ES: 1 trial, 4.48 kg as/ha, PHI: 6 d</p> <p>Glyphosate: <0.05 mg/kg</p> <p>IT: 2 trials, 4.48 kg as/ha, PHI: 7 d</p> <p>Glyphosate: all <0.05 mg/kg</p> <p>S-FR: 1 trial, 4.48 kg as/ha, PHI: 7 d</p> <p>Glyphosate: <0.05 mg/kg</p> <p>AMPA: -</p> <p>US: 10 trials, 2 x 4.48 - 1 x 8.96 kg as/ha, PHI: 10 - 13 d</p> <p>Glyphosate: all <0.05 mg/kg</p> <p>AMPA: all <0.05 mg/kg</p> <p>2 trials, 3 x 3.74 - 4.48 kg as/ha, PHI: 17 - 37 d</p> <p>Glyphosate: <0.05, 0.08 mg/kg</p> <p>AMPA: all <0.05 mg/kg</p> <p>CA: 4 trials, 2 x 5.04 kg as/ha, PHI: 10 - 26 d</p> <p>Glyphosate: 2 x <0.05, 0.05, 0.09 mg/kg</p> <p>AMPA: all <0.05 mg/kg</p> <p>ES: 2 trials, 4.5 kg as/ha, PHI: 7 d</p> <p>Glyphosate: all <0.05 mg/kg</p> <p>AMPA: all <0.05 mg/kg</p>
				<p>US: 18 trials, 3 x 3.36 - 2 x 4.48, 1 x 8.96 kg as/ha, PHI: 3, 13, 30, 31 d</p> <p>Glyphosate: 16 x <0.05, 0.05, 0.1 mg/kg</p> <p>AMPA: all <0.05 mg/kg</p> <p>US: 1 trial, 3 x 4.48 kg as/ha, PHI: 30 d</p> <p>Glyphosate: 0.05 mg/kg</p> <p>AMPA: <0.05 mg/kg</p>
Nectarines				

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Plums				<p>US: 15 trials, 2-3 x 4.48, 1 x 8.96 kg as/ha, PHI: 13, 31 d Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg</p> <p>CA: 4 trials, 3 x 3.36 kg as/ha, PHI: 17 d Glyphosate: 0.1, 0.12, 0.13, 0.16 mg/kg AMPA: all <0.05 mg/kg</p> <p>All fruit types: $R_{max} = 0.14$ mg/kg, $R_{ber} = 0.17$ mg/kg, STMR = 0.05 mg/kg</p>
1.5 Berries and small fruit Grapes	none	0.1*	0.5	<p>cGAP: AT: 4.32 kg as/ha, ground treatment, PHI: 14 d. S-EU: 4.32 kg as/ha, ground treatment, PHI: 28 d.</p> <p>DE: 10 trials, 0.72 - 2.4 kg as/ha, PHI: 0 - 4 d Glyphosate: 13 x <0.05 mg/kg and 0.7 mg/kg (low hanging fruits)</p> <p>ES: 2 trials, 0.72 kg as/ha, PHI: 0 - 8 d AMPA: all <0.05 mg/kg Glyphosate: 3 x <0.05 mg/kg (middle hanging fruits) and 0.2, 0.3 mg/kg (low and middle hanging fruits)</p> <p>GR: 2 trials, 4.8 - 9.6 kg as/ha, PHI: 7 d AMPA: all <0.05 mg/kg Glyphosate: all <0.05 mg/kg</p> <p>US: 40 trials, 4.48 - 8.96 kg as/ha, PHI: 13 - 31 d Glyphosate: 22 x <0.05, 17 x <0.1, 0.2 mg/kg AMPA: all <0.05 mg/kg</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Current like berries	none	0.1*	0.1*	<p>$R_{max} = 0.46 \text{ mg/kg}$, $R_{ber} = 0.10 \text{ mg/kg}$, $STMR = 0.05 \text{ mg/kg}$</p> <p>cGAP: DE: 1.8 kg as/ha, ground treatment, PHI: 42 d. S-EU: No GAP.</p> <p>DE: 2 trials on currants, 1.8 kg as/ha, PHI: 42 d Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg</p>
Other berries and small fruit		0.1*	0.1*	
1.6 Miscellaneous fruit				
Banana	none		0.1*	<p>cGAP: S-EU only: 4.32 kg as/ha, ground treatment, PHI: 30 d. ES: 12 trials, 2.87 - 5.74 kg as/ha, PHI: 30, 70 d Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg</p>
Kiwi	0.1*		0.1*	<p>cGAP: ES; 4.32 kg as/ha, ground treatment, PHI: -. N-EU: No GAP.</p> <p>IT: 6 trials on kiwi, 1.35 - 3.08 kg as/ha, PHI: 93-108 d Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg</p>
Olives				<p>cGAP: S-EU; 4.32 kg as/ha, ground treatment, PHI: 7 d. N-EU: No GAP.</p>
Table olives	none	0.1*	0.1*	<p>ES: 24 trials, 2.16 - 4.32 kg as/ha, PHI: 0 - 27 d (0 = day of application) <u>fruit samples from canopy:</u> MLL30469 MLL 30297</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Olives for oil production	none	2	1	<p data-bbox="296 47 400 1301"> Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg 4 trials (2 with glyphosate trimesium), 1.44 - 5.9 kg as/ha, PHI: 7, A20-II RIP 97-00243 MILL 30319 </p> <p data-bbox="408 47 480 1301"> IT: 13 d <u>fruit samples from canopy:</u> Glyphosate: 2 x <0.05, 0.06, 0.08 mg/kg AMPA: 2 x <0.05 mg/kg </p> <p data-bbox="488 47 560 1301"> GR: 7 trials, 4.8 kg as/ha, PHI: 6 - 7 d <u>fruit samples from canopy:</u> Glyphosate: 7 x <0.05 mg/kg AMPA: - No reports on Greece </p> <p data-bbox="568 47 639 1301"> ES: 4 trials, 2.16 kg as/ha, PHI: 7 d <u>groundlying fruit samples:</u> Glyphosate: 2 x <0.1, 0.5, 0.9 mg/kg AMPA: all <0.05 mg/kg Spain and Italy see above No reports for Greece </p>
	Others		0.1*	0.1*

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
2. Vegetables 2.1 Root and tuber vegetables Beetroot, Carrots, Witloof (Chicory)	none	0.1*	0.1*	<p>cGAP: IT; 4.32 kg as/ha in carrots, wiping, PHI: -; N-EU: 1.44 kg as/ha, pre-emergence, PHI: -; FR: 12 trials on carrots (pre-plant spraying), 1.44 - 8.64 kg as/ha, PHI: 101 - 140 d</p> <p><u>roots:</u> Glyphosate: 10 x <0.05, 0.07, 0.08 mg/kg AMPA: all <0.05 mg/kg</p> <p>DE: 3 trials on turnips (pre-plant spraying), 2.16 kg as/ha, PHI: 89 - 106 d</p> <p><u>roots and leaves:</u> Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg</p> <p>GB: 4 trials on swedes (pre-plant spraying), 1.8 - 3.6 kg as/ha, PHI: 199 - 229 d</p> <p><u>roots and leaves:</u> Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg</p> <p>The chosen cGAP in Italy is considered to cause a low residue situation in root vegetables because treated plants will be damaged and would not be suitable to harvest. Therefore, no special data according to this GAP from southern EU region are considered necessary. All available data can be used for the MRL proposal of the whole group.</p>
2.2 Bulb vegetables Onions	none	0.1*	0.1*	<p>cGAP: N-EU only; 2.1 kg as/ha, pre-plant spraying, PHI: -;</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
				<p>FR: 6 trials, 1.44 - 8.64 kg as/ha, PHI: 120 - 181 d Glyphosate: 7 x <0.05, 0.05 mg/kg AMPA: all <0.05 mg/kg</p> <p>GB: 8 trials, 1.8 or 3.6 kg as/ha, PHI: 80 - 94 d Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg</p>
2.3 Fruiting vegetables Cucumber, Melones, Courgettes (cultivation on plastic mulch)	none	0.1*	0.1*	<p>cGAP: DE only; 2.88 kg as/ha, post-emergence spraying between rows with shielding, PHI: - No residue data necessary, no residue situation.</p>
2.4 Brassica vegetables	none	0.1*	0.1*	<p>cGAP: No special GAP for brassica vegetables. However, seed bed preparation (pre-plant ground treatment) for vegetables and other crops at rates up to 4.32 kg as/ha possible.</p> <p>DE: 3 trials on kale, 2.1 kg as/ha, PHI: 59 - 106 d <u>leaves:</u> Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg</p> <p>GB: 6 trials on kale, 1.44 - 3.6 kg as/ha, PHI: 144 - 148 d <u>leaves:</u> Glyphosate: all <0.05 mg/kg AMPA: all <0.05 mg/kg</p>
2.5 Leaf vegetables and fresh herbs	none	0.1*	0.1*	<p>cGAP: No special GAP for leaf vegetables and fresh herbs. However, seed bed preparation (pre-plant ground treatment) for vegetables and</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Lettuce				<p>other crops at rates up to 4.32 kg as/ha possible.</p> <p>FR: 15 trials, 1.44 - 8.64 kg as/ha, PHI: 54 - 89 d</p> <p>Glyphosate: 10 x <0.05, 4 x 0.05, 0.06 mg/kg</p> <p>AMPA: all <0.05 mg/kg</p>
2.6 Legume vegetables (fresh)	none	0.1*	0.1*	<p>cGAP: No special GAP for legume vegetables. However, seed bed preparation (pre-plant ground treatment) for vegetables and other crops at rates up to 4.32 kg as/ha possible.</p> <p>No residue data available.</p>
2.7 Stem vegetables Asparagus	none	0.1*	0.1*	<p>cGAP: IT: max. 4.32 kg as/ha, pre-emergence spraying, PHI: -.</p> <p>DE: 3.6 kg as/ha, spraying, PHI: -.</p> <p>DE: 1 trial, 1.8 kg as/ha, PHI: 1 - 21 d</p> <p>Glyphosate: 0.05 mg/kg / PHI: 1 d</p> <p><0.05 mg/kg / PHI: 3, 5, 7, 14, 21 d</p> <p>AMPA: all <0.05 mg/kg</p> <p>FR: 4 trials, 4.3 - 8.6 kg as/ha, PHI: 256 - 326 d</p> <p>Glyphosate: all <0.05 mg/kg</p> <p>AMPA: all <0.05 mg/kg</p> <p>1 trial, 4.3 kg as/ha, PHI: 2 - 6 d</p> <p>Glyphosate: 0.3 mg/kg / PHI: 2 d, 0.05 mg/kg / PHI: 4 d, <0.05 mg/kg / PHI: 6 d;</p> <p>AMPA: all <0.05 mg/kg</p> <p>2 trials, 2 x 4.3 or 2 x 8.6 kg as/ha, PHI: 336 d</p> <p>Glyphosate: all <0.05 mg/kg</p> <p>AMPA: all <0.05 mg/kg</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
2.8 Fungi Mushrooms Wild mushrooms	none none	0.1* 50	0.1* 50	<p>cGAP: N-EU; 3.6 kg as/ha, forestry, PHI: - S-EU; 4.32 kg as/ha, forestry, PHI: -</p> <p>DE: 17 trials, 1.8 or 2.4 kg as/ha, PHI: 0 - 16 d Glyphosate - PHI = 0 - 1 d: 4.4, 6.41, 9.27, 13.0, 14.0, 14.71, 18.5, 21.91, 24.2, 27.0, 28.0, 31.15, 34.0, 34.17, 40.65, 43.6 mg/kg PHI = 2 - 10 d: 0.19, 0.26, 0.27, 0.3, 0.32, 0.74, 1.0, 1.1, 1.2, 1.39, 1.46, 2.69, 3.5, 3.5, 4.26, 5.2, 5.5, 8.5, 10.4, 29.4 mg/kg PHI = 12 - 16 d: <0.05, 0.05, 0.07, 0.08, 0.17, 0.19, 0.2, 0.25, 0.97, 1.0, 3, 2.2, 3.1, 12.3, 56.0 mg/kg R_{max} = 38.86 mg/kg, R_{ber} = 29.42 mg/kg, STMR = 3.50 mg/kg AMPA: PHI = 0 - 14 d: 9 x <0.05, 2 x 0.05, 0.06, 0.07, 0.08, 0.1, 0.25, 0.4, 0.44, 0.48, 0.5, 0.77 mg/kg</p>
3. Pulses Beans	2	2	2	<p>cGAP: N-EU: 2.16 kg as/ha, PHI: 7 d. IT: 4.32 kg as/ha, wiping, PHI: -</p> <p>N-EU: 40 trials, 0.72 - 2.88 kg as/ha, PHI: 7 - 10 d Glyphosate: 10 x <0.05, 0.05, 0.07, 0.08, 2 x 0.09, 5 x 0.1, 2 x 0.13, 0.14, 0.15, 2 x 0.3, 0.33, 0.5, 0.53, 0.8, 1.8 mg/kg R_{max} = 0.85 mg/kg, R_{ber} = 0.42 mg/kg, STMR = 0.12 mg/kg</p> <p>Only for UK No data for Southern Europe</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Peas	5	3	10	<p>AMPA: 27 x <0.05 mg/kg</p> <p>cGAP: N-EU: 2.16 kg as/ha, PHI: 7 d. IT: 4.32 kg as/ha, wiping, PHI: -. N-EU: 63 trials, 0.72 - 2.88 kg as/ha, PHI: 5 - 14 d</p> <p>Glyphosate: 6 x <0.05, 5 x 0.06, 0.08, <0.1, 5 x 0.1, 0.12, 0.13, 0.14, 0.17, 0.18, 0.19, 4 x 0.2, 0.22, 0.23, 3 x 0.3, 0.33, 2 x 0.4, 0.43, 3 x 0.5, 0.5, 0.7, 3 x 0.8, 0.9, 1.1, 2 x 1.2, 1.4, 1.5, 2 x 1.7, 1.8, 1.9, 2.1, 2.4, 2.5, 6.9, 7.62, 8.0, 8.3, 35 (maybe outlier) mg/kg R_{max} = 11 mg/kg, R_{ber} = 2.4 mg/kg, STMR = 0.30 mg/kg R_{max} = 4.835 mg/kg, R_{ber} = 2.25 mg/kg, STMR = 0.30 mg/kg (without 35 mg/kg)</p> <p>AMPA: 0.11, 32 x <0.05 mg/kg</p> <p>No residue data available.</p> <p>The extrapolation document allows extrapolation from beans and/or peas to the whole group. According to the information available time of sowing, yield/ha and ratio of straw and seeds of peas and lupines are comparable.</p> <p>MRL proposal is based on data generated in peas as lupines are more like a pea than a bean.</p> <p>Only for Northern Europe</p>
Lupines			10	
Others	none	0.1*	0.1*	
4. Oil seeds				
Linseed	none	10	10	<p>cGAP: DE, UK: 1.44 kg as/ha, PHI: 14 d. S-EU: No GAP. GB: 6 trials, 0.72 - 2.88 kg as/ha, PHI: 5 - 7 d</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Sunflower seed (with shell)	none		20	<p>Glyphosate: 1.27, 1.29, 1.9, 2.23, 3.97, 4.6 mg/kg R_{max} = 7.78 mg/kg, R_{ber} = 8.26 mg/kg, STMR = 2.07 mg/kg AMPA: 4 x <0.05 mg/kg</p> <p>cGAP: HU: 1.8 kg as/ha, PHI: 7 d. N-EU: No GAP.</p> <p>HU: 8 trials, 1.58 - 1.89 kg as/ha, PHI: 7 d Glyphosate: 0.087, 0.097, 0.35, 0.75, 1.27, 1.28, 4.46, 13.08 mg/kg (PHI: 7-14 d) R_{max} = 14.96 mg/kg, R_{ber} = 7.58 mg/kg, STMR = 1.13 mg/kg</p>
Rape seed	10	10	10	<p>cGAP: <u>Non tolerant oilseed rape</u>: N-EU: 2.01 kg as/ha, PHI: 10 - 14 d. S-EU: 2.01 kg as/ha, pre-emergence, PHI: -.</p> <p>N-EU: 161 trials on <u>glyphosate non tolerant oilseed rape</u>, 0.72 - 2.94 kg as/ha, PHI: 7 - 21 d</p> <p>Glyphosate: 0.06, 0.08, 2 x 0.10, 0.12, 0.14, 0.15, 0.16, 4 x 0.20, 0.21, 3 x 0.23, 0.26, 2 x 0.30, 3 x 0.32, 0.33, 2 x 0.35, 11 x 0.40, 0.43, 0.45, 0.46, 0.48, 4 x 0.50, 0.51, 0.54, 0.55, 0.55, 0.57, 12 x 0.60, 0.63, 0.65, 3 x 0.70, 0.73, 0.78, 5 x 0.80, 0.82, 0.86, 0.87, 0.88, 2 x 0.90, 0.93, 2 x 0.95, 0.96, 2 x 0.98, 1.00, 1.05, 1.08, 2 x 1.10, 5 x 1.20, 1.23, 5 x 1.30, 4 x 1.40, 1.43, 1.48, 2 x 1.50, 1.52, 1.57, 1.60, 1.64, 1.70, 1.78, 1.83, 2 x 1.80, 1.85, 1.92, 1.99, 2.00, 2.07, 2.11, 2.34, 2.40, 2.70, 2.74, 2.80, 2.90, 3.04, 3.10, 3.19, 3.20, 3.20, 3 x 3.28, 3.40, 3 x 3.50, 3.60, 3.70, 3.74, 3.98, 4.00, 4.11, 4.40, 4.65, 5.41, 5.56, 5.73, 2 x 6.30, 6.53, 8.40, 2 x</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
				<p>8.60, 10.00, 11.60 mg/kg $R_{max} = 5.51 \text{ mg/kg}$, $R_{ber} = 3.99 \text{ mg/kg}$, $STMR = 0.95 \text{ mg/kg}$ AMPA: 0.08, 0.09, 0.1, 0.13, 0.15, all other <0.05 mg/kg</p> <p>N-EU: 29 trials on <u>glyphosate tolerant oilseed rape</u>, 0.9 - 1.44 kg as/ha, PHI: 69 - 163 d Glyphosate: 28 x <0.05 or <0.02, 0.08 mg/kg AMPA: 17 x <0.05 or <0.02, 2 x 0.06, 0.09, 2 x 0.1, 3 x 0.2, 2 x 0.3, 0.4, 0.5 mg/kg</p> <p>Glyphosate + AMPA: 17 x <0.05 or <0.02, 0.09, 2 x 0.1, 2 x 0.2, 2 x 0.3, 0.4, 2 x 0.5, 0.6, 0.8 mg/kg</p> <p>According to the results of trials with non tolerant oilseed rape a MRL of 10 mg/kg is proposed. This covers also the use in tolerant oilseed rape, if applied according to the GAP given. This proposal is in line with the Codex MRL. Since the commercial commodity of oilseed rape contains both the <u>CP4 EPSPS</u> enzyme and the GOX gene there is a difference in the residue behaviour of glyphosate within the tolerant and non tolerant rape plant. Because GOX accelerates the formation of AMPA this metabolite appears at higher levels than in glyphosate non tolerant rape plant parts. Therefore, AMPA should be included in the residue definition for oilseed rape for enforcement purpose and for risk assessment.</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Soybeans	20	20	20	<p>cGAP: <u>Tolerant soybeans</u>: N-EU and S-EU: 2 x 1.08 kg as/ha, BBCH 19 at the latest, PHI: -. US: <u>tolerant soybeans</u>: 1 x <u>≤1.7 kg glyphosate/ha</u>, PHI: 14 d. (request for import tolerance)</p> <p>N-EU and S-EU: 1.44 kg as/ha, BBCH 19 at the latest, PHI: - US: 120 trials with 4 applications at rates of 1 x 6.38 (pre emergence) and 3 x 0.84 kg as/ha (PHI: 10 - 133 d).</p> <p>Glyphosate: 3 x <0.05, 0.05, 0.06, 0.07, 6 x 0.1, 9 x 0.2, 11 x 0.3, 4 x 0.4, 8 x 0.5, 8 x 0.6, 6 x 0.7, 2 x 0.9, 9 x 1.0, 2 x 1.1, 2 x 1.3, 5 x 1.4, 2 x 1.5, 2 x 1.6, 2 x 1.7, 4 x 1.8, 5 x 1.9, 3 x 2.0, 2.1, 5 x 2.3, 2 x 2.4, 2 x 2.6, 2 x 2.7, 2.8, 2.9, 2 x 3.0, 3.2, 3.3, 3.5, 3.6, 3.7, 4.4, 5.3, 5.6 mg/kg</p> <p>AMPA: 2 x <0.05, 2 x 0.05, 2 x 0.07, 5 x 0.1, 9 x 0.2, 8 x 0.3, 5 x 0.4, 7 x 0.5, 6 x 0.6, 4 x 0.7, 0.8, 2 x 0.9, 4 x 1.0, 5 x 1.1, 2 x 1.2, 3 x 1.3, 2 x 1.4, 2 x 1.5, 4 x 1.6, 4 x 1.7, 2 x 1.8, 4 x 1.9, 2 x 2.0, 2.1, 2.2, 2.3, 2.4, 2.5, 3 x 2.6, 4 x 2.7, 2 x 2.8, 3 x 3.0, 3.1, 3.2, 2 x 3.3, 2 x 3.4, 3.5, 2 x 3.6, 2 x 3.9, 4.5, 4.6, 5.0, 5.4, 7.6 mg/kg.</p> <p>Glyphosate + AMPA: <0.05, 0.06, 0.08, 2 x 0.1, 0.2, 3 x 0.3, 4 x 0.4, 6 x 0.5, 0.6,</p> <p>France and Italy: MLL 30437 MLL 30438 MLL 30435 MLL 30436 MLL 30487 MLL 30488</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
				<p>0.7, 5 x 0.8, 4 x 0.9, 2 x 1.0, 2 x 1.1, 3 x 1.2, 2 x 1.3, 1.4, 3 x 1.5, 3 x 1.6, 1.7, 1.8, 3 x 2.0, 2.1, 2.2, 2.3, 3 x 2.4, 2 x 2.5, 3 x 2.7, 2.8, 2 x 2.9, 3.2, 3.3, 2 x 3.4, 3.5, 2 x 3.6, 3 x 3.7, 3.8, 3.9, 2 x 4.0, 2 x 4.2, 4.3, 4.5, 4.7, 3 x 4.9, 3 x 5.1, 5.4, 2 x 5.8, 2 x 5.9, 2 x 6.2, 4 x 6.6, 6.7, 6.9, 7.1, 7.2, 7.3, 2 x 7.6, 2 x 7.9, 2 x 8.2, 8.3, 8.5, 9.1, 9.6, 3 x 11, 17 mg/kg.</p> <p>No trial according to GAP. $R_{\max} = 6.72 \text{ mg/kg}$, $R_{\text{ber}} = 10.65 \text{ mg/kg}$, $\text{STMR} = 2.7 \text{ mg/kg}$</p> <p>GAP for <u>tolerant soybeans</u>: 1 x 1.122 kg <u>glyphosate-trimesium/ha</u>, PHI: 7 d.</p> <p>20 trials with 3 applications at rates of 4.03 (pre emergence), 1.61 and 0.806 kg <u>glyphosate-trimesium/ha</u> (PHI: 7d).</p> <p>Glyphosate: 0.26, 0.44, 0.54, 0.63, 0.73, 0.75, 0.81, 0.83, 0.98, 1.0, 1.24, 1.68, 1.73, 2.42, 2.61, 2.81, 3.25, 3.62, 3.92, 6.73 mg/kg (PHI: 7 d).</p> <p>AMPA: - No trial according to GAP. $R_{\max} = 5.71 \text{ mg/kg}$, $R_{\text{ber}} = 5.52 \text{ mg/kg}$, $\text{STMR} = 1.12 \text{ mg/kg}$</p> <p>S-FR / IT: GAP for <u>tolerant soybeans</u>: 2 x 0.72 - 1.08 kg <u>glyphosate/ha</u> (max. 1.44 kg as/ha), PHI: F. 28 trials with 2, 3 or 4 applications at rates of 0.72 and 1.08 each (flowering til mature) (PHI = 109 - 12 d). Glyphosate: 3 x <0.05, 0.05, 0.06, 2 x 0.07, 2 x 0.1, 3 x 0.2, 3 x 0.3, 7 x</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Mustard seed		10	10	<p>0.4, 0.5, 3 x 0.6, 2 x 0.7, 3 x 0.8, 2 x 0.9, 2 x 1.0, 2 x 1.1, 1.2, 1.4, 1.8 mg/kg. AMPA: 2 x <0.05, 2 x 0.05, 2 x 0.06, 0.08, 0.09, 2 x 0.2, 4 x 0.4, 4 x 0.5, 3 x 0.6, 0.7, 3 x 0.8, 3 x 0.9, 2 x 1.0, 2 x 1.1, 1.2, 1.3, 1.4, 1.7, 1.8, 2 x 2.0, 2.5 mg/kg. Glyphosate + AMPA: 0.09, 3 x 0.1, 3 x 0.2, 0.4, 3 x 0.8, 1.1, 6 x 1.2, 1.4, 1.5, 2 x 1.6, 1.8, 1.9, 2.0, 2 x 2.1, 2.3, 2.4, 2.5, 2.6, 2.8, 2.9, 3.0, 3.2, 3.5, 4.4, 4.6, 4.8 mg/kg. $R_{max} = 4.39$ mg/kg, $R_{ber} = 4.95$ mg/kg, STMR = 1.45 mg/kg</p> <p>According to the results of trials with tolerant soybeans a MRL of 20 mg/kg is proposed. This covers also the use in non-tolerant soybeans for desiccation purpose close to harvest, if applied according to the GAP given. This proposal is in line with the Codex MRL which is acceptable. This proposal will cover uses of glyphosate in tolerant and non-tolerant soybeans in Europe and in the USA. Since glyphosate non tolerant soybeans itself as well as soybean plants containing <u>CP4 EPSPS</u> metabolise glyphosate to AMPA there is no difference in the residue behaviour of glyphosate in both kind of plants. However, AMPA reaches residue levels as high as glyphosate itself in soybean seeds this metabolite should be included in the residue definition for enforcement purpose and for risk assessment.</p> <p>cGAP: IE, UK: 1.44 kg as/ha, PHI: 8 d.</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Cotton seed	0.5 (10, Step 3(a))		10	<p>S-EU: No GAP.</p> <p>GB: 4 trials, 1.44 - 2.88 kg as/ha, PHI: 7 - 8 d Glyphosate: 0.2, 0.5, 2.6, 3.2 mg/kg</p> <p>cGAP: ES: 1.8 kg as/ha, PHI: 7 d. N-EU: No GAP.</p> <p>ES: 24 trials on <u>glyphosate non tolerant cotton</u>, 1.34 - 1.65 kg as/ha, PHI: 6 - 9 d</p> <p>Glyphosate: 0.04, 0.05, 0.06, 2 x 0.07, 2 x 0.08, 0.10, 0.12, 2 x 0.13, 2 x 0.15, 0.16, 0.19, 0.22, 0.24, 0.25, 2 x 0.26, 0.31, 0.33, 0.41, 0.51 mg/kg</p> <p>R_{max} = 0.46 mg/kg, R_{ber} = 0.52 mg/kg, STMR = 0.15 mg/kg</p> <p>AMPA: all <0.05 mg/kg</p> <p>US: (request for import tolerance) GAP: 1 x 1.68 kg as/ha, PHI: 7 d 18 trials with 1, 2 or 4 applications and application rates at 4.48 - 8.97 kg as/ha. The majority of trials were conducted with 1 application of 5.04 kg as/ha;</p> <p>Glyphosate: 0.15, 0.26, 0.27, 0.47, 0.49, 0.54, 0.63, 0.92, 1.48, 1.87, 2.02, 2.15, 2.68, 2.89, 2.90, 3.62, 4.10, 5.93 mg/kg (PHI: 3 - 14 d).</p> <p>No trial according to GAP. R_{max} = 6.52 mg/kg, R_{ber} = 5.79 mg/kg, STMR = 1.68 mg/kg</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
				<p><u>Glyphosate tolerant cotton</u> cGAP: S-EU: 2 x 0.72 kg as/ha (before 4 leaf stage), 1 x 1.8 kg as/ha (8-10 leaf stage), 1 x 1.8 kg as/ha (preharvest), PHI: 20 d Two ES trials not according to GAP. N-EU: No GAP.</p> <p>US (request for import tolerance): cGAP: 1 x 1.68 kg as/ha (4 leaf stage), 2 x 0.84 kg as/ha (12 leaf stage), 1 x 1.68 kg as/ha (pre-harvest), PHI: 7 d 48 results from 16 trials with different application rates (4-5 applications, up to 8.8 kg as/ha, PHI: 6-17 d); Glyphosate: 0.1, 3 x 0.3, 4 x 0.4, 6 x 0.5, 0.6, 3 x 0.7, 2 x 0.8, 0.9, 1.0, 1.1, 1.2, 2 x 1.5, 1.9, 2.0, 2.1, 2.2, 2.3, 2.4, 2 x 2.5, 2.6, 2.9, 4.2, 4.4, 4.6, 4.9, 5.0, 5.2, 5.4, <u>6.4</u> 2 x 3.0, 3.4, 4.0, mg/kg seeds. R_{max} = 5.47 mg/kg, R_{ber} = 5.95 mg/kg, STMR = 1.35 mg/kg seeds. AMPA: 30 x <0.05, 3 x 0.05, 0.06, 0.07, 3 x 0.08, 0.09, 6 x 0.1, 3 x <u>0.2</u> mg/kg R_{max} = 0.15 mg/kg, R_{ber} = 0.16 mg/kg, STMR = 0.05 mg/kg</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
				<p>STMR (sum of glyphosate and AMPA) = 1.4 mg/kg</p> <p>According to the results of trials with tolerant cotton, a MRL of 5 mg/kg could be sufficient. This covers also the use in non-tolerant cotton, if applied according to the GAP given. The proposed Codex MRL however, is acceptable. Therefore, a MRL of 10 mg/kg is proposed for cotton seed. This proposal will cover all uses of glyphosate in tolerant and non-tolerant cotton in Europe and in the USA.</p> <p>Since the commercial commodity of cotton contains only the <u>CP4 EPSPS</u> there is no difference in the residue behaviour of glyphosate within the tolerant plant. Therefore no increased residue level of AMPA are observed and there is no need to include this main metabolite of glyphosate in the residue definition for enforcement purpose and for risk assessment.</p>
Others		0.1*	0.1*	
5. Potatoes	none	0.1*	0.5	<p>cGAP: NL: 2.2 kg as/ha, PHI: 7 d. IT: 4.32 kg as/ha, wiping, PHI: -. CH: 3 trials, 1.8 kg as/ha, PHI: 7 d Glyphosate: 3 x <0.05 mg/kg AMPA: 2 x <0.05 mg/kg NL: 11 trials, 0.72 - 2.88 kg as/ha, PHI: 6 - 7 d Glyphosate: 4 x <0.05, 0.07, 0.08, 0.09, 0.11, 0.12, 0.21, 0.59 mg/kg AMPA: all <0.05 mg/kg R_{max} = 0.58 mg/kg, R_{ber} = 0.24 mg/kg, STMR = 0.08 mg/kg</p>
6. Tea	none	0.1*	2	<p>cGAP: JP; 2.3 kg as/ha, PHI: 7 d. Only data for US and The Netherlands</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
7. Hops	none	0.1*	0.1*	IN / TW: 9 trials, 3 x 2.16 kg as/ha, PHI: 8 - 15 d Glyphosate: 3 x <0.08, 0.1, 0.15, 0.61, 0.64, 0.8, 1.13 mg/kg AMPA: all <0.08 mg/kg R _{max} = 1.61 mg/kg, R _{ber} = 1.44 mg/kg, STMR = 0.15 mg/kg No GAP, no residue data.
8. Cereals Buckwheat Barley	20	20	0.1* 20	No GAP, no residue data. cGAP: N-EU: FR; 1 x 2.16 kg as/ha (pre-harvest, desiccation), PHI: 7 d. S-EU except FR: 2.7 kg as/ha, per-emergence, PHI: -. North: 10 trials, 1 x 1.78 - 2.88 kg as/ha, PHI: 7 - 16 d South: 4 trials in S-FR; 1 x 2.04 - 2.22 kg as/ha, PHI: 7 d Glyphosate: 0.09, 0.4, 1.16, 1.2, 1.3, 1.4, 2 x 1.5, 2 x 1.6, 1.75, 3 x 1.8, 1.9, 2.1, 2 x 2.2, 2.24, 2.3, 2.37, 2.6, 2 x 2.7, 2.8, 2.9, 3.0, 3.3, 3.5, 3.6, 3.7, 2 x 3.8, 2 x 4.0, 4.1, 4.2, 4.3, 4.4, 2 x 4.6, 2 x 4.7, 2 x 4.8, 5.0, 5.1, 5.17, 5.2, 2 x 5.4, 5.5, 5.8, 5.81, 2 x 5.9, 5.92, 6.0, 2 x 6.2, 3 x 6.4, 6.7, 6.71, 6.8, 6.99, 7.0, 3 x 7.2, 7.3, 2 x 7.4, 7.6, 2 x 7.9, 8.0, 8.1, 8.4, 8.6, 8.9, 9.5, 2 x 9.6, 9.8, 9.93, 3 x 11.0, 11.2, 11.8, 12.0, 12.47, 12.6, 12.7, 2 x 13.0, 13.99, 14.8, 16.1, 18.0, 19.2, 20.3, 23.4, 32.8 mg/kg 15 trials, N-EU, 1.96 - 3.2 kg glyphosate-trimesium/ha: Glyphosate (PMG-Anion): 1.3, 1.6, 2.8, 3.6, 3.7, 4.4, 4.7, 5.0, 2 x 6.3, 8.1, 8.9, 9.1, 13.0, 19.0 mg/kg R _{max} = 16.4 mg/kg, R _{ber} = 17.0 mg/kg, STMR = 5.8 mg/kg AMPA: 46 x <0.05, 4 x 0.05, 9 x 0.06, 4 x 0.07, 8 x 0.08, 5 x 0.09, 4 x 0.1, 4 x 0.12, 0.13,

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Oat	20	20	20	<p>2 x 0.14, 4 x 0.16, 0.17, 0.19, 3 x 0.2, 2 x 0.3 mg/kg $R_{max} = 0.18$ mg/kg, $R_{ber} = 0.18$ mg/kg, STMR = 0.05 mg/kg S-EU: No GAP for pre-harvest desiccation of cereals in S-EU therefore, no residue data available and required. MRL proposal based on data from trials in the northern region is sufficient for all EU Member States.</p> <p>cGAP: N-EU: FR: 1 x 2.16 kg as/ha (pre-harvest, desiccation), PHI: 7 d. S-EU except FR: 2.7 kg as/ha, per-emergence, PHI: -. N-EU: 17 trials, 1 x 1.8 - 2.16 kg as/ha, PHI: 6 - 13 d Glyphosate: 1.2, 2.1, 2.4, 3.2, 3.8, 5.3, 5.5, 7.1, 8.4, 8.5, 10.4, 12.4, 13.8, 17.1, 18.2 mg/kg 2 trials, DE, 2.4 kg glyphosate-trimesium/ha: Glyphosate (PMG-Anion): 8.3, 14.0 mg/kg $R_{max} = 21.5$ mg/kg, $R_{ber} = 26.2$ mg/kg, STMR = 8.3 mg/kg AMPA: 5 x <0.05, 0.07, 3 x 0.1, 0.12, 0.31, 0.33 mg/kg S-EU: No GAP for pre-harvest desiccation of cereals in S-EU therefore, no residue data available and required. MRL proposal based on data from trials in the northern region is sufficient for all EU Member States.</p>
Millet				No special GAP. No residue data.
Maize Maize grain (Maize forage)	1		1 1)	<p>cGAP: N-EU and S-EU (pending): Maize tolerant to glyphosate (line NK603), 1.44 kg as/ha at BBCH 19, PHI: 90 d. N-FR: 4 trials with interrow treatments of <u>non-tolerant maize</u> 1 x 0.54 -</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
				<p>4.32 kg as/ha, PHI: 55 d. Glyphosate: 0.07, 0.08, 0.15, 0.45 mg/kg. AMPA: all <0.05 mg/kg.</p> <p>S-FR: 8 trials with interrow treatments of <u>non-tolerant maize</u> 1 x 4.32 or 8.64 kg as/ha, PHI: 64 d. Glyphosate: 0.1, 2 x 0.2, 2 x 0.3, 2 x 0.4, 0.5 mg/kg. AMPA: all <0.05 mg/kg. R_{max} = 0.67 mg/kg, R_{ber} = 0.75 mg/kg, STMR = 0.25 mg/kg</p> <p>N-EU: 10 trials on <u>glyphosate tolerant maize</u> (line NK603: only CP4 EPSPS), S-EU: 18 trials on <u>glyphosate tolerant maize</u> (line NK603: only CP4 EPSPS): GAP: 3 subsequent uses at 1.1-1.2, 0.7-1.2, 1.1-1.5 kg as/ha each, PHI: 83 - 128 d Glyphosate in grain: 26 x <0.05, 0.05, 0.07 mg/kg (PHI: 83-128 d). AMPA in grain: all <0.05 mg/kg Glyphosate in fodder: 8 x <0.05, 4 x 0.06, 2 x 0.08, 2 x 0.09, 0.1, 0.11, 0.16, 0.17, 0.32, 0.35, 0.39, 0.44, 0.5, 0.52, 0.7, 0.96 mg/kg (PHI: 50-102 d). R_{max} = 0.72 mg/kg, R_{ber} = 0.56 mg/kg, STMR = 0.09 mg/kg AMPA in fodder: 27 x <0.05, 0.09 mg/kg No trial according to GAP, all uses overdosed.</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Rye	5	10		<p>US: 22 trials on glyphosate tolerant maize (line MON 802: CP4 EPSPS + GOX):</p> <p>GAP: 2 - 4 subsequent uses at 6.38+0.84, 6.38+0.84+0.84 or 6.38+0.84+0.84+0.84 kg as/ha each, PHI: 6-8 d.</p> <p>Glyphosate: 19 x <0.05, 0.06, 0.1, 0.4 mg/kg.</p> <p>AMPA: 2 x <0.05, 5 x 0.1, 3 x 0.2, 6 x 0.3, 2 x 0.4, 0.5, 0.7, 1.0, 1.4 mg/kg.</p> <p>Glyphosate + AMPA: 0.05, 5 x 0.2, 2 x 0.3, 2 x 0.4, 6 x 0.5, 2 x 0.6, 0.8, 1.1, 1.5, 2.1 mg/kg.</p> <p>R_{max} = 1.67 mg/kg, R_{ber} = 1.05 mg/kg, STMR = 0.5 mg/kg</p> <p>USA-trials not according to EU-GAP (overdosed and pre-harvest treatment).</p> <p>Based on the available data a MRL of 1 mg glyphosate/kg maize grain and of 1 mg glyphosate/kg maize fodder for the use in Europe is proposed. Based on the low residue situation of AMPA after treatment of glyphosate non-tolerant and glyphosate tolerant maize (line NK603 containing only CP4 EPSPS which does not accelerate the formation of AMPA) there is no need to include this metabolite in the residue definition for maize. 5.1.2.f Woo</p> <p>cGAP: N-EU: FR; 1 x 2.16 kg as/ha (pre-harvest, desiccation), PHI: 7 d. S-EU except FR: 2.7 kg as/ha, per-emergence, PHI: -.</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Rice	0.1*		0.1*	<p>N-EU: 8 trials, 1 x 1.8 - 2.16 kg as/ha, PHI: 7 - 14 d Glyphosate: 2.9, 3.1, 4.6, 4.74, 5.3, 5.44, 15.6, 16.7 mg/kg $R_{max} = 25.0$ mg/kg, $R_{ber} = 26.1$ mg/kg, STMR = 5.0 mg/kg AMPA: <0.05, 2 x 0.21, 0.3, 0.35 mg/kg</p> <p>S-EU: No GAP for pre-harvest desiccation of cereals in S-EU therefore, no residue data available and required. MRL proposal based on data from trials in the northern region is sufficient for all EU Member States. A MRL of 20 mg/kg rye could be proposed based on these results. However, since this data base is small compared to the results of barley and wheat and extrapolation of wheat data to derive a MRL of rye is possible these data are included in the data pool of wheat. Therefore, a joint MRL of 10 mg/kg for both rye and wheat is proposed.</p> <p>cGAP: IT; 4.32 kg as/ha, pre-plant treatment, PHI: -. N-EU: No GAP. No residue data available. No exceedence of MRL proposal expected. Extrapolation of data from pre-emergence treatment of other small grain cereals possible.</p>
Sorghum	20	20	20	<p>cGAP: US; ≤ 1.7 kg as/ha pre-harvest, PHI: 7 d. No GAP in EU, no residue data available. Existing EU import tolerance is based on residue data from trials conducted in the USA. This is confirmed by following data to which five further data from 1997 was recently submitted: US: 13 trials and 2 processing studies, 1 x 1.7 kg as/ha, PHI: 6-8 d. Glyphosate:</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Triticale		5	10	<p>1.08, 1.09, 1.30, 1.42, 1.73, 1.83, 4.41, 4.47, 4.64, 5.29, 6.03, 6.31, 6.38, 12.50, 13.50 mg/kg.</p> <p>$R_{max} = 14.77$ mg/kg, $R_{ber} = 12.62$ mg/kg, STMR = 4.47 mg/kg</p> <p>AMPA: 3 x <0.05, 0.05, 0.07, 2 x 0.08, 3 x 0.09, 4 x 0.1, 0.2 mg/kg</p> <p>cGAP: N-EU: FR; 1 x 2.16 kg as/ha (pre-harvest, desiccation), PHI: 7 d. S-EU except FR: 2.7 kg as/ha, per-emergence, PHI: -.</p> <p>No residue data available.</p> <p>A MRL of 10 mg/kg is proposed based on the results from trials on wheat.</p>
Wheat	5	5	10	<p>cGAP: N-EU: FR; 1 x 2.16 kg as/ha (pre-harvest, desiccation), PHI: 7 d. S-EU except FR: 2.7 kg as/ha, per-emergence, PHI: -.</p> <p>N-EU: 147 trials, 1 x 1.6 - 2.88 kg as/ha, PHI: 6 - 15 d</p> <p>Glyphosate in wheat:</p> <p>0.09, 0.15, 2 x 0.16, 0.17, 4 x 0.2, 2 x 0.24, 2 x 0.28, 4 x 0.3, 0.31, 0.32, 0.34,</p> <p>7 x 0.4, 0.43, 2 x 0.45, 0.46, 2 x 0.5, 0.52, 0.55, 0.58, 4 x 0.6, 2 x 0.63, 0.64, 0.65,</p> <p>2 x 0.66, 0.67, 5 x 0.7, 2 x 0.75, 0.76, 3 x 0.8, 2 x 0.83, 0.84, 2 x 0.85, 3 x 0.9,</p> <p>2 x 0.93, 0.97, 2 x 1.0, 1.09, 5 x 1.1, 1.12, 6 x 1.2, 4 x 1.3, 1.39, 2 x 1.4, 1.42,</p> <p>7 x 1.5, 1.57, 2 x 1.6, 1.69, 7 x 1.7, 2.0, 4 x 2.1, 3 x 2.2, 2 x 2.4, 2.5, 2.6, 3.0, 3.1, 3.11, 2 x 3.3, 3.4, 3.72, 2 x 3.8, 2 x 3.9, 4.03, 4.2, 4.6, 4.7, 4.8, 4.86, 5.5, 5.8, 7.9, 8.5, 8.81, 9.83, 16.9 mg/kg</p> <p>Glyphosate in rye:</p> <p>2.9, 3.1, 4.6, 4.74, 5.3, 5.44, 15.6, 16.7 mg/kg</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
other cereals		0.1*		<p>$R_{max} = 7.2 \text{ mg/kg}$, $R_{ber} = 4.4 \text{ mg/kg}$, $STMR = 1.1 \text{ mg/kg}$</p> <p>AMPA in wheat: $85 \times <0.05$, 7×0.05, 0.06, 2×0.08, 0.06, 2×0.1, 4×0.11, 0.12,</p> <p>2×0.36, 0.38, 0.66 mg/kg</p> <p>AMPA in rye: <0.05, 2×0.21, 0.3, 0.35 mg/kg</p> <p>S-EU: No GAP for pre-harvest desiccation of cereals in S-EU therefore, no residue data available and required.</p> <p>MRL proposal based on data from trials on rye and wheat in the northern region is sufficient for all EU Member States.</p> <p>In contrast to the evaluation in the DAR residue data of straw are not revised again for intake calculation by livestock. More important in livestock nutrition are grass and hay. Since grassland treatment cause higher residues in grass and hay MRL derivation for food of animal origin is based on the corresponding data.</p>
Sugar beets Fodder beets	none	--	--	<p>cGAP: <u>Non-tolerant beets:</u></p> <p>N-EU; wiping with 50 % solution, PHI: -;</p> <p>IT; wiping with 50 % solution, PHI: -;</p> <p>North: 31 trials, wiping with 25 - 50 % solution, PHI: 30 - 91 d</p> <p>Glyphosate in roots:</p> <p>$23 \times <0.05$, 7×0.1, 0.5 mg/kg</p> <p>$R_{max} = 0.26 \text{ mg/kg}$, $R_{ber} = 0.1 \text{ mg/kg}$, $STMR = 0.05 \text{ mg/kg}$</p> <p>Glyphosate in leaves:</p> <p>$15 \times <0.05$, 7×0.1, 0.2, 0.25, 0.4, 0.7, 1.0 mg/kg</p> <p>$R_{max} = 0.65 \text{ mg/kg}$, $R_{ber} = 0.2 \text{ mg/kg}$, $STMR = 0.05 \text{ mg/kg}$</p> <p>AMPA in roots and leaves: all $<0.05 \text{ mg/kg}$</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
				<p>South: No residue data available.</p> <p>cGAP: <u>Tolerant beets</u>: DE; 2 x 1.08 or 3 x 0.72 kg as/ha (total: 2.16 kg as/ha) at the latest BBCH 39, PHI: -.</p> <p>S-EU; 2 x 1.08 or 3 x 0.72 kg as/ha (total: 2.16 kg as/ha) at the latest BBCH 19, PHI: -.</p> <p>The shortest PHI from the latest application timing at BBCH 39 is considered at least 60 days. Therefore, only residue data obtained under these worst case conditions are used for evaluation:</p> <p>North: 7 trials in BE, DK, GB; < 3.0 kg as/ha, PHI: 63 - 89 d. South: 8 trials in ES, IT, S-FR; < 3.0 kg as/ha, PHI: 63 - 64 d.</p> <p>Glyphosate in roots: 0.08, 0.09, 0.1, 5 x 0.2, 2 x 0.3, 3 x 0.4, 2 x 0.5, , 2 x 0.7, 1.3 mg/kg R_{max} = 1.1 mg/kg, R_{ber} = 0.8 mg/kg, STMR = 0.3 mg/kg</p> <p>Glyphosate in leaves: <0.05, 0.08, 0.1, 4 x 0.2, 2 x 0.3, 0.4, 4 x 0.5, 2 x 0.7, 0.8, 0.9 mg/kg R_{max} = 1.03 mg/kg, R_{ber} = 1.0 mg/kg, STMR = 0.35 mg/kg</p> <p>AMPA in roots and leaves: all <0.05 mg/kg</p> <p>From the entire residue data generated in N-EU and S-EU the highest residue levels of 1 mg/kg beet roots and tops is derived which can be used for assessing feed intake levels of domestic animals to derive MRL's of food of animal origin.</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
Grass	50 (hay or dry fodder)	--	--	<p>cGAP: N-EU; 3.6 kg/ha (spraying), PHI: 5 d. IT; 4.32 kg/ha (spraying, pre-plant, post-harvest), PHI: - North: 78 trials, 1 x 0.72 - 2.88 kg as/ha, PHI: 5 - 16 d</p> <p>Glyphosate in grass: 1.0, 1.2, 1.8, 2.0, 2.4, 2.5, 2.6, 3.0, 2 x 3.2, 3.5, 3.6, 3.7, 3.8, 4.0, 2 x 4.2, 4.3, 4.4, 4.7, 5.3, 5.5, 5.6, 5.9, 3 x 6.0, 6.1, 6.2, 7.7, 8.2, 8.3, 8.7, 9.2, 9.6, 9.7, 10.6, 11.2, 13.9, 14.1, 14.5, 14.9, 2 x 15.7, 16.0, 17.3, 17.5, 18.2, 19.3, 2 x 19.6, 2 x 20.4, 2 x 21.2, 22.0, 25.0, 2 x 28.0, 28.5, 31.4, 34.4, 36.8, 38.0, 39.0, 40.0, 41.8, 43.3, 49.8, 50.0, 69.6, 80.8, 84.8, 93.7, 119.6, 138.0, 138.7, 344.2 mg/kg.</p> <p>$R_{max} = 118.9$ mg/kg, $R_{ber} = 56.0$ mg/kg, STMR = 14.0 mg/kg</p> <p>Glyphosate in hay: 3.5, 7.1, 9.4, 11.2, 12.1, 12.8, 14.8, 15.6, 17.4, 18.6, 20.0, 21.2, 21.4, 22.2, 23.2, 27.1, 32.6, 41.2, 47.4, 81.8, 100.8, 166.0 mg/kg</p> <p>Glyphosate: grass and hay: $R_{max} = 114.7$ mg/kg, $R_{ber} = 56.0$ mg/kg, STMR = 15.7 mg/kg</p> <p>AMPA in grass: 2 x 0.05, 0.06, 3 x 0.07, 2 x 0.09, 6 x 0.1, 0.11, 2 x 0.12, 0.14, 4 x 0.17, 2 x 0.18, 4 x 0.2, 2 x 0.21, 2 x 0.22, 0.23, 3 x 0.24, 2 x 0.28, 2 x 0.3, 0.31, 0.32, 2 x</p>

Groups of products	CODEX MRL	Existing EU MRL	MRL proposal	Comments
				<p>0.34, 2 x 0.38, 0.41, 0.42, 0.43, 0.44, 2 x 0.51, 0.53, 0.59, 0.61, 0.78, 0.8, 0.85, 0.86, 0.93, 1.3, 1.57, 3.41, 5.9 mg/kg</p> <p>AMPA in hay: <0.05, 0.21, 2 x 0.22, 0.28, 0.3, 0.37, 0.38, 0.49, 0.57, 0.79, 0.96, 2 x 1.72 mg/kg</p> <p>According to the critical GAP, spraying 5 days before use of grass or hay, residues of glyphosate of up to >300 mg/kg are expected in grass and hay. The "MRL" is derived from all residue values of grass and hay obtained at PHI = 5 - 16 days. Since in the laying hen feeding studies glyphosate residues reached a plateau quickly the most suitable value from the MRL calculation is R_{calc}. Glyphosate treated grass desiccates quickly. Therefore, there is no significant difference in the residue levels of grass and hay. This is confirmed by a couple of data obtained in grass and hay at PHI = 5 d in trials conducted in GB in 1992 from which no clear drying factors can be derived (f = -0.8 to +4.4).</p> <p>South: No residue data available.</p> <p>Despite of lacking data from S-EU the residue data pool from N-EU are considered to be sufficient to propose a highest residue level at 56 mg/kg grass and hay which can be used for assessing feed intake levels of domestic animals to derive MRL's of food of animal origin.</p>

Conclusions**Glyphosate:**

MRLs proposed	50	mg/kg	wild mushrooms
	20	mg/kg	barley, oats, sorghum, soybeans, sunflower seed
	10	mg/kg	cotton seed, linseed, lupine seed, mustard seed, peas, rape seed, rye, triticale, v
	2	mg/kg	beans, tea, kidney of cattle
	1	mg/kg	maize grain, olives for oil production
	0.2	mg/kg	liver of cattle
	0.5	mg/kg	orange, tangerine, grapes, potatoes, kidney of pig
	0.1	mg/kg	grapefruit, lemon, mandarin, kidney of poultry
	0.1*	mg/kg	other products of plant origin

TMDI (WHO model): 17 %

TMDI (German model 4-6 year old girl, bw 13.5 kg): 30 %

An IEDI calculation was not performed since TMDI calculation suggest that no risk may occur.

The proposed MRLs are acceptable.

Documents

1. Draft assessment report on glyphosate, glyphosate trimesium, 27 July 1999
2. Commission Directive 2001/99/EC of 20.11.2001, OJ No L 304, p 14

APPENDIX 3 : Studies submitted to the RMS in 2016

A.3.1. Additional residue studies conducted in 2014/2015 for consideration by EFSA for Art 12 review of glyphosate MRLs

Use	Crop	Rate (kg/ha)	PHI (days)	Number of trials		Report number
				North	South	
Pre-harvest	Sunflower	2.16	7		4	MSL0027504
						MSL0027073
Pasture renovation	Grass	3.6	7		4	MSL0027072
Applied during dormancy	Alfalfa	0.36			2	MSL0027221
Weed control in orchards	Nuts	3.6	7		2	MSL0027487
	Apricots	3.6	7		4	MSL0027488
	Grapes	3.6	7	7	8	MSL0027069
						MSL0027070
						MSL0027071
	Bananas	3.6	1		4	MSL0027222
Kiwi	3.6	7		2	MSL0027501	
Inter-row application	Parsley	1.08	60	2	2	MSL0027492
	Tomatoes	1.08	60		4	MSL0027498
	Cotton	1.8	30		4	MSL0027491
	Onions	1.08	60	2	4	MSL0027499
	Strawberries	1.08	30	1	2	MSL0027495
	Courgettes	1.08	60	2	2	MSL0027496
	Cucumber	1.08	60	2	2	MSL0027497
	Radish	1.08	30		2	MSL0027500
	Carrots	1.08	60		4	MSL0027502

A.3.2. Earlier studies that were not reviewed at EU level (only at MS level)

Use	Crop	Rate (kg/ha)	PHI (days)	Number of trials		Report number
				North	South	
Pre-harvest	Corn	1.80	14	8		99GLY02 00MONAA1503

A 3.3. Available since end of April 2016 (not submitted)

Use	Crop	Rate (kg/ha)	PHI (days)	Number of trials		Report number
				North	South	
Inter-row	Lettuce	1.08	45-19	2	4	MSL0027493
	Green beans		60-30	4	4	MSL0027494
Orchards	Grapes	3.6	7	2		MSL0027503
Weed wiper	Turnips	1.44	61-59	4	4	MSL0027489
	Rice		30-20			MSL0027490

A.3.4. List of studies submitted to the RMS (October 2016) in support of Import tolerances/Codex MRLs

Note: The highlighted studies aren't Monsanto studies and were not submitted by Monsanto but by the other data owners

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5.1.2.e Woo 1993a. Final Report on Projekt AS/1900/CN: Report on the Field Phase of a Programme to generate Crop Samples for Residue Analysis following the Application of CHE 3607 on Winter Field Beans. Cheminova A/S, Report GLY 140. Unpublished

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5.1.2.e Woo 1993. Determination of Residues of Glyphosate in Winter Field Beans (Seed and Haulm) - Treatment with CHE 3607 - UK, Season 1993. Cheminova A/S, Report GLY 305. Unpublished

5.1.2.e Woo. 1987. Residual glyphosate and aminomethylphosphonic acid in oilseedrape, beans and peas following application of MON 8762 - MON 8795 and Roundup herbicide, UK 1986 field trials. Monsanto Company, Report MLL 30180. Unpublished

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5.1.2.e Woo. 1987. Residual glyphosate and aminomethylphosphonic acid in oilseedrape, beans and peas following application of MON 8762 - MON 8795 and Roundup herbicide, UK 1986 field trials. Monsanto Company, Report MLL 30180. Unpublished

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5.1.2.e Woo. 1983. Glyphosate residues in soybeans and soybean fractions following recirculating sprayer and preharvest topical treatments with Roundup herbicide. Monsanto Company, Report MSL 3259. Unpublished

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Maize

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Oats

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Wheat

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Lentils

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