

**STATEMENT**

# Targeted review of the maximum residue levels (MRLs) for ethephon

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In accordance with Article 43 of Regulation (EC) 396/2005, EFSA received a request from the European Commission to perform a targeted review of the existing maximum residue levels (MRLs) for ethephon which are based on revoked codex maximum residue limits (CXLs), considering the new toxicological reference values and the new residue definitions derived during the renewal of the approval of ethephon and the most recent version of the EFSA Pesticide Residues Intake Model (PRIMo) (rev.3.1). EFSA investigated the origin of the current EU MRLs. For existing EU MRLs that are based on revoked CXLs, EFSA verified whether an alternative MRL could be proposed based on the data evaluated in previous EFSA and JMPR assessments and proposed a revised list of MRLs. Data submitted by Member States during the written procedure was also considered. EFSA performed an indicative chronic and acute dietary risk assessment for the revised list of MRLs to support risk managers during the decision-making. For some of the commodities under assessment, further risk management discussions are required to decide which of the risk management options proposed by EFSA should be implemented in the EU MRL legislation.

**KEYWORDS**

ethephon, MRLs, peer review, Regulation (EC) No 396/2005

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## BACKGROUND AND TERMS OF REFERENCE

On 8 October 2009, EFSA provided a reasoned opinion on the review of the existing maximum residue limits (MRLs) for the active substance ethephon in compliance with Article 12(1) of Regulation (EC) No 396/2005<sup>1</sup> (EFSA, 2009). In the review of the MRLs, the chronic and acute consumer exposures were calculated using revision 2 of the EFSA pesticide residues intake model (PRIMO) and compared with the toxicological reference values for ethephon valid at that time. The MRLs resulting from this review were implemented by Regulation (EU) No 559/2011.<sup>2</sup>

In the framework of the renewal of the approval of ethephon under Regulation (EC) No 1107/2009,<sup>3</sup> EFSA published a conclusion proposing lowering the existing acceptable daily intake (ADI) from 0.03 to 0.02 mg/kg. In addition, EFSA proposed a new residue definition for enforcement in cereals as sum of ethephon free and conjugates, expressed as ethephon (EFSA, 2023). The new definition proposed for cereals is the same as the definition for cereals and straw used in Codex Alimentarius. In 2016, the Codex MRLs (CXLs) for cereals (wheat, barley and rye) were not implemented in the EU legislation due to the incompatibility of the residue definitions. In addition, since then, some of the CXLs which were implemented in the EU legislation have been revoked (CAC, 2016).

Furthermore, a recent preliminary risk assessment indicated that the existing MRLs of ethephon might pose acute risks to consumers according to the intake calculations performed with the most recent version of PRIMO (rev.3.1).

Taking all this into consideration, in October 2023, in accordance with Article 43 of Regulation (EC) No 396/2005, the European Commission mandated EFSA to issue a statement with a targeted review of the existing MRLs for ethephon.

In particular, EFSA was requested to:

- revise MRLs that are based on revoked<sup>4</sup> CXLs, with a view to possible implementation of existing CXLs for cereals into the EU legislation, considering the new proposed residue definition for enforcement and its compatibility with the residue definition used by Codex Alimentarius;
- perform an assessment of the chronic and acute risk to consumers of the revised list of MRLs, considering the newest toxicological reference values, the residue data available according to the new residue definitions derived in the framework of the renewal of the approval of ethephon and the newest version of PRIMO;
- consult Member States (MSs) on information about good agricultural practices (GAPs) authorised in the EU and in the third countries and already evaluated at Member State level on the commodities where the MRLs are based on revoked CXLs and on the commodities of concern, which might support setting of safe fall-back MRLs, where this is necessary in view of consumer protection;
- derive a list of MRLs that reflects the new residue definition derived during the renewal and does not pose an unacceptable risk to consumers, and/or advise risk managers on alternative options.

In January 2024, EFSA circulated a draft statement to Member States for consultation via a written procedure. In line with the terms of reference, during the consultation, Member States were requested to submit information about GAPs and supporting residue trials on the commodities for which the current MRLs are based on revoked CXLs and on the commodities for which a concern was identified according to the risk assessment. Comments and additional data received on 5 February 2024 were considered during the finalisation of this statement. The GAPs received and a conclusion on whether the uses could be considered to derive a revised or fall-back MRL were reported in the GAP overview file. The details of the critical GAPs for ethephon submitted by Member States during the written procedure and the supporting residue trials considered to derive the revised and the fall-back MRLs are given in Appendices A and B, respectively.

The Member States consultation report with the collation of comments received on the draft statement (EFSA, 2024), the evaluation reports submitted by Member states during the written procedure (France, 2024; Italy, 2024; Netherlands, 2024; Spain, 2024), the chronic and acute exposure calculations performed using the EFSA PRIMO 3.1 for all crops covered by this assessment and the GAP overview file are considered background documents and are made publicly available as supporting documents to this statement. A screenshot of the report sheet of the PRIMO is presented in Appendix D.

<sup>1</sup>Regulation (EC) No 396/2005 of the European 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, pp. 1–16.

<sup>2</sup>Commission Regulation (EU) No 559/2011 of 7 June 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for captan, carbendazim, cyromazine, ethephon, fenamiphos, thiophanate-methyl, triasulfuron and triticonazole in or on certain products. OJ L 152, 11.6.2011, pp. 1–21.

<sup>3</sup>Commission Regulation (EC) No 1107/2009 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, pp. 1–50.

<sup>4</sup>The wording 'withdrawn or obsolete' used in the mandate was amended into 'revoked' for consistency with the procedural manual of the Codex Alimentarius Commission (<https://www.fao.org/3/cc5042en/cc5042en.pdf>).

## ASSESSMENT

### 1.1 | Existing and new residue definitions

Table 1 provides a comparison of the residue definitions considered in the framework of the MRL review of Article 12 of Regulation (EC) No 396/2005 (EFSA, 2009) and currently applicable in accordance to Regulation (EC) No 396/2005 (hereafter referred to as 'old residue definitions') and the 'new residue definitions' derived in the framework of the renewal (EFSA, 2023; European Commission, 2023) and considered in the present assessment.

It is underlined that during the peer review for the renewal the following data gaps, relevant for the new proposed residue definitions, were identified:

- Aneugenic potential of the metabolite HEPA has not been addressed according to the latest state of the art – criteria not available at the time of the dossier submission or ongoing peer review;
- A new metabolism study in lactating ruminants (goats) according to current guidelines.

**TABLE 1** Comparison of residue definitions for ethephon.

Type of residue definition	Commodity group	Old residue definition (EFSA, 2009)	New residue definition (EFSA, 2023; European Commission, 2023)
Enforcement	Cereals (grain and straw)	Ethephon	Sum of ethephon free and conjugates, expressed as ethephon
	Fruit crops, pulses and oilseed	Ethephon	Ethephon
	Animal products	Ethephon	Ethephon (provisional for ruminants) <sup>a</sup>
Risk assessment	Cereals (grain and straw)	Ethephon	RD 1: sum of ethephon free and conjugates, expressed as ethephon. RD 2: 2-hydroxyethyl phosphonic acid (HEPA) (provisional) <sup>b</sup>
	Fruit crops	Ethephon	Ethephon (for PHI shorter than 12 days) Ethepon (provisional for PHI longer than 12 days) <sup>b</sup>
	Pulses and oilseeds	Ethephon	RD 1: sum of ethephon free and conjugates, expressed as ethephon. RD 2: 2-hydroxyethyl phosphonic acid (HEPA) (provisional) <sup>c</sup>
	Animal products	Ethephon	RD 1: ethephon (provisional for ruminants) <sup>a</sup> RD 2: 2-hydroxyethyl phosphonic acid (HEPA) (provisional) <sup>c</sup>

<sup>a</sup>Provisional pending the submission of a metabolism study in lactating ruminants (goats) performed according to the current guidelines (EFSA, 2023).

<sup>b</sup>The residue definition is derived from the tomato metabolism study conducted at a short PHI of 12 days where the conjugates of ethephon were not recovered in fruit and is valid for all uses with PHI values within 12 days. For uses with PHI above 12 days, further data will be needed to exclude the relevance of conjugates in fruits harvested at PHI longer than 12 days (EFSA, 2023).

<sup>c</sup>Considering that the aneugenic potential of metabolite HEPA has not been addressed according to the latest state of the art as these criteria were not available at the time of the dossier submission, a separate RD (RD 2) was provisionally agreed for cereals, pulses and oilseeds, pending submission of further information on the aneugenic potential of this metabolite (EFSA, 2023; European Commission, 2023).

### 1.2 | Existing EU MRL and revised MRL proposals

In order to address the first term of reference of the mandate, EFSA investigated the origin of the current EU MRLs. For existing EU MRLs that are based on revoked CXLs, EFSA verified whether a revised MRL could be proposed based on the data already evaluated under the framework of the MRL review (EFSA, 2009), during the peer review for the renewal of the approval (EFSA, 2023; Netherlands, 2017), in subsequent MRL applications (EFSA, 2014, 2017) and by the JMPR (FAO and WHO, 2015). Additional data submitted by Member States during the written procedure were also considered (France, 2024; Italy, 2024; Netherlands, 2024; Spain, 2024). In line with the terms of reference, the new residue definition for enforcement in cereals (sum of ethephon free and conjugates, expressed as ethephon) agreed for the renewal (Table 1) was considered.

The existing EU MRLs for the respective crops and the proposed revised MRL (when needed because the MRL is based on a revoked CXL) are reported in Table 2 together with the information on the source of the MRLs and the references to the assessments where the MRLs were derived. It is noted that for almonds, Brazil nuts, cashew nuts, chestnuts, coconuts, macadamias, pecans, pine nut kernels and pistachios, the existing EU MRL is currently set at levels above the limit of quantification (LOQ) (0.1 mg/kg). Nevertheless, for these commodities, according to the information submitted for the MRL review and in subsequent EFSA and JMPR assessments, there are no relevant authorisations or import tolerances reported at EU level and no CXL is available. Therefore, they were not considered further in the assessment.

**TABLE 2** Existing MRLs and revised MRL proposal for ethephon.

Commodity	Existing EU MRL (mg/kg)	Source of existing MRL	MRL based on revoked CXL? (Y/N)	Revised MRL proposal (mg/kg)	Source of the revised MRL
Hazelnuts/cobnuts	0.2	IT (USA) (EFSA, 2009)	N	0.2	IT (USA) (EFSA, 2009)
<b>Walnuts</b>	<b>0.5</b>	<b>CXL (FAO and WHO, 1994)</b>	<b>Y (CAC, 2016)</b>	<b>0.5<sup>a</sup></b>	<b>IT (USA) (EFSA, 2009)</b>
Apples	0.8	CXL (FAO and WHO, 2015)	N	0.8	CXL (FAO and WHO, 2015)
Pears	0.05*	NEU (EFSA, 2009)	N	0.05*	NEU (EFSA, 2009)
Cherries (sweet)	5	CXL (FAO and WHO, 2015)	N	5	CXL (FAO and WHO, 2015)
Table grapes	1 <sup>b</sup>	SEU (EFSA, 2014)	N	1 <sup>b</sup>	SEU (EFSA, 2014)
Wine grapes	2	NEU (EFSA, 2009)	N	2	NEU (EFSA, 2009)
<b>Blueberries</b>	<b>20<sup>c</sup></b>	<b>CXL (FAO and WHO, 1994)</b>	<b>Y (CAC, 2016)</b>	<b>n.a.</b>	<b>n.a.</b>
Figs	3	CXL (FAO and WHO, 2015)	N	3	CXL (FAO and WHO, 2015)
Table olives	7	SEU (EFSA, 2014)	N	7	SEU (EFSA, 2014)
Kaki/Japanese persimmons	0.3	SEU (EFSA, 2017)	N	0.3	SEU (EFSA, 2017)
<b>Pineapples</b>	<b>2</b>	<b>CXL (FAO and WHO, 1994)</b>	<b>Y (CAC, 2016)</b>	<b>1.5</b>	<b>CXL (FAO and WHO, 2015)</b>
Tomatoes	2	CXL (FAO and WHO, 2015)	N	2	CXL (FAO and WHO, 2015)
Cotton seeds	6	CXL (FAO and WHO, 2015)	N	6	CXL (FAO and WHO, 2015)
Olives for oil production	10	SEU (EFSA, 2009)	N	10	SEU (EFSA, 2009)
<b>Barley grain</b>	<b>1</b>	<b>CXL (FAO and WHO, 1994)</b>	<b>Y (CAC, 2016)</b>	<b>1.5<sup>d</sup></b>	<b>CXL (FAO and WHO, 2015)</b>
<b>Rye grain</b>	<b>1</b>	<b>CXL (FAO and WHO, 1994)</b>	<b>Y (CAC, 2016)</b>	<b>0.8<sup>d,e</sup></b>	<b>SEU (Italy, 2024, Spain, 2024)</b>
<b>Wheat grain</b>	<b>1</b>	<b>CXL (FAO and WHO, 1994)</b>	<b>Y (CAC, 2016)</b>	<b>0.5<sup>d</sup></b>	<b>CXL (FAO and WHO, 2015) NEU (EFSA, 2023)</b>
Muscle and fat from swine, bovine, sheep, goat, equine and other farmed terrestrial animals	0.05*	EFSA (2009)	N	0.05*	EFSA (2009)
Liver, kidney and edible offal from swine, bovine, sheep, goat, equine and other farmed terrestrial animals	0.4	CXL (FAO and WHO, 2015)	N	0.4	CXL (FAO and WHO, 2015)
Muscle and fat from poultry	0.05*	EFSA (2009)	N	0.05*	EFSA (2009)
Liver, kidney and edible offal from poultry	0.08	CXL (FAO and WHO, 2015)	N	0.08	CXL (FAO and WHO, 2015)
Milks and eggs	0.05*	EFSA (2009)	N	0.05*	EFSA (2009)

Note: n.a. since no additional data on uses is available, it was not possible to derive a revised MRL proposal. Commodities for which the current EU MRL is based on a revoked CXL and need to be revised are reported in bold.

Abbreviations: CXL, codex maximum residue limit; IT, import tolerance; NEU, Northern Europe; SEU, Southern Europe.

<sup>a</sup>Although a lower MRL of 0.4 has been derived during the MRL review based on the  $R_{\text{ber}}/R_{\text{max}}$  methodology, an MRL of 0.5 mg/kg is calculated by using the OECD (Organisation for Economic Co-operation and Development) MRL calculator (spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: <http://www.oecd.org> MRL calculator).

<sup>b</sup>Although EFSA recommended setting a new MRL on table grapes at the level of 1.5 mg/kg, which was derived by rounding up the value of 1 mg/kg calculated with the Organisation for Economic Cooperation and Development (OECD) MRL calculator, risk managers considered more appropriate to set the MRL at the unrounded level of 1 mg/kg (Reg. (EU) 2015/846) (Commission Regulation (EU) 2015/846 of 28 May 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, ametoctradin, amisulbrom, bupirimate, clofentezine, ethephon, ethirimol, fluopicolide, imazapic, propamocarb, pyraclostrobin and tau-fluvalinate in or on certain product. OJ L 140, 5.6.2015, pp. 1–49).

<sup>c</sup>It is underlined that, although in the risk assessment performed during the MRL review, the CXL was concluded to be safe by considering the HR/STMR in PRIMo 2 (EFSA, 2009), an exceedance of the ARfD is identified when using PRIMo 3.1.

<sup>d</sup>The revised MRL is expressed according to the new residue definition for enforcement derived during the renewal of the approval of ethephon as reported in Table 1 (sum of ethephon free and conjugates, expressed as ethephon).

<sup>e</sup>The proposed revised MRL based on an EU GAP received in the framework of this assessment is higher than the existing CXL (0.5 mg/kg) but is not expected to have an impact on the dietary burden and on the existing EU MRLs for livestock.

\*Indicates that the MRL is set at the limit of quantification.

Based on the information available and presented in Table 2, the existing EU MRLs for walnuts, blueberries, pineapples, barley grain, rye grain and wheat grain are based on revoked CXLs and need to be reconsidered. EFSA identified revised MRL proposals for all these commodities, except for blueberries for which no data is available to derive an alternative MRL.

### 1.3 | Consumer risk assessment of the revised list of MRLs and identification of fall-back MRLs

Chronic and acute exposure calculations for the revised list of MRLs reported in [Table 2](#) were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019).

Input values as derived in previous MRL assessments and by the JMPR, as well as data submitted by Member States during the written procedure, were considered for the exposure calculations. The data currently available for the existing and the revised MRLs were considered as described below. In line with the terms of reference, EFSA considered the new residue definitions for enforcement and risk assessment presented in [Table 1](#). Uncertainties related to missing data were highlighted. All input values included in the exposure calculations are summarised in [Appendix C](#).

According to the new residue definitions proposed during the renewal, conjugates were considered relevant for enforcement and risk assessment of cereals, risk assessment of pulses and oilseeds and potentially relevant for risk assessment of fruit crops harvested at PHI longer than 12 days. Additionally, HEPA metabolite was provisionally considered relevant for the risk assessment of cereals, pulses and oilseeds and animal commodities.

For what concerns **cereals** (wheat, barley and rye), revised MRLs proposed in [Table 2](#) are based on the existing CXLs or on the EU GAPs and the supporting residue data submitted in the framework of this assessment and during the peer review for the renewal according to the new residue definitions for enforcement and risk assessment as ethephon and its conjugates, expressed as ethephon (RD 1, see also [Table 1](#)). It is noted that for wheat, the MRL supporting the EU uses derived in [Appendix B](#) is the same as the current CXL. Therefore, for these commodities the STMR as derived by JMPR (FAO and WHO, 2015) and under this assessment (see [Appendix B](#)) was considered for risk assessment. Nevertheless, pending additional data on the aneugenic potential of HEPA (RD 2, see also [Table 1](#)), it was not possible to perform a risk assessment for this metabolite.

It should be noted nevertheless that:

- According to the EFSA conclusions, metabolite HEPA is a minor metabolite observed in rat studies; it is less toxic than the parent, not sharing its potential for ChE inhibition (for this reason, it was proposed to have this metabolite included in a separate residue definition for risk assessment) and it is unlikely to be genotoxic, i.e. does not produce gene mutation or chromosome aberrations (EFSA, 2023);
- In the EFSA conclusions, this data gap was not leading to a critical area of concern but reported in the 'list of other outstanding issues'<sup>5</sup> (EFSA, 2023);
- Metabolite HEPA was analysed in some of the trials on wheat and barley considered by the JMPR and during the peer review for the renewal and found at levels lower than parent compound in most of the trials<sup>6</sup> (FAO and WHO, 2015; Netherlands, 2017);
- According to the risk assessment (see PRIMo calculations), there is a large margin of safety for cereals (estimated exposure max 3% of ARfD for wheat, max 2% of ARfD for rye and max 1% of ARfD for barley). Therefore, assuming that HEPA will be present at the same level as the parent and share the same toxicity, this is not expected to result in exceedances of the TRVs.

This information is reported for consideration by risk managers during the decision-making process.

For what concerns **oilseeds**, the current MRL for cotton seeds is based on a CXL derived in 2016 and set for parent compound only, in line with the residue definition for enforcement derived during the renewal. The trials considered by the JMPR did not analyse for the conjugates (FAO and WHO, 2015) which are included in the new residue definition for risk assessment. Nevertheless, the metabolism study on cotton seeds evaluated in the framework of the peer review for the renewal (EFSA, 2023) can be used to derive a conversion factor of 1.2 from enforcement to risk assessment. Therefore, for the risk assessment of cotton seeds according to RD 1 (see [Table 1](#)), the STMR as derived by the JMPR (FAO and WHO, 2015) multiplied by the conversion factor derived in the present assessment was considered. For what concern HEPA (RD 2, see also [Table 1](#)), the same considerations on the toxicological profile as reported for cereals are valid also for this commodity. No acute consumption data is included in PRIMo 3.1 for cotton seeds, and therefore, it was not possible to calculate the acute exposure for this commodity. Nevertheless, cotton seeds are expected to have low relevance in the European diets. The contribution of cotton seeds to the chronic intake accounted for a maximum of 1% of the ADI (GEMS/Food G06).

For what concerns **fruit crops**, current MRLs are based on uses assessed at EU level and on CXLs derived according to the residue definition for enforcement and risk assessment as ethephon only. During the renewal, these residue definitions were confirmed for fruit crops harvested at PHI up to 12 days. Since the metabolism in fruit crops harvested at PHI longer than 12 days was not investigated, it was concluded that it was not possible to exclude conjugates to be formed at longer PHI (EFSA, 2023). Based on the information available in the relevant JMPR (FAO and WHO, 2015) and EFSA assessments (EFSA, 2009, 2014, 2017), all the current MRLs for fruit crops are based on uses with PHI shorter than 12 days, except for the following commodities:

<sup>5</sup>Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

<sup>6</sup>Metabolite HEPA was found at levels higher than the parent only in 2 out of the 12 trials on wheat and in none of the 15 trials on barley assessed by the JMPR and during the peer review for the renewal. In these 2 trials both parent and metabolite were measured at low levels (max 0.019 mg/kg).

- Pears (use assessed during the MRL review): PHI was not defined in the GAP but, since the last application is foreseen at flowering, it is expected that the crop is harvested more than 12 days after treatment (EFSA, 2009). No information is available on the method used for the analysis of the samples from the trials but being the residue definition for enforcement set for parent compound only it is expected that a hydrolysis step was not included.
- Wine grapes (use assessed during the MRL review): PHI of 28 days (EFSA, 2009). The same considerations as for pears related to the analysis of the samples are valid.
- Table grapes (use assessed under an MRL application): PHI 21 days (EFSA, 2014). The analytical method used for the analysis of the samples from the trials did not include a hydrolysis step.

Therefore, for the fruit crops, STMR and HR as derived by JMPR (FAO and WHO, 2015) and by EFSA during the MRL review and in subsequent MRLs applications (EFSA, 2009, 2014, 2017) were considered for risk assessment, noting that for pears, wine and table grapes, the risk assessment covering parent compound only might be underestimated since it is not possible to exclude that conjugates are also formed at longer PHI. It is underlined that for pears, according to the risk assessment (see PRIMo calculations), there is a large margin of safety (max 6% of ARfD). Therefore, even assuming that conjugates will be present in pears at harvest, this is not expected to result in exceedances of the toxicological reference values (TRVs). On the contrary, a narrow margin is noted for grapes, with acute exposure accounting for up to 82% of ARfD for table grapes and 71% of the ARfD for wine grapes (see PRIMo calculations).

Current MRLs for **animal products** are based on uses assessed at EU level and on CXLs considering the residue definition for enforcement and risk assessment as ethephon only. Since these residue definitions are in line with the new residue definition proposed during the renewal, for these commodities STMR and HR as derived by JMPR (FAO and WHO, 2015) and by EFSA during the MRL review (EFSA, 2009) were considered for risk assessment, noting that, due the data gaps related to the aneugenicity potential of metabolite HEPA and the missing metabolism study on ruminants, the risk assessment is only tentative. For what concerns HEPA, the same considerations on toxicological profile as reported for cereals are also valid for livestock. According to the risk assessment (see PRIMo calculations), there is a large margin of safety for animal commodities (max 12% of ARfD for cattle milk and max 5% of ARfD for all other animal commodities). Therefore, assuming that HEPA will be present at the same level as the parent and share the same toxicity, this is not expected to result in exceedances of the TRVs.

Exposures calculated were compared with the TRVs derived in the framework of the renewal of ethephon (EFSA, 2023; European Commission, 2023).

The highest chronic exposure was calculated for Dutch toddler, representing 32% of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for the CXL on apples, representing 106% of the ARfD. A second exposure calculation was therefore performed, considering the most critical fall-back GAP for this crop and the supporting residue trials submitted by Member States in the framework of this assessment and presented in Appendices A and B. According to the results of this second calculation, the highest chronic exposure represents 36% of the ADI for Dutch toddler; the highest acute exposure is then calculated for tomatoes, representing 92% of the ARfD (see PRIMo calculations).

## CONCLUSIONS AND RECOMMENDATIONS

Based on the information available, the existing EU MRLs for walnuts, blueberries, pineapples, barley grain, rye grain and wheat grain are based on revoked CXLs and need to be reconsidered. EFSA identified revised MRL proposals for all these commodities, except for blueberries for which no additional data is available, and proposed a revised list of MRLs.

According to the chronic and acute exposure calculations, a potential risk to consumers was identified for the CXL of ethephon on apples. For the remaining MRLs, although uncertainties remain due to the data gaps identified, the indicative exposure calculation did not indicate a risk to consumers.

MRL recommendations were derived in compliance with the assessment described above and they are summarised in Table 3. Several MRLs require further consideration by risk managers (see footnotes of Table 3 for details). In particular, some proposed MRLs need to be confirmed by the following data:

1. Additional data to address the relevance of conjugates at PHI longer than 12 days;
2. Additional information on the aneugenic potential of the metabolite HEPA according to the latest state of the art – criteria not available at the time of the dossier submission or ongoing peer review;
3. A new metabolism study in lactating ruminants (goats) according to current guidelines.

TABLE 3 Summary table.

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
<b>Enforcement residue definition (existing): Ethephon</b>					
<b>Enforcement residue definition (proposed): Ethephon</b>					
120060	Hazelnuts/cobnuts	0.2	-	0.2	Recommended <sup>a</sup>
120110	Walnuts	0.5	-	0.5	Recommended <sup>b</sup>
130010	Apples	0.8	0.8	0.7 or LOQ	Recommended <sup>c</sup>
130020	Pears	0.05*	-	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gap # 1
140020	Cherries (sweet)	5	5	5	Recommended <sup>e</sup>
151010	Table grapes	1	0.8	1 or LOQ	Further consideration needed <sup>d</sup> Data gap # 1
151020	Wine grapes	2	0.8	2 or LOQ	Further consideration needed <sup>d</sup> Data gap # 1
154010	Blueberries	20	-	-	Further consideration needed <sup>f</sup>
161020	Figs	3	3	3	Recommended <sup>e</sup>
161030	Table olives	7	7	7	Recommended <sup>g</sup>
161060	Kaki/Japanese persimmons	0.3	-	0.3	Recommended <sup>g</sup>
163080	Pineapples	2	1.5	1.5	Recommended <sup>h</sup>
231010	Tomatoes	2	2	2	Recommended <sup>e</sup>
401090	Cotton seeds	6	6	6 or LOQ	Further consideration needed <sup>i</sup> Data gap # 2
402010	Olives for oil production	10	10	10	Recommended <sup>g</sup>
1011010	Swine: Muscle/meat	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1011020	Swine: Fat tissue	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1011030	Swine: Liver	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1011040	Swine: Kidney	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1011050	Swine: Edible offals (other than liver and kidney)	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1012010	Bovine: Muscle/meat	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1012020	Bovine: Fat tissue	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1012030	Bovine: Liver	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1012040	Bovine: Kidney	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1012050	Bovine: Edible offals (other than liver and kidney)	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1013010	Sheep: Muscle/meat	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1013020	Sheep: Fat tissue	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1013030	Sheep: Liver	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1013040	Sheep: Kidney	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1013050	Sheep: Edible offals (other than liver and kidney)	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1014010	Goat: Muscle/meat	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3



TABLE 3 (Continued)

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1014020	Goat: Fat tissue	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1014030	Goat: Liver	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1014040	Goat: Kidney	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1014050	Goat: Edible offals (other than liver and kidney)	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1015010	Equine: Muscle/meat	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1015020	Equine: Fat tissue	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1015030	Equine: Liver	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1015040	Equine: Kidney	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1015050	Equine: Edible offals (other than liver and kidney)	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1016010	Poultry: Muscle/meat	0.05*	0.02	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gap # 2
1016020	Poultry: Fat tissue	0.05*	0.04	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gap # 2
1016030	Poultry: Liver	0.08	0.08	0.08 or LOQ	Further consideration needed <sup>i</sup> Data gap # 2
1016040	Poultry: Kidney	0.08	0.08	0.08 or LOQ	Further consideration needed <sup>i</sup> Data gap # 2
1016050	Poultry: Edible offals (other than liver and kidney)	0.08	0.08	0.08 or LOQ	Further consideration needed <sup>i</sup> Data gap # 2
1017010	Other farmed animals: Muscle/meat	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1017020	Other farmed animals: Fat tissue	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1017030	Other farmed animals: Liver	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1017040	Other farmed animals: Kidney	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1017050	Other farmed animals: Edible offals (other than liver and kidney)	0.4	0.4	0.4 or LOQ	Further consideration needed <sup>i</sup> Data gaps # 2, 3
1020010	Milk: Cattle	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1020020	Milk: Sheep	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1020030	Milk: Goat	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1020040	Milk: Horse	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gaps # 2, 3
1030010	Eggs: Chicken	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gap # 2
1030020	Eggs: Duck	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gap # 2
1030030	Eggs: Goose	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gap # 2

(Continues)

TABLE 3 (Continued)

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1030040	Eggs: Quail	0.05*	0.01*	0.05* or LOQ <sup>†</sup>	Further consideration needed <sup>d</sup> Data gap # 2
-	Other commodities of plant and/or animal origin	See Reg. 2017/1777	-	-	Further consideration needed <sup>d</sup>
<b>Enforcement residue definition (existing):</b> Ethephon					
<b>Enforcement residue definition (proposed):</b> Sum of ethephon free and conjugates, expressed as ethephon					
500010	Barley	1	1.5	1.5 or LOQ	Further consideration needed <sup>k</sup> Data gap # 2
500070	Rye	1	0.5	0.8 or LOQ	Further consideration needed <sup>l</sup> Data gap # 2
500090	Wheat	1	0.5	0.5 or LOQ	Further consideration needed <sup>m</sup> Data gap # 2

Abbreviations: CXL, codex maximum residue limit; LOQ, limit of quantification; MRL, maximum residue level.

<sup>a</sup>Existing EU MRL is based on a GAP for import tolerance evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified. Therefore, the existing EU MRL can be maintained.

<sup>b</sup>Existing EU MRL is based on a CXL which was revoked. A revised MRL was derived based on a GAP for import tolerance evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified.

<sup>c</sup>Existing EU MRL is based on a CXL still in place but a risk for consumers cannot be excluded. A fall-back MRL was derived based on an EU GAP which is fully supported by data and for which no risk to consumers is identified.

<sup>d</sup>Existing EU MRL is based on an EU GAP which is not fully supported by data but for which no risk to consumers is identified.

<sup>e</sup>Existing EU MRL is based on a CXL still in place which is fully supported by data and for which no risk to consumers is identified. Therefore, the existing EU MRL can be maintained.

<sup>f</sup>Existing EU MRL is based on a CXL which was revoked and for which a risk for consumers cannot be excluded. No data are available to derive a revised MRL.

<sup>g</sup>Existing EU MRL is based on an EU GAP which is fully supported by data and for which no risk to consumers is identified. Therefore, the existing EU MRL can be maintained.

<sup>h</sup>Existing EU MRL is based on a CXL which was revoked. A revised MRL was derived based on the existing CXL, which is fully supported by data and for which no risk to consumers is identified.

<sup>i</sup>Existing EU MRL is based on a CXL still in place which is not fully supported by data but for which no risk to consumers is identified.

<sup>j</sup>There are no relevant authorisations or import tolerances reported at EU level; no CXL is available.

<sup>k</sup>Existing EU MRL is based on a CXL which was revoked. A revised MRL was derived based on the existing CXL, which is not fully supported by data but for which no risk to consumers is identified.

<sup>l</sup>Existing EU MRL is based on a CXL which was revoked. A revised MRL was derived based on a EU GAP, which is not fully supported by data but for which no risk to consumers is identified.

<sup>m</sup>Existing EU MRL is based on a CXL which was revoked. A revised MRL was derived based on a EU GAP and on the existing CXL, which are not fully supported by data but for which no risk to consumers is identified.

\*Indicates that the MRL is set at the limit of quantification.

<sup>†</sup>According to the data evaluated during the peer review for the renewal, ethephon can be enforced at LOQ of 0.01 mg/kg in plant matrices and at LOQs of 0.01 and 0.005 mg/kg in milk, eggs, meat, fat and liver.

## ABBREVIATIONS

CAC	Codex Alimentarius Commission
CF	conversion factor
ChE	cholinesterase
CXL	codex maximum residue limit
DAR	draft assessment report
EMS	evaluating Member State
GAP	Good Agricultural Practice
HR	highest residue
ISO	International Organisation for Standardization
IT	import tolerance
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	limit of determination
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	Northern Europe
PeF	peeling factor
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
RMS	rappporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	Southern European

SL soluble concentrate  
STMR supervised trials median residue

## CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact [interestmanagement@efsa.europa.eu](mailto:interestmanagement@efsa.europa.eu).

## REQUESTOR

European Commission

## QUESTION NUMBER

EFSA-Q-2023-00714

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## APPENDIX A

## Summary of the most critical authorised uses reported during the written procedure and considered to derive revised and fall-back MRLs

## A.1 | Authorised outdoor uses in northern EU

Crop and/or situation	MS or country	F, G or I <sup>a</sup>	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days) <sup>d</sup>	Remarks
				Type <sup>b</sup>	Conc. a.s.	Method kind	Range of growth stages and season <sup>c</sup>	Number min-max	Interval between application (min)	a.s./hL min-max	Water L/ha min-max	Rate and unit		
Apples	DE, IE	F	Fruit quality improvement, standardisation of fruit ripeness	SL	480 g/L	Foliar treatment – broadcast spraying	78–85	1	-	-	-	360 g a.s./ha	10	008664-00/01-004, use from September to October. Fall-back GAP
Rye	AT, DE, CZ, NL, IE	F	Stabilisation of culm; growth regulator	SL	660 g/L	Foliar treatment – broadcast spraying	31–49	1	-	-	-	726 g a.s./ha	n.a.	-
Wheat	AT, DE, IE	F	Stabilisation of culm	SL	480 g/L	Foliar treatment – broadcast spraying	41–51	1	-	-	-	480 g a.s./ha	n.a.	Most critical GAP considered to derive a revised MRL.

Abbreviations: MS, Member State; n.a., not applicable; SL, soluble concentrate.

<sup>a</sup>Outdoor or field use (F), greenhouse application (G) or indoor application (I).

<sup>b</sup>CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

<sup>c</sup>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.

<sup>d</sup>PHI – minimum preharvest interval.

## A.2 | Authorised outdoor uses in southern EU

Crop and/or situation	MS or country	F, G or I <sup>a</sup>	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days) <sup>d</sup>	Remarks
				Type <sup>b</sup>	Conc. a.s.	Method kind	Range of growth stages and season <sup>c</sup>	Number min-max	Interval between application (min)	a.s./hL min-max	Water L/ha min-max	Rate and unit		
Apples	FR	F	Growth regulation (thinning and coloration)	SL	120 g/L	Foliar treatment – broadcast spraying	57–89	3	40	-	-	360 g a.s./ha	14	GAP authorised for the PPP PRM 12RP on dessert apples only
Rye	IT, ES	F	Stabilisation of culm; Growth regulator	SL	660 g/L	Foliar treatment – broadcast spraying	31–49	1	-	-	-	726 g a.s./ha	n.a.	Mechanical foliar spray to avoid cereal lodging. Most critical GAP considered to derive a revised MRL.

(Continued)

Crop and/or situation	MS or country	F, G or I <sup>a</sup>	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				Remarks
				Type <sup>b</sup>	Conc. a.s.	Method kind	Range of growth stages and season <sup>c</sup>	Number min-max	Interval between application (min)	a.s./hL min-max	Water L/ha min-max	Rate and unit	PHI (days) <sup>d</sup>	
Wheat	EL	F	-	SL	480 g/L	Foliar treatment – broadcast spraying	32–39	1	-	-	-	720 g a.s./ha	n.a.	

Abbreviations: MS, Member State; n.a., not applicable; SL, soluble concentrate.

<sup>a</sup>Outdoor or field use (F), greenhouse application (G) or indoor application (I).

<sup>b</sup>CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

<sup>c</sup>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.

<sup>d</sup>PHI – minimum preharvest interval.

## APPENDIX B

## Summary of residues data from the supervised residue trials considered to derive revised and fall-back MRLs

Commodity	Region <sup>a</sup>	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR <sup>b</sup> (mg/kg)	STMR <sup>c</sup> (mg/kg)
<b>Residue definition for enforcement and risk assessment 1: ethephon</b>						
Apples	NEU	0.06; 0.08; 0.08; 0.13; 0.14 <sup>d</sup> ; 0.14; 0.15 <sup>d</sup> ; 0.20 <sup>d</sup> ; 0.25 <sup>d</sup> ; 0.26; 0.27; 0.29 <sup>d</sup> ; 0.29 <sup>d</sup> ; 0.35 <sup>d</sup> ; 0.40; 0.40	Residue trials on apples compliant with GAP or performed with three applications instead of 1 considered acceptable (France, 2024).	<b>0.7</b>	<b>0.40</b>	<b>0.23</b>
	SEU	2 × < 0.05 <sup>d</sup> ; 2 × < 0.05; 0.05; 0.05 <sup>d</sup> ; 0.07; 0.08; 0.09 <sup>d</sup> ; 0.10; 0.12 <sup>d</sup> ; 0.13; 0.14 <sup>d</sup> ; 0.15 <sup>d</sup> ; 0.18 <sup>d</sup> ; 0.31 <sup>d</sup> ; 0.40	Residue trials on apples compliant with GAP or performed with 1 application instead of 3 considered acceptable (France, 2024; Spain, 2024).	0.6	0.40	0.08
<b>Residue definition for enforcement and risk assessment 2: Sum of ethephon free and conjugates, expressed as ethephon<sup>e</sup></b>						
Rye	NEU	BBCH 39: 0.077; 0.084; 2 × 0.11 BBCH 41: 0.087; 0.36 BBCH 49: 0.31 BBCH 52: 0.095	Residue trials on rye compliant with GAP or with BBCH of 39, 41 or 52 at last application (instead of 49) considered acceptable since, according to the results, this deviation is not expected to have a significant impact on the final residue level (Netherlands, 2024).	0.6	0.36	0.10
	SEU	BBCH 39: < 0.010; 0.094; 0.15 BBCH 41: 0.10; 0.12; 0.22; 0.52 BBCH 43: 0.158	Residue trials on rye with BBCH of 39–43 at last application (instead of 49) considered acceptable since, according to the results, this deviation is not expected to have a significant impact on the final residue level (Italy, 2024; Spain, 2024).	<b>0.8</b>	<b>0.52</b>	<b>0.14</b>
Wheat	NEU	0.052; 2 × 0.059; 0.083; 0.11; 0.14; 0.23; 0.31	Residue trials on wheat compliant with GAP (EFSA, 2023).	<b>0.5</b>	<b>0.31</b>	<b>0.097</b>
	SEU	Unscaled values: 0.011; 0.025; 0.03; 0.035; 0.043; 0.049; 0.053; 0.055; 0.056; 0.057; 0.072; 0.099; 3 × 0.10; 0.13 Scaled values: 0.017; 0.038; 0.046; 0.05; 0.065; 0.074; 0.078; 0.079; 0.08; 0.084; 0.096; 0.133; 0.138; 0.15; 0.15; 0.195	Results from underdosed residue trials on wheat submitted during the peer review (Netherlands, 2017) and under this assessment (Italy, 2024; Spain, 2024) were scaled up applying the proportionality approach (scaling factors from 1.3 to 1.5).	0.3	0.195	0.017

Note: Values in bold were selected to derive a revised MRL for wheat and rye and a fall-back MRL for apples.

Abbreviations: GAP, Good Agricultural Practice; MRL, maximum residue level.

<sup>a</sup>NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials, Country code: if non-EU trials.

<sup>b</sup>Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

<sup>c</sup>Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

<sup>d</sup>Residue levels correspond to residue trials performed with three applications instead of 1 (NEU data set) or with 1 application instead of 3 (SEU data set). This is considered acceptable because results from these trials were in the same range compared to GAP compliant trials showing that the last application has the most impact on the final residue.

<sup>e</sup>According to the additional information reported in the evaluation reports submitted during the written procedure, residues were analysed by using an analytical method covering the conjugates.

## APPENDIX C

## Input values for the exposure calculations

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Residue definition for risk assessment 1: Ethephon</b>				
Hazelnuts/cobnuts	0.05	STMR (EFSA, 2009)	0.1	HR (EFSA, 2009)
<b>Walnuts</b>	0.04	STMR (EFSA, 2009)	0.27	HR (EFSA, 2009)
Apples	0.15	STMR (NEU and SEU; FAO and WHO, 2015)	0.49	HR (NEU and SEU; FAO and WHO, 2015)
	0.23	STMR Fall-back (NEU, France, 2024)	0.4	HR Fall-back (NEU, France, 2024)
Pears	0.02	STMR (EFSA, 2009)	0.02	HR (EFSA, 2009)
Cherries (sweet)	0.65	STMR (FAO and WHO, 2015)	2.7	HR (FAO and WHO, 2015)
Table grapes	0.22	STMR (EFSA, 2014)	0.56	HR (EFSA, 2014)
Wine grapes	0.31	STMR (EFSA, 2009)	1.5	HR (EFSA, 2009)
<b>Blueberries</b>	-	n.a.	-	n.a.
Figs	0.73	STMR (FAO and WHO, 2015)	0.75	HR (FAO and WHO, 2015)
Table olives	1.9	STMR (EFSA, 2014)	4.3	HR (EFSA, 2014)
Kaki/Japanese persimmons	0.09	STMR (EFSA, 2017)	0.12	HR (EFSA, 2017)
<b>Pineapples</b>	0.11	STMR (FAO and WHO, 2015) × PeF (EFSA, 2009)	0.18	HR (FAO and WHO, 2015) × PeF (EFSA, 2009)
Tomatoes	0.52	STMR (FAO and WHO, 2015)	0.79	HR (FAO and WHO, 2015)
Olives for oil production	2.6	STMR (EFSA, 2009)	2.6	STMR (EFSA, 2009)
Meat and fat from swine, bovine, sheep, goat, equine and other farmed terrestrial animals	0.05*	STMR (EFSA, 2009)	0.05*	HR (EFSA, 2009)
Liver and edible offal from swine, bovine, sheep, goat, equine and other farmed terrestrial animals	0.13	STMR (FAO and WHO, 2015)	0.29	HR (FAO and WHO, 2015)
Kidney from swine, bovine, sheep, goat, equine and other farmed terrestrial animals	0.06	STMR (FAO and WHO, 2015)	0.07	HR (FAO and WHO, 2015)
Meat and fat from poultry	0.05*	STMR (EFSA, 2009)	0.05*	HR (EFSA, 2009)
Liver, kidney and edible offal from poultry	0.04	STMR (FAO and WHO, 2015)	0.07	HR (FAO and WHO, 2015)
Milks	0.05*	STMR (EFSA, 2009)	0.05*	STMR (EFSA, 2009)
Eggs	0.05*	STMR (EFSA, 2009)	0.05*	STMR (EFSA, 2009)
<b>Residue definition for risk assessment 2: sum of ethephon free and conjugates, expressed as ethephon</b>				
Cotton seeds	0.654	STMR (FAO and WHO, 2015) × CF (1.2)	0.654	STMR (FAO and WHO, 2015) × CF (1.2)
<b>Barley grain</b>	0.13	STMR (FAO and WHO, 2015)	0.13	STMR (FAO and WHO, 2015)
<b>Rye grain</b>	0.14	STMR (Italy, 2024; Spain, 2024)	0.14	STMR (Italy, 2024; Spain, 2024)
<b>Wheat grain</b>	0.097	STMR (EFSA, 2023)	0.097	STMR (EFSA, 2023)

Note: Commodities for which the current EU MRL is based on a revoked CXL and need to be revised are reported in bold.

Abbreviations: HR, highest residue; STMR, supervised trials median residue.

\*Indicates that the input value corresponds to the limit of quantification.

APPENDIX D

Pesticide residue intake model (PRIMo 3.1)

D.1 | Scenario CX 1 (revised list of MRLs without mitigation measures)



Ethephon			
LODs (mg/kg) range from:		0.05	to: 0.10
Toxicological reference values			
ADI (mg/kg bw/day):	0.02	ARID (mg/kg bw):	0.05
Source of ADI:	EC	Source of ARID:	EC
Year of evaluation:	2023	Year of evaluation:	2023

Input values	
Details - chronic risk assessment	Supplementary results - chronic risk assessment
Details - acute risk assessment/children	Details - acute risk assessment/adults

Comments:										
Scenario including the revised list of MRLs without risk mitigation measures										
Refined calculation mode										
Chronic risk assessment: JMPR methodology (IEDI/TMDI)										
No of diets exceeding the ADI: ---										
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)		2nd contributor to MS diet (in % of ADI)		3rd contributor to MS diet (in % of ADI)		Exposure resulting from MRLs set at the LOQ (in % of ADI)	
			Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)		
32%	NL toddler	6.38	15%	Milk: Cattle	6%	Apples	3%	Tomatoes		32%
24%	DE child	4.78	9%	Apples	5%	Milk: Cattle	3%	Tomatoes		24%
23%	GEMS/Food G08	4.55	11%	Olives for oil production	3%	Tomatoes	2%	Wheat		23%
23%	GEMS/Food G06	4.51	9%	Tomatoes	5%	Olives for oil production	4%	Wheat		23%
20%	ES child	4.07	10%	Olives for oil production	3%	Milk: Cattle	3%	Tomatoes		20%
17%	NL child	3.43	6%	Milk: Cattle	4%	Apples	2%	Wheat		17%
16%	GEMS/Food G07	3.29	4%	Olives for oil production	3%	Tomatoes	2%	Wine grapes		16%
16%	RO general	3.15	5%	Tomatoes	3%	Milk: Cattle	3%	Wine grapes		16%
16%	GEMS/Food G10	3.12	5%	Olives for oil production	4%	Tomatoes	2%	Wheat		16%
16%	FR child 3 15 yr	3.10	6%	Milk: Cattle	2%	Wheat	2%	Tomatoes		16%
15%	FR toddler 2 3 yr	2.96	7%	Milk: Cattle	2%	Apples	1%	Wheat		15%
15%	GEMS/Food G15	2.95	3%	Tomatoes	2%	Olives for oil production	2%	Wheat		15%
15%	GEMS/Food G11	2.94	3%	Olives for oil production	2%	Tomatoes	2%	Milk: Cattle		15%
14%	UK infant	2.90	10%	Milk: Cattle	1%	Wheat	1%	Apples		14%
14%	DK child	2.79	4%	Rye	3%	Milk: Cattle	2%	Wheat		14%
14%	PT general	2.78	4%	Wine grapes	3%	Olives for oil production	2%	Tomatoes		14%
13%	ES adult	2.57	5%	Olives for oil production	2%	Tomatoes	1%	Milk: Cattle		13%
12%	DE woman 14-50 yr	2.48	3%	Milk: Cattle	2%	Apples	2%	Tomatoes		12%
12%	DE general	2.41	3%	Milk: Cattle	2%	Apples	2%	Tomatoes		12%
11%	UK toddler	2.22	5%	Milk: Cattle	2%	Wheat	2%	Tomatoes		11%
10%	SE general	1.92	3%	Milk: Cattle	2%	Tomatoes	2%	Wheat		10%
9%	FR adult	1.88	4%	Wine grapes	1%	Tomatoes	1%	Milk: Cattle		9%
8%	IT toddler	1.65	4%	Tomatoes	3%	Wheat	0.7%	Apples		8%
8%	IE adult	1.64	2%	Wine grapes	1%	Wheat	1%	Milk: Cattle		8%
8%	NL general	1.56	2%	Milk: Cattle	1%	Apples	1%	Tomatoes		8%
7%	DK adult	1.33	1%	Wine grapes	1%	Tomatoes	1%	Milk: Cattle		7%
7%	FR infant	1.33	4%	Milk: Cattle	1%	Apples	0.4%	Wheat		7%
6%	IT adult	1.25	3%	Tomatoes	2%	Wheat	0.6%	Apples		6%
6%	LT adult	1.19	2%	Tomatoes	1%	Apples	1.0%	Milk: Cattle		6%
6%	UK vegetarian	1.10	2%	Tomatoes	1%	Wine grapes	1.0%	Wheat		6%
5%	UK adult	1.04	2%	Wine grapes	1%	Tomatoes	0.8%	Wheat		5%
5%	PL general	0.90	2%	Tomatoes	2%	Apples	0.4%	Table grapes		5%
4%	FI 3 yr	0.77	1%	Tomatoes	0.7%	Apples	0.6%	Wheat		4%
3%	FI adult	0.65	1%	Tomatoes	0.5%	Rye	0.5%	Wine grapes		3%
3%	FI 6 yr	0.60	1%	Tomatoes	0.5%	Wheat	0.4%	Apples		3%
2%	IE child	0.42	0.9%	Milk: Cattle	0.6%	Wheat	0.2%	Apples		2%

**Conclusion:**  
 The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.  
 The long-term intake of residues of Ethephon 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.



Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				
<p>The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.</p> <p>The calculation is based on the large portion of the most critical consumer group.</p>								
<b>Show results for all crops</b>								
<b>Unprocessed commodities</b>	<b>Results for children</b>				<b>Results for adults</b>			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	1				---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	108%	Apples	0.8 / 0.49	53	71%	Wine grapes	2 / 1.5	36
	92%	Tomatoes	2 / 0.79	46	54%	Cherries (sweet)	5 / 2.7	27
	82%	Table grapes	1 / 0.56	41	38%	Table grapes	1 / 0.56	19
	66%	Cherries (sweet)	5 / 2.7	33	28%	Apples	0.8 / 0.49	14
	36%	Pineapples	1.5 / 0.18	18	25%	Tomatoes	2 / 0.79	13
29%	Table olives	7 / 4.3	14	17%	Figs	3 / 0.75	8.4	
28%	Wine grapes	2 / 1.5	14	11%	Pineapples	1.5 / 0.18	5.3	
18%	Figs	3 / 0.75	8.8	9%	Table olives	7 / 4.3	4.3	
12%	Milk: Cattle	0.05 / 0.05	6.2	5%	Kaki/Japanese persimmons	0.3 / 0.12	2.6	
11%	Kaki/Japanese persimmons	0.3 / 0.12	5.6	4%	Olives for oil production	10 / 2.6	2.0	
7%	Olives for oil production	10 / 2.6	3.3	4%	Milk: Cattle	0.05 / 0.05	1.9	
6%	Pears	0.05 / 0.02	2.8	2%	Bovine: Liver	0.4 / 0.29	1.2	
5%	Bovine: Liver	0.4 / 0.29	2.3	2%	Bovine: Edible offals (other than liver and kidney)	0.4 / 0.29	0.96	
4%	Bovine: Edible offals (other than liver and kidney)	0.4 / 0.29	2.1	2%	Milk: Goat	0.05 / 0.05	0.92	
3%	Wheat	0.5 / 0.1	1.4	2%	Wheat	0.5 / 0.1	0.82	
Expand/collapse list								
<b>Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)</b>								
1								
<b>Processed commodities</b>	<b>Results for children</b>				<b>Results for adults</b>			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	59%	Pineapples / canned	1.5 / 0.72	30	28%	Wine grapes / wine	2 / 1.5	14
	27%	Wine grapes / juice	2 / 0.31	14	19%	Pineapples / canned	1.5 / 0.72	9.5
	20%	Tomatoes / juice	2 / 0.52	9.9	13%	Table grapes / raisins	2 / 5.49	6.7
	16%	Apples / juice	0.8 / 0.15	8.1	13%	Wine grapes / juice	2 / 0.31	6.4
	12%	Pineapples / juice	1.5 / 0.42	6.1	10%	Apples / juice	0.8 / 0.15	5.0
10%	Tomatoes / sauce/puree	2 / 0.52	5.0	9%	Tomatoes / sauce/puree	2 / 0.52	4.3	
4%	Figs / jam	3 / 0.73	2.2	7%	Pineapples / juice	1.5 / 0.42	3.7	
4%	Table olives / canned	7 / 1.9	2.1	5%	Table olives / canned	7 / 1.9	2.4	
2%	Wheat / milling (flour)	0.5 / 0.1	1.2	2%	Barley / beer	1.5 / 0.03	0.94	
1%	Pears / juice	0.05 / 0.02	0.65	0.9%	Wheat / bread/pizza	0.5 / 0.1	0.43	
1%	Wheat / milling (wholemeal)-baking	0.5 / 0.1	0.54	0.7%	Wheat / pasta	0.5 / 0.1	0.37	
1%	Rye / boiled	0.8 / 0.14	0.51	0.7%	Wheat / bread (wholemeal)	0.5 / 0.1	0.34	
1.0%	Rye / milling (wholemeal)-baking	0.8 / 0.14	0.49					
0.9%	Barley / cooked	1.5 / 0.13	0.47					
0.5%	Barley / milling (flour)	1.5 / 0.13	0.24					
Expand/collapse list								
<p><b>Conclusion:</b>                  The estimated short term intake (IESTI) exceeded the toxicological reference value for 1 commodities.                  For processed commodities, no exceedance of the ARfD/ADI was identified.</p>								

D.2 | Scenario CX 2 (revised list of MRLs with mitigation measures)



Ethepon			
LODs (mg/kg) range from:	0.05	to:	0.10
Toxicological reference values			
ADI (mg/kg bw/day):	0.02	ARID (mg/kg bw):	0.05
Source of ADI:	EC	Source of ARID:	EC
Year of evaluation:	2023	Year of evaluation:	2023

Input values

- Details - chronic risk assessment
- Supplementary results - chronic risk assessment
- Details - acute risk assessment/children
- Details - acute risk assessment/adults

Comments: Scenario including the revised list of MRLs with risk mitigation measures

**Refined calculation mode**

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

	Calculated exposure (% of ADI)		Exposure (µg/kg bw per day)		Highest contributor to MS diet (in % of ADI)		2nd contributor to MS diet (in % of ADI)		3rd contributor to MS diet (in % of ADI)		Exposure resulting from MRLs set at the LOQ (in % of ADI)	
	MS Diet	MS Diet	(µg/kg bw per day)	(in % of ADI)	Commodity / group of commodities	(in % of ADI)	Commodity / group of commodities	(in % of ADI)	Commodity / group of commodities	(in % of ADI)	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	36%	NL toddler	7.24	15%	Milk: Cattle	12%	Apples	3%	Tomatoes	36%		
	29%	DE child	5.78	14%	Apples	5%	Milk: Cattle	3%	Tomatoes	29%		
	23%	GEMS/Food G08	4.65	11%	Olives for oil production	3%	Tomatoes	2%	Wheat	23%		
	23%	GEMS/Food G06	4.58	9%	Tomatoes	5%	Olives for oil production	4%	Wheat	23%		
	21%	ES child	4.16	10%	Olives for oil production	3%	Milk: Cattle	3%	Tomatoes	21%		
	19%	NL child	3.89	7%	Apples	6%	Milk: Cattle	2%	Wheat	19%		
	17%	GEMS/Food G07	3.37	4%	Olives for oil production	3%	Tomatoes	2%	Wine grapes	17%		
	16%	RO general	3.27	5%	Tomatoes	3%	Milk: Cattle	3%	Wine grapes	16%		
	16%	FR child 3-15 yr	3.24	6%	Milk: Cattle	2%	Wheat	2%	Tomatoes	16%		
	16%	FR toddler 2-3 yr	3.21	7%	Milk: Cattle	4%	Apples	1%	Wheat	16%		
	16%	GEMS/Food G10	3.18	5%	Olives for oil production	4%	Tomatoes	2%	Wheat	16%		
	15%	GEMS/Food G11	3.07	3%	Olives for oil production	2%	Tomatoes	2%	Milk: Cattle	15%		
	15%	GEMS/Food G15	3.04	3%	Tomatoes	2%	Olives for oil production	2%	Wheat	15%		
	15%	UK infant	3.02	10%	Milk: Cattle	2%	Apples	1%	Wheat	15%		
	15%	DK child	2.98	4%	Rye	3%	Milk: Cattle	3%	Apples	15%		
	14%	PT general	2.86	4%	Wine grapes	3%	Olives for oil production	2%	Tomatoes	14%		
	13%	DE women 14-50 yr	2.69	3%	Milk: Cattle	3%	Apples	2%	Tomatoes	13%		
	13%	ES adult	2.63	5%	Olives for oil production	2%	Tomatoes	1%	Milk: Cattle	13%		
	13%	DE general	2.61	3%	Milk: Cattle	3%	Apples	2%	Tomatoes	13%		
	12%	UK toddler	2.36	5%	Milk: Cattle	2%	Apples	2%	Wheat	12%		
	10%	SE general	2.01	3%	Milk: Cattle	2%	Tomatoes	2%	Wheat	10%		
	10%	FR adult	1.94	4%	Wine grapes	1%	Tomatoes	1%	Milk: Cattle	10%		
	9%	IT toddler	1.72	4%	Tomatoes	3%	Wheat	1%	Apples	9%		
	8%	IE adult	1.70	2%	Wine grapes	1%	Wheat	1%	Milk: Cattle	8%		
	8%	NL general	1.68	2%	Milk: Cattle	2%	Apples	1%	Tomatoes	8%		
	7%	FR infant	1.46	4%	Milk: Cattle	2%	Apples	0.4%	Wheat	7%		
	7%	DK adult	1.41	1%	Wine grapes	1%	Tomatoes	1%	Milk: Cattle	7%		
	7%	LT adult	1.34	2%	Apples	2%	Tomatoes	1.0%	Milk: Cattle	7%		
	7%	IT adult	1.31	3%	Tomatoes	2%	Wheat	0.9%	Apples	7%		
	6%	UK vegetarian	1.15	2%	Tomatoes	1%	Wine grapes	1.0%	Wheat	6%		
5%	UK adult	1.08	2%	Wine grapes	1%	Tomatoes	0.8%	Wheat	5%			
5%	PL general	1.06	2%	Apples	2%	Tomatoes	0.4%	Table grapes	5%			
4%	FI 3 yr	0.85	1%	Tomatoes	1%	Apples	0.6%	Wheat	4%			
4%	FI adult	0.70	1%	Tomatoes	0.7%	Apples	0.5%	Rye	4%			
3%	FI 6 yr	0.65	1%	Tomatoes	0.7%	Apples	0.5%	Wheat	3%			
2%	IE child	0.45	0.9%	Milk: Cattle	0.6%	Wheat	0.4%	Apples	2%			

**Conclusion:**  
 The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.  
 The long-term intake of residues of Ethepon 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.

Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				
<p>The acute risk assessment is based on the ARID. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.</p> <p>The calculation is based on the large portion of the most critical consumer group.</p>								
<b>Show results for all crops</b>								
<b>Unprocessed commodities</b>	<b>Results for children</b>				<b>Results for adults</b>			
	No. of commodities for which ARID/ADI is exceeded (IESTI): ---				No. of commodities for which ARID/ADI is exceeded (IESTI): ---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
92%	Tomatoes	2 / 0.79	46	71%	Wine grapes	2 / 1.5	36	
86%	Apples	0.7 / 0.4	43	54%	Cherries (sweet)	5 / 2.7	27	
82%	Table grapes	1 / 0.56	41	38%	Table grapes	1 / 0.56	19	
66%	Cherries (sweet)	5 / 2.7	33	25%	Tomatoes	2 / 0.79	13	
36%	Pineapples	1.5 / 0.18	18	22%	Apples	0.7 / 0.4	11	
29%	Table olives	7 / 4.3	14	17%	Figs	3 / 0.75	8.4	
28%	Wine grapes	2 / 1.5	14	11%	Pineapples	1.5 / 0.18	5.3	
18%	Figs	3 / 0.75	8.8	9%	Table olives	7 / 4.3	4.3	
12%	Milk: Cattle	0.05 / 0.05	6.2	5%	Kaki/Japanese persimmons	0.3 / 0.12	2.6	
11%	Kaki/Japanese persimmons	0.3 / 0.12	5.6	4%	Olives for oil production	10 / 2.6	2.0	
7%	Olives for oil production	10 / 2.6	3.3	4%	Milk: Cattle	0.05 / 0.05	1.9	
6%	Pears	0.05 / 0.02	2.8	2%	Bovine: Liver	0.4 / 0.29	1.2	
5%	Bovine: Liver	0.4 / 0.29	2.3	2%	Bovine: Edible offals (other than liver and kidney)	0.4 / 0.29	0.96	
4%	Bovine: Edible offals (other than liver and kidney)	0.4 / 0.29	2.1	2%	Milk: Goat	0.05 / 0.05	0.92	
3%	Wheat	0.5 / 0.1	1.4	2%	Wheat	0.5 / 0.1	0.82	
Expand/collapse list								
<b>Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)</b>								
<b>Processed commodities</b>	<b>Results for children</b>				<b>Results for adults</b>			
	No. of processed commodities for which ARID/ADI is exceeded (IESTI): ---				No. of processed commodities for which ARID/ADI is exceeded (IESTI): ---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
59%	Pineapples / canned	1.5 / 0.72	30	28%	Wine grapes / wine	2 / 1.5	14	
27%	Wine grapes / juice	2 / 0.31	14	19%	Pineapples / canned	1.5 / 0.72	9.5	
25%	Apples / juice	0.7 / 0.23	12	15%	Apples / juice	0.7 / 0.23	7.7	
20%	Tomatoes / juice	2 / 0.52	9.9	13%	Table grapes / raisins	2 / 5.49	6.7	
12%	Pineapples / juice	1.5 / 0.42	6.1	13%	Wine grapes / juice	2 / 0.31	6.4	
10%	Tomatoes / sauce/puree	2 / 0.52	5.0	9%	Tomatoes / sauce/puree	2 / 0.52	4.3	
4%	Figs / jam	3 / 0.73	2.2	7%	Pineapples / juice	1.5 / 0.42	3.7	
4%	Table olives / canned	7 / 1.9	2.1	5%	Table olives / canned	7 / 1.9	2.4	
2%	Wheat / milling (flour)	0.5 / 0.1	1.2	2%	Barley / beer	1.5 / 0.03	0.94	
1%	Pears / juice	0.05 / 0.02	0.65	0.9%	Wheat / bread/pizza	0.5 / 0.1	0.43	
1%	Wheat / milling (wholemeal)-baking	0.5 / 0.1	0.54	0.7%	Wheat / pasta	0.5 / 0.1	0.37	
1%	Rye / boiled	0.8 / 0.14	0.51	0.7%	Wheat / bread (wholemeal)	0.5 / 0.1	0.34	
1.0%	Rye / milling (wholemeal)-baking	0.8 / 0.14	0.49					
0.9%	Barley / cooked	1.5 / 0.13	0.47					
0.5%	Barley / milling (flour)	1.5 / 0.13	0.24					
Expand/collapse list								
<b>Conclusion:</b>								
No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Ethephon is unlikely to present a public health risk.								
For processed commodities, no exceedance of the ARID/ADI was identified.								