REASONED OPINION

APPROVED: 22 August 2018

doi: 10.2903/j.efsa.2018.5411

Modification of the existing maximum residue levels for potassium phosphonates in certain berries and small fruits

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant LTZ Augustenberg submitted a request to the competent national authority in Germany to modify the existing maximum residue levels (MRLs) for the active substance potassium phosphonates in raspberries, blackberries, currants, blueberries, gooseberries and elderberries. The data submitted in support of the request were found to be sufficient to derive MRL proposals for all crops under consideration. Adequate analytical methods for enforcement are available to control the residues of potassium phosphonates in plant matrices under consideration. Based on the risk assessment results, EFSA concluded that the proposed uses of potassium phosphonates on raspberries, blackberries, currants, blueberries, gooseberries and elderberries will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to present a risk to consumers' health.

Keywords: potassium phosphonates, fosetyl, various crops, berries, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2018-00238

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Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B and Villamar-Bouza L, 2018. Reasoned opinion on the modification of the existing maximum residue levels for potassium phosphonates in certain berries and small fruits. EFSA Journal 2018; 16(9):5411, 26 pp. https://doi.org/10.2903/j.efsa.2018.5411

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, LTZ Augustenberg submitted an application to the competent national authority in Germany (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance potassium phosphonates in cane fruits, small fruits and berries. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 8 March 2018. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRLs in blackberries and raspberries from 100 to 300 mg/kg, and in blueberries, currants, gooseberries and elderberries from 2 mg/kg (limit of quantification (LOQ)) to 80 mg/kg. The MRLs were derived according to the current residue definition for enforcement with residues expressed as fosetyl equivalents.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessment and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of potassium phosphonates was assessed during the EU pesticides peer review. It was concluded that data from the public literature are sufficient to address the metabolism in plants which mainly involves transformation of potassium phosphonate salts into phosphonic acid. Studies investigating the effect of processing on the nature of potassium phosphonates (hydrolysis studies) were conducted with its main transformation product and demonstrated that phosphonic acid is stable.

As the proposed uses of potassium phosphonates are on (semi)-permanent crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of the metabolite, the EU pesticides peer review proposed a general residue definition for potassium phosphonates in plant products as 'phosphonic acid and its salts, expressed as phosphonic acid' for both enforcement and risk assessment. The current residue definition for enforcement set in Regulation (EC) No 396/2005 is 'the sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl'.

EFSA concluded that for the crops assessed in this application, metabolism of potassium phosphonates is sufficiently addressed.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition set in the EU legislation and proposed during the EU pesticides peer review. The methods enable quantification of residues at 0.01 mg fosetyl/kg and 0.1 mg phosphonic acid/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive MRL proposals for raspberries, blackberries, currants, gooseberries, blueberries and elderberries. EFSA derived MRL proposals for the different residue definitions proposed in previous assessments.

Specific studies investigating the magnitude of potassium phosphonates residues in processed commodities were not provided and are in principle triggered. Considering the expected low contribution of these minor crops to the dietary burden and the stability of residues under standard hydrolysis conditions, EFSA is of the opinion that such studies are not essential to perform the consumer risk assessment.

Residues of potassium phosphonates in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

The toxicological profile of potassium phosphonates was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 2.25 mg/kg body weight (bw) per day for phosphonic acid, which is the toxicologically relevant metabolite of potassium phosphonates in plants. An acute reference dose (ARfD) was deemed unnecessary. During the process of the renewal of the approval for fosetyl, an ADI of 1 mg/kg bw per day and an ARfD of 1 mg/kg bw per day have been derived. Although this ADI and ARfD have not yet been noted by the European Commission, additional risk assessment scenarios (i.e. acute dietary intake calculation considering the ARfD of 1 mg/kg bw and a chronic dietary intake calculation considering the ADI of 1 mg/kg bw per day) have been performed.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo).

As long as no ARfD is formally established, a short-term exposure assessment would not be required. However, anticipating the formal decision on the setting of the ARfD as proposed by EFSA, a short-term exposure assessment was performed taking into account the highest residue (HR) values derived for the crops assessed in this application (expressed as phosphonic acid) and comparing the expected exposure with the proposed ARfD of 1 mg/kg bw. Among the crops under assessment, the short-term dietary intake accounted for up to 87.3% of the ARfD for blackberries, 45.7% for raspberries and 29.2% for currants; for the remaining crops, the short-term exposure was below 20% of the ARfD. Thus, for the crops under assessment, a short-term consumer intake risk is unlikely.

The long-term exposure assessment was performed taking into account the STMR values derived for the crops assessed in this application and in previous EFSA assessments (expressed as phosphonic acid). For the remaining commodities, the existing MRLs set for fosety-Al in Regulation (EC) No 2018/832, recalculated to phosphonic acid, were used as input values. MRLs at the LOQ were not considered. The estimated long-term dietary intake of phosphonic acid residues was in the range of 7–41% considering an ADI of 2.25 mg/kg bw per day and in the range of 16–93% considering an ADI of 1 mg/kg bw per day, respectively.

EFSA concluded that the proposed use of potassium phosphonates on raspberries, blackberries, blueberries, currants, gooseberries and elderberries will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)		Comment/justification
			1)	2)	
1) Existing enforcement residue definition: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) (Reg. (EC) No 396/2005) 2) Proposed enforcement residue definition: Phosphonic acid and their salts expressed as phosphonic acid (EFSA, 2012b)					
0153010	Blackberries	100	300	200	The submitted data on raspberries are sufficient to derive a MRL proposal for the NEU use, with an extrapolation to blackberries. A risk to consumers is unlikely
0153030	Raspberries (red and yellow)	100	300	200	
0154010	Blueberries	2*	80	60	The submitted data on currants are sufficient to derive a MRL proposal for the NEU use, with an extrapolation to blueberries, gooseberries and elderberries. A risk to consumers is unlikely
0154030	Currants (black, red and white)	2*	80	60	
0154040	Gooseberries	2*	80	60	
0154080	Elderberries	2*	80	60	

MRL: maximum residue level; NEU: northern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Assessment

The detailed description of the intended uses of potassium phosphonates authorised, which are the basis for the current MRL application, is reported in Appendix A.

Potassium phosphonates are a mixture of potassium hydrogen phosphonate and dipotassium phosphonate (EFSA, 2012b). The International Organization for Standardization (ISO) has not assigned a common name for potassium phosphonates. The IUPAC name is potassium hydrogen phosphonate and dipotassium phosphonate. The chemical structures of the active substance and relevant compounds are reported in Appendix E.

Potassium phosphonates were evaluated in the framework of Directive 91/414/EEC[1] with France designated as rapporteur Member State (RMS) for the representative use of foliar spraying on grapes. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2012b). Potassium phosphonates was approved[2] for the use as fungicide on 1 October 2013.

The EU MRLs for potassium phosphonates are established in Annex III of Regulation (EC) No 396/2005[3]. It is noted that the current enforcement residue definition relevant for potassium phosphonate also covers fosetyl and disodium phosphonate; the latter being an approved active substance that forms phosphonic acid as a metabolite. The current residue definition for enforcement is set as the sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl. Thus, the existing MRLs reflect the uses of fosetyl, disodium phosphonate and from the uses of potassium phosphonates.

For fosetyl, EFSA performed the review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review). However, the proposed modifications of the existing MRLs have not yet been legally implemented since the European Commission is of the opinion that it is appropriate to await the MRL review for the related active substances, i.e. potassium phosphonates and disodium phosphonate, since these active substances share the common metabolite phosphonic acid. The review of existing MRLs following the use of potassium phosphonates acid and disodium phosphonate has not yet been initiated.

In accordance with Article 6 of Regulation (EC) No 396/2005 LTZ Augustenberg submitted an application to the competent national authority in Germany (EMS) to modify the existing MRLs to accommodate for the intended use of the active substance potassium phosphonates in cane fruits and other small fruits and berries. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 8 March 2018.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2018), the DAR (and their addenda) on potassium phosphonates (France, 2005a, 2012) and the DARon fosetyl (France, 2003, 2005b) prepared under Council Directive 91/414/EEC and the renewal assessment report (RAR) on fosetyl (France, 2017, 2018) prepared under Regulation (EU) No 1107/2009, the Commission review report on potassium phosphonates (European Commission, 2013), the conclusions on the peer review of the pesticide risk assessment of potassium phosphonates (EFSA, 2012b) and fosetyl (EFSA, 2005 (revised 2013), 2018b) as well as the conclusions from a previous reasoned opinion on potassium phosphonates and fosetyl-Al (EFSA, 2018a) and the MRL review of fosetyl-Al (EFSA, 2012a).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[4].

As the review of the existing MRLs covering the three active substances that share the common metabolite phosphonic acid (i.e. fosetyl, phosphonic acid and disodium phosphonate) under Article 12

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

[2] Commission Implementing Regulation (EU) No 369/2013 of 22 April 2013 approving the active substance potassium phosphonates, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 111, 23.4.2013, p. 39–42.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

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

of Regulation 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the MRL review.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation report submitted by the EMS (Germany, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of potassium phosphonates was assessed during the EU pesticides peer review (EFSA, 2012b). It was concluded that data from the public literature are sufficient to address the metabolism in plants which mainly involves transformation of potassium phosphonate salts into phosphonic acid.

1.1.2. Nature of residues in rotational crops

Since the crops under consideration are (semi-)permanent crops, investigations of residues in rotational crops are not required (OECD, 2007).

1.1.3. Nature of residues in processed commodities

Studies investigating the effect of processing on the nature of the major metabolite of potassium phosphonates, phosphonic acid, were assessed during the EU pesticides peer review (EFSA, 2012b) and a previous MRL review on fosetyl (EFSA, 2012a). It was concluded, that phosphonic acid is hydrolytically stable during typical processing operations and no toxicologically relevant metabolites were formed.

1.1.4. Methods of analysis in plants

A set of analytical methods for the determination of residues of potassium phosphonates according to the existing residue definition for enforcement in the MRL regulation (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) and to the residue definition proposed in the framework of the EU pesticides peer review (sum of phosphonic acid and their salts expressed as phosphonic acid) in plant commodities was assessed during a previous MRL review on fosetyl (EFSA, 2012a). It was concluded that residues of potassium phosphonates in food of plant origin can be monitored by high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with a limit of quantification (LOQ) of 0.01 mg fosetyl/kg and 0.1 mg phosphonic acid/kg, respectively.

1.1.5. Stability of residues in plants

The storage stability of the main transformation product of potassium phosphonates, phosphonic acid, in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2012b) and in a previous MRL application (EFSA, 2018a). Phosphonic acid and their salts as well as phosphonic acid itself are stable under storage conditions at −18°C for at least 25 months in matrices with high acid content, to which group the crops under consideration belong.

1.1.6. Proposed residue definitions

The following residue definitions have been derived in previous assessments of potassium phosphonates[5]:

[5] For residue definitions derived for fosetyl, see also EFSA (2018a).

- Residue definition for enforcement:
  - Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl (current residue definition set in Regulation (EC) No 396/2005);
  - Phosphonic acid and its salts, expressed as phosphonic acid (peer review of potassium phosphonates, EFSA, 2012b);
- Residue definition for risk assessment:
  - Phosphonic acid and its salts, expressed as phosphonic acid (peer review of potassium phosphonates, EFSA, 2012b)

It is noted that in previous assessments of fosetyl, different residue definitions have been derived which have not been legally implemented (e.g. sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid (EFSA, 2018b) or separate residue definitions for phosphonic acid and fosetyl (EFSA, 2012a)); for the current application, MRL proposals were derived for the following residue definitions:

1) Sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl[6] (MRL scenario 1);
2) Phosphonic acid and its salts, expressed as phosphonic acid (MRL scenario 2);

Considering that the final decision on the residue definition for risk assessment has not yet been taken, in line with the previously issued reasoned opinion of EFSA (2018a) the consumer risk assessment was performed for the following residue definition: Phosphonic acid and its salts, expressed as phosphonic acid.

The residue definitions apply to primary crops, rotational crops and processed products.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of residues resulting from the reported Good Agricultural Practices (GAPs) for potassium phosphonate, EFSA considered all residue trials reported by the EMS in its evaluation report (Germany, 2018). All residue trial samples considered in this framework were stored in compliance with the storage conditions for which integrity of the samples was demonstrated. Decline of residues during storage of the trial samples is therefore not expected. According to the assessment of the RMS, the analytical methods used were sufficiently validated and fit for purpose. The residue concentrations measured in the samples were expressed as phosphonic acid and therefore can be used to derive a MRL proposal for MRL scenario 2. The EMS recalculated the results to fosetyl, using a molecular weight conversion factor of 1.34; the recalculated residue levels can be used to derive the MRL proposals for MRL scenario 1.

The results of the residue trials, the related risk assessment input values (highest residue (HR) and supervised trials median residue (STMR)) and the MRL proposals are summarised in Appendix B.1.2.1.

Raspberries and blackberries

In total, four outdoor trials on raspberries were provided. All trials were conducted in Germany over two seasons. For one trial, a minor deviation from the northern Europe (NEU) GAP was identified, where the second application took place 14 days after the first application, while the GAP defines an interval of 7–10 days. However, the minor deviation was considered to have no impact on the validity of the trial. An extrapolation to blackberries is possible (European Commission, 2017).

Based on the four residue trials, a MRL proposal of 300 mg/kg is derived when residues are expressed as fosetyl (MRL scenario 1) and a MRL of 200 mg/kg when residues are expressed as phosphonic acid (MRL scenario 2). The MRL proposal for raspberries can be extrapolated to blackberries (European Commission, 2017).

Currants, blueberries, gooseberries and elderberries

A total of six outdoor trials on currants were provided. All trials were conducted in Germany over two seasons. One trial was not fully compliant with the NEU GAP as the samples were taken 7 days after the last application, instead of 14 days as defined in the GAP. This trial was disregarded from the dataset. Thus, five trials on currants are available for the NEU GAP.

[6] For crops with uses of potassium phosphonates, the contribution of fosetyl is not relevant.

Currants are considered as minor crop and at least six trials would be required to derive a MRL proposal for the whole group of other small fruits and berries (European Commission, 2017). Instead of a group MRL, the EMS proposed an extrapolation from currants to the three individual minor crops blueberries, gooseberries and elderberries, which is acceptable.

Based on the five residue trials in currants, the MRL proposal of 80 mg/kg is calculated (MRL scenario 1, residues expressed as fosetyl) and a MRL proposal of 60 mg/kg for the MRL scenario 2 (expressing the residues as phosphonic acid), with an extrapolation to blueberries, gooseberries and elderberries.

1.2.2. Magnitude of residues in rotational crops

Since the crops under consideration are (semi)-permanent crops, investigations on the magnitude of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

In the framework of this application, specific processing studies for the crops under assessment were not provided and are in principle triggered. Residues in the raw commodities were above 0.1 mg/kg. Considering the expected low contribution of these minor crops to the dietary burden, the stability of residues under standard hydrolysis conditions and the high acceptable daily intake (ADI) set for phosphonic acid, EFSA is of the opinion that such studies are not essential to perform the consumer risk assessment.

1.2.4. Proposed MRLs

The available residue trials are sufficient to derive MRL proposals for raspberries, blackberries, currants, blueberries, gooseberries and elderberries (Appendix B.1.2.1). Two sets of MRLs are proposed: MRL scenario 1 (in accordance with the residue definition for enforcement currently set in Regulation (EC) No 396/2005) and MRL scenario 2, according to the residue definition proposed during the EU pesticides peer review for potassium phosphonate (EFSA, 2012b); this MRL proposal would be also compatible with the recently proposed residue definition for fosetyl (EFSA, 2018b).

2. Residues in livestock

The crops under consideration are not feed items according to the EU Guidance document. Therefore, the nature and magnitude of potassium phosphonate residues in livestock was not investigated.

3. Consumer risk assessment

The toxicological profile of potassium phosphonates was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an ADI value of 2.25 mg/kg body weight (bw) day for phosphonic acid, the relevant component of residues in the plant. An acute reference dose (ARfD) was deemed unnecessary (EFSA, 2012b).

During the process of renewal of the approval for fosetyl (EFSA, 2018b), an ADI of 1 mg/kg bw per day and an ARfD of 1 mg/kg bw per day have been derived. The amended toxicological reference values will be formally reflected in a revised review report for fosetyl and presented to the Standing Committee for note taking.

In the framework of this assessment, EFSA performed the risk assessment for phosphonic acid, using the ADI derived in the framework of the peer review of potassium phosphonates (EFSA, 2012b, risk assessment scenario 1) and the recently amended toxicological reference values (EFSA, 2018b, risk assessment scenario 2), anticipating the decision on the revision of the existing toxicological reference values.

The consumer risk assessment was performed with revision 2 of the PRIMo (EFSA, 2007).

As long as no ARfD is formally established, a short-term exposure assessment would not be required (risk assessment scenario 1). In risk assessment scenario 2, the short-term exposure assessment was performed taking into account the HR values derived for the crops assessed in this application (residues expressed as phosphonic acid). The estimated short-term dietary intake accounted for up to 87.3% of the ARfD for UK Toddlers. EFSA concludes that the short-term intake of residues of potassium phosphonates resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

For the chronic risk assessment, the recent risk assessment performed in the framework of the MRL application (EFSA, 2018a) was updated, including the STMR values derived for the commodities assessed under this application. For the remaining crops, the existing MRLs set for fosety-Al in

Regulation (EC) No 2018/832[7], recalculated to phosphonic acid, were used as input values. Crops with MRLs set at the LOQ were disregarded.

In risk assessment scenario 1 (using the ADI of 2.25 mg/kg bw per day) no chronic consumer intake concerns were identified for any of the European diets. The total calculated long-term intake accounted for a maximum of 41% of the ADI for DE child. Among the crops under consideration, raspberries were the major contributor to the long-term exposure accounting for a maximum of 0.31% of the ADI (NL child).

In risk assessment scenario 2 (using the ADI of 1 mg/kg bw per day), the exposure accounts for up to 93% of the ADI. Raspberries were the major contributor to the total consumer exposure accounting for a maximum of 0.7% of the ADI (NL child).

The contribution of residues expected in the individual crops under consideration to the overall long-term exposure is presented in Appendix B.3. EFSA concludes that the long-term intake of residues of potassium phosphonates resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

For further details on the exposure calculations, screenshots of the Report sheet of the PRIMo are presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of the request were found to be sufficient to derive MRL proposals for raspberries, blackberries, currants, blueberries, gooseberries and elderberries.

EFSA concluded that the intended use of potassium phosphonates on the above mentioned crops will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CS	capsule suspension

DAR	draft assessment report
DAT	days after treatment
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
InChiKey	International Chemical Identifier Keys
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
SL	soluble concentrate
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
WHO	World Health Organization

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation[a]	MS Country	NEU SEU G	Product name	F G or I[b]	Pests or group of pests controlled[c]	Preparation		Application				Application rate per treatment			PHI (days)[m]	Remarks
						Type[d]–[f]	Conc. a.s.[i]	Method kind[f]–[h]	Growth stages and season[j]	Number min–max[k]	Interval between application min–max	g/hL min–max[l]	Water L/ha min–max	g/ha min–max[l]		
Blackberries (0153010)	DE	NEU	Veriphos	F	Downy mildew (*Peronospora sparsa*)	SL	755 g/L	Spraying or fine spraying (low volume spraying)	BBCH 51-81, at beginning of infestation and/or when first symptoms become visible	3	7–10	302	1,000	3,020	5	
Raspberries (red and yellow) (0153030)	DE	NEU	Veriphos	F	Red core of strawberry (*Phytophthora fragariae*)	SL	755 g/L		BBCH 51-81, at beginning of infestation and/or when first symptoms become visible	3	7–10	302	1,000	3,020	5	At beginning of infestation and/or when first symptoms become visible
Currants (black, red and white, gooseberries (0154030, 0154040)	DE	NEU	Veriphos	F	Leaf spot (*Drepanopeziza ribis*)	SL	755 g/L		From BBCH 57, at beginning of infestation and/or when first symptoms become visible	3	7–10	302	1,000	3,020	14	
Blueberries (0154010)	DE	NEU	Veriphos	F	*Colletotrichum*	SL	755 g/L		From BBCH 59, at beginning of infestation and/or when first symptoms become visible	3	7–10	302	1,000	3,020	14	

Crop and/or situation[a]	MS Country	NEU SEU G	Product name	F G or I[b]	Pests or group of pests controlled[c]	Preparation		Application				Application rate per treatment			PHI (days)[m]	Remarks
						Type[d]–[f]	Conc. a.s.[i]	Method kind[f]–[h]	Growth stages and season[j]	Number min–max[k]	Interval between application min–max	g/hL min–max[l]	Water L/ha min–max	g/ha min–max[l]		
Elderberries (0154080)	DE	NEU	Veriphos	F	*Colletotrichum*	SL	755 g/L		From BBCH 59, at beginning of infestation and/or when first symptoms become visible	3	7–10	302	1,000	3,020	14	

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; MS: Member State; a.s.: active substance; SL: soluble concentrate; BBCH: growth stages of mono- and dicotyledonous plants.
(a): For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure).
(b): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(c): e.g. biting and sucking insects, soil born insects, foliar fungi, weeds.
(d): e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
(e): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(f): All abbreviations used must be explained.
(g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
(h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated.
(i): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j): Growth stage 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; BF = at beginning of infestation and/or when first symptoms become visible.
(k): Indicate the minimum and maximum number of applications possible under practical conditions of use.
(l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200,000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha.
(m): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/source**
	Fruit crops	No experimental study available. Given the elementary nature of potassium phosphonates and according to available data from the public literature, the main metabolite of potassium phosphonates in plants will be phosphonic acid (EFSA, 2012b)			
	Root crops				
	Leafy crops				
	Cereals/grass				
	Pulses/oilseeds				
	Miscellaneous				

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/source**
	Root/tuber crops	Radish	Bare soil, 4.9 mg phosphonic acid/kg soil	32, 182	Potassium phosphonates degrade rapidly in the soil to phosphonic acid (EFSA, 2012b) The nature of phosphonic acid in rotational crops was investigated in the peer review of fosetyl-Al and indicate phosphonic acid as the main metabolite in rotational crops (EFSA, 2005, 2018b)
	Leafy crops	Lettuce		32	
	Cereal (small grain)	Barley		32	

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	EFSA (2018b)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	EFSA (2018b)
	Sterilisation (20 min, 120°C, pH 6)	Yes	EFSA (2018b)
	Other processing conditions	–	

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2012b)
Rotational crop and primary crop metabolism similar?	Not triggered	
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2012b)
Plant residue definition for monitoring (RD-Mo)	MRL scenario 1: Sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl (Reg. (EC) No 396/2005) MRL scenario 2. Phosphonic acid and its salts expressed as phosphonic acid (EFSA, 2012b)	
Plant residue definition for risk assessment (RD-RA)	Phosphonic acid and its salts expressed as phosphonic acid (EFSA, 2012b)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content (lettuce and cucumber), high oil content (avocado), high acid content (oranges, grapes) and dry matrices (wheat): HPLC–MS/MS, 1. LOQ 0.01 mg fosetyl/kg 2. LOQ 0.1 mg phosphonic acid/kg. ILV available (EFSA, 2012a)	

DAT: days after treatment; PBI: plant-back interval; MRL: maximum residue level; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ source**
				Value	**Unit**		
	High water content	Cucumber, lettuce	−18	12	Months	Sum of phosphonic acid and fosetyl	EFSA (2012b)
		Cucumber, cabbage	−18	25	Months	Phosphonic acid	EFSA (2012b)
		Potato	−18	12	Months	Sum of phosphonic acid and fosetyl	EFSA (2012b)
			−18	25	Months	Phosphonic acid	EFSA (2012b)
		Apples	−18	12	Months	Phosphonic acid	EFSA (2018a)
		Peaches	−18	307	Days	Phosphonic acid	EFSA (2018a)
	High oil content	Almond	−20	218	Days	Phosphonic acid	EFSA (2018a)
		Pistachio	−20	221	Days	Phosphonic acid	EFSA (2018a)
		Walnut	−20	146	Days	Phosphonic acid	EFSA (2018a)
	High acid content	Grapes	−18	12	Months	Sum of phosphonic acid and fosetyl	EFSA (2012a)
			−18	25	Months	Phosphonic acid	EFSA (2012b)
	Processed commodities	Peach jam, purée, nectar and canned peaches	−18	112–114	Days	Phosphonic acid	EFSA (2018a)

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)
Raspberries	NEU	**Mo** (MRL scenario 1, residues expressed as fosetyl) 68.1, 74.9, 81.5, 110 **Mo** (MRL scenario 2, residues expressed as phosphonic acid) 50.6, 55.8, 60.6, 81.5 **RA** (residues expressed as phosphonic acid) 50.6, 55.8, 60.6, 81.5	Residue trials on raspberries compliant with GAP. All trials conducted in Germany Extrapolation to blackberries possible 1) MRL_{OECD} = 251 (unrounded) 2) MRL_{OECD} = 186 (unrounded)	1) 300 2) 200	81.5 (HR_{RA})	58.2 ($STMR_{RA}$)
Currants	NEU	**Mo** (MRL scenario 1, residues expressed as fosetyl) 16.9, 20.7, 24.7, 28.6, 42.3 **Mo** (MRL scenario 2, residues expressed as phosphonic acid) 12.6, 15.4, 18.4, 21.3, 31.4 **RA** (residues expressed as phosphonic acid) 12.6, 15.4, 18.4, 21.3, 31.4	Residue trials on currants compliant with GAP. All trials conducted in Germany. Higher residue level from samples collected at a longer PHI (underlined) Extrapolation to blueberries, gooseberries and elderberries proposed 1) MRL_{OECD} = 80 (unrounded) 2) MRL_{OECD} = 59 (unrounded)	1) 80 2) 60	31.4 (HR_{RA})	18.4 ($STMR_{RA}$)

MRL: maximum residue level; Mo: monitoring; RA: risk assessment; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; PHI: preharvest interval.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue: The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue: The median residue for risk assessment refers to the whole commodity and not to the edible portion.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

ARfD	Risk assessment scenario 1: no ARfD necessary; Risk assessment scenario 2: 1 mg/kg bw per day (EFSA, 2018b)
Highest IESTI, according to EFSA PRIMo	Risk assessment scenario 1: not relevant Risk assessment scenario 2: Blackberries: 87.3% of ARfD (UK, Toddler) Raspberries: 45.7% of ARfD (DE, Child) Currants: 29.2% of ARfD (DE, Child) Gooseberries: 19.4% of ARfD (DE, Child) Blueberries: 9.7% of ARfD (DE, Child) Elderberries: 1.5% of ARfD (DE, Child)
Assumptions made for the calculations	Risk assessment scenario 2: The calculation is based on the highest residue concentration derived from residue trials in raspberries (extrapolated to blackberries) and currants (extrapolated to gooseberries, elderberries and blueberries)
ADI	Risk assessment scenario 1: 2.25 mg/kg bw per day (EFSA, 2012b)
Highest IEDI, according to EFSA PRIMo	41% ADI (DE child) Contribution of crops assessed: Blackberries: 0.30% of ADI (IE adult) Raspberries: 0.31% of ADI (NL child) Currants: 0.11% of ADI (NL child) Gooseberries: 0.16% of ADI (WHO cluster diet B) Elderberries: 0.03% of ADI (DE child) Blueberries: 0.02% of ADI (FI adult)
Assumptions made for the calculations	The calculation is based on the median residue level derived for blackberries, raspberries, currants, gooseberries, elderberries and blueberries from the trials assessed in this application. For the remaining commodities, the STMR derived in previous EFSA assessments (expressed as phosphonic acid) and the MRLs established for fosetyl-Al in Regulation (EC) No 1003/2016, recalculated to phosphonic acid (crops with MRLs at the LOQ were not considered), were used as input values. The molecular weight CF of 0.75 was used to express residue levels as phosphonic acid.
ADI	Risk assessment scenario 2: 1 mg/kg bw per day (EFSA, 2018b)
Highest IEDI, according to EFSA PRIMo	93% ADI (DE child) Contribution of crops assessed: Blackberries: 0.68% of ADI (IE adult) Raspberries: 0.70% of ADI (NL child) Currants: 0.24% of ADI (NL child) Gooseberries: 0.37% of ADI (WHO cluster diet B) Elderberries: 0.07% of ADI (DE child) Blueberries: 0.05% of ADI (FI adult)
Assumptions made for the calculations	Same assumptions as for risk assessment scenario 1.

ARfD: acute reference dose; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model: ADI: acceptable daily intake; WHO: World Health Organization; CF: conversion factor for enforcement to risk assessment residue definition.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)		Comment/justification
			1)	2)	
1) Existing enforcement residue definition: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) (Reg. (EC) No 396/2005) 2) Proposed enforcement residue definition: Phosphonic acid and their salts expressed as phosphonic acid (EFSA, 2012b)					
0153010	Blackberries	100	300	200	The submitted data on raspberries are sufficient to derive a MRL proposal for the NEU use with an extrapolation to blackberries. A risk to consumers is unlikely
0153030	Raspberries (red and yellow)	100	300	200	
0154010	Blueberries	2*	80	60	The submitted data on currants are sufficient to derive a MRL proposal for the NEU use with an extrapolation to blueberries, gooseberries and elderberries. A risk to consumers is unlikely
0154030	Currants (black, red and white)	2*	80	60	
0154040	Gooseberries	2*	80	60	
0154080	Elderberries	2*	80	60	

MRL: maximum residue level; NEU: northern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

Phosphonic acid			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**2.25**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2012**	Year of evaluation:	**2015**

MRLs from fosetyl Reg. 2018/832 were imported (expressed as fosetyl);
for chronic RA, the STMR values (expressed as phosphonic acid) were included; in case no STMR was available for a crop, the MRL was used (after recalculation to phosphonic acid). LOQs were not taken into account.
For acute RA, only crops under consideration were taken into account.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum
7 41

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
41	DE child	12	Apples	10	Oranges	4	Table grapes	
36	WHO Cluster diet B	10	Tomatoes	6	Wine grapes	2	Peppers	
30	NL child	8	Oranges	7	Apples	3	Table grapes	
25	IE adult	4	Wine grapes	3	Oranges	2	Melons	
21	FR all population	13	Wine grapes	1	Tomatoes	1	Oranges	
20	FR toddler	5	Oranges	3	Apples	3	Tomatoes	
19	PT General population	8	Wine grapes	3	Tomatoes	2	Potatoes	
17	WHO cluster diet E	5	Wine grapes	2	Tomatoes	1	Potatoes	
15	ES child	5	Oranges	3	Tomatoes	1	Apples	
15	WHO regional European diet	4	Tomatoes	1	Potatoes	1	Oranges	
15	NL general	4	Oranges	2	Wine grapes	1	Tomatoes	
14	WHO cluster diet D	3	Tomatoes	1	Potatoes	1	Wine grapes	
14	SE general population 90th percentile	3	Tomatoes	2	Oranges	1	Potatoes	
14	DK child	4	Cucumbers	2	Apples	2	Tomatoes	
14	UK Toddler	5	Oranges	2	Tomatoes	2	Apples	
13	ES adult	3	Oranges	3	Tomatoes	1	Wine grapes	
13	FR infant	3	Apples	2	Oranges	2	Courgettes	
13	WHO Cluster diet F	2	Tomatoes	2	Oranges	2	Wine grapes	
12	IT kids/toddler	5	Tomatoes	1	Oranges	1	Apples	
11	UK vegetarian	3	Wine grapes	2	Oranges	2	Tomatoes	
11	IT adult	4	Tomatoes	1	Lettuce	1	Oranges	
10	DK adult	5	Wine grapes	1	Tomatoes	1	Apples	
10	UK Adult	4	Wine grapes	1	Tomatoes	1	Oranges	
10	PL general population	3	Tomatoes	2	Apples	1	Potatoes	
9	UK Infant	3	Oranges	2	Apples	1	Tomatoes	
8	FI adult	2	Oranges	1	Tomatoes	1	Wine grapes	
7	LT adult	2	Tomatoes	2	Apples	1	Potatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Phosphonic acid is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

Acute risk assessment is not necessary.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
	IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			

Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
			***)				***)	
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of Phosphonic acid residues is unlikely to present a pulbic health concern.

Phosphonic acid			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	1	ARfD (mg/kg bw):	1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

MRLs from fosetyl Reg. 2018/832 were imported (expressed as fosetyl);
for chronic RA, the STMR values (expressed as phosphonic acid) were included; in case no STMR was available for a crop, the MRL was used (after recalculation to phosphonic acid). LOQs were not taken into account.
For acute RA, only crops under consideration were taken into account.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
16	93
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
93	DE child	28	Apples	21	Oranges	10	Table grapes	
81	WHO Cluster diet B	23	Tomatoes	13	Wine grapes	5	Peppers	
69	NL child	18	Oranges	15	Apples	6	Table grapes	
55	IE adult	9	Wine grapes	6	Oranges	5	Melons	
48	FR all population	30	Wine grapes	3	Tomatoes	2	Oranges	
46	FR toddler	11	Oranges	6	Apples	6	Tomatoes	
43	PT General population	19	Wine grapes	7	Tomatoes	4	Potatoes	
37	WHO cluster diet E	12	Wine grapes	4	Tomatoes	3	Potatoes	
34	ES child	12	Oranges	7	Tomatoes	3	Apples	
34	WHO regional European diet	8	Tomatoes	3	Potatoes	3	Oranges	
34	NL general	8	Oranges	5	Wine grapes	3	Tomatoes	
32	WHO cluster diet D	8	Tomatoes	3	Potatoes	3	Wine grapes	
32	SE general population 90th percentile	6	Tomatoes	4	Oranges	3	Potatoes	
32	DK child	9	Cucumbers	5	Apples	4	Tomatoes	
32	UK Toddler	11	Oranges	4	Tomatoes	4	Apples	
30	ES adult	7	Oranges	6	Tomatoes	3	Wine grapes	
30	FR infant	6	Apples	5	Oranges	4	Courgettes	
29	WHO Cluster diet F	5	Tomatoes	5	Oranges	4	Wine grapes	
28	IT kids/toddler	11	Tomatoes	3	Oranges	2	Apples	
26	UK vegetarian	6	Wine grapes	5	Oranges	5	Tomatoes	
26	IT adult	9	Tomatoes	2	Lettuce	2	Oranges	
24	DK adult	10	Wine grapes	3	Tomatoes	2	Apples	
22	UK Adult	8	Wine grapes	3	Tomatoes	3	Oranges	
21	PL general population	7	Tomatoes	5	Apples	2	Potatoes	
21	UK Infant	7	Oranges	4	Apples	3	Tomatoes	
18	FI adult	5	Oranges	3	Tomatoes	2	Wine grapes	
16	LT adult	5	Tomatoes	4	Apples	2	Potatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Phosphonic acid is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
87.3	Blackberries	81.5/-	87.3	Blackberries	81.5/-	32.3	Raspberries	81.5/-	32.3	Raspberries	81.5 / -
45.7	Raspberries	81.5/-	45.7	Raspberries	81.5/-	17.5	Blackberries	81.5/-	17.5	Blackberries	81.5 / -
29.2	Currants (red, black	31.4/-	29.2	Currants (red,	31.4/-	10.0	Blueberries	31.4/-	10.0	Blueberries	31.4 / -
19.4	Gooseberries	31.4/-	19.4	Gooseberries	31.4/-	8.3	Currants (red, black	31.4/-	8.3	Currants (red, black and white)	31.4 / -
9.7	Blueberries	31.4/-	9.7	Blueberries	31.4/-	6.9	Gooseberries	31.4/-	6.9	Gooseberries	31.4 / -
1.5	Elderberries	31.4/-	1.5	Elderberries	31.4/-						
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
97.7	Raspberries juice	81.5/-					
50.3	Elderberry juice	31.4/-					
31.7	Cuurant juice	31.4/-					
22.8	Blueberries	31.4/-					

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Phosphonic acid. IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

Appendix D – Input values for the exposure calculations

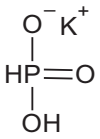
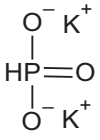
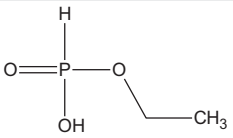
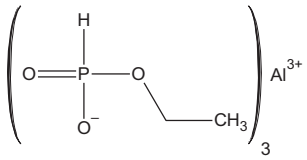
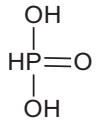
D.1. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Phosphonic acid (sum of phosphonic acid and its salts, expressed as phosphonic acid)				
Blackberries	58.2	STMR	81.5	HR
Raspberries	58.2	STMR	81.5	HR
Blueberries	18.4	STMR	31.4	HR
Currants	18.4	STMR	31.4	HR
Gooseberries	18.4	STMR	31.4	HR
Elderberries	18.4	STMR	31.4	HR
Tree nuts (except coconut)	64.5	STMR (EFSA, 2018a)	Acute risk assessment is performed only for the crops under assessment	
Pome fruit	23.2	STMR (EFSA, 2018a)		
Peaches	12.5	STMR (EFSA, 2018a)		
Potatoes	6.0	STMR (EFSA, 2018a)		
Celeriacs	0.21	STMR (EFSA, 2015)		
Kiwi fruits	23.5	STMR (EFSA, 2012c)		
Spices	74	STMR (EFSA, 2012c)		
Other commodities of plant and animal origin	MRL[(a)]	Commission Regulation (EU) No 1003/2016		

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.

(a): Existing MRLs in Regulation (EC) No 396/2005 are expected to be expressed as fosetyl, therefore for RA purposes the values above the LOQ were recalculated to phosphonic acid by applying a CF for molecular weight of 0.75 (MW phosphorous acid (82)/fosetyl (110).

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
potassium hydrogen phosphonate	potassium hydrogen phosphonate	
dipotassium phosphonate	dipotassium phosphonate	
fosetyl	ethyl hydrogen phosphonate	
fosetyl-Al fosetyl aluminium	aluminium tris(ethyl phosphonate)	
phosphonic acid **Phosphorous acid** [PHO(OH)2], (HO)2HPO H3PO3	Phosphonic acid	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Keys.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).