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Setting of an import tolerance for potassium phosphonates in blueberries

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Exponent International Ltd. (on behalf of the U.S. Highbush Blueberry Council (USHBC)) submitted a request to the competent national authority in France to set an import tolerance for the active substance potassium phosphonates in blueberries. The data submitted in support of the request were found to be sufficient to derive a maximum residue level (MRL) proposal for blueberries. Adequate analytical methods for enforcement are available to control the residues of phosphonic acid on the commodity under consideration at the validated limit of quantification (LOQ) of 0.1 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of potassium phosphonates according to the reported agricultural practice is unlikely to present a risk to consumer health. The consumer risk assessment shall be regarded as indicative and a refined intake assessment will be performed in the framework of the joint review of MRLs for fosetyl and phosphonates.

Keywords: potassium phosphonates, fosetyl, phosphonic acid, blueberries, fungicide, import tolerance, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Exponent International Ltd. (on behalf of the U.S. Highbush Blueberry Council (USHBC)) submitted an application to the competent national authority in France (rapporteur Member State, RMS) to set an import tolerance for the active substance potassium phosphonates in blueberries. The RMS 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 11 September 2020. The RMS proposed to establish a maximum residue level (MRL) for blueberries imported from the USA at the level of 150 mg/kg, in accordance with both the existing enforcement residue definition (fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)) and the proposed enforcement residue definition for potassium phosphonates (phosphonic acid and its salts, expressed as phosphonic acid). 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 assessments and the additional data provided by the RMS in the framework of this application, the following conclusions are derived.

The European Union (EU) pesticides peer review concluded that, given the elementary nature of potassium phosphonates and according to available data from public literature, the main metabolite of potassium phosphonates in plants is phosphonic acid. Studies investigating the effect of processing on the nature of potassium phosphonates (hydrolysis studies) demonstrated that the active substance is stable. As the authorised use of potassium phosphonates is on imported crop, 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 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)'. This residue definition for enforcement is in common with other two active substances approved for use in plant protection products in the EU, disodium phosphonate and fosetyl. The residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crop assessed in this application, metabolism of potassium phosphonates in primary and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on high-performance liquid chromatography coupled with tandem mass spectrometry (HPLC–MS/MS) are available to quantify residues in the crop assessed (high acid content commodity) in this application according to the current enforcement residue definition in Regulation (EC) No 396/2005 and the one proposed during the EU pesticides peer review (as phosphonic acid). The methods enable quantification of residues at or above an limit of quantification (LOQ) of 0.1 mg phosphonic acid/kg.

The available residue trials are sufficient to derive an MRL proposal of 150 mg/kg for blueberries in accordance with both the existing residue enforcement definition (fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)) and the proposed enforcement residue definition for potassium phosphonates (phosphonic acid and its salts, expressed as phosphonic acid).

Specific studies investigating the magnitude of residues in processed commodities are not required, since the contribution of blueberries in the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI).

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

The toxicological profile of potassium phosphonates was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 2.25 mg/kg body weight (bw) per day for phosphonic acid, which is the toxicologically relevant metabolite of potassium phosphonates in products of plants and animal origin. An acute reference dose (ARfD) was deemed unnecessary.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA used the median residue values (STMR) as derived from the residue trials on blueberries, the STMR available from previously issued EFSA opinions and from recently implemented Codex MRLs. For the remaining commodities of plant and animal

origin, the existing MRLs as established in the EU legislation, recalculated to express them as phosphonic acid, were included in the risk assessment. Using the toxicological reference value set for potassium phosphonates, no long-term consumer intake concerns were identified; the calculated long-term exposure accounted for a maximum of 48% of the ADI (DE child diet). The contribution of phosphonic acid residues expected in blueberries is minor, accounting for 0.05% of the ADI (NL toddler diet).

EFSA also performed an indicative risk assessment using the proposed revised ADI of 1 mg/kg bw per day applicable to phosphonic acid according to the recent EFSA conclusion on fosetyl, noting that the value is not yet formally taken note. The long-term dietary exposure accounted for a maximum of 97% of the ADI (DE child, and NL toddler diets). When excluding from this exposure calculation the commodities for which the existing EU MRLs are set at the LOQ, assuming that no uses are authorised on these crops, and taking into account the peeling factor for citrus fruits, the overall chronic exposure to phosphonic acid residues is lower (91% of the ADI; DE child). In both scenarios, the contribution of phosphonic acid residues in blueberries to the overall long-term exposure is minor (0.11% of the ADI; NL toddler diet).

All these exposure calculations shall be regarded as indicative since information on the contribution for all authorised uses and all sources leading to residues of phosphonic acid is not available at this stage. For a number of products, the exposure calculations were performed with the MRLs instead of the STMRs which is likely to overestimate the exposure to residues arising from the use of potassium phosphonates in plants.

EFSA concluded that the existing USA authorised use of potassium phosphonates on blueberries will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

As the joint review of MRLs for fosetyl and phosphonates under Article 12 and 43 of Regulation (EC) No 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion are indicative and may need to be reconsidered in the light of the outcome of the MRL review.

EFSA proposes to amend the existing MRL as reported in the summary table below. However, it should be noted that in a previous reasoned opinion an MRL on blueberries has been also proposed, based on EU trials on currants and blueberries. An MRL of 200 mg/kg was calculated for blueberries according to the existing enforcement residue definition (fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)), or 150 mg/kg according to the proposed enforcement residue definition for potassium phosphonates (phosphonic acid and its salts, expressed as phosphonic acid).

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
Enforcement residue definition: 1) Existing enforcement residue definition: fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) 2) Proposed enforcement residue definition: phosphonic acid and its salts, expressed as phosphonic acid				
0154010	Blueberries	80	1) 150 2) 150	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely. In a previous reasoned opinion an MRL of 200 mg/kg (expressed in accordance with the existing enforcement definition) or 150 mg/kg (expressed in accordance with the proposed enforcement residue definition) has been proposed by EFSA on the basis of an indoor use EU GAP, which has not yet been implemented in the MRL legislation.

MRL: maximum residue level; GAP: Good Agricultural Practice.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Assessment

The European Food Safety Authority (EFSA) received an application to set an import tolerance for potassium phosphonates in blueberries. The detailed description of the existing use of potassium phosphonates in blueberries authorised in the USA, which is the basis for the current MRL application, is reported in Appendix A.

Potassium phosphonates is the ISO common name for potassium hydrogen phosphonate and dipotassium phosphonate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

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

The process of renewal of the first approval has not yet been initiated.

The European Union (EU) MRLs for potassium phosphonates are established in Annexes III of Regulation (EC) No 396/2005[3]. The current residue definition for enforcement is set as 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)', reflecting the residues of the active substances fosetyl, disodium phosphonate and potassium phosphonates. The review of existing MRLs for potassium phosphonates according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is not yet finalised. For fosetyl, the MRL review is completed (EFSA, 2012a). EFSA has received from the European Commission a mandate to provide a reasoned opinion on the joint review of MRLs for fosetyl and phosphonates in or on food and feed according to Articles 12 and 43 of Regulation (EC) No 396/2005 and this assessment is currently ongoing. EFSA has issued several reasoned opinions on the modification of MRLs for fosetyl and potassium phosphonates (EFSA, 2009, 2012c, 2015, 2018b,d, 2019b, 2020a,b,c). The proposals from previous reasoned opinions (EFSA, 2009, 2012c, 2015, 2018b,d) have been considered in recent MRL regulations.[4] However, recent proposed modifications of the existing MRLs (EFSA, 2019b, 2020a,b,c) have not yet been implemented in the MRL legislation. Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.[5]

In accordance with Article 6 of Regulation (EC) No 396/2005, Exponent International Ltd. (on behalf of the U.S. Highbush Blueberry Council (USHBC)) submitted an application to the competent national authority in France (RMS) to set an import tolerance for the active substance potassium phosphonates in blueberries. The RMS 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 EFSA on 11 September 2020. The RMS proposed to establish MRLs for blueberries imported from the US at the level of 150 mg/kg, in accordance with both the existing residue definition for potassium phosphonates as 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)' and the proposed enforcement residue definition as 'phosphonic acid and its salts, expressed as phosphonic acid'.

EFSA assessed the application and the evaluation report, as required by Article 10 of the MRL regulation.

EFSA based its assessment on the evaluation report submitted by the RMS (France, 2020), the DAR and its addendum (France, 2005, 2012) prepared under Council Directive 91/414/EEC and the renewal assessment report (RAR) on fosetyl (France, 2017, 2019) prepared under Regulation (EU) No 1107/2009[6], the Commission review report on potassium phosphonates (European Commission, 2013), the conclusion

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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 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN.

5 Commission Regulation (EU) 2019/552 of 4 April 2019 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 azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim in or on certain products C/2019/2496. OJ L 96, 5.4.2019, p. 6–49.

6 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

on the peer review of the pesticide risk assessment of the active substances potassium phosphonates (EFSA, 2012b) and fosetyl (EFSA, 2018c), as well as the conclusions from previous EFSA opinions on potassium phosphonates and fosetyl (EFSA, 2009, 2012c, 2015, 2018b,d, 2019b, 2020a,b,c) including the reasoned opinion on the MRL review on fosetyl according to Article 12 of Regulation No 396/2005 (EFSA, 2012a).

For this application, the data requirements established in Regulation (EU) No 544/2011[7] and the guidance documents applicable at the date of submission of the application to the RMS 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[8].

As the joint review of MRLs for fosetyl and phosphonates under Article 12 and Article 43 of Regulation (EC) No 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion may 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, is presented in Appendix B.

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

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of potassium phosphonates in primary crops 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 the transformation of potassium phosphonate salts into phosphonic acid. No further studies on the metabolism of potassium phosphonates in primary crops were submitted in the present MRL application and are not required.

For the intended use, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

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

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of phosphonic acid, which is the main product produced from the metabolism of potassium phosphonates, was investigated in the framework of the EU pesticides peer reviews for potassium phosphonates and fosetyl (EFSA, 2012b, 2018c). These studies showed that phosphonic acid is hydrolytically stable under standard processing conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of phosphonic acid residues, using high-performance liquid chromatography coupled with tandem mass spectrometry (HPLC–MS/MS), were assessed during the peer review of fosetyl (EFSA, 2018c). The methods are sufficiently validated for residues of phosphonic acid in matrices with high water, high oil content, and dry commodities at the limit of quantification (LOQ) of 0.01 mg/kg and in high acid content matrices at the LOQ of 0.1 mg/kg (EFSA, 2018c). In the framework of the current assessment, the applicant submitted a modified European Reference Laboratories for Pesticide Residues (EURL) method (QuPPe method; LC–MS/MS; LOQ: 0.5 mg/kg) for the determination of phosphonic acid residues in blueberries' samples. However, according

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

[8] 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.

to the RMS the method is not highly specific (only one mass transition monitored) and an ILV is missing (France, 2020). Since this modified method is not fully validated, it is not recommended for enforcement monitoring.

1.1.5. Storage stability of residues in plants

The storage stability of phosphonic acid in commodities with high acid content under frozen conditions was investigated in the framework of the MRL review of fosetyl (EFSA, 2012a), and the peer review of potassium phosphonates (EFSA, 2012b). In addition, a study on the stability of phosphonic acid residues in blueberries was submitted with the current application, which demonstrated that residues were stable for at least 14 months when stored at −20°C (France, 2020). Overall, the available information demonstrates that residues of phosphonic acid in commodities with high acid content, to which blueberries belong, are stable for up to 25 months when stored at −18°C (EFSA, 2012a).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of the metabolite, the capability of the analytical method, the following residue definitions were proposed during the EU pesticides peer review of potassium phosphonates (EFSA, 2012b):

- residue definition for risk assessment: Phosphonic acid and its salts, expressed as phosphonic acid.
- residue definition for enforcement: Phosphonic acid and its salts, expressed as phosphonic acid.

The same residue definitions are applicable to rotational crops and processed products.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is different and residues of potassium phosphonates are currently covered by the enforcement residue definition for fosetyl:

- Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl).[9]

Taking into account the proposed uses assessed in these applications, EFSA concluded that these residue definitions are appropriate, and further information is not required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the import tolerance application, the applicant submitted 8 residue trials conducted on outdoor blueberries in the USA in 2016 (France, 2020). Trials were performed according to the registered use, with six foliar applications 1.81–2.07 kg a.s./ha, with an interval of 7–10 days and a preharvest interval (PHI) of 2–3 days, and one trial was performed as a residue decline trial (PHI 1, 3, 7 and 14 days). Two trials, performed on different varieties at the same location and application dates, were considered different experimental conditions within a same trial and the highest residue value was selected. Overall, EFSA considered seven trials are sufficiently independent.

The samples were stored under conditions for which integrity of the residue has been demonstrated. According to the assessment of the RMS, the analytical method used was sufficiently validated and fit for purpose. In all trials, duplicate samples were collected and analysed for phosphonic acid residues (experimental replicates). The mean values were used to derive risk assessment value and for the MRL calculation. The results were also expressed as fosetyl equivalents, by applying the molecular weight conversion factor of 1.34, in order to derive the MRL proposals according to the existing enforcement residue definition and are presented in Table B.1.2.1.

An MRL proposal for blueberries is calculated at 150 mg/kg for both phosphonic acid and fosetyl equivalents.

It should be noted that an MRL on blueberries was proposed in a recent reasoned opinion (EFSA, 2020a), but not yet implemented. Based on an EU indoor Good Agricultural Practice (GAP) (greenhouse application, 3 × 3.02 kg a.s./ha, 7-10 days interval, PHI: 14 days), an MRL for blueberries was calculated at 150 mg/kg as phosphonic acid and at 200 mg/kg as fosetyl equivalents (EFSA, 2020a).

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

1.2.2. Magnitude of residues in rotational crops

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

1.2.3. Magnitude of residues in processed commodities

In the framework of the current assessment, no new processing studies were submitted by the applicant. Specific processing studies for blueberries are not required, since their contribution to the theoretical maximum daily intake (TMDI) is not expected to exceed the trigger value of 10% of the ADI (European Commission, 1997d).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation. EFSA derived MRL proposals according to both the existing and the proposed residue definition for enforcement (Appendix B.4). In Section 3 EFSA assessed whether residues on blueberries resulting from the use authorised in USA are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as blueberries are not used for feed purposes.

3. Consumer risk assessment

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

The assessment was performed according to the residue definition 'phosphonic acid and its salts, expressed as phosphonic acid'.

The toxicological profile for potassium phosphonates was assessed in the framework of the EU pesticide peer review of this active substance (EFSA, 2012b). Considering that phosphonic acid is the relevant component of residues in plant and animal products, the acceptable daily intake (ADI) derived was related to phosphonic acid and was set at 2.25 mg/kg body weight (bw) per day (European Commission, 2013). Later, as phosphonic acid is a metabolite in common with fosetyl, during the process of the renewal of the approval for fosetyl, a revised ADI of 1 mg/kg bw per day has been derived and considered applicable also to phosphonic acid (EFSA, 2018c). Although this ADI is not yet formally taken note, an indicative risk assessment has been calculated according to this reference value as well. The short-term exposure assessment is not required since no ARfD is established or proposed.

For the calculation of the chronic exposure, EFSA used the median residue values (STMR) as derived from the residue trials on blueberries, the STMR values reported in previously issued EFSA reasoned opinions (EFSA, 2012c, 2015, 2018b,d, 2019b, 2020a,b,c) and the STMR values of the recently implemented Codex MRLs (FAO, 2017). For the remaining commodities of plant and animal origin, in the absence of risk assessment values for refinement, the existing MRLs set in the EU legislation for fosetyl, recalculated to phosphonic acid,[10] were used.

Considering the conclusions of the consumer risk assessment derived in the previous reasoned opinion (EFSA, 2020a) a lower consumer exposure is now calculated, since a lower STMR value for blueberries is derived from trials submitted within the current application (35 vs 42.25 mg phosphonic acid/kg). The input values used in the exposure calculations are summarised in Appendix D.1.

Considering the current ADI of 2.25 mg/kg bw per day for phosphonic acid (scenario 1), the estimated long-term dietary exposure accounted for a maximum of 48% of the ADI (DE child). The contribution of phosphonic acid residues expected in blueberries to the overall long-term exposure is minor (0.05% of the ADI; NL toddler diet).

EFSA also performed an indicative risk assessment using the revised ADI of 1 mg/kg bw per day for phosphonic acid as proposed in the framework of the EU pesticides peer review of fosetyl (scenario 2, option a). The long-term dietary exposure accounted for a maximum of 97% of the ADI (DE child, and

[10] Using the molecular weight conversion factor of 0.75.

NL toddler). The contribution of phosphonic acid residues in blueberries to the overall long-term exposure is minor (0.11% of the ADI; NL toddler diet).

When excluding from the exposure calculation the commodities for which the existing EU MRL is set at the LOQ, assuming that no uses are authorised for these crops, and applying to the MRL on citrus fruits the peeling factor of 0.81 as derived in the MRL review of fosetyl (EFSA, 2012a) (Scenario 2, option b), the overall chronic exposure to phosphonic acid residues is lower (91% of the ADI, DE child). The contribution of residues expected in blueberries to the overall long-term exposure is again minor (0.11% of the ADI; NL toddler diet).

EFSA concluded that the long-term intake of residues of potassium phosphonates resulting from the existing and the intended use in blueberries is unlikely to present a risk to consumers' health.

It is noted that all these exposure calculations shall be regarded as indicative since information on the contribution for all authorised uses and all sources leading to residues of phosphonic acid is not available at this stage. For a number of products, the exposure calculations were performed with the MRL instead of the STMR which is likely to overestimate the exposure to residues arising from the use of potassium phosphonates in plants. A refined consumer risk assessment will be conducted in the framework of the joint review of MRLs for fosetyl and phosphonates, according to Article 12 and 43 of Regulation (EC) No 396/2005.

For further details on the exposure calculations, screenshots of the Report sheet of the PRIMo for the scenarios 1, 2a and 2b are presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for blueberries.

EFSA concluded that the proposed use of potassium phosphonates on blueberries 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
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
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
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
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I[(a)]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s.	Method kind	Range of growth stages and season[(c)]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Blueberries	USA	F	Downy mildew	Liquid	648 g/L	Foliar treatment – broadcast spraying	BBCH 71–89	6	7–10	200–1,000	190–950	1,890 (equivalent to 1181 phosphonic acid)	g a.s./ha	3	Application should be made in conjunction with an appropriate spray adjuvant (non-ionic surfactant)

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	No experimental studies available. The EU peer review concluded that, given the elementary nature of potassium phosphonates and according to available data from public literature, the main metabolite of potassium phosphonates in plants is phosphonic acid (EFSA, 2012b).			
	Root crops				
	Leafy crops				
	Cereals/grass				
	Pulses/oilseeds				
	Miscellaneous				

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish	32; 182	No experimental studies submitted. Bridging data from fosetyl. Study not conducted with radiolabelled material (EFSA, 2018c). Residues of phosphonic acid are observed in plants grown only one month after application to the soil. Radish root: 0.8 mg/kg,; lettuce: 0.76 mg/kg. In all other crop parts phosphonic acid residues < LOQ (0.5 mg/kg).
	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	According to experimental studies provided in the peer review of potassium phosphonates and fosetyl (EFSA, 2012b, 2018c), phosphonic acid is hydrolytically stable.
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	
	Sterilisation (20 min, 120°C, pH 6)	Yes	
	Other processing conditions	–	–

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2012b)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2012b)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2012b)

Plant residue definition for monitoring (RD-Mo)	Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012b) Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) (Regulation (EC) No 396/2005)
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)	HPLC–MS/MS: matrices with high water content, high oil content and dry matrices at LOQ of 0.01 mg/kg and in matrices with high acid content at LOQ 0.1 mg/kg (fosetyl, and phosphonic acid) (EFSA, 2018c).

DAT: days after treatment; PBI: plant-back interval; LOQ: limit of quantification; HPLC-MS/MS: high - performance liquid chromatography with tandem mass spectrometry.

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	Potato	–20	12	Months	Phosphonic acid	EFSA (2019b)
			–18	12	Months	Sum of phosphonic acid and fosetyl	EFSA (2012b)
			–18	25	Months	Phosphonic acid	EFSA (2012b)
		Wheat, whole plant	–20	12	Months	Phosphonic acid	EFSA (2019b)
		Cucumber, lettuce	–18	12	Months	Sum of phosphonic acid and fosetyl	EFSA (2012b)
		Cucumber, cabbage	–18	25	Months	Phosphonic acid	EFSA (2012b)
		Apples	–18	12	Months	Phosphonic acid	EFSA (2018b)
		Peaches	–18	307	Days	Phosphonic acid	EFSA (2018b)
	High oil content	Almond	–20	218	Days	Phosphonic acid	EFSA (2018b)
		Pistachio	–20	221	Days	Phosphonic acid	EFSA (2018b)
		Walnut	–20	146	Days	Phosphonic acid	EFSA (2018b)
	High protein content	–	–	–	–	–	–
	Dry/High starch	Wheat, grain	–20	12	Months	Phosphonic acid	EFSA (2019b)
	High acid content	Grapes	–18	25	Months	Sum of phosphonic acid and fosetyl	EFSA (2012a)
						Phosphonic acid	
			–18	12	Months	Phosphonic acid	EFSA (2012b)
		Blueberries	–20	14	Months	Phosphonic acid	France (2020)
	Processed products	Peach jam, puree, nectar and canned peaches	–18	112–114	Days	Phosphonic acid	EFSA (2018b)
	Others	Wheat, straw	–20	12	Months	Phosphonic acid	EFSA (2019b)

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ 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)	CF[(d)]
Blueberries	USA	**Mo:** 35, 36[(e)], 40, 47, 62, 63, 64 **RA:** 26, 27[(e)], 30, 35, 46, 47, 48	Residue trials on blueberries compliant with US GAP.	150 (as phosphonic acid) 150 (as fosetyl)	48 (as phosphonic acid)	35 (as phosphonic acid)	n/a

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment; n/a: not applicable.
(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.
(c): Supervised trials median residue.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Higher residue value at later PHI selected (7 days PHI).

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	Rotational crop field studies are summarised in the peer review of fosetyl (EFSA, 2018c). Residues in rotational crops cannot be excluded. Member States should consider setting specific pre-planting intervals.
Residues in rotational and succeeding crops expected based on field rotational crop study?	Yes	

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

An acute consumer risk assessment is not relevant since no ARfD has been considered necessary.

Scenario 1 – with implemented TRVs (ADI = 2.25 mg/kg bw per day for phosphonic acid)

ADI	2.25 mg/kg bw per day (European Commission, 2013)
Highest IEDI, according to EFSA PRIMo	48% ADI (DE child) Contribution of crops assessed: Blueberries: 0.05% of ADI (NL toddler)
Assumptions made for the calculations	The calculation is based on the STMRs (expressed as phosphonic acid) derived for raw agricultural commodities assessed in the current application, in previous assessments (EFSA, 2012c, 2015, 2018b,d, 2019b, 2020a,b,c) and the STMRs of the implemented CXLs (FAO, 2017). For the remaining commodities, the MRLs established for fosetyl in the EU legislation, recalculated to phosphonic acid were used. The molecular weight conversion factor of 0.75 was used to express residue levels as phosphonic acid. The consumer risk assessment is indicative since information on the contribution for all authorised uses and all sources leading to residues of phosphonic acid is not available at this stage. A refined chronic intake assessment will be performed in the framework of the MRL review for potassium phosphonates. Calculations performed with PRIMo revision 3.1.

Scenario 2 – indicative consumer RA with revised TRVs (ADI = 1.0 mg/kg bw per day for phosphonic acid)

ADI	1 mg/kg bw per day (not implemented yet, EFSA, 2018c)
Highest IEDI, according to EFSA PRIMo	**Option a** (including all MRLs): 97% ADI (DE child, NL toddler)
	Option b (excluding MRLs <LOQ; applying peeling factor for citrus): 91% ADI (DE child) Contribution of crops assessed: Blueberries: 0.11% of ADI (NL toddler) for both options.
Assumptions made for the calculations	**Option a:** The calculation is based on the STMRs (expressed as phosphonic acid) derived for raw agricultural commodities assessed in the current application, in previous assessments (EFSA, 2012c, 2015, 2018b,d, 2019b, 2020a,b,c) and the STMRs of the implemented CXLs (FAO, 2017). For the remaining commodities, the MRLs established for fosetyl in the EU legislation, recalculated to phosphonic acid were used. The molecular weight conversion factor of 0.75 was used to express residue levels as phosphonic acid. **Option b:** The calculation is based on the STMRs (expressed as phosphonic acid) derived for raw agricultural commodities assessed in the current application, in previous assessments (EFSA, 2012c, 2015, 2018b,d, 2019b, 2020a,b,c), the STMRs of the implemented CXLs (FAO, 2017) and the MRLs above the LOQ established for fosetyl in the EU legislation, recalculated to phosphonic acid by a CF of 0.75, were used. The commodities, for which the existing EU MRL is set at the LOQ, were excluded from the calculation, under the assumption that there are no authorised uses supporting the MRL. The existing MRL for citrus fruits was multiplied by a peeling factor of 0.81 for phosphonic acid derived by the MRL review of fosetyl (EFSA, 2012a). The consumer risk assessment is indicative, since information on the contribution for all authorised uses and all sources leading to residues of phosphonic acid is not available at this stage. A refined chronic intake assessment will be performed in the framework of the joint review of the existing MRLs for fosetyl and phosphonates. Calculations performed with PRIMo revision 3.1.

ARfD: acute reference dose; TRV: toxicity reference values; ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; STMR: supervised trials median residue; MRL: maximum residue level; CXL: codex maximum residue limit; PRIMo: (EFSA) Pesticide Residues Intake Model; LOQ: limit of quantification.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: 1) Existing enforcement residue definition: fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) 2) Proposed enforcement residue definition: phosphonic acid and its salts, expressed as phosphonic acid				
0154010	Blueberries	80	1) 150 2) 150	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely. In a previous reasoned opinion an MRL of 200 mg/kg (expressed according to the existing enforcement definition) or 150 mg/kg (expressed according to the proposed RD-Mo) has been proposed by EFSA, not yet implemented by MRL Regulation.

MRL: maximum residue level; GAP: Good Agricultural Practice.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

- Scenario 1

efsa
European Food Safety Authority
EFSA PRIMo revision 3.0; 2017/12/11

Potassium phosphonates (phosphonic acid)

LOQs (mg/kg) range from:	0.375	to:	3.8
Toxicological reference values			
ADI (mg/kg bw per day):	**2.25**	ARfD (mg/kg bw):	**Not necessary**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2012**	Year of evaluation:	**2012**

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
48%	DE child	1070.95	13%	Apples	10%	Oranges	4%	Wheat	0.4%	
47%	NL toddler	1062.53	11%	Apples	6%	Oranges	5%	Potatoes	2%	
41%	GEMS/Food G06	924.97	12%	Tomatoes	7%	Wheat	3%	Watermelons	0.7%	
31%	NL child	700.47	6%	Apples	4%	Wheat	4%	Potatoes	1%	
28%	RO general	619.90	6%	Tomatoes	5%	Wheat	4%	Potatoes	0.3%	
27%	GEMS/Food G11	617.85	5%	Potatoes	4%	Wheat	3%	Tomatoes	0.8%	
27%	GEMS/Food G08	606.04	5%	Potatoes	4%	Wheat	4%	Tomatoes	0.6%	
27%	FR child 3 15 yr	605.81	9%	Oranges	5%	Wheat	3%	Tomatoes	0.6%	
26%	GEMS/Food G15	595.65	5%	Wheat	4%	Potatoes	4%	Tomatoes	0.6%	
26%	GEMS/Food G10	592.85	5%	Tomatoes	4%	Wheat	4%	Potatoes	0.7%	
26%	GEMS/Food G07	591.82	4%	Potatoes	4%	Wheat	4%	Tomatoes	0.6%	
24%	IE adult	542.82	3%	Potatoes	3%	Oranges	2%	Wheat	0.7%	
22%	ES child	500.15	5%	Oranges	5%	Wheat	3%	Tomatoes	0.3%	
22%	PT general	499.87	6%	Potatoes	4%	Wheat	3%	Tomatoes	0.3%	
21%	SE general	479.80	5%	Potatoes	3%	Wheat	3%	Tomatoes	0.3%	
21%	UK toddler	467.22	5%	Oranges	4%	Potatoes	4%	Wheat	0.5%	
21%	FR toddler 2 3 yr	465.98	4%	Oranges	3%	Apples	3%	Wheat	0.5%	
20%	DE women 14-50 yr	459.03	5%	Oranges	3%	Apples	2%	Tomatoes	0.6%	
19%	IT toddler	434.20	7%	Wheat	5%	Tomatoes	1%	Oranges	0.2%	
18%	DE general	413.80	4%	Oranges	3%	Apples	2%	Tomatoes	0.6%	
18%	DK child	397.11	5%	Wheat	3%	Potatoes	2%	Apples	0.6%	
16%	NL general	370.55	3%	Potatoes	3%	Oranges	2%	Wheat	0.5%	
16%	ES adult	358.84	3%	Oranges	3%	Tomatoes	2%	Wheat	0.2%	
16%	FI 3 yr	352.71	6%	Potatoes	2%	Tomatoes	1%	Wheat	0.3%	
15%	IT adult	345.52	4%	Wheat	4%	Tomatoes	0.9%	Oranges	0.1%	
15%	UK infant	342.18	4%	Potatoes	3%	Oranges	3%	Wheat	0.5%	
13%	FR adult	294.51	2%	Wine grapes	2%	Wheat	2%	Tomatoes	0.3%	
13%	FI 6 yr	290.47	5%	Potatoes	1%	Tomatoes	1%	Wheat	0.3%	
13%	UK vegetarian	282.51	2%	Oranges	2%	Wheat	2%	Tomatoes	0.2%	
12%	PL general	271.98	4%	Potatoes	3%	Tomatoes	2%	Apples	0.1%	
10%	LT adult	234.17	4%	Potatoes	2%	Tomatoes	2%	Apples	0.1%	
10%	UK adult	223.12	2%	Wheat	2%	Potatoes	1%	Tomatoes	0.2%	
10%	FR infant	217.08	2%	Potatoes	2%	Apples	0.8%	Wheat	0.3%	
9%	DK adult	211.74	2%	Tomatoes	2%	Potatoes	1%	Wheat	0.1%	
9%	FI adult	197.06	2%	Tomatoes	1%	Potatoes	1%	Oranges	1%	
3%	IE child	73.30	1%	Wheat	0.7%	Potatoes	0.3%	Apples	0.1%	

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

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
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)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
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)
Expand/collapse list							

Conclusion:

- Scenario 2a

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Potassium phosphonates (phosphonic acid)

LOQs (mg/kg) range from:	0.375	to:	3.8
Toxicological reference values			
ADI (mg/kg bw per day):	1	ARfD (mg/kg bw):	Not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
97%	DE child	973.81	29%	Apples	23%	Oranges	7%	Tomatoes	1%	
97%	NL toddler	971.31	25%	Apples	13%	Oranges	11%	Potatoes	4%	
76%	GEMS/Food G06	757.63	27%	Tomatoes	6%	Watermelons	6%	Oranges	2%	
61%	NL child	605.36	13%	Apples	9%	Potatoes	8%	Oranges	2%	
53%	GEMS/Food G11	534.44	11%	Potatoes	7%	Tomatoes	4%	Oranges	2%	
51%	GEMS/Food G08	511.63	11%	Potatoes	9%	Tomatoes	3%	Apples	1%	
50%	RO general	502.71	15%	Tomatoes	10%	Potatoes	4%	Sweet peppers/bell peppers	0.7%	
50%	GEMS/Food G10	502.18	10%	Tomatoes	8%	Potatoes	6%	Oranges	2%	
50%	FR child 3 15 yr	499.54	19%	Oranges	6%	Tomatoes	4%	Potatoes	1%	
49%	GEMS/Food G07	494.22	10%	Potatoes	8%	Tomatoes	8%	Oranges	1%	
49%	GEMS/Food G15	490.55	10%	Potatoes	9%	Tomatoes	5%	Sweet peppers/bell peppers	1%	
49%	IE adult	489.73	6%	Potatoes	6%	Oranges	4%	Grapefruits	2%	
41%	DE women 14-50 yr	409.39	11%	Oranges	6%	Apples	6%	Tomatoes	1%	
41%	PT general	409.24	14%	Potatoes	7%	Tomatoes	6%	Wine grapes	0.6%	
41%	SE general	405.75	11%	Potatoes	6%	Tomatoes	4%	Oranges	0.7%	
40%	ES child	397.56	12%	Oranges	7%	Tomatoes	5%	Potatoes	0.6%	
39%	FR toddler 2 3 yr	394.83	8%	Oranges	7%	Apples	5%	Potatoes	1%	
38%	UK toddler	376.60	11%	Oranges	9%	Potatoes	4%	Tomatoes	1%	
37%	DE general	370.21	9%	Oranges	6%	Apples	5%	Tomatoes	1%	
33%	NL general	325.84	7%	Potatoes	6%	Oranges	3%	Apples	1%	
33%	FI 3 yr	325.12	13%	Potatoes	4%	Tomatoes	2%	Mandarins	0.8%	
30%	ES adult	304.53	7%	Oranges	6%	Tomatoes	3%	Potatoes	0.4%	
29%	DK child	294.91	7%	Potatoes	5%	Apples	4%	Tomatoes	1%	
28%	UK infant	281.56	9%	Potatoes	7%	Oranges	4%	Apples	1%	
28%	IT toddler	280.46	11%	Tomatoes	3%	Oranges	2%	Potatoes	0.5%	
27%	PL general	271.98	9%	Potatoes	7%	Tomatoes	5%	Apples	0.2%	
27%	FI 6 yr	267.94	10%	Potatoes	3%	Tomatoes	2%	Mandarins	0.6%	
25%	IT adult	249.87	9%	Tomatoes	2%	Oranges	2%	Apples	0.3%	
24%	FR adult	243.08	6%	Wine grapes	3%	Tomatoes	3%	Oranges	0.6%	
24%	UK vegetarian	235.14	5%	Oranges	5%	Tomatoes	4%	Potatoes	0.4%	
21%	LT adult	209.84	9%	Potatoes	5%	Tomatoes	4%	Apples	0.3%	
20%	FR infant	198.91	5%	Potatoes	4%	Apples	1%	Oranges	0.6%	
19%	FI adult	189.65	4%	Tomatoes	3%	Potatoes	2%	Oranges	2%	
19%	DK adult	185.75	4%	Tomatoes	3%	Potatoes	2%	Wine grapes	0.3%	
18%	UK adult	184.35	4%	Potatoes	3%	Tomatoes	3%	Oranges	0.3%	
5%	IE child	46.40	2%	Potatoes	0.8%	Apples	0.5%	Oranges	0.1%	

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

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
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)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
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)
Expand/collapse list							

Conclusion:

- Scenario 2b

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Potassium phosphonates (phosphonic acid)

LOQs (mg/kg) range from:	0.375	to:	3.8
Toxicological reference values			
ADI (mg/kg bw per day):	1	ARfD (mg/kg bw):	Not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
91%	DE child	911.25	29%	Apples	18%	Oranges	7%	Tomatoes		
90%	NL toddler	901.35	25%	Apples	11%	Potatoes	10%	Oranges		
72%	GEMS/Food G06	723.38	27%	Tomatoes	6%	Watermelons	5%	Potatoes		
56%	NL child	556.34	13%	Apples	9%	Potatoes	6%	Oranges		
50%	GEMS/Food G11	498.68	11%	Potatoes	7%	Tomatoes	4%	Apples		
49%	RO general	490.09	15%	Tomatoes	10%	Potatoes	4%	Sweet peppers/bell peppers		
48%	GEMS/Food G08	484.62	11%	Potatoes	9%	Tomatoes	3%	Apples		
47%	GEMS/Food G10	468.35	10%	Tomatoes	8%	Potatoes	5%	Oranges		
47%	GEMS/Food G15	465.55	10%	Potatoes	9%	Tomatoes	5%	Sweet peppers/bell peppers		
46%	GEMS/Food G07	458.60	10%	Potatoes	8%	Tomatoes	6%	Oranges		
45%	IE adult	447.86	6%	Potatoes	5%	Oranges	3%	Grapefruits		
45%	FR child 3 15 yr	445.31	16%	Oranges	6%	Tomatoes	4%	Potatoes		
39%	PT general	394.97	14%	Potatoes	7%	Tomatoes	6%	Wine grapes		
38%	SE general	381.34	11%	Potatoes	6%	Tomatoes	3%	Oranges		
37%	DE women 14-50 yr	371.27	9%	Oranges	6%	Apples	6%	Tomatoes		
36%	ES child	364.96	10%	Oranges	7%	Tomatoes	5%	Potatoes		
36%	FR toddler 2 3 yr	357.65	7%	Apples	7%	Oranges	5%	Potatoes		
34%	UK toddler	340.34	9%	Potatoes	9%	Oranges	4%	Tomatoes		
34%	DE general	336.14	7%	Oranges	6%	Apples	5%	Tomatoes		
31%	FI 3 yr	311.38	13%	Potatoes	4%	Tomatoes	2%	Apples		
30%	NL general	300.96	7%	Potatoes	5%	Oranges	3%	Apples		
28%	ES adult	284.18	6%	Oranges	6%	Tomatoes	3%	Potatoes		
28%	DK child	276.01	7%	Potatoes	5%	Apples	4%	Tomatoes		
27%	PL general	268.67	9%	Potatoes	7%	Tomatoes	5%	Apples		
27%	IT toddler	267.42	11%	Tomatoes	2%	Potatoes	2%	Oranges		
26%	FI 6 yr	256.88	10%	Potatoes	3%	Tomatoes	1%	Mandarins		
25%	UK infant	254.13	9%	Potatoes	6%	Oranges	4%	Apples		
24%	IT adult	240.31	9%	Tomatoes	2%	Apples	2%	Oranges		
23%	FR adult	228.33	6%	Wine grapes	3%	Tomatoes	3%	Oranges		
22%	UK vegetarian	219.68	5%	Tomatoes	4%	Oranges	4%	Potatoes		
20%	LT adult	204.70	9%	Potatoes	5%	Tomatoes	4%	Apples		
19%	FR infant	188.14	5%	Potatoes	4%	Apples	1%	Spinaches		
18%	DK adult	179.07	4%	Tomatoes	3%	Potatoes	2%	Wine grapes		
17%	UK adult	173.02	4%	Potatoes	3%	Tomatoes	3%	Wine grapes		
16%	FI adult	159.68	4%	Tomatoes	3%	Potatoes	2%	Oranges		
4%	IE child	43.85	2%	Potatoes	0.8%	Apples	0.4%	Tomatoes		

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

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
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)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
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)
Expand/collapse list							

Conclusion:

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 and its salts, expressed as phosphonic acid				
Blueberries	35	STMR-RAC An STMR of 42.25 mg/kg was previously derived by EFSA based on an EU indoor GAP (EFSA, 2020a) for which MRL proposals are not yet implemented in the EU Legislation.		Considering the toxicological profile of the active substance, an acute risk assessment was not needed as the setting of an ARfD for the active substance was considered not necessary.
Almonds, Chestnuts, Hazelnuts/cobnuts, Pistachios, Walnuts	358.5	STMR-RAC (EFSA, 2020a)[(a)]		
Brazil nuts, cashew nuts, macadamias, pecans, pine nut kernels	64.5	STMR-RAC (EFSA, 2018b)		
Pome fruits	23.2	STMR-RAC (EFSA, 2018b)		
Peaches	12.51	STMR-RAC (EFSA, 2018b)		
Table grapes	15.5	STMR-RAC (FAO, 2017)[(b)]		
Wine grapes	24.1	STMR-RAC (EFSA, 2020c)[(a)]		
Strawberries	11	STMR-RAC (FAO, 2017)		
Blackberries, Raspberries	36.9	STMR-RAC (EFSA, 2020a)[(a)]		
Currants, Gooseberries	42.25	STMR-RAC (EFSA, 2020a)[(a)]		
Elderberries	18.4	STMR-RAC (EFSA, 2018d)		
Table olives	23	STMR-RAC (EFSA, 2020c)[(a)]		
Kiwi fruits	23.5	STMR-RAC (EFSA, 2012c)[(b)]		
Avocados	14.88	STMR-RAC (EFSA, 2020c)[(a)]		
Granate apples/ pomegranates	25	STMR-RAC (EFSA, 2020a)[(a)]		
Potatoes	26.9	STMR-RAC (EFSA, 2019b)		
Celeriacs/turnip rooted celeries	0.21	STMR-RAC (EFSA, 2015)		
Horseradishes	41.18	STMR-RAC (EFSA, 2020c)[(a)]		
Garlic, Shallots	4.4	STMR-RAC (EFSA, 2020c)[(a)]		
Cucumbers	14	STMR-RAC (FAO, 2017)[(b)]		
Courgettes	25.5	STMR-RAC (FAO, 2017)[(b)]		
Melons	14	STMR-RAC (FAO, 2017)[(b)]		
Flowering brassica	11.35	STMR-RAC (EFSA, 2020b)[(a)]		
Leafy brassica	4.9	STMR-RAC (EFSA, 2020b)[(a)]		
Lettuces	41	STMR-RAC (FAO, 2017)[(b)]		
Spinaches	47	STMR-RAC (EFSA, 2020b)[(a)]		
Herbs and edible flowers	98.25	STMR-RAC (EFSA, 2020a)[(a)]		
Olives for oil production	23	STMR-RAC (EFSA, 2020c)[(a)]		
Wheat	23.13	STMR-RAC (EFSA, 2019b)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Hops	350	STMR-RAC (FAO, 2017)[(b)]		
Spices	74	STMR-RAC (EFSA, 2012c)[(b)]		
Horseradish, root spices	41.18	STMR-RAC (EFSA, 2020c)[(a)]		
Other commodities of plant and animal origin (with MRL above LOQ)	MRL[(c)]	Draft Commission Regulation SANTE/11822/2019[(e)]		
Other commodities of plant and animal origin (with MRL at the LOQ)	LOQ[(d)]	Draft Commission Regulation SANTE/11822/2019[(e)]		

STMR-RAC: supervised trials median residue in raw agricultural commodity; MRL: maximum residue level; LOQ: limit of quantification.

(a): STMR derived by EFSA based on GAPs of potassium phosphonates which MRL proposals are not yet implemented in the EU legislation.

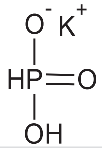
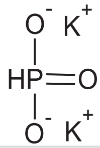
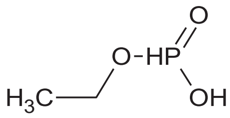
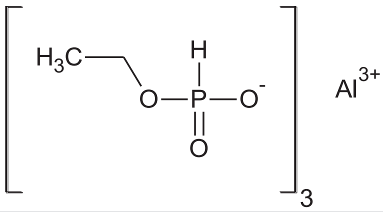
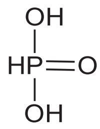
(b): STMR derived based on the GAPs of Fosetyl-Al.

(c): Expressed as phosphonic acid by applying the molecular weight conversion factor of 0.75.

(d): In Scenario 2, Option b of the risk assessment: the commodities with MRLs established at the LOQ were excluded from the exposure calculation, assuming that the use of fosetyl and potassium phosphonate is not approved on these crops. In addition, the MRL for citrus fruits was multiplied by the peeling factor of 0.81.

(e): Draft Commission Regulation SANTE/11822/2019 revising MRLs in potatoes, wheat and products of animal origin has been voted at the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Residues held on 26-27 September 2019. The regulation is not yet published in the Official Journal of the European Union.

Appendix E – Used compound codes

Code/trivial name[(a)]	IUPAC name/SMILES notation/InChiKey[(b)]	Structural formula[(c)]
potassium hydrogen phosphonate	potassium hydrogen phosphonate [K+].O[PH]([O-])=O GNSKLFRGEWLPPA-UHFFFAOYSA-M	
dipotassium phosphonate	Dipotassium phosphonate [K+].[K+].[O-][PH]([O-])=O OZYJVQJGKRFVHQ-UHFFFAOYSA-L	
fosetyl	ethyl hydrogen phosphonate O=P(O)OCC VUERQRKTYBIULR-UHFFFAOYSA-N	
fosetyl-Al fosetyl aluminium	aluminium tris(ethyl phosphonate) [Al+3].[O-]P(=O)OCC.[O-]P(=O)OCC.[O-]P(=O)OCC ZKZMJOFIHHZSRW-UHFFFAOYSA-K	
phosphonic acid phosphorous acid	phosphonic acid O=P(O)O ABLZXFCXXLZCGV-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(c): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).