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Modification of the existing maximum residue levels for potassium phosphonates in various crops

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants Tilco-Alginure GmbH, ADAMA Agriculture BV, Lainco S.A., Exclusivas Sarabia S.A., Biovert S.L. and Landwirtschaftskammer Steiermark submitted requests to the competent national authorities in Germany, France, Greece and Austria to modify the existing maximum residue levels (MRLs) for the active substance potassium phosphonates in various crops. The data submitted in support of the different requests were found to be sufficient to derive MRL proposals for all crops under assessment. Adequate analytical methods for enforcement are available to control the residues of potassium phosphonates in the crops under assessment. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of potassium phosphonates according to the reported agricultural practices is unlikely to present a risk to consumer health. The consumer risk assessment shall be regarded as indicative and a more realistic intake assessment will be performed in the framework of the joint review of MRLs for fosetyl and phosphonates. The reliable end points, appropriate for use in regulatory risk assessment are presented.

Keywords: potassium phosphonates, fosetyl, phosphonic acid, various crops, fungicide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Tilco Alginure GmbH 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 garlic and shallots. 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 07 April 2020. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRLs expressed as fosetyl equivalent from the limit of quantification (LOQ) of 2.0 to 30 mg/kg in garlic and shallots.

Moreover, still in accordance with Article 6 of Regulation (EC) No 396/2005, ADAMA Agriculture BV submitted an application to the competent national authority in France (EMS) to modify the existing MRL for the active substance potassium phosphonates in wine grapes. 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 EFSA on 11 July 2018. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and further clarifications, which were requested from the EMS. On 20 July 2020, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation reports. To accommodate for the intended use of potassium phosphonates, the EMS proposed to raise the existing MRLs expressed as fosetyl equivalent from 100 to 200 mg/kg in wine grapes.

Furthermore, also in accordance with Article 6 of Regulation (EC) No 396/2005, Lainco S.A., Exclusivas Sarabia S.A. and Biovert S.L. submitted an application to the competent national authority in Greece (EMS) to modify the existing MRLs for the active substance potassium phosphonates in avocados, table olives and olives for oil production. 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 EFSA on 14 May 2020. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA requested some clarifications from the EMS on 16 June 2020. On 12 August 2020, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRLs expressed as fosetyl equivalent from 50 to 70 mg/kg for avocados and from the limit of quantification (LOQ) of 2 to 100 mg/kg in table olives and olives for oil production.

Finally, still in accordance with Article 6 of Regulation (EC) No 396/2005, Landwirtschaftskammer Steiermark submitted an application to the competent national authority in Austria (EMS) to modify the existing MRL for the active substance potassium phosphonates in horseradishes. 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 EFSA on 1 June 2018. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps, which were requested from the EMS. On 30 June 2020, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report. To accommodate for the intended use of potassium phosphonates, the EMS proposed to raise the existing MRLs expressed as fosetyl equivalent from the limit of quantification (LOQ) of 2.0 to 200 mg/kg in horseradishes.

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 EMSs in the framework of these applications, the following conclusions are derived.

The 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 (hydrolysis studies) of potassium phosphonates conducted with its main metabolite demonstrated that phosphonic acid is stable. In rotational crops, the major residue was phosphonic acid. 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-Al. The residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in these applications, the metabolism of potassium phosphonates in primary and in rotational crops, and the possible degradation in processed products have been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues of potassium phosphonates in the crops assessed in these applications according to the enforcement residue definition set in the EU legislation (as fosetyl equivalents) and proposed during the EU pesticides peer review (as phosphonic acid). The methods enable quantification of residues at or above an LOQ of 0.01 mg fosetyl/kg and 0.1 mg phosphonic acid/kg.

The available residue trials are sufficient to derive MRL proposals for all the crops under consideration. EFSA derived MRL proposals according to both the existing and the proposed residue definition for enforcement.

Specific studies investigating the magnitude of potassium phosphonates in processed products were provided for olive oil and allowed concluding that concentration of residues is not expected (median processing factor < 0.05). A tentative processing factor of 1.3 in wine was derived in the framework of the EU pesticides peer review. A peeling factor of 1.1 could also be derived for avocados from the data submitted in the related MRL application.

The occurrence of residues of potassium phosphonates in rotational crops was investigated in the framework of the EU pesticides peer review. Based on the available information, EFSA could not exclude that the uses of potassium phosphonates according to the proposed GAP will not result in significant residues of phosphonic acid in rotational crops. Therefore, Member States should consider the need for setting specific risk mitigation measures to avoid the presence of potassium phosphonates residues in rotational crops.

Residues of potassium phosphonates in commodities of animal origin were not assessed since the crops under consideration in these MRL applications are 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 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 products of plant 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 the crops under consideration, 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).

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 adopted. The long-term dietary exposure accounted for a maximum of 97% of the ADI (DE child, NL toddler). The contribution of residues in the crops under consideration is minor (all individually at or below 6% of the ADI). 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 below the ADI (91% of the ADI). 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 are likely to overestimate the exposure to residues arising from the use of potassium phosphonates in plants.

EFSA concluded that the proposed uses of potassium phosphonates on garlic, shallots, wine grapes, avocados, table olives, olives for oil production and horseradishes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

As the joint review of MRLs for fosetyl and phosphonates under Article 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 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
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				
0220010	Garlic	2*	1) 30 2) 20	The submitted data on onions are sufficient to derive an MRL proposal for the intended NEU use on garlic by extrapolation. Risk for consumers unlikely
0220030	Shallots	2*	1) 30 2) 20	The submitted data on onions are sufficient to derive an MRL proposal for the intended NEU use on shallots by extrapolation. Risk for consumers unlikely
0151020	Wine grapes	100	1) 200 2) 150	The submitted data are sufficient to derive an MRL proposal for the intended NEU and SEU uses on wine grapes. The MRL proposal reflects the more critical residues situation of NEU use. Risk for consumers unlikely
0163010	Avocados	50	1) 70 2) 50	The submitted data are sufficient to derive an MRL proposal for the intended SEU use on avocados. Risk for consumers unlikely
0161030	Table Olives	2*	1) 100 2) 80	The submitted data on olives are sufficient to derive an MRL proposal for the intended SEU use on table olives. Risk for consumers unlikely
0402010	Olives for oil production	2*	1) 100 2) 80	The submitted data on olives are sufficient to derive an MRL proposal for the intended SEU use on olives for oil production. Risk for consumers unlikely
2013040	Horseradishes	2*	1) 200 2) 150	The submitted data are sufficient to derive an MRL proposal for the intended NEU use on horseradishes. Risk for consumers unlikely

MRL: maximum residue level; NEU: northern Europe; SEU: southern 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 European Food Safety Authority (EFSA) received different applications to modify the existing maximum residue levels (MRLs) for potassium phosphonates in various crops. The detailed description of the intended uses of potassium phosphonates in these crops, which are the basis for the current MRL applications, is reported in Appendix A.

Potassium phosphonates is the ISO common name for potassium hydrogen phosphonate and dipotassium phosphonate (IUPAC names). 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, 2005, 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 EU MRLs for potassium phosphonates are established in Annexes IIIA of Regulation (EC) No 396/2005[3]. 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 use of fosetyl-(Aluminium), disodium phosphonate or potassium phosphonates leading to the higher residue. The review of existing MRLs 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). However, the modifications of the existing MRLs proposed have not yet been legally implemented since it is appropriate to await the MRL review for the related active substances, i.e. potassium phosphonates and disodium phosphonate, as these active substances share the common metabolite phosphonic acid. EFSA has received from the European Commission a mandate to provide a reasoned opinion on the joint review of maximum residue levels (MRLs) for fosetyl and phosphonates in or on food and feed according to Article 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 potassium phosphonates (EFSA, 2018b,d, 2019b, 2020a,b). The proposals from these reasoned opinions have been considered in recent MRL regulation (s).[4] 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, Tilco Alginure GmbH submitted an application to the competent national authority in Germany (EMS) to modify the existing MRLs for the active substance potassium phosphonates in garlic and shallots. The EMS drafted an evaluation reports 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 7 April 2020. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRL expressed as fosetyl equivalent from the limit of quantification (LOQ) of 2.0 to 30 mg/kg in garlic and shallots.

Moreover, still in accordance with Article 6 of Regulation (EC) No 396/2005, ADAMA Agriculture BV submitted an application to the competent national authority in France (EMS) to modify the existing MRL for the active substance potassium phosphonates in grapes. The EMS drafted an evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 11 July 2018. EFSA identified data gaps and further clarifications, which were requested from the EMS. On 20 July 2020, the EMS submitted a revised

[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.

evaluation report (France, 2018), which replaced the previously submitted evaluation reports. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRL expressed as fosetyl equivalent from 100 to 200 mg/kg in wine grapes.

Furthermore, also in accordance with Article 6 of Regulation (EC) No 396/2005, the applicants Lainco S.A., Exclusivas Sarabia S.A. and Biovert S.L. submitted an application to the competent national authority in Greece (EMS) to modify the existing MRLs for the active substance potassium phosphonates in avocados, table olives and olives for oil production. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 14 May 2020. EFSA assessed the application and the evaluation report (Greece, 2020) as required by Article 10 of the MRL regulation. EFSA requested some clarifications from the EMS on 16 June 2020. On 12 August 2020, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRLs expressed as fosetyl equivalent from 50 to 70 mg/kg for avocados and from the limit of quantification (LOQ) of 2.0 to 100 mg/kg in table olives and olives for oil production.

Finally, still in accordance with Article 6 of Regulation (EC) No 396/2005, Landwirtschaftskammer Steiermark submitted an application to the competent national authority in Austria (EMS) to modify the existing MRLs for the active substance potassium phosphonates in horseradishes. 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 EFSA on 1 June 2018. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps, which were requested from the EMS. On 30 June 2020, the EMS submitted a revised evaluation report (Austria, 2018), which replaced the previously submitted evaluation report. To accommodate for the intended use of potassium phosphonates, the EMS proposed to raise the existing MRLs expressed as fosetyl equivalent from the limit of quantification (LOQ) of 2.0 to 200 mg/kg in horseradishes.

EFSA based its assessment on the evaluation reports submitted by the individual EMSs (Austria, 2018; France, 2018; Germany, 2020; Greece, 2020;), the draft assessment report (DAR) and its addendum on potassium phosphonates (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 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, 2015b, 2018b,d, 2019b, 2020a,b) and the MRL review of fosetyl (EFSA, 2012a). For reasons of efficiency, the four MRL applications were combined in one reasoned opinion.

For these applications, 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 EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[8].

As the joint review of MRLs for fosetyl and phosphonates under 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 these MRL applications including the end points of relevant studies assessed previously, are presented in Appendix B.

The evaluation reports submitted by the EMSs (Austria, 2018; France, 2018; Germany, 2020; Greece, 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.

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

[7] 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.

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 applications and are required.

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

1.1.2. Nature of residues in rotational crops

Among all crops under consideration garlic, shallots and horseradishes could be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the EU pesticides peer review of fosetyl, moderate to high soil persistence (DT_{90} 91 to > 1,000 days) is reported for phosphonic acid, which is a common metabolite of fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2018c). Therefore, transfer of soil residues from treatments of antecedent crops need to be considered. EFSA noted that no confined residue study is available for potassium phosphonates. However, due to the chemical nature of potassium phosphonates, no other breakdown products than phosphonic acid are expected, and therefore, studies addressing the nature of residues in rotational crops were not deemed necessary.

Moreover, studies on the nature of residues in rotational crops (root/tuber crops, leafy crops and cereals) were assessed in the framework of the EU pesticides peer review of fosetyl (EFSA, 2018c) and support the conclusion that the metabolite phosphonic acid is the major residue observed in rotational crops.

For the intended uses, the metabolic behaviour in rotational crops is sufficiently addressed.

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

Different analytical methods were previously assessed with view on their use for enforcement of the MRLs for potassium phosphonates (EFSA, 2012b, 2018c). Sufficiently validated methods using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available for the determination of residues as phosphonic acid and fosetyl in matrices with high water, dry/high starch, high acid and high oil content. The methods can be used for the determination of fosetyl in all plant commodity groups with an LOQ of 0.01 mg fosetyl/kg and for the determination of phosphonic acid in high water, high acid content commodities and dry matrices with an LOQ of 0.1 mg phosphonic acid/kg and in high oil content commodities with an LOQ of 0.5 mg phosphonic acid/kg (EFSA, 2012b, 2018c).

EFSA concluded that for all crops under assessment sufficiently validated analytical methods are available to enforce the MRLs for potassium phosphonates according to the existing residue definition (Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)) as well as the residue definition proposed in the EU pesticides peer review of potassium phosphonates (phosphonic acid and its salts, expressed as phosphonic acid).

1.1.5. Storage stability of residues in plants

The storage stability of phosphonic acid under frozen conditions was investigated in the framework of the peer review of potassium phosphonates (EFSA, 2012b), the peer review of fosetyl (EFSA, 2018c) and in a previous MRL application (EFSA, 2019b). Phosphonic acid is stable under frozen

conditions for up to 25 months in commodities with high water, high oil, high protein, dry/high starch and high acid contents.

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-Al:

- 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 intended GAPs, four different applications were submitted and are merged into this reasoned opinion. These different applications refer to:

i) garlic and shallots
ii) wine grapes
iii) avocados, table olives and olives for oil production
iv) horseradishes

In all crop field trials, samples were analysed for phosphonic acid. The results were expressed also as fosetyl, by applying the molecular weight conversion factor of 1.34 in order to derive the MRL proposals according to the existing enforcement residue definition.

According to the EMSs, the methods of analysis used to analyse the residue trial samples were sufficiently validated and were fit for purpose (Austria, 2018; France, 2018; Germany, 2020; Greece, 2020). All samples of these residue trials prior to analysis were stored under conditions for which integrity of the samples has been demonstrated.

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

Garlic and Shallots

In support of the proposed Northern Europe (NEU) GAP, the applicant Tilco-Alginure GmbH provided a total of nine crop field trials on onions, out of which four are considered as compliant with the intended GAP which comprises a PHI of 14 days. The other five trials, conducted at a shorter PHI of 7 days, are not compliant with the intended GAP and therefore were not considered further. The four GAP-compliant residue trials were conducted in three different sites in Germany. The two trials located in the same site were conducted on different crop varieties and with a treatment date more than 30 days apart. Hence, according to EFSA guidance document on residue trials and MRL calculations (EFSA, 2015a) and the OECD Guideline on crop field trials (OECD, 2016), these trials are accepted as independent.

The applicant proposes to extrapolate the residue data on onions to garlic and shallots. Such extrapolation is acceptable according to the EU guidance document (European Commission, 2017). Therefore, the intended uses are supported by a sufficient number of GAP-compliant and independent residue trials for minor crops like garlic and shallots.

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

An MRL proposal for garlic and shallots is thus calculated at 20 mg/kg as phosphonic acid and at 30 mg/kg as fosetyl equivalents.

Wine grapes

In support of the intended NEU and SEU GAP, the applicant ADAMA Agriculture BV submitted five residue trials (two in NEU and three in SEU) investigating the residue level of phosphonic acid in wine grapes following six applications of ca. 2.7 kg of potassium phosphonate/ha with a PHI of 28 days. One trial (in SEU) was disregarded since a product containing potassium phosphonates was applied two times before the trial started.

To complete the NEU and SEU data sets, the results from several other residue trials of potassium phosphonates in wine grapes were referred to in the application. These previous residue trials were assessed in the framework of the EU pesticides peer review of the active substance potassium phosphonates to support the representative use on grapes with a PHI of 60 days (France, 2012; EFSA, 2012b) and include:

- six studies (two in NEU and four in SEU) assessed in the addendum to the potassium phosphonates DAR (France, 2012) and conducted with five applications of ca. 2.92 kg of potassium phosphonate/ha and a PHI of 14–21 days;
- sixteen residue trials originally submitted and assessed in the monograph (France, 2005), out of which:
  - eight (four in NEU and four in SEU) were conducted with six applications of ca. 2.92 kg of potassium phosphonate/ha and a PHI of 15 days;
  - four (two in NEU and two in SEU) were conducted with five applications of ca. 2.92 kg of potassium phosphonate/ha with samples collected at several PHIs up to 60 days, including the intended PHI of 28 days;
  - four (two in NEU and two in SEU) were conducted with five applications of ca. 2.92 kg of potassium phosphonate/ha with samples collected at several PHIs up to PHI of 60 days, excluding the intended PHI of 28 days.

Therefore, several trials performed in NEU and SEU are available to investigate the residue level of phosphonic acid in wine grapes following five or six applications of ca. 2.7–2.9 kg of potassium phosphonates/ha with PHIs ranging from 15 days to 60 days. However, none of them is fully compliance with the intended NEU and SEU GAP.

Firstly, regarding the number of applications and rate, EFSA noted that the new intended GAP is based on one application of 1.173 kg of potassium phosphonates/ha (at BBCH 10–13) followed by five applications of 2.68 kg of potassium phosphonates/ha (at BBCH 14–85). This corresponds to a total rate of ca. 14.5 kg of potassium phosphonates/ha per year. None of the trials available was conducted with the first foliar application at the early BBCH growth stage. However, the four newly submitted residue trials were performed with a total application rate of 16.2 kg of potassium phosphonates/ha per year (six applications of 2.7 kg/ha) while for the residue trials assessed in the framework of the EU pesticides peer review, the total application rate range from ca. 15 to 18 kg of potassium phosphonates/ha per year depending if five or six applications were used. Since for all trials, the total applied rates are in the +/– 25% tolerance, EFSA agrees with the EMS that these trials can be considered comparable to the intended GAP in terms of number of applications and total application rate.

Secondly, in relation to the different PHIs, in only eight trials (four in NEU and four in SEU), the intended PHI of 28 days was tested whereas in the remaining trials, the PHIs ranged from 15 up to 60 days. The EMS subscribed its previous conclusion that residues of phosphonic acid decline very slowly or they are stable after reaching a plateau at ca. 10 days after last application (France, 2012, 2018). In line with the EFSA conclusion on the EU pesticides peer review for the active substances potassium phosphonates which considered supportive for the PHI of 60 days the residue trials conducted with PHIs from 15 to 60 days, these trials could represent residues expected at the intended PHI of 28 days as well. However, EFSA highlights this non-standard approach and its related uncertainties.

Since residues in the NEU and in the SEU did not show to belong to the same population (U-test, 5%), results were not combined. The MRL proposal of 150 mg/kg as phosphonic acid and at 200 mg/kg as fosetyl equivalents was derived from the NEU data set, more critical in view of the expected residue behaviour.

Avocados

In support of the proposed Southern Europe (SEU) GAP, the applicants Lainco S.A., Exclusivas Sarabia S.A. and Biovert S.L. provided a total of six crop field trials on avocados.

EFSA noted that all six trials were conducted at different sites but in very close areas in Malaga, Spain (less than 20 km apart) during three different years (2014, 2016 and 2017) on the same crop variety and with the same or similar treatment dates for the trials performed within the same year. Therefore, based on the current guidance, EFSA cannot conclude if these trials can be considered independent or not. However, avocado is a subtropical fruit cultivated only in restricted areas and the variability of the agricultural systems is low compared to other fruits crops. Moreover, the province of Malaga reflects the representative weather conditions and the main type of agricultural practices for avocado cultivation in the EU. Hence, EFSA considers the residue trials provided as sufficient to derive an MRL for this minor crop.

An MRL proposal for avocados is thus calculated at 50 mg/kg as phosphonic acid and at 70 mg/kg fosetyl equivalents.

Table olives and olives for oil production

In support of the proposed Southern Europe (SEU) GAP, the applicants Lainco S.A., Exclusivas Sarabia S.A. and Biovert S.L. provided a total of 11 crop field trials on olives. However, EFSA noted that three trials (as indicated in the evaluation report with the number 18 F OL LAI P01) were performed with the same total application rate but with only one application instead of three, as indicated for the intended GAP. Since these trials could lead to an overestimation of the residue levels and were not compliant with the intended GAP, EFSA excluded them from the MRL calculation. The remaining eight residue trials (four decline and four harvest studies) were performed in different geographical locations in Spain over two seasons and are considered as independent and compliant with the intended GAP. Therefore, the intended use is supported by a sufficient number of GAP-compliant and independent residue trials for a major crop like olives for oil production. This MRL proposal is extrapolated to table olives and olives for oil production (European Commission, 2017).

An MRL proposal for table olives and olives for oil production is thus calculated at 80 mg/kg as phosphonic acid and at 100 mg/kg fosetyl equivalents.

Horseradishes

In support of the proposed Northern Europe (NEU) GAP, the applicant Landwirtschaftskammer Steiermark provided a total of six crop field trials on horseradishes.

Originally, with the first submission of the application, four residue trials were provided to support the intended GAP. All these initially submitted residue trials were conducted in 2017 in Austria (Styria) in almost the same locations (about 30 km apart), on the same crop variety with the same treatment dates and the same experimental conditions. Therefore, to derive an MRL proposal for potassium phosphonates in horseradishes, EFSA requested the applicant to conduct at least two additional trials on horseradishes compliant with the NEU GAP or, alternatively, four residue trials on other root vegetables compliant with the intended NEU GAP which could be extrapolated to horseradishes. The applicant provided then two additional residue trials on horseradishes compliant with the NEU GAP and still conducted in Styria region (Austria) in 2019 to fulfil the data gap indicated by EFSA. It should be noted that Styrian horseradish is cultivated only in a small area in the south of Styria (Austria) and carries the protected geographical indication from the European Union. No other representative areas are available. EFSA considers the data gap addressed and the residue trials provided as sufficient to derive an MRL for horseradishes.

An MRL proposal for horseradishes is thus calculated at 150 mg/kg as phosphonic acid and at 200 mg/kg as fosetyl equivalents.

1.2.2. Magnitude of residues in rotational crops

EFSA noted that rotational crops studies were not submitted in the present MRL applications. However, the occurrence of residues of the metabolite of potassium phosphonates, phosphonic acid, in rotational root crops, leafy crops and cereals was investigated in two studies submitted for the EU pesticides peer review of fosetyl (EFSA, 2018c). Based on all available information on the magnitude of residues, it is not possible to exclude that the uses of potassium phosphonates according to the proposed GAP will not result in residue levels of phosphonic acid in some rotational crops at 30-day PBI, and therefore, Member States should take risk mitigation measures (e.g. define pre-planting

intervals) or request the applicant to submit additional rotational crop field trials to establish residues in rotational crops.

1.2.3. Magnitude of residues in processed commodities

In the framework of the application for avocados, table olives and olives for oil production, avocados were analysed for residues in the whole fruit and pulp; therefore, a median peeling factor could be derived.

The applicants submitted also two studies where the magnitude of phosphonic acid was investigated in olive oil obtained from olives for oil production (Greece, 2020). One of the processing studies used three samples from the crop field trials after application of potassium phosphonates according to the GAP (3 applications at 1.275 kg/ha) whereas in the other processing study, other three samples were treated with a single exaggerated (3X) application rate. While residue levels in olives for oil production varied between 3.76 and 31.80 mg phosphonic acid equivalents/kg, residues in the oil were all < LOQ (1.0 mg phosphonic acid equivalents/kg). Studies indicated no concentration of residues in olive oil.

A tentative processing factor of 1.3 in wine was derived in the framework of the EU pesticides peer review (EFSA, 2012b). No new specific study on grapes was submitted in the MRL application and is in principle triggered as residues in the raw commodities were above 0.1 mg/kg. Considering that the individual contribution to the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI, 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 as well as risk assessment values for all commodities under consideration. 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 these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as all crops under assessment in these applications are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using version 3.1 of the EFSA PRIMo (EFSA, 2018a). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2019a). 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 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-Al, 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 adopted, 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 the crops under consideration, the STMR reported in previously issued EFSA reasoned opinions (EFSA, 2012c, 2015b, 2018b,d, 2019b, 2020a,b) and the STMRs 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-Al, recalculated to phosphonic acid[10] , were used.

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).

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

EFSA also performed an indicative risk assessment using the revised ADI of 1 mg/kg bw per day proposed to be applied to phosphonic acid 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, NL toddler), with apples being the main contributors (29% of the ADI). The contribution of residues in the crops under consideration is minor (individually at or below 6% of the ADI).

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 below the ADI (91% of the ADI, DE child).

The complete list of input values used in the exposure calculations is presented in Appendix D.1.

EFSA concluded that the proposed use of potassium phosphonates on garlic, shallots, wine grapes, avocados, table olives, olives for oil production and horseradishes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose 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 more realistic consumer risk assessment will be conducted in the framework of the joint review of MRLs for fosetyl and phosphonates, according to Article 43 of Regulation (EC) No 396/2005.

The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix C. For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMos (Scenario 1, 2a and 2b) is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of the present MRL applications were found to be sufficient to derive MRL proposals for potassium phosphonates in all crops under consideration. Adequate analytical methods for enforcement are available to control the residues of potassium phosphonates in the plant matrices under consideration.

EFSA concluded that the proposed use of potassium phosphonates on the crops under consideration will not result in a consumer exposure exceeding the currently set toxicological reference value for phosphonic acid. The overall calculated consumer exposure accounted for a maximum of 48% of the ADI (DE child).

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 adopted. The long-term dietary exposure accounted for a maximum of 97% of the ADI (DE child, NL toddler) and decreased to 91% of the ADI (DE child) when excluding from the calculation the products for which the existing EU MRL is set at the LOQ, assuming that no uses are authorised for these crops, and taking into account the peeling factor for citrus fruits derived in the MRL review of fosetyl. The contribution of residues in the crops under consideration to the consumer risk assessment is minor (individually at or below 6% of the ADI).

The consumer risk assessment shall be regarded as indicative and a more realistic intake assessment will be performed in the framework of the joint review of MRLs for fosetyl and phosphonates under Article 43 of Regulation (EC) No 396/2005.

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
CAS	Chemical Abstract Service
CF	conversion factor for enforcement to risk assessment residue definition
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DAR	draft assessment report

DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EDI	estimated daily intake
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GS	growth stage
HPLC	high-performance liquid chromatography
HPLC-MS	high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
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
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TAR	total applied radioactivity
TMDI	theoretical maximum daily intake
UV	ultraviolet (detector)
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	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 growth stages & season[c]	Number max	Interval between application (min)	g a.s./ hL max	Water L/ha min	Rate	Unit		
Garlic	NEU	F	Peronosporaceae	SL	342.0 g/L	Foliar treatment – broadcast spraying	11–48	4	7	342	600	1,368	g a.i./ ha	14	a.s. rate refers to potassium phosphonates
Shallots	NEU	F	Peronosporaceae	SL	342.0 g/L	Foliar treatment – broadcast spraying	11–48	4	7	342	600	1,368	g a.i./ ha	14	a.s. rate refers to potassium phosphonates
Wine grape	NEU and SEU	F	Fungal diseases	SC	670 g/L	Foliar spray	10–85	6	12	536	100–500	1,172.5–2,680	g a.i./ ha	28	Intended GAP is based on 1 application up to 1.17 kg a.s./ha at BBCH 10–13 followed by 5 applications up to 2.68 kg a.s./ha at BBCH 14-85. a.s. rate refers to potassium phosphonates
Avocados	SEU	F	Phytophthora cinnamomi	SL	510 g/L	Foliar treatment – broadcast spraying	59–85	3	10	127.5	500–1,500	1,912	g a.i./ ha	15	a.s. rate refers to phosphonic acid equivalents

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 growth stages & season[c]	Number max	Interval between application (min)	g a.s./ hL max	Water L/ha min	Rate	Unit		
Olives	SEU	F	Cycloconium oleaginum	SL	510 g/L	Foliar treatment – broadcast spraying	11–81	3	10	127.5	800–1,000	1,275	g a.i./ ha	15	a.s. rate refers to phosphonic acid equivalents
Horseradishes	NEU	F	Albugo candida	SL	755 g/L	Foliar treatment – broadcast spraying	41–46	4	10	689	300	2,068	g a.i./ ha	60	a.s. rate refers to potassium phosphonates

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

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling**	**Comment/Source**
	Fruit crops Root crops Leafy crops Cereals/grass Pulses/oilseeds Miscellaneous	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)			

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)	Matrices with high water, high acid, high oil content and dry matrices: HPLC–MS/MS: LOQ of 0.01 mg fosetyl/kg (EFSA, 2012a) Matrices with high water, dry/high starch and high acid content: HPLC–MS/MS: LOQ of 0.1 mg phosphonic acid /kg Matrices with high oil content: HPLC–MS/MS: LOQ of 0.5 mg phosphonic acid/kg (EFSA, 2018c)	

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

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 (2018c)
		Peaches	–18	307	Days	Phosphonic acid	EFSA (2018c)
	High oil content	Almond	–20	218	Days	Phosphonic acid	EFSA (2018c)
		Pistachio	–20	221	Days	Phosphonic acid	EFSA (2018c)
		Walnut	–20	146	Days	Phosphonic acid	EFSA (2018c)
	High protein content	–	–	–	–	–	–
	Dry/High starch	Wheat, grain	–20	12	Months	Phosphonic acid	EFSA (2019b)

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	High acid content	Grapes	–18	12	Months	Sum of phosphonic acid and fosetyl	EFSA (2012b)
			–18	25	Months	Phosphonic acid	EFSA (2012b)
	Processed products	Peach jam, puree, nectar and canned peaches	–18	112-114	Days	Phosphonic acid	EFSA (2018c)
	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]
Garlic, Shallots	NEU	**Mo:** 3.6, 5.5, 6.3, 14.7 **RA:** 2.7, 4.1, 4.7, 11.0	GAP-compliant residue trials on onions. Extrapolation to garlic and shallots possible	20 (as phosphonic acid) 30 (as fosetyl)	11.0 (as phosphonic acid)	4.4 (as phosphonic acid)	n/a
Wine grapes	NEU	**Mo:** *PHI 28 d*: 28.14, 32.16, 96.48, 103.05 *PHI 14–16 d*: 22.38, 26.67, 31.36, 35.91 *PHI 21 d*: 32.43, 40.32 *PHI 60 d*: 17.42, 62.98 **RA:** *PHI 28 d*: 21, 24, 72, 76.9 *PHI 14–16 d*: 16.7, 19.9, 23.4, 26.8 *PHI 21 d*: 24.2, 30.09 *PHI 60 d*: 13, 47	Merged NEU data set of new (underlined values) and previously assessed residue data (EFSA, 2012b) conducted with 5–6 applications at different rates (ca. 2.7–2.9 kg /ha) and at the different PHIs, including the intended PHI of 28 days	**150** (as phosphonic acid) **200** (as fosetyl)	**76.9** (as phosphonic acid)	**24.10** (as phosphonic acid)	n/a
	SEU	**Mo:** *PHI 28 d*: 17.42, 22.78, 24.25, 100.37 *PHI 14–16 d*: 4.76, 5.9, 6.57, 6.87, 8.56, 30,15, 31.49, 34.71 PHI 21 d: *PHI 60 d*: 5.36, 13.27 **RA:** *PHI 28 d*: 13, 17, 18.1, 74.9 *PHI 14–16 d*: 3.55, 4.4, 4.9, 5.13, 6.39, 22.5, 23.5, 25.9 PHI 21 d *PHI 60 d*: 4, 9.9	Merged SEU data set of new (underlined values) and previously assessed residue data (EFSA, 2012b) conducted with 5–6 applications at different rates (ca. 2.7–2.9 kg/ha) and at the different PHIs, including the intended PHI of 28 days	90 (as phosphonic acid) 150 (as fosetyl)	74.9 (as phosphonic acid)	10.95 (as phosphonic acid)	n/a

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]
Avocados	SEU	**Mo:** 11.39, 17.59, 18.19, 21.69, 25.88, 33.36 **RA:** 8.50, 13.13, 13.57, 16.18, 19.31, 24.90	GAP-compliant residue trials on avocados	50 (as phosphonic acid) 70 (as fosetyl)	24.90 (as phosphonic acid)	14.88 (as phosphonic acid)	n/a
Olives	SEU	**Mo:** 21.39, 22.66, 26.80, 29.48, 32.16, 32.32, 43.99, 45.40 **RA:** 15.96, 16.91, 20.00, 22.00, 24.00, 24.12, 32.83, 33.88	GAP-compliant residue trials on olives	80 (as phosphonic acid) 100 (as fosetyl)	33.88 (as phosphonic acid)	23.00 (as phosphonic acid)	n/a
Horseradishes	NEU	**Mo:** 29.88, 33.84, 52.34, 58.18, 69.6, 86.1 **RA:** 22.26, 25.21, 39.00, 43.35, 51.9, 64.2	GAP-compliant residue trials on horseradishes	150 (as phosphonic acid) 200 (as fosetyl)	64.2 (as phosphonic acid)	41.18 (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. 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.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

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

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF		
Avocado, peeled	4	0.94, 1.10, 1.12, 1.14	1.11	n/a	Greece (2020)
Grape, wine	1	1.3[c]	–	n/a	Tentative (EFSA, 2012b)
Olives for oil production	6	< 0.031; < 0.037; < 0.041; < 0.059; < 0.063; < 0.266	< 0.05	n/a	residues in olive oil all < LOQ (1.0 mg phosphonic acid equivalents/kg) (Greece, 2020)

n/a. not applicable.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.
(c): A tentative PF is derived based on a limited data set.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

Acute consumer risk assessment 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: Wine grapes: 2.67% of ADI Garlic: 0.02% of ADI Shallots: 0.02% of ADI Avocados: 0.12% of ADI Table olives: 0.06% of ADI Olives for oil production: 0.83% of ADI Horseradishes: 0.08% of ADI
Assumptions made for the calculations	The calculation is based on the median residue levels (expressed as phosphonic acid) derived for raw agricultural commodities assessed in the current applications, in previous assessments (EFSA, 2012c, 2015b, 2018b,d, 2019b, 2020a,b) and the STMR of the implemented CXLs (FAO, 2017). For the remaining commodities, the MRLs established for fosetyl-Al 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 more realistic chronic intake assessment will be performed in the framework of the MRL review for potassium phosphonates Calculations were performed with PRIMo rev. 3.1.

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) PesticideResidues Intake Model; STMR: supervised trials median residue; CXL: codex maximum residue limit; MRL: maximum residue level.

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

ADI	1.0 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) Contribution of crops assessed: Wine grapes: 6.00% of ADI Garlic: 0.04% of ADI Shallots: 0.04% of ADI Avocados: 0.27% of ADI Table olives: 0.14% of ADI Olives for oil production: 1.87% of ADI Horseradish: 0.19% of ADI **Option b** (excluding MRLs <LOQ; Peeling Factor citrus): 91% ADI (DE child)
Assumptions made for the calculations	**Option a:** The calculation is based on the STMR (expressed as phosphonic acid) derived for raw agricultural commodities assessed in the current applications, in previous assessments (EFSA, 2012c, 2015b, 2018b,d, 2019b, 2020a,b) and the STMR of the implemented CXLs (FAO, 2017). For the remaining commodities, the MRLs established for fosetyl-Al 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 STMR (expressed as phosphonic acid) derived for raw agricultural commodities assessed in the current applications, in previous assessments (EFSA, 2012c, 2015b, 2018b,d, 2019b, 2020a,b), the STMR of the implemented CXLs (FAO, 2017) and the MRLs above the LOQ established for fosetyl-Al 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 more realistic chronic intake assessment will be performed in the framework of the of the joint review of the existing MRLs for fosetyl and phosphonates Calculations were performed with PRIMo rev. 3.1

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; CXL: codex maximum residue limit; MRL: maximum residue level; 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				
0220010	Garlic	2*	1) 30 2) 20	The submitted data on onions are sufficient to derive an MRL proposal for the intended NEU use on garlic by extrapolation. Risk for consumers unlikely
0220030	Shallots	2*	1) 30 2) 20	The submitted data on onions are sufficient to derive an MRL proposal for the intended NEU use on shallots by extrapolation. Risk for consumers unlikely
0151020	Wine grapes	100	1) 200 2) 150	The submitted data are sufficient to derive an MRL proposal for the intended NEU and SEU uses on wine grapes. The MRL proposal reflects the more critical residues situation of NEU use. Risk for consumers unlikely
0163010	Avocados	50	1) 70 2) 50	The submitted data are sufficient to derive an MRL proposal for the intended SEU use on avocados. Risk for consumers unlikely
0161030	Table Olives	2*	1) 100 2) 80	The submitted data on olives are sufficient to derive an MRL proposal for the intended SEU use on table olives. Risk for consumers unlikely
0402010	Olives for oil production	2*	1) 100 2) 80	The submitted data on olives are sufficient to derive an MRL proposal for the intended SEU use on olives for oil production. Risk for consumers unlikely
2013040	Horseradishes	2*	1) 200 2) 150	The submitted data are sufficient to derive an MRL proposal for the intended NEU use on horseradishes. Risk for consumers unlikely

MRL: maximum residue level; NEU: northern Europe; SEU: southern 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)

- Scenario 1

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/day):	2.25	ARfD (mg/kg bw):	Not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
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	1071.20	13%	Apples	10%	Oranges	4%	Wheat	0.4%	
	47%	NL toddler	1062.75	11%	Apples	6%	Oranges	5%	Potatoes	2%	
	41%	GEMS/Food G06	926.09	12%	Tomatoes	7%	Wheat	3%	Watermelons	0.7%	
	31%	NL child	700.60	6%	Apples	4%	Wheat	4%	Potatoes	1%	
	28%	RO general	619.90	6%	Tomatoes	5%	Wheat	4%	Potatoes	0.3%	
	28%	GEMS/Food G11	619.40	5%	Potatoes	4%	Wheat	3%	Tomatoes	0.8%	
	27%	GEMS/Food G08	607.69	5%	Potatoes	4%	Wheat	4%	Tomatoes	0.6%	
	27%	FR child 3 15 yr	605.83	9%	Oranges	5%	Wheat	3%	Tomatoes	0.6%	
	26%	GEMS/Food G15	595.67	5%	Wheat	4%	Potatoes	4%	Tomatoes	0.6%	
	26%	GEMS/Food G10	593.82	5%	Tomatoes	4%	Wheat	4%	Potatoes	0.7%	
	26%	GEMS/Food G07	593.15	4%	Potatoes	4%	Wheat	4%	Tomatoes	0.6%	
	24%	IE adult	542.82	3%	Potatoes	3%	Oranges	2%	Wheat	0.7%	
	22%	ES child	500.23	5%	Oranges	5%	Wheat	3%	Tomatoes	0.3%	
	22%	PT general	499.94	6%	Potatoes	4%	Wheat	3%	Tomatoes	0.3%	
	21%	SE general	479.86	5%	Potatoes	3%	Wheat	3%	Tomatoes	0.3%	
	21%	UK toddler	467.29	5%	Oranges	4%	Potatoes	4%	Wheat	0.5%	
	21%	FR toddler 2 3 yr	466.04	4%	Oranges	3%	Apples	3%	Wheat	0.5%	
	20%	DE women 14-50 yr	459.13	5%	Oranges	3%	Apples	2%	Tomatoes	0.6%	
	19%	IT toddler	434.26	7%	Wheat	5%	Tomatoes	1%	Oranges	0.2%	
	18%	DE general	413.90	4%	Oranges	3%	Apples	2%	Tomatoes	0.6%	
	18%	DK child	397.13	5%	Wheat	3%	Potatoes	2%	Apples	0.6%	
	16%	NL general	370.59	3%	Potatoes	3%	Oranges	2%	Wheat	0.5%	
	16%	ES adult	358.99	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	345.58	4%	Wheat	4%	Tomatoes	0.9%	Oranges	0.1%	
	15%	UK infant	342.53	4%	Potatoes	3%	Oranges	3%	Wheat	0.5%	
	13%	FR adult	294.52	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	282.64	2%	Oranges	2%	Wheat	2%	Tomatoes	0.2%	
	12%	PL general	272.00	4%	Potatoes	3%	Tomatoes	2%	Apples	0.1%	
	10%	LT adult	234.17	4%	Potatoes	2%	Tomatoes	2%	Apples	0.1%	
	10%	UK adult	223.21	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/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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	97%	DE child	974.05	29%	Apples	23%	Oranges	7%	Tomatoes	1%	
	97%	NL toddler	971.53	25%	Apples	13%	Oranges	11%	Potatoes	4%	
	76%	GEMS/Food G06	758.76	27%	Tomatoes	6%	Watermelons	6%	Oranges	2%	
	61%	NL child	605.49	13%	Apples	9%	Potatoes	8%	Oranges	2%	
	54%	GEMS/Food G11	535.98	11%	Potatoes	7%	Tomatoes	4%	Oranges	2%	
	51%	GEMS/Food G08	513.28	11%	Potatoes	9%	Tomatoes	3%	Apples	1%	
	50%	GEMS/Food G10	503.16	10%	Tomatoes	8%	Potatoes	6%	Oranges	2%	
	50%	RO general	502.71	15%	Tomatoes	10%	Potatoes	4%	Sweet peppers/bell peppers	0.7%	
	50%	FR child 3 15 yr	499.56	19%	Oranges	6%	Tomatoes	4%	Potatoes	1%	
	50%	GEMS/Food G07	495.55	10%	Potatoes	8%	Tomatoes	8%	Oranges	1%	
	49%	GEMS/Food G15	490.58	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	409.50	11%	Oranges	6%	Apples	6%	Tomatoes	1%	
	41%	PT general	409.31	14%	Potatoes	7%	Tomatoes	6%	Wine grapes	0.6%	
	41%	SE general	405.81	11%	Potatoes	6%	Tomatoes	4%	Oranges	0.7%	
	40%	ES child	397.63	12%	Oranges	7%	Tomatoes	5%	Potatoes	0.6%	
	39%	FR toddler 2 3 yr	394.89	8%	Oranges	7%	Apples	5%	Potatoes	1%	
	38%	UK toddler	376.67	11%	Oranges	9%	Potatoes	4%	Tomatoes	1%	
	37%	DE general	370.31	9%	Oranges	6%	Apples	5%	Tomatoes	1%	
	33%	NL general	325.88	7%	Potatoes	6%	Oranges	3%	Apples	1%	
	33%	FI 3 yr	325.12	13%	Potatoes	4%	Tomatoes	2%	Mandarins	0.8%	
	30%	ES adult	304.68	7%	Oranges	6%	Tomatoes	3%	Potatoes	0.4%	
	29%	DK child	294.94	7%	Potatoes	5%	Apples	4%	Tomatoes	1%	
	28%	UK infant	281.91	9%	Potatoes	7%	Oranges	4%	Apples	1%	
	28%	IT toddler	280.52	11%	Tomatoes	3%	Oranges	2%	Potatoes	0.5%	
	27%	PL general	272.00	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	249.93	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	235.27	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	184.44	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/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)
	91%	DE child	911.49	29%	Apples	18%	Oranges	7%	Tomatoes		
	90%	NL toddler	901.57	25%	Apples	11%	Potatoes	10%	Oranges		
	72%	GEMS/Food G06	724.51	27%	Tomatoes	6%	Watermelons	5%	Potatoes		
	56%	NL child	556.46	13%	Apples	9%	Potatoes	6%	Oranges		
	50%	GEMS/Food G11	500.23	11%	Potatoes	7%	Tomatoes	4%	Apples		
	49%	RO general	490.09	15%	Tomatoes	10%	Potatoes	4%	Sweet peppers/bell peppers		
	49%	GEMS/Food G08	486.27	11%	Potatoes	9%	Tomatoes	3%	Apples		
	47%	GEMS/Food G10	469.33	10%	Tomatoes	8%	Potatoes	5%	Oranges		
	47%	GEMS/Food G15	465.58	10%	Potatoes	9%	Tomatoes	5%	Sweet peppers/bell peppers		
	46%	GEMS/Food G07	459.94	10%	Potatoes	8%	Tomatoes	6%	Oranges		
	45%	IE adult	447.86	6%	Potatoes	5%	Oranges	3%	Grapefruits		
	45%	FR child 3 15 yr	445.32	16%	Oranges	6%	Tomatoes	4%	Potatoes		
	40%	PT general	395.03	14%	Potatoes	7%	Tomatoes	6%	Wine grapes		
	38%	SE general	381.40	11%	Potatoes	6%	Tomatoes	3%	Oranges		
	37%	DE women 14-50 yr	371.38	9%	Oranges	6%	Apples	6%	Tomatoes		
	37%	ES child	365.04	10%	Oranges	7%	Tomatoes	5%	Potatoes		
	36%	FR toddler 2 3 yr	357.71	7%	Apples	7%	Oranges	5%	Potatoes		
	34%	UK toddler	340.40	9%	Potatoes	9%	Oranges	4%	Tomatoes		
	34%	DE general	336.24	7%	Oranges	6%	Apples	5%	Tomatoes		
	31%	FI 3 yr	311.38	13%	Potatoes	4%	Tomatoes	2%	Apples		
	30%	NL general	301.00	7%	Potatoes	5%	Oranges	3%	Apples		
	28%	ES adult	284.33	6%	Oranges	6%	Tomatoes	3%	Potatoes		
	28%	DK child	276.03	7%	Potatoes	5%	Apples	4%	Tomatoes		
	27%	PL general	268.70	9%	Potatoes	7%	Tomatoes	5%	Apples		
	27%	IT toddler	267.48	11%	Tomatoes	2%	Potatoes	2%	Oranges		
	26%	FI 6 yr	256.88	10%	Potatoes	3%	Tomatoes	1%	Mandarins		
	25%	UK infant	254.48	9%	Potatoes	6%	Oranges	4%	Apples		
	24%	IT adult	240.37	9%	Tomatoes	2%	Apples	2%	Oranges		
	23%	FR adult	228.33	6%	Wine grapes	3%	Tomatoes	3%	Oranges		
	22%	UK vegetarian	219.82	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	179.08	4%	Tomatoes	3%	Potatoes	2%	Wine grapes		
	17%	UK adult	173.12	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

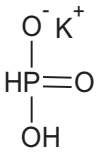
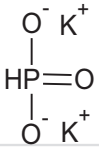
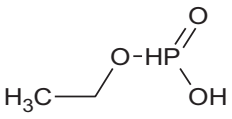
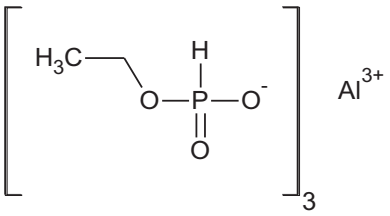
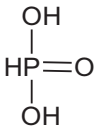
D.1. Consumer risk assessment

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				
Wine grapes	24.10	STMR	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	
Table olives	23	STMR		
Avocados	14.88	STMR		
Horseradishes	41.18	STMR		
Garlic	4.4	STMR		
Shallots	4.4	STMR		
Olives for oil production	23	STMR		
Spinaches	47	STMR (EFSA, 2020b)[a]		
Flowering brassica	11.35	STMR (EFSA, 2020b)[a]		
Kales	4.90	STMR (EFSA, 2020b)[a]		
Chinese cabbages	4.90	STMR (EFSA, 2020b)[a]		
Almonds, hazelnuts, pistachios, chestnuts, walnuts	358.5	STMR (EFSA, 2020a)[a]		
Blackberries	36.9	STMR (EFSA, 2020a)[a]		
Raspberries	36.9	STMR (EFSA, 2020a)[a]		
Blueberries	42.25	STMR (EFSA, 2020a)[a]		
Currants	42.25	STMR (EFSA, 2020a)[a]		
Gooseberries	42.25	STMR (EFSA, 2020a)[a]		
Granate apples/pomegranates	25	STMR (EFSA, 2020a)[a]		
Herbs and edible flowers	98.25	STMR (EFSA, 2020a)[a]		
Brazil nuts, cashew nuts, macadamias, pecans, pine nut kernels,	64.5	STMR (EFSA, 2018b)		
Potato	26.9	STMR (EFSA, 2019b)		
Wheat	23.13	STMR (EFSA, 2019b)		
Pome fruit	23.2	STMR (EFSA, 2018b)		
Peaches	12.51	STMR (EFSA, 2018b)		
Strawberries	11	STMR (FAO, 2017)[b]		
Elderberries	18.4	STMR (EFSA, 2018d)		
Kiwi fruits	23.5	STMR (EFSA, 2012c)[b]		
Lettuces	41	STMR (FAO, 2017)		
Celeriac	0.21	STMR (EFSA, 2015b)		
Cucumbers	14	STMR (FAO, 2017)[b]		
Courgettes	25.5	STMR (FAO, 2017)[b]		
Melons	14	STMR (FAO, 2017)[b]		
Spices	74	STMR (EFSA, 2012c)[b]		
Hops	350	STMR (FAO, 2017)[b]		
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: supervised trials median residue; 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 2018.2.2 ACD/Labs 2018 Release (File version N50E41, Build 103230, 21 July 2018).
(c): ACD/ChemSketch 2018.2.2 ACD/Labs 2018 Release (File version C60H41, Build 106041, 7 December 2018).