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Modification of the existing MRLs for potassium phosphonates in lemons, limes and mandarins and in herbal infusions from leaves and herbs

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants Lainco S.A., Exclusivas Sarabia S.A., Biovert S.L., Sipcam Inagra S.A. and Tilco-Alginure GmbH submitted respectively two requests to the competent national authorities in Greece and Germany, to modify the existing maximum residue levels (MRLs) for the active substance potassium phosphonates in certain citrus fruits and in herbal infusions from leaves and herbs. The data submitted in support of both requests were found to be sufficient to derive MRL proposals for lemons, limes, mandarins, strawberries leaves and the remaining plants included in the group of herbal infusions from leaves and herbs. Adequate analytical methods for enforcement are available to control potassium phosphonates residues in the commodities under consideration. Based on the risk assessment results using the currently set acceptable daily intake (ADI) of 2.25 mg/kg body weight (bw) per day for phosphonic acid, EFSA concluded that the long-term intake of residues resulting from the uses of potassium phosphonates according to the reported good agricultural practices is unlikely to present a risk to consumer health. The consumer risk assessment shall be regarded as indicative; a more realistic intake assessment will be performed in the framework of the joint review of MRLs for fosetyl and potassium phosphonates.

Keywords: potassium phosphonates, fosetyl, phosphonic acid, citrus fruits, herbal infusions, fungicide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Lainco S.A., Exclusivas Sarabia S.A., Biovert S.L. and Sipcam Inagra S.A. submitted an application to the competent national authority in Greece (evaluating Member State, EMS-EL) to modify the existing maximum residue levels (MRLs) for the active substance potassium phosphonates in lemons, limes and mandarins. 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 13 January 2021. The EMS proposed to increase the existing MRLs for lemons, limes and mandarins from 75 to 150 mg/kg, in accordance with the existing enforcement residue definition (fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl).

Moreover, still 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-DE) to modify the existing MRLs for the active substance potassium phosphonates in herbal infusions from leaves and herbs. 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 18 February 2021. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRL for strawberry leaves (to cover the use on hemps to which the same MRL applies) from 500 to 2,000 mg/kg for the existing enforcement residue definition (fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl).

EFSA assessed the applications and the evaluation reports 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 each EMS 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 of potassium phosphonates (hydrolysis studies) demonstrated that the metabolite phosphonic acid is stable.

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 currently 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 these two applications, the metabolism of potassium phosphonates in primary and rotational crops and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Adequate analytical methods are available to monitor potassium phosphonates in the crops under consideration according to the existing and proposed residue definitions for enforcement. The available methods enable quantification of residues at or above the limit of quantification (LOQ) of 0.01 mg/kg (as fosetyl-Al) and 0.1 mg/kg (as phosphonic acid) in high acid content commodities, to which citrus belong. Validation data specific for herbal infusions were not provided. However, an LOQ of 2 mg/kg (as fosetyl-Al) and 20 mg kg (as phosphonic acid) was concluded to be validated in hops, a typical representative commodity within this category. Taking into account the successful validation in hops and the low relevance of herbal infusions with regard to consumer exposure, this analytical method is assumed to be able to determine residues of potassium phosphonates in herbal infusions.

The available residue trials are sufficient to derive MRL proposals of 150 mg/kg for lemons, limes and mandarins and of 2,000 mg/kg for strawberry leaves as well as for extension to the whole group of herbal infusions from leaves and herbs, in accordance with the existing enforcement residue definition (fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl). MRL proposals derived according to the proposed enforcement residue definition (phosphonic acid and its salts, expressed as phosphonic acid) were also provided. Although not explicitly proposed by the EMS, EFSA is putting forward the possible extension of the MRL proposal for strawberry leaves to the whole group of herbal infusions from leaves and herbs, as requested by the applicant, for risk managers' consideration.

Based on all available information, EFSA could not exclude that the use of potassium phosphonates following multi-annual applications will result in significant residues in succeeding or rotational crops. Therefore, Member States are recommended to consider risk mitigation measures to avoid possible uptake of residues from soil when potassium phosphonates are used in herbal infusion plants according to the intended indoor GAP.

Peeling factors for mandarins and oranges and processing factors for pasteurised juice, marmalade and sterilised canned were derived from the field residue trials and the specific processing studies submitted. For the remaining commodities (herbal infusions), specific processing studies were not provided and are not required due to the low contribution of these commodities to the overall consumer exposure.

As the citrus fruit by-product dried citrus pulp is used as feed item, a potential carry-over of residues into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species. However, the intended use on citrus fruits under assessment has no significant impact on the livestock exposure, which is mainly driven by the existing use on potatoes, and a modification of the MRLs set for animal commodities is not required.

The toxicological profile of potassium phosphonates was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 2.25 mg/kg 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). In addition to the citrus fruits under consideration, EFSA assessed the safety for consumers considering exposure from possible use on strawberries leaves as well as on rooibos and mate leaves, in order to allow an informed risk management decision on the proposed extrapolation to the whole group of herbal infusions from leaves and herbs. For the calculation of the chronic exposure, EFSA used the median residue values (STMR) as derived from the residue trials submitted, the STMR available from previously issued EFSA opinions and from the implemented Codex MRLs. For the remaining commodities of plant and animal origin, the existing MRLs/LOQs as established in the EU legislation, recalculated to express them as phosphonic acid, were included in the risk assessment. For citrus fruits, the relevant peeling factors were applied to refine the calculation. 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 45% of the ADI of 2.25 mg/kg bw per day (NL toddler diet). The contributions of residues expected in the commodities assessed in the present MRL applications to the overall long-term exposure were all less than 2% of the ADI.

EFSA also performed a preliminary risk assessment using the proposed revised ADI of 1 mg/kg bw per day for phosphonic acid proposed in the EFSA Conclusion on fosetyl, noting that the value is not yet formally taken note. The long-term dietary exposure including MRLs/LOQs accounted for 100% of the proposed revised ADI of 1 mg/kg bw per day for phosphonic acid (NL toddler diet). The major contributor was apple (25% of the proposed revised ADI). When excluding from the exposure calculation the commodities for which the existing EU MRLs are set at the LOQ assuming that no uses are authorised on these crops, the estimated chronic exposure to phosphonic acid residues was lower (97% of the proposed revised 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.

EFSA concluded that the intended uses of potassium phosphonates on lemons, limes, mandarins, strawberries leaves and the remaining crops included in the group of herbal infusions from leaves and herbs will not result in a consumer exposure exceeding the toxicological reference value currently in place. Regarding the preliminary results of the consumer risk assessment performed with the proposed revised ADI of 1 mg/kg bw per day for phosphonic acid not yet formally taken note, further refinement would be possible for a number of products, because the exposure calculations were performed with the MRLs instead of the STMRs and with the LOQs, 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.

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				
0110030	Lemons	75	1) 150 2) 150 Risk management consideration	The submitted data are sufficient to derive an MRL proposal for the intended SEU use. The MRL proposal is derived by extrapolation from residue trials on mandarins. A risk for consumers is not identified according to the current ADI of 2.25 mg/kg bw per day for phosphonic acid. The estimated consumer exposure accounts for 100% of the proposed revised ADI of 1 mg/kg bw per day for phosphonic acid (NL toddler), but when LOQ values are excluded from the calculation assuming no use on those commodities, the estimated exposure accounts for 97% of the proposed revised ADI. The contribution of crops under assessment is less than 2% of the proposed revised ADI. Thus, further risk management considerations are required to decide whether the MRL proposals are acceptable.
0110040	Limes	75	1) 150 2) 150 Risk management consideration	
0110050	Mandarins	75	1) 150 2) 150 Risk management consideration	
0632010	Strawberry	500	1) 2,000 2) 1,500 Risk management consideration	The submitted data are sufficient to derive an MRL proposal for the intended indoor use. The MRL proposal is derived by extrapolation from residue trials on open leaf lettuce, applying a default dehydration factor of 10.A risk for consumers is not identified according to the current ADI of 2.25 mg/kg bw per day for phosphonic acid.See comments for 0110030/ 40/50 for the results of the calculations using the proposed revised ADI of 1 mg/kg bw per day for phosphonic acid.
0632020	Rooibos	500	1) 2,000 2) 1,500 Risk management consideration	The submitted data are sufficient to derive an MRL proposal, by extrapolation, for the intended indoor use on the group of herbal infusions from leaves and herbs. Although not explicitly proposed by the EMS, EFSA is putting forward the possible extension of the MRL proposal for strawberry leaves to the whole group of herbal infusions from leaves and herbs as requested by the applicant for risk managers' consideration. For the outcome of the consumer risk assessment, see comments for 0632010.
0632030	Mate/maté	500	1) 2,000 2) 1,500 Risk management consideration	
0632990	Other herbal infusions from leaves and herbs	500	1) 2,000 2) 1,500 Risk management consideration	

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 two applications to modify the existing maximum residue levels (MRLs) for potassium phosphonates in lemons, limes and mandarins and in herbal infusions from leaves and herbs. The detailed description of the intended uses of potassium phosphonates, which is 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). The chemical structures of the phosphonates active substances and its main metabolite 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 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 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 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 fosetyl and potassium phosphonates (EFSA, 2009, 2012a,c, 2015, 2018b,d, 2019b, 2020a,b,c, 2021). The proposals from previous reasoned opinions (EFSA, 2009, 2012c, 2015, 2018b,d) have been considered in recent MRL regulations.[4] Still a number of modifications of the existing MRLs proposed by EFSA (EFSA, 2019b, 2020a,b,c, 2021) have not yet been implemented in the MRL legislation, since the European Commission considered appropriate to await the MRL review for the related active substances. 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, Lainco, S.A., Exclusivas Sarabia S.A., Biovert S.L. and Sipcam Inagra S.A. submitted an application to the competent national authority in Greece (evaluating Member State, EMS-EL) to modify the existing MRLs for the active substance potassium phosphonates in lemons, limes and mandarins. 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 13 January 2021. The EMS proposed to increase the MRLs for lemons, limes and mandarins from 75 mg/kg to 150 mg/kg, in accordance with the existing enforcement residue definition (fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)).

submitted an application. . ..

Moreover, still 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-DE) to modify the existing MRLs for the active substance potassium phosphonates in herbal infusions from leaves and herbs. 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

[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.

European Food Safety Authority (EFSA) on 18 February 2021. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRL from 500 to 2,000 mg/kg for strawberry leaves to cover the use on hemp to which the same MRL applies.

EFSA assessed the applications and the evaluation reports, as required by Article 10 of the MRL regulation. EFSA based its assessment on the evaluation reports submitted by the EMSs (Germany, 2020; Greece, 2020), the draft assessment report (DAR) and its addendum (France, 2005, 2012) prepared under 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, 2012a,c, 2018b,d, 2019b, 2020a,b,c, 2021) and the MRL review of fosetyl (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 EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2020; 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, is presented in Appendix B.

The evaluation reports submitted by the EMSs (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.

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 of this active substance (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 they are not required.

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

1.1.2. Nature of residues in rotational crops

Studies on nature of residue in rotational crops are not available for potassium phosphonates. Nevertheless, as highlighted for primary crops, considering the elementary nature of the active substance, the metabolic pathway of potassium phosphonates is expected to be similar also in rotational crops, with phosphonic acid being the main compound present in the soil and uptake in the rotated crops. Studies on the nature of residues in rotational crops are available for fosetyl. They were assessed in the framework of the MRL review for potassium phosphonates and the EU pesticides peer

[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.

review fosetyl (EFSA, 2012a, 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

Sufficiently validated methods using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available to determine residues of potassium phosphonates in plant matrices, including high acid content matrices to which the citrus fruits under consideration belong. The methods enable quantification of residues of potassium phosphonates in high water, high acid and high oil content commodities and in dry matrices at or above an LOQ of 0.01 mg/kg (as fosetyl-Al) and the LOQ of 0.1 mg kg (as phosphonic acid). In high oil content commodities, a higher LOQ of 0.5 mg/kg (phosphonic acid) was also reported (EFSA, 2012a, 2018c).

Validation data specific for herbal infusions were not provided (Germany, 2020). Herbal infusions are usually considered as a 'difficult' matrix for which separate validation data would be required to demonstrate the applicability of the analytical method (European Commission, 2010b). Both the GC-FPD and the HPLC methods were concluded to be sufficiently validated in hops (dried cones), a typical representative commodity within this category. The LOQ achieved was reported to be 1 or 2 mg/kg (as fosetyl-Al) and 20 mg/kg (as phosphonic acid) (EFSA, 2012a; FAO, 2017). Taking into account the successful validation in hops and the low relevance of herbal infusions with regard to consumer exposure, the analytical method using GC-FPD is assumed to be capable to determine residues of potassium phosphonates also in the herbal infusions. However, confirmation would be desirable.

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 EU pesticides peer review of potassium phosphonates (EFSA, 2012b), the peer review of fosetyl (EFSA, 2018c) and in previous MRL applications (EFSA, 2018b,d). It was demonstrated that in crops assessed in the framework of these applications, residues of phosphonic acid were stable for at least 25 months when stored at –18/20°C.

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 definition was 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 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).

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

Taking into account the proposed uses assessed in these applications, EFSA concluded that the previously derived residue definitions are applicable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the intended uses, the applicants submitted the results of residue trials on mandarins and on lettuce for extrapolation purpose. The samples collected from these trials were analysed for phosphonic acid residues. In order to derive the MRL proposals according to the existing enforcement residue definition, the results measured as phosphonic acid were expressed as fosetyl by applying the molecular weight conversion factor of 1.34.

According to each EMS, the methods of analysis used to analyse the residue trial samples were sufficiently validated and were fit for purpose (Germany, 2020; Greece, 2020). All samples from these residue trials were stored prior to analysis 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.

Lemons, limes and mandarins

A total of twelve GAP-complaint residue trials on mandarins conducted in different locations in Spain over three seasons were provided. Generally, trials should be spread over different Member States to represent different cultivation practices. However, considering that the trial sites were widely distributed over the main citrus producing country in the EU, the data were judged as sufficiently representative. The proposed extrapolation of the results from the residue trials on mandarins to lemons and limes is acceptable (European Commission, 2020). EFSA concluded that the data are sufficient to derive an MRL proposal.

Strawberry leaves, rooibos leaves, mate leaves and other herbal infusions from leaves and herbs[9]

To support the intended indoor use, the applicant referred to residue trials on open leaf lettuce varieties that were already assessed by EFSA previously (EFSA, 2020b). Only the results from the decline trials with PHI of 10 days were fully compliant with the intended GAP. It is noted that residues above the LOQ of 0.1 mg phosphonic acid/kg were observed in two untreated control samples (0.15 and 0.30 mg/kg). The proposed extrapolation of residue data from lettuce to the whole group of herbal infusions from leaves and herbs is acceptable (European Commission, 2020).

EFSA concluded that the data are sufficient to derive an MRL proposal. In the absence of specific processing studies, EFSA applied the default dehydration factor of 10[10] previously used to recalculate residue concentrations measured in fresh lettuces to dried herbs (EFSA, 2017).

1.2.2. Magnitude of residues in rotational crops

For the herbs under evaluation, EFSA agreed with the EMS' assessment that relevant amounts of residues are not expected to occur in crops planted as succeeding/rotational crops. Nonetheless, the possible uptake of phosphonic acid residues following multi-annual applications cannot be excluded and positive detections in untreated samples were already observed. New rotational crops studies with potassium phosphonates are not available. However, the occurrence of residues of the metabolite of potassium phosphonates, phosphonic acid, in rotational root crops, leafy crops and cereals was confirmed in studies submitted for the EU pesticides peer review of fosetyl (EFSA, 2018c). Based on all available information on the magnitude of residues, Member States are recommended to consider risk mitigation measures to avoid possible uptake of residues from soil when potassium phosphonates are used in plants used for herbal infusion according to the intended indoor GAP.

[9] The MRL application submitted refers to an intended use of potassium phosphonates for the entire group of herbal infusions from leaves and herbs (0632000), whilst according to the EMS the triggering factor for the request is a national GAP on hemp (Germany, 2020). Hemp (Cannabis sativa subsp. sativa 0632010-045 and Cannabis sativa subsp. spontanea 0632010-046) is a product listed in part B of Annex I to Regulation (EC) No 396/2005, attributed to strawberry leaves (0632010) in part A to the Annex.

[10] The EMS proposed a dehydration factor of 8 based on the ratio of the moisture content in fresh and dried hemp leaves (Germany, 2020). Since the residue data submitted are on lettuces, EFSA is of the opinion that the dehydration factor proposed by the EMS is not suitable for the submitted data package and may underestimate expected residues.

1.2.3. Magnitude of residues in processed commodities

In the MRL application on citrus fruits, the distribution of residues into the peel and pulp of mandarins and oranges and the results of processing studies in oranges were evaluated. Residues were located in the fruit peel and diluted in orange juice, marmalade and canned oranges (Greece, 2020). Peeling and processing factor were derived and are reported in Appendix B.1.2.3.

For the remaining commodities (herbal infusions), specific processing studies were not provided and are not required, considering the very low contribution of this group of products to the overall consumer exposure (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. Although not explicitly proposed by the EMS in the evaluation report, EFSA is putting forward the possible extension of the MRL proposal for strawberries leaves to the whole group of herbal infusions from leaves and herbs as requested by the Applicant for risk managers' consideration. Thus, considering that (i) the Application Form forwarded to the Commission and EFSA requested to set an MRL for the use of potassium phosphonates on the entire group of herbal infusions from leaves and herbs as confirmed in the evaluation report (refer to Appendix A – 'GAP supported in the MRL application'), (ii) the residue data package submitted supports by extrapolation an MRL proposal for the whole group in line with the EU requirements, (iii) EFSA did not identify a restriction for the MRL proposal to strawberry leaves.

EFSA derived MRL proposals according to both the existing and the proposed residue definitions for enforcement (Appendix B.4). In Section 3, EFSA assessed whether residues on the crops under assessment resulting from the intended uses are likely to pose a consumer health risk. EFSA assessed the safety for consumers considering exposure from possible use on strawberries leaves as well as on rooibos and mate leaves in order to allow an informed risk management decision on the proposed extrapolation to the whole group of herbal infusions from leaves and herbs.

2. Residues in livestock

The use of potassium phosphonates resulted in significant residue levels in the citrus fruits, for which the by-product citrus dried pulp is a feed item. Therefore, EFSA assessed whether the intended use of potassium phosphonates required a modification of the MRLs set for animal commodities.

EFSA updated the most recent animal dietary burden for potassium phosphonates (EFSA, 2020b), which was calculated using the feeding tables listed in the OECD guidance (OECD, 2013), including the residues expected to occur in citrus dried pulp from the intended use of potassium phosphonates. The input values for the exposure calculation for livestock are presented in Appendix D.1. The results of the dietary burden calculation are presented in Appendix B.2.

The updated livestock dietary burden still exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species. However, comparing the results of the revised dietary burden calculation with the dietary burden derived previously (EFSA, 2019b, 2020b, 2021), it is evident that the residues in citrus dried pulp have no significant impact on the current livestock exposure, which is mainly driven by the existing use on potatoes. EFSA concluded that a modification of the MRLs set for animal commodities is not required.

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 (FAO, 2016).

The toxicological profile for potassium phosphonates was assessed in the framework of the EU pesticides 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, 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 was calculated according to this reference value as well. A short-term exposure assessment is not required since no ARfD is established or proposed for phosphonic acid.

For the calculation of the chronic exposure, EFSA used the median residue values (STMR) derived from the residue trials for the crops under consideration, the STMR values reported in previously issued EFSA reasoned opinions (EFSA, 2009, 2012c, 2015, 2018b,d, 2019b, 2020a,b,c) and the STMR values corresponding to the Codex MRLs (FAO, 2017) which were implemented in the EU legislation.

For the remaining commodities of plant and animal origin, in the absence of risk assessment input values for refinement, the existing MRLs/LOQs set in the EU legislation for fosetyl, recalculated to phosphonic acid,[11] were used. For citrus, the relevant peeling factors were applied. The input values used in the exposure calculations are summarised in Appendix D.2.

Using the current ADI of 2.25 mg/kg bw per day set for potassium phosphonates **(scenario 1)**, no long-term consumer intake concerns were identified. The calculated long-term exposure accounted for a maximum of 45% of the ADI (NL toddler diet). The contributions of residues expected in the commodities assessed in the present MRL applications to the overall long-term exposure were all less than 2% of the ADI.

EFSA also performed a preliminary risk assessment using the proposed revised ADI of 1 mg/kg bw per day for phosphonic acid proposed in the EFSA conclusion on fosetyl, noting that the value is not yet formally taken note. The long-term dietary exposure including MRLs/LOQs accounted for 100% of the proposed revised ADI of 1 mg/kg bw per day **(Scenario 2, option a).** The major contributor was apple (25% of the ADI, NL toddler diet). When excluding from the exposure calculation the commodities for which the existing EU MRLs are set at the LOQ assuming that no uses are authorised on these crops **(Scenario 2, option b),** the estimated chronic exposure to phosphonic acid residues was lower (97% of the proposed revised ADI of 1 mg/kg bw). The contributions of residues expected in the commodities assessed in the present MRL applications to the overall long-term exposure did not change significantly among the different scenarios. 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.

EFSA concluded that the intended uses of potassium phosphonates on lemons, limes, mandarins, strawberries leaves and the remaining plants included in the group of herbal infusions from leaves and herbs will not result in a consumer exposure exceeding the toxicological reference value currently in place. Regarding the preliminary results of the consumer risk assessment performed with the proposed revised ADI of 1 mg/kg bw per day for phosphonic acid not yet formally adopted, further refinement would be possible for a number of products, because the exposure calculations were performed with the MRLs instead of the STMRs and with the LOQs, which is likely to overestimate the exposure to residues arising from the uses 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 when full information on the authorised uses of phosphonates fungicides supported by data will be available to EFSA.

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 both requests were found to be sufficient to derive MRL proposals for lemons, limes and mandarins and for strawberry leaves as well as for the whole group of herbal infusions from leaves and herbs. Although not expressly proposed by the EMS, EFSA is putting forward the possible extension of the MRL proposal for strawberries leaves to the whole group of herbal infusions from leaves and herbs as requested by the Applicant for risk managers' consideration.

EFSA concluded that the long-term intake of residues using the currently set acceptable daily intake (ADI) and resulting from the uses 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; a more realistic intake assessment will be performed in the framework of the joint review of MRLs for fosetyl and potassium phosphonates. Based on the available information on the magnitude of residues in rotational crops, Member States are recommended to consider risk mitigation measures to avoid possible uptake of residues from soil when potassium phosphonates are used in plants used for herbal infusion according to the intended indoor GAP.

The MRL recommendations are summarised in Appendix B.4.

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

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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
CIRCA	(EU) Communication & Information Resource Centre Administrator
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
DS	powder for dry seed treatment
EDI	estimated daily intake
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FPD	flame photometric detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-FPD	gas chromatography with flame photometric 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
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 min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min—max	Rate	Unit		
Lemons	SEU	F	*Phytophthora* spp.	SL	Potassium phosphates 790 g/L (510 g/L phosphonic acid equivalents)	Foliar treatment – broadcast spraying	From BBCH 19	3	20 days	33.86–691.3 (21.86–446.3 g a.s./hL phosphonic acid equivalents)	1,000–3,500	1,185–6,913 (765–4,463 g/ha phosphonic acid equivalents)	g a.i./ha	15	Applications in spring, summer, autumn
Mandarins	SEU	F	*Phytophthora* spp.	SL	Potassium phosphates 790 g/L (510 g/L phosphonic acid equivalents)	Foliar treatment – broadcast spraying	From BBCH 19	3	20 days	33.86–691.3 (21.86–446.3 g a.s./hL phosphonic acid equivalents)	1,000–3,500	1,185–6,913 (765–4,463 g/ha phosphonic acid equivalents)	g a.i./ha	15	Applications in spring, summer, autumn
Limes	SEU	F	*Phytophthora* spp.	SL	Potassium phosphates 790 g/L (510 g/L phosphonic acid equivalents)	Foliar treatment – broadcast spraying	From BBCH 19	3	20 days	33.86–691.3 (21.86–446.3 g a.s./hL phosphonic acid equivalents)	1,000–3,500	1,185–6,913 (765–4,463 g/ha phosphonic acid equivalents)	g a.i./ha	15	Applications in spring, summer, autumn
Strawberry leaves	EU	G	Downy mildew, Powdery mildew, Phytophthora, *Fusarium, Septoria*	SL	Potassium phosphates 342 g/L (228 g/L phosphonic acid equivalents)	Foliar treatment – broadcast spraying	BBCH 12–39	1–4	7 days	137–228 (91.3–152 g a.s./hL phosphonic acid equivalents)	600–1,000	1,370 (913 g/ha phosphonic acid equivalents)	g a.i./ha	10	DE GAP on hemp (part B of Annex I) attributed to strawberry leaves in part A to Reg. (EC) No 396/2005.
Rooibos	EU	G	Downy mildew, Powdery mildew, Phytophthora, *Fusarium, Septoria*	SL	Potassium phosphates 342 g/L (228 g/L phosphonic acid equivalents)	Foliar treatment – broadcast spraying	BBCH 12–39	1–4	7 days	137–228 (91.3–152 g a.s./hL phosphonic acid equivalents)	600–1,000	1,370 (913 g/ha phosphonic acid equivalents)	g a.i./ha	10	

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 min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min—max	Rate	Unit		
Mate/maté	EU	G	Downy mildew, Powdery mildew, Phytophthora, *Fusarium, Septoria*	SL	Potassium phosphates 342 g/L (228 g/L phosphonic acid equivalents)	Foliar treatment – broadcast spraying	BBCH 12–39	1–4	7 days	137–228 (91.3–152 g a.s./hL phosphonic acid equivalents)	600–1,000	1,370 (913 g/ha phosphonic acid equivalents)	g a.i./ ha	10	
Others herbal infusions from leaves and herbs	EU	G	Downy mildew, Powdery mildew, Phytophthora, *Fusarium, Septoria*	SL	Potassium phosphates 342 g/L (228 g/L phosphonic acid equivalents)	Foliar treatment – broadcast spraying	BBCH 12–39	1–4	7 days	137–228 (91.3–152 g a.s./hL phosphonic acid equivalents)	600–1,000	1,370 (913 g/ha phosphonic acid equivalents)	g a.i./ ha	10	

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; xx: formulation type.
(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 submitted. 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 (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 on fosetyl. Study not conducted with radiolabelled material (EFSA, 2018c).
	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 EU pesticides 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)	Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) (Regulation (EC) No 396/2005) Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012b)	
Plant residue definition for risk assessment (RD-RA)	Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012b)	

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water, high acid, high oil content and dry matrices: • HPLC–MS/MS LOQ of 0.01 mg fosetyl-Al/kg (EFSA, 2012a, 2018c) LOQ of 0.1 mg phosphonic acid/kg (EFSA, 2018c) Matrices with high oil content: • HPLC–MS/MS (QuPPe) LOQ of 0.5 mg phosphonic acid/kg (EFSA, 2012a; 2018c) Difficult matrix hops: • HPLC–MS/MS LOQ of 1 mg fosetyl-Al/kg (FAO, 2017) LOQ of 20 mg phosphonic acid /kg (FAO, 2017) • GC-FPD LOQ of 2 mg fosetyl-Al/kg (EFSA, 2012a) LOQ of 20 mg phosphonic acid /kg (EFSA, 2012a)

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; LOQ: limit of quantification; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; QuPPe: Quick Polar Pesticides; GC-FPD: gas chromatography with flame photometric detector

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	Grape	–18	25	Months	Sum of phosphonic acid and fosetyl	EFSA (2012a)
						Phosphonic acid	
			–18	12	Months	Phosphonic acid	EFSA (2012b)
		Blueberry	–20	14	Months	Phosphonic acid	EFSA (2021)
	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]
Mandarins, Lemons, Limes	SEU	**Measured as phosphonic acid:** 9.16; 14.31; 22.00; 24.37; 29.10; 31.40; 34.00; 35.00; 44.70; 53.80; 55.53; 72.50 **Recalculated as fosetyl[d]:** 12.27; 19.18; 29.48; 32.66; 38.99; 42.08; 45.56; 46.90; 59.90; 72.09; 74.41; 97.15	Residue trials on mandarins compliant with the SEU GAP conducted over 3 seasons in Spain. Underlined: higher residue measured at a longer PHI of 21 days. Proposed extrapolation to lemons and limes acceptable.	150 (as phosphonic acid) 150 (as fosetyl-Al)	72.50 (as phosphonic acid)	32.70 (as phosphonic acid)	n/a
Strawberry, rooibos, mate leaves and other herbal infusions from leaves and herbs	Indoor	**Measured as phosphonic acid:** 31.5, 31.6, 44.4, 84.8 **Recalculated as fosetyl[e]:** 42.21, 42.34, 59.50, 113.63 (values refer to lettuce fresh leaves)	Residue trials on open leaf lettuces compliant with the indoor GAP. To derive the MRL and the risk assessment values for dried herbal infusions, a default dehydration factor of 10 is applied. The EMS proposed to set an MRL for strawberries leaves only EFSA considered extrapolation to the group of herbal infusions acceptable.	1,500 (as phosphonic acid) 2,000 (as fosetyl-Al) (values refer to dried herbal infusions leaves and herbs)	848 (as phosphonic acid)	380 (as phosphonic acid)	n/a

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
(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.
(e): Individual residues were recalculated to express them as fosetyl by applying the molecular weight (MW) conversion factor of 1.34 - MW fosetyl (110 g/mol)/MW phosphonic acid (82 g/mol)

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 of phosphonic acid after bare soil application at a rate equivalent to 4.9 mg phosphonic acid/kg were observed in plants grown 30 days after application to the soil. Radish root: 0.8 mg/kg Lettuce: 0.76 mg/kg Barley grain: 0.14 mg/kg Barley straw: 0.42 mg/kg. Residues in rotational crops cannot be excluded.
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[c]	Comment/ Source
		Individual values[b]	Median PF		
Mandarin, peeled	12	0.20, 0.28, 0.52, 0.55, 0.57, 0.59, 0.65, 0.72, 0.83, 0.89, 0.90, 1.03	0.62	–	Greece (2020)
Orange, peeled	8	0.51, 0.55, 0.65, 0.66, 0.67, 0.86, 0.88, 0.90	0.67	–	Greece (2020)
Orange, juice (pasteurised)	4	0.46, 0.51, 0.78, 0.91	0.65	–	Greece (2020)
Orange, marmalade	4	0.27, 0.27. 0.33, 0.53	0.30	–	Greece (2020)
Orange, canned (sterilised)	4	0.30, 0.32, 0.41, 0.52	0.37	–	Greece (2020)
Orange, dried pomace	1	3.19	–	–	Greece (2020)

(a): Studies with residues in the RAC at or close to the LOQ are disregarded (unless concentration may occur).
(b): Individual processing factors for each study derived for residues expressed as phosphonic acid.
(c): Conversion factor for risk assessment in the processed commodity.

B.2. Residues in livestock

Dietary burden calculations according to OECD, 2013.

Relevant groups	Dietary burden expressed in				Most critical diet[a]	Most critical commodity[b]		Trigger exceeded (Yes/No)	Previous assessment (EFSA, 2020b)
	mg/kg bw per day		mg/kg DM					0.10	Max burden
	Median	Maximum	Median	Maximum				mg/kg DM	mg/kg DM
Cattle (all diets)	7.698	11.584	245.73	346.78	Dairy cattle	Potato	Process waste	Yes	346.78
Cattle (dairy only)	7.698	11.584	200.14	301.18	Dairy cattle	Potato	Process waste	Yes	301.18
Sheep (all diets)	8.031	11.781	240.93	353.43	Ram/Ewe	Potato	Process waste	Yes	353.43
Sheep (ewe only)	8.031	11.781	240.93	353.43	Ram/Ewe	Potato	Process waste	Yes	353.43

Relevant groups	Dietary burden expressed in				Most critical diet[a]	Most critical commodity[b]		Trigger exceeded (Yes/No)	Previous assessment (EFSA, 2020b)
	mg/kg bw per day		mg/kg DM					0.10	Max burden
	Median	Maximum	Median	Maximum				mg/kg DM	mg/kg DM
Swine (all diets)	4.777	9.405	173.84	328.09	Swine (finishing)	Potato	Culls	Yes	329.69
Poultry (all diets)	5.478	9.885	76.69	138.39	Turkey	Potato	Culls	Yes	138.39
Poultry (layer only)	4.765	7.249	69.64	105.94	Poultry layer	Potato	Culls	Yes	105.94

(a): When several diets are relevant (e.g. cattle, sheep and poultry 'all diets'), the most critical diet is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.3. Consumer risk assessment

An acute consumer risk assessment is not required 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	45% of the ADI (NL toddler) Contribution of crops assessed: lemons: 0.34% of ADI limes: 0.03% of the ADI mandarins: 0.76% of the ADI herbal infusions: 0.17% of the ADI (for matè)
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 applications, in previous assessments (EFSA, 2009, 2012c, 2015, 2018b,d, 2019b, 2020a,b,c) and the STMRs of the CXLs implemented in the EU legislation (FAO, 2017). For the remaining commodities, the MRLs/LOQs 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 peeling factor of 0.62 was used for mandarins, lemons and limes and of 0.67 for oranges and grapefruits. It is assumed that certain MRLs will be amended as proposed in recently issued reasoned opinions on fosetyl/ potassium phosphonates (EFSA, 2020a,b,c). 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 joint review of the existing MRLs for fosetyl and 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 (EFSA, 2018c)
Highest IEDI, according to EFSA PRIMo	**Option a** (including all MRLs): 100% of the ADI (NL toddler) **Option b** (excluding MRLs <LOQ): 97% ADI (DE child) Contribution of crops assessed (option a and b): lemons: 0.75% of ADI limes: 0.08% of the ADI mandarins: 1.71% of the ADI herbal infusions: 0.38% of the ADI (for matè)
Assumptions made for the calculations	**Option a:**
	The calculation is based on the same approach and assumptions as in Scenario 1 **Option b:** In this calculation, the commodities for which the existing EU MRLs are set at the LOQ were excluded from the calculation, under the assumption that there are no authorised uses supporting the MRL set at LOQ. These consumer risk assessments are indicative, since the ADI is not yet formally adopted and the 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 joint review of the existing MRLs for fosetyl and potassium 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				
0110030	Lemons	75	1) 150 2) 150 Risk management consideration	The submitted data are sufficient to derive an MRL proposal for the intended SEU use. The MRL proposal is derived by extrapolation from residue trials on mandarins. A risk for consumers is not identified according to the current ADI of 2.25 mg/kg bw per day for phosphonic acid. The estimated consumer exposure accounts for 100% of the proposed revised ADI of 1 mg/kg bw per day for phosphonic acid (NL toddler), but when LOQ values are excluded from the calculation assuming no use on those commodities, the estimated exposure accounts for 97% of the proposed revised ADI. The contribution of crops under assessment is less than 2% of the proposed revised ADI. Thus, further risk management considerations are required to decide whether the MRL proposals are acceptable.
0110040	Limes	75	1) 150 2) 150 Risk management consideration	
0110050	Mandarins	75	1) 150 2) 150 Risk management consideration	
0632010	Strawberry	500	1) 2,000 2) 1,500 Risk management consideration	The submitted data are sufficient to derive an MRL proposal for the intended indoor use. The MRL proposal is derived by extrapolation from residue trials on open leaf lettuce, applying a default dehydration factor of 10. A risk for consumers is not identified according to the current ADI of 2.25 mg/kg bw per day for phosphonic acid. See comments for 0110030/40/50 for the results of the calculations using the proposed revised ADI of 1 mg/kg bw per day for phosphonic acid.
0632020	Rooibos	500	1) 2,000 2) 1,500 Risk management consideration	The submitted data are sufficient to derive an MRL proposal, by extrapolation, for the intended indoor use on the group of herbal infusions from leaves and herbs. Although not explicitly proposed by the EMS, EFSA is putting forward the possible extension of the MRL proposal for strawberry leaves to the whole group of herbal infusions from leaves and herbs as requested by the applicant for risk managers' consideration. For the outcome of the consumer risk assessment, see comments for 0632010.
0632030	Mate/maté	500	1) 2,000 2) 1,500 Risk management consideration	
0632990	Other herbal infusions from leaves and herbs	500	1) 2,000 2) 1,500 Risk management consideration	

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Potassium Phosphonates

LOQs (mg/kg) range from: 0.5 to: 5.0

Toxicological reference values

ADI (mg/kg bw per day):	2.25	ARfD (mg/kg bw):	not necessary
Source of ADI:	EU COM	Source of ARfD:	EU COM
Year of evaluation:	2013	Year of evaluation:	2013

Input values

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

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

Comments: Scenario 1 – with implemented TRVs

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)
45%	NL toddler	1017.27	11%	Apples	5%	Potatoes	4%	Pears	2%	45%
43%	DE child	957.78	13%	Apples	7%	Oranges	4%	Wheat	0.6%	43%
39%	GEMS/Food G06	881.23	12%	Tomatoes	7%	Wheat	3%	Watermelons	1.0%	39%
29%	NL child	654.13	6%	Apples	4%	Wheat	4%	Potatoes	1%	29%
27%	RO general	612.50	6%	Tomatoes	5%	Wheat	4%	Potatoes	0.4%	27%
26%	GEMS/Food G08	577.48	5%	Potatoes	4%	Wheat	4%	Tomatoes	0.9%	26%
26%	GEMS/Food G15	576.26	5%	Wheat	4%	Potatoes	4%	Tomatoes	0.8%	26%
25%	GEMS/Food G11	566.06	5%	Potatoes	4%	Wheat	3%	Tomatoes	1%	25%
25%	GEMS/Food G10	551.58	5%	Tomatoes	4%	Wheat	4%	Potatoes	0.9%	25%
24%	GEMS/Food G07	551.02	4%	Potatoes	4%	Wheat	4%	Tomatoes	0.8%	24%
24%	FR child 3 15 yr	538.48	6%	Oranges	5%	Wheat	3%	Tomatoes	0.8%	24%
22%	PT general	485.54	6%	Potatoes	4%	Wheat	3%	Tomatoes	0.4%	22%
21%	IE adult	483.64	3%	Potatoes	2%	Wheat	2%	Oranges	1.0%	21%
20%	ES child	455.40	5%	Wheat	4%	Oranges	3%	Tomatoes	0.3%	20%
20%	SE general	447.52	5%	Potatoes	3%	Wheat	3%	Tomatoes	0.4%	20%
19%	UK toddler	425.43	4%	Potatoes	4%	Wheat	3%	Oranges	0.6%	19%
19%	IT toddler	418.02	7%	Wheat	5%	Tomatoes	1%	Potatoes	0.3%	19%
18%	FR toddler 2 3 yr	412.93	3%	Apples	3%	Wheat	2%	Oranges	0.6%	18%
18%	DE women 14-50 yr	412.69	3%	Oranges	3%	Apples	2%	Tomatoes	0.7%	18%
17%	DK child	393.36	5%	Wheat	3%	Potatoes	2%	Apples	0.8%	17%
17%	DE general	375.46	3%	Oranges	3%	Apples	2%	Tomatoes	0.7%	17%
15%	NL general	347.92	3%	Potatoes	2%	Wheat	2%	Oranges	0.6%	15%
15%	FI 3 yr	342.55	6%	Potatoes	2%	Tomatoes	1%	Wheat	0.5%	15%
15%	IT adult	332.36	4%	Wheat	4%	Tomatoes	0.8%	Apples	0.2%	15%
15%	ES adult	329.40	3%	Tomatoes	2%	Wheat	2%	Oranges	0.2%	15%
14%	UK infant	320.74	4%	Potatoes	3%	Wheat	2%	Oranges	0.7%	14%
12%	FR adult	281.03	2%	Wine grapes	2%	Wheat	2%	Tomatoes	0.4%	12%
12%	FI 6 yr	280.82	5%	Potatoes	1%	Tomatoes	1%	Wheat	0.3%	12%
12%	PL general	268.76	4%	Potatoes	3%	Tomatoes	2%	Apples	0.1%	12%
12%	UK vegetarian	263.03	2%	Wheat	2%	Tomatoes	2%	Potatoes	0.2%	12%
10%	LT adult	233.16	4%	Potatoes	2%	Tomatoes	2%	Apples	0.2%	10%
9%	UK adult	210.05	2%	Wheat	2%	Potatoes	1%	Tomatoes	0.2%	9%
9%	FR infant	208.77	2%	Potatoes	2%	Apples	0.8%	Wheat	0.3%	9%
9%	DK adult	205.65	2%	Tomatoes	2%	Potatoes	1%	Wheat	0.2%	9%
9%	FI adult	193.16	2%	Tomatoes	1%	Potatoes	1%	Coffee beans	1%	9%
3%	IE child	71.66	1%	Wheat	0.7%	Potatoes	0.3%	Apples	0.1%	3%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Potassium Phosponates
is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

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 2 – Option a

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Potassium Phosphonates

LOQs (mg/kg) range from:	0.5	to:	5.0

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: Scenario 2 - Option a – with revised TRV not yet implemented

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

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)
100%	NL toddler	1004.51	25%	Apples	11%	Potatoes	10%	Pears	0.0%	100%
95%	DE child	954.46	29%	Apples	15%	Oranges	10%	Wheat	0.0%	95%
88%	GEMS/Food G06	875.74	27%	Tomatoes	17%	Wheat	6%	Watermelons		88%
65%	NL child	646.56	13%	Apples	10%	Wheat	9%	Potatoes	0.0%	65%
61%	RO general	610.20	15%	Tomatoes	12%	Wheat	10%	Potatoes	0.0%	61%
57%	GEMS/Food G08	572.62	11%	Potatoes	9%	Wheat	9%	Tomatoes		57%
57%	GEMS/Food G15	571.73	11%	Wheat	10%	Potatoes	9%	Tomatoes		57%
56%	GEMS/Food G11	560.18	11%	Potatoes	8%	Wheat	7%	Tomatoes		56%
55%	GEMS/Food G10	546.35	10%	Tomatoes	9%	Wheat	8%	Potatoes		55%
55%	GEMS/Food G07	546.33	10%	Potatoes	10%	Wheat	8%	Tomatoes		55%
53%	FR child 3 15 yr	534.01	13%	Oranges	11%	Wheat	6%	Tomatoes	0.0%	53%
48%	PT general	483.51	14%	Potatoes	9%	Wheat	7%	Tomatoes		48%
48%	IE adult	478.25	6%	Potatoes	5%	Wheat	4%	Oranges		48%
45%	ES child	453.47	10%	Wheat	8%	Oranges	7%	Tomatoes	0.0%	45%
45%	SE general	445.22	11%	Potatoes	7%	Wheat	6%	Tomatoes	0.0%	45%
42%	UK toddler	421.93	9%	Potatoes	9%	Wheat	7%	Oranges	0.0%	42%
42%	IT toddler	416.30	15%	Wheat	11%	Tomatoes	2%	Potatoes		42%
41%	FR toddler 2 3 yr	409.30	7%	Apples	7%	Wheat	5%	Oranges	0.0%	41%
41%	DE women 14-50 yr	408.55	7%	Oranges	6%	Apples	6%	Tomatoes	0.0%	41%
39%	DK child	388.93	10%	Wheat	7%	Potatoes	5%	Apples		39%
37%	DE general	371.33	6%	Oranges	6%	Apples	5%	Tomatoes	0.0%	37%
34%	NL general	344.47	7%	Potatoes	4%	Wheat	4%	Oranges	0.0%	34%
34%	FI 3 yr	339.98	13%	Potatoes	4%	Tomatoes	3%	Wheat	0.0%	34%
33%	IT adult	331.24	10%	Wheat	9%	Tomatoes	2%	Apples		33%
33%	ES adult	328.13	6%	Tomatoes	5%	Wheat	5%	Oranges	0.0%	33%
32%	UK infant	316.82	9%	Potatoes	6%	Wheat	5%	Oranges	0.0%	32%
28%	FR adult	278.97	6%	Wine grapes	5%	Wheat	3%	Tomatoes	0.0%	28%
28%	FI 6 yr	278.89	10%	Potatoes	3%	Tomatoes	2%	Wheat	0.0%	28%
27%	PL general	268.11	9%	Potatoes	7%	Tomatoes	5%	Apples		27%
26%	UK vegetarian	261.68	5%	Wheat	5%	Tomatoes	4%	Potatoes		26%
23%	LT adult	232.07	9%	Potatoes	5%	Tomatoes	4%	Apples		23%
21%	UK adult	208.92	4%	Wheat	4%	Potatoes	3%	Tomatoes	0.0%	21%
21%	FR infant	206.84	5%	Potatoes	4%	Apples	2%	Wheat	0.0%	21%
20%	DK adult	204.72	4%	Tomatoes	3%	Potatoes	3%	Wheat		20%
19%	FI adult	185.18	4%	Tomatoes	3%	Potatoes	2%	Coffee beans		19%
7%	IE child	71.21	3%	Wheat	2%	Potatoes	0.8%	Apples	0.0%	7%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 100.5 % of the ADI.
For 1 diet(s) the ADI is exceeded.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

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 2 – Option b

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Potassium Phosponates

LOQs (mg/kg) range from: 0.5 to: 5.0

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: Scenario 2 - Option b – with revised TRV not yet implemented, without MRLs at LOQ

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%	NL toddler	966.22	25%	Apples	11%	Potatoes	10%	Pears		97%
94%	DE child	944.44	29%	Apples	15%	Oranges	10%	Wheat		94%
86%	GEMS/Food G06	859.30	27%	Tomatoes	17%	Wheat	6%	Watermelons		86%
62%	NL child	623.82	13%	Apples	10%	Wheat	9%	Potatoes		62%
60%	RO general	603.29	15%	Tomatoes	12%	Wheat	10%	Potatoes		60%
56%	GEMS/Food G15	558.15	11%	Wheat	10%	Potatoes	9%	Tomatoes		56%
56%	GEMS/Food G08	558.05	11%	Potatoes	9%	Wheat	9%	Tomatoes		56%
54%	GEMS/Food G11	542.55	11%	Potatoes	8%	Wheat	7%	Tomatoes		54%
53%	GEMS/Food G07	532.24	10%	Potatoes	10%	Wheat	8%	Tomatoes		53%
53%	GEMS/Food G10	530.66	10%	Tomatoes	9%	Wheat	8%	Potatoes		53%
52%	FR child 3 15 yr	520.61	13%	Oranges	11%	Wheat	6%	Tomatoes		52%
48%	PT general	477.43	14%	Potatoes	9%	Wheat	7%	Tomatoes		48%
46%	IE adult	462.09	6%	Potatoes	5%	Wheat	4%	Oranges		46%
45%	ES child	447.67	10%	Wheat	8%	Oranges	7%	Tomatoes		45%
44%	SE general	438.28	11%	Potatoes	7%	Wheat	6%	Tomatoes		44%
41%	UK toddler	411.41	9%	Potatoes	9%	Wheat	7%	Oranges		41%
41%	IT toddler	411.14	15%	Wheat	11%	Tomatoes	2%	Potatoes		41%
40%	FR toddler 2 3 yr	398.40	7%	Apples	7%	Wheat	5%	Oranges		40%
40%	DE women 14-50 yr	396.09	7%	Oranges	6%	Apples	6%	Tomatoes		40%
38%	DK child	375.63	10%	Wheat	7%	Potatoes	5%	Apples		38%
36%	DE general	358.93	6%	Oranges	6%	Apples	5%	Tomatoes		36%
33%	NL general	334.12	7%	Potatoes	4%	Wheat	4%	Oranges		33%
33%	FI 3 yr	332.26	13%	Potatoes	4%	Tomatoes	3%	Wheat		33%
33%	IT adult	327.87	10%	Wheat	9%	Tomatoes	2%	Apples		33%
32%	ES adult	324.29	6%	Tomatoes	5%	Wheat	5%	Oranges		32%
31%	UK infant	305.05	9%	Potatoes	6%	Wheat	5%	Oranges		31%
27%	FI 6 yr	273.10	10%	Potatoes	3%	Tomatoes	2%	Wheat		27%
27%	FR adult	272.80	6%	Wine grapes	5%	Wheat	3%	Tomatoes		27%
27%	PL general	266.17	9%	Potatoes	7%	Tomatoes	5%	Apples		27%
26%	UK vegetarian	257.62	5%	Wheat	5%	Tomatoes	4%	Potatoes		26%
23%	LT adult	228.78	9%	Potatoes	5%	Tomatoes	4%	Apples		23%
21%	UK adult	205.51	4%	Wheat	4%	Potatoes	3%	Tomatoes		21%
20%	DK adult	201.93	4%	Tomatoes	3%	Potatoes	3%	Wheat		20%
20%	FR infant	201.05	5%	Potatoes	4%	Apples	2%	Wheat		20%
16%	FI adult	161.24	4%	Tomatoes	3%	Potatoes	2%	Oranges		16%
7%	IE child	69.85	3%	Wheat	2%	Potatoes	0.8%	Apples		7%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Potassium Phosponates
is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

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. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cabbage	7.50	MRL 10 × CF_{MW} 0.75	7.50	MRL 10 × CF_{MW} 0.75
Kale	7.50	MRL 10 × CF_{MW} 0.75	7.50	MRL 10 × CF_{MW} 0.75
Wheat straw	19.78	STMR (EFSA, 2019b)	81.39	HR (EFSA, 2019b)
Potato	26.90	STMR (EFSA, 2019b)	88.60	HR (EFSA, 2019b)
Wheat grain	23.13	STMR (EFSA, 2019b)	23.13	STMR (EFSA, 2019b)
Apple pomace wet[(a)]	25.98	23.20 STMR × 1.12 PF (EFSA, 2018b)	25.98	23.20 STMR × 1.12 PF (EFSA, 2018b)
Citrus dried pulp[(b)]	327.00	32.7 STMR × (10) PF	327,00	32.7 STMR × (10) PF
Distiller's grain dried[(b)]	76.33	23.13 STMR × (3.3) PF (EFSA, 2019b)	76.33	23.13 STMR × (3.3) PF (EFSA, 2019b)
Potato process waste[(a)]	57.84	26.90 STMR × 2.2 PF (EFSA, 2018b)	57.84	26.90 STMR × 2.2 PF (EFSA, 2019b)
Potato dried pulp[(a)]	129.12	26.90 STMR × 4.8 PF (EFSA, 2019b)	129.12	26.90 STMR × 4.8 PF (EFSA, 2019b)
Wheat gluten meal[(b)]	41.63	23.13 STMR × (1.8) PF (EFSA, 2019b)	41.63	23.13 STMR × (1.8) PF (EFSA, 2019b)
Wheat milled by-products[(b)]	161.91	23.13 STMR × (7) PF (EFSA, 2019b)	161.91	23.13 STMR × (7) PF (EFSA, 2019b)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

(a): For apple pomace wet, potato process waste and potato dried pulp, the specific processing factor of 1.12, 2.2 and 4.8, respectively, were included in the calculation to consider the potential concentration of residues in these by-products (EFSA, 2018b, 2019b).

(b): For citrus dried pulp, distiller's grain dried, wheat gluten meal and wheat milled by-products in the absence of processing factors supported by data, default processing factors of 10, 3.3, 1.8 and 7 were respectively included in the calculation to consider the potential concentration of residues in these commodities.

D.2. Consumer risk assessment

Commodity	Existing/ proposed MRL[a]	Source of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment[b]	Input value (mg/kg)	Comment
Risk assessment residue definition: Phosphonic acid and its salts, expressed as phosphonic acid						
Grapefruits	75	Existing MRL	37.69	MRL*CF*PeF	An acute risk assessment was not required as the setting of an ARfD for the active substance was considered not necessary.	
Oranges	75	Existing MRL	37.69	MRL*CF*PeF		
Lemons	150	Intended use	20.27	STMR-RAC*PeF		
Limes	150	Intended use	20.27	STMR-RAC*PeF		
Mandarins	150	Intended use	21.91	STMR-RAC*PeF		
Other citrus fruit	75	Existing MRL	37.69	MRL*CF*PeF		
Almonds	500 (1,500)	EFSA (2020a)	358.50	STMR-RAC		
Brazil nuts	500	EFSA (2018b)	64.50	STMR-RAC		
Cashew nuts	500	EFSA (2018b)	64.50	STMR-RAC		
Chestnuts	500 (1,500)	EFSA (2020a)	358.50	STMR-RAC		
Coconuts	500	EFSA (2018b)	64.50	STMR-RAC		
Hazelnuts/cobnuts	500 (1500)	EFSA (2020a)	358.50	STMR-RAC		
Macadamia	500	EFSA (2018b)	64.50	STMR-RAC		
Pecans	500	EFSA (2018b)	64.50	STMR-RAC		
Pine nut kernels	500	EFSA (2018b)	64.50	STMR-RAC		
Pistachios	500	EFSA (2020a)	64.50	STMR-RAC		
Walnuts	500 (1500)	EFSA (2020a)	358.50	STMR-RAC		
Other tree nuts	500	EFSA (2018b)	64.50	STMR-RAC		
Apples	150	EFSA (2018b)	23.20	STMR-RAC		
Pears	150	EFSA (2018b)	23.20	STMR-RAC		
Quinces	150	EFSA (2018b)	23.20	STMR-RAC		
Medlar	150	EFSA (2018b)	23.20	STMR-RAC		
Loquats/J. medlars	150	EFSA (2018b)	23.20	STMR-RAC		
Other pome fruit	150	EFSA (2018b)	23.20	STMR-RAC		
Peaches	50	EFSA (2018b)	12.51	STMR-RAC		
Table grapes	100	FAO, (2017)	15.50	STMR-RAC		
Wine grapes	100 (200)	EFSA (2020c)	24.10	STMR-RAC		
Strawberries	100	FAO (2017)	11.00	STMR-RAC		
Blackberries	300	EFSA (2018d)	58.20	STMR-RAC		
Raspberries (red and yellow)	300	EFSA (2018d)	58.20	STMR-RAC		
Blueberries	80 (200)	EFSA (2020a)	42.25	STMR-RAC		
Currants (red, black and white)	80 (200)	EFSA (2020a)	42.25	STMR-RAC		
Gooseberries (green, red and yellow)	80 (200)	EFSA (2020a)	42.25	STMR-RAC		
Azarole/ Mediterranean medlar	50	Existing MRL	37.50	MRL*CF		
Elderberries	80	EFSA (2018d)	18.40	STMR-RAC		
Table olives	2 (100)	EFSA (2020c)	23.00	STMR-RAC		
Kaki/Japanese persimmons	50	Existing MRL	37.50	MRL*CF		
Kiwi fruits (green, red, yellow)	150	EFSA (2012c)	23.50	STMR-RAC		

Commodity	Existing/ proposed MRL[a]	Source of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment[b]	Input value (mg/kg)	Comment
Avocados	50 (70)	EFSA (2020c)	14.88	STMR-RAC		
Granate apples/ pomegranates	2 (90)	EFSA (2020a)	25.00	STMR-RAC		
Pineapples	50	Existing MRL	37.50	MRL*CF		
Potatoes	200	EFSA (2019b)	26.9	STMR-RAC		
Celeriacs/turnip-rooted celeries	8	EFSA (2015)	0.21	STMR-RAC		
Horseradishes	2 (200)	EFSA (2020c)	41.18	STMR-RAC		
Radishes	25	EFSA (2009)	7.70	STMR-RAC		
Garlic	2 (30)	EFSA (2020c)	4.40	STMR-RAC		
Onions	50	Existing MRL	37.50	MRL*CF		
Shallots	2 (30)	EFSA (2020c)	4.40	STMR-RAC		
Spring onions/green and Welsh onions	30	Existing MRL	22.50	MRL*CF		
Tomatoes	100	EXISTING MRL	75.00	MRL*CF		
Sweet peppers/bell peppers	130	Existing MRL	97.50	MRL*CF		
Aubergines/egg plants	100	Existing MRL	75.00	MRL*CF		
Cucumbers	80	FAO (2017)	14.00	STMR-RAC		
Gherkins	75	Existing MRL	56.25	MRL*CF		
Courgettes	100	FAO (2017)	25.50	STMR-RAC		
Other cucurbits – edible peel	75	Existing MRL	56.25	MRL*CF		
Melons	75	FAO (2017)	14.00	STMR-P		
Pumpkins	75	Existing MRL	56.25	MRL*CF		
Watermelons	75	Existing MRL	56.25	MRL*CF		
Other cucurbits – inedible peel	75	Existing MRL	56.25	MRL*CF		
Sweet corn	5	Existing MRL	3.75	MRL*CF		
Broccoli	10 (70)	EFSA (2020b)	11.35	STMR-RAC		
Cauliflowers	10 (70)	EFSA (2020b)	11.35	STMR-RAC		
Other flowering brassica	10 (70)	EFSA (2020b)	11.35	STMR-RAC		
Brussels sprouts	10	Existing MRL	7.50	MRL*CF		
Head cabbages	10	Existing MRL	7.50	MRL*CF		
Other head brassica	10	Existing MRL	7.50	MRL*CF		
Chinese cabbages/ pe-tsai	10 (30)	EFSA (2020b)	4.90	STMR-RAC		
Kales	10 (30)	EFSA (2020b)	4.90	STMR-RAC		
Other leafy brassica	10 (30)	EFSA (2020b)	4.90	STMR-RAC		
Kohlrabies	10	Existing MRL	7.50	MRL*CF		
Lamb's lettuce/corn salads	75	Existing MRL	56.25	MRL*CF		
Lettuces	300	FAO (2017)	41.00	STMR-RAC		
Escaroles/broad-leaved endives	75	Existing MRL	56.25	MRL*CF		
Cress and other sprouts and shoots	75	Existing MRL	56.25	MRL*CF		

Commodity	Existing/ proposed MRL[a]	Source of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment[b]	Input value (mg/kg)	Comment
Land cress	75	Existing MRL	56.25	MRL*CF		
Roman rocket/rucola	75	Existing MRL	56.25	MRL*CF		
Red mustards	75	Existing MRL	56.25	MRL*CF		
Baby leaf crops (including brassica spp.)	75	Existing MRL	56.25	MRL*CF		
Other lettuce and other salad plants	75	Existing MRL	56.25	MRL*CF		
Spinaches	75 (300)	EFSA (2020b)	47.00	STMR-RAC		
Chards/beet leaves	15	Existing MRL	11.25	MRL*CF		
Witloofs/BE endives	75	Existing MRL	56.25	MRL*CF		
Chervil	75 (400)	EFSA (2020a)	98.25	STMR-RAC		
Chives	75 (400)	EFSA (2020a)	98.25	STMR-RAC		
Celery leaves	75 (400)	EFSA (2020a)	98.25	STMR-RAC		
Parsley	75 (400)	EFSA (2020a)	98.25	STMR-RAC		
Sage	75 (400)	EFSA (2020a)	98.25	STMR-RAC		
Rosemary	75 (400)	EFSA (2020a)	98.25	STMR-RAC		
Thyme	75 (400)	EFSA (2020a)	98.25	STMR-RAC		
Basil & edible flowers	75 (400)	EFSA (2020a)	98.25	STMR-RAC		
Laurel/bay leaves	75 (400)	EFSA (2020a)	98.25	STMR-RAC		
Tarragon	75 (400)	EFSA (2020a)	98.25	STMR-RAC		
Other herbs	75 (400)	EFSA (2020a)	98.25	STMR-RAC		
Globe artichokes	50	Existing MRL	37.50	MRL*CF		
Leeks	30	Existing MRL	22.50	MRL*CF		
Olives for oil production	2 (100)	EFSA (2020c)	23.00	STMR-RAC		
Wheat	150	EFSA (2019b)	23.13	STMR-RAC		
Chamomile	500	Existing MRL	375.00	MRL*CF		
Hibiscus/roselle	500	Existing MRL	375.00	MRL*CF		
Rose	500	Existing MRL	375.00	MRL*CF		
Jasmine	500	Existing MRL	375.00	MRL*CF		
Lime/linden	500	Existing MRL	375.00	MRL*CF		
Other herbal infusions (dried flowers)	500	Existing MRL	375.00	MRL*CF		
Strawberry leaves	2000	Intended use	380.00	STMR-RAC		
Rooibos	2000	Intended use	380.00	STMR-RAC		
Mate/maté	2000	Intended use	380.00	STMR-RAC		
Other herbal infusions (dried leaves)	2000	Intended use	380.00	STMR-RAC		
Valerian root	500	Existing MRL	375.00	MRL*CF		
Ginseng root	500	Existing MRL	375.00	MRL*CF		
Other herbal infusions (dried roots)	500	Existing MRL	375.00	MRL*CF		
Hops (dried)	2000	FAO, 2017	350.00	STMR-RAC		
Anise/aniseed	400	EFSA (2012c)	74.00	STMR-RAC		

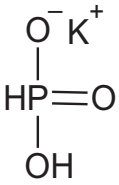
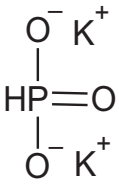
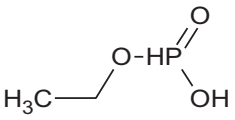
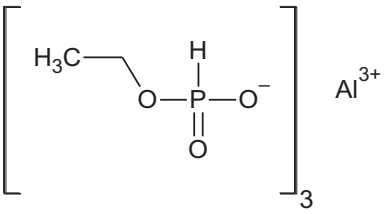
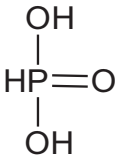
Commodity	Existing/ proposed MRL[a]	Source of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment[b]	Input value (mg/kg)	Comment
Black caraway/black cumin	400	EFSA (2012c)	74.00	STMR-RAC		
Celery seed	400	EFSA (2012c)	74.00	STMR-RAC		
Coriander seed	400	EFSA (2012c)	74.00	STMR-RAC		
Cumin seed	400	EFSA (2012c)	74.00	STMR-RAC		
Dill seed	400	EFSA (2012c)	74.00	STMR-RAC		
Fennel seed	400	EFSA (2012c)	74.00	STMR-RAC		
Fenugreek	400	EFSA (2012c)	74.00	STMR-RAC		
Nutmeg	400	EFSA (2012c)	74.00	STMR-RAC		
Other spices (seeds)	400	EFSA (2012c)	74.00	STMR-RAC		
Allspice/pimento	400	EFSA (2012c)	74.00	STMR-RAC		
Sichuan pepper	400	EFSA (2012c)	74.00	STMR-RAC		
Caraway	400	EFSA (2012c)	74.00	STMR-RAC		
Cardamom	400	EFSA (2012c)	74.00	STMR-RAC		
Juniper berry	400	EFSA (2012c)	74.00	STMR-RAC		
Peppercorn (black, green and white)	400	EFSA (2012c)	74.00	STMR-RAC		
Vanilla pods	400	EFSA (2012c)	74.00	STMR-RAC		
Tamarind	400	EFSA (2012c)	74.00	STMR-RAC		
Other spices (fruits)	400	EFSA (2012c)	74.00	STMR-RAC		
Cinnamon	400	EFSA (2012c)	74.00	STMR-RAC		
Other spices (bark)	400	EFSA (2012c)	74.00	STMR-RAC		
Liquorice	400	EFSA (2012c)	74.00	STMR-RAC		
Turmeric/curcuma	400	EFSA (2012c)	74.00	STMR-RAC		
Other spices (roots)	400	EFSA (2012c)	74.00	STMR-RAC		
Cloves	400	EFSA (2012c)	74.00	STMR-RAC		
Capers	400	EFSA (2012c)	74.00	STMR-RAC		
Other spices (buds)	400	EFSA (2012c)	74.00	STMR-RAC		
Saffron	400	EFSA (2012c)	74.00	STMR-RAC		
Other spices (flower stigma)	400	EFSA (2012c)	74.00	STMR-RAC		
Mace	400	EFSA (2012c)	74.00	STMR-RAC		
Other spices (aril)	400	EFSA (2012c)	74.00	STMR-RAC		
Chicory roots	75	Existing MRL	56.25	MRL*CF		
Swine: Muscle/meat	0.7	EFSA (2019b)	0.50	STMR-RAC		
Swine: Fat tissue	1.5	EFSA (2019b)	0.38	STMR-RAC		
Swine: Liver	0.8	EFSA (2019b)	0.24	STMR-RAC		
Swine: Kidney	6	EFSA (2019b)	1.69	STMR-RAC		
Swine: Edible offal (other than liver and kidney)	6	EFSA (2019b)	1.69	STMR-RAC		
Bovine: Muscle/meat	0.7	EFSA (2019b)	0.50	STMR-RAC		
Bovine: Fat tissue	1.5	EFSA (2019b)	0.59	STMR-RAC		
Bovine: Liver	1.5	EFSA (2019b)	0.38	STMR-RAC		
Bovine: Kidney	8	EFSA (2019b)	2.66	STMR-RAC		
Bovine: Edible offal (other than liver and kidney)	8	EFSA (2019b)	2.66	STMR-RAC		

Commodity	Existing/ proposed MRL[a]	Source of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment[b]	Input value (mg/kg)	Comment
Sheep: Muscle/meat	0.7	EFSA (2019b)	0.50	STMR-RAC		
Sheep: Fat tissue	1.5	EFSA (2019b)	0.64	STMR-RAC		
Sheep: Liver	1.5	EFSA (2019b)	0.40	STMR-RAC		
Sheep: Kidney	8	EFSA (2019b)	3.07	STMR-RAC		
Sheep: Edible offal (other than liver and kidney)	8	EFSA (2019b)	3.07	STMR-RAC		
Goat: Muscle/meat	0.7	EFSA (2019b)	0.50	STMR-RAC		
Goat: Fat tissue	1.5	EFSA (2019b)	0.64	STMR-RAC		
Goat: Liver	1.5	EFSA (2019b)	0.40	STMR-RAC		
Goat: Kidney	8	EFSA (2019b)	3.07	STMR-RAC		
Goat: Edible offal (other than liver and kidney)	8	EFSA (2019b)	3.07	STMR-RAC		
Equine: Liver	0.5	Existing MRL	0.375	MRL*CF		
Equine: Kidney	0.5	Existing MRL	0.375	MRL*CF		
Equine: Edible offal (other than liver and kidney)	0.5	Existing MRL	0.375	MRL*CF		
Poultry: Muscle/meat	0.7	EFSA (2019b)	0.50	STMR-RAC		
Poultry: Fat tissue	0.7	EFSA (2019b)	0.50	STMR-RAC		
Poultry: Liver	0.7	EFSA (2019b)	0.50	STMR-RAC		
Poultry: Edible offal (other than liver and kidney)	0.7	EFSA (2019b)	0.50	STMR-RAC		
Other farmed animals: Liver	0.5	Existing MRL	0.38	MRL*CF		
Other farmed animals: Kidney	0.5	Existing MRL	0.38	MRL*CF		
Other farmed animals: Edible offal (other than liver and kidney)	0.5	Existing MRL	0.38	MRL*CF		
Milk: Cattle	0.5	EFSA (2019b)	0.15	STMR-RAC		
Milk: Sheep	0.5	EFSA (2019b)	0.15	STMR-RAC		
Milk: Goat	0.5	EFSA (2019b)	0.15	STMR-RAC		
Milk: Horse	0.5	EFSA (2019b)	0.15	STMR-RAC		
Milk: Others	0.5	EFSA (2019b)	0.15	STMR-RAC		
Eggs: Chicken	0.7	EFSA (2019b)	0.50	STMR-RAC		
Eggs: Duck	0.7	EFSA (2019b)	0.50	STMR-RAC		
Eggs: Goose	0.7	EFSA (2019b)	0.50	STMR-RAC		
Eggs: Quail	0.7	EFSA (2019b)	0.50	STMR-RAC		
Eggs: Others	0.7	EFSA (2019b)	0.50	STMR-RAC		
Other commodities/ products	LOQs	In Scenario 2 – Option b of the consumer 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.				

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

(a): According to Draft Commission Regulation SANTE/11822/2019 revising MRLs in potatoes, wheat and products of animal origin (EFSA, 2019b, 2020a,b,c, 2021) which has been voted at the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals (SCoPAFF)– Residues held on 26–27 September 2019. The regulation is not yet published in the Official Journal of the European Union. MRLs (in brackets) were proposed by EFSA based on GAPs of potassium phosphonates (EFSA, 2020a,b,c,) but are not yet discussed at the SCoPAFF.
(b): Existing MRLs/LOQs were expressed as phosphonic acid by applying the molecular weight conversion factor (CF) of 0.75.

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).