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Modification of the existing maximum residue levels for fosetyl/phosphonic acid in apricots, cherries and plums resulting from the use of potassium phosphonates

EFSA (European Food Safety Authority),
Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, German Giner, Luna Greco, Samira Jarrah, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant LAINCO S.A. submitted a request to the competent national authority in Greece to modify the existing maximum residue levels (MRLs), currently expressed as fosetyl in the MRL Regulation, resulting from the use of the active substance potassium phosphonates on apricots, cherries and plums. The data submitted in support of the request were found to be sufficient to derive MRL proposals and address the data gap for residue trials compliant with the Southern EU uses identified in the joint MRL review for cherries and plums, but insufficient for apricots. Adequate analytical methods for enforcement are available to control the residues on the commodities under consideration. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the uses of potassium phosphonates according to the intended agricultural practices is unlikely to present a risk to consumer health.

Keywords: potassium phosphonates, phosphonic acid, fosetyl, stone fruits, fungicide, MRL, consumer risk assessment

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Correspondence: pesticides.mrl@efsa.europa.eu

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, LAINCO S.A. submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to modify maximum residue levels (MRLs), currently expressed as fosetyl in the MRL Regulation, resulting from the use of the active substance potassium phosphonates on apricots, cherries and plums. 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. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRLs, expressed as fosetyl, from the limit of quantification (LOQ) of 2 to 10 mg/kg for cherries and plums, whereas no proposal was made for apricots.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested from the EMS. On 19 October 2021, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated in the EFSA joint review of MRLs for fosetyl, disodium phosphonates and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005 (hereafter, joint MRL review), the assessments issued after the joint MRL review and considering the additional information provided by the EMS in the framework of this MRL application, the following conclusions are derived.

In the recent joint MRL review assessment, it was confirmed that data from public literature provide sufficient evidence to address the metabolism of potassium phosphonates in plants. In primary crops and in rotational crops, phosphonic acid is expected to be the main residue. The metabolite phosphonic acid is hydrolytically stable under standard processing conditions representative of pasteurisation, baking/brewing/boiling and sterilisation. Phosphonic acid is also the predominant metabolite of the closely related fungicides fosetyl and disodium phosphonate.

Based on the metabozlic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of the metabolite phosphonic acid, the joint MRL review and the EU pesticides peer review on potassium phosphonates proposed a residue definition in plant products as 'phosphonic acid and its salts, expressed as phosphonic acid' for both enforcement and risk assessment. The proposed enforcement residue definition has not been legally endorsed yet. The existing 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)'. The residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concludes that for the crops assessed in the present application, the metabolism of potassium phosphonates in primary crops and the possible degradation in processed products has been sufficiently addressed and that the residue definitions as proposed by the joint MRL review are applicable.

Sufficiently validated analytical methods are available to quantify residues in the crops under assessment according to the existing residue definition for enforcement 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)' with an LOQ of 0.01 mg/kg. These methods also allow the monitoring of residues expressed in accordance with the residue definition for enforcement 'phosphonic acid and its salts, expressed as phosphonic acid' derived in the joint MRL review and the EU pesticides peer review at or below the LOQ of 0.1 mg/kg.

The available residue trials are sufficient to derive MRL proposals for cherries and plums according to the existing and the proposed residue definitions for enforcement derived in the joint MRL review and the EU pesticides peer review. An MRL cannot be proposed for apricots since the intended use is not sufficiently supported by residue data. Residue data from cherries and plums address the data gaps for residue trials compliant with the Southern EU uses of potassium phosphonates identified in the joint MRL review.

Considering the low contribution of phosphonic acid residues resulting from the intended uses to the total chronic consumers' exposure, specific studies investigating the magnitude of residues in processed commodities were not deemed necessary.

As the intended uses of potassium phosphonates are on permanent crops, investigations of residues in rotational crops are not required. Residues of phosphonic acid in commodities of animal origin were also not assessed since the crops under consideration in the present MRL application are normally not fed to livestock.

The toxicological profile of potassium phosphonates was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an

acceptable daily intake (ADI) of 2.25 mg/kg body weight (bw) per day for phosphonic acid. An acute reference dose (ARfD) was deemed unnecessary. In the framework of the renewal of the approval for fosetyl, a revised ADI of 1 mg/kg bw per day has been derived, which was also recommended to be applied to phosphonic acid. Although this new ADI is not formally adopted yet, an indicative risk assessment was calculated based on this reference value as well.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the joint MRL review, a comprehensive long-term exposure assessment was performed considering residue data originating from the authorised uses of fosetyl (formulated as its aluminium salt), disodium phosphonate and potassium phosphonates, monitoring data as well as certain CXLs established for fosetyl-Al and phosphonic acid. EFSA updated these calculations with the relevant supervised trials median residue (STMR) values derived from the residue trials on cherries and plums submitted in support of the present MRL application and with the STMRs derived in the EFSA reasoned opinions on the modification of the existing MRLs in lemons, limes, mandarins and herbal infusions from leaves and herbs and in chards/beet leaves and honey.

Provided that the existing MRLs will be amended as proposed in the joint MRL review and in the EFSA reasoned opinion on chards/beet leaves and honey the estimated long-term dietary intake considering the currently applicable ADI of 2.25 mg/kg bw per day, accounted for 36% of the ADI (Dutch toddler diet). Expressing the exposure as percentage of the revised ADI of 1 mg/kg bw per day as proposed by the EU pesticides peer review, the highest chronic exposure was calculated at 81% of the ADI (Dutch toddler diet). The contribution of residues in the cherries and plums to the total long-term consumer intake was individually below 0.10% of the ADI, for both scenarios.

EFSA concludes that the proposed uses of potassium phosphonates on cherries and plums will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

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

Full details of all end points 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) (Joint MRL review)[b]		Proposed EU MRL (mg/kg) Present assessment		Comment/justification
RD-1: Existing enforcement residue definition: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) **RD-2: Proposed new enforcement residue definition (not yet implemented):** Phosphonic acid and its salts, expressed as phosphonic acid								
0140010	Apricots	RD-1	2*	RD-2	(60)	No MRL proposal		The submitted data are insufficient to derive an MRL proposal for the SEU use.
0140020	Cherries (sweet)	RD-1	2*	RD-2	(2[c])	RD-2 RD-1	8 10	The submitted data are sufficient to derive an MRL proposal for the SEU use. These data address the data gap for residue trials compliant with the SEU use identified in the joint MRL review. Risk for consumers unlikely.
0140040	Plums	RD-1	2*	RD-2	(1[c])	RD-2 RD-1	8 10	The submitted data are sufficient to derive an MRL proposal for the SEU use. These data address the data gap for residue trials compliant with the SEU use identified in the joint MRL review. Risk for consumers unlikely.

MRL: maximum residue level; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): MRL in brackets were derived in the framework of the EFSA joint review of MRLs for fosetyl, disodium phosphonates and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005 (joint MRL review) but are not discussed for implementation in the EU MRL legislation yet.
(c): MRL was derived from available monitoring data.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRL), expressed as fosetyl in the MRL Regulation, resulting from the use of the active substance potassium phosphonates on apricots, cherries and plums. The detailed description of the intended uses of potassium phosphonates which are the basis for the current MRL application is reported in Appendix A.

Potassium phosphonates is the name commonly used for the mixture of potassium hydrogen phosphonate and dipotassium phosphonate. The chemical structures of the components of the active substance and related compounds are reported in Appendix E.

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

The EU MRLs related to the use of potassium phosphonates are established in Annex IIIA 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)'. Hence, the existing MRLs cover not only the uses of potassium phosphonates but also the uses of fosetyl and disodium phosphonate.

A joint review of MRLs for the three active substances (fosetyl, disodium phosphonate and potassium phosphonates) in accordance with Articles 12 and 43 of Regulation (EC) No 396/2005 (hereafter, joint MRL review) has been performed recently (EFSA, 2021b); the proposed modifications have not been implemented in the EU MRL legislation yet. It is noted that other modifications of the existing MRLs proposed by EFSA (2021a) have been voted at the Standing Committee on Plants, Animals, Food and Feed (PAFF), but the draft regulation (SANTE/10884/2021) is not implemented in the MRL legislation. Additionally, EFSA proposed other MRL modifications (EFSA, 2021c,d) which are not discussed in the PAFF Committee yet. Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation[4].

In accordance with Article 6 of Regulation (EC) No 396/2005, LAINCO S.A. submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to modify maximum residue levels (MRLs) resulting from the use of the active substance potassium phosphonates on apricots, cherries and plums. 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. To accommodate for the intended SEU uses of potassium phosphonates, the EMS proposed to raise the existing MRLs, expressed as fosetyl, from the limit of quantification (LOQ) of 2–10 mg/kg for cherries and plums, whereas no proposal was made for apricots because the intended use was not sufficiently supported by residue data.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested from the EMS. On 19 October 2021, the EMS submitted a revised evaluation report (Greece, 2020), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Greece, 2020), the DAR on potassium phosphonates and its addendum (France, 2005, 2012) prepared under Directive 91/414/EEC and the revised renewal assessment report (RAR) on fosetyl (France, 2018) prepared under Regulation (EU) No 1107/2009[5], the Commission review report on potassium phosphonates (European

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, 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, 23.04.2013, 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, 16.03.2005, p. 1–16.

[4] 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, 05.04.2019, p. 6–49.

[5] 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.

Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substances potassium phosphonates (EFSA, 2012) and fosetyl (EFSA, 2018c), the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005 (EFSA, 2021c) and on the conclusions from the EFSA reasoned opinions issued after the joint MRL review (EFSA, 2021c,d).

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2010a,b, 2017a,b; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[7].

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

The evaluation report submitted by the EMS (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 (EFSA, 2012) and reconsider during the joint MRL review (EFSA, 2021b). It was concluded that data from the public literature are sufficient to address the metabolism in plants which mainly involves the transformation of potassium phosphonate salts into phosphonic acid. No further studies on the metabolism of potassium phosphonates in primary crops were submitted in the present MRL application and are required.

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

1.1.2. Nature of residues in rotational crops

As the proposed uses of potassium phosphonates are on permanent crops, further investigation of nature of residues in rotational crops is not required (European Commission, 1997c). Although not required, information on the nature of residues in rotational crops is available (see Appendix B.1.1.1).

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of phosphonic acid, which is the main metabolite of potassium phosphonates, was investigated in the framework of the EU pesticides peer review for potassium phosphonates and fosetyl (EFSA, 2012, 2018c) and reconsidered in the joint MRL review (EFSA, 2021b). These studies showed that phosphonic acid is hydrolytically stable under standard processing conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of residues of potassium phosphonates measured as phosphonic acid and as fosetyl in the crops under assessment were assessed during the EU pesticides peer review of potassium phosphonates and fosetyl and the joint MRL review (EFSA, 2012, 2018c, 2021b).

Sufficiently validated methods using high-performance liquid chromatography coupled with tandem mass spectrometry (HPLC-MS/MS) are available to determine residues of phosphonic acid in high water content matrices, to which apricots, cherries and plums belong. The methods allow quantifying

[6] 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.

[7] 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.

residues at or above the LOQ of 0.1 mg/kg. During routine analysis, phosphonic acid can be enforced with an LOQ of 0.1 mg/kg in high water content commodities by means of a single residue method (Quick Polar Pesticides Method – QuPPe) using liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS) (EFSA, 2021b).

Moreover, the methods allow quantification of residues according to the current residue definition 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)' in high water content commodities with an LOQ of 0.01 mg/kg.

Extraction efficiency data for the analytical methods applied for enforcement according to the requirements of the extraction efficiency guidance, SANTE 2017/10632 (European Commission, 2017b) are not available. To be noted that metabolism studies testing potassium phosphonates in plants with extraction of radio-labelled phosphonic acid are not available. Due to the high and rapid solubility in water, extraction with solvents containing water seems adequately dissolving potassium phosphonates. Nevertheless, EFSA would recommend reconsidering this point in the framework of the peer review for the renewal of approval of the active substance.

1.1.5. Storage stability of residues in plants

All available information on the stability of residues under frozen conditions were collected by the joint MRL review (EFSA, 2021b). It was demonstrated that in high water content commodities, to which the crops assessed in the framework of the present application belong, residues of phosphonic acid are stable for at least 25 months when stored at a temperature range of –18 to –25°C. No further storage stability studies were submitted in the present MRL application and are not required.

1.1.6. Proposed residue definitions

In the joint MRL review, the following residue definitions for plant commodities were proposed for the residues resulting from the use of potassium phosphonates (EFSA, 2021b):

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

The proposed residue definition for enforcement has not been implemented in Regulation (EC) No 396/2005 yet. The current MRLs established in this regulation refer to the residue definition as:

- Residue definition for enforcement: 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.

In the current reasoned opinion, EFSA will derive MRL proposals according to both the revised and the existing residue definitions for enforcement.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the present MRL application, the applicant submitted residue trials performed on apricots, peaches, cherries and plums. The samples collected from these trials were analysed for phosphonic acid. To derive MRL proposals for the existing enforcement residue definition, the individual results were recalculated as fosetyl using a conversion factor of 1.34 based on molecular weights[8]. According to the assessment of the EMS, the analytical methods used were sufficiently validated and fit for purpose. The samples of the residue trials submitted were stored under conditions for which integrity has been demonstrated (Greece, 2020).

1.2.1.1. Apricots

To support the intended SEU use, the applicant submitted the results of eight good agricultural practice (GAP)-compliant residue trials on apricots (4) and peaches (4) conducted over two seasons. The proposed extrapolation of residue data from peaches to apricots is acceptable

[8] Conversion factor based on molecular weight ratio (fosetyl/phosphonic acid) (110 g/mol)/82 g/mol)

(European Commission, 2017a). Significant residues of phosphonic acid were reported in the untreated samples from one trial on peaches (coded as SRIT17-110-061FR). A history of use of a fertiliser containing phosphonic acid was recorded on the plot more than 12 months before the start of the trial, which may justify the presence of extremely high amounts of phosphonic acid in untreated samples (12.7 and 7.78 mg/kg just after treatment and 14 days after the last application in the corresponding treated sample, respectively). EFSA agrees with the conclusion of the EMS that this trial is not representative for the intended use and its result was disregarded (Greece, 2020).

Due the rejection of one trial, the total number of valid trials (7) is not sufficient to derive an MRL proposal for apricots, which is a major crop in the SEU (European Commission, 2017b).

Cherries

To support the intended SEU use, the applicant submitted the results of four GAP-compliant residue trials on cherries conducted over two seasons. The number of valid trials is sufficient to derive an MRL proposal for cherries, which are minor crop in the SEU (European Commission, 2017b).

Plums

To support the intended SEU use, the applicant submitted the results of eight GAP-compliant residue trials on plums conducted over two seasons. The number of valid trials is sufficient to derive an MRL proposal for plums, which are major crop in the SEU (European Commission, 2017b).

1.2.2. Magnitude of residues in rotational crops

As the proposed uses of potassium phosphonates are on permanent crops, investigations of residues in rotational crops are not required (European Commission, 1997c).

1.2.3. Magnitude of residues in processed commodities

Although phosphonic acid residues are expected to occur in significant amounts (above 0.1 mg/kg) in unprocessed commodities under assessment, considering the low individual contribution of phosphonic acid residues to the total chronic consumers' exposure, specific studies investigating the magnitude of residues in processed commodities were not deemed necessary (European Commission, 1997d).

The results of processing studies with destoned peaches processed into jam, puree, nectar and canned peaches assessed in a previous EFSA opinion indicated that residues of phosphonic acid decrease in jam and puree (50% reduction) and remain stable in nectar and canned fruit (EFSA, 2018b).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for cherries and plums, except for apricots (see Appendix B).

In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses of potassium phosphonates are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as the crops under assessment are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019). This exposure assessment model contains food consumption data for different subgroups 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 of potassium phosphonates was assessed in the framework of the EU pesticides peer review (EFSA, 2012). For phosphonic acid, which is the relevant component of residues in plant and animal products, an acceptable daily intake (ADI) of 2.25 mg/kg bw per day was derived (European Commission, 2013). In 2018, in the framework of the renewal of the approval for fosetyl, a revised ADI of 1 mg/kg bw per day has been derived, which was also recommended to be applied to

phosphonic acid (EFSA, 2018c). Although this new ADI is not yet formally adopted, an indicative risk assessment was calculated based on this reference value as well.

Short-term (acute) dietary risk assessment

Considering the toxicological profile of the active substance, a short-term dietary risk assessment is not required.

Long-term (chronic) dietary risk assessment

In the framework of the joint MRL review, a comprehensive long-term exposure assessment was performed taking into account consumer exposure to residues originating from the uses of fosetyl (formulated as its aluminium salt), disodium phosphonate and potassium phosphonates as plant protection products, monitoring data as well as certain CXLs established for fosetyl-Al and phosphonic acid (EFSA, 2021b).

EFSA updated these calculations with the relevant STMR values derived from the residue trials on cherries and plums submitted in support of the present MRL application and with the STMRs derived in the EFSA opinions on the modification of the existing MRLs in lemons, limes, mandarins and herbal infusions from leaves and herbs and in chards/beet leaves and honey (EFSA, 2021a,d). The input values used in the exposure calculations are summarised in Appendix D.1.

Provided that that the existing MRLs will be amended as proposed by the joint MRL review and the reasoned opinion on chards/beet leaves and honey, the estimated long-term dietary intake considering the currently applicable ADI of 2.25 mg/kg bw per day (**scenario 1**), accounted for 36% of the ADI (Dutch toddler diet). Expressing the exposure as percentage of the revised ADI of 1 mg/kg bw per day as proposed by the EU pesticides peer review (**scenario 2**), the highest chronic exposure was calculated at 81% of the ADI (Dutch toddler diet). The contribution of the expected residues in cherries and plums to the total long-term consumer intake was individually below 0.10% of the ADI, for both scenarios (See Appendix B.3).

EFSA concludes that the proposed uses of potassium phosphonates on cherries and plums will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found sufficient to derive an MRL proposal for cherries and plums, but insufficient for apricots. Residue data from cherries and plums address the data gaps for residue trials compliant with the Southern EU uses of potassium phosphonates identified in the joint MRL review (EFSA, 2021b).

Based on the risk assessment results, EFSA concludes that the long-term intake of residues resulting from the uses of potassium phosphonates according to the intended agricultural practices is unlikely to present a risk to consumer health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EMS	evaluating Member State
Eq	residue expressed as a.s. equivalent
ESI	electrospray ionisation
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
FPD	flame photometric detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FPD	gas chromatography with flame photometric detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GLP	Good Laboratory Practice
GR	Granule
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
HPLC-UVD	High-performance liquid chromatography with ultra-violet detector
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
IPCS	International Programme of Chemical Safety
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
NOAEL	no observed adverse effect level
NPD	nitrogen/phosphorous detector
OECD	Organisation for Economic Co-operation and Development
PAFF	Standing Committee on Plants, Animals, Food and Feed
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number max	Interval between application (days) min–max	g a.s./hL max	Water (L/ha) min–max	Rate min–max	Unit		
Apricots	SEU	F	*Phytophthora* spp.	SC	Potassium phosphonates 406.8 g/L (255 g/L phosphonic acid equivalents)	Foliar treatment – broadcast spraying	1st appl: BBCH 91–92 (autumn) 2nd appl: BBCH 60–69 (spring) 3rd appl: BBCH 70–81 (summer)	3	1st and 2nd appl: not needed (early applications) 2nd and 3rd appl: covered by time between BBCH 60–69 and BBCH 70–81	122 (76.5 as phosphonic acid equivalents)	300–1000	366.1–1220.4 (230–765 as phosphonic acid equivalents)	g a.s./ha	15	Spray concentration: 300 mL/hL
Cherries (sweet)	SEU	F	*Phytophthora* spp.	SC	Potassium phosphonates 406.8 g/L (255 g/L phosphonic acid equivalents)	Foliar treatment – broadcast spraying	1st appl: BBCH 91–92 (autumn) 2nd appl: BBCH 60–69 (spring) 3rd appl: BBCH 70–81 (summer)	3	1st and 2nd appl: not needed (early applications) 2nd and 3rd appl: covered by time between BBCH 60–69 and BBCH 70–81	122 (76.5 as phosphonic acid equivalents)	300–1000	366.1–1,220.4 (230–765 as phosphonic acid equivalents)	g a.s./ha	15	Spray concentration: 300 mL/hL

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number max	Interval between application (days) min–max	g a.s./hL max	Water (L/ha) min–max	Rate min–max	Unit		
Plums	SEU	F	*Phytophthora* spp.	SC	Potassium phosphonates 406.8 g/L (255 g/L phosphonic acid equivalents)	Foliar treatment – broadcast spraying	1st appl: BBCH 91–92 (autumn) 2nd appl: BBCH 60–69 (spring) 3rd appl: BBCH 70–81 (summer)	3	1st and 2nd appl: not needed (early applications) 2nd and 3rd appl: covered by time between BBCH 60–69 and BBCH 70–81	122 (76.5 as phosphonic acid equivalents)	300–1000	366.1–1,220.4 (230–765 as phosphonic acid equivalents)	g a.s./ha	15	Spray concentration: 300 mL/hL

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; SC: suspension concentrate; a.s.: active substance.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application (s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	No experimental studies submitted. The EU pesticides peer review concluded that, given the elementary nature of potassium phosphonates and according to the available data from public literature, the main residue resulting from the foliar and soil applications of potassium phosphonates in plants is phosphonic acid (EFSA, 2012).			
	Root crops				
	Leafy crops				
	Cereals/grass				
	Pulses/ oilseeds				
	Miscellaneous				
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application (s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish		32; 182	No experimental studies submitted for potassium phosphonates. Bridging data on studies with fosetyl (EFSA, 2018c) considered sufficient to assess the nature of potassium phosphonates in rotational crops. Residues of phosphonic acid are observed in plants grown only 1 month after application to the soil. Radish root: 0.8 mg/kg Lettuce: 0.76 mg/kg In all other parts of the crop phosphonic acid residues < LOQ of 0.5 mg/kg. (EFSA, 2021b).
	Leafy crops	Lettuce		32	
	Cereals (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 fosetyl (EFSA, 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 (2021b)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2021b)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2021b)
Plant residue definition for monitoring (RD-Mo)	Existing residue definition (Regulation (EC) No 396/2005): Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl Proposed residue definition (not implemented yet): Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012, 2021b)	
Plant residue definition for risk assessment (RD-RA)	Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012, 2021b)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	• HPLC–MS/MS (matrices: high water, dry/high starch, high acid, high oil). ILV provided and validated. Analyte fosetyl, LOQ: 0.01 mg/kg Analyte phosphonic acid, LOQ: 0.1 mg/kg (EFSA, 2021b) • LC–MS/MS Single (QuPPe) residue method for enforcement in routine analysis (matrices: high water and high acid) Analyte phosphonic acid, LOQ: 0.1 mg/kg (EFSA, 2021b) (matrices: high oil, dry) Analyte phosphonic acid, LOQ: 0.2 mg/kg (EFSA, 2021b) • GC-FPD (hops) Analyte fosetyl, LOQ: 2 mg/kg Analyte phosphonic acid, LOQ: 20 mg/kg (EFSA, 2021b)	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuPPE: quick polar pesticides method; GC-FPD: gas chromatography with flame photometric detector.

B.1.1.2. Stability of residues in plants

Plant product (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	High water content	Cucumbers	−18 to −25	25	Months	Phosphonic acid and its salts expressed as phosphonic acid.	EFSA (2021b)
		Lettuces		24	Months	Phosphonic acid and its salts expressed as phosphonic acid.	EFSA (2021b)
		Head cabbages		24	Months	Phosphonic acid and its salts expressed as phosphonic acid.	EFSA (2021b)
		Cherry tomatoes		24	Months	Phosphonic acid and its salts expressed as phosphonic acid.	EFSA (2021b)
		Wheat, whole plants		12	Months	Phosphonic acid	EFSA (2021b)
		Apples		12	Months	Phosphonic acid	EFSA (2021b)
		Peaches		307	Days	Phosphonic acid	EFSA (2021b)

Plant product (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	High oil content	Avocados		25	Months	Phosphonic acid and its salts expressed as phosphonic acid.	EFSA (2021b)
		Almonds		218	Days	Phosphonic acid	EFSA (2021b)
		Pistachios		221	Days	Phosphonic acid	EFSA (2021b)
		Walnuts		146	Days	Phosphonic acid	EFSA (2021b)
	High protein content	Beans, dry		24	Months	Phosphonic acid and its salts expressed as phosphonic acid.	EFSA (2021b)
	High starch content	Potatoes		25	Months	Phosphonic acid and its salts expressed as phosphonic acid.	EFSA (2021b)
				12	Months	Phosphonic acid	EFSA (2021b)
		Wheat, grain		12	Months	Phosphonic acid	EFSA (2021b)
	High acid content	Grapes		25	Months	Phosphonic acid and its salts expressed as phosphonic acid.	EFSA (2021b)
		Oranges		24	Months	Phosphonic acid and its salts expressed as phosphonic acid.	EFSA (2021b)
	Processed products	Peach jam, puree, nectar and canned peaches		112–114	Days	Phosphonic acid	EFSA (2021b)
	Others	Wheat, straw		12	Months	Phosphonic acid	EFSA (2021b)

B.1.2. Magnitude of residues in plants

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

Commodity	Region[a]	Residue levels observed in the supervised residue trials[b] (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[c] (mg/kg)	STMR[d] (mg/kg)	CF[e]
Residue definition for enforcement (no implemented yet): Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2021b) **Residue definition for risk assessment (RD-RA):** Phosphonic acid and its salts, expressed as phosphonic acid **Residue definition for enforcement (existing RD-Mo)[e]:** Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) (Reg (EC) No 396/2005)							
Apricots	SEU	RD-Mo as phosphonic acid: < 1.00; 1.21; 2.02; 3.67; 4.10; 4.37; 4.56 RD-Mo as fosetyl: < 1.34; 1.62; 2.70; 4.92; 5.49; 5.86; 6.11	Insufficient number of residue trials on apricots and peaches (underlined) compliant with the GAP on apricots. Extrapolation of residues from peaches to apricots possible, but not supported by a sufficient number of residue data.	–	RD-RA: 4.56	RD-RA: 3.67	–
Cherries	SEU	RD-Mo as phosphonic acid: 1.62; 2.16; 2.84; 3.18 RD-Mo as fosetyl: 2.16; 2.89; 3.80; 4.27	Residue trials on cherries compliant with the GAP.	RD-Mo as phosphonic acid: 8 RD-Mo as fosetyl: 10	RD-RA: 3.18	RD-RA: 2.50	–
Plums	SEU	RD-Mo as phosphonic acid: 2 × < 1.00; 1.21; 1.65; 1.89; 1.98; 3.23; 4.56 RD-Mo as fosetyl: 2 × < 1.34; 1.62; 2.21; 2.53; 2.65; 4.33; 6.10	Residue trials on plums compliant with the GAP.	RD-Mo as phosphonic acid: 8 RD-Mo as fosetyl: 10	RD-RA: 4.56	RD-RA: 1.77	–

MRL: maximum residue level; GAP: Good Agricultural Practice; RD: residue definition; Mo: monitoring; RA: risk assessment.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.
(b): Individual residue values measured as phosphonic acid were recalculated to express them as fosetyl by a molecular weight (MW) conversion factor of 1.34 - MW fosetyl (110 g/mol)/MW phosphonic acid (82 g/mol).
(c): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	As the proposed uses of potassium phosphonates are on permanent crops, investigations of residues in rotational crops are not required.
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Not relevant as the crops under assessment are not used for feed purposes.

B.3. Consumer risk assessment

ARfD	ARfD not relevant (European Commission, 2013)
Highest IESTI, according to EFSA PRIMo	-
Assumptions made for the calculations	-

ADI	**Scenario 1:** 2.25 mg/kg bw per day (European Commission, 2013) - (TRV currently in place) **Scenario 2:** 1 mg/kg bw per day (EFSA, 2018c) - (TRV not yet endorsed).
Highest IEDI, according to EFSA PRIMo	**Scenario 1** 36% ADI (Dutch toddler diet) Contribution of crops assessed: Cherries (sweet): 0.042% of ADI (German child diet) Plums: 0.022% of ADI (GEMS/Food G15 diet) **Scenario 2** 81% ADI (Dutch toddler diet) Contribution of crops assessed: Cherries(sweet): 0.095% of ADI (German child diet) Plums: 0.049% of ADI (GEMS/Food G15 diet)
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities under consideration in the present application (cherries, plums) and the input values derived in the framework of the joint MRL review (EFSA, 2021b) and in the EFSA opinions on the modification of the existing MRLs in lemons, limes, mandarins and herbal infusions from leaves and herbs and in chards/beet leaves and honey (EFSA, 2021a,d), noting that none of these proposals are so far implemented in the MRL legislation. The following peeling factors were used: for citrus 0.73 (EFSA, 2021c); for avocados 1.1, pineapples 0.83 and cucurbits with inedible peel 0.93 (EFSA, 2021b).

Consumer risk assessment assumed that existing MRLs will be revised as recommended by the joint MRL review and the related EFSA opinions (EFSA, 2021b,d) Calculations performed with PRIMo revision 3.1

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)		Proposed EU MRL (mg/kg) (Joint MRL review)[(b)]		Proposed EU MRL (mg/kg) Present assessment		Comment/justification
RD-1: Existing enforcement residue definition: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) **RD-2: Proposed new enforcement residue definition (not yet implemented):** Phosphonic acid and its salts, expressed as phosphonic acid								
0140010	Apricots	RD-1	2*	RD-2	(60)	No MRL proposal		The submitted data are insufficient to derive an MRL proposal for the SEU use.
0140020	Cherries (sweet)	RD-1	2*	RD-2	(2[(c)])	RD-2 RD-1	8 10	The submitted data are sufficient to derive an MRL proposal for the SEU use. These data address the data gap for residue trials compliant with the SEU use identified in the joint MRL review. Risk for consumers unlikely.
0140040	Plums	RD-1	2*	RD-2	(1[(c)])	RD-2 RD-1	8 10	The submitted data are sufficient to derive an MRL proposal for the SEU use. These data address the data gap for residue trials compliant with the SEU use identified in the joint MRL review. Risk for consumers unlikely.

MRL: maximum residue level; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): MRL in brackets were derived in the framework of the EFSA joint review of MRLs for fosetyl, disodium phosphonates and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005 (joint MRL review) but are not discussed for implementation in the EU MRL legislation yet.
(c): MRL was derived from available monitoring data.

Appendix C – Pesticide Residue Intake Model (PRIMo)

- Scenario 1

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Phosphonic acid (resulting from use of fosetyl, potassium and disodium phosphonates)

LOQs (mg/kg) range from: 0.1 to: 0.10

Toxicological reference values

ADI (mg/kg bw per day):	2.25	ARfD (mg/kg bw):	not necessary
Source of ADI:	European	Source of ARfD:	European Commision
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: Assuming MRLs will be amended as proposed in the RO on the joint review of MRLs for fosetyl, disodium phosphonates and potassium phosphonates according to Article 12 and 43 of Regulation (EC) No 396/2005 and the RO on the modification of the MRLs in chards/beet leaves and honey (not yet discussed in

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	36%	NL toddler	813.86	10%	Apples	5%	Potatoes	4%	Wheat		36%
	34%	DE child	755.97	11%	Apples	4%	Wheat	3%	Potatoes		34%
	24%	NL child	544.38	5%	Apples	4%	Wheat	4%	Potatoes		24%
	23%	GEMS/Food G06	510.13	7%	Wheat	2%	Potatoes	2%	Tomatoes		23%
	19%	GEMS/Food G08	435.08	5%	Potatoes	4%	Wheat	2%	Wine grapes		19%
	19%	GEMS/Food G11	432.30	5%	Potatoes	4%	Wheat	2%	Wine grapes		19%
	19%	GEMS/Food G07	422.44	4%	Potatoes	4%	Wheat	2%	Wine grapes		19%
	18%	PT general	412.61	6%	Potatoes	4%	Wheat	4%	Wine grapes		18%
	18%	RO general	400.04	5%	Wheat	4%	Potatoes	3%	Wine grapes		18%
	17%	GEMS/Food G15	387.68	5%	Wheat	4%	Potatoes	2%	Wine grapes		17%
	17%	IE adult	386.61	3%	Potatoes	2%	Wheat	2%	Wine grapes		17%
	17%	FR child 3 15 yr	382.52	5%	Wheat	3%	Oranges	2%	Potatoes		17%
	17%	GEMS/Food G10	372.72	4%	Wheat	4%	Potatoes	0.9%	Tomatoes		17%
	15%	SE general	326.71	5%	Potatoes	3%	Wheat	0.9%	Apples		15%
	14%	DK child	323.16	5%	Wheat	3%	Potatoes	2%	Apples		14%
	14%	UK toddler	322.63	4%	Potatoes	4%	Wheat	2%	Apples		14%
	14%	ES child	316.82	5%	Wheat	2%	Potatoes	2%	Oranges		14%
	14%	FR toddler 2 3 yr	313.45	3%	Wheat	3%	Apples	2%	Potatoes		14%
	13%	DE women 14-50 yr	291.98	2%	Apples	2%	Wheat	1%	Oranges		13%
	13%	IT toddler	288.42	7%	Wheat	1%	Potatoes	0.9%	Tomatoes		13%
	12%	FI 3 yr	277.52	6%	Potatoes	1%	Wheat	1%	Cucumbers		12%
	12%	NL general	272.37	3%	Potatoes	2%	Wheat	1%	Apples		12%
	12%	DE general	270.00	2%	Apples	2%	Wheat	1%	Potatoes		12%
	11%	UK infant	241.75	4%	Potatoes	3%	Wheat	1%	Apples		11%
	11%	FR adult	236.92	4%	Wine grapes	2%	Wheat	0.9%	Potatoes		11%
	10%	ES adult	228.64	2%	Wheat	1%	Potatoes	1.0%	Oranges		10%
	10%	FI 6 yr	221.36	5%	Potatoes	1%	Wheat	0.8%	Cucumbers		10%
	10%	IT adult	216.73	4%	Wheat	0.7%	Tomatoes	0.7%	Potatoes		10%
	9%	UK vegetarian	192.24	2%	Wheat	2%	Potatoes	1%	Wine grapes		9%
	8%	PL general	191.04	4%	Potatoes	2%	Apples	0.6%	Tomatoes		8%
	8%	LT adult	182.34	4%	Potatoes	2%	Apples	1%	Wheat		8%
	8%	UK adult	169.15	2%	Wheat	2%	Wine grapes	2%	Potatoes		8%
	7%	FR infant	167.29	2%	Potatoes	2%	Apples	0.8%	Wheat		7%
	7%	DK adult	163.61	2%	Potatoes	2%	Wine grapes	1%	Wheat		7%
	5%	FI adult	117.24	1%	Potatoes	0.5%	Apples	0.5%	Wine grapes		5%
	3%	IE child	62.38	1%	Wheat	0.7%	Potatoes	0.3%	Apples		3%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Phosphonic acid (resulting from use of fosetyl, potassium and disodium phosphonates) 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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Phosphonic acid (resulting from use of fosetyl potassium and disodium phosphonates)

LOQs (mg/kg) range from: 0.1 to: 0.10

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: Assuming MRLs will be amended as proposed in the RO on the joint review of MRLs for fosetyl, disodium phosphonates and potassium phosphonates according to Article 12 and 43 of Regulation (EC) No 396/2005 and the RO on the modification of the MRLs in chards/beet leaves and honey (not yet discussed in

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
81%	NL toddler	813.86	22%	Apples	11%	Potatoes	9%	Wheat		81%
76%	DE child	755.97	25%	Apples	10%	Wheat	7%	Potatoes		76%
54%	NL child	544.38	12%	Apples	10%	Wheat	9%	Potatoes		54%
51%	GEMS/Food G06	510.13	17%	Wheat	5%	Potatoes	5%	Tomatoes		51%
44%	GEMS/Food G08	435.08	11%	Potatoes	9%	Wheat	4%	Wine grapes		44%
43%	GEMS/Food G11	432.30	11%	Potatoes	8%	Wheat	4%	Wine grapes		43%
42%	GEMS/Food G07	422.44	10%	Potatoes	10%	Wheat	5%	Wine grapes		42%
41%	PT general	412.61	14%	Potatoes	9%	Wheat	9%	Wine grapes		41%
40%	RO general	400.04	12%	Wheat	10%	Potatoes	6%	Wine grapes		40%
39%	GEMS/Food G15	387.68	11%	Wheat	10%	Potatoes	4%	Wine grapes		39%
39%	IE adult	386.61	6%	Potatoes	5%	Wheat	4%	Wine grapes		39%
38%	FR child 3 15 yr	382.52	11%	Wheat	6%	Oranges	4%	Potatoes		38%
37%	GEMS/Food G10	372.72	9%	Wheat	8%	Potatoes	2%	Tomatoes		37%
33%	SE general	326.71	11%	Potatoes	7%	Wheat	2%	Apples		33%
32%	DK child	323.16	10%	Wheat	7%	Potatoes	5%	Apples		32%
32%	UK toddler	322.63	9%	Potatoes	9%	Wheat	3%	Apples		32%
32%	ES child	316.82	10%	Wheat	5%	Potatoes	4%	Oranges		32%
31%	FR toddler 2 3 yr	313.45	7%	Wheat	6%	Apples	5%	Potatoes		31%
29%	DE women 14-50 yr	291.98	5%	Apples	5%	Wheat	3%	Oranges		29%
29%	IT toddler	288.42	15%	Wheat	2%	Potatoes	2%	Tomatoes		29%
28%	FI 3 yr	277.52	13%	Potatoes	3%	Wheat	3%	Cucumbers		28%
27%	NL general	272.37	7%	Potatoes	4%	Wheat	3%	Apples		27%
27%	DE general	270.00	5%	Apples	4%	Wheat	3%	Potatoes		27%
24%	UK infant	241.75	9%	Potatoes	6%	Wheat	3%	Apples		24%
24%	FR adult	236.92	8%	Wine grapes	5%	Wheat	2%	Potatoes		24%
23%	ES adult	228.64	5%	Wheat	3%	Potatoes	2%	Oranges		23%
22%	FI 6 yr	221.36	10%	Potatoes	2%	Wheat	2%	Cucumbers		22%
22%	IT adult	216.73	10%	Wheat	2%	Tomatoes	2%	Potatoes		22%
19%	UK vegetarian	192.24	5%	Wheat	4%	Potatoes	3%	Wine grapes		19%
19%	PL general	191.04	9%	Potatoes	4%	Apples	1%	Tomatoes		19%
18%	LT adult	182.34	9%	Potatoes	4%	Apples	2%	Wheat		18%
17%	UK adult	169.15	4%	Wheat	4%	Wine grapes	4%	Potatoes		17%
17%	FR infant	167.29	5%	Potatoes	3%	Apples	2%	Wheat		17%
16%	DK adult	163.61	3%	Potatoes	3%	Wine grapes	3%	Wheat		16%
12%	FI adult	117.24	3%	Potatoes	1%	Apples	1%	Wine grapes		12%
6%	IE child	62.38	3%	Wheat	2%	Potatoes	0.7%	Apples		6%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Phosphonic acid (resulting from use of fosetyl potassium and disodium phosphonates) 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. Consumer risk assessment

Commodity	Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
Risk assessment residue definition: Phosphonic acid and its salts, expressed as phosphonic acid						
Grapefruits	100 (tentative)[b]	EFSA (2021b)	17.11	STMR-RAC × PeF (0.73)[c]	28.47	HR-RAC × PeF (0.73)[c]
Oranges	100 (tentative)[b]	EFSA (2021b)	17.11	STMR-RAC × PeF (0.73)[c]	28.47	HR-RAC × PeF (0.73)[c]
Lemons	150[d]	EFSA (2021a)	23.87	STMR-RAC × PeF (0.73)[c]	52.93	HR-RAC × PeF (0.73)[c]
Limes	150[d]	EFSA (2021a)	23.87	STMR-RAC × PeF (0.73)[c]	52.93	HR-RAC × PeF (0.73)[c]
Mandarins	150[d]	EFSA (2021a)	23.87	STMR-RAC × PeF (0.73)[d]	52.93	HR-RAC × PeF (0.73)[c]
Other citrus fruits	100 (tentative)[b]	EFSA (2021b)	17.11	STMR-RAC × PeF (0.73)[c]	28.47	HR-RAC × PeF (0.73)[c]
Cherries	8	Intended	2.50	STMR-RAC	3.18	HR-RAC
Plums	8	Intended	1.77	STMR-RAC	4.56	HR-RAC
Chards/beet leaves	70	EFSA (2021b)	15.00	STMR-RAC (EFSA, 2021d)	37.00	HR-RAC × CF (1) (EFSA, 2021b)
Strawberry leaves	1,500[d]	EFSA (2021a)	380	STMR-RAC	848	HR-RAC
Rooibos	1,500[d]	EFSA (2021a)	380	STMR-RAC	848	HR-RAC
Mate/maté	1,500[d]	EFSA (2021a)	380	STMR-RAC	848	HR-RAC
Other herbal infusions (dried leaves)	1,500[d]	EFSA (2021a)	380	STMR-RAC	848	HR-RAC
Honey	100	EFSA (2021d)	10.37	STMR-RAC	46.00	HR-RAC
Other commodities of plant[e] or animal origin	EFSA (2021b)	Input values derived in the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005.				

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.

(a): An acute consumer risk assessment is not necessary (no ARfD set), input values are reported in grey.

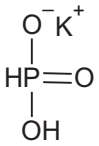
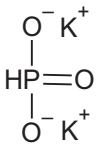
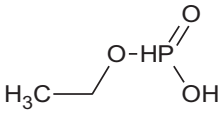
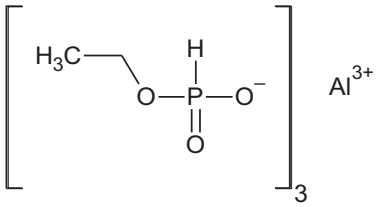
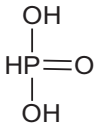
(b): MRLs (here expressed as phosphonic acid) as tentatively recommended by EFSA in the framework of the joint MRL review since a data gap for residue data was identified (EFSA, 2021b).

(c): Peeling factor derived for citrus fruits (EFSA, 2021c).

(d): MRLs (here expressed as phosphonic acid) of the draft regulation (SANTE/10884/2021) not implemented yet.

(e): The residue definition for risk assessment in plant commodities resulting from the use of fosetyl is proposed as 'sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid' (EFSA, 2021b).

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 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).