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Modification of the existing maximum residue levels for fosetyl/phosphonic acid in citrus fruits 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, Aija Kazocina, 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 Luxembourg Industries (Pamol) Ltd submitted a request to the competent national authority in Spain to modify the existing maximum residue levels (MRLs) for fosetyl/phosphonic acid (fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)) in citrus fruits. Adequate analytical methods for enforcement are available to control the residues of potassium phosphonates according to the existing and proposed residue definitions for enforcement in the commodities under consideration. Since EFSA raised concerns regarding the independence of some of the residue trials submitted in support of the MRL application, EFSA presented three options of MRL proposals for further risk management consideration. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of potassium phosphonates on citrus crops according to the reported agricultural practices is unlikely to present a risk to consumer health.

Keywords: fosetyl, phosphonic acid, potassium phosphonates, citrus 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, Luxembourg Industries (Pamol) Ltd submitted an application to the competent national authority in Spain (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for fosetyl/phosphonic acid in citrus fruits resulting from the use of potassium phosphonates. 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 11 September 2020. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRL of 75 mg/kg (set for the existing enforcement residue definition 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)') to 90 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which did not allow to derive a conclusion on the application. To address the data gaps, the EMS submitted a revised evaluation report on 31 May 2021; this evaluation report replaced the previously submitted report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The recent joint review of MRLs for fosetyl and phosphonates according to Article 43 of Regulation (EC) No 396/2005 concluded that the data from public literature provide sufficient evidence to address the metabolism of potassium phosphonates in plants. In crops treated with salts of potassium phosphonate, phosphonic acid is expected to be the main residue.

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 phosphonic acid, the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates proposed a 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 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 concluded that for the citrus crops assessed in this application, the metabolism of potassium phosphonates in plants and the possible degradation in processed products have been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues according to the existing residue definition for enforcement (i.e. fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)) in high acid content commodities with a limit of quantification (LOQ) of 0.01 mg/kg. Moreover, the methods allow the monitoring of residues expressed in accordance with the proposed new residue definition for enforcement (i.e. phosphonic acid and its salts, expressed as phosphonic acid), and an LOQ of 0.1 mg/kg is achievable.

In the present application, eight trials on oranges and eight on mandarins were submitted. EFSA raised concerns that two trials in oranges and two trials in mandarins were not independent, while for the EMS, the independency of the trials was sufficiently addressed by the applicant. Considering the possible deficiency of the data set of residue trials, EFSA presented three options for further risk management consideration. **Option 1:** MRL proposal based on all 16 trials (8 in oranges and 8 in mandarins). However, EFSA is of the opinion that additional evidence would still be required to demonstrate that the trials are independent. Residue data from oranges and mandarins can be extrapolated to all citrus fruits. **Option 2:** MRL proposal based on seven trials in oranges and seven trials in mandarins, assuming that the two trials in oranges and mandarins were not independent. **Option 3:** An MRL proposal for limes could be derived by extrapolation from seven trials on mandarins and MRLs cannot be derived for the other citrus fruits.

EFSA calculated MRLs for the three options in line with both existing and proposed residue definitions for enforcement.

In the recently published reasoned opinion on the joint review of fosetyl, disodium phosphonate and potassium phosphonates, EFSA proposed MRLs for citrus fruits according to the proposed new enforcement residue definition (i.e. phosphonic acid and its salts, expressed as phosphonic acid) at the level of 100 mg/kg. MRLs were proposed tentatively for grapefruits and oranges, and are recommended for lemons, limes and mandarins. The MRL recommendations have not yet been implemented by MRL legislation.

Processing factors (PF) for the crops under assessment were derived from new processing studies. These PF were combined with previous data to derive more robust factors as follows:

- citrus fruits/pulp: 0.73
- citrus fruits/juice: 0.44
- oranges/marmalade: 0.33
- oranges/canned fruits: 0.35
- oranges/dried pomace: 2.93
- oranges/essential oil: < 0.04

The use of potassium phosphonates resulted in significant residue levels in citrus fruit by-products (dried citrus pulp), which can be used as feed item. In the framework of the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates, the dietary burden for livestock was calculated and MRLs on products of animal origin were proposed. EFSA concluded that the previously derived MRL proposals and the risk assessment values for animal products are not affected by the current application.

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. 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 yet formally adopted, 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 review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates, a comprehensive long-term exposure assessment was performed. EFSA updated these calculations considering all available residue data on citrus fruits and the updated peeling factor. Considering the currently applicable ADI of 2.25 mg/kg bw per day, the estimated long-term dietary intake accounted for 36% of the ADI (Dutch toddler diet) for **options 1, 2 and 3**. Expressing the exposure as percentage of the revised ADI of 1 mg/kg bw per day as proposed by the peer review of fosetyl the highest chronic exposure was calculated for Dutch toddler, representing 81% of the ADI (Dutch toddler diet) for **options 1, 2 and 3**. The highest contribution to the total consumer intake was observed for oranges and amounted to 3%, when considering an ADI of 2.25 mg/kg bw per day, and 6.9% for an ADI of 1 mg/kg bw per day.

EFSA concluded that the proposed uses of potassium phosphonates on citrus crops are not expected to result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

Since EFSA could not conclude regarding the independence of some of the residue trials submitted in support of the MRL application, EFSA presented in the summary table below three options for risk managers' consideration to amend existing MRLs for citrus fruits.

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

Code[a]	Commodity	Existing EU MRL/new MRL proposal[b] (mg/kg)	Proposed EU MRL: Existing enforcement RD/Proposed new enforcement RD (mg/kg)	Comment/justification
Existing enforcement residue definition: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) **Proposed new enforcement residue definition (not yet implemented):** Phosphonic acid and its salts, expressed as phosphonic acid				
0110010	Grapefruits	75/100[c]	Further risk management considerations required.	**Option 1:** For the SEU use on citrus trees, an MRL proposal of 90 and 60 mg/kg was calculated, according to existing enforcement RD and proposed new enforcement RD, respectively. MRL proposal is based on all 16 GAP compliant trials on oranges and mandarins. Further evidence needs to be provided to demonstrate the independence of certain residue trials (2 trials in oranges and 2 trials in mandarins performed on closely located test sites). Residue data from oranges and mandarins can be extrapolated to all citrus fruits. The MRL proposal is lower than that of the joint MRL review for fosetyl and phosphonates (EFSA, 2021c). Risk for consumers unlikely.
0110020	Oranges	75/100[c]		
0110030	Lemons	75/100		
0110040	Limes	75/100		
0110050	Mandarins	75/100		
0110010	Grapefruits	75/100[c]	Further risk management considerations required.	**Option 2:** For the SEU use on citrus trees, an MRL proposal of 90 and 70 mg/kg was calculated, according to existing enforcement RD and proposed new enforcement RD, respectively. MRL proposal is based on 7 trials in oranges and 7 trials in mandarins, assuming that 2 trials in oranges and mandarins are not independent. Further risk management considerations required to decide whether the data set which is not fully compliant with the number of trials defined in the relevant EU guidance document (minimum data set of 8 trials in oranges and 8 trials in mandarins) is sufficiently robust to derive an MRL for the citrus fruits crop group. The MRL proposal is lower than that of the joint MRL review for fosetyl and phosphonates (EFSA, 2021c). Risk for consumers unlikely.
0110020	Oranges	75/100[c]		
0110030	Lemons	75/100		
0110040	Limes	75/100		
0110050	Mandarins	75/100		
0110040	Limes	75/100	100/80	**Option 3:** An MRL proposal for limes could be derived by extrapolation from 7 independent GAP compliant trials on mandarins. The MRL proposal is lower than that of the joint MRL review for fosetyl and phosphonates (EFSA, 2021c). For other citrus fruits, no MRL proposal derived. Risk for consumers unlikely.

SEU: southern Europe; RD: residue definition; MRL: maximum residue level; EMS: evaluating Member State.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): MRL proposal, according to proposed new enforcement residue definition, derived in a recently published reasoned opinion of EFSA, not yet implemented (EFSA, 2021c).
(c): Tentative MRL derived from a GAP evaluated at EU level for potassium phosphonates (EFSA, 2021c).

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for fosetyl/phosphonic acid in citrus fruits resulting from the use of potassium phosphonates. The detailed description of the intended uses of potassium phosphonates on citrus crops, which are the basis for the current MRL application, is reported in Appendix A.

Potassium phosphonates are 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 was 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 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)'. 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 maximum residue levels (MRLs) for these three active substances (fosetyl, disodium phosphonate and potassium phosphonates) in accordance with Art.43 of Regulation (EC) No 396/2005 has been performed recently (EFSA, 2021c); the proposed modifications have not yet been implemented in the EU MRL legislation.[4] It is noted that still a number of other modifications of the existing MRLs previously proposed by EFSA (EFSA, 2019a, 2020a–c, 2021a,b) have not yet been implemented in the MRL legislation, since the European Commission considered appropriate to await the MRL joint 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, Luxembourg Industries (Pamol) Ltd submitted an application to the competent national authority in Spain (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for fosetyl/phosphonic acid in citrus fruits resulting from the use of potassium phosphonates. 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 11 September 2020. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRL set for the existing enforcement residue definition (i.e. 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl') from 75 mg/kg to 90 mg/kg. The MRL suggested by the EMS expressed for the new proposed residue definition 'phosphonic acid and its salts, expressed as phosphonic acid' is 60 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which did not allow to derive a conclusion on the application. The EMS submitted a revised evaluation report on 31 May 2021 (Spain, 2020); this evaluation report replaced the previously submitted report.

EFSA based its assessment on the revised evaluation report submitted by the EMS (Spain, 2020), the draft assessment report (DAR) and its addendum (France, 2005, 2012) prepared under Directive 91/414/EEC and the revised renewal assessment report (RAR) on fosetyl (France, 2018) prepared

[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: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

[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.

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, 2012) and fosetyl (EFSA, 2018c), as well as from the joint review of maximum residue levels (MRLs) for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005 (EFSA, 2021c).

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, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[8].

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 (Spain, 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, 2012) and the joint review of MRLs for fosetyl and phosphonates (EFSA, 2021c). It was concluded that data from the public literature are sufficient to address the metabolism in plants. In crops treated with salts of potassium phosphonate, phosphonic acid is expected to be the main residue. No further studies on the metabolism of potassium phosphonates in primary crops were submitted in the framework of the present MRL application. For the intended uses on citrus, 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 is on permanent crops, further investigation of residues in rotational crops is not required.

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 review for fosetyl (EFSA, 2018c) and the joint review of MRLs for fosetyl and phosphonates (EFSA, 2021c). 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

In the framework of the joint review of MRLs for fosetyl and phosphonates, various analytical methods were reported. 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 plant matrices, including high acid content matrices to which the citrus fruits

[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.

belong. The methods enable quantification of residues according to the current residue definition (i.e. fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) in high acid content commodities with an LOQ of 0.01 mg/kg. Moreover, the methods allow the monitoring of residues expressed in accordance with the proposed new residue definition for enforcement (i.e. phosphonic acid and its salts, expressed as phosphonic acid), and an LOQ of 0.1 mg/kg is achievable (EFSA, 2021c).

According to the information provided by the EURLs, during routine analysis, phosphonic acid can be enforced with an LOQ of 0.1 mg/kg in high acid content commodities (relevant to citrus fruits) and with an LOQ of 0.2 mg/kg by means of a single residue method (Quick Polar Pesticides Method – QuPPe), using LC-MS/MS (EURLs, 2020).

1.1.5. Storage stability of residues in plants

All available data on the storage stability of residues under frozen conditions were assessed in the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021c).

In high acid content commodities, such as citrus fruits, the available studies demonstrated acceptable storage stability for phosphonic acid for 25 months when stored at –18 to –25°C.

1.1.6. Proposed residue definitions

In the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021c) the following residue definitions were proposed for plant commodities:

- 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 recently derived residue definition for enforcement has not yet been implemented in Regulation (EC) No 396/2005; the current MRLs established in this regulation refer to the residue definition:

- 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, the uses in citrus fruits were assessed in view of deriving MRL proposals for the existing and the proposed new residue definition for enforcement.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Citrus crops

SEU, outdoor, foliar: 3 × 6 kg a.s./ha; 1st application: BBCH 59, 2nd application: BBCH 79; 3rd application: latest PHI 14 days, PHI: 14 days

In support of the present MRL application, the applicant submitted eight trials on oranges and eight trials on mandarins, compliant with the intended good agricultural practice (GAP) for potassium phosphonates on citrus fruits. Trials were conducted in Spain during growth seasons 2009 and 2010. Half of the trials were designed as decline studies, where samples were collected 0, 3, 7, 14 and 21 days after the third treatment. Two trials on oranges (TRC09-03R7 and TRC09-03R8) and two trials on mandarins (TRC09-02R3 and TRC09-02R4) were conducted on sites located at very close geographic locations (7 and 8 km, respectively), and on the same or very close treatment dates (0–1 day).

Samples were analysed for phosphonic acid. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Spain, 2020). The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

In the decline studies, it was found that the residues stay at a constant level, or even increase over time. A clear trend of a decline of residues in fruits was generally not observed. In three out of eight decline trials, a higher residue was determined at a longer PHI of 21 days compared to the PHI specified in the GAP (14 days); to reflect the worst case, for these trials the result of 14 days PHI was considered for the calculation of the MRL proposal.

In certain samples collected from untreated plots, phosphonic acid was quantified above the LOQ. The applicant attributed this contamination to possible use of fertilisers. EFSA accepted this

justification, since the presence of phosphonic acid in untreated samples has previously been observed (EFSA, 2020a, 2021b) attributed to other possible sources (e.g. fertilisers, plant strengtheners, manure, soil amendments) (EFSA, 2021c).

EFSA questioned the independence of two of the trials in oranges and two trials in mandarins. The trials were performed in closely located test sites (7/8 km), with treatment on the same day or just one day difference. The trials were performed in different crop varieties (orange varieties: Novel Powell and Lane Late; mandarin varieties: Clemenules and Mioro); no details were provided whether the varieties used in the trials differed sufficiently to contribute to the overall variability of the trial conditions, e.g. in terms of fruit size.

In the OECD guidance document on crop field trials (OECD, 2016), no guidance is given on the required minimum distance between test sites to consider the trials as independent. In the most recent EU guidance document on extrapolation (European Commission, 2020), not applicable at the time of the submission of the MRL application, it is suggested that test sites should be at least 20 km apart, unless sufficient evidence is available to demonstrate that in shorter distances significant variation occurs in the relevant test conditions, e.g. weather conditions, soil types, etc. The applicant provided an argumentation in support of the independency of the trials: According to his view, the trials can be considered independent as '*the experimental location sites were different, belonging to different "comarcas" and that different varieties were used. The term "comarca" in Spain refers to territory divisions, which correspond to common natural conditions, i.e. weather, soil, vegetation… (beside historical and demographic aspects)*'. EMS accepted this justification and considered all trials as sufficiently independent.

EFSA does not fully share the view of the EMS and the applicant: overall the evidence is considered insufficient to demonstrate the independence of the trials (lack of information on weather conditions, details on characteristics of the varieties used in the residue trials such as fruit size).

All the citrus fruits for which the GAP was notified (grapefruits, oranges, lemons, limes, mandarins) are classified as major crops except grapefruits and limes. To derive an MRL proposal for the whole group of citrus fruits, a minimum of eight trials on oranges and/or grapefruits and eight trials on lemons and/or mandarins are required. For deriving MRLs for the individual citrus crops, eight trials on oranges, lemons and mandarins, respectively, would be required. For grapefruits and limes, four trials would be sufficient. For limes, an MRL proposal could be derived by extrapolation from at least four residue trials in mandarins (European Commission, 2017). The guidance document does not recommend other extrapolation options. However, wider extrapolations might be considered acceptable on a case-by-case basis.

EFSA concluded that if the two trials in oranges and two trials in mandarins are not independent, they should be treated as trials performed with different experimental conditions within the same experimental site. In this case, the number of independent residue trials would not be sufficient to derive a group MRL for citrus fruits. In case of non-independent trials, the plot in which the highest residue level is observed is selected for maximum residue level estimation and dietary intake assessment (EFSA, 2015).

EFSA calculated two options for the MRL proposal for the citrus fruits group:

Option 1: An MRL proposal was derived from the eight trials in oranges and eight trials in mandarins assuming the trials fulfil the criteria of independent trials. In case residues at the later sampling point were higher than at the minimum PHI, the result of the later sampling point was used to calculate the MRL. In order to demonstrate the appropriateness of MRL proposal derived as option 1, EFSA is of the opinion that further information to demonstrate the independence of the residue trials, as discussed in the sections above, would be required.

Option 2: An MRL proposal based on seven trials in oranges and seven trials in mandarins, assuming that the two trials in oranges and mandarin were not independent. Since the trials were performed in close proximity, they should be treated as trials conducted under different experimental conditions within the same experimental site (EFSA, 2015). Hence, the highest residue value of the two trials, respectively, was selected to estimate the MRL proposal. It is noted that for this option the number of trials would not be compliant with the data requirements and the conditions specified in the EU guidance document on extrapolation (European Commission, 2017). Hence, EFSA recommends further risk management discussions whether the MRL proposal is considered sufficiently robust, noting the assessment is based on a reduced dataset compared to the requirements defined in the relevant guidance document.

For both options 1 and 2, MRL proposals were calculated for the proposed new residue definition (expressing the residues as phosphonic acid) and for the existing residue definition (expressing the

residues as fosetyl equivalents). To recalculate the residue trials which are expressed as phosphonic acid to fosetyl the molecular weight conversion factor of 1.34 was used.

EFSA also derived the highest residue (HR) and median residue (STMR) values for the residue definition for risk assessment. For both options, the HR and the STMR are identical. The results of the risk assessment are reported in Section 4.

Further risk management discussions are required to decide whether additional information can be taken into account to address the deficiencies of the residue data set (MRL proposal option 1) or whether the MRL proposal presented as option 2 is sufficiently robust to derive a group MRL for citrus fruits, considering that due to the lack of evidence to demonstrate independence of the residue trials the number of independent trials does not comply with the provisions of the guidance document on extrapolation.

Option 3: If options 1 and 2 are not supported by risk managers, an MRL proposal for limes could be derived by extrapolation from seven trials in mandarins, as described in option 2. Under this option, no MRL proposals are derived for the remaining citrus fruits.

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.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was discussed in detail in the framework of the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021c). Robust processing factors (fully supported by data) for potassium phosphonates were derived for peeled oranges/mandarins, oranges (juice, marmalade) and other processed products, while for other processed citrus commodities, such as wet and dry pomace, only tentative processing factors could be derived, since the number of studies was not sufficient and/or the analytical method used in the study was not sufficiently validated.

In four field trials on oranges and four on mandarins, submitted in support of the present MRL application, phosphonic acid was determined in the pulp, peel and the whole fruit at the PHI of 14 days (Spain, 2020).

Additional processing studies were submitted (Spain, 2020), where oranges and mandarins were treated with a different treatment regime (i.e. 3 × 6 kg potassium phosphonates/ha foliar spray with a PHI of 30 days, followed by a post-harvest spray or drench treatment at 1 or 0.75 kg potassium phosphonates/hL, respectively) compared to the intended GAP reported in Appendix A. Residues in the peel and the pulp were estimated twice in each trial, 0 and 28 days after the different post-harvest treatments. EFSA selected the highest out of these two PeF for calculations, representing the worst case with respect to consumer risk assessment. Moreover, additional trials investigating the transfer of residues in processed orange products (juice, marmalade, dry pomace, canned fruits and orange essential oil) were performed on oranges treated with the above-mentioned foliar/drenching applications.

Processing factors from all submitted trials were combined with previous data reported in the joint review of MRLs (EFSA, 2021c) to derive more robust factors for processed citrus fruit products (see Section B.1.2.3).

1.2.4. Proposed MRLs

EFSA presents three options for further risk management consideration (see Section 1.2.1). For all three options, MRL proposals are calculated for the current and the new proposed residue definition for enforcement (see Section 1.1.6).

Option 1: MRL proposal is based on all 16 trials (8 in oranges and 8 in mandarins); this option would require additional information to demonstrate that the two trials in mandarins and the two trials in oranges performed in closely located test sites are independent. Residue data from oranges and mandarins can be extrapolated to all citrus fruits.

- Existing residue definition for enforcement (Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)): 90 mg/kg.
- Proposed new enforcement residue definition (Phosphonic acid and its salts, expressed as phosphonic acid) (EFSA, 2021c): 60 mg/kg.

Option 2: MRL proposal is based on seven trials in oranges and seven trials in mandarins, assuming that the two trials in oranges and mandarins were not independent. The assessment is based on a reduced data set compared to the requirements defined in the relevant guidance document.

- Existing residue definition for enforcement (Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)): 90 mg/kg.
- Proposed new enforcement residue definition (Phosphonic acid and its salts, expressed as phosphonic acid) (EFSA, 2021c): 70 mg/kg.

Option 3: An MRL proposal for limes could be derived by extrapolation from seven independent trials on mandarins.

- Existing residue definition for enforcement (Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)): 100 mg/kg.
- Proposed new enforcement residue definition (Phosphonic acid and its salts, expressed as phosphonic acid) (EFSA, 2021c): 80 mg/kg.

In Section 3, EFSA assessed whether residues in these commodities resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

The use of potassium phosphonates resulted in significant residue levels in citrus fruit by-products (dried citrus pulp), which are used as feed item. Therefore, EFSA assessed whether the intended uses of potassium phosphonates required a modification of the MRLs set for animal commodities.

In the framework of the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021c), the dietary burden for livestock was calculated and MRLs on products of animal origin were proposed taking into consideration authorised EU uses, existing CXLs and monitoring data. Comparing the residue levels in citrus fruits by-products resulting from the uses assessed in the current application and those from the uses assessed in the joint MRL review, it becomes evident that the new uses are less critical in view of livestock dietary burden. Hence, the previously derived MRL proposals and the risk assessment values for animal products are not affected by the current application. No further assessment of residues in livestock is deemed necessary.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019b). 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 for 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 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. A short-term exposure assessment is not required since no ARfD is established or proposed for phosphonic acid.

In the framework of the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates, a comprehensive long-term exposure assessment was performed combining residue data originating from the use of the three active substances and the monitoring data as well as certain CXLs established for fosetyl and phosphonic acid (EFSA, 2021c).

STMR values for **options 1 and 2** are 21.5 mg/kg based on residue data from the present application. This risk assessment value is lower than the STMR derived in the joint MRL review (i.e. 23.44 mg/kg; EFSA, 2021c). Hence, EFSA updated the exposure calculations by using the updated PeF of 0.73 (see Section 1.2.3), derived from the combination of previous data and new submitted data on residues in pulp, while an update of STMR value was not considered necessary. All input values used in the exposure calculations are presented in Appendix D.2.

For **option 3,** the STMR value for limes (26 mg/kg) was higher than the STMR value used in the joint MRL review. Hence, the old input value was replaced with the new STMR. In addition, for all citrus fruits, the updated PeF of 0.73 was used (see Section 1.2.3). All input values used in the exposure calculations are presented in Appendix D.2.

Considering the currently applicable ADI of 2.25 mg/kg bw per day (scenario 1), the estimated long-term dietary intake accounted for 36% of the ADI (Dutch toddler diet) for **options 1, 2 and 3**. Expressing the exposure as percentage of the revised ADI of 1 mg/kg bw per day as proposed by the peer review (EFSA, 2018c; scenario 2), the highest chronic exposure was calculated for Dutch toddler, representing 81% of the ADI (Dutch toddler diet) for **options 1, 2 and 3**. The highest contribution to the total consumer intake was observed for oranges and amounted to 3%, when considering an ADI of 2.25 mg/kg bw per day, and 6.9% for an ADI of 1 mg/kg bw per day. Outcome of the calculations is similar to that of the performed risk assessment during the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021c).

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

4. Conclusion and Recommendations

EFSA presented three options, proposing MRLs for citrus fruits, requiring further risk managers consideration.

Option 1: An MRL proposal of 90 mg/kg (according to the existing residue definition for enforcement) and 60 mg/kg (according to the proposed new enforcement residue definition) was derived from the eight trials on oranges and eight trials on mandarins. In order to demonstrate the appropriateness of MRL proposal derived as option 1, EFSA is of the opinion that further information to demonstrate the independence of the residue trials, as discussed in the sections above, would be required.

Option 2: An MRL proposal of 90 mg/kg (according to the existing residue definition for enforcement) and 70 mg/kg (according to proposed new enforcement residue definition) based on seven trials in oranges and seven trials in mandarins, assuming that the two trials in oranges and mandarins were not independent. For this option, the number of trials would not be compliant with the data requirements and the conditions specified in the EU guidance document on extrapolation, where a minimum of eight trials in oranges and eight trials on mandarins are required for setting an MRL in citrus fruit (European Commission, 2017). Hence, EFSA recommends further risk management discussions whether the MRL proposal is considered sufficiently robust.

Option 3: If options 1 and 2 are not supported by risk managers, an MRL proposal of 100 mg/kg (according to the existing residue definition for enforcement) and 80 mg/kg (according to proposed new enforcement residue definition) for limes could be derived by extrapolation from seven independent trials in mandarins. Under this option, no MRL proposals are derived for the remaining citrus fruits.

It is noted that the existing EU MRL for potassium phosphonates on citrus fruits is 75 mg/kg (expressed in accordance with the existing enforcement residue definition). In the recently published reasoned opinion on the joint review of fosetyl, disodium phosphonate and potassium phosphonates, EFSA proposed the following MRLs for the proposed new enforcement residue definition (i.e. phosphonic acid and its salts, expressed as phosphonic acid): 100 mg/kg is proposed tentatively for grapefruit and oranges, and is recommended for lemons, limes and mandarins (EFSA, 2021c). The MRL recommendations have not yet been implemented by MRL legislation.

EFSA concluded that the proposed uses of potassium phosphonates on citrus crops are not expected to result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a risk to consumers' health.

The MRL proposals derived in the current assessment are summarised in Appendix B.4.

References

EFSA (European Food Safety Authority), 2012. Conclusion on the peer review of the pesticide risk assessment of the active substance potassium phosphonates. EFSA Journal 2012;10(12):2963, 43 pp. https://doi.org/10.2903/j.efsa.2012.2963

EFSA (European Food Safety Authority), 2015. Residues trials and MRL calculations. Proposals for a harmonised approach for the selection of the trials and data used for the estimation of MRL, STMR and HR, September 2015, 10 pp.

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018a. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2018b. Reasoned Opinion on the modification of the existing maximum residue levels for fosetyl-Al in tree nuts, pome fruit, peach and potato. EFSA Journal 2018;16(2):5161, 36 pp. https://doi.org/10.2903/j.efsa.2018.5161

EFSA (European Food Safety Authority), 2018c. Conclusion on the peer review of the pesticide risk assessment of the active substance fosetyl. EFSA Journal 2018;16(7):5307, 25 pp. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019a. Reasoned Opinion on the modification of the existing residue levels for fosetyl/phosphonic acid for potatoes and wheat. EFSA Journal 2019;17(5):5703, 31 pp. https://doi.org/10.2903/j.efsa.2019.5703

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019b. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). EFSA supporting publication 2019;EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.en-1605

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020a. Reasoned opinion on the modification of the existing maximum residue levels for fosetyl/phosphonic acid in various crops. EFSA Journal 2020;18(1):5964, 33 pp. https://doi.org/10.2903/j.efsa.2020.5964

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020b. Reasoned Opinion on the modification of the existing maximum residue levels for potassium phosphonates in flowering brassica, Chinese cabbages, kales and spinaches. EFSA Journal 2020;18(5):6122, 31 pp. https://doi.org/10.2903/j.efsa.2020.6122

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Theobald A, Vagenende B and Verani A, 2020c. Reasoned Opinion on the modification of the existing maximum residue levels for potassium phosphonates in various crops. EFSA Journal 2020;18(9):6240, 37 pp. https://doi.org/10.2903/j.efsa.2020.6240

EFSA (European Food Safety Authority), Anastassiadou M, Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021a. Reasoned Opinion on the setting of an import tolerance for potassium phosphonates in blueberries. EFSA Journal 2021;19(3):6478, 28 pp. https://doi.org/10.2903/j.efsa.2021.6478

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021b. Reasoned Opinion on the modification of the existing MRLs for potassium phosphonates in lemons, limes and mandarins and in herbal infusions from leaves and herbs. EFSA Journal 2021;19(6):6673, 41 pp. https://doi.org/10.2903/j.efsa.2021.6673

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021c. Reasoned opinion on the joint review of maximum residue levels (MRLs) for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(8):6782, 203 pp. https://doi.org/10.2903/j.efsa.2021.6782

EURLs (European Union Reference Laboratories for Pesticide Residues), 2020. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for disodium phosphonate and potassium phosphonates. May 2020. Available online: www.efsa.europa.eu

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/VI/95-rev.3, 22 July 1997.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.
European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.
European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2000. Residue analytical methods. For pre-registration data requirements for Annex II (part A, section 4) and Annex III (part A, section 5) of Directive 91/414. SANCO/3029/99-rev. 4. 11 July 2000.
European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2013. Review report for the active substance potassium phosphonates. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 March 2013 in view of the approval of potassium phosphonates as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/10416/2013 rev 2, 15 March 2013.
European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.
European Commission, 2020. Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation on residue data on products from plant and animal origin. SANTE/2019/12752, 23 November 2020.
FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.
France, 2005. Draft Assessment Report (DAR) on the active substance potassium phosphite prepared by the rapporteur Member State France in the framework of Directive 91/414/EEC, January 2005. Available online: www.efsa.europa.eu
France, 2012. Final addendum to the draft assessment report on potassium phosphonates, compiled by EFSA, November 2012. Available online: www.efsa.europa.eu
France, 2018. Revised Renewal Assessment Report (RAR) on fosetyl prepared by the rapporteur Member State France in the framework of Regulation (EC) No 1107/2009, March 2018. Available online: www.efsa.europa.eu
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org
OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 4 September 2013.
OECD (Organisation for Economic Co-operation and Development), 2016. Guidance Document on Crop Field Trials. In: Series on Pesticides No 66/Series on Testing and Assessment No 164. 2nd Edition. ENV/JM/MONO(2011)50/REV1, ENV/JM/MONO(2011)50/REV1/ANN, 7 September 2016.
Spain, 2020. Evaluation report on the modification of MRLs for potassium phosphonates in citrus. July 2020, revised in May 2021, 56 pp. Available online: www.efsa.europa.eu

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
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC	gas chromatography

GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GC-FPD	gas chromatography with flame photometric detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
HPLC-MS/MS	High-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
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
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
SCPAFF	Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH).
SEU	southern Europe
SL	soluble concentrate
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]
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number max	Interval between application (days)	kg a.s./hL max	Water (L/ha) max	Rate max	Unit	
Grapefruits, Oranges, Lemons, Limes, Mandarins	SEU	F	Fungal diseases	SL	755 g/L Potassium phosphonates	Foliar treatment – broadcast spraying	1st application: BBCH 59; 2nd application: BBCH 79; 3rd application: latest PHI 14 days	3	–	0.3	2,000	6	kg a.s./ha	14

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

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops Root crops Leafy crops Cereals/grass Pulses/oilseeds Miscellaneous	No experimental studies submitted. The EU pesticides peer review and the joint review of MRLs for fosetyl and phosphonates concluded that, given the elementary nature of potassium phosphonates and according to the available data from public literature, the main residue resulting from the use of potassium phosphonates in plants is phosphonic acid (EFSA, 2012, 2021c).			

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish	32; 182	No experimental studies submitted for potassium phosphonates. Bridging data on fosetyl. Residues of phosphonic acid are observed in plants grown only one month after application to the soil. Radish root: 0.8 mg/kg Lettuce: 0.76 mg/kg In all other crop parts phosphonic acid residues < LOQ (0.5 mg/kg) (EFSA, 2021c).
	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 fosetyl (EFSA, 2018c), fosetyl and phosphonic acid are hydrolytically stable (EFSA, 2021c).
	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 (2021c)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2021c)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2021c)
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, 2021c)	
Plant residue definition for risk assessment (RD-RA)	Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2021c)	
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. Fosetyl LOQ: 0.01 mg/kg Phosphonic acid LOQ: 0.1 mg/kg (EFSA, 2021c) • GC-FPD (hops) Fosetyl LOQ: 2 mg/kg Phosphonic acid LOQ: 20 mg/kg (EFSA, 2021c) • Single residue method (QuPPe) for enforcement in routine analysis, LOQ 0.1 mg/kg (as phosphonic acid) for high water and high acid content commodities, and 0.2 mg/kg (as phosphonic acid) for high oil content and dry commodities (EURLs, 2020).	

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; GC-FPD: gas chromatography with flame photometric detector; HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuPPe: Quick Polar Pesticides.

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	Cucumbers	–18 to 25	25	Months	Phosphonic acid and its salts expressed as phosphonic acid.	France (2018), EFSA (2018c)
		Lettuces		24	Months	Phosphonic acid and its salts expressed as phosphonic acid.	France (2018), EFSA (2018c)
		Head cabbages		24	Months	Phosphonic acid and its salts expressed as phosphonic acid.	France (2018), EFSA (2018c)
		Cherry tomatoes		24	Months	Phosphonic acid and its salts expressed as phosphonic acid.	France (2018), EFSA (2018c)
		Wheat, whole plants		12	Months	Phosphonic acid	EFSA (2019a, 2020a–c, 2021a,b)

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
		Apples		12	Months	Phosphonic acid	EFSA (2018b)
		Peaches		307	Days	Phosphonic acid	EFSA (2018b)
	High oil content	Avocados		25	Months	Phosphonic acid and its salts expressed as phosphonic acid.	France (2018), EFSA (2018c)
		Almonds		218	Days	Phosphonic acid	EFSA (2018b)
		Pistachios		221	Days	Phosphonic acid	EFSA (2018b)
		Walnuts		146	Days	Phosphonic acid	EFSA (2018b)
	High protein content	Beans, dry		24	Months	Phosphonic acid and its salts expressed as phosphonic acid.	France (2018), EFSA (2018c)
	High starch content	Potatoes		25	Months	Phosphonic acid and its salts expressed as phosphonic acid.	France (2018), EFSA (2018c)
				12	Months	Phosphonic acid	EFSA (2019a, 2020a–c, 2021a,b)
		Wheat, grain		12	Months	Phosphonic acid	EFSA (2019a, 2020a–c, 2021a,b)
	High acid content	Grapes		25	Months	Phosphonic acid and its salts expressed as phosphonic acid.	France (2018), EFSA (2018c)
		Oranges		24	Months	Phosphonic acid and its salts expressed as phosphonic acid.	France (2018), EFSA (2018c)
	Processed products	Peach jam, puree, nectar and canned peaches		112–114	Days	Phosphonic acid	EFSA (2018b)
	Others	Wheat, straw		12	Months	Phosphonic acid	EFSA (2019a, 2020a–c, 2021a,b)

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 (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)
RD-Mo (existing): Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) **RD-RA/RD-Mo (proposed (**EFSA, **2021c)):** Phosphonic acid and its salts, expressed as phosphonic acid						
Citrus fruits (grapefruits, oranges, lemons, limes, mandarins)	SEU	**RD-Mo (existing)[d]:** Mandarins: 13.40[e]; 14.74[f]; 28.14[e,f]; 30.82; 34.84[e]; 36.18; 44.22; 52.26 Oranges: 11.26; 12.06; 13.40; 20.10; 28.14; 29.48[g]; 29.48[g]; 34.84 **RD-RA/RD-Mo (proposed):** Mandarins: 10.00[e]; 11.00[f]; 21.00[e],[f]; 23.00; 26.00[e]; 27.00; 33.00; 39.00 Oranges: 8.40; 9.00; 10.00; 15.00; 21.00; 22.00[g]; 22.00[g]; 26.00	Residue trials on oranges and mandarins compliant with GAPs on citrus crops. Residue data from oranges and mandarins can be extrapolated to all citrus fruits. **Option 1:** MRL proposal is based on all 16 trials (8 on oranges and 8 on mandarins), in the case these are considered as independent. **Option 2:** MRL proposal is based on 7 trials in oranges and 7 trials in mandarins, assuming that the 2 trials in oranges and mandarins were not independent. The highest residue value of the two trials was selected for calculations.	**Option 1:** RD-Mo (existing): **90** RD-Mo (proposed): **60**	RD-RA: 39	RD-RA: 21.5
				Option 2: RD-Mo (existing): **90** RD-Mo (proposed): **70**	RD-RA: 39	RD-RA: 21.5
Limes	SEU	**RD-Mo (existing)[d]:** Mandarins: 13.40[e]; 28.14[e]; 30.82; 34.84[e]; 36.18; 44.22; 52.26 **RD-RA/RD-Mo (proposed):** Mandarins: 10.00[e]; 21.00[e]; 23.00; 26.00[e]; 27.00; 33.00; 39.00	Residue trials on mandarins compliant with GAP in limes. Residue data can be extrapolated to limes. **Option 3:** An MRL proposal for limes could be derived by extrapolation from 7 independent trials on mandarins.	RD-Mo (existing): **100** RD-Mo (proposed): **80**	RD-RA: 39	RD-RA: 26

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, EU: 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): 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).
(e): Residue value selected if higher at a longer PHI of 21 days.
(f): Trials were conducted on sites at very close geographic locations (7 km) and on the same treatment dates.
(g): Trials were conducted on sites at very close geographic locations (8 km) and treatment dates difference by 1 day.

B.1.2.2. Residues in rotational crops

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

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		Comment/Source
		Individual values	Median PF	
Citrus fruits, peeled	48	Oranges: 1.06; 1.67; 0.6; 0.88; 0.67; 0.51; 0.90; 0.86; 0.55; 0.55; 0.66; 0.88; 0.63[c]; 0.52[c]; 0.49[c]; 0.72[c]; 0.72[c]; 0.83[c]; 0.61[c]; 0.79[c]; 0.91[d]; 1.04[d]; 0.91[d]; 1.05[d] Tangerines: 0.55; 0.57; 0.83; 1.03; 0.90; 0.72; 0.89; 0.20; 0.65; 0.59; 0.28; 0.52; 0.49[c]; 0.52[c]; 0.77[c]; 0.82[c]; 0.69[c]; 0.68[c]; 0.77[c]; 0.74[c]; 0.88[d]; 1[d]; 0.85[d]; 1.09[d]	0.73	Processing studies on oranges and tangerines extrapolated to all citrus fruits (EFSA, 2021c; Spain, 2020). Underlined values refer to processing factors derived from studies submitted in the present MRL application.
Citrus fruits, juice	9	0.44; 0.44; 0.46; 0.91; 0.78; 0.51; 0.29[c]; 0.34[c]; 0.27[c]	0.44	Processing studies on oranges extrapolated to all citrus fruits (EFSA, 2021c; Spain, 2020). Underlined values refer to processing factors derived from studies submitted in the present MRL application.
Citrus fruits, wet pomace	2	1.48; 1.85	1.67	Tentative[b] Processing studies on oranges extrapolated to all citrus fruits (EFSA, 2021c).
Oranges, marmalade	9	0.62; 0.43; 0.27; 0.53; 0.33; 0.27; 0.33[c]; 0.30[c]; 0.37[c]	0.33	(EFSA, 2021c; Spain, 2020) Underlined values refer to processing factors derived from studies submitted in the present MRL application.
Oranges, canned fruits	9	0.54; 0.35; 0.32; 0.52; 0.41; 0.30; 0.34[c]; 0.39[c]; 0.22[c]	0.35	(EFSA, 2021c; Spain, 2020) Underlined values refer to processing factors derived from studies submitted in the present MRL application.
Oranges, dried pomace	4	3.19; 2.03[c]; 3.44[c]; 2.67[c]	2.93	(EFSA, 2021c; Spain, 2020) Underlined values refer to processing factors derived from studies submitted in the present MRL application.
Oranges, essential oil	3	< 0.04[c]; < 0.02[c]; < 0.04[c]	< 0.04	Residues in essential oil below the LOQ of 0.1 mg/kg in all samples. (Spain, 2020) Underlined values refer to processing factors derived from studies submitted in the present MRL application.

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo).
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): A tentative PF is derived based on a limited data set.
(c): Application parameters: 3 × 6 kg potassium phosphonates/ha foliar spray; PHI of 30 days, followed by a post-harvest drench treatment 1 × 0.75 kg phosphonic acid eq./hL for 30 seconds; sampling 0–1 days after drenching.
(d): Application parameters: 3 × 6 kg potassium phosphonates/ha foliar spray; PHI: 14 days (intended use; see Appendix A).

B.2. Residues in livestock

Dietary burden calculations, performed in the framework of the joint review of MRLs for fosetyl and the phosphonates, are still valid (EFSA, 2021c).

B.3. Consumer risk assessment

Acute risk assessment not relevant, since no ARfD has been considered necessary (European Commission, 2013; EFSA, 2018).

Option 1 (MRL proposal is based on all 16 trials, in the case these are considered as independent) and **Option 2** (MRL proposal is based on 7 trials in oranges and 7 trials in mandarins, assuming that the 2 trials in oranges and mandarins were not independent).

ADI	**Scenario 1 (TRV currently in place for phosphonic acid):** 2.25 mg/kg bw per day (European Commission, 2013). **Scenario 2 (TRV not yet endorsed):** 1 mg/kg bw per day (EFSA, 2018).
Highest IEDI, according to EFSA PRIMo	**Scenario 1 (TRV currently in place for phosphonic acid)** 36% of the ADI (NL toddler diet) Contribution of crops assessed: Grapefruits: 0.53% (IE adult diet) Oranges: 3.06% (DE child diet) Lemons: 0.28% (GEMS/Food G11) Limes: 0.03% (IE adult) Mandarins: 0.59% (FR toddler 2-3 yr diet) **Scenario 2 (TRV not yet endorsed):** 81% of the ADI (NL toddler diet) Contribution of crops assessed: Grapefruits: 1.19% (IE adult diet) Oranges: 6.88% (DE child diet) Lemons: 0.64% (GEMS/Food G11) Limes: 0.07% (IE adult) Mandarins: 1.34% (FR toddler 2-3 yr diet)
Assumptions made for the calculations	**Scenarios 1 and 2** The long-term exposure assessment calculated during the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021c) was updated, considering the additional information from present application. For citrus fruits, median values derived during the MRL review were used (i.e. STMR of 23.44 mg/kg (tentative only for oranges and grapefruits)). These values are higher than those derived from the submitted residue trials (i.e. 21.5 mg/kg) for both options 1 and 2. Updated median PeF (i.e. 0.73) calculated from the combination of old and new data was used for all citrus fruits. Calculations performed with PRIMo revision 3.1.

Option 3 (An MRL proposal for limes could be derived by extrapolation from 7 independent trials on mandarins. For the remaining citrus fruits, no MRL proposals are derived).

ADI	**Scenario 1 (TRV currently in place for phosphonic acid):** 2.25 mg/kg bw per day (European Commission, 2013). **Scenario 2 (TRV not yet endorsed):** 1 mg/kg bw per day (EFSA, 2018).
Highest IEDI, according to EFSA PRIMo	**Scenario 1 (TRV currently in place for phosphonic acid)** 36% of the ADI (NL toddler diet) Contribution of crops assessed: Grapefruits: 0.53% (IE adult diet) Oranges: 3.06% (DE child diet) Lemons: 0.28% (GEMS/Food G11) **Limes**: 0.03% (IE adult) Mandarins: 0.59% (FR toddler 2-3 yr diet) **Scenario 2 (TRV not yet endorsed):** 81% of the ADI (NL toddler diet) Contribution of crops assessed: Grapefruits: 1.19% (IE adult diet) Oranges: 6.88% (DE child diet) Lemons: 0.64% (GEMS/Food G11) **Limes**: 0.07% (IE adult) Mandarins: 1.34% (FR toddler 2-3 yr diet)
Assumptions made for the calculations	**Scenarios 1 and 2** The long-term exposure assessment was calculated during the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021c). For grapefruits, oranges, lemons and mandarins median values derived during the review were used (i.e. STMR of 23.44 mg/kg, tentative only for oranges and grapefruit). For limes an STMR of 26 mg/kg, derived from 7 independent trials on mandarins, was used. Updated median PeF for citrus fruits (i.e. 0.73) calculated from the combination of old and new data was used for further refinement. 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; STMR: supervised trials median residue; PeF: peeling factor.

B.4. Recommended MRLs

Code[a]	Commodity	Existing EU MRL/new MRL proposal[b] (mg/kg)	Proposed EU MRL: Existing enforcement RD/Proposed new enforcement RD (mg/kg)	Comment/justification
Existing enforcement residue definition: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) **Proposed new enforcement residue definition (not yet implemented):** Phosphonic acid and its salts, expressed as phosphonic acid				
0110010	Grapefruits	75/100[c]	Further risk management considerations required.	**Option 1:** For the SEU use on citrus trees, an MRL proposal of 90 and 60 mg/kg was calculated, according to existing enforcement RD and proposed new enforcement RD, respectively. MRL proposal is based on all 16 GAP compliant trials on oranges and mandarins. Further evidence needs to be provided to demonstrate the independence of certain residue trials (2 trials in oranges and 2 trials in mandarins performed on closely located test sites). Residue data from oranges and mandarins can be extrapolated to all citrus fruits. The MRL proposal is lower than that of the joint MRL review for fosetyl and phosphonates (EFSA, 2021c). Risk for consumers unlikely.
0110020	Oranges	75/100[c]		
0110030	Lemons	75/100		
0110040	Limes	75/100		
0110050	Mandarins	75/100		
0110010	Grapefruits	75/100[c]	Further risk management considerations required.	**Option 2:** For the SEU use on citrus trees, an MRL proposal of 90 and 70 mg/kg was calculated, according to existing enforcement RD and proposed new enforcement RD, respectively. MRL proposal is based on 7 trials in oranges and 7 trials in mandarins, assuming that 2 trials in oranges and mandarins are not independent. Further risk management considerations required to decide whether the data set which is not fully compliant with the number of trials defined in the relevant EU guidance document (minimum data set of 8 trials in oranges and 8 trials in mandarins) is sufficiently robust to derive an MRL for the citrus fruits crop group. The MRL proposal is lower than that of the joint MRL review for fosetyl and phosphonates (EFSA, 2021c). Risk for consumers unlikely.
0110020	Oranges	75/100[c]		
0110030	Lemons	75/100		
0110040	Limes	75/100		
0110050	Mandarins	75/100		
0110040	Limes	75/100	100/80	**Option 3:** An MRL proposal for limes could be derived by extrapolation from 7 independent GAP compliant trials on mandarins. The MRL proposal is lower than that of the joint MRL review for fosetyl and phosphonates (EFSA, 2021c).

Code[(a)]	Commodity	Existing EU MRL/new MRL proposal[(b)] (mg/kg)	Proposed EU MRL: Existing enforcement RD/Proposed new enforcement RD (mg/kg)	Comment/justification
				For other citrus fruits, no MRL proposal derived. Risk for consumers unlikely.

SEU: southern Europe; RD: residue definition; MRL: maximum residue level; EMS: evaluating Member State.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): MRL proposal, according to proposed new enforcement residue definition, derived in a recently published reasoned opinion of EFSA, not yet implemented (EFSA, 2021c).
(c): Tentative MRL derived from a GAP evaluated at EU level for potassium phosphonates (EFSA, 2021c).

Appendix C – Pesticide Residue Intake Model (PRIMo)

- Scenario 1 (options 1,2; ADI 2.25 mg/kg bw per day)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Phosphonic acid

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:	EC	Source of ARfD:	EC
Year of evaluation:	2012	Year of evaluation:	2012

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	36%	NL toddler	809.45	10%	Apples	5%	Potatoes	4%	Wheat		36%
	33%	DE child	749.95	11%	Apples	4%	Wheat	3%	Potatoes		33%
	24%	NL child	538.28	5%	Apples	4%	Wheat	4%	Potatoes		24%
	22%	GEMS/Food G06	505.68	7%	Wheat	2%	Potatoes	2%	Tomatoes		22%
	19%	GEMS/Food G08	431.35	5%	Potatoes	4%	Wheat	2%	Wine grapes		19%
	19%	GEMS/Food G11	428.50	5%	Potatoes	4%	Wheat	2%	Wine grapes		19%
	19%	GEMS/Food G07	419.70	4%	Potatoes	4%	Wheat	2%	Wine grapes		19%
	18%	PT general	411.63	6%	Potatoes	4%	Wheat	4%	Wine grapes		18%
	18%	RO general	398.60	5%	Wheat	4%	Potatoes	3%	Wine grapes		18%
	17%	GEMS/Food G15	385.28	5%	Wheat	4%	Potatoes	2%	Wine grapes		17%
	17%	IE adult	382.10	3%	Potatoes	2%	Wheat	2%	Wine grapes		17%
	17%	FR child 3 15 yr	380.81	5%	Wheat	3%	Oranges	2%	Potatoes		17%
	16%	GEMS/Food G10	369.92	4%	Wheat	4%	Potatoes	0.9%	Tomatoes		16%
	14%	SE general	322.47	5%	Potatoes	3%	Wheat	0.9%	Apples		14%
	14%	DK child	322.30	5%	Wheat	3%	Potatoes	2%	Apples		14%
	14%	UK toddler	320.21	4%	Potatoes	4%	Wheat	2%	Apples		14%
	14%	ES child	314.41	5%	Wheat	2%	Potatoes	2%	Oranges		14%
	14%	FR toddler 2 3 yr	307.63	3%	Wheat	3%	Apples	2%	Potatoes		14%
	13%	DE women 14-50 yr	288.98	2%	Apples	2%	Wheat	1%	Oranges		13%
	13%	IT toddler	285.89	7%	Wheat	1%	Potatoes	0.9%	Tomatoes		13%
	12%	FI 3 yr	274.64	6%	Potatoes	1%	Wheat	1%	Cucumbers		12%
	12%	NL general	270.81	3%	Potatoes	2%	Wheat	1%	Apples		12%
	12%	DE general	267.25	2%	Apples	2%	Wheat	1%	Potatoes		12%
	11%	UK infant	240.92	4%	Potatoes	3%	Wheat	1%	Apples		11%
	10%	FR adult	236.03	4%	Wine grapes	2%	Wheat	0.9%	Potatoes		10%
	10%	ES adult	226.47	2%	Wheat	1%	Potatoes	1.0%	Oranges		10%
	10%	FI 6 yr	218.97	5%	Potatoes	1%	Wheat	0.8%	Cucumbers		10%
	10%	IT adult	214.57	4%	Wheat	0.7%	Tomatoes	0.7%	Potatoes		10%
	9%	UK vegetarian	191.69	2%	Wheat	2%	Potatoes	1%	Wine grapes		9%
	8%	PL general	189.88	4%	Potatoes	2%	Apples	0.6%	Tomatoes		8%
	8%	LT adult	182.09	4%	Potatoes	2%	Apples	1%	Wheat		8%
	7%	UK adult	168.51	2%	Wheat	2%	Wine grapes	2%	Potatoes		7%
	7%	FR infant	165.90	2%	Potatoes	2%	Apples	0.8%	Wheat		7%
	7%	DK adult	162.76	2%	Potatoes	2%	Wine grapes	1%	Wheat		7%
	5%	FI adult	116.22	1%	Potatoes	0.5%	Apples	0.5%	Wine grapes		5%
	3%	IE child	62.27	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 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 (options 1,2; ADI 1 mg/kg bw per day)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Phosphonic acid

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:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	81%	NL toddler	809.45	22%	Apples	11%	Potatoes	9%	Wheat		81%
	75%	DE child	749.95	25%	Apples	10%	Wheat	7%	Potatoes		75%
	54%	NL child	538.28	12%	Apples	10%	Wheat	9%	Potatoes		54%
	51%	GEMS/Food G06	505.68	17%	Wheat	5%	Potatoes	5%	Tomatoes		51%
	43%	GEMS/Food G08	431.35	11%	Potatoes	9%	Wheat	4%	Wine grapes		43%
	43%	GEMS/Food G11	428.50	11%	Potatoes	8%	Wheat	4%	Wine grapes		43%
	42%	GEMS/Food G07	419.70	10%	Potatoes	10%	Wheat	5%	Wine grapes		42%
	41%	PT general	411.63	14%	Potatoes	9%	Wheat	9%	Wine grapes		41%
	40%	RO general	398.60	12%	Wheat	10%	Potatoes	6%	Wine grapes		40%
	39%	GEMS/Food G15	385.28	11%	Wheat	10%	Potatoes	4%	Wine grapes		39%
	38%	IE adult	382.10	6%	Potatoes	5%	Wheat	4%	Wine grapes		38%
	38%	FR child 3 15 yr	380.81	11%	Wheat	6%	Oranges	4%	Potatoes		38%
	37%	GEMS/Food G10	369.92	9%	Wheat	8%	Potatoes	2%	Tomatoes		37%
	32%	SE general	322.47	11%	Potatoes	7%	Wheat	2%	Apples		32%
	32%	DK child	322.30	10%	Wheat	7%	Potatoes	5%	Apples		32%
	32%	UK toddler	320.21	9%	Potatoes	9%	Wheat	3%	Apples		32%
	31%	ES child	314.41	10%	Wheat	5%	Potatoes	4%	Oranges		31%
	31%	FR toddler 2 3 yr	307.63	7%	Wheat	6%	Apples	5%	Potatoes		31%
	29%	DE women 14-50 yr	288.98	5%	Apples	5%	Wheat	3%	Oranges		29%
	29%	IT toddler	285.89	15%	Wheat	2%	Potatoes	2%	Tomatoes		29%
	27%	FI 3 yr	274.64	13%	Potatoes	3%	Wheat	3%	Cucumbers		27%
	27%	NL general	270.81	7%	Potatoes	4%	Wheat	3%	Apples		27%
	27%	DE general	267.25	5%	Apples	4%	Wheat	3%	Potatoes		27%
	24%	UK infant	240.92	9%	Potatoes	6%	Wheat	3%	Apples		24%
	24%	FR adult	236.03	8%	Wine grapes	5%	Wheat	2%	Potatoes		24%
	23%	ES adult	226.47	5%	Wheat	3%	Potatoes	2%	Oranges		23%
	22%	FI 6 yr	218.97	10%	Potatoes	2%	Wheat	2%	Cucumbers		22%
	21%	IT adult	214.57	10%	Wheat	2%	Tomatoes	2%	Potatoes		21%
	19%	UK vegetarian	191.69	5%	Wheat	4%	Potatoes	3%	Wine grapes		19%
	19%	PL general	189.88	9%	Potatoes	4%	Apples	1%	Tomatoes		19%
	18%	LT adult	182.09	9%	Potatoes	4%	Apples	2%	Wheat		18%
	17%	UK adult	168.51	4%	Wheat	4%	Wine grapes	4%	Potatoes		17%
	17%	FR infant	165.90	5%	Potatoes	3%	Apples	2%	Wheat		17%
	16%	DK adult	162.76	3%	Potatoes	3%	Wine grapes	3%	Wheat		16%
	12%	FI adult	116.22	3%	Potatoes	1%	Apples	1%	Wine grapes		12%
	6%	IE child	62.27	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 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 1 (option 3; ADI 2.25 mg/kg bw per day)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Phosphonic acid

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:	EC	Source of ARfD:	EC
Year of evaluation:	2012	Year of evaluation:	2012

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	36%	NL toddler	809.44	10%	Apples	5%	Potatoes	4%	Wheat		36%
	33%	DE child	749.95	11%	Apples	4%	Wheat	3%	Potatoes		33%
	24%	NL child	538.27	5%	Apples	4%	Wheat	4%	Potatoes		24%
	22%	GEMS/Food G06	505.67	7%	Wheat	2%	Potatoes	2%	Tomatoes		22%
	19%	GEMS/Food G08	431.35	5%	Potatoes	4%	Wheat	2%	Wine grapes		19%
	19%	GEMS/Food G11	428.49	5%	Potatoes	4%	Wheat	2%	Wine grapes		19%
	19%	GEMS/Food G07	419.69	4%	Potatoes	4%	Wheat	2%	Wine grapes		19%
	18%	PT general	411.63	6%	Potatoes	4%	Wheat	4%	Wine grapes		18%
	18%	RO general	398.60	5%	Wheat	4%	Potatoes	3%	Wine grapes		18%
	17%	GEMS/Food G15	385.28	5%	Wheat	4%	Potatoes	2%	Wine grapes		17%
	17%	IE adult	382.17	3%	Potatoes	2%	Wheat	2%	Wine grapes		17%
	17%	FR child 3 15 yr	380.79	5%	Wheat	3%	Oranges	2%	Potatoes		17%
	16%	GEMS/Food G10	369.91	4%	Wheat	4%	Potatoes	0.9%	Tomatoes		16%
	14%	SE general	322.50	5%	Potatoes	3%	Wheat	0.9%	Apples		14%
	14%	DK child	322.30	5%	Wheat	3%	Potatoes	2%	Apples		14%
	14%	UK toddler	320.23	4%	Potatoes	4%	Wheat	2%	Apples		14%
	14%	ES child	314.40	5%	Wheat	2%	Potatoes	2%	Oranges		14%
	14%	FR toddler 2 3 yr	307.62	3%	Wheat	3%	Apples	2%	Potatoes		14%
	13%	DE women 14-50 yr	288.99	2%	Apples	2%	Wheat	1%	Oranges		13%
	13%	IT toddler	285.89	7%	Wheat	1%	Potatoes	0.9%	Tomatoes		13%
	12%	FI 3 yr	274.64	6%	Potatoes	1%	Wheat	1%	Cucumbers		12%
	12%	NL general	270.81	3%	Potatoes	2%	Wheat	1%	Apples		12%
	12%	DE general	267.25	2%	Apples	2%	Wheat	1%	Potatoes		12%
	11%	UK infant	240.92	4%	Potatoes	3%	Wheat	1%	Apples		11%
	10%	FR adult	236.02	4%	Wine grapes	2%	Wheat	0.9%	Potatoes		10%
	10%	ES adult	226.46	2%	Wheat	1%	Potatoes	1.0%	Oranges		10%
	10%	FI 6 yr	218.97	5%	Potatoes	1%	Wheat	0.8%	Cucumbers		10%
	10%	IT adult	214.57	4%	Wheat	0.7%	Tomatoes	0.7%	Potatoes		10%
	9%	UK vegetarian	191.70	2%	Wheat	2%	Potatoes	1%	Wine grapes		9%
	8%	PL general	189.88	4%	Potatoes	2%	Apples	0.6%	Tomatoes		8%
	8%	LT adult	182.09	4%	Potatoes	2%	Apples	1%	Wheat		8%
	7%	UK adult	168.51	2%	Wheat	2%	Wine grapes	2%	Potatoes		7%
	7%	FR infant	165.90	2%	Potatoes	2%	Apples	0.8%	Wheat		7%
	7%	DK adult	162.76	2%	Potatoes	2%	Wine grapes	1%	Wheat		7%
	5%	FI adult	116.22	1%	Potatoes	0.5%	Apples	0.5%	Wine grapes		5%
	3%	IE child	62.27	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 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 3; ADI 1 mg/kg bw per day)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Phosphonic acid

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:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	81%	NL toddler	809.44	22%	Apples	11%	Potatoes	9%	Wheat		81%
	75%	DE child	749.95	25%	Apples	10%	Wheat	7%	Potatoes		75%
	54%	NL child	538.27	12%	Apples	10%	Wheat	9%	Potatoes		54%
	51%	GEMS/Food G06	505.67	17%	Wheat	5%	Potatoes	5%	Tomatoes		51%
	43%	GEMS/Food G08	431.35	11%	Potatoes	9%	Wheat	4%	Wine grapes		43%
	43%	GEMS/Food G11	428.49	11%	Potatoes	8%	Wheat	4%	Wine grapes		43%
	42%	GEMS/Food G07	419.69	10%	Potatoes	10%	Wheat	5%	Wine grapes		42%
	41%	PT general	411.63	14%	Potatoes	9%	Wheat	9%	Wine grapes		41%
	40%	RO general	398.60	12%	Wheat	10%	Potatoes	6%	Wine grapes		40%
	39%	GEMS/Food G15	385.28	11%	Wheat	10%	Potatoes	4%	Wine grapes		39%
	38%	IE adult	382.17	6%	Potatoes	5%	Wheat	4%	Wine grapes		38%
	38%	FR child 3 15 yr	380.79	11%	Wheat	6%	Oranges	4%	Potatoes		38%
	37%	GEMS/Food G10	369.91	9%	Wheat	8%	Potatoes	2%	Tomatoes		37%
	32%	SE general	322.50	11%	Potatoes	7%	Wheat	2%	Apples		32%
	32%	DK child	322.30	10%	Wheat	7%	Potatoes	5%	Apples		32%
	32%	UK toddler	320.23	9%	Potatoes	9%	Wheat	3%	Apples		32%
	31%	ES child	314.40	10%	Wheat	5%	Potatoes	4%	Oranges		31%
	31%	FR toddler 2 3 yr	307.62	7%	Wheat	6%	Apples	5%	Potatoes		31%
	29%	DE women 14-50 yr	288.99	5%	Apples	5%	Wheat	3%	Oranges		29%
	29%	IT toddler	285.89	15%	Wheat	2%	Potatoes	2%	Tomatoes		29%
	27%	FI 3 yr	274.64	13%	Potatoes	3%	Wheat	3%	Cucumbers		27%
	27%	NL general	270.81	7%	Potatoes	4%	Wheat	3%	Apples		27%
	27%	DE general	267.25	5%	Apples	4%	Wheat	3%	Potatoes		27%
	24%	UK infant	240.92	9%	Potatoes	6%	Wheat	3%	Apples		24%
	24%	FR adult	236.02	8%	Wine grapes	5%	Wheat	2%	Potatoes		24%
	23%	ES adult	226.46	5%	Wheat	3%	Potatoes	2%	Oranges		23%
	22%	FI 6 yr	218.97	10%	Potatoes	2%	Wheat	2%	Cucumbers		22%
	21%	IT adult	214.57	10%	Wheat	2%	Tomatoes	2%	Potatoes		21%
	19%	UK vegetarian	191.70	5%	Wheat	4%	Potatoes	3%	Wine grapes		19%
	19%	PL general	189.88	9%	Potatoes	4%	Apples	1%	Tomatoes		19%
	18%	LT adult	182.09	9%	Potatoes	4%	Apples	2%	Wheat		18%
	17%	UK adult	168.51	4%	Wheat	4%	Wine grapes	4%	Potatoes		17%
	17%	FR infant	165.90	5%	Potatoes	3%	Apples	2%	Wheat		17%
	16%	DK adult	162.76	3%	Potatoes	3%	Wine grapes	3%	Wheat		16%
	12%	FI adult	116.22	3%	Potatoes	1%	Apples	1%	Wine grapes		12%
	6%	IE child	62.27	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 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

See EFSA (2021c).

D.2. Consumer risk assessment

Options 1, 2

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: phosphonic acid and its salts, expressed as phosphonic acid		
Grapefruits Oranges	17.11	STMR-RAC (23.44 mg/kg, potassium phosphonates, tentative (EFSA, 2021c)) × PeF (0.73, potassium phosphonates, Appendix B.1.2.3)
Lemons Limes Mandarins	17.11	STMR-RAC (23.44 mg/kg, potassium phosphonates (EFSA, 2021c)) × PeF (0.73, potassium phosphonates, Appendix B.1.2.3)
Other commodities of plant or animal origin	Input values derived from the joint review of maximum residue levels (MRLs) for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005 (EFSA, 2021c).	

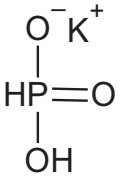
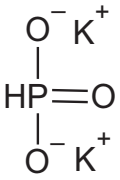
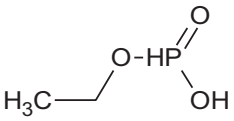
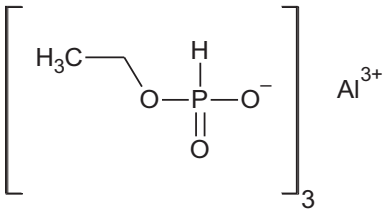
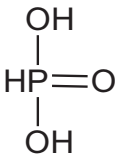
STMR-RAC: supervised trials median residue in raw agricultural commodity; PeF: Peeling factor.

Option 3

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: phosphonic acid and its salts, expressed as phosphonic acid		
Grapefruits Oranges	17.11	STMR-RAC (23.44 mg/kg potassium phosphonates, tentative (EFSA, 2021c)) × PeF (0.73, potassium phosphonates, Appendix B.1.2.3)
Lemons Mandarins	17.11	STMR-RAC (23.44 mg/kg potassium phosphonates (EFSA, 2021c)) × PeF (0.73, potassium phosphonates, Appendix B.1.2.3)
Limes	18.98	STMR-RAC (26 mg/kg, potassium phosphonates) × PeF (0.73, potassium phosphonates)
Other commodities of plant or animal origin	Input values derived from the joint review of maximum residue levels (MRLs) for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005 (EFSA, 2021c).	

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

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).