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Modification of the existing maximum residue levels in leeks and spring onions/green onions/Welsh onions resulting from the use of potassium phosphonates

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF Agro B.V. Arnhem (NL) Freienbach Branch submitted a request to the competent national authority in the Netherlands to modify the existing maximum residue levels (MRLs) for the active substance potassium phosphonates in leeks and spring onions/green onions/Welsh onions. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the commodities under assessment. Adequate analytical methods for enforcement are available to control the residues of potassium phosphonates in accordance with the proposed residue definition 'phosphonic acid and its salts expressed as phosphonic acid' on the commodities under consideration. Based on the risk assessment results and assuming that the exiting MRLs will be amended as proposed by EFSA in previous outputs, EFSA concluded that the long-term intake of residues resulting from the use of potassium phosphonates according to the reported agricultural practices is unlikely to present a risk to consumer health. Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required. The risk assessment shall be regarded as indicative because some MRL proposals derived by EFSA in the framework of the MRL review according to Articles 12 and 43 of Regulation (EC) No 396/2005 require further consideration by risk managers.

Keywords: potassium phosphonates, phosphonic acid, leeks, spring/green/Welsh onions, fungicide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF Agro B.V. Arnhem (NL) Freienbach Branch submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance potassium phosphonates in leeks and spring onions/green onions/Welsh onions.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 4 April 2022. The appointed EMS (the Netherlands) assessed the dossier and declared its admissibility on 8 June 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 22 December 2022 to 12 January 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the 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 7 February 2023. To accommodate for the intended uses of potassium phosphonates, the EMS proposed for both leeks and spring onions an MRL of 10 mg/kg according to the residue definition as phosphonic acid, corresponding to an MRL of 15 mg/kg expressed as fosetyl. It should be noted that the MRL proposal of 15 mg/kg calculated as fosetyl equivalents is not exceeding the existing MRL of 30 mg/kg for these commodities. However, the MRL application was proactively put forward considering the request for lowering the existing MRLs proposed by the reasoned opinion on the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005 (joint MRL review for fosetyl and phosphonates) to 0.8 mg/kg in leeks and to 6 mg/kg in spring onions (both set from available monitoring data) expressed as phosphonic acid equivalents. The Standing Committee on Plants, Animals, Food and Feed (PAFF) of the European Commission has not yet taken a decision on a measure to lower these MRLs as recommended by EFSA.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. The current assessment is based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments, including the joint MRL review for fosetyl and phosphonates, the recently published scientific statement on the MRLs for potassium phosphonates and the additional data provided by the EMS in the framework of this application. It should be noted that the modifications proposed by the joint MRL review for fosetyl and phosphonates, the various EFSA opinions issued after the joint review combined in the scientific statement on MRLs for potassium phosphonates have not yet been considered for implementation in the EU MRL Regulation. Based on these assessments, the following conclusions are derived.

The recent joint MRLs review for fosetyl and phosphonates confirmed that the data from public literature provide sufficient evidence to address the metabolism of potassium phosphonates in plants. In primary crops and in rotational crops, phosphonic acid is expected to be the main residue. To be noted that phosphonic acid is also the predominant metabolite of the active substances fosetyl-Al and disodium phosphonate. Studies investigating the effect of processing on the nature of residues (hydrolysis studies) demonstrated that the metabolite phosphonic acid is stable.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of the metabolite phosphonic acid, the joint MRL review for fosetyl and 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 residue definitions are applicable to primary crops, rotational crops and processed products and cover residues in food and feed resulting from the use of other two active substances, fosetyl and disodium phosphonate, which are approved for use in plant protection products in the EU. 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 European Commission confirmed that the assessment of the present MRL application on potassium phosphonates should consider only the new enforcement residue definition '*Phosphonic acid and its salts expressed as phosphonic acid*' since already exclusively used in the scientific statement on MRLs for potassium phosphonates, which is the latest EFSA output on potassium phosphonates. Hence, EFSA derived MRL proposals according to the new residue definition only.

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

Sufficiently validated analytical methods are available to monitor residues of potassium phosphonates expressed according to the residue definition for enforcement '*phosphonic acid and its salts, expressed as phosphonic acid*' in the crops under assessment with an limit of quantification (LOQ) of 0.1 mg/kg. However, extraction efficiency of the method has not been demonstrated and further investigation on this matter would in principle be required.

The available residue trials are sufficient to derive MRL proposals for leeks and spring onions according to the residue definition for enforcement proposed in the joint MRL review for fosetyl and phosphonates.

Specific studies investigating the magnitude of the degradation product of potassium phosphonates, phosphonic acid, in processed commodities of leeks and spring onions are not required considering the low individual contribution of residues resulting from the intended uses to the total chronic consumers' exposure.

The occurrence of phosphonic acid residues in rotational crops after the use of potassium phosphonates, fosetyl and disodium phosphonates in plants was investigated in the framework of the joint review for fosetyl and phosphonates. All these compounds generate phosphonic acid. In the framework of that assessment, monitoring data were also considered to derive MRLs proposals which are expected to cover phosphonic acid residues in rotational crops from the soil uptake potentially resulting from the intended uses on leeks and spring onions.

Residues of phosphonic acid in commodities of animal origin were not assessed since leeks and spring onions are normally not fed to livestock.

The toxicological profile of potassium phosphonates was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 2.25 mg/kg body weight (bw) per day for phosphonic acid. An acute reference dose (ARfD) was deemed unnecessary. In the framework of the renewal of the approval for fosetyl, a revised ADI of 1 mg/kg bw per day has been derived, which was recommended to be applied to phosphonic acid. Although the European Commission has not endorsed yet the revised Review Report including this new ADI, a second chronic risk assessment scenario was calculated based on this reference value as well.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the joint MRL review for fosetyl and phosphonates a comprehensive long-term exposure assessment was performed considering residue data originating from the authorised uses of fosetyl, disodium phosphonate and potassium phosphonates, monitoring data as well as certain CXLs established for fosetyl-Al and phosphonic acid. EFSA updated these calculations with the relevant supervised trials median residue (STMR) values derived from the residue trials on leeks and spring onions submitted in support of the present MRL application and with the STMRs derived in the EFSA opinions adopted following the joint MRL review in line with the EFSA statement on the MRLs for potassium phosphonates. Under the assumption that the MRLs will be amended as recommended by the joint MRL review of fosetyl and phosphonates and the statement of potassium phosphonates, EFSA concluded that the proposed uses of potassium phosphonates on leeks and spring onions will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health. The risk assessment shall be regarded as indicative because some MRL proposals derived by EFSA in the framework of the MRL review according to Articles 12 and 43 of Regulation (EC) No 396/2005 require further consideration by risk managers.

The EU pesticides peer review for the renewal of the approval of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg) RD #1	Proposed EU MRL (mg/kg) RD #2	Comment/justification
Existing enforcement residue definition, RD #1: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) **Proposed enforcement residue definition, RD #2:** Phosphonic acid and its salts expressed as phosphonic acid				
0270060	Leek	30[(b)]	10	The submitted data are sufficient to derive an MRL proposal for the NEU and SEU use. Risk for consumers unlikely.
0220040	Spring onions/ green onions and Welsh onions	30[(b)]	10	The submitted data are sufficient to derive an MRL proposal for the NEU and SEU use. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): EFSA has proposed to lower the MRLs to 0.8 mg/kg in leeks and to 6 mg/kg in spring/green/Welsh onions according to RD#2 in the reasoned opinion on the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for potassium phosphonates in leeks and spring onions/green onions/ Welsh onions. The detailed description of the intended uses of potassium phosphonates, which are the basis for the current MRL application, is reported in Appendix A.

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

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

The EU MRLs related to the use of potassium phosphonates are established in Annex IIIA of Regulation (EC) No 396/2005[3]. The current residue definition for enforcement is set as '*fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl')*. Hence, the existing MRLs cover not only the uses of potassium phosphonates, but also the uses of fosetyl and disodium phosphonate. A joint review of maximum residue levels (MRLs) for these three active substances (fosetyl, disodium phosphonate and potassium phosphonates) in accordance with Articles 12 and 43 of Regulation (EC) No 396/2005 (joint MRL review for fosetyl and phosphonates) has been performed in 2021 (EFSA, 2021c); The Standing Committee on Plants, Animals, Food and Feed (PAFF) of the European Commission has not yet taken a decision on a measure on the proposed modifications.[4] It is noted that a number of other modifications of the existing MRLs previously proposed by EFSA (EFSA, 2021a,b,d, 2022a,b) have not yet been implemented in the MRL legislation, since the European Commission considered appropriate to await the joint MRL review for the related active substances. For this reason, EFSA was mandate from the Commission to issue a statement (EFSA, 2022) combining the conclusions of the scientific opinions published by EFSA in the time frame between June 2021 and January 2022 (EFSA, 2021a,b,c,d, 2022a,b) on potassium phosphonates including the joint MRL review of fosetyl and phosphonates. Certain Codex maximum residue limits (CXLs) have also been taken over in the EU MRL legislation.[5]

In accordance to Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[6], the applicant BASF Agro B.V. Arnhem (NL) Freienbach Branch submitted on 4 April 2022 an MRL application to the competent national authority in the Netherlands alongside the dossier containing the supporting data using the IUCLID format.

EFSA based its assessment on the evaluation report submitted by the EMS (Netherlands, 2023), 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 under Regulation (EU) No 1107/2009[7], the Commission review report on potassium phosphonates

[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 and Commission Regulation (EU) 2022/1324 of 28 July 2022 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 benzovindiflupyr, boscalid, fenazaquin, fluazifop-P, flupyradifurone, fluxapyroxad, fosetyl-Al, isofetamid, metaflumizone, pyraclostrobin, spirotetramat, thiabendazole and tolclofos-methyl in or on certain products. OJ L 200, 29.7.2022, p. 68–108.

[6] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

[7] 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.

(European Commission, 2022), the conclusion on the peer review of the pesticide risk assessment of the active substances potassium phosphonates (EFSA, 2012) and fosetyl (EFSA, 2018), 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), as well as from the scientific statement on maximum residue levels for potassium phosphonates (EFSA, 2022c).

For this application, the data requirements established in Regulation (EU) No 544/2011[8] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a,b,c,d,e,f,g, 2010, 2017a,b, 2021 OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[9].

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 (Netherlands, 2023) 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.[10]

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 in the framework of the EU pesticides peer review of this active substance (EFSA, 2012) and the joint MRLs review of fosetyl and phosphonates (EFSA, 2021c). It was concluded that data from the public literature are sufficient to address the metabolism in plants which mainly involves the transformation of potassium phosphonate salts into phosphonic acid. No further studies on the metabolism of potassium phosphonates in primary crops were submitted in the present MRL application.

For the intended uses in leeks and spring onions, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Potassium phosphonates is authorised on several crops that can be grown in rotation with other crops and leeks and spring onions can also be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review of fosetyl (EFSA, 2018), moderate to high soil persistence (DT_{90} 91 to > 1,000 days) is reported for phosphonic acid, which is a common metabolite of fosetyl, disodium phosphonate and potassium phosphonates. Therefore, further investigation on the nature of residues in rotational crops is required.

Studies investigating the rate of degradation in soil of potassium phosphonates were not available in the framework of the peer review of potassium phosphonates (EFSA, 2012). However, as highlighted for primary crops, considering the elementary nature of potassium phosphonates, the metabolic pathway of potassium phosphonates is expected to be similar in primary and in rotational crops, with phosphonic acid being the main compound present in the treated soil and in the rotated crops (EFSA, 2021c). Studies investigating the nature of phosphonic acid in rotational crops (root/tuber crops, leafy crops and cereals) were assessed in the framework of the EU pesticides peer review of fosetyl (EFSA, 2018), confirming that the metabolite phosphonic acid is the major residue observed in rotational crops.

For the intended uses on leeks and spring onions, the metabolic behaviour in rotational crops is sufficiently addressed.

[8] 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.

[9] 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.

[10] Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-2022-00361

1.1.3. Nature of residues in processed commodities

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

1.1.4. Analytical methods for enforcement purposes in plant commodities

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

Sufficiently validated methods using high-performance liquid chromatography coupled with tandem mass spectrometry (HPLC–MS/MS) are available to determine residues of potassium phosphonates in high water content matrices, to which leeks and spring onions belong. The methods allow the monitoring of residues expressed in accordance with the residue definition for enforcement *'phosphonic acid and its salts, expressed as phosphonic acid'* with an limit of quantification (LOQ) of 0.1 mg/kg. (EFSA, 2021c).

Additionally, according to information provided by the EU Reference Laboratories (EURLs), during routine analysis, phosphonic acid can be enforced with an LOQ of 0.1 mg/kg in high water content commodities by means of a single residue method (Quick Polar Pesticides Method – QuPPe) using liquid chromatography coupled with tandem mass spectrometry (LC–MS/MS) (EURLs, 2020, EFSA, 2021c).

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

1.1.5. Storage stability of residues in plants

All available data on the storage stability of phosphonic acid under frozen conditions were reported in the joint MRLs review of fosetyl and phosphonates (EFSA, 2021c). It was demonstrated that in high water content commodities, to which leeks and spring onions belong, residues of phosphonic acid are stable for at least 25 months when stored at a range between −18°C to −25°C.

No further storage stability studies were submitted in the present MRL application.

1.1.6. Proposed residue definitions

The EU pesticides peer review of potassium phosphonates (EFSA, 2012) and the joint MRLs review of fosetyl and phosphonates (EFSA, 2021c) proposed the following residue definitions for potassium phosphonates 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 residue definitions apply to primary crops, rotational crops and processed products. The proposed residue definition for enforcement has not yet been implemented in Regulation (EC) No 396/2005 and the current MRLs established in this regulation refer to the residue definition as:

- Residue definition for enforcement: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl).

In the current reasoned opinion, the potassium phosphonates uses on leeks and spring onions were assessed in view of deriving MRL proposals only according to the residue definition for enforcement '*Phosphonic acid and its salts expressed as phosphonic acid*' which was already applied in the latest EFSA output for this active substance, the scientific statement on MRLs for potassium phosphonates (EFSA, 2022c).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To support the intended NEU and SEU uses on leeks and spring onions, the applicant submitted the results of 12 independent and GAP-compliant residue trials on leeks (8 in the NEU and 4 in the SEU). The NEU trials were conducted over two seasons (2018 and 2019), whereas the SEU trials in a single season (2019) but widespread in different territories and the deviation is considered as minor and accepted. All trials were designed as decline studies and sampling was performed from the treated and the untreated plots at day 0 and 2–4, 7–8 (intended PHI) and 13–14 days after the application. Results indicate that phosphonic acid slowly declined in leeks over time. This number of independent and GAP-compliant residue trials is sufficient for leeks, which is considered a major crop for the NEU and a minor crop for the SEU and the residue data can be extrapolated to spring onions which is a minor crop in both NEU and SEU according to the Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (Technical Guidelines on MRL setting (European Commission, 2020)).

The EMS derives an MRL proposal by merging the NEU and SEU datasets since these trials were conducted according to the same GAPs and the NEU and SEU data sets are statistically belonging to the same population according to the Mann–Whitney U-test. EFSA notes that in principle residue trials from NEU and SEU should not be combined, unless all the three criteria for combining NEU and SEU trial data sets described in the Technical Guidelines on MRL setting (European Commission, 2020) are met. In this case, EFSA further notes that one of the criteria is not met since the MRL proposals derived for the individual NEU and SEU data sets do not fall into the same or neighbouring MRL classes (see Table B.1.2.1). However, considering that two criteria are met, that leeks is a minor crop in the SEU and in order to derive an MRL on a larger data set and in line with the ALARA principle, EFSA agreed with the approach of the EMS to derive an MRL proposal based on the combined NEU and SEU data sets.

Finally, EFSA notes that residue levels of phosphonic acid at or above the LOQ (0.1 mg/kg) were detected in most of the untreated control samples. The study reports of these residue trials indicated that no product containing the test item was used in the untreated plots during the previous year, with the only exception of one residue trial study (study code: L180489). The applicant justified the presence of phosphonic acid in leek specimens from control plots most likely due to the fertiliser treatments during the study conduct or from previous year. The EMS considered this justification acceptable. EFSA has previously observed and accepted the presence of phosphonic acid in untreated samples, which could be justified and attributed to other possible sources (e.g. fertilisers, plant strengtheners, manure, soil amendments) (EFSA, 2020, 2021a,d, 2022a). Therefore, also in this application, all residue trials were deemed valid and residues data were considered for deriving risk assessment values and for the MRL calculation.

The samples of these residue trials were analysed for phosphonic acid. According to the assessment of the EMS, the analytical method used were sufficiently validated and fit for purpose. It should be noted that the extraction efficiency of the method was not provided. However, as indicated in Section 1.1.4 above, considering the high solubility in water of potassium phosphonates and the extraction performed with a mixture of methanol/water (50/50 v/v), the method seems suitable for adequately dissolving potassium phosphonates. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (Netherlands, 2023).

1.2.2. Magnitude of residues in rotational crops

Leeks and spring onions can be grown in rotation with other crops and since phosphonic acid exhibits moderate to high soil persistence (DT_{90} 91 to > 1,000 days), the presence of residues in succeeding crops should be investigated.

New studies on the magnitude of residues in rotational crops were not submitted in the framework of the present MRL application but the possible transfer of phosphonic acid residue to crops that are grown in crop rotation has been assessed in the in the joint MRL review (EFSA, 2021c), taking into consideration previous assessments of EFSA available for both fosetyl and potassium phosphonates.

According to the confined rotational crops metabolism study evaluated in the framework of the EU pesticides peer review for the renewal of fosetyl (EFSA, 2018b), when phosphonic acid is applied to

bare soil at a dose rate of 4.9 mg a.s./kg soil (equivalent to 14.7 kg phosphonic acid/ha[11]), residues are taken up from the soil by the plant. Based on the results of this study, residue concentrations of phosphonic acid accounted for 0.35 and 0.8 mg/kg in radish tops and roots, respectively, 0.76 mg/kg in lettuce leaves and 0.14 and 0.42 mg/kg in barley grain and straw, respectively, at 30-day plant-back interval (PBI). Residues were not analysed at longer PBI but phosphonic acid residues in radish tops and roots planted 6 months after soil treatment were recovered at a level below 0.1 mg/kg.

Rotational crop field trials were considered in the framework of the EU pesticides peer review for the renewal of the approval of fosetyl (EFSA, 2018b). These field trials were conducted on lettuces, carrots and cereals (winter wheat and barley) following treatment of lettuces as a target crop three times with fosetyl at a total dose rate of 2.3 kg fosetyl/ha (corresponding to 1.73 kg phosphonic acid equivalents/ha) at PBI of 30 days. Residues of fosetyl and phosphonic acid were shown to be below the LOQ of the methods in all rotational crop edible parts at the 30-day PBI, except in wheat grain (0.21 mg/kg for phosphonic acid). The rotational crop field trials have been performed with higher application rate, about 1.7 times the intended application for potassium phosphonates on leeks/spring onions (0.96 kg phosphonic acid equivalents/ha).

EFSA notes that the conducted studies were only performed with a 30 days PBI and not suitable to evaluate the possible accumulation of phosphonic acid for the most critical authorised GAPs and further investigations would be desirable (EFSA, 2021c).

Nevertheless, in the framework of the joint MRL review, monitoring data were considered to derive MRL proposals at 0.8 mg/kg in leeks and at 6 mg/kg in spring onions covering all sources of phosphonic acid and their residues uptake from the soil. The intended uses assessed in this application are expected to cover possible uptake of phosphonic acid as observed in monitoring data since these monitoring data are indeed of a comparable magnitude with the observed findings in untreated control samples from the residue trials submitted (see Section 1.2.1).

Therefore, additional rotational crops field trials are not required in the framework of this application.

1.2.3. Magnitude of residues in processed commodities

Although phosphonic acid residues are expected to occur in significant amounts, above the trigger value of 0.1 mg/kg in unprocessed leeks and spring onions, considering the low individual contribution of these commodities to the total consumers' chronic exposure (below 1% to the theoretical maximum daily intake (TDMI)) to phosphonic acid residues, investigations on the effect of processing on the magnitude of residues in processed commodities is not deemed necessary (European Commission, 1997d).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B.1.2.1). EFSA derived the MRL proposals according to the enforcement residue definition '*Phosphonic acid and its salts expressed as phosphonic acid*' only which was requested to be exclusively used to derive MRL proposals in the latest EFSA output on this compound, the scientific statement on MRLs for potassium phosphonates (EFSA, 2022c). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses of potassium phosphonates are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as leeks and spring onions are normally not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

[11] The dose rate of application of 14.7 kg phosphonic acid/ha was calculated based on the soil concentration of phosphonic acid (4.9 mg/kg soil) that was applied on bare soil, provided soil ploughing at a depth of 20 cm and considering a soil density of 1.5 kg/L (EFSA, 2021c).

The toxicological profile of potassium phosphonates was assessed in the framework of the EU pesticides peer review (EFSA, 2012). For phosphonic acid, which is the relevant component of residues in plant and animal products, an acceptable daily intake (ADI) of 2.25 mg/kg body weight (bw) per day was derived (European Commission, 2022). An acute reference dose (ARfD) was not deemed necessary due to the low acute toxicity of phosphonic acid.

In 2018, in the framework of the renewal of the approval for fosetyl (EFSA, 2018b), a revised ADI of 1 mg/kg bw per day has been derived for fosetyl, which was also recommended to be applied to phosphonic acid. Although the European Commission has not endorsed yet the revised Review Report including this new ADI, a second chronic risk assessment was calculated based on this reference value as well.

Short-term (acute) dietary risk assessment

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

Long-term (chronic) dietary risk assessment

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

EFSA updated these calculations with the relevant STMR values for leeks and spring onions derived from the residue trials on leeks submitted in support of the present MRL application and with the STMRs derived in the EFSA opinions adopted following the joint MRL review (EFSA, 2021b, 2022a,b) in line with the EFSA statement (EFSA, 2022c). The input values used in the exposure calculations are summarised in Appendix D.1.

EFSA calculated two exposure scenarios: **scenario 1** using the existing ADI value for phosphonic acid of 2.25 mg/kg bw per day and **scenario 2** with the proposed and not yet formally adopted ADI value of 1 mg/kg bw per day.

Provided that that the existing MRLs will be amended as proposed in the joint MRL review and the EFSA statement, the estimated long-term dietary intake considering the currently applicable ADI of 2.25 mg/kg bw per day (**scenario 1**), accounted for 36% of the ADI (Dutch toddler diet). Expressing the exposure as percentage of the revised ADI of 1 mg/kg bw per day as proposed by the EU pesticides peer review of fosetyl (**scenario 2**), the highest chronic exposure was calculated at 82% of the ADI (Dutch toddler diet). The contribution of the expected residues in leeks and spring onions to the total long-term consumer intake was individually below 0.05% of the ADI, for both scenarios (See Appendix B.3).

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

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for leeks and spring/green/Welsh onions in accordance with the residue definition for enforcement '*phosphonic acid and its salts expressed as phosphonic acid*'.

Based on the risk assessment results and assuming that the exiting MRLs will be amended as proposed by EFSA joint review of fosetyl and phosphonates and the statement on potassium phosphonates (EFSA, 2021c, 2022c), EFSA concluded that the long-term intake of residues resulting from the use of potassium phosphonates according to the reported agricultural practices is unlikely to present a risk to consumer health. Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required. The risk assessment shall be regarded as indicative because MRL proposals derived by EFSA in the framework of the MRL review according to Articles 12 and 43 of Regulation (EC) No 396/2005 require further consideration by risk managers.

The MRL recommendations are summarised in Appendix B.3.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC-FPD	gas chromatography with flame photometric detector
GC–MS	gas chromatography with 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
InChiKey	International Chemical Identifier Key
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PAFF	Standing Committee on Plants, Animals, Food and Feed
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Leeks	NEU	F	*Phytophthora porri* (PHYTPO)	SC	453 g/L potassium phosphonates corresponding to 300 g/L phosphonic acid equivalents	Foliar treatment – broadcast spraying	15–49	1	–	145–1,450	100–1,000	1.450[(1)] Corresponding to 0.96 expressed as phosphonic acid equivalents	kg a.i./ha	7	
Leeks	SEU	F	*Phytophthora porri* (PHYTPO)	SC	453 g/L potassium phosphonates corresponding to 300 g/L phosphonic acid equivalents	Foliar treatment – broadcast spraying	15–49	1	–	145–1,450	100–1,000	1.450[(1)] Corresponding to 0.96 expressed as phosphonic acid equivalents	kg a.i./ha	7	
Spring onions/ green onions and Welsh onions	NEU	F	Downy mildew	SC	453 g/L potassium phosphonates corresponding to 300 g/L phosphonic acid equivalents	Foliar treatment – broadcast spraying	15–49	1	–	145–1450	100–1000	1.450[(1)] corresponding to 0.96 expressed as phosphonic acid equivalents	kg a.i./ha	7	

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Spring onions/ green onions and Welsh onions	SEU	F	Downy mildew	SC	453 g/L potassium phosphonates corresponding to 300 g/L phosphonic acid equivalents	Foliar treatment – broadcast spraying	15–49	1	–	145–1,450	100–1,000	1.450[(1)] Corresponding to 0.96 expressed as phosphonic acid equivalents	kg a.i./ ha	7	

(1): Max. rate per application and total rate per crop/season.
MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: Suspension concentrate; a.i.: active ingredient.
(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 analytical methods for enforcement purposes in plant commodities

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	No experimental studies submitted. The EU pesticides peer review 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 foliar and soil applications of potassium phosphonates in plants is phosphonic acid (EFSA, 2012, 2021c).			
	Root crops				
	Leafy crops				
	Cereals/grass				
	Pulses/oilseeds				
	Miscellaneous				

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application (s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish		32; 182	No experimental studies submitted for potassium phosphonates. Bridging data on studies with fosetyl not conducted with radiolabelled material (EFSA, 2018b) considered sufficient to assess the nature of potassium phosphonates in rotational crops.
	Leafy crops	Lettuce		32	
	Cereal (small grain)	Barley		32	
	Other				

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, 2018b), phosphonic acid is 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)	Existing residue definition (Regulation (EC) No 396/2005): *Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)* Proposed residue definition ((EFSA, 2012, 2021c), not implemented yet): *Phosphonic acid and its salts, expressed as phosphonic acid*
Plant residue definition for risk assessment (RD-RA)	*Phosphonic acid and its salts, expressed as phosphonic acid* (EFSA, 2012, 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. Phosphonic acid, LOQ: 0.1 mg/kg (EFSA, 2021c) • GC-FPD (hops) Phosphonic acid, LOQ: 20 mg/kg (EFSA, 2021c) • LC–MS/MS, Single residue method (QuPPe) for enforcement in routine analysis. Phosphonic Acid, LOQ: 0.1 mg/kg for high water and high acid content commodities and 0.2 mg/kg for high oil content and dry commodities (EFSA 2021c). Extraction efficiency not proven (Netherland, 2023)

DAT: days after treatment; PBI: plant-back interval; MRL: maximum residue level; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; GC-FPD: gas chromatography with flame photometric detector.

B.1.1.2. Stability of residues in plants

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

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

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)	CF[d]
Leeks, spring/ green/Welsh onions	NEU	Measured as phosphonic acid: 0.66, 0.99, 1.2, 1.3, 2 × 1.5, 2.0, 2.5	Residue trials on leeks compliant with the GAP. As the NEU and SEU data are based on the same GAPs and residue data sets statistically belong to same populations according to a Mann–Whitney U-test, the calculated MRL from the combined (NEU + SEU) dataset is used for the MRL proposal even though individual MRL proposals do not fall under a neighbour class. $MRL_{OECD\ NEU}$ = 5 mg/kg $MRL_{OECD\ SEU=}$15 mg/kg Extrapolation from leeks to spring onions/green onions and Welsh onions is possible according to SANTE/2019/12752.	10.0 (as phosphonic acid)	7.30	1.45	n.a.
Leeks, spring/ green/Welsh onions	SEU	Measured as phosphonic acid: 1.2, 1.4, 4.9, 7.3					

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): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. n.a., not applicable.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	Based on the results of the confined metabolism study with phosphonic acid applied at 4.9 mg phosphonic acid/kg onto bare soil (calculated as 14.7 kg phosphonic acid equivalents/ha, which is 15N the intended application rate in leeks and spring onions), residue concentrations of phosphonic acid accounted for 0.35 and 0.8 mg/kg in radish tops/leaves and roots, respectively, 0.76 mg/kg in lettuce leaves and 0.14 and 0.42 mg/kg in barley grain and straw, respectively, at 30-day PBI. Residues were not analysed at longer plant-back interval but phosphonic acid residues in radish tops and roots planted 6 months after soil treatment were recovered at a level of <0.1 mg/kg (EFSA, 2018b; 2021c).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Inconclusive	From the field trials conducted on lettuces, carrots and cereals (winter wheat and barley) following treatment of lettuces as a target crop with fosetyl at a total dose rate of 2.3 kg a.s./ha (corresponding to 1.73 kg phosphonic acid equivalents/ha, which is about 1.7N the intended application rate in the crop under assessment), residues of phosphonic acid were shown to be below the LOQ in all rotational crops edible parts at the 30-day PBI, except in wheat grain (0.21 mg/kg for phosphonic acid) (EFSA, 2018b). EFSA notes that the conducted studies were only performed with a 30 days PBI and not suitable to evaluate the possible accumulation of phosphonic acid for the most critical authorised GAPs and further investigations would be desirable (EFSA 2021c). Nevertheless, the intended uses assessed in this application are expected to cover possible uptake of phosphonic acid as observed in monitoring data since these monitoring data are of a comparable magnitude with the observed findings in untreated control samples from the residue trials submitted.

B.1.2.3. Processing factors

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

B.2. Consumer risk assessment

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

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 for Phosphonic Acid): 1 mg/kg bw per day (EFSA, 2018b).
Highest IEDI, according to EFSA PRIMo	**Scenario 1** (ADI 2.25 mg/kg bw/day): 36% of ADI (NL toddler diet) Contribution of crops assessed: Spring onions: 0.003% of ADI (IE adult diet) Leeks: 0.02% of ADI (GEMS/Food G11 diet) **Scenario 2** (ADI 1.0 mg/kg bw/day): 82% of ADI (NL toddler diet) Contribution of crops assessed: Spring onions: 0.01% of ADI (IE adult diet) Leeks: 0.04% of ADI (GEMS/Food G11 diet)
Assumptions made for the calculations	The long-term exposure assessment calculated during the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021c) was updated with median residue levels for leeks and spring onions as derived from the residue trials submitted in the present assessment and with the STMRs derived in the EFSA opinions adopted following the joint MRL review (EFSA, 2021b, 2022a, 2022b) in line with the EFSA statement (EFSA, 2022c). Peeling factors were included to refine the calculation for citrus, avocados, pineapples, and cucurbits with inedible peel. The risk assessment is based on the assumption that the existing MRLs will be amended as proposed by EFSA and shall be regarded as indicative because MRL proposals derived by EFSA in the framework of the joint MRL review (EFSA, 2021c) require further consideration by risk managers. 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; CXL: codex maximum residue limit.

B.3. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg) RD #1	Proposed EU MRL (mg/kg) RD #2	Comment/justification
Existing enforcement residue definition, RD #1: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) **Proposed enforcement residue definition, RD #2:** Phosphonic acid and its salts expressed as phosphonic acid				
0270060	Leek	30[(b)]	10	The submitted data are sufficient to derive an MRL proposal for the NEU and SEU use. Risk for consumers unlikely.
0220040	Spring onions/ green onions and Welsh onions	30[(b)]	10	The submitted data are sufficient to derive an MRL proposal for the NEU and SEU use. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): EFSA has proposed to lower the MRLs to 0.8 mg/kg in leeks and to 6 mg/kg in spring/green/Welsh onions according to RD#2 in the reasoned opinion on the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

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

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

Toxicological reference values

ADI (mg/kg bw per day):	2.25	ARfD (mg/kg bw):	Not necessary
Source of ADI:	European	Source of ARfD:	European Commision
Year of evaluation:	2013	Year of evaluation:	2013

Input values

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

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

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

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
36%	NL toddler	820.08	10%	Apples	5%	Potatoes	4%	Wheat		36%
34%	DE child	756.73	11%	Apples	4%	Wheat	3%	Potatoes		34%
24%	NL child	541.54	5%	Apples	4%	Wheat	4%	Potatoes		24%
23%	GEMS/Food G06	506.32	7%	Wheat	2%	Potatoes	2%	Tomatoes		23%
19%	GEMS/Food G08	432.39	5%	Potatoes	4%	Wheat	2%	Wine grapes		19%
19%	GEMS/Food G11	430.40	5%	Potatoes	4%	Wheat	2%	Wine grapes		19%
19%	GEMS/Food G07	420.45	4%	Potatoes	4%	Wheat	2%	Wine grapes		19%
18%	PT general	411.73	6%	Potatoes	4%	Wheat	4%	Wine grapes		18%
18%	RO general	399.36	5%	Wheat	4%	Potatoes	3%	Wine grapes		18%
17%	GEMS/Food G15	386.35	5%	Wheat	4%	Potatoes	2%	Wine grapes		17%
17%	IE adult	386.20	3%	Potatoes	2%	Wheat	2%	Wine grapes		17%
17%	FR child 3 15 yr	383.78	5%	Wheat	3%	Oranges	2%	Potatoes		17%
16%	GEMS/Food G10	370.41	4%	Wheat	4%	Potatoes	0.9%	Tomatoes		16%
14%	SE general	324.59	5%	Potatoes	3%	Wheat	0.9%	Apples		14%
14%	DK child	323.71	5%	Wheat	3%	Potatoes	2%	Apples		14%
14%	UK toddler	320.91	4%	Potatoes	4%	Wheat	2%	Apples		14%
14%	ES child	316.15	5%	Wheat	2%	Potatoes	2%	Oranges		14%
14%	FR toddler 2 3 yr	311.17	3%	Wheat	3%	Apples	2%	Potatoes		14%
13%	DE women 14-50 yr	290.30	2%	Apples	2%	Wheat	1%	Oranges		13%
13%	IT toddler	288.46	7%	Wheat	1%	Potatoes	0.9%	Tomatoes		13%
12%	FI 3 yr	275.98	6%	Potatoes	1%	Wheat	1%	Cucumbers		12%
12%	NL general	271.82	3%	Potatoes	2%	Wheat	1%	Apples		12%
12%	DE general	268.59	2%	Apples	2%	Wheat	1%	Potatoes		12%
11%	UK infant	241.59	4%	Potatoes	3%	Wheat	1%	Apples		11%
11%	FR adult	237.26	4%	Wine grapes	2%	Wheat	0.9%	Potatoes		11%
10%	ES adult	228.87	2%	Wheat	1%	Potatoes	1.0%	Oranges		10%
10%	FI 6 yr	219.87	5%	Potatoes	1%	Wheat	0.8%	Cucumbers		10%
10%	IT adult	217.26	4%	Wheat	0.7%	Tomatoes	0.7%	Potatoes		10%
9%	UK vegetarian	192.09	2%	Wheat	2%	Potatoes	1%	Wine grapes		9%
8%	PL general	190.54	4%	Potatoes	2%	Apples	0.6%	Tomatoes		8%
8%	LT adult	182.19	4%	Potatoes	2%	Apples	1%	Wheat		8%
8%	UK adult	168.95	2%	Wheat	2%	Wine grapes	2%	Potatoes		8%
7%	FR infant	166.98	2%	Potatoes	2%	Apples	0.8%	Wheat		7%
7%	DK adult	163.33	2%	Potatoes	2%	Wine grapes	1%	Wheat		7%
5%	FI adult	116.42	1%	Potatoes	0.5%	Apples	0.5%	Wine grapes		5%
3%	IE child	62.56	1%	Wheat	0.7%	Potatoes	0.3%	Apples		3%

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

Unprocessed commodities

Results for children	Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	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	Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---	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:

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

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

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:	European Commision
Year of evaluation:	2018	Year of evaluation:	2013

Input values

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

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

Refined calculation 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)	82%	NL toddler	820.08	22%	Apples	11%	Potatoes	9%	Wheat		82%
	76%	DE child	756.73	25%	Apples	10%	Wheat	7%	Potatoes		76%
	54%	NL child	541.54	12%	Apples	10%	Wheat	9%	Potatoes		54%
	51%	GEMS/Food G06	506.32	17%	Wheat	5%	Potatoes	5%	Tomatoes		51%
	43%	GEMS/Food G08	432.39	11%	Potatoes	9%	Wheat	4%	Wine grapes		43%
	43%	GEMS/Food G11	430.40	11%	Potatoes	8%	Wheat	4%	Wine grapes		43%
	42%	GEMS/Food G07	420.45	10%	Potatoes	10%	Wheat	5%	Wine grapes		42%
	41%	PT general	411.73	14%	Potatoes	9%	Wheat	9%	Wine grapes		41%
	40%	RO general	399.36	12%	Wheat	10%	Potatoes	6%	Wine grapes		40%
	39%	GEMS/Food G15	386.35	11%	Wheat	10%	Potatoes	4%	Wine grapes		39%
	39%	IE adult	386.20	6%	Potatoes	5%	Wheat	4%	Wine grapes		39%
	38%	FR child 3 15 yr	383.78	11%	Wheat	6%	Oranges	4%	Potatoes		38%
	37%	GEMS/Food G10	370.41	9%	Wheat	8%	Potatoes	2%	Tomatoes		37%
	32%	SE general	324.59	11%	Potatoes	7%	Wheat	2%	Apples		32%
	32%	DK child	323.71	10%	Wheat	7%	Potatoes	5%	Apples		32%
	32%	UK toddler	320.91	9%	Potatoes	9%	Wheat	3%	Apples		32%
	32%	ES child	316.15	10%	Wheat	5%	Potatoes	4%	Oranges		32%
	31%	FR toddler 2 3 yr	311.17	7%	Wheat	6%	Apples	5%	Potatoes		31%
	29%	DE women 14-50 yr	290.30	5%	Apples	5%	Wheat	3%	Oranges		29%
	29%	IT toddler	288.46	15%	Wheat	2%	Potatoes	2%	Tomatoes		29%
	28%	FI 3 yr	275.98	13%	Potatoes	3%	Wheat	3%	Cucumbers		28%
	27%	NL general	271.82	7%	Potatoes	4%	Wheat	3%	Apples		27%
	27%	DE general	268.59	5%	Apples	4%	Wheat	3%	Potatoes		27%
	24%	UK infant	241.59	9%	Potatoes	6%	Wheat	3%	Apples		24%
	24%	FR adult	237.26	8%	Wine grapes	5%	Wheat	2%	Potatoes		24%
	23%	ES adult	228.87	5%	Wheat	3%	Potatoes	2%	Oranges		23%
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	19%	PL general	190.54	9%	Potatoes	4%	Apples	1%	Tomatoes		19%
	18%	LT adult	182.19	9%	Potatoes	4%	Apples	2%	Wheat		18%
	17%	UK adult	168.95	4%	Wheat	4%	Wine grapes	4%	Potatoes		17%
	17%	FR infant	166.98	5%	Potatoes	3%	Apples	2%	Wheat		17%
	16%	DK adult	163.33	3%	Potatoes	3%	Wine grapes	3%	Wheat		16%
	12%	FI adult	116.42	3%	Potatoes	1%	Apples	1%	Wine grapes		12%
	6%	IE child	62.56	3%	Wheat	2%	Potatoes	0.7%	Apples		6%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Phosphonic acid (resulting from use of fosetyl, potassium and disodium phosphonates and monitoring data) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

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

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion:

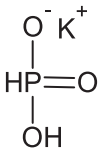
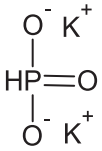
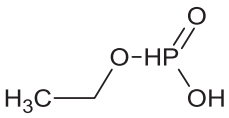
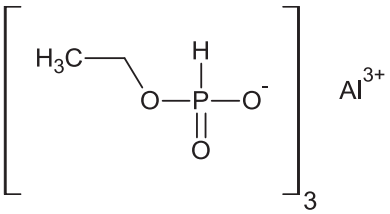
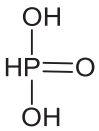
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment[(b)]
Risk assessment residue definition: Phosphonic acid and its salts, expressed as phosphonic acid						
Leeks	10	Intended	1.450	STMR-RAC	7.300	HR-RAC
Spring onions/green onions and Welsh onions	10	Intended	1.450	STMR-RAC	7.300	HR-RAC
Cherries (sweet)	8	EFSA (2022b)	2.50	STMR-RAC	3.10	HR-RAC
Plums	8	EFSA (2022b)	1.77	STMR-RAC	4.56	HR-RAC
Kiwi fruits (green, red, yellow)	150	EFSA (2021b) (CXL)	34.50	STMR-RAC	67.00	HR-RAC
Honey and other apiculture products	100	EFSA (2021d)	10.37	STMR-RAC	46.00	HR-RAC
Other commodities of plant or animal origin	EFSA (2021b)	Input values derived in the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005.				

PeF: Peeling factor.
(a): Figures in the table are rounded to 2 digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.
(b): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

Appendix E – Used compound codes

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

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).