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Modification of the existing maximum residue levels for fosetyl/phosphonic acid in chards/beet leaves and honey 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 SE submitted a request to the competent national authority in the Netherlands 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 chards/beet leaves and honey. 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 fosetyl and phosphonic acid in chards/beet leaves and honey. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of phosphonic acid residues resulting in chard/beet leaves and honey from the use of potassium phosphonates according to the reported agricultural practice is unlikely to present a risk to consumer health.

Keywords: fosetyl, phosphonic acid, potassium phosphonates, chards, beet leaves, honey, fungicide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted two applications to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify maximum residue levels (MRLs) for fosetyl/phosphonic acid in chards/beet leaves and honey resulting from the use of potassium phosphonates. The EMS drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 29 June 2021. To accommodate for the NEU/SEU intended uses of potassium phosphonates on chards/beet leaves, the EMS proposed to raise the existing MRL of 15 to 60 mg/kg or to 40 mg/kg according to the existing or proposed new residue definition for enforcement, respectively. Moreover, the EMS proposed to raise the existing MRL in honey from the limit of quantification (LOQ) of 0.5 to 150 mg/kg or to 100 mg/kg according to the existing or proposed new residue definition, respectively.

EFSA assessed both applications and evaluation reports as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested from the EMS. On 12 October 2021, the EMS submitted two revised evaluation reports, which replaced the previously submitted reports.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments, including the recent EFSA joint review of MRLs for fosetyl, disodium phosphonates and potassium phosphonates according to Article 12 and 43 of Regulation (EC) No 396/2005 (hereafter, joint MRL review) 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 concluded that the data from public literature provide sufficient evidence to address the metabolism of potassium phosphonates in plants. In primary crops treated with salts of potassium phosphonate and in rotational crops, phosphonic acid is expected to be the main residue. The phosphonic acid is also the main metabolite of the active substances fosetyl and disodium phosphonate.

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 and the toxicological significance of the metabolite phosphonic acid, the joint MRL review 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 proposed enforcement residue definition has not been legally endorsed yet. The existing residue definition for enforcement set in Regulation (EC) No 396/2005 is 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)'. The residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for chards/beet leaves, assessed in this application, the metabolism of potassium phosphonates in plants 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. In the absence of specific metabolism studies for honey, but considering the elementary nature of potassium phosphonates and the fact that metabolism of the active substance in primary and rotational crops proceeds according to the same metabolic pathway, EFSA concluded that the above-mentioned residue definitions are also applicable to honey.

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 water 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. For honey, a sufficiently validated analytical method is available with an individual LOQ of 0.05 mg/kg for phosphonic acid and fosetyl.

The occurrence of phosphonic acid residues in rotational crops was investigated in the framework of the joint review of MRLs for fosetyl and phosphonates. The MRLs derived during the MRL review and the present assessment for primary crops are expected to cover phosphonic acid residues in rotational crops from the soil uptake or from other sources.

Although phosphonic acid residues are expected to occur above 0.1 mg/kg in unprocessed chards/beet leaves and honey, considering the low contribution of phosphonic acid residues in these commodities to the total chronic consumers' exposure (below 1% of the theoretical maximum daily

intake (TDMI)), investigations on the effect of processing on the magnitude of residues in processed commodities were not deemed necessary.

The available residue trials are sufficient to derive MRL proposals for chards/beet leaves and honey according to the existing and the proposed new residue definition for enforcement.

Residues of phosphonic acid in commodities of animal origin were not assessed since chards/beet leaves and honey 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. 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 combining residue data originating from the use of the three active substances and the monitoring data, as well as certain codex maximum residue limits (CXLs) established for fosetyl and phosphonic acid. EFSA now updated exposure calculations with supervised trials median residue (STMR) values derived for commodities under assessment (chards/beet leaves and honey). In addition, the updated peeling factor for citrus fruits, derived from a previous assessment, was used to refine calculations.

Provided that the conclusions of the joint MRL review are implemented, the estimated long-term dietary intake considering the currently applicable ADI of 2.25 mg/kg bw per day (**scenario 1**), accounted for 36% of the ADI (Dutch toddler diet). Expressing the exposure as percentage of the revised ADI of 1 mg/kg bw per day as proposed by the EU pesticides peer review (**scenario 2**), the highest chronic exposure was calculated at 81% of the ADI (Dutch toddler diet). The contribution of residues in chard/beet leaves and honey to the total consumer intake was individually below 0.12% of the ADI, for both scenarios.

EFSA concluded that the proposed use of potassium phosphonates on chards/beet leaves and the consumption of honey, produced by bees foraging on melliferous crops treated with potassium phosphonates at the application rate considered in the present assessment, 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.

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/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				
0252030	Chards/ beet leaves	15/70	60/40	The submitted data are sufficient to derive an MRL proposal for the NEU/SEU uses. The MRL proposal is lower than that of the joint MRL review for fosetyl and phosphonates, derived from NEU trials on spinaches treated with fosetyl (EFSA, 2021c). Risk for consumers unlikely.
1040000	Honey	0.5*/0.3	150/100	The MRL proposal reflects residues in honey from tunnel trials performed on buckwheat treated with potassium phosphonates.

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
				In the framework of the joint MRL review for fosetyl and phosphonates, an MRL for honey was derived from available monitoring data (EFSA, 2021c). Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): MRL proposal, according to proposed new enforcement residue definition, derived in a recently published reasoned opinion of EFSA, not yet implemented (EFSA, 2021c).

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Assessment

The European Food Safety Authority (EFSA) received two applications to modify the existing maximum residue levels (MRL) for fosetyl/phosphonic acid in chards/beet leaves and honey resulting from the use of potassium phosphonates. The detailed description of the intended SEU/NEU use of potassium phosphonates in chards/beet leaves, which is the basis for the current MRL application, is reported in Appendix A. For honey, the MRL application is not linked to a specific GAP/crop but is related to intended uses on crops attractive to bees and that would be a potential source for residues of phosphonic acid in honey.

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 were evaluated in the framework of Directive 91/414/EEC[1] with France designated as rapporteur Member State (RMS); the representative use assessed was a foliar spray on grapes. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2012). The active substance potassium phosphonates were 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 Articles 12 and 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, 2021a,b,d) 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, BASF SE submitted two applications to the competent national authority in the Netherlands (Netherlands, 2021a,b) to modify maximum residue levels (MRL) for fosetyl/phosphonic acid in chards/beet leaves and honey resulting from the use of potassium phosphonates. The EMS drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 29 June 2021.

To accommodate for the intended use of potassium phosphonates on chards/beet leaves, the EMS proposed to raise the existing MRL of 15 to 60 mg/kg or to 40 mg/kg according to the existing or proposed new residue definition, respectively. Moreover, the EMS proposed to raise the existing MRL in honey from the limit of quantification (LOQ) from 0.5 to 150 mg/kg or to 100 mg/kg according to the existing or proposed new residue definition, respectively.

EFSA assessed both applications and evaluation reports as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were

[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.

requested from the EMS. On 12 October 2021, the EMS submitted revised evaluation reports (Netherlands, 2021a,b), which replaced the previously submitted reports.

EFSA based its assessment on the evaluation reports submitted by the EMS (Netherlands, 2021a,b), the draft assessment report (DAR) on potassium phosphonates and its addendum (France, 2005, 2012) prepared under Directive 91/414/EEC and the revised renewal assessment report (RAR) on fosetyl (France, 2018) prepared under Regulation (EU) No 1107/2009[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, 2018b), 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, 2010, 2018, 2020, 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[8].

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

The evaluation reports submitted by the EMS (Netherlands, 2021a,b) 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 and honey

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

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 framework of the present MRL application. For the intended use on chards/beet leaves, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

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

During the peer review of potassium phosphonates (EFSA, 2012), studies investigating the rate of degradation in soil of potassium phosphonates were not available. However, as highlighted for primary crops, considering the elementary nature of the active substance, the metabolic pathway of potassium phosphonates is expected to be similar also in rotational crops, with phosphonic acid being the main compound present in the treated soil and in the rotated crops (EFSA, 2021c).

[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.

Studies on 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, 2018b) (phosphonic acid applied to bare soil at 4.9 mg phosphonic acid/kg soil), confirming that the metabolite phosphonic acid is the major residue observed in rotational crops.

For the intended use on chards/beet leaves, the metabolic behaviour in rotational crops is sufficiently addressed.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of phosphonic acid, which is the main metabolite of potassium phosphonates, was investigated in the framework of the EU pesticides peer review for fosetyl (EFSA, 2018b) and the joint review of MRLs for 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. Nature of residues in honey

Honey is a product originated from sugary secretions of plants (floral nectar mainly) through regurgitation, enzymatic conversion and water evaporation, followed by storage in the beehives for a certain time period.

In the absence of specific metabolism studies investigating the nature of phosphonic acid during formation of honey, data on the nature of residues in primary crops, rotational crops and processed commodities were considered to determine the nature of residues in honey (European Commission, 2018). Since the nature of residues is the same in primary and rotational crops and phosphonic acid is hydrolytically stable, it is expected that in pollen and nectar collected from primary and rotational crops, as well as in honey (resulting from the residues in floral nectar), the main residue will be phosphonic acid.

However, it would be desirable to further investigate whether enzymatic processes involved in the production of honey occurring in the bee gut or during the storage in the beehive have an impact on the nature of residues in honey.

1.1.5. Methods of analysis in plants and honey

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 water content matrices to which chards/beet leaves belong. The methods enable quantification of residues according to the current residue definition 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)' in high water content commodities with an LOQ of 0.01 mg/kg. Moreover, the methods allow the monitoring of residues expressed in accordance with the proposed new residue definition for enforcement '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 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).

For honey, a sufficiently validated analytical method based on LC-MS/MS is available with an individual LOQ for phosphonic acid and fosetyl of 0.05 mg/kg (EFSA, 2021c). Although independent laboratory validation (ILV) and extraction efficiency data were not available, the EU pesticides peer review for fosetyl concluded that according to the data requirements applicable, the method was sufficiently validated (EFSA, 2018b).

1.1.6. Storage stability of residues in plants and honey

All available data on the storage stability of phosphonic acid residues under frozen conditions were assessed in the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021c). In high water content commodities (relevant to chards/beet leaves), the available studies demonstrated acceptable storage stability for phosphonic acid for 25 months when stored at −18 to −25°C.

In the framework of the present application, a new study was submitted demonstrating the stability of phosphonic acid in honey and pollen for at least 6 months when stored at −18°C (Netherlands, 2021a).

1.1.7. Proposed residue definitions

The EU pesticides peer review of potassium phosphonates (EFSA, 2012) and the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021c) proposed the following residue definitions 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 residue definitions apply to primary crops, rotational crops and processed products. For honey, in the absence of specific metabolism studies, the proposed residue definitions for risk assessment and enforcement as derived by the joint MRL review are applicable.

The proposed 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).

In the current reasoned opinion, the potassium phosphonate uses on chards/beet leaves and honey 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 and honey

1.2.1. Magnitude of residues in primary crops

Chards/beet leaves

SEU/NEU, outdoor, foliar spray, 2 × 1.45 kg/ha potassium phosphonates/ha; interval between applications: 7–10 days; PHI: 7 days

In support of the present MRL application on chards/beet leaves, the applicant submitted 16 residue trials conducted on lettuces during growth seasons of 2018 and 2019. Trials were widespread in both EU zones (8 in NEU and 8 in SEU). All trials were designed as decline studies. Sampling was performed from the treated and the untreated plot at day 0 and 2–4, 6–8 and 13–14 days after the last application. Results indicate that phosphonic acid declined in lettuces by time.

Trial L180464 was disregarded by EFSA, as the plot was treated with a formulated product containing also fosetyl. Phosphonic acid is the common metabolite for fosetyl and potassium phosphonates; hence, the total residue was affected. In trials L190400 and L190401, phosphonic acid was present in samples obtained from untreated plots. Since residues in the samples from untreated plots were low compared to samples taken from treated plots, trials were deemed acceptable and residue data were considered for deriving risk assessment values and for the MRL calculation. EFSA notes that phosphonic acid residues have been also previously observed in samples from untreated plots (EFSA, 2020, 2021b, 2021d) and attributed to other possible sources (e.g. fertilisers, plant strengtheners, manure, soil amendments) (EFSA, 2021c).

The samples were analysed for phosphonic acid; to derive MRL proposals for the existing enforcement residue definition, the results were expressed as fosetyl by applying the molecular weight conversion factor. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (Netherlands, 2021b).

According to the 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 (European Commission, 2020) residue data from trials conducted on lettuces (open leaf varieties) can be extrapolated to chards/beet leaves. Number of trials is sufficient to support the use on chards/beet leaves (minor crop; minimum 4 trials per zone required). Since residue data from trials in the NEU and SEU were similar (U-test, 5%), data were merged to derive a more robust MRL.

An MRL proposal of 40 mg/kg according to the proposed new residue definition for enforcement or 60 mg/kg according to the existing residue definition for enforcement, for chards/beet leaves were derived (see Appendix B.1.2.1). It is noted that during the joint review of MRLs for fosetyl and phosphonates, a higher MRL of 70 mg/kg was derived for the proposed new residue definition for enforcement on the basis of residue data extrapolation from five NEU trials on spinaches treated with fosetyl (EFSA, 2021c); these MRL proposals have not been yet legally endorsed.

1.2.2. Magnitude of residues in honey

Buckwheat (surrogate crop), tunnel trials, foliar spray: 3 × 2.36 kg potassium phosphonates/ha; 1st application at BBCH 55–59, 2nd at beginning of flowering at BBCH 61–63 and 3rd at full flowering at BBCH 63–65; PHI: 7–14 days.

In support of the MRL application on honey, the applicant submitted four independent residue trials performed on buckwheat treated with potassium phosphonates under semi-field conditions (tunnel trials). Trials were conducted in Germany during 2020. Hives were introduced in the tunnels just before the second application (beginning of flowering period). Tunnels were of the required size and access to water was provided. Honey was collected 7–14 days after the last application, at maturity (water content < 20%) before the end of flowering period. The sample size ranged from 21 to 57 g in the different trials, but this was considered as a minor deviation from the Technical Guidelines for honey requiring minimum of 100 g sample (European Commission, 2018), not affecting the validity of the trials. The samples of the residue trials were stored under conditions for which integrity of the samples was demonstrated. Samples were analysed for phosphonic acid; to derive MRL proposals for the existing enforcement residue definition, the results were expressed as fosetyl by applying the molecular weight conversion factor. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. Phosphonic acid residues were not present in honey samples from untreated plots (Netherlands, 2021a).

Phosphonic acid residues in honey ranged from 0.71 to 46 mg/kg, allowing to derive an MRL proposal of 100 mg/kg according to the proposed residue definition for monitoring or 150 mg/kg according to the existing residue definition for enforcement. It is noted that during the joint review of MRLs for fosetyl and phosphonates, an MRL of 0.3 mg/kg for honey was derived for the existing monitoring data using CI95 approach,[9] when considering 62 honey samples analysed during the 2015–2018 EU MS control programmes (EFSA, 2021c).

Data on residues in pollen and inflorescences of buckwheat were also presented in the evaluation report (Netherlands, 2021a). According to Commission Regulation (EU) 2018/62[10] MRLs are currently applicable only to honey; therefore, these additional results are considered as supplementary information only.

It is noted that the present MRL application for honey is related to intended uses on crops attractive to bees and that would be a potential source for residues of phosphonic acid in honey. EFSA notes that other uses of potassium phosphonates on melliferous crops authorised in the EU, might lead to higher phosphonic acid residues, however not expected when considering available monitoring data (EFSA, 2021c).

1.2.3. Magnitude of residues in rotational crops

Chards can be grown in rotation with other crops and phosphonic acid exhibits moderate to high soil persistence (see Section 1.1.2); hence, the presence of residues in succeeding crops should be investigated. In the framework of the present MRL application studies on rotational crops were not submitted. The possible transfer of phosphonic acid residues to crops that are grown in crop rotation was assessed in the joint MRL review (EFSA, 2021c), taking into consideration previous assessments of EFSA available for fosetyl and potassium phosphonates.

According to the confined rotational crops metabolism study evaluated in the framework of the 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 (equivalent to 14.7 kg phosphonic acid/ha), residues are taken up from the soil by the plant. Actually, based on the results of this study, residue concentrations of phosphonic

[9] Upper confidence interval (CI95) of the calculated P95. For honey (n > 59), CI95 was calculated. Residues below LOQ were included in the calculation by replacing them by the LOQ of the reporting laboratory (upper bound scenario).

[10] Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. C/2018/0138. OJ L 18, 23.1.2018, p. 1–73.

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 PBI. Residues were not analysed at longer plant back intervals, 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 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 plant back interval (PBI) of 30 days. Within 7 days after the last application (32–69 days after planting), the primary crop lettuce was destroyed, and the remaining plant parts were incorporated into the soil. Relevant rotational crops were sown/planted 30 days following the incorporation of lettuce in the soil. No other plant back intervals have been investigated. Residues of fosetyl and phosphonic acid were shown to be below the LOQ of the method 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 only slightly lower application rate than in the intended seasonal application on chards/beet leaves (1.9 kg phosphonic acid/ha).

In the framework of the joint MRL review, EFSA noted that rotational field trials conducted with fosetyl were under dosed compared to the critical GAPs authorised for potassium phosphonates, and the magnitude of residues of fosetyl and phosphonic acid was determined at the 30-day PBI only and not at later PBIs (EFSA, 2021c). A firm conclusion could not be derived on the actual residue levels of phosphonic acid in rotational crops and on the most appropriated risk mitigation measures, since these studies did not cover the maximum dose rates of application of the authorised GAPs and were also not expected to cover the possible accumulation of phosphonic acid residues following successive years of application as this compound is considered as highly persistent.

Therefore, additional rotational crops' field trials performed at a dose rate covering the maximum dose rates of application and the possible accumulation of phosphonic acid (max PEC_{soil} for phosphonic acid) are in principle required. Nevertheless, in the framework of the joint MRL review, monitoring data were also considered to derive MRL proposals covering all sources of phosphonic acid and their residues uptake from the soil. These data were expected to cover also the possible uptake of phosphonic acid in succeeding crops resulting from the use of fosetyl, potassium and disodium phosphonates in compliance with the authorised GAPs and from the use of other products of agricultural relevance (e.g. fertilisers, plant strengthens, manure, soil amendments). Therefore, additional rotational crops' field studies are only desirable (EFSA, 2021c).

For the intended use on chards/beet leaves, the seasonal application rate of potassium phosphonates is lower than application rates reported for the authorised uses in the joint MRL review; therefore, the previous conclusions are still valid and further investigations are not required.

1.2.4. Magnitude of residues in processed commodities

Although phosphonic acid residues are expected to occur above 0.1 mg/kg in unprocessed chards/beet leaves and honey, considering the low 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 were not deemed necessary.

1.2.5. 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). In Section 3, EFSA assessed whether residues of phosphonic acid in chards/beet leaves resulting from the intended use of potassium phosphonates, and residues in honey resulting from the use of potassium phosphonates on melliferous crops (according to the use pattern assessed in the present application) are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as chards/beet leaves and honey 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, 2018a, 2019). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological profile 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 was derived (European Commission, 2013). 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, a revised ADI of 1 mg/kg bw per day has been derived, which was also recommended to be applied to phosphonic acid (EFSA, 2018b). 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). The input values were expressed as phosphonic acid equivalents. EFSA updated these exposure calculations with median residue values derived for commodities under assessment (chards/beet leaves and honey). In addition, the updated peeling factors for citrus fruits, which were not available for the joint MRL review and were derived from a recent reasoned opinion were used (EFSA, 2021d). All input values used in the exposure calculations are presented 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, lower ADI value of 1 mg/kg bw per day.

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). Expressing the exposure as percentage of the revised ADI of 1 mg/kg bw per day as proposed by the peer review on fosetyl (EFSA, 2018b; **scenario 2**), the highest chronic exposure was calculated for Dutch toddler, representing 81% of the ADI (Dutch toddler diet). The contribution to the total consumer intake for both commodities under assessment was below 0.12% of the ADI for both scenarios.

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

4. Conclusion and Recommendations

The data submitted in support of the MRL applications were found to be sufficient to derive MRL proposals for chards/beet leaves and honey. The MRL proposals were derived for the current enforcement residue definition as well as for the enforcement residue definition proposed by the EU pesticides peer review for potassium phosphonates and the joint MRL review. EFSA notes that the MRL proposal for chards/beet leaves as derived in the present assessment for the proposed residue definition is lower than the MRL proposal derived for chards/beet leaves by the joint MRL review; however, the value is not legally endorsed yet. For honey, a significantly lower MRL proposal was derived from available monitoring data (2015–2018 EU MS control programmes) during the joint MRL review.

Provided that the conclusions of the joint MRL review are implemented, EFSA concluded that the proposed SEU/NEU uses of potassium phosphonates on chards/beet leaves and the consumption of honey, produced by bees foraging melliferous crops treated with potassium phosphonates according to the use pattern assessed in the present application, will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
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)
EC	emulsifiable concentrate
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-MS	gas chromatography with mass spectrometry
HPLC	High-performance liquid chromatography
HPLC-MS	high performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UVD	high performance liquid chromatography with ultra-violet detector
HR	highest residue
IEDI	international estimated daily intake
ILV	independent laboratory validation

IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
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
SC	suspension concentrate
SCPAFF	Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH)
SEU	southern Europe
STMR	supervised trials median residue
WHO	World Health Organization

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

For honey, the MRL application is not linked to a specific GAP/crop but is related to intended uses on crops attractive to bees and that would be a potential source for residues of phosphonic acid in honey. In the framework of the joint review of fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021c), various uses were reported for crops that might be attractive to bees. These uses might lead to higher phosphonic acid residues in honey, however not expected when considering available monitoring data.

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) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate max	Unit	
Chards/beet leaves	NEU/SEU	F	*Bremia lactuca Peronospora sp*.	SC	453 g/L Potassium phosphonates	Foliar treatment – broadcast spraying	41–49	2	7–10	145–1,450	100–1,000	1450	g a.s./ha	7

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): 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/honey

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

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)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish	32; 182	No experimental studies submitted for potassium phosphonates. Bridging data on studies with fosetyl (EFSA,) considered sufficient to assess the nature of potassium phosphonates in rotational crops. 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	
	Cereals (small grain)	Barley	32	

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	According to experimental studies provided in the EU pesticides peer review of fosetyl (EFSA, 2018b), 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)	Existing residue definition: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) (Regulation (EC) No 396/2005) Proposed residue definition (not implemented yet): 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). • LC–MS/MS (Honey) Fosetyl LOQ: 0.05 mg/kg Phosphonic acid LOQ: 0.05 mg/kg (EFSA, 2018b, 2021c)	

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–MS: gas chromatography with mass spectrometry; QuPPe: Quick Polar Pesticides; LC–MS/MS: liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation

B.1.1.2. Stability of residues in plants and honey

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)

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
		Peaches		307	Days	Phosphonic acid	EFSA (2021c)
	High oil content	Avocados		25	Months	Phosphonic acid and its salts expressed as phosphonic acid.	EFSA (2021c)
		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 content	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)
		Pollen	–18	6	Months	Phosphonic acid	Netherlands (2021a)
Products of animal origin (available studies)		Honey	–18	6	Months	Phosphonic acid	Netherlands (2021a)

B.1.2. Magnitude of residues in plants and honey

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-Mo (proposed (**EFSA, 2021c**)):** Phosphonic acid and its salts, expressed as phosphonic acid **RD-RA (**EFSA, 2021c**):** Phosphonic acid and its salts, expressed as phosphonic acid						
Chards/beet leaves	NEU/SEU	**RD-Mo (existing)[d]:** 8.3; 8.4; 9.1; 11.3; 13.4; 14.7; 18.8; 2 × 20.1; 2 × 22.8; 24.1; 2 × 25.5; 26.8 **RD-RA=RD-Mo (proposed):** 6.2; 6.3; 6.8; 8.4; 10; 11; 14; 2 × 15; 2 × 17; 18; 2 × 19; 20	Residue trials on open-leaf lettuces compliant with GAP on chards. Extrapolation to chards/beet leaves possible. EFSA notes that in the joint MRL review, a higher MRL of 70 mg/kg was derived for the proposed RD-Mo from the use of fosetyl on spinach; the derived risk assessment values[e] were lower (STMR of 9 mg/kg and HR of 37 mg/kg) (EFSA, 2021c).	RD-Mo (existing): **60** RD-Mo (proposed): **40**	RD-RA: 20	RD-RA: 15
Honey	EU	**RD-Mo (existing)[d]:** 0.95; 0.98; 26.8; 61.6 **RD-RA=RD-Mo (proposed):** 0.71; 0.73; 27; 46	Semi-field (tunnel) trials with buckwheat treated with potassium phosphonates (3 × 2.36 kg/ha) at BBCH 55–65 via foliar application. The number of trials is sufficient to derive an MRL in honey.	RD-Mo (existing): **150** RD-Mo (proposed): **100**	RD-RA: 46	RD-RA: 10.37

MRL: maximum residue level; GAP: Good Agricultural Practice; RD: residue definition; Mo: monitoring; RA: risk assessment.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.
(b): 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)

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 to bare soil at 4.9 mg phosphonic acid/kg, 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), residues of fosetyl and 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). However, no firm conclusion can be drawn on the actual residue levels of fosetyl and phosphonic acid in rotational crops since these trials do not cover the maximum dose rates of application of the GAPs currently authorized in Europe and are also not expected to cover the possible accumulation of phosphonic acid residues following successive years of application as this compound is considered as highly persistent. Nevertheless in the framework of the joint MRL review, monitoring data were also considered to derive MRL proposals which are expected to cover also the possible uptake of phosphonic acid in succeeding crops resulting from the use of fosetyl, potassium and disodium phosphonates in compliance with the authorized GAPs and from the use of other products of agricultural relevance. Additional rotational crops field studies are therefore only desirable (EFSA, 2021c).

a.s.: active substance; eq: equivalents; PBI: plant-back interval; LOQ: limit of quantification; GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Not relevant as chards/beet leaves and honey are not used for feed purposes.

B.3. Consumer risk assessment

Not relevant since no ARfD has been considered necessary.

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, 2018b).
Highest IEDI, according to EFSA PRIMo	**Scenario 1 (TRV currently in place for phosphonic acid):** 36% ADI (NL toddler) Contribution of commodities assessed: Chards/beet leaves: 0.05% of ADI (ES adult diet) Honey: 0.05% of ADI (DE child diet) **Scenario 2 (TRV not yet endorsed):** 81% ADI (NL toddler) Contribution of commodities assessed: Chards/beet leaves: 0.12% of ADI (ES adult diet) Honey: 0.1% of ADI (DE child 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 derived from residue trials for chards/beet leaves and honey as derived from the residue trials submitted for the present assessment. Additionally, for citrus fruits the processing factors as derived in a recent EFSA opinion (not voted yet) (EFSA, 2021b) were applied to the input values for citruses. Calculations performed with PRIMo revision 3.1.

ARfD: acute reference dose; ADI: acceptable daily intake; TRV: toxicological refence values; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level.

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				
0252030	Chards/beet leaves	15/70	60/40	The submitted data are sufficient to derive an MRL proposal for the NEU/SEU uses. The MRL proposal is lower than that of the joint MRL review for fosetyl and phosphonates, derived from NEU trials on spinaches treated with fosetyl (EFSA, 2021c). Risk for consumers unlikely.
1040000	Honey	0.5*/0.3	150/100	The MRL proposal reflects residues in honey from tunnel trials performed on buckwheat treated with potassium phosphonates. In the framework of the joint MRL review for fosetyl and phosphonates, an MRL for honey was derived from available monitoring data (EFSA, 2021c). Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): MRL proposal, according to proposed new enforcement residue definition, derived in a recently published reasoned opinion of EFSA, not yet implemented (EFSA, 2021c).

Appendix C – Pesticide Residue Intake Model (PRIMo)

Scenario 1 (TRV currently in place for phosphonic acid)

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:	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:

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	809.91	10%	Apples	5%	Potatoes	4%	Wheat		36%
	33%	DE child	751.07	11%	Apples	4%	Wheat	3%	Potatoes		33%
	24%	NL child	538.56	5%	Apples	4%	Wheat	4%	Potatoes		24%
	22%	GEMS/Food G06	505.76	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	398.77	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	381.12	5%	Wheat	3%	Oranges	2%	Potatoes		17%
	16%	GEMS/Food G10	369.92	4%	Wheat	4%	Potatoes	0.9%	Tomatoes		16%
	14%	SE general	322.96	5%	Potatoes	3%	Wheat	0.9%	Apples		14%
	14%	DK child	322.30	5%	Wheat	3%	Potatoes	2%	Apples		14%
	14%	UK toddler	320.50	4%	Potatoes	4%	Wheat	2%	Apples		14%
	14%	ES child	315.38	5%	Wheat	2%	Potatoes	2%	Oranges		14%
	14%	FR toddler 2 3 yr	308.10	3%	Wheat	3%	Apples	2%	Potatoes		14%
	13%	DE women 14-50 yr	289.38	2%	Apples	2%	Wheat	1%	Oranges		13%
	13%	IT toddler	286.48	7%	Wheat	1%	Potatoes	0.9%	Tomatoes		13%
	12%	FI 3 yr	274.74	6%	Potatoes	1%	Wheat	1%	Cucumbers		12%
	12%	NL general	270.95	3%	Potatoes	2%	Wheat	1%	Apples		12%
	12%	DE general	267.69	2%	Apples	2%	Wheat	1%	Potatoes		12%
	11%	UK infant	241.42	4%	Potatoes	3%	Wheat	1%	Apples		11%
	11%	FR adult	236.30	4%	Wine grapes	2%	Wheat	0.9%	Potatoes		11%
	10%	ES adult	227.43	2%	Wheat	1%	Potatoes	1.0%	Oranges		10%
	10%	FI 6 yr	219.06	5%	Potatoes	1%	Wheat	0.8%	Cucumbers		10%
	10%	IT adult	215.18	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	189.89	4%	Potatoes	2%	Apples	0.6%	Tomatoes		8%
	8%	LT adult	182.09	4%	Potatoes	2%	Apples	1%	Wheat		8%
	7%	UK adult	168.65	2%	Wheat	2%	Wine grapes	2%	Potatoes		7%
	7%	FR infant	166.29	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	62.32	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 (TRV not yet endorsed)

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 : ---

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)
	81%	NL toddler	809.91	22%	Apples	11%	Potatoes	9%	Wheat		81%
	75%	DE child	751.07	25%	Apples	10%	Wheat	7%	Potatoes		75%
	54%	NL child	538.56	12%	Apples	10%	Wheat	9%	Potatoes		54%
	51%	GEMS/Food G06	505.76	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	398.77	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	381.12	11%	Wheat	6%	Oranges	4%	Potatoes		38%
	37%	GEMS/Food G10	369.92	9%	Wheat	8%	Potatoes	2%	Tomatoes		37%
	32%	SE general	322.96	11%	Potatoes	7%	Wheat	2%	Apples		32%
	32%	DK child	322.30	10%	Wheat	7%	Potatoes	5%	Apples		32%
	32%	UK toddler	320.50	9%	Potatoes	9%	Wheat	3%	Apples		32%
	32%	ES child	315.38	10%	Wheat	5%	Potatoes	4%	Oranges		32%
	31%	FR toddler 2 3 yr	308.10	7%	Wheat	6%	Apples	5%	Potatoes		31%
	29%	DE women 14-50 yr	289.38	5%	Apples	5%	Wheat	3%	Oranges		29%
	29%	IT toddler	286.48	15%	Wheat	2%	Potatoes	2%	Tomatoes		29%
	27%	FI 3 yr	274.74	13%	Potatoes	3%	Wheat	3%	Cucumbers		27%
	27%	NL general	270.95	7%	Potatoes	4%	Wheat	3%	Apples		27%
	27%	DE general	267.69	5%	Apples	4%	Wheat	3%	Potatoes		27%
	24%	UK infant	241.42	9%	Potatoes	6%	Wheat	3%	Apples		24%
	24%	FR adult	236.30	8%	Wine grapes	5%	Wheat	2%	Potatoes		24%
	23%	ES adult	227.43	5%	Wheat	3%	Potatoes	2%	Oranges		23%
	22%	FI 6 yr	219.06	10%	Potatoes	2%	Wheat	2%	Cucumbers		22%
	22%	IT adult	215.18	10%	Wheat	2%	Tomatoes	2%	Potatoes		22%
	19%	UK vegetarian	191.69	5%	Wheat	4%	Potatoes	3%	Wine grapes		19%
	19%	PL general	189.89	9%	Potatoes	4%	Apples	1%	Tomatoes		19%
	18%	LT adult	182.09	9%	Potatoes	4%	Apples	2%	Wheat		18%
	17%	UK adult	168.65	4%	Wheat	4%	Wine grapes	4%	Potatoes		17%
	17%	FR infant	166.29	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	62.32	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:

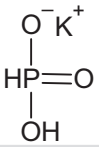
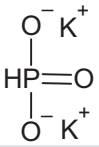
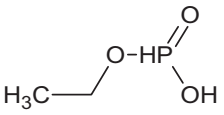
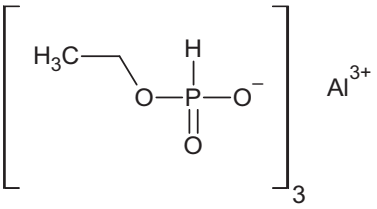
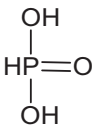
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	**Comment**
Risk assessment residue definition: phosphonic acid and its salts, expressed as phosphonic acid		
Chards/beet leaves	15	STMR-RAC
Honey	10.37	STMR-RAC
Grapefruits Oranges	17.11	STMR-RAC (23.44 mg/kg, potassium phosphonates, tentative; EFSA, 2021c) × PeF (0.73; EFSA, 2021d)
Lemons Limes Mandarins	17.11	STMR-RAC (23.44 mg/kg, potassium phosphonates; EFSA, 2021c) × PeF (0.73; EFSA, 2021d)
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 (see Appendix D.2; 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 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).