Scientific statement on the maximum residue levels for potassium phosphonates

European Food Safety Authority (EFSA)

Abstract

The European Commission mandated EFSA to issue a scientific statement, in accordance with Article 31 of Regulation (EC) No 178/2002, providing an overview of the maximum residue levels for potassium phosphonates in different products. This statement should be based on the maximum residue levels recently proposed by EFSA in several Reasoned Opinions published between June 2021 and January 2022 and the maximum residue levels supported in preparation of an EU position at the 52nd Codex Committee on Pesticides Residues. EFSA prepared a scientific statement containing a summary of the maximum residue levels proposed, including a reference to the scientific output on which the recommendation for each product is based and a justification for the selected values when different ones were proposed by the different outputs. An updated consumer risk assessment, based on the consolidated list of MRLs for the enforcement of phosphonic acid residues, was calculated. No risk for consumers was identified.

© 2022 Wiley-VCH Verlag GmbH & Co. KgaA on behalf of the European Food Safety Authority.

Keywords: fosetyl, potassium phosphonates, disodium phosphonate, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, fungicide

Requestor: European Commission

Question number: EFSA-Q-2022-00279

Correspondence: pesticides.mrl@efsa.europa.eu
Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Suggested citation: EFSA (European Food Safety Authority), 2022. Statement on the scientific statement on the maximum residue levels for potassium phosphonates. EFSA Journal 2022;20 (7):7400, 19 pp. https://doi.org/10.2903/j.efsa.2022.7400

ISSN: 1831-4732

© 2022 Wiley-VCH Verlag GmbH & Co. KgaA on behalf of the European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.
Summary

Between June 2021 and January 2022, the European Food Safety Authority (EFSA) published a Reasoned Opinion on the joint review of maximum residue levels (MRLs) for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005, a Scientific Report providing support for preparing an EU position for the 52nd Session of the Codex Committee on Pesticide Residues (CCPR) and four Reasoned Opinions on the modification of MRLs for potassium phosphonates based on applications received in accordance with Article 6 of that same Regulation.

Since several evaluations based on different uses (Good Agricultural Practices, GAPs) and different data sets were performed in parallel (namely the joint review of existing MRLs under Art. 12 and Art. 43 and the assessment of new applications under Art. 6 of Regulation (EC) No 396/2005), in certain outputs EFSA proposed diverging MRL values for the same products (e.g. citrus fruits).

In order to proceed with the legal implementation of the proposed MRLs and to ensure full transparency of the decision-making process, the European Commission required additional guidance from EFSA on the appropriate MRLs to be considered for potassium phosphonates, for all the products that were covered by the concerned Reasoned Opinions and the Scientific Report providing support for preparing an EU position for the 52nd CCPR.

To this purpose, on 8 April 2022, the European Commission sent a mandate to EFSA, to deliver, in accordance with Article 31 of Regulation (EC) No 178/2002, a scientific statement, providing an overview of the maximum residue levels recently proposed by EFSA in the concerned Reasoned Opinions on potassium phosphonates in different products and the Scientific Report for the 52nd CCPR. For each recommended MRL a reference shall be given to the EFSA scientific output and related recommendations on which the proposal is based. The proposed MRLs shall be expressed according to the residue definition for enforcement as proposed by EFSA in the joint MRL review: ‘phosphonic acid and its salts expressed as phosphonic acid’. Furthermore, an updated consumer risk assessment, based on the consolidated list of recommended MRLs and related input values for risk assessment, shall be calculated.

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 consolidated list of maximum residue levels for phosphonic acid was prepared by EFSA focusing on the crops for which divergent MRLs in recent EFSA outputs were published: citrus fruits, cherries, plums, kiwi, beet leaves (chard), dried flowers of herbal infusions (strawberry leaves, rooibos, mate) and honey. The following conclusions are derived:

- for citrus fruits, beet leaves (chard), herbal infusions from leaves and herbs the MRL proposals as derived by the joint MRL review are recommended;
- for cherries, plums and honey the MRLs as derived in the Article 10 EFSA reasoned opinions are recommended;
- for kiwi fruits the Codex MRL proposal as derived by the JMPR in 2019 is recommended.

It has to be noted that MRL proposals for oranges and grapefruits are still affected by data gaps identified by the joint MRL review.

The updated consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). In the framework of the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates, a comprehensive long-term exposure assessment was performed. EFSA updated these calculations considering the consolidated list of MRLs for potassium phosphonates derived within this statement and their related input values for risk assessment.

Considering the currently applicable ADI of 2.25 mg/kg bw per day, the estimated long-term dietary intake accounted for 36% of the ADI (Dutch toddler diet). When considering an ADI of 1 mg/kg bw per day, the estimated long-term dietary intake accounted for 82% of the ADI (Dutch toddler diet).

EFSA concluded that the MRLs recommended in this statement for the enforcement of residues of phosphonic acid and derived in the framework of various EFSA assessments issued between June 2021 and January 2022 supporting the authorised or intended uses of potassium phosphonates or fosetyl, 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.
Table of contents

Abstract ................................................................................................................................................. 1
Summary ............................................................................................................................................... 3
1. Terms of Reference ........................................................................................................................... 5
2. Summary of the MRLs derived in the different outputs and recommended MRLs .................................... 5
3. Consumer risk assessment ................................................................................................................. 13
4. Conclusion and Recommendations .................................................................................................... 13
References ............................................................................................................................................. 14
Abbreviations ......................................................................................................................................... 15
Appendix A – Pesticide Residue Intake Model (PRIMo). ........................................................................... 16
1. Terms of Reference

Between June 2021 and January 2022, EFSA published a Reasoned Opinion on the joint review of Maximum Residue Levels (MRLs) for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/20051 (EFSA, 2021c), a Scientific Report providing support for preparing an EU position for the 52nd Session of the Codex Committee on Pesticide Residues (CCPR) (EFSA, 2021) and four Reasoned Opinions on the modification of MRLs for potassium phosphonates based on applications received in accordance with Article 6 of that same Regulation (EFSA, 2021a,d, 2022a,b).

On 8 April 2021, the European Commission mandated EFSA to issue a scientific statement in accordance with Article 31 of Regulation (EC) No 178/20022, providing an overview list of the maximum residue levels proposed for potassium phosphonates in different crops assessed in the abovementioned EFSA outputs; for each MRL proposal a reference to the specific output and related recommendations shall be included. The proposed MRLs should be expressed according to the residue definition for enforcement as proposed by EFSA in the joint MRL review (EFSA, 2021c). An updated consumer risk assessment, based on the consolidated list of MRLs for potassium phosphonates that will be provided by the statement and their related input values for risk assessment, should also be calculated.

EFSA accepted the mandate to deliver the scientific statement by 8 July 2022.

2. Summary of the MRLs derived in the different outputs and recommended MRLs

A summary of the MRLs proposed in the different EFSA scientific outputs indicated in the terms of reference are summarised below and the MRLs recommended by this statement in Table 1. This table reports, together with the recommended MRLs, a reference to the scientific output on which the recommendation for each product is based. Moreover, where different MRL values were proposed by different scientific outputs, a justification for the selected values is also reported and this justification is further elaborated in this section.

The MRL proposals discussed hereafter refer to the crops for which the proposed MRLs were covered by various EFSA outputs produced within June 2021 and January 2022: citrus fruits, cherries, plums, beet leaves/chards, herbal infusions from leaves and herbs, and honey.

Additionally, EFSA was requested to consider the MRLs for fosetyl-Al as evaluated recently by the JMPR and assessed by EFSA in the Scientific Report providing support for preparing an EU position for the 52nd CCPR (EFSA, 2021). In this report, EFSA indicated that the only supported crop for which the proposed Codex MRL is higher than existing or proposed EU MRL is kiwi.

It is important to note that throughout the statement the MRL proposals refer to the enforcement residue definition proposed by the joint MRL review as ‘phosphonic acid and its salts expressed as phosphonic acid’ (EFSA, 2021c), in accordance with the terms of reference of the mandate (see Section 1).

Citrus crops

In addition to the MRLs proposed by the joint MRL review (EFSA, 2021c), EFSA proposed MRLs for products belonging to the citrus fruit crop group in two separate Reasoned Opinions (EFSA, 2021a,d). All derived MRLs were based on different uses (i.e. GAPs) and different datasets.

Grapefruits and oranges

For grapefruits and oranges, the joint MRL review (EFSA, 2021c) recommended a tentative MRL of 100 mg/kg based on the EU use of potassium phosphonates. A data gap indicating the need for additional eight trials on oranges and/or grapefruits supporting the authorised use was noted.

Shortly after the publication of the joint MRL review, EFSA issued a reasoned opinion on the modification of the existing MRLs for fosetyl/phosphonic acid in citrus fruits resulting from the use of potassium phosphonates (EFSA, 2021d). In this reasoned opinion for grapefruits and oranges, EFSA

---

1 Regulation (EC) No 396/2005 of the European 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.

2 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.
presented two MRL proposals (60 mg/kg (option 1) and 70 mg/kg (option 2)) for risk management consideration, noting deficiencies related to number and independency of residue trials. The MRLs proposed by both options are lower than the MRL proposed by the joint MRL review.

Therefore, considering that the MRL proposal derived in the joint MRL review is based on a more critical authorised GAP in the SEU for which no consumer intake concerns have been identified and considering the fact that none of the current pending MRL proposals is fully supported by data, EFSA recommends for grapefruits and oranges the tentative MRL of 100 mg/kg as proposed by the joint MRL review with a footnote related to the data gap.

**Lemons, limes and mandarins**

For lemons, limes and mandarins, the joint MRL review (EFSA, 2021c) recommended an MRL of 100 mg/kg on the basis of the EU use of potassium phosphonates (EFSA, 2021c). Shorty before and shortly after the publication of the EFSA joint MRL review, EFSA issued two other reasoned opinions, where different MRL proposals in limes, lemons and mandarins were presented for risk managers’ consideration (EFSA, 2021a,d).

On June 2021, before the publication of the joint MRL review, EFSA issued a reasoned opinion on the modification of the existing MRLs for potassium phosphonates in lemons, limes and mandarins and in herbal infusions from leaves and herbs, based on the intended EU uses of potassium phosphonates (EFSA, 2021a). EFSA recommended an MRL of 150 mg/kg for these citrus fruits (extrapolation of mandarin residue data).

On August 2021, a reasoned opinion on the joint MRL review was published where the MRL proposal of 100 mg/kg was derived for lemons, limes and mandarins. The MRL proposal was based on the same mandarin residue trials as assessed in the previous Article 10 MRL application but merged with additional residue trials on oranges (these orange residue trials were not available in the application supporting the Art. 10 reasoned opinion). In fact, in the joint MRL review EFSA noted this higher MRL of 150 mg/kg previously derived in the framework of an MRL application, not yet legally implemented and based on the dataset on mandarins only (EFSA, 2021a). However, since residue trials data on oranges were available in the framework of the joint MRL review and considering that the datasets on oranges and mandarins belong to the same population, the joint MRL review supported a lower MRL based on the merged dataset.

On November 2021, following the publication of the joint MRL review, EFSA issued another reasoned opinion on the modification of the existing MRLs for fosetyl/phosphonic acid in citrus fruits resulting from the intended EU use of potassium phosphonates (EFSA, 2021d). For lemons, limes and mandarins, EFSA presented three MRL options for risk managers consideration: 60 mg/kg (option 1) or 70 mg/kg (option 2) for lemons, limes and mandarins or 80 mg/kg (option 3) for limes only. It was noted that the MRLs proposed by these options were lower than the MRLs derived by the joint MRL review and affected by deficiencies related to independency and number of residue trials.

Considering that the MRL proposal of 100 mg/kg as derived by the joint MRL review is based on a more critical EU GAP and is sufficiently supported by residue data covering also the intended use assessed prior the finalisation of the joint MRL review (i.e., in EFSA, 2021a), for lemons, limes and mandarins, EFSA recommends the setting of the MRL of 100 mg/kg as derived in the joint MRL review.

**Beet leaves (chards)**

Different MRL proposals for beet leaves/chards have been derived in the joint MRL review (EFSA, 2021c) and in the subsequent EFSA assessment of the intended use of potassium phosphonates as applied for in an MRL application (EFSA, 2022a). The GAPs referred to in both assessments are different.

The joint MRL review proposed an MRL of 70 mg/kg for beet leaves/chards as an extrapolation of residue data on spinaches on the basis of the authorised EU use of fosetyl.

Following the publication of the joint MRL review, on January 2022, EFSA issued a reasoned opinion on the modification of the existing MRLs for fosetyl/phosphonic acid in chards/beet leaves and honey resulting from the use of potassium phosphonates (EFSA, 2022a). An MRL of 40 mg/kg was proposed in beet leaves/chards in support of the intended use of potassium phosphonates. The data obtained from residue trials on open-leaf lettuces were extrapolated to beet leaves/chards.

Since the intended GAP of potassium phosphonates on beet leaves/chard assessed in the Article 10 Reasoned Opinion results in a less critical residue situation in a crop than from the authorised GAP on fosetyl assessed during the MRL review, EFSA recommends the setting of the MRL proposal of 70 mg/kg for beet leaves/chards as derived in the joint MRL review.
Honey

Different MRL proposals for honey have been derived in the joint MRL review (EFSA, 2021c) and in the subsequent EFSA assessment of phosphonic acid residues in honey resulting from uses of potassium phosphonates as applied for in an MRL application (EFSA, 2022a).

The joint MRL review proposed an MRL for honey of 0.3 mg/kg based on the available monitoring data (EFSA, 2021c).

Following the publication of the joint MRL review, on January 2022, EFSA issued a reasoned opinion on the modification of the existing MRLs for fosetyl/phosphonic acid in chards/beet leaves and honey resulting from the use of potassium phosphonates (EFSA, 2022a). An MRL for honey of 100 mg/kg was proposed based on the treatment of buckwheat (selected as surrogate melliferous crop) with potassium phosphonates.

EFSA concludes it appropriate to set the MRL for honey at the level of 100 mg/kg on the basis of buckwheat residue field (tunnel) trials as assessed in the Article 10 reasoned opinion since in cases where both field trials and monitoring data are available, the data from field trials should prevail.

Cherries, plums

Different MRL proposals for cherries and plums have been derived in the joint MRL review (EFSA, 2021c) and in the subsequent EFSA assessment of the intended use of potassium phosphonates as applied for in an article 10 MRL application (EFSA, 2022b).

The joint MRL review proposed a tentative MRL of 2 mg/kg for cherries and 1 mg/kg for plums, both based on the monitoring data, noting that the reported SEU use of potassium phosphonates is not supported by residue data and no uses of fosetyl or disodium phosphate or import tolerances have been reported. A data gap for residue trials supporting the authorised SEU GAP was noted (four trials on cherries and eight trials on plums) (EFSA, 2021c).

Following the publication of the joint MRL review, on January 2022, EFSA issued a reasoned opinion on the modification of the existing MRLs for fosetyl/phosphonic acid in apricots, cherries and plums resulting from the intended SEU use of potassium phosphonates (EFSA, 2022b). In this reasoned opinion, EFSA proposed an MRL of 8 mg/kg for cherries and plums supporting both the intended SEU use and the authorised SEU use reported for the joint MRL review and addressing the confirmatory data gap noted by the joint MRL review.

As a conclusion, EFSA recommends setting the MRL for cherries and plums at a level of 8 mg/kg as proposed in the Article 10 reasoned opinion and to consider the confirmatory data requirement identified by the joint MRL review as addressed.

Strawberry leaves, rooibos, mate and other herbal infusion from leaves and herbs

For strawberry leaves, rooibos, mate and other herbal infusion from leaves and herbs, EFSA notes that the same MRL of 1,500 mg/kg has been proposed by the joint MRL review (EFSA, 2021c) and the EFSA reasoned opinion on the modification of the existing MRLs for potassium phosphonates in lemons, limes and mandarins and in herbal infusions from leaves and herbs (EFSA, 2021a). This MRL value is therefore recommended for these products in support of the uses of potassium phosphonates.

Kiwi fruits

According to the JMPR evaluation report (FAO, 2019), for kiwi fruits, six residue trials are available in support of the use of fosetyl-Al, and this is considered a sufficient number according to Codex classification even if the EU rules would require at least eight residue trials (EFSA, 2021).

JMPR derived an MRL of 150 mg/kg for kiwi fruits expressed as phosphonic acid, which is higher than the MRL of 100 mg/kg proposed by the joint MRL review in support of the authorised use of fosetyl (EFSA, 2021c). The reported uses of fosetyl are supported by residue data and no consumer intake concerns have been noted for the Codex MRL proposal and therefore, EFSA recommends the implementation of the proposed Codex MRL of 150 mg/kg expressed as phosphonic acid for kiwi fruits (considering the proposed enforcement residue definition ‘phosphonic acid and its salts expressed as phosphonic acid’).

In the Section 3 of this Statement, EFSA assessed whether enforcement of MRLs for phosphonic acid residues in the above-mentioned commodities is likely to pose a consumer health risk.

An overview of the MRLs proposed is provided in Table 1.
### Table 1: Overview of the MRLs proposed

| Code number | Commodity  | Existing EU MRL (mg/kg) (SANTE/10016/2022) | Existing CXLs (mg/kg) | Report supporting 52nd CCPR (EFSA, 2021) | MRL proposals derived by various EFSA outputs within a period from June 2021 until January 2022 (mg/kg) | Final recommended MRL (mg/kg) | Source | Comments |
|-------------|------------|------------------------------------------|----------------------|-----------------------------------------|----------------------------------------------------------------------------------------------------------------|-----------------------------|--------|----------|
|             |            |                                          |                      |                                         | EFSA (2021a)                                                                                                               | EFSA (2021d)                | EFSA (2022a) | EFSA (2022b) |                      |                      |                      |        |
| 0110010     | Grapefruits| 75                                       | –                    | –                                       | 100 Further consideration needed(a)                                                                                           | –                           | –              | 100 (tentative) | Joint MRL review (EFSA, 2021c) | The recommended MRL is based on the joint MRL review for a more critical GAP on potassium phosphonates. Since data gaps related to missing trials were noted by the joint MRL review, the MRL was proposed on tentative basis. Also MRLs derived in the Art.10 RO issued before the joint MRL review are subject to risk management decision and are lower than the MRL proposed by the joint MRL review. Risk for consumers unlikely. |
| 0110020     | Oranges    | 75                                       | 20                   | –                                       | 100 Further consideration needed(a)                                                                                           | –                           | –              | 100 (tentative) | Joint MRL review (EFSA, 2021c) |                      |                      |        |

**Enforcement residue definition (existing EU):** Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)

**Enforcement residue definition (CXL):** Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid

**Enforcement residue definition (proposed; EFSA, 2021c):** Phosphonic acid and its salts, expressed as phosphonic acid

All values reported below as MRL proposals derived by different outputs and final recommended MRLs refer to the residue definition for enforcement as proposed in the joint MRL review (EFSA, 2021c).

(a) Further consideration needed for RM based on the joint MRL review.
| Code number | Commodity | Existing EU MRL (mg/kg) (SANTE/10016/2022) | Existing CXLs (mg/kg) | MRL proposals derived by various EFSA outputs within a period from June 2021 until January 2022 (mg/kg) | Final recommended MRL (mg/kg) | Source | Comments |
|------------|-----------|------------------------------------------|----------------------|-------------------------------------------------------------------------------------------------|--------------------------|--------|----------|
| 0110030    | Lemons    | 150                                      | –                    | 150/RM considerations                                                                              | 100                      | –      | Joint MRL review (EFSA, 2021c) The recommended MRL is based on the joint MRL review for a more critical GAP on potassium phosphonates and where trials on mandarins were merged with trials on oranges (orange trials not available for the Art.10 RO (EFSA, 2021a). All MRLs proposed for RM considerations in the Art.10 RO (EFSA, 2021d) are subject to risk management decision and are lower than the MRL proposed by the joint MRL review. Risk for consumers unlikely. |
| 0110040    | Limes     | 150                                      | –                    | 150/RM considerations                                                                              | 100                      | –      | Joint MRL review (EFSA, 2021c) |
| 0110050    | Mandarins | 150                                      | 50                   | 150/RM considerations                                                                              | 100                      | –      | Joint MRL review (EFSA, 2021c) |
| 0140020    | Cherries  | 2*                                       | –                    | 2 Further consideration needed                                                                     | –                        | 8      | EFSA (2022b) MRL proposal based on Art.10 RO issued following the joint MRL review and based on a more thorough risk assessment. |

**Statement on the MRLs for potassium phosphonates**
## Statement on the MRLs for potassium phosphonates

| Code number | Commodity                | Existing EU MRL (mg/kg) (SANTE/10016/2022) | Existing CXLs (mg/kg) | Report supporting 52nd CCPR (EFSA, 2021) | Joint MRL review (EFSA, 2021c) | EFSA (2021d) | EFSA (2022a) | EFSA (2022b) | Final recommended MRL (mg/kg) | Source | Comments |
|-------------|--------------------------|-------------------------------------------|----------------------|------------------------------------------|-------------------------------|---------------|---------------|---------------|---------------------------------|--------|----------|
| 0140040     | Plums                    | 2*                                        | –                    | 1 Further consideration needed<sup>(e)</sup> | –                             | –             | –             | –             | 8                               | EFSA (2022b) | MRL proposal based on Art.10 RO issued following the joint MRL review and based on a more critical GAP and different data set not available at the time of the joint MRL review. The Art.12 confirmatory data are considered addressed. Risk for consumer unlikely. |
| 0162010     | Kiwi fruits (green, red, yellow) | 200                                      | –                    | 150                                      | 100 Recommended<sup>(f)</sup> | –             | –             | –             | 150                             | Report supporting 52nd CCPR (FAO, 2019) | EFSA recommends the implementation of the Codex MRL of 150 mg/kg based on the use of fosetyl. Risk for consumer unlikely. |
| Code number | Commodity          | Existing EU MRL (mg/kg) (SANTE/10016/2022) | Existing CXLs (mg/kg) | Report supporting 52nd CCPR (EFSA, 2021) | Joint MRL review (EFSA, 2021c) | EFSA (2021d) | EFSA (2022a) | EFSA (2022b) | Final recommended MRL (mg/kg) | MRL Source                  | Comments                                                                                                                                 |
|-------------|-------------------|---------------------------------------------|----------------------|------------------------------------------|-------------------------------|----------------|----------------|----------------|--------------------------------|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| 0252030     | Chards/beet leaves | 15                                          | –                    | –                                        | 70 Recommended               | –              | –              | –              | 70                             | Joint MRL review (EFSA, 2021c) | MRL proposal based on the joint MRL review for a more critical GAP of potassium phosphonates. Risk for consumers unlikely.                   |
| 0632010     | Strawberry leaves | 2000                                        | –                    | 1,500/RM considerations                  | 1,500 Recommended             | –              | –              | –              | 1,500                          | Joint MRL review (EFSA, 2021c) | The same MRL proposed by joint MRL review and Art.10 RO. Risk for consumers unlikely.                                                  |
| 0632020     | Rooibos           | 2000                                        | –                    | 1,500/RM considerations                  | 1,500 Recommended             | –              | –              | –              | 1,500                          | Joint MRL review (EFSA, 2021c) |                                                                                                                                                                         |
| 0632030     | Mate/maté         | 2000                                        | –                    | 1,500/RM considerations                  | 1,500 Recommended             | –              | –              | –              | 1,500                          | Joint MRL review (EFSA, 2021c) |                                                                                                                                                                         |
| 1,040,000   | Honey             | 0.5*                                        | –                    | 0.3 Further consideration needed         | 100                           |                |                |                | 100                            | EFSA (2022a)                 | 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. Risk for consumers unlikely. |

**Statement on the MRLs for potassium phosphonates**

www.efsa.europa.eu/efsajournal 11 EFSA Journal 2022;20(7):7400
MRL: maximum residue level; CXL: Codex maximum residue limit; RM: risk management; GAP: Good Agricultural Practice; RO: reasoned opinion.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

(a): Tentative MRL derived from a GAP evaluated at EU level for potassium phosphonates. No risk to consumers identified. The GAP evaluated at EU level for fosetyl and the monitoring data are covered by the proposed MRL. There are no relevant authorisations or import tolerances reported at EU level for disodium phosphonate. No CXL exists. Data gap: eight trials on oranges and/or grapefruits complaint with the SEU GAP.

(b): Tentative MRL derived from a GAP evaluated at EU level for potassium phosphonates. No risk to consumers identified. The GAP evaluated at EU level for fosetyl, the monitoring data and the existing CXL are covered by the proposed MRL. There are no relevant authorisations or import tolerances reported at EU level for disodium phosphonate.

(c): MRL derived from a GAP evaluated at EU level for potassium phosphonates. No risk to consumers identified. The GAP evaluated at EU level for fosetyl and the monitoring data are covered by the proposed MRL. There are no relevant authorisations or import tolerances reported at EU level for disodium phosphonate. No CXL exists.

(d): MRL derived from a GAP evaluated at EU level for potassium phosphonates. No risk to consumers identified. The GAP evaluated at EU level for fosetyl, the monitoring data and the existing CXL are covered by the proposed MRL. There are no relevant authorisations or import tolerances reported at EU level for disodium phosphonate.

(e): MRL derived from available MoD using CI95 approach. No risk to consumers identified. The GAP evaluated at EU level for potassium phosphonates is not supported by data. There are no relevant authorisations or import tolerances reported at EU level for fosetyl and disodium phosphonate. No CXL exists. Data gap: four residue trials on cherries complaint with the SEU GAP and eight residue trials on plums complaint with the SEU GAP.

(f): MRL derived from a GAP evaluated at EU level for fosetyl. No risk to consumers identified. Monitoring data are covered by the proposed MRL. There are no relevant authorisations or import tolerances reported at EU level for fosetyl and disodium phosphonate. No CXL exists.

(g): MRL derived from a GAP evaluated at EU level for potassium phosphonates. No risk to consumers identified. There are no relevant authorisations or import tolerances reported at EU level for fosetyl and disodium phosphonate. No CXL exists. Monitoring data are not available.

(h): MRL derived from a GAP evaluated at EU level for potassium phosphonates. No risk to consumers identified. Monitoring data are covered by the proposed MRL. There are no relevant authorisations or import tolerances reported at EU level for fosetyl and disodium phosphonate. No CXL exists.

(i): MRL derived from available monitoring data using CI95 approach. No risk to consumers identified. There are no relevant authorisations or import tolerances reported at EU level for fosetyl, potassium phosphonates and disodium phosphonate. No CXL exists.
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 subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological profile of potassium phosphonates was assessed in the framework of the EU pesticides peer review (EFSA, 2012). For phosphonic acid, which is the relevant component of residues in plant and animal products, an acceptable daily intake (ADI) of 2.25 mg/kg body weight (bw) per day was derived (European Commission, 2013). In 2018, in the framework of the renewal of the approval for fosetyl, a revised ADI of 1 mg/kg bw per day has been derived, which was also recommended to be applied to phosphonic acid (EFSA, 2018). Although this new ADI is not yet formally adopted, an indicative risk assessment was calculated based with this reference value as well.

**Short-term (acute) dietary risk assessment**

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

**Long-term (chronic) dietary risk assessment**

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

EFSA updated these calculations with the relevant STMR values derived from the residue trials on kiwi fruits (EFSA, 2021), honey (EFSA, 2022a), and cherries and plums (EFSA, 2022b) the only products for which EFSA proposed in this statement different MRLs than the MRLs recommended by the joint MRL review (see Table 1 and Section 2 above).

Provided that that the existing MRLs will be amended as proposed by the joint MRL review, 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 82% of the ADI (Dutch toddler diet).

EFSA concludes that the recommended MRLs for potassium phosphonates considered in the present statement 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, screenshots of the Report sheet of the PRIMo files are presented in Appendix A.

4. **Conclusion and Recommendations**

In the present statement, EFSA provided a list of the MRLs recommended to enforce the residues of phosphonic acid occurring in citrus fruits, cherries, plums, beet leaves/chards, herbal infusions from leaves and herbs, honey and kiwis from the existing or intended uses of potassium phosphonates or fosetyl. For these crops divergent MRL proposals were derived by EFSA in 2021 and 2022 as a result of parallel assessments of different uses (GAPs) of potassium phosphonates and fosetyl.

EFSA revised the available MRL proposals and derived following conclusions:

- for citrus fruits, beet leaves/chards, herbal infusions from leaves and herbs the MRL proposals as derived by the joint MRL review are recommended.
- for cherries, plums and honey the MRLs as derived in the Article 10 EFSA reasoned opinions are recommended.
- for kiwi fruits the Codex MRL proposal as derived by the JMPR in 2019 is recommended.

It has to be noted that MRL proposals for oranges and grapefruits are still affected by data gaps identified by the joint MRL review.

EFSA concluded that the MRLs recommended in this statement for the enforcement of residues of phosphonic acid and derived in the framework of various EFSA assessments issued in 2021 and 2022 supporting the authorised or intended uses of potassium phosphonates or fosetyl, are not expected to
result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a risk to consumers’ health.

The final overview of the MRL proposals recommended to enforce the residues of phosphonic acid in different products, with respective reference to the EFSA scientific outputs and related recommendations on which each MRL is based, is provided under Section 2.

References

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

EFSA (European Food Safety Authority), 2018b. Conclusion on the peer review of the pesticide risk assessment of the active substance fosetyl. EFSA Journal 2018;16(7):5307, 25 pp. https://doi.org/10.2903/j.efsa.2018.5307

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

EFSA (European Food Safety Authority), 2018b. Conclusion on the peer review of the pesticide risk assessment of the active substance fosetyl. EFSA Journal 2018;16(7):5307, 25 pp. https://doi.org/10.2903/j.efsa.2018.5307

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

EFSA (European Food Safety Authority), 2021b. Scientific support for preparing an EU position for the 52nd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2021;19(8):6766, 342 pp. https://doi.org/10.2903/j.efsa.2021.6766

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

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrahi S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021d. Reasoned Opinion on the modification of the existing maximum residue levels for fosetyl/phosphonic acid in citrus fruits resulting from the use of potassium phosphonates. EFSA Journal 2021;19(11):6926, 36 pp. https://doi.org/10.2903/j.efsa.2021.6926

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrahi S, Leuschner R, Oriol Magrans J, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Pia Scarlato A, Theobald A, Vagenende B and Verani A, 2022a. Reasoned Opinion on the modification of the existing maximum residue levels for fosetyl/phosphonic acid in chards/beet leaves and honey resulting from the use of potassium phosphonates. EFSA Journal 2022;20(1):6992, 30 pp. https://doi.org/10.2903/j.efsa.2022.6992

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Cabrera LC, Ferreira L, Giner G, Greco L, Jarrahi S, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Pia Scarlato A, Theobald A, Vagenende B and Verani A, 2022b. Reasoned Opinion on the modification of the existing maximum residue levels for fosetyl/phosphonic acid in apricots, cherries and plums resulting from the use of potassium phosphonates. EFSA Journal 2022;20(1):7106, 27 pp. https://doi.org/10.2903/j.efsa.2022.7106

European Commission, 2013. Final Review report for the active substance potassium phosphonates Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 March 2013 in view of the approval of potassium phosphonates as active substance in accordance with Regulation (EC) No 1107/2009. Potassium phosphonates. SANCO/10416/2013 rev 2. 15 March 2013

FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.

FAO (Food and Agriculture Organization of the United Nations), 2019. Report of the extra Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Ottawa, Canada, 7–17 May 2019. Pesticide residue in food 2019. 360 pp.
Abbreviations

ADI       acceptable daily intake
CCPR      Codex Committee on Pesticide Residues
EMS       evaluating Member State
FAO       Food and Agriculture Organization of the United Nations
GAP       Good Agricultural Practice
JMPR      Joint FAO/WHO Meeting on Pesticide Residues
LOQ       limit of quantification
MRL       maximum residue level
MS        Member States
PRIMo     (EFSA) Pesticide Residues Intake Model
RMS       rapporteur Member State
STMR      supervised trials median residue
Appendix A – Pesticide Residue Intake Model (PRiMo)

Scenario 1 (ADI 2.25 mg/kg bw per day).

Statement on the MRLs for potassium phosphonates

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

| Commodity/group of commodities | Highest contributor to ADI (in % of ADI) | 2nd contributor to ADI (in % of ADI) | 3rd contributor to ADI (in % of ADI) |
|-------------------------------|----------------------------------------|--------------------------------------|--------------------------------------|
|                              | Calculated exposure (µg/kg bw per day) | Estimated long-term dietary intake (TMDI/NEDI/IEDI) | Estimated long-term dietary intake (TMDI/NEDI/IEDI) |
|                              |                                       |                                      |                                      |
| Wheat                        | 36%                                    | 819.92                               | 11%                                  |
| Potatoes                     | 34%                                    | 755.24                               | 11%                                  |
| Tomatoes                     | 22%                                    | 506.25                               | 7%                                   |
| Wine grapes                  | 19%                                    | 420.35                               | 7%                                   |
| Potatoes                     | 18%                                    | 411.73                               | 6%                                   |
| Wheat                        | 18%                                    | 399.36                               | 5%                                   |
| Wine grapes                  | 17%                                    | 386.32                               | 5%                                   |
| Potatoes                     | 17%                                    | 382.57                               | 4%                                   |
| Wheat                        | 16%                                    | 370.39                               | 4%                                   |
| Apples                       | 14%                                    | 324.52                               | 3%                                   |
| Potatoes                     | 14%                                    | 320.89                               | 3%                                   |
| Wheat                        | 13%                                    | 290.21                               | 2%                                   |
| Apples                       | 12%                                    | 275.93                               | 2%                                   |
| Potatoes                     | 12%                                    | 271.64                               | 2%                                   |
| Wheat                        | 11%                                    | 241.59                               | 1%                                   |
| Apples                       | 10%                                    | 228.83                               | 1%                                   |
| Potatoes                     | 10%                                    | 216.19                               | 0.9%                                 |
| Wheat                        | 9%                                     | 192.04                               | 0.9%                                 |
| Apples                       | 8%                                     | 190.49                               | 0.6%                                 |
| Potatoes                     | 8%                                     | 182.19                               | 0.5%                                 |
| Wheat                        | 7%                                     | 168.92                               | 0.5%                                 |
| Apples                       | 7%                                     | 166.59                               | 0.3%                                 |
| Potatoes                     | 6%                                     | 163.30                               | 0.3%                                 |
| Wheat                        | 5%                                     | 150.94                               | 0.3%                                 |
| Apples                       | 5%                                     | 148.49                               | 0.3%                                 |
| Potatoes                     | 4%                                     | 146.05                               | 0.3%                                 |
| Wheat                        | 4%                                     | 143.56                               | 0.2%                                 |
| Apples                       | 3%                                     | 141.11                               | 0.2%                                 |
| Potatoes                     | 3%                                     | 139.68                               | 0.2%                                 |
| Wheat                        | 2%                                     | 137.24                               | 0.2%                                 |
| Apples                       | 2%                                     | 135.79                               | 0.2%                                 |
| Potatoes                     | 2%                                     | 134.35                               | 0.2%                                 |
| Wheat                        | 2%                                     | 131.91                               | 0.2%                                 |
| Apples                       | 1%                                     | 129.69                               | 0.1%                                 |
| Potatoes                     | 1%                                     | 127.35                               | 0.1%                                 |
| Wheat                        | 1%                                     | 125.01                               | 0.1%                                 |
| Apples                       | 1%                                     | 122.67                               | 0.1%                                 |
| Potatoes                     | 1%                                     | 120.33                               | 0.1%                                 |
| Wheat                        | 1%                                     | 118.00                               | 0.1%                                 |

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Phosphonic acid (resulting from use of fosetyl, potassium and disodium phosphonates) is unlikely to present a public health concern.

DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Show results for all crops

| ESTI | 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) |
|------|------------------------|-------------|---------------------------|---------------------|------------------------|-------------|---------------------------|---------------------|
|      |                        | IESTI       |                           |                     |                        | IESTI       |                           |                     |

Results for children

No. of commodities for which ARfD/ADI is exceeded (ESTI):

| ESTI | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|------|------------------------|-------------|---------------------------|---------------------|

Results for adults

No. of commodities for which ARfD/ADI is exceeded (ESTI):

| ESTI | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|------|------------------------|-------------|---------------------------|---------------------|

### Show results for processed commodities

| ESTI | Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|------|------------------------|-----------------------|---------------------------|---------------------|

Results for children

No. of processed commodities for which ARfD/ADI is exceeded (ESTI):

| ESTI | Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|------|------------------------|-----------------------|---------------------------|---------------------|

Results for adults

No. of processed commodities for which ARfD/ADI is exceeded (ESTI):

| ESTI | Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|------|------------------------|-----------------------|---------------------------|---------------------|

### Conclusion:

Total number of commodities exceeding the ARfD/ADI in children and adult diets (ESTI calculation):

- Children:
- Adults:

Acute risk assessment/children

Details – acute risk assessment/children

Acute risk assessment/adults/general population

Details – acute risk assessment/adults

Statement on the MRLs for potassium phosphonates
## Scenario 2 (ADI 1 mg/kg bw per day).

Statement on the MRLs for potassium phosphonates

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

**Toxicological reference values**

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|------------------------|-----------------|
|                         |                 |

### Details – chronic risk assessment

**Toxicological reference values**

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|------------------------|-----------------|
|                         |                 |

### Details – acute risk assessment

**Toxicological reference values**

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|------------------------|-----------------|
|                         |                 |

### Source of ADI

- 2013
- 2013

### Year of evaluation

- 2013
- 2013

### Comments

- Assuming MRLs will be amended as proposed in the RO on the joint review of MRLs for fosetyl, disodium phosphonates and phosphonic acid (resulting from use of fosetyl, potassium and disodium phosphonates) in chard/beet leaves and honey (not yet discussed in the context of the joint review of MRLs for fosetyl, disodium phosphonates and phosphonic acid (resulting from use of fosetyl, potassium and disodium phosphonates) in chard/beet leaves and honey (not yet discussed in the context of the joint review of MRLs for fosetyl, disodium phosphonates and phosphonic acid (resulting from use of fosetyl, potassium and disodium phosphonates) in chard/beet leaves and honey (not yet discussed in the context of the joint review of MRLs for fosetyl, disodium phosphonates and phosphonic acid (resulting from use of fosetyl, potassium and disodium phosphonates) in chard/beet leaves and honey)."

### Calculated exposure (% of ADI)

| Commodity/Group of commodities | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) |
|-------------------------------|--------------------------------------------|----------------------------------------|----------------------------------------|
|                               |                                            |                                        |                                        |

### Exposure resulting from commodities not under assessment

| Commodity/Group of commodities | Exposure (mg/kg bw per day) |
|-------------------------------|-----------------------------|
|                               |                             |

### Details – MRLs for fosetyl, disodium phosphonates and phosphonic acid (resulting from use of fosetyl, potassium and disodium phosphonates)

| Commodity/Group of commodities | MRL (mg/kg) |
|-------------------------------|-------------|
|                               |             |

### Details – Refined calculation mode

**Chronic risk assessment: JMPR methodology (EDI/TMDI)**

| Commodity/Group of commodities | No of diets exceeding the ADI | Exposure (mg/kg bw per day) |
|-------------------------------|------------------------------|-----------------------------|
|                               |                             |                             |

### Conclusion

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of phosphonic acid (resulting from use of fosetyl, potassium and disodium phosphonates) is unlikely to present a public health concern.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

| Commodities | MRL/input | Exposure (µg/kg bw) |
|-------------|-----------|---------------------|
|            |           |                     |

### Conclusion:

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation):

| 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): |

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