Modification of the existing maximum residue level for fosetyl/phosphonic acid for potatoes and wheat

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants Luxembourg Industries (Pamol) Ltd and De Sangosse SAS submitted a request to the competent national authority in France to modify the existing maximum residue level (MRL) for fosetyl/phosphonic acid related to the use of potassium phosphonates on potatoes, wheat and some animal commodities. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the crops under assessments and for animal commodities. Adequate analytical methods for enforcement are available to control the residues of phosphonic acid on the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg for high water- and dry matrices and at LOQ of 0.1 mg/kg in high acid matrices and in animal matrices and eggs at the validated LOQ of 0.05 mg/kg and in milk at the validated LOQ of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the intake of residues resulting from the use of potassium phosphonates according to the reported agricultural practices is unlikely to present a risk to consumers.

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Keywords: potassium phosphonates, fosetyl/phosphonic acid, potatoes, wheat, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants Luxembourg Industries (Pamol) Ltd and De Sangosse SAS submitted a request to the competent national authority in France to modify the existing maximum residue level (MRL) for fosetyl and phosphonic acid related to the use of potassium phosphonates in potatoes, wheat and some animal commodities. The evaluating Member State (EMS) drafted the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 25 September 2018. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRL for fosetyl in wheat from the limit of quantification (LOQ) of 2 mg/kg to 150 mg/kg for fosetyl or to set an MRL of 80 mg/kg for phosphonic acid, if risk managers agree to change the residue definition as previously proposed by EFSA. For potato, the EMS proposed to raise the existing MRL for fosetyl from 30 mg/kg to 200 mg/kg or to set an MRL of 150 mg/kg for phosphonic acid. Furthermore, the EMS also proposed to modify or set several MRLs in animal commodities.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

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

The metabolism of potassium phosphonates was assessed during the European Union (EU) peer review where it was agreed that data from public literature are sufficient to address the metabolism in plants which mainly involves transformation of potassium phosphonates into phosphonic acid.

Studies investigating the effect of processing on the nature of potassium phosphonates (hydrolysis studies) were conducted with its main transformation product and demonstrated that phosphonic acid is stable.

In rotational crops, the major residue identified was phosphonic acid.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of the metabolite, the EU peer review proposed a general residue definition for the active substance potassium phosphonates in plant products as ‘phosphonic acid and its salts, expressed as phosphonic acid’ for both enforcement and risk assessment. The current residue definition for enforcement set in Regulation (EC) 396/2005 is the ‘sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl’. These residue definitions are applicable to primary crops, rotational crops and processed products.

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC-MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definitions set in the EU Regulation and proposed during the EU peer review. The methods enable quantification of residues of fosetyl (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) at 0.01 mg/kg and residues of phosphonic acid and its salts at LOQ of 0.01 mg/kg for high water and dry matrices; in high acid matrices, an LOQ of 0.1 mg/kg was achieved for the fosetyl and phosphonic acid, respectively.

The available residue trials are sufficient to derive MRL proposals for the crops under assessment.

In the framework of this MRL application, processing studies were submitted by the applicant which give an indication that residues of phosphonic acid are accumulating in potato process waste and potato dried pulp which are used as feed items. Therefore, these processing factors are used to calculate the animal dietary burden. However, since the number of processing studies is not sufficient to derive robust processing factors to be used in MRL enforcement, EFSA does not recommend including the indicative processing factors in Annex VI of Regulation (EC) No 396/2009.

The occurrence of residues of potassium phosphonates in rotational crops was investigated in the framework of the EU pesticides peer review. Based on the available information on the nature and magnitude of residues, it was not possible to exclude residue levels occurring in rotational crops and therefore Member States should take risk mitigation measures (e.g. define pre-planting intervals) or request the applicant to submit an application to establish MRLs for rotational crops.

As potato, wheat and their by-products are used as feed products, a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species. Therefore, the possible occurrence of potassium phosphonates residues in commodities of animal origin had to be considered. The nature of potassium phosphonates residues in livestock has been investigated during the MRL review of
fosetyl and the residue definition was proposed as ‘phosphonic acid and its salts, expressed as phosphonic acid’ for both enforcement and risk assessment. Based on the estimated dietary burdens and the results of livestock feeding studies, MRLs were proposed for product of animal origin.

The toxicological profile of potassium phosphonates was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 2.25 mg/kg body weight (bw) per day for phosphonic acid, which is the toxicologically relevant metabolite of potassium phosphonates in plants. An acute reference dose (ARfD) was deemed unnecessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo).

The estimated long-term dietary intake was in the range of 10-48% of the ADI of 2.25 mg/kg bw per day (scenario 1). The contribution of wheat and potatoes to the total long-term exposure accounted for maximum of 8.8% and 7% of the ADI, respectively; among the animal products, milk was the highest contributor with a maximum of 0.2% of the ADI.

During the process of the renewal of the approval for fosetyl, a revised ADI of 1 mg/kg bw per day has been derived; this ADI was considered appropriate also for phosphonic acid. Although this ADI has not yet been noted by the European Commission, an indicative risk assessment scenario has been calculated (scenario 2). For the indicative risk assessment, the same input values were used as for scenario 1, except for table and wine grapes, strawberries, cucumbers, courgettes, melons and hops, where supervised trials median residue (STMR) values were derived by JMPR in 2017, which reflect EU uses. Since the residue trials for these EU uses were not yet assessed by EFSA, the use of STMR values derived by JMPR is considered as a source of a non-standard uncertainty.

In this scenario, the long-term exposure was in the range of 19-95% of the revised ADI. The contribution of wheat and potatoes to the total long-term exposure accounted for maximum of 19.7% and 15.9% of the ADI, respectively; among the animal products, milk was the highest contributor with a maximum of 0.4% of the ADI.

EFSA concluded that the proposed use of potassium phosphonates on potatoes and wheat will not result in a consumer exposure exceeding the existing toxicological reference value and therefore is unlikely to pose a risk to consumers’ health.

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

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

| Code(a) | Commodity   | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-------------|-------------------------|-------------------------|-----------------------|
|         |             | 1)                      | 2)                      |                       |
| 0211000 | Potatoes    | 30                      | 200                     | 150                   | The submitted data are sufficient to derive a MRL proposal for the NEU and SEU use. Risk for consumers, following chronic exposure, is unlikely. Residues in rotational crops cannot be excluded. Member States should consider setting specific pre-planting back intervals. |
| 050090  | Wheat       | 2.0*                    | 150                     | 80                    | The MRL proposals are sufficiently supported by data. Risk for consumers, following chronic exposure, is unlikely. |
| 1011010 | Swine: muscle | 0.5*                    | 0.7                     | 0.5*                  |                       |
| 1011020 | Swine: fat  | 0.5*                    | 1.1                     | 0.8                   |                       |
| 1011030 | Swine: liver | 0.5*                    | 0.8                     | 0.6                   |                       |
| 1011040 | Swine: kidney | 0.5*                    | 5.4                     | 4                     |                       |
| 1012010 | Bovine: muscle | 0.5*                    | 0.7                     | 0.5*                  |                       |
| 1012020 | Bovine: fat  | 0.5*                    | 1.3                     | 1.0                   |                       |
| 1012030 | Bovine: liver | 0.5*                    | 1.1                     | 0.8                   |                       |
| 1012040 | Bovine: kidney | 0.5*                    | 8.0                     | 6                     |                       |

Enforcement residue definition:

1) Existing enforcement residue definition: fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) (Reg. (EC) No 396/2005)

2) Proposed enforcement residue definition: phosphonic acid and their salts expressed as phosphonic acid (EFSA, 2012b)
### Table 1: Modification of the existing maximum residue level for fosetyl/phosphonic acid in various commodities

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|-----------|------------------------|------------------------|------------------------|
| 1013010           | Sheep: muscle | 0.5*                   | 0.7                    | 0.5*                   |
| 1013020           | Sheep: fat | 0.5*                   | 1.3                    | 1.0                    |
| 1013030           | Sheep: liver | 0.5*                   | 1.1                    | 0.8                    |
| 1013040           | Sheep: kidney | 0.5*                   | 8.0                    | 6                      |
| 1014010           | Goat: muscle | 0.5*                   | 0.7                    | 0.5*                   |
| 1014020           | Goat: fat | 0.5*                   | 1.3                    | 1.0                    |
| 1014030           | Goat: liver | 0.5*                   | 1.1                    | 0.8                    |
| 1014040           | Goat: kidney | 0.5*                   | 8.0                    | 6                      |
| 1016010           | Poultry: muscle | 0.5*                   | 0.7                    | 0.5*                   |
| 1016020           | Poultry: fat | 0.5*                   | 0.7                    | 0.5*                   |
| 1016030           | Poultry: liver | 0.5*                   | 0.7                    | 0.5*                   |
| 1020000           | Milk | 0.1*                   | 0.5                    | 0.4                    |
| 1030000           | Eggs | 0.1*                   | 0.7                    | 0.5*                   |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.

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

<sup>(a)</sup>: Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Assessment

The European Food Safety Authority (EFSA) received application to modify maximum residue levels (MRLs) relevant for the use of potassium phosphonates in potatoes and wheat. The detailed description of the intended uses of potassium phosphonates in the crops concerned which are the basis for the current MRL application is reported in Appendix A.

Potassium phosphonates is the name commonly used for the mixture of potassium hydrogen phosphonate and dipotassium phosphonate (EFSA, 2012b). The chemical structures of the components of the active substance and related compounds are reported in Appendix E.

The active substance potassium phosphonates was evaluated in the framework of Directive 91/414/EEC1 with France designated as rapporteur Member State (RMS) for the representative use of foliar spraying on grapes. The draft assessment report (DAR) prepared by the RMS (France, 2005, 2012) has been peer reviewed by EFSA (2012a). The active substance potassium phosphonates was approved2 for the use as a fungicide on 1 October 2013.

The EU MRLs reflecting the use of potassium phosphonates are established in Annex III of Regulation (EC) No 396/20053. The current residue definition for enforcement is set as the ‘sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl’. Thus, the existing MRLs reflect the uses of fosetyl, disodium phosphonate and the uses of potassium phosphonates.

The review of existing MRLs following the use of potassium phosphonates acid and disodium phosphonate has not yet been initiated. For fosetyl, EFSA performed the review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review). However, the proposed modifications of the existing MRLs have not yet been legally implemented since it is appropriate to await the MRL review for the related active substances, i.e. potassium phosphonates and disodium phosphate, as these active substances share the common metabolite phosphonic acid.

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants Luxembourg Industries (Pamol) Ltd and De Sangosse SAS submitted a request to the competent national authority in France to modify the existing MRL related to the use of potassium phosphonates in potatoes, wheat and some animal commodities.

The evaluating Member State (EMS) drafted the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 25 September 2018. To accommodate for the intended uses of potassium phosphonates, the EMS proposed to raise the existing MRL for fosetyl in wheat from the limit of quantification (LOQ) of 2 mg/kg to 150 mg/kg for fosetyl; for potato the EMS proposed to raise the existing MRL from 30 mg/kg to 200 mg/kg for fosetyl. The EMS also derived MRL proposals for the proposed residue definition derived in the framework of the EU peer review of fosetyl (EFSA, 2012b)): if the residue definition will modified as suggested by EFSA (i.e. sum of phosphonic acid and their salts expressed as phosphonic acid), according to the EMS, the MRLs required for wheat and for potatoes are 80 mg/kg and 150 mg/kg, respectively. Furthermore, the EMS also proposed to modify or set several MRLs in animal commodities.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2018a), the DARs (and their addendum) on potassium phosphonates4 (France, 2005, 2012) and the renewal assessment report (RAR) on fosetyl (France, 2017, 2018b) prepared under Regulation (EU) No 1107/20095, the Commission review report on potassium phosphonates (European Commission, 2013), the conclusions on the peer review of the pesticide risk assessment of potassium phosphonates (EFSA, 2012b) and fosetyl (EFSA, 2018c) as well as the conclusions from previous reasoned opinions on potassium phosphonates and fosetyl (EFSA, 2012c, 2015, 2018b and the MRL review of fosetyl (EFSA, 2012a).

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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 In the French DAR (France, 2005), the active substance ‘potassium phosphonates’ were referred to as ‘potassium phosphite’.
5 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50
For this application, the data requirements established in Regulation (EU) No 544/2011\textsuperscript{6} and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011\textsuperscript{7}.

As the reviews of the existing MRLs covering the three active substances that share the common metabolite phosphonic acid (i.e. fosetyl, phosphonic acid and disodium phosphonate) under Article 12 of Regulation 396/2005 are not all finalised yet, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the MRL reviews for the active substances concerned. A selected list of end points of the studies assessed by EFSA in the framework of this MRL application and the end points of relevant studies assessed previously are presented in Appendix B.

The evaluation report submitted by the EMS (France, 2018a) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo revision 2) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of potassium phosphonates was assessed during the EU peer review (EFSA, 2012b). It was concluded that, given the elementary nature of potassium phosphonates and taking into account the available data from public literature, the metabolism in plants involves the transformation of potassium phosphonates into phosphonic acid.

1.1.2. Nature of residues in rotational crops

Potatoes and wheat can be grown in rotation with other crops. No studies on residues in succeeding crops were evaluated during the EU peer review of potassium phosphonates (EFSA, 2012b). However, soil degradation studies were evaluated during the EU peer review of fosetyl which is expected to degrade rapidly in soil to its metabolite phosphonic acid (EFSA, 2018c). The DT\textsubscript{90} of phosphonic acid is greater than 1 year (EFSA, 2012a). It was concluded that the metabolism of potassium phosphonates in rotational crops is similar to the metabolic pathway depicted in primary crops.

1.1.3. Nature of residues in processed commodities

Standard hydrolysis studies simulating processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the MRL review of fosetyl and in the peer review of potassium phosphonates and fosetyl (EFSA, 2012a,b, 2018c). It was concluded that phosphonic acid is hydrolytically stable under the representative conditions.

1.1.4. Methods of analysis in plants

Different analytical methods, using liquid chromatography with tandem mass spectrometry (LC-MS/MS), were previously assessed with view on their use for enforcement of the MRLs for phosphonic acid (EFSA, 2018c). A method from Bayer was found to be sufficiently validated for the determination of phosphonic acid in matrices with high water content, high acid content and dry/high starch content LOQ of 0.1 mg/kg. For matrices with high oil content, an LOQ of 0.5 mg/kg was sufficiently validated. For the determination of fosetyl in the same matrices, a LOQ of 0.01 mg/kg was achieved.

A second sufficiently validated method allowed the determination of both phosphonic acid and fosetyl in matrices with high water-, dry/high starch- and high oil content at LOQ of 0.01 mg/kg while for both compounds a LOQ of 0.1 mg/kg was achieved in high acid matrices.

\textsuperscript{6} Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

\textsuperscript{7} Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
Thus, for potatoes and wheat, sufficiently validated analytical methods are available for enforcing the MRL for potassium phosphonates according to both the existing residue definition (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) and the residue definition proposed in the EU peer review (sum of phosphonic acid and their salts, expressed as phosphonic acid) (EFSA, 2012b).

1.1.5. Stability of residues in plants

The storage stability of phosphonic acid under frozen conditions was investigated in the framework of peer review of fosetyl (EFSA, 2018c), peer review of potassium phosphonates (EFSA, 2012b) and in previous MRL applications (EFSA, 2018a,b). Furthermore, additional storage stability studies on potato and wheat are available (France, 2018a).

Phosphonic acid is stable under frozen conditions at $-18^\circ$C for at least 25 months in potato and at $-20^\circ$C for at least 12 months in wheat.

1.1.6. Proposed residue definitions

The following residue definitions have been derived in previous assessments of potassium phosphonates:

- Residue definition for enforcement:
  - Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl (current residue definition set in Regulation (EC) No 396/2005);
  - Phosphonic acid and its salts, expressed as phosphonic acid (peer review of potassium phosphonates, EFSA, 2012b).

- Residue definition for risk assessment:
  - Phosphonic acid and its salts, expressed as phosphonic acid (peer review of potassium phosphonates, EFSA, 2012b)

It is noted that in previous assessments of fosetyl, different residue definitions have been derived which have not been legally implemented (e.g. sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid (EFSA, 2018c) or separate residue definitions for phosphonic acid and fosetyl (EFSA, 2012a)).

For the current application, MRL proposals were derived for the following residue definitions:

- Phosphonic acid and its salts, expressed as phosphonic acid (MRL scenario 1);
- Sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl9 (MRL scenario 2).

Considering that the final decision on the residue definition for risk assessment has not yet been taken, in line with the previously issued reasoned opinion of EFSA (2018b), the consumer risk assessment was performed for the following residue definition:

- Phosphonic acid and its salts, expressed as phosphonic acid.

The residue definitions apply to primary crops, rotational crops and processed products.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials performed in potatoes and wheat. All samples were analysed for phosphonic acid. According to the assessment of the EMS, the analytical methods used to analyse the residue trial samples were sufficiently validated and fit for purpose (France, 2018a).

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The available studies are sufficient to derive a MRL proposal for the crops under consideration.

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8 For residue definitions derived for fosetyl, see also EFSA (2018a)
9 For crops with uses of potassium phosphonates, the contribution of fosetyl is not relevant.
**Potatoes**

*(Northern Europe (NEU) and southern Europe (SEU) Good Agricultural Practice (GAP): 3 × 3.020 kg/ha (expressed as potassium phosphonate) at 7 day interval, preharvest interval (PHI) 7 days)*

The applicant submitted 25 residue trials (12 SEU and 13 NEU). Among the 25 residue trials, 13 are decline studies (6 SEU and 7 NEU), and in 12 trials, samples were taken at harvest only (harvest studies; 6 SEU and 6 NEU).

In four of the decline studies (two SEU and two NEU), the samples for analysis were collected between 7 and 56 days after the last treatment while in the remaining nine trials (four SEU and five NEU) the sampling was performed between 1 and 15 days after the last treatment. In most of these studies, the residue levels were higher at longer PHI than 7 days. Particularly, in SEU decline studies, the highest residues were found at 14, 15 and 44 days after the last treatment (88.6, 45.9 and 64.5 mg/kg, respectively) while in the NEU decline studies the highest residues were found at PHI of 14 days (13.7 and 26.9 mg/kg) and at PHI of 20 days (59.9 and 72.8 mg/kg) days. However, the residues levels at the longest PHI were in a comparable range as the residues found at PHI 7 days.

For calculating the MRL proposal and the risk assessment values, EFSA followed the EMS suggestion, selecting the highest residue levels observed in the residue decline studies at later PHI than the one defined in the GAP.

In the harvest studies, in eight trials (eight SEU and eight NEU), the sampling was performed at PHI 7 days while in four trials (two SEU and two NEU) samples were collected at PHI 40–49 days.

EFSA did not consider the four harvest trials (two SEU and two NEU) with PHI 40–49 days since they are not compliant with the GAP.

The EMS stated that the comparison of the SEU and NEU data sets did not show any statistical difference and therefore MRL is calculated also for the pooled data set. EFSA agreed with this approach.

**Wheat**

*NEU GAP: 2 × 3.020 kg/ha (expressed as potassium phosphonate) at BBCH 25–59, 14 days interval between applications, PHI not specified*

The applicant submitted eight residue trials performed in NEU. In two out of eight trials, the interval between applications was longer than the one defined in the GAP (34 and 41 days, respectively, instead of 14 days) which exceeded the acceptable deviation of ±25%.

According to the EMS, the deviation from the GAP in terms of interval between the two treatments does not have an impact on the residues in the harvested crop, since phosphonic acid is a persistent compound. Residue concentrations in these two trials were comparable to the levels measured in the compliant trials. EFSA agreed with this approach.

Based on the eight trials, EFSA calculated an MRL proposal.

*SEU GAP: 2 × 3.020 kg/ha at BBCH 25–59, 23 days interval, PHI not specified*

The applicant submitted eight residue trials compliant with the SEU GAP. Samples were taken between 54 and 66 days after the last treatment.

The number of trials was sufficient to derive a MRL proposal.

Since the comparison of the SEU and NEU data sets did not show a statistically significant difference, the MRL for wheat was calculated based on the pooled data set.

In all trials, straw samples were also analysed; the results of these analysis were used to update the dietary burden calculation (see Section 2).

### 1.2.2. Magnitude of residues in rotational crops

The magnitude of residues of phosphonic acid in rotational crops was investigated in the framework of the peer review of fosetyl (EFSA, 2018c). Phosphonic acid was applied on bare soil to radishes, lettuce and barley at 4.9 mg phosphonic acid/kg soil which corresponds to the concentration in a 15-cm soil layer resulting from the application of 15 kg/ha of fosetyl-Al (corresponding 11 kg/ha of phosphonic acid or approximately 16 kg/ha of potassium phosphonates). Radishes were sown 32 and 182 days after soil treatment; lettuce and barley were planted/sown at the plant-back interval of 32 days.

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10 It should be noted that among all NEU trials, the highest residue value (94.4 mg/kg) was determined in the trial at PHI 42. However, this result was still in the range of the residues measured in trials compliant with the GAP.
Residues of phosphonic acid above the LOQ of 0.5 mg/kg were found only in radish root and lettuce leaves (from crops planted at the plant-back interval of 32 days). The peer review concluded that a pre-planting period of 30 days is applicable to ensure that residues of phosphonic acid above the LOQ are not present in succeeding crops (EFSA, 2018c).

Rotational field trials with carrots, lettuce and winter wheat or winter barley were performed following three spraying applications with fosetyl at a dose rate of 0.775 kg a.s./ha (total rate 2.3 kg/ha, corresponding to 1.7 kg/ha of phosphonic acid or approximately 2.9 kg/ha of potassium phosphonates). The residues of phosphonic acid were below the LOQ in all crops at the 30-day plant-back interval (PBI) except in wheat grain where residues of 0.21 mg/kg were measured (EFSA, 2018c).

Based on the comparison of application rates of phosphonic acid between the crops under assessment and previous available rotational studies, residues of phosphonic acid in succeeding crops cannot be excluded and therefore Member States should take risk mitigation measures (e.g. define pre-planting intervals) or request the applicant to submit an application to establish MRLs for rotational crops.

1.2.3. Magnitude of residues in processed commodities

In the framework of this MRL application, new processing studies on potato and wheat have been submitted by the applicant (France, 2018a).

For potato, the following processes were investigated by the applicant: cooking, preparation of French fries, microwaving and production of flakes. The processing factors are tentative due to the limited number of processing studies (potato, dried waste) or because additional recovery data for the analytical method are needed.

For calculating the dietary burden in livestock, as proposed by the EMS, the tentative processing factors for potato process waste and potato dried pulp (2.2 and 4.8, respectively) were considered as more appropriate than default processing factors.

For wheat, processing studies on wheat germ, wheat flour, wheat bran, whole meal bread and gluten feed meal were provided by the applicant. The EMS considered that for whole meal bread and gluten feed meal the number of samples analysed for accuracy is insufficient and therefore additional data should be provided to fully validate the analytical method. Considering that only two studies per processed wheat product were available, the calculated processing factor (PF) are also considered tentative values.

1.2.4. Proposed MRLs

The available residue trials are sufficient to derive MRL proposals for potato and wheat (Appendix B.4). Two sets of MRLs are proposed: MRL scenario 1 (according to the residue definition proposed during the peer review of potassium phosphonates (EFSA, 2012b)) and MRL scenario 2 (according to the residue definition for enforcement for fosetyl currently set in Regulation (EC) No 396/2005).

2. Residues in livestock

Since potatoes, wheat and their by-products are used as feed items, it is necessary to assess whether the intended uses of potassium phosphonates in these crops require a modification of the MRLs set for animal commodities. EFSA calculated the dietary burden for phosphonic acid using the OECD methodology (OECD, 2013), including the data for potatoes, wheat and the related feed items. The input values for the exposure calculation for livestock are presented in Appendix D.1.

Comparing the results of the revised dietary burden calculation with the dietary burden derived previously (EFSA, 2018a), it becomes evident that the intended uses will not significantly impact on the overall dietary burden, since the new processing studies submitted by the applicant for potato process waste and potato dried pulp allowed to refine the calculation using the tentative processing factors which are lower than the default ones used in the previous assessment.

MRLs for animal commodities are calculated considering the contribution of the feed items assessed in the current application. However, it should be noted, as also reflected in the previous opinion (EFSA, 2018a), that the conclusions of the MRL review on fosetyl (EFSA, 2012a) have not been implemented in Regulation (EC) No 396/2005 and therefore the calculated dietary burden may not fully reflect the uses currently approved in the Member States.

The results of the dietary burden calculation are presented in Appendix B.2.
2.1. Nature of residues and methods of analysis in livestock

Three metabolism studies in lactating goat, dosed with radiolabelled fosetyl-Al, were previously assessed in the framework of peer review (EFSA, 2018c). Based on these studies, the peer review concluded that fosetyl is rapidly and extensively metabolised in tissues by breakdown to ethanol and phosphonic acid and that, because of the similarity between ruminant and rat metabolism, a metabolism study in pigs was not necessary. Furthermore, the peer review concluded that based on the simple nature of fosetyl-Al and the extensive metabolism shown in ruminant, a metabolism study in poultry was not necessary. Based on the above findings, the EFSA conclusion for fosetyl (EFSA, 2018c) concluded that the residue definition for enforcement and risk assessment was defined as phosphonic acid. The same residue definitions are considered appropriate to reflect the use of potassium phosphonates on feed items.

Sufficiently validated LC-MS/MS analytical method, including independent laboratory validation (ILV), are available for the enforcement of the residue definition phosphonic acid in milk with an LOQ of 0.01 mg/kg and in eggs, muscle, fat, kidney and liver with an LOQ of 0.05 mg/kg (EFSA, 2018c).

2.2. Magnitude of residues in livestock

In support of the application, a new feeding study with dairy cows was submitted by the applicant (France, 2018a) and it was considered acceptable. Cows were dosed for 28 consecutive days with potassium phosphonates at levels corresponding to 11, 22 and 66 mg phosphonic acid equivalents/kg body weight (bw) per day. Samples were stored for less than a month under frozen conditions and therefore storage stability in tissues and milk was not performed. Residues were present in fat, liver and kidney at all doses while in meat no residues were present at the lowest dose. Resides levels in milk reached the plateau in milk after 1 day. The dietary burden calculated in the current application falls within the dose range of the new feeding study.

A feeding study in laying hens was assessed in the MRL review of fosetyl (EFSA, 2012a) where animals were dosed for 28 consecutive days with fosetyl at 0.118, 0.353 and 1.1774 mg/kg bw per day and phosphonic acid at 1.226, 3.678 and 12.255 mg/kg bw per day. Residues levels of fosetyl and phosphonic acid were found to be below LOQ in all tissues and eggs.

In Appendix B.2.2.1, the MRL proposals and the risk assessment values for animal products are summarised.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMO.

The toxicological reference values for potassium phosphonates used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD) values) were assessed in the framework of the EU peer review (EFSA, 2012b). Considering that phosphonic acid is the relevant component of residues in plants, the ADI derived was related to phosphonic acid and was set at 2.25 mg/kg bw per day. An ARfD was deemed unnecessary.

During the process of the renewal of the approval for fosetyl, a revised ADI of 1 mg/kg bw per day has been derived and considered applicable also to phosphonic acid. Although this ADI has not yet been noted by the European Commission, an indicative risk assessment scenario has been calculated.

Short-term (acute) dietary risk assessment

The short-term exposure assessment is not required since no ARfD is established.

Long-term (chronic) dietary risk assessment

For the chronic risk assessment, the recent risk assessment performed in the framework of the MRL application (EFSA, 2018b) was updated by including median residue levels of phosphonic acid for the crops under assessment and for animal commodities. For the remaining crops, the existing MRLs set for fosetyl-Al in Commission Regulation (EU) No 2016/100311, recalculated to phosphonic acid, were used. Crops with MRLs set at the LOQ were disregarded (scenario 1).

11 Commission Regulation (EU) 2016/1003 of 17 June 2016 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 abamectin, acequinocyl, acetamiprid, benzoavindiflupyr, bromoxynil, fluoxonil, flupicinolide, fosetyl, meipiquat, procinazid, propanocarb, prohexadione and tebuconazole in or on certain products. C/2016/3685,. OJ L 167, 24.6.2016, p. 46–103
The complete list of input values used in the exposure calculations is presented Appendix D.2. The estimated long-term dietary intake was in the range of 10–48% of the ADI (2.25 mg/kg bw per day). The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix C. The contribution of wheat and potatoes to the total long-term exposure accounted for maximum of 8.8% and 7% of the ADI, respectively; among the animal products, milk was the highest contributor with a maximum of 0.2% of the ADI.

EFSA concluded that the long-term intake of residues of potassium phosphonates resulting from the existing and the intended uses is unlikely to present a risk to consumer health. An indicative risk assessment was performed using the proposed revised ADI of 1 mg/kg (scenario 2). This calculation is considered indicative, since the ADI is not yet formally adopted. For the indicative risk assessment, the same input values were used as for scenario 1, except for table and wine grapes, strawberries, cucumbers, courgettes, melons and hops, where supervised trials median residue (STMR) values were derived by JMPR in 2017, which reflect EU uses. Since the residue trials for these EU uses were not yet assessed by EFSA, the use of STMR values derived by JMPR is considered as a source of a non-standard uncertainty.

In this scenario, the long-term exposure was in the range of 19–95% of the revised ADI. The contribution of wheat and potatoes to the total long-term exposure accounted for maximum of 19.7% and 15.9% of the ADI, respectively; among the animal products, milk was the highest contributor with a maximum of 0.4% of the ADI.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for potatoes and wheat and for animal commodities.
EFSA concluded that the consumer exposure is unlikely to pose a risk to consumers’ health when the existing ADI of 2.25 mg/kg bw per day is used as toxicological reference value. The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement to risk assessment residue definition
DAR draft assessment report
DAT days after treatment
DM dry matter
DT₉₀ period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
Modification of the existing maximum residue level for fosetyl/phosphonic acid in various commodities

FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HPLC–MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
InChiKey International Chemical Identifier Key
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS/MS tandem mass spectrometry detector
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RAC raw agricultural commodity
RAR renewal assessment report
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SEU southern Europe
SL soluble concentrate
STMR supervised trials median residue
WHO World Health Organization
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|-------------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
|                       |                         |             |                                   | Type(b)     | Conc. a.s.   | Method kind                   | Range of growth stages & season(c) | Number min–max | Interval between appl. (min) | kg a.s./hl min–max | Water L/ha min–max | Rate (in kg/ha) |         |
| Potato                | France SEU              | F           | Late blight (Phytophthora infestans) | SL          | 755 g/L potassium phosphonates | Foliar application, using a sprayer | From BBCH stage 10 (leaf development) | 3                  | 7                   | 0.6–3.0 | 100–500 | 3.020 | 7       |
|                       | Belgium NEU             | F           | Late blight (Phytophthora infestans) | SL          | 755 g/L potassium phosphonates | Foliar application, using a sprayer | From BBCH stage 10 (leaf development) | 3                  | 7                   | 0.6–3.0 | 100–500 | 3.020 | 7       |
| Wheat                 | France SEU              | F           | Septoria (Septoria tritici)        | SL          | 755 g/L potassium phosphonates | Foliar application, using a sprayer | BBCH 25–59 | 2                  | 23                  | 0.6–3.0 | 100–500 | 3.020 | n.a     |
| Wheat                 | Belgium, UK NEU         | F           | Septoria (Septoria tritici)        | SL          | 755 g/L potassium phosphonates | Foliar application, using a sprayer | BBCH 25–59 | 2                  | 14                   | 0.6–3.0 | 100–500 | 3.020 | n.a     |

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SL: soluble concentrate; PHI: minimum preharvest interval.

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. 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.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|---------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops   |             |         |                |                | No experimental studies available |
| Root crops    |             |         |                |                | The EU peer review concluded that, given the elementary nature of potassium phosphonates and according to available data from public literature, the main metabolite of potassium phosphonates in plants is phosphonic acid (EFSA, 2012b) |
| Leafy crops   |             |         |                |                | |
| Cereals/grass |             |         |                |                | |
| Pulses/oilseeds |         |         |                |                | |
| Miscellaneous |             |         |                |                | |

| Rotational crops | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops |             |         |                |           | No studies available due to the simple nature of residue |
| Leafy crops      |             |         |                |           | |
| Cereal (small grain) |       |         |                |           | In the peer review of fosetyl, the nature of phosphonic acid (the soil degradation product of fosetyl) was investigated; in rotational crops phosphonic acid was found to be the main metabolite in rotational crops (EFSA 2012b, 2018c). |
| Other            |             |         |                |           | |

| Processed commodities | Conditions | Stable? | Comment/Source |
|-----------------------|------------|---------|----------------|
|                       | Pasteurisation (20 min, 90°C, pH 4) | Yes | According to peer review on fosetyl and peer review on potassium phosphonates, phosphonic acid is hydrolytically stable (EFSA, 2012b, 2018c) |
|                       | 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 (2012b)

Rotational crop and primary crop metabolism similar?
Yes | EFSA (2012b)

Residue pattern in processed commodities similar to residue pattern in raw commodities?
Yes | EFSA (2012b)

Plant residue definition for monitoring (RD-Mo)

| Option 1: Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012b) |
| Option 2: Sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl (Regulation (EC) No 396/2005) |

Plant residue definition for risk assessment (RD-RA)

Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012b)

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

HPLC–MS/MS: matrices with high water content, high oil content and dry matrices at LOQ of 0.01 mg/kg and in matrices with high acid content at LOQ 0.1 mg/kg (EFSA, 2018c)

DAT: days after

**B.1.1.2. Stability of residues in plants**

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|-----------------|-------------------|---------------|
| High water content                | Potato   | –20       | 12 Months | Phosphonic acid | France (2018a,b) |
|                                  |         | –18       | 12 Months | Sum of phosphonic acid and fosetyl | EFSA (2012b) |
|                                  | Wheat, whole plant | –18 | 25 Months | Phosphonic acid | EFSA (2012b) |
|                                  | Cucumber, lettuce | –18 | 12 Months | Sum of phosphonic acid and fosetyl | EFSA (2012b) |
|                                  | Cucumber, cabbage | –18 | 25 Months | Phosphonic acid | EFSA (2012b) |
|                                  | Apples   | –18       | 12 Months | Phosphonic acid | EFSA (2018a) |
|                                  | Peaches  | –18       | 307 Days | Phosphonic acid | EFSA (2018a) |
| High oil content                 | Almond   | –20       | 218 Days | Phosphonic acid | EFSA (2018a) |
|                                  | Pistachio | –20       | 221 Days | Phosphonic acid | EFSA (2018a) |
|                                  | Walnut   | –20       | 146 Days | Phosphonic acid | EFSA (2018a) |
| High protein content             |          |          |        |                 |                   |               |
| Dry/High starch                  | Wheat, grain | –20 | 12 Months | Phosphonic acid | France (2018a,b) |
| High acid content                | Grapes   | –18       | 12 Months | Sum of phosphonic acid and fosetyl | EFSA (2012a) |
|                                  |          |          |        |                 |                   |               |
| Processed products               | Peach jam, puree, nectar and canned peaches | –18 | 112–114 Days | Phosphonic acid | EFSA (2018a) |
| Others                            | Wheat, straw | –20 | 12 Months | Phosphonic acid | France (2018a,b) |
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials<sup>(b)</sup> (mg/kg) | Comments/Source | Calculated MRL<sup>(c)</sup> (mg/kg) | HR<sup>(d)</sup> (mg/kg) | STMR<sup>(e)</sup> (mg/kg) | CF |
|-----------|-----------------------------|--------------------------------------------------------------------------|-----------------|---------------------------------|-----------------|-----------------------|-----|
| **Residue definition for enforcement:** | | | | **Scenario 1:** | **Scenario 2:** |
| MRL scenario 1: Phosphonic acid and its salts, expressed as phosphonic acid. | | | | Phosphonic acid and its salts, expressed as phosphonic acid. | | |
| MRL scenario 2: Sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl. | | | | | | |
| **Residue definition for risk assessment:** | | | | | | |
| Phosphonic acid and its salts, expressed as phosphonic acid. | | | | | | |
| **Note:** the values reported below refer to residue levels of phosphonic acid. A conversion factor of 1.34 was applied to convert residue values of phosphonic acid to residues of fosetyl for deriving MRL proposal under scenario 2. | | | | | | |
| **Potatoes** | NEU | < 0.5, 9.1, 12.7, 13.7<sup>(f)</sup>, 22.5, 25.5, 25.9, 26.9<sup>(f)</sup>, 33.1, 59.9<sup>(f)</sup>, 72.8<sup>(f)</sup> | Residue trials on potatoes compliant with NEU GAP. The data set was pooled with the SEU trials for deriving the MRL. | | | | |
| | SEU | 4.2, 9.1, 11.4, 32.8, 36.6, 40.8, 45.9<sup>(f)</sup>, 64.5<sup>(f)</sup>, 81.4<sup>(f)</sup>, 88.6<sup>(f)</sup> | Residue trials on potatoes compliant with SEU GAP. The data set was pooled with the NEU trials for deriving the MRL. | | | | |
| **Wheat, grain** | NEU | 12.31, 17, 17.03, 20.61, 24.12, 26.08, 37.3, 40.69 | Residue trials on wheat grain compliant with NEU GAP. The data set was pooled with the SEU trials for deriving the MRL. | | | | |
| | SEU | 15.01, 21.06, 21.94, 22.13, 24.98, 34.82, 39.41, 52.58 | Residue trials on wheat grain compliant with SEU GAP. The data set was pooled with the NEU trials for deriving the MRL. | | | | |
| **Wheat, straw** | SEU | 5.64, 18.56, 25.22, 26.52, 31.46, 37.4, 42.17, 81.39 | STMR and HR values from NEU and SEU trials were pooled together to calculate animal dietary burden intake | | | | |
| | NEU | 2.16, 5.27, 5.58, 10.71, 11.65, 13.68, 21, 34.43 | | | | | |

**MRL:** maximum residue level; **GAP:** Good Agricultural Practice; **STMR:** supervised trials median residue; **HR:** highest residue; **CF:** conversion factor for enforcement to risk assessment residue definition.

<sup>*</sup>: Indicates that the MRL is proposed at the limit of quantification.

<sup>(a)</sup>: NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

<sup>(b)</sup>: The residue levels observed in the supervised residue trials refer to the residue definition for risk assessment which is identical with the MRL scenario 1.

<sup>(c)</sup>: MRL proposals were calculated for the residue definition derived in the framework of the peer review of potassium phosphonates (EFSA, 2012b) (Scenario 1) and for the residue definition currently implemented in the MRL legislation (Regulation (EC) No 396/2005) (Scenario 2). A conversion factor of 1.34 was applied to convert residue values of phosphonic acid to residues of fosetyl.

<sup>(d)</sup>: Highest residue. The highest residue for risk assessment refers to the whole commodity and is expressed for the residue definition for risk assessment.

<sup>(e)</sup>: Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and is expressed for the residue definition for risk assessment.

<sup>(f)</sup>: Residue concentration measured at later PHI than defined in intended GAP.
B.1.2.2. Residues in rotational crops

| Yes | Rotational crop field studies are summarised in the peer review of fosetyl (EFSA, 2018c). Residues in rotational crops cannot be excluded. Member States should consider setting specific pre-planting-back intervals.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) Individual values | Median PF | CFp(b) | Comment/Source |
|---------------------|-----------------------------|------------------------------------------|-----------|--------|----------------|
| Potato, cooked or boiled tuber | 4 | 0.5, 0.7, 1.2, 3.4 | 1.0 | Tentative(c), France (2018a,b) |
| Potato, French fries | 4 | 1.1, 1.9, 2.3, 3.1 | 2.1 | Tentative(c), France (2018a,b) |
| Potato, baked tuber | 4 | 1.1, 1.4, 1.6, 1.7 | 1.5 | Tentative(c), France (2018a,b) |
| Potato, microwaved tuber | 4 | 0.6, 0.7, 2.8, 3.3 | 1.8 | Tentative(c), France (2018a,b) |
| Potato, flakes (dehydrated tuber) | 4 | 2.4, 4.7, 4.8, 6.3 | 4.8 | Tentative(c), France (2018a,b) |
| Potato, dried waste | 2 | 1.7, 2.6 | 2.15 | Tentative(c), France (2018a,b) |
| Wheat, flour (whole meal) | 2 | 1.0, 1.1 | 1.1 | Tentative(c), France (2018a,b) |
| Wheat, bran (total) | 2 | 1.0, 1.2 | 1.1 | Tentative(c), France (2018a,b) |
| Wheat, flour (white) | 2 | 0.8, 1.0 | 0.9 | Tentative(c), France (2018a,b) |
| Wheat, whole meal bread | 2 | 0.7, 0.9 | 0.8 | Tentative(c), France (2018a,b) |
| Wheat, gluten feed meal | 2 | 0.2, 0.2 | 0.2 | Tentative(c), France (2018a,b) |
| Wheat, germ | 2 | 1.2, 1.4 | 1.3 | Tentative(c), France (2018a,b) |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.
(c): The PF is tentative because it is based on a limited data set or because analytical method was not sufficiently validated (for processed potato products).

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day Median Maximum | mg/kg DM Median Maximum | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|-----------------------------|---------------------------------------------------------------|---------------------------|---------------------------|-----------------------------|------------------------|
| Cattle (all) | 7.513 11.584 | 240.93 346.78 | Dairy cattle | Potato process waste | Y |
| Cattle (dairy only) | 7.513 11.584 | 195.33 301.18 | Dairy cattle | Potato process waste | Y |
| Sheep (all) | 8.031 11.781 | 240.93 353.43 | Ram/Ewe | Potato process waste | Y |
| Sheep (ewe only) | 8.031 11.781 | 240.93 353.43 | Ram/Ewe | Potato process waste | Y |
| Swine (all) | 4.777 9.405 | 171.44 325.69 | Swine (finishing) | Potato culls | Y |
### Relevant groups (subgroups)

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup<sup>(a)</sup> | Most critical commodity<sup>(b)</sup> | Trigger exceeded (Y/N) |
|---------------------------|-----------------------------|-----------------------------------|-------------------------------------|------------------------|
|                           | mg/kg bw per day            | mg/kg DM                          |                                     |                        |
|                           | Median | Maximum | Median | Maximum |                                      |                        |
| Poultry (all)             | 5.478  | 9.885   | 77.69  | 139.39  | Turkey                               | Potato culls           | Y                      |
| Poultry (layer only)      | 4.683  | 7.249   | 68.44  | 105.94  | Poultry layer                        | Potato culls           | Y                      |
| Fish                      | N/A                                           |                                    |                                     |                        |

bw: body weight; DM: dry matter.

(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

### B.2.1. Nature of residues and methods of analysis in livestock

#### B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | Comment/Source |
|-------------------------------|--------|-------------------------|----------------|----------------|
|                               | Lactating ruminants – Goat study 1 | 0.41 | 7 | 14C-fosetyl (radiolabeled in the ethyl group). The nature of fosetyl residues was investigated in the framework of peer review (France, 2005). It was concluded that fosetyl is rapidly and extensively metabolised in tissues by breakdown to ethanol and phosphonic acid |
|                               | Lactating ruminants – Goat study 2 | 0.51 | 7 | |
|                               | Lactating ruminants – Goat study 3 | 1.49 | 7 | |
|                               | Laying hens | – | – | No study available |

Time needed to reach a plateau concentration in milk and eggs (days)

|                        | Milk: 1 day                | France (2018) |
|------------------------|-----------------------------|----------------|
|                        | Eggs: below LOQ             | EFSA (2012a)  |

Metabolism in rat and ruminant similar

|                        | Yes                         | EFSA (2012a)  |
|------------------------|-----------------------------|----------------|

Can a general residue definition be proposed for animals?

|                        | Yes                         | EFSA (2012a)  |
|------------------------|-----------------------------|----------------|

Animal residue definition for monitoring (RD-Mo)

|                        | Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012a) |
|------------------------|---------------------------------------------------------------------------|

Animal residue definition for risk assessment (RD-RA)

|                        | Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012a) |
|------------------------|---------------------------------------------------------------------------|

Fat soluble residues

|                        | No                          |
|------------------------|-----------------------------|

Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)

|                        | Validated LC–MS/MS analytical method is available to enforce phosphonic acid in milk with an LOQ of 0.01 mg/kg and in eggs, muscle, fat, kidney and liver with an LOQ of 0.05 mg/kg. ILV available (EFSA, 2018c) |
|------------------------|---------------------------------------------------------------------------|

bw: body weight; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period Value | Compounds covered | Comment/Source |
|-------------------------------------|--------|-----------|--------|------------------------|-------------------|----------------|
|                                      | Goat   | –         | –      | –                      | –                 | Samples from feeding study stored for less than one month under freezer conditions (France, 2018a,b) |
|                                      | Hen    | –         | –      | –                      | –                 | No information on the sample storage period. However, peer review on fosetyl concluded that, based on the elementary nature of the residues it is considered unlikely that significant degradation will have occurred (EFSA, 2018c) |

### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity         | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) | CF(c) |
|--------------------------|---------------------------------------------|--------------------------------------------|-------|
|                          | MeanHighestSTMR(a)(mg/kg)HR(b)(mg/kg)         |                                            |       |
| **Cattle (all)**         |                                             |                                            |       |
| Closest feeding level (11 mg/kg bw; 0.9 N rate)(d) |                                             |                                            |       |
| Muscle                   | 0.50 0.50 0.50 0.50 0.50 0.5*                |                                            |       |
| Fat                      | 0.87 0.87 0.59 0.94 1.0                   |                                            |       |
| Liver                    | 0.55 0.55 0.38 0.76 0.8                   |                                            |       |
| Kidney                   | 3.90 3.90 2.66 5.48 6                    |                                            |       |
| **Cattle (dairy only)**  |                                             |                                            |       |
| Closest feeding level (11 mg/kg bw; 0.9 N rate)(d) |                                             |                                            |       |
| Milk(d)                  | 0.22 0.22 0.15 0.32 0.4                   |                                            |       |
| **Sheep (all)**(e)       |                                             |                                            |       |
| Closest feeding level (11 mg/kg bw; 0.9 N rate)(d) |                                             |                                            |       |
| Muscle                   | 0.50 0.50 0.50 0.51 0.5*                |                                            |       |
| Fat                      | 0.87 0.87 0.64 0.96 1.0                   |                                            |       |
| Liver                    | 0.55 0.55 0.40 0.78 0.8                   |                                            |       |
| Kidney                   | 3.90 3.90 3.07 5.61 6                    |                                            |       |
| **Sheep (ewe only)**(e)  |                                             |                                            |       |
| Closest feeding level (11 mg/kg bw; 0.9 N rate)(d) |                                             |                                            |       |
| Milk(d)                  | 0.22 0.22 0.27 0.32 0.4                   |                                            |       |
| **Swine (all)**(e)       |                                             |                                            |       |
| Closest feeding level (11 mg/kg bw; 1.2 N rate)(d) |                                             |                                            |       |
| Muscle                   | 0.50 0.50 0.50 0.50 0.5*                |                                            |       |
| Fat                      | 0.87 0.87 0.38 0.74 0.8                   |                                            |       |
| Liver                    | 0.55 0.55 0.24 0.54 0.6                   |                                            |       |
| kidney                   | 3.90 3.90 1.69 4.00 4                    |                                            |       |
| **Poultry (all)**        |                                             |                                            |       |
| Closest feeding level (12.255 mg/kg bw; 1.2 N rate)(d) |                                             |                                            |       |
| Muscle                   | 0.50 0.50 0.50 0.50 0.5*                |                                            |       |
| Fat                      | 0.50 0.50 0.50 0.50 0.5*                |                                            |       |
| Liver                    | 0.50 0.50 0.50 0.50 0.5*                |                                            |       |
### B.3. Consumer risk assessment

| Scenario       | ADI: 2.25 mg/kg bw per day (EFSA, 2012b) |
|----------------|----------------------------------------|
| Highest IEDI   | 48% ADI (DE child)                     |
| Assumptions    | 95% ADI (DE child)                     |
| Calculation    | The calculation is performed for the crops under assessment considering the median residue levels of phosphonic acid derived from the supervised filed trials. For the remaining commodities, STMR (expressed as phosphonic acid) derived in previous assessments (EFSA, 2012c, 2015, 2018a,b) were used; for the remaining crops, the MRLs established for fosetyl in Regulation (EC) No 2016/1003, recalculated to phosphonic acid were used. Crops with MRLs at the LOQ were not considered. The molecular weight conversion factor of 0.75 was used to express residue levels as phosphonic acid |

*ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; LOQ: limit of quantification; MRL: maximum residue level.*
## B.4. Recommended MRLs

| Code(a)  | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------|-----------|-------------------------|-------------------------|------------------------|
|          |           | 1)                      | 2)                      |                        |
|          |           | 1)                      | 2)                      |                        |
| 0211000  | Potatoes  | 30                      | 200                     | 150                    | The submitted data are sufficient to derive a MRL proposal for the NEU and SEU use. Risk for consumers, following chronic exposure, is unlikely. Residues in rotational crops cannot be excluded. Member States should consider setting specific pre-planting back intervals. |
| 0500090  | Wheat     | 2.0*                    | 150                     | 80                     |                        |
| 1011010  | Swine: muscle | 0.5*                    | 0.7                     | 0.5*                   | The MRLs proposal are sufficiently supported by data. Risk for consumers, following chronic exposure, is unlikely. |
| 1011020  | Swine: fat | 0.5*                    | 1.1                     | 0.8                    |                        |
| 1011030  | Swine: liver | 0.5*                    | 0.8                     | 0.6                    |                        |
| 1011040  | Swine: kidney | 0.5*                    | 5.4                     | 4                      |                        |
| 1012010  | Bovine: muscle | 0.5*                    | 0.7                     | 0.5*                   |                        |
| 1012020  | Bovine: fat | 0.5*                    | 1.3                     | 1.0                    |                        |
| 1012030  | Bovine: liver | 0.5*                    | 1.1                     | 0.8                    |                        |
| 1012040  | Bovine: kidney | 0.5*                    | 8.0                     | 6                      |                        |
| 1013010  | Sheep: muscle | 0.5*                    | 0.7                     | 0.5*                   |                        |
| 1013020  | Sheep: fat | 0.5*                    | 1.3                     | 1.0                    |                        |
| 1013030  | Sheep: liver | 0.5*                    | 1.1                     | 0.8                    |                        |
| 1013040  | Sheep: kidney | 0.5*                    | 8.0                     | 6                      |                        |
| 1014010  | Goat: muscle | 0.5*                    | 0.7                     | 0.5*                   |                        |
| 1014020  | Goat: fat | 0.5*                    | 1.3                     | 1.0                    |                        |
| 1014030  | Goat: liver | 0.5*                    | 1.1                     | 0.8                    |                        |
| 1014040  | Goat: kidney | 0.5*                    | 8.0                     | 6                      |                        |
| 1016010  | Poultry: muscle | 0.5*                    | 0.7                     | 0.5*                   |                        |
| 1016020  | Poultry: fat | 0.5*                    | 0.7                     | 0.5*                   |                        |
| 1016030  | Poultry: liver | 0.5*                    | 0.7                     | 0.5*                   |                        |
| 1020000  | Milk       | 0.1*                    | 0.5                     | 0.4                    |                        |
| 1030000  | Eggs       | 0.1*                    | 0.7                     | 0.5*                   |                        |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.

*: 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.

Enforcement residue definition:

1) Existing enforcement residue definition: fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) (Reg. (EC) No 396/2005)

2) Proposed enforcement residue definition: phosphonic acid and their salts expressed as phosphonic acid (EFSA, 2012b)
Appendix C – Pesticide Residue Intake Model (PRIMo)

| Phosphonic acid |
|-----------------|
| Status of the active substance: Code no. |
| LOQ (mg/kg bw): Proposed LOQ. |
| Toxicological end points |
| ADI (mg/kg bw per day): 1 |
| ARD (mg/kg bw): n.n. |
| Source of ADI: EFSA 2012 |
| Year of evaluation: Year of evaluation: 1995 |

No of diets exceeding ADI:

| TMDI (range) in % of ADI |
|--------------------------|
| minimum – maximum 19–95 |

Chronic risk assessment – refined calculations

| Commodity/group of commodities |
|---------------------------------------|
| MS Diet |
| TMDI values in % of ADI |
| 2019–2020 |
| 95 DE child |
| 89 WHO Cluster diet B |
| 84 NL child |
| 96 FR toddler |
| 51 IE adult |
| 50 WHO cluster diet D |
| 47 ES child |
| 46 UK Toddler |
| 45 WHO regional European diet |
| 42 IT kids/adolescent |
| 41 WHO cluster diet E |
| 39 WHO Cluster diet F |
| 38 NL general |
| 35 FR infant |
| 34 IT adult |
| 34 ES adult |
| 32 UK Infant |
| 31 FR all population |
| 27 UK vegetarian |
| 26 PL general population |
| 23 LT adult |
| 21 DK adult |
| 21 UK Adult |
| 19 FI adult |

| Commodity/group of commodities |
|---------------------------------------|
| MS Diet |
| Minimum – maximum 19–95 |
| 95 DE child |
| 89 WHO Cluster diet B |
| 84 NL child |
| 96 FR toddler |
| 51 IE adult |
| 50 WHO cluster diet D |
| 47 ES child |
| 46 UK Toddler |
| 45 WHO regional European diet |
| 42 IT kids/adolescent |
| 41 WHO cluster diet E |
| 39 WHO Cluster diet F |
| 38 NL general |
| 35 FR infant |
| 34 IT adult |
| 34 ES adult |
| 32 UK Infant |
| 31 FR all population |
| 27 UK vegetarian |
| 26 PL general population |
| 23 LT adult |
| 21 DK adult |
| 21 UK Adult |
| 19 FI adult |

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Phosphonic acid is unlikely to present a public health concern.
Acute risk assessment is not necessary.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|
| IESTI 1 *) **) IESTI 2 *) **) IESTI 1 *) **) IESTI 2 *) **) | | | |
| Highest % of ARfD/ADI commodities | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI commodities | pTMRL/threshold MRL (mg/kg) |

No of commodities for which ARfD/ADI is exceeded:

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|-----------------------------------------------------------|-----------------------------------------------------------|
| No of critical MRLs (IESTI 1) | No of critical MRLs (IESTI 2) |

No of commodities for which ARfD/ADI is exceeded (IESTI 1):

| No of commodities for which ARfD/ADI is exceeded: |
|--------------------------------------------------|
| --- |

No of commodities for which ARfD/ADI is exceeded (IESTI 2):

| No of commodities for which ARfD/ADI is exceeded: |
|--------------------------------------------------|
| --- |

Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of Phosphonic acid residues is unlikely to present a public health concern.

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values >90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.
### Phosphonic acid

| Status of the active substance: | Code no. |
|--------------------------------|-----------|
| LOQ (mg/kg bw) | Proposed LOQ |

| Toxicological end points | ADI (mg/kg bw per day): | ARD (mg/kg bw): | Source of ADI: | Source of ARD: | Year of evaluation: |
|--------------------------|-------------------------|----------------|----------------|----------------|-------------------|
|                          | 2.25                    | n.n.           | EFSA           |                  | 2012              |

| No of diets exceeding ADI: | --- |

| Commodity/ group of commodities | pTMRLs at LOQ (in % of ADI) |
|---------------------------------|----------------------------|
| 48 DE child                     | Table grapes 4 |
| 47 WHO Cluster diet B           | Tomatoes 10 |
| 41 NL child                     | Oranges 10 |
| 29 IE adult                     | Potatoes 7 |
| 28 PT General population        | Potatoes 3 |
| 28 FR toddler                   | Wheat 6 |
| 26 FR all population            | Potatoes 6 |
| 25 WHO cluster diet D           | Wheat 7 |
| 24 WHO cluster diet E           | Potatoes 5 |
| 22 DK child                     | Wheat 6 |
| 22 WHO regional European diet   | Tomatoes 5 |
| 22 ES child                     | Oranges 5 |
| 21 UK Toddler                   | Potatoes 5 |
| 21 SE general population 90th percentile | Potatoes 5 |
| 20 IT kids/toddler              | Wheat 7 |
| 20 NL general                   | Oranges 4 |
| 20 WHO Cluster diet F           | Potatoes 4 |
| 18 FR infant                    | Potatoes 5 |
| 17 ES adult                     | Oranges 3 |
| 16 IT adult                     | Wheat 4 |
| 15 UK vegetarian                | Oranges 2 |
| 15 UK infant                    | Potatoes 3 |
| 14 DK adult                     | Wheat 5 |
| 13 UK Adult                     | Wheat 5 |
| 13 PL general population        | Potatoes 4 |
| 11 LT adult                     | Potatoes 4 |
| 10 FI adult                     | Oranges 2 |

| Commodity/ group of commodities | TMDI (range) in % of ADI |
|---------------------------------|-------------------------|
| 48 DE child                     | Table grapes 4 |
| 47 WHO Cluster diet B           | Tomatoes 10 |
| 41 NL child                     | Oranges 10 |
| 29 IE adult                     | Potatoes 7 |
| 28 PT General population        | Potatoes 3 |
| 28 FR toddler                   | Wheat 6 |
| 26 FR all population            | Potatoes 6 |
| 25 WHO cluster diet D           | Wheat 7 |
| 24 WHO cluster diet E           | Potatoes 5 |
| 22 DK child                     | Wheat 6 |
| 22 WHO regional European diet   | Tomatoes 5 |
| 22 ES child                     | Oranges 5 |
| 21 UK Toddler                   | Potatoes 5 |
| 21 SE general population 90th percentile | Potatoes 5 |
| 20 IT kids/toddler              | Wheat 7 |
| 20 NL general                   | Oranges 4 |
| 20 WHO Cluster diet F           | Potatoes 4 |
| 18 FR infant                    | Potatoes 5 |
| 17 ES adult                     | Oranges 3 |
| 16 IT adult                     | Wheat 4 |
| 15 UK vegetarian                | Oranges 2 |
| 15 UK infant                    | Potatoes 3 |
| 14 DK adult                     | Wheat 5 |
| 13 UK Adult                     | Wheat 5 |
| 13 PL general population        | Tomatoes 4 |
| 11 LT adult                     | Potatoes 4 |
| 10 FI adult                     | Oranges 2 |

### Chronic risk assessment – refined calculations

#### pTMRLs at LOQ

| Commodity/ group of commodities | Minimum – Maximum |
|---------------------------------|-------------------|
| 48 DE child                     | Table grapes 4 |
| 47 WHO Cluster diet B           | Tomatoes 10 |
| 41 NL child                     | Oranges 10 |
| 29 IE adult                     | Potatoes 7 |
| 28 PT General population        | Potatoes 3 |
| 28 FR toddler                   | Wheat 6 |
| 26 FR all population            | Potatoes 6 |
| 25 WHO cluster diet D           | Wheat 7 |
| 24 WHO cluster diet E           | Potatoes 5 |
| 22 DK child                     | Wheat 6 |
| 22 WHO regional European diet   | Tomatoes 5 |
| 22 ES child                     | Oranges 5 |
| 21 UK Toddler                   | Potatoes 5 |
| 21 SE general population 90th percentile | Potatoes 5 |
| 20 IT kids/toddler              | Wheat 7 |
| 20 NL general                   | Oranges 4 |
| 20 WHO Cluster diet F           | Potatoes 4 |
| 18 FR infant                    | Potatoes 5 |
| 17 ES adult                     | Oranges 3 |
| 16 IT adult                     | Wheat 4 |
| 15 UK vegetarian                | Oranges 2 |
| 15 UK infant                    | Potatoes 3 |
| 14 DK adult                     | Wheat 5 |
| 13 UK Adult                     | Wheat 5 |
| 13 PL general population        | Tomatoes 4 |
| 11 LT adult                     | Potatoes 4 |
| 10 FI adult                     | Oranges 2 |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Phosphonic acid is unlikely to present a public health concern.
### Acute risk assessment/children – refined calculations

Acute risk assessment is not necessary.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS, with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

| No of critical MRLs (IESTI 1) | No of critical MRLs (IESTI 2) |
|------------------------------|------------------------------|

### Acute risk assessment/adults/general population – refined calculations

The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**p**TMRL: provisional temporary MRL.

---

### Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of Phosphonic acid residues is unlikely to present a public health concern.
### Appendix D – Input values for the exposure calculations

#### D.1. Livestock dietary burden calculations

| Feed commodity       | Median dietary burden | Maximum dietary burden |
|----------------------|------------------------|------------------------|
|                      | Input value (mg/kg)    | Comment                | Input value (mg/kg)    | Comment                |
| Cabbage              | 0.20 STMR (EFSA, 2012a)| 1.30 HR (EFSA, 2012a) |
| Kale                 | 2.19 STMR (EFSA, 2012a)| 3.68 HR (EFSA, 2012a) |
| Wheat straw          | 19.78 STMR             | 81.39 HR               |
| Potato               | 26.90 STMR             | 88.6 HR                |
| Wheat grain          | 23.13 STMR             | 23.13 STMR             |
| Triticale grain      | 23.13 STMR             |                        |
| Apple pomace wet     | 25.98 23.20 STMR x 1.12 PF (EFSA, 2018a) | 25.98 23.20 STMR x 1.12 PF (EFSA, 2018a) |
| Citrus dried pulp    | 120 12 STMR x 10 PF (EFSA, 2012a) | 120 12 STMR x 10 PF (EFSA, 2012a) |
| Distiller’s grain dried | 76.33 23.13 STMR x 3.3 PF (EFSA, 2012a) | 76.33 23.13 STMR x 3.3 PF (EFSA, 2012a) |
| Potato process waste | 57.84 26.90 STMR x 2.2 PF | 57.84 26.90 STMR x 2.2 PF |
| Potato dried pulp    | 129.12 26.90 STMR x 4.8 PF | 129.12 26.90 STMR x 4.8 PF |
| Wheat gluten meal    | 41.63 23.13 STMR x 1.8 PF | 41.63 23.13 STMR x 1.8 PF |
| Wheat milled by-products | 161.91 23.13 STMR x 7 PF | 161.91 23.13 STMR x 7 PF |

**Risk assessment residue definition:** phosphonic acid

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

(a): For apple pomace wet, a processing factor of 1.1 was included in the calculation to consider the potential concentration of residues in these commodities. For potato process waste and potato dried pulp, EMS proposed to use processing factors of 2.2 and 4.8, respectively as more relevant than default processing factors even if the EMS stated that additional data should be provided to fully validate these processing factors.

(b): For citrus dried pulp, distiller’s grain dried, wheat gluten meal and wheat milled by-products in the absence of processing factors supported by data, default processing factors of 10, 3.3, 1.8 and 7 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

#### D.2. Consumer risk assessment

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| Potato                           | 26.90 STMR (NEU and SEU)|                      |                        |                      |
| Wheat                            | 23.13 STMR (NEU and SEU)|                      |                        |                      |
| Tree nuts (except coconut)       | 64.5 STMR (EFSA, 2018a) |                      |                        |                      |
| Pome fruit                       | 23.2 STMR (EFSA, 2018a) |                      |                        |                      |
| Peaches                          | 12.5 STMR (EFSA, 2018a) |                      |                        |                      |
| Table and wine grapes (scenario 2)| 15.5 STMR (FAO, 2017)    |                      |                        |                      |
| Strawberry (scenario 2)          | 11.0 STMR (FAO, 2017)    |                      |                        |                      |
| Blackberries                     | 58.2 STMR (EFSA, 2018b) |                      |                        |                      |
| Raspberries                      | 58.2 STMR (EFSA, 2018b) |                      |                        |                      |
| Blueberries                      | 18.4 STMR (EFSA, 2018b) |                      |                        |                      |
| Currants                         | 18.4 STMR (EFSA, 2018b) |                      |                        |                      |
| Gooseberries                     | 18.4 STMR (EFSA, 2018b) |                      |                        |                      |
| Elderberries                     | 18.4 STMR (EFSA, 2018b) |                      |                        |                      |
| Kiwi                             | 23.5 STMR (EFSA, 2012c) |                      |                        |                      |

**Risk assessment residue definition:** Phosphonic acid (sum of phosphonic acid and its salts, expressed as phosphonic acid)

Modifications of the existing maximum residue level for fosetyl/phosphonic acid in various commodities.

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### Commodity	| Chronic risk assessment | Acute risk assessment |
|-----------------|------------------------|-----------------------|
| Celeriac        | 0.20 STMR (EFSA, 2015) |                       |
| Cucumbers (scenario 2) | 14.0 STMR (FAO, 2017) |                       |
| Courgettes (scenario 2) | 25.5 STMR (FAO, 2017) |                       |
| Melons (scenario 2) | 14.0 STMR (FAO, 2017) |                       |
| Spices          | 74 STMR (EFSA, 2012c)  |                       |
| Hops (scenario 2) | 350 STMR (FAO, 2017)  |                       |
| Swine: meat     | 0.50 STMR              |                       |
| Swine: fat      | 0.38 STMR              |                       |
| Swine: liver    | 0.24 STMR              |                       |
| Swine: kidney   | 1.69 STMR              |                       |
| Bovine, Goat: meat | 0.50 STMR             |                       |
| Bovine, Goat: fat | 0.59 STMR             |                       |
| Bovine, Goat: liver | 0.38 STMR             |                       |
| Bovine, Goat: kidney | 2.66 STMR            |                       |
| Sheep: meat     | 0.50 STMR              |                       |
| Sheep: fat      | 0.64 STMR              |                       |
| Sheep: liver    | 0.40 STMR              |                       |
| Sheep: kidney   | 3.07 STMR              |                       |
| Poultry: meat   | 0.50 STMR              |                       |
| Poultry: fat    | 0.50 STMR              |                       |
| Poultry: liver  | 0.50 STMR              |                       |
| Milk (cattle)   | 0.15 STMR              |                       |
| Eggs            | 0.50 STMR              |                       |
| Other commodities of plant origin (with MRL above LOQ) | MRL\(^{(a)}\) | Commission Regulation (EC) No 2016/1003 |

**STMR:** supervised trials median residue; **MRL:** maximum residue level; **LOQ:** limit of quantification.

\(^{(a)}\): Existing MRLs in Regulation (EC) No 396/2005 are expected to be expressed as fosetyl, therefore for RA purposes the values above the LOQ were recalculated to phosphonic acid by applying a CF for molecular weight of 0.75 (MW phosphonic acid (82)/fosetyl (110)).
### Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|--------------------------------|-------------------------------------------------|---------------------------------|
| potassium hydrogen phosphonate | potassium hydrogen phosphonate [K⁺]O[PH][O⁻]O GNSKLFRGEWLPPA-UHFFFAOYSA-M | ![Structural formula](image) |
| dipotassium phosphonate | dipotassium phosphonate [K⁺][K⁺][O⁻][PH][O⁻]O OZYJQIQGRFVHQ-UHFFFAOYSA-L | ![Structural formula](image) |
| Fosetyl | ethyl hydrogen phosphonate O=P(O)OCC VUERQRKTYBIULR-UHFFFAOYSA-N | ![Structural formula](image) |
| fosetyl-Al | aluminium tris(ethyl phosphonate) [Al⁻³][O⁻]P(O)OCC,[O⁻]P(O)OCC,[O⁻]P(O)OCC ZKZMJOFIHHZSRW-UHFFFAOYSA-K | ![Structural formula](image) |
| phosphonic acid | phosphonic acid O=P(O)O ABLZXFCXLZCGV-UHFFFAOYSA-N | ![Structural formula](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup> ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(c)</sup> ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).