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Modification of the existing maximum residue levels for fosetyl-Al in tree nuts, pome fruit, peach and potato

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants Bayer CropScience Europe and Oxon Italia S.p.A. submitted requests to the competent national authority in Spain and Italy, respectively, to modify the existing maximum residue levels (MRLs) for fosetyl in peach and potato from the intended southern Europe (SEU) uses of fosetyl-Al. The applicants Adama Agriculture B.V., Fitosanitarios Bajo Riesgo AIE and Almond Board of California submitted each an application to the competent national authority in France to modify the MRLs for fosetyl-Al in pome fruits, peaches and tree nuts (except coconut) for the intended/authorised uses of the active substance potassium phosphonates. The data submitted in support of the requests were found to be sufficient to derive MRL proposals for all the crops under consideration. Adequate analytical methods for enforcement are available to control the residues of fosetyl-Al and phosphonic acid in plant matrices under consideration. EFSA concluded that the proposed use of fosetyl-Al on potatoes and the proposed uses of potassium phosphonates on pome fruits and peaches and the authorised use of potassium phosphonates on tree nuts in the United States are unlikely to result in a consumer exposure exceeding the toxicological reference values for phosphonic acid and fosetyl and therefore are unlikely to pose a risk to consumers' health. However, the risk assessment is considered to be tentative and has to be updated as soon as the approval of the renewal of fosetyl and the review of existing uses of potassium phosphonates and disodium phosphonate is finalised.

Keywords: fosetyl, potassium phosphonates, phosphonic acid, various crops, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience Europe and Oxon Italia S.p.A. submitted applications to the competent national authority in Spain and Italy, respectively (evaluating Member State (EMS)), to modify the existing maximum residue levels (MRLs) for fosetyl in peaches and potatoes to accommodate the intended use of the active substance fosetyl-Al. In accordance with Article 6 of Regulation (EC) No 396/2005, Adama Agriculture B.V., Fitosanitarios Bajo Riesgo AIE and Almond Board of California submitted each an application to the competent national authority in France (EMS) to modify the existing maximum residue levels (MRLs) for fosetyl in pome fruits, peaches and tree nuts (except coconut) in order to accommodate intended or authorised uses of the active substance potassium phosphonates.

Spain, Italy and France drafted evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 8 March 2017 (pome fruit), on 17 July 2017 (peaches; use of fosetyl-Al), on 1 June 2017 (potatoes), on 2 October 2017 (peaches; use of potassium phosphonates) and on 31 October 2017 (tree nuts). To accommodate intended European uses of fosetyl-Al and potassium phosphonates, the EMSs proposed to raise the existing MRL for fosetyl to 50 mg/kg for potatoes, to 30 mg/kg for peaches from the use of fosetyl-Al or to 50 mg/kg from the use of potassium phosphonates and to 150 mg/kg for pome fruits. For the registered use of potassium phosphonates in the United States on tree nuts, the EMS proposed to raise the existing MRL for fosetyl in tree nuts (except coconut) from a temporary MRL of 75 mg/kg or the LOQ to 500 mg/kg.

EFSA assessed the applications and the related evaluation reports as required by Article 10 of the MRL regulation. The conclusions derived by EFSA in the framework of Directive 91/414/EEC and the data evaluated under previous MRL assessments were also taken into consideration to derive the following conclusions. EFSA identified points which needed further clarification, which were requested from the EMS. On 14 December 2017, the EMS submitted revised evaluation reports (France, 2017a,c,d), which replaced the previously submitted evaluation reports.

The metabolism of fosetyl following foliar application was investigated in fruit crops, with phosphonic acid being the main toxicologically relevant metabolite. For potassium phosphonates, the peer review concluded that data from the public literature are sufficient to address the uptake and metabolism in plants which mainly involves transformation of potassium phosphonate salts into phosphonic acid. Given the elementary nature of fosetyl-Al and potassium phosphonates, and given the similar results obtained from the metabolism study of fosetyl-Al on fruits and leafy parts of plant, the peer review concluded that metabolic pattern is similar in all crop groups.

Fosetyl-Al and phosphonic acid are considered hydrolytically stable under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation. In rotational crops, the major residue identified is phosphonic acid.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, studies in rotational crops and the toxicological significance of metabolites, the residue definitions for fosetyl-Al in plant products were initially proposed by the peer review as 'sum of fosetyl, phosphonic acid and their salts expressed as fosetyl' and this residue definition was consequently enforced in Regulation (EC) No 396/2005. In succeeding assessments (MRL review, revised EFSA Conclusion), different residue definitions were derived, which have not been implemented in the EU legislation yet.

The residue definition for potassium phosphonates in the plant products was proposed by the peer review as 'phosphonic acid and its salts, expressed as phosphonic acid' for enforcement and risk assessment, but residues are enforced according to the residue definition set in Regulation (EC) No 396/2005 as 'the sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl'.

EFSA concluded that the nature of fosetyl-Al and potassium phosphonates in the crops under consideration is sufficiently investigated.

Sufficiently validated analytical methods are available to enforce MRLs for the current legal residue definition and for the alternative residue definitions in high water content matrices.

The submitted data for the intended southern Europe (SEU) use of fosetyl-Al in peaches were not sufficient to derive a MRL proposal. However, the available residue trials are sufficient to derive MRL proposals for the other uses for which MRL modifications were requested. EFSA derived MRL proposals for the different residue definitions proposed in previous assessments.

Specific studies investigating the magnitude of residues in processed pears and peaches were submitted for the use of potassium phosphonates. In peach jam and canned peaches, a reduction of residues was observed while in other processed commodities of peaches and pears residues remained

stable. However, due to deficiencies of the studies in peaches, no reliable processing factors (PF) could be derived. In the processing studies with pears, a concentration of residues was observed in dried pears and dry pomace. The following PF are recommended to be included in Annex VI of Regulation (EC) No 396/2005:

- pears/dried: 3.1
- pears, juice: 1.0
- pears, canned: 0.9
- pear/wet pomace: 1.1
- pears, purée: 1.1

The magnitude of phosphonic acid residues in rotational crops was investigated in the framework of the peer review. From the results of these studies, it is concluded that significant phosphonic acid residues are unlikely to occur in rotational crops grown after potatoes, provided that fosetyl-Al is used according to the proposed good agricultural practice (GAP).

Potatoes, pome fruit and their by-products are used as livestock feed and therefore a potential carry-over of fosetyl and phosphonic acid residues into food of animal origin has to be assessed. EFSA updated the livestock dietary burden calculation previously performed for phosphonic acid, including the new information for potatoes and pome fruit. Comparing the results of the dietary burden calculations with and without the uses on potatoes and pome fruit, it becomes evident that the overall contribution of the new uses is low. EFSA concluded that livestock exposure to phosphonic acid and fosetyl residues and the possible need to revise the existing MRLs for animal products on the basis of appropriate livestock feeding studies has to be re-assessed once the renewal of the approval of fosetyl has been completed and the data on existing uses that result in residues of phosphonic acid in feed commodities are available. For the current application, only an indicative impact assessment was possible, which gave an indication that the new uses on pome fruit and potatoes will not significantly change the dietary exposure of livestock.

The toxicological profile of fosetyl-Al and 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 3 mg/kg body weight (bw) per day for fosetyl, extrapolated to potassium phosphonates. For the main metabolite phosphonic acid, the ADI was derived by the EU pesticides peer review as 2.25 mg/kg bw per day. An acute reference dose (ARfD) was deemed unnecessary. The ADI for fosetyl (2.8 mg/kg bw per day) is calculated from the ADI of fosetyl-Al, by applying a molecular weight conversion factor.

The consumer risk assessment was performed separately for phosphonic acid and their salts, expressed as phosphonic acid (hereafter phosphonic acid scenario) and for the sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl (hereafter fosetyl scenario), using the revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The long-term exposure assessment was performed taking into account the STMR values derived for fosetyl and phosphonic acid for the crops under consideration. For the remaining commodities, the STMR values, where available from the previous EFSA assessments, or the MRLs established in Regulation (EC) No 2016/1003 were used as input values. For the exposure assessment to phosphonic acid, the existing EU MRLs were recalculated to phosphonic acid by applying the molecular weight conversion factor and used as input values. The calculations should be considered as tentative since information on the contribution of other sources leading to residues of phosphonic acid (e.g. potassium phosphonates and disodium phosphonate) is not available at that stage.

The estimated long-term dietary intake of fosetyl residues was in the range of 8–45% of the ADI. The total calculated intake of phosphonic acid residues accounted for a maximum 42% of the ADI.

EFSA concluded that based on the basis of the tentative risk assessment, the long-term intake of phosphonic acid and fosetyl residues resulting from the existing and the intended uses of fosetyl-Al and potassium phosphonates is unlikely to present a risk to consumer health.

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

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

Code[(a)]	Commodity	Existing EU MRL[(a)] (mg/kg)	Proposed EU MRL (mg/kg)			Comment/justification
			(1)	(2)	(3)	
Enforcement residue definitions: 1) Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) 2) Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid 3) Fosetyl (only for crops with intended uses of fosetyl-Al)						
0120010	Almonds	75	500	400	–	The submitted data are sufficient to derive an import tolerance for the US GAP on potassium phosphonates. Based on tentative risk assessment, the risk for consumers is unlikely
0120020	Brazil nuts	2*				
010030	Cashew nuts	75				
0120040	Chestnuts	2*				
0120060	Hazelnuts/cobnuts	75				
0120070	Macadamias	75				
0120080	Pecans	2*				
0120090	Pine nut kernels	2*				
0120100	Pistachios	75				
0120110	Walnuts	75				
013000	Pome fruits	75	150	90	–	The submitted data are sufficient to derive a MRL proposal for the SEU use of potassium phosphonates. Based on tentative risk assessment, the risk for consumers is unlikely
0140030	Peaches	2*	50	40	–	The submitted data are sufficient to derive a MRL proposal for the SEU use of potassium phosphonates. Based on tentative risk assessment, the risk for consumers is unlikely. The submitted data for the intended SEU use of fosetyl-Al were not sufficient to derive a MRL proposal
0211000	Potatoes	30	40	30	0.05*[(b)]	The submitted data are sufficient to derive a MRL proposal for the SEU use of fosetyl-Al. Based on tentative risk assessment, the risk for consumers is unlikely

MRL: maximum residue level; GAP: good agricultural practice; 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.
(b): The MRL proposal is tentative due to a possible degradation of fosetyl residues during the storage of the sample.

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Assessment

The detailed description of the intended uses of fosetyl-Al on peaches and potatoes and of potassium phosphonates on pome fruits and stone fruits and the authorised use of potassium phosphonates on tree nuts in the United States is reported in Appendix A.

Fosetyl is the ISO common name for ethyl hydrogen phosphonate (IUPAC). In formulated plant protection products, the variant fosetyl aluminium (fosetyl-Al: aluminium tris-*O*-ethylphosphonate) is used.

Potassium phosphonates are a reaction mixture of phosphonic acid and potassium hydroxide with a pH of 5.9–6.4, containing a mixture of potassium hydrogen phosphonate and dipotassium phosphonate (EFSA, 2012b). An ISO common name is not assigned to this active substance.

The chemical structures of active substances and their main metabolites are reported in Appendix E.

Fosetyl and potassium phosphonates were evaluated in the framework of Directive 91/414/EEC[1] with France designated as rapporteur Member State (RMS). The representative uses assessed were foliar spraying on citrus, cucumber, grapes (for fosetyl) and grapes (for potassium phosphonates). The draft assessment reports (DAR) prepared by the RMS have been peer reviewed by the European Food Safety Authority (EFSA) for fosetyl in 2005, revised in 2013 (EFSA, 2005) and for potassium phosphonates in 2012 (EFSA, 2012b). Fosetyl was approved[2] for the use as a fungicide on 1 May 2007. The process of renewal of the first approval of fosetyl is currently ongoing. Potassium phosphonates were approved[3] for the uses as a fungicide on 1 October 2013.

The European Union (EU) maximum residue levels (MRLs) for potassium phosphonates and fosetyl are established in Annex IIIA of Regulation (EC) No 396/2005[4] under a common enforcement residue definition 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)'.

For fosetyl-Al, the review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2012a) but the proposed modifications have not yet been implemented in the EU MRL legislation since the European Commission is of the opinion that it is appropriate to await the MRL review for the related active substances, i.e. potassium phosphonates and disodium phosphonate, since these active substances share the common metabolite phosphonic acid. After completion of the MRL review of fosetyl-Al, EFSA has issued several reasoned opinions on the modification of MRLs for fosetyl. The proposals from these reasoned opinions have been considered in recent regulations[5] of EU MRL legislation. In addition, in 2014, EFSA issued a statement on the dietary risk assessment for proposed temporary MRLs for fosetyl-Al in certain crops (EFSA, 2014). The current MRLs for almonds, cashew nuts, hazelnuts, macadamias, pistachios and walnuts were derived on the basis of monitoring data. The MRLs will be replaced by the limit of quantification (LOQ) of 2 mg/kg on 1 March 2019 unless data will be provided to substantiate a different MRL.

For potassium phosphonates, the review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed.

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience Europe and Oxon Italia S.p.A. submitted applications to the competent national authority in Spain and Italy, respectively (evaluating Member State (EMS)), to modify the existing MRLs for the active substance fosetyl-Al in peach and potato resulting from the use of fosetyl-Al. Spain and Italy drafted evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to EFSA on 17 July 2017 for peaches and on 1 June 2017 for potatoes. To accommodate for the intended uses of fosetyl-Al in southern Europe (SEU), the EMSs proposed to raise the existing MRL for fosetyl-Al from 30 to 50 mg/kg in potato and from the LOQ of 2 to 30 mg/kg in peach.

In accordance with Article 6 of Regulation (EC) No 396/2005, Adama Agriculture B.V., Fitosanitarios Bajo Riesgo AIE and Almond Board of California submitted applications to the competent national authority in France (EMS) to modify the existing MRLs for fosetyl-Al on pome fruits, peaches/nectarines

[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 Directive 2006/64/CE of 18 July 2006 amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances, OJ L 206, 27.7.2006, p. 107–111.

[3] 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.

[4] 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.

[5] For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

and tree nuts (except coconut) related to the uses of potassium phosphonates. France drafted three evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to EFSA on 8 March 2017 for pome fruit, on 2 October 2017 for peaches/nectarines and on 31 October 2017 for tree nuts (except coconut). To accommodate for the intended European uses of potassium phosphonates on pome fruit and peaches/nectarines and the authorised uses of this active substance on tree nuts in the United States, the EMS proposed to raise the existing MRLs for fosetyl-Al to 150 mg/kg in pome fruits, to 50 mg/kg in peaches and to 500 mg/kg in tree nuts (except coconut).

It is noted that in the United States phosphonic acid is exempted from the setting of tolerances; for fosetyl-Al, the US tolerance is set only for macadamia nuts (0.2 mg/kg).[6]

EFSA assessed the applications and evaluation reports as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS. On 14 December 2017, the EMS submitted revised evaluation reports (France, 2017a,c,d), which replaced the previously submitted evaluation reports.

EFSA based its assessment on the evaluation reports submitted by the EMSs (Spain, 2016, France, 2017a,c,d, Italy, 2017), the DARs (and their addenda) on fosetyl (France, 2003, 2005b) and potassium phosphonates (France, 2005a, 2012) prepared under Council Directive 91/414/EEC, the conclusions on the peer review of the pesticide risk assessment of the active substance fosetyl (EFSA, 2005, revised in 2013) and potassium phosphonates (EFSA, 2012b), as well as the conclusions from previous EFSA opinions on fosetyl including the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2012a,c, 2015) and the statement on the dietary risk assessment for temporary MRLs for fosetyl-Al (EFSA, 2014).

The data requirements established in Regulation (EU) No 544/2011[7] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

As the review of the existing uses of potassium phosphonates under Article 12 of Regulation 396/2005 and the renewal of the approval of fosetyl is not yet finalised, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the MRL review.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application, including the end points of relevant studies assessed previously, are presented in Appendix B.

The evaluation reports submitted by the EMSs (Spain, 2016; France, 2017a,c,d; Italy, 2017) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The nature of fosetyl-Al in primary plants was investigated in the framework of the EU pesticides peer review following foliar application on fruit crops. In addition, metabolism of fosetyl-Al has been investigated in apple and vine leaves (EFSA, 2005). Phosphonic acid is the main toxicologically relevant metabolite. Although metabolism studies are not available in root crops, given the elementary nature of fosetyl-Al, and the similar results obtained on fruits and leafy parts of plant, the peer review concluded that the metabolic pattern is expected to be similar in all crop groups.

The nature of potassium phosphonates in primary plants was discussed in the framework of the EU pesticides peer review (EFSA, 2012b), which assumed that, given the elementary nature of the active substance, only transformation of the potassium phosphonate salts into phosphonic acid is expected in plants, and agreed that the available data from the public literature were sufficient to address the uptake and metabolism of potassium phosphonates in plants.

[6] Federal Register, Vol. 64, No 130/July 8, 1999/Rules and Regulations.

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

EFSA concludes that the nature of fosetyl and potassium phosphonates in the crops under consideration is sufficiently investigated.

1.1.2. Nature of residues in rotational crops

Potatoes can be grown in a crop rotation. According to soil degradation studies evaluated in the framework of the EU pesticides peer review, fosetyl-Al rapidly degrades in the soil to its metabolite phosphonic acid. Phosphonic acid has a $DT_{90field}$ value of 521 days and therefore the potential uptake and fate of this metabolite in rotational crops has to be further investigated (EFSA, 2005, 2012b).

A confined study to investigate the nature of phosphonic acid in rotational crops has not been performed due to difficulties labelling the compound and therefore only a field study with unlabelled phosphonic acid is available, which is acceptable.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of fosetyl-Al and phosphonic acid has been investigated under the EU pesticides peer review in hydrolysis studies with each substance individually (EFSA, 2005, 2012b). From these studies, it was concluded that both compounds are hydrolytically stable under conditions representative for pasteurisation, baking/brewing/boiling and sterilisation.

1.1.4. Methods of analysis in plants

The availability of analytical enforcement methods has been investigated in the framework of the MRL review of fosetyl-Al (EFSA, 2012a). It is concluded that in high water-, high acid-, high oil- and high starch content matrices the residues of fosetyl-Al and phosphonic acid can be enforced at the validated LOQs of 0.01 and 0.1 mg/kg, respectively.

In the framework of the import tolerance application of potassium phosphonates on tree nuts, the applicant submitted validation data for the method that has been developed by the European Reference Laboratories for Pesticide Residues (EURLs) for the determination of phosphonic acid residues in high oil content matrices (nuts) (France, 2017d). The method was validated for the one mass transition only at the LOQ of 1 mg/kg and, as it is less sensitive than the methods previously assessed, it is not proposed for enforcement purposes.

1.1.5. Stability of residues in plants

The stability of fosetyl-Al and phosphonic acid residues during the frozen storage has been investigated in the framework of the EU pesticides peer review of fosetyl-Al and in the studies submitted during the MRL review (EFSA, 2005, 2012a). Available studies indicate that the sum of fosetyl, phosphonic acid and their salts as well as phosphonic acid itself is stable under storage conditions at $-18°C$ for at least 25 months in matrices with high water, high starch and high acid content (EFSA, 2012a). Fosetyl-Al under storage conditions rapidly degrades in a way which varies from one plant matrix to the other; the phosphonic acid formed as a result of fosetyl-Al degradation is stable (EFSA, 2005).

A new study on the storage stability of phosphonic acid in nuts (high oil content commodity) has been submitted for the current assessment (France, 2017d). Control samples of almonds, pistachios and walnuts were fortified with phosphonic acid at 1 mg/kg and stored at $-20°C$ for 218, 221 and 146 days, respectively. Samples were analysed concurrently with the stored field trial samples. Data demonstrate that phosphonic acid is stable over the investigated time intervals in high oil content matrices.

1.1.6. Proposed residue definitions

1.1.6.1. Fosetyl-Al

The following residue definitions have been derived in previous assessments:

- Residue definitions for enforcement:
  - Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl (Regulation (EC) No 396/2005);
  - Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid (revision in 2013 of the EFSA peer review conclusion of 2005 due to lowering of the ADI for phosphonic acid);
  - Phosphonic acid (MRL review (EFSA, 2012a));

- Fosetyl (optional, MRL review (EFSA, 2012a)).

- Residue definitions for risk assessment:
  - Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid (revision in 2013 of the EFSA peer review conclusion of 2005 due to lowering of the ADI for phosphonic acid);
  - Phosphonic acid (MRL review (EFSA, 2012a));
  - Fosetyl (optional, MRL review (EFSA, 2012a));
  - Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl (EFSA, 2014, 2015).

1.1.6.2. Potassium phosphonates

The following residue definitions have been derived in previous assessments:

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

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

For the current application, considering that the enforcement residue definitions revised by the peer review of fosetyl in 2013 and proposed by the MRL review are still not enforced, the MRL proposals were derived for the following residue definitions:

1) Sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl (for crops with uses of fosetyl and potassium phosphonates[8]) (MRL scenario 1);
2) Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid (for crops with uses of fosetyl and potassium phosphonates[9]) (MRL scenario 2);
3) Fosetyl (for crops with uses of fosetyl-Al) (MRL scenario 3); and

considering that the final decision on the residue definition for risk assessment has not yet been taken, the consumer risk assessment was performed separately for two scenarios:

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

1.2. Magnitude of residues in plants

The applicants submitted residue trials on apples, pears, peaches, nectarines, almonds, walnuts, pistachios and potatoes. Residue trial samples reflecting the use of fosetyl-Al were analysed for fosetyl and phosphonic acid separately and, according to the EMS Spain and EMS Italy, the analytical methods have been sufficiently validated for both compounds at the LOQ of 0.2 mg/kg in peaches and at the LOQ of 0.05 mg/kg for fosetyl and 0.2 mg/kg for phosphonic acid in potatoes (Spain, 2016; Italy, 2017).

Residue trial samples reflecting the use of potassium phosphonates were analysed for phosphonic acid using methods that have been sufficiently validated at the LOQ of 0.1 mg/kg for pome fruits and at the LOQ of 0.5 mg/kg for nuts, peaches and nectarines.

Before analysis, the residue trial samples of peaches/nectarines (use of fosetyl-Al) were stored from 161 up to 360 days (ca. 5–12 months) and potato samples for up to 134 days (4.5 months) (Spain, 2016; Italy, 2017). Since in high water content matrices fosetyl rapidly degrades to phosphonic acid, the magnitude of fosetyl residues in potatoes and peaches might be underestimated and are not valid for proposing MRLs for fosetyl alone. The residue data for phosphonic acid alone and for the total

[8] For crops with uses for potassium phosphonates, the contribution of fosetyl is not relevant. Thus, for uses of potassium phosphonates, the MRL proposals for MRL scenario 1 would also cover the first residue definition derived for potassium phosphonates (i.e. phosphonic acid and its salts expressed as fosetyl).

[9] For crops with uses for potassium phosphonates, the contribution of fosetyl is not relevant. Thus, for uses of potassium phosphonates, the MRL proposals for MRL scenario 2 would also cover the second residue definition derived for phosphonic acid (i.e. phosphonic acid and its salts expressed as phosphonic acid).

residues of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid are considered valid with regard to storage stability.

The trial samples of apples, pears, peaches and nectarines (use of potassium phosphonates) were stored for a period not exceeding the demonstrated storage stability of phosphonic acid in high water content matrices. The tree nut samples have been stored for 12–20 days longer than the period for which the storage stability of phosphonic acid has been investigated/demonstrated in high oil content matrices, but such a small deviation is not expected to have a major impact on the final residues in tree nuts.

In order to express fosetyl-Al residues as fosetyl, a molecular weight conversion factor of 0.93[10] was applied to values above the LOQs. To express residues of phosphonic acid as fosetyl, a molecular weight conversion factor of 1.34[11] was applied.

1.2.1. Magnitude of residues in primary crops

Tree nuts

In support of the authorised use of potassium phosphonates in the United States, the applicant submitted five residue trials on almonds, five residue trials on pistachios and five residue trials on walnuts which have been performed in seven regions of California (United States) in 2015. One trial on almonds was performed with five instead of six applications, and one trial on walnuts was performed with eight instead of six applications. These trials were disregarded by the EMS and EFSA as good agricultural practice (GAP) incompliant. According to a common agriculture practice in the USA (reported by the applicant), tree nuts are knocked down (harvested) from the tree some days after the treatment and then allowed to dry on the ground for up to 6 days (France, 2017d). In the residue trials with almonds, nuts were harvested 1–4 days following the treatment and then allowed to dry on the ground for 0–8 days. For pistachios, nuts were collected 3–4 days after treatment without drying phase. For walnuts, nuts were harvested 3 days after the treatment and only in two trials allowed to dry for 1–2 days. Control samples were free of residues.

The EMS and the applicant propose to combine available residue data on almonds, walnuts and pistachios and to extrapolate them to the whole group of tree nuts (except coconut). According to the EU Guidelines, such an extrapolation is acceptable (European Commission, 2017). The applicant confirmed that at the time of the treatment, pistachios were not open and thus residue data on pistachios can be used for extrapolation purposes. The combined residue data set results in a MRL proposal of 500 mg/kg (MRL scenario 1) and 400 mg/kg (MRL scenario 2) in all tree nuts, except coconut.

Pome fruits

In support of the intended northern Europe (NEU) use of potassium phosphonates, the applicant submitted seven residue trials on apples and three residue trials on pears. Residue trials were performed in France, Hungary, Poland and Germany over growing seasons of 2013–2014. The trials were performed with 10 instead of 8 applications and thus considered non-compliant with the intended GAP.

In support of the SEU use of potassium phosphonates, the applicant submitted eight GAP-compliant residue trials on apples (6) and pears (2). Trials were performed in France, Spain and Italy over growing seasons of 2013–2014. In some of the control samples, residues of phosphonic acid were detected but the amounts were negligible compared to the levels in the treated crop.

The SEU use results in the MRL proposal of 150 mg/kg (MRL scenario 1) and 90 mg/kg (MRL scenario 2). The number of residue trials is sufficient to support the extrapolation of residue data from apples and pears to the whole pome fruit group according to the EU guidance document (European Commission, 2017).

Peaches, nectarines

In support of the SEU use of fosetyl-Al, the applicant submitted nine residue trials on peaches (8) and nectarines (1), which were performed in Greece, Italy, Portugal and France over growing seasons of 2001–2002. All trials were performed with three instead of two applications, thus exceeding the maximum seasonal application rate of 6 kg a.s./ha. Additionally, the intended time interval of 30 days between applications in most of the trials was either too long before the first two applications (41–106 days) or too short between the last two applications (9–15 days). EFSA disregarded all residue trials as they were not GAP compliant.

[10] MW fosetyl (110 g/mol; 3 molecules of fosetyl)/MW fosetyl-Al (354.1 g/mol).
[11] MW fosetyl (110 g/mol)/MW phosphonic acid (82 g/mol).

In support of the intended SEU use of potassium phosphonates on stone fruit, the applicant submitted eight residue trials on peaches (6) and nectarines (2) reflecting each type of treatment (foliar and drip irrigation). Trials were performed in Spain, France and Greece over growing seasons of 2015–2016. At each trial site, one plot was subject to foliar spraying while in other plot the active substance was applied via drip irrigation. In all trials, a history use of either a fertiliser or fosetyl-Al was reported but only in one trial negligible phosphonic acid residues were identified in the control sample. Following drip irrigation, the residues in the fruit were in the range of 0.81–5.54 mg/kg and following foliar treatment in the range of 3.76–20.53 mg/kg, latter demonstrating a more critical residue situation in the crop. The number of residue trials is sufficient to derive a MRL proposal of 50 mg/kg for MRL scenario 1 and 40 mg/kg for MRL scenario 2 following foliar treatment.

EFSA notes that the EMS and the applicant reported an intended GAP of potassium phosphonates on stone fruit but the MRL was requested only for peaches/nectarines. Therefore, MRL proposals were derived only for this crop.

Potatoes

In support of the intended SEU use of fosetyl-Al, the applicant submitted eight GAP-compliant residue trials on potatoes, which were performed in various regions of Italy in 2014. Residue data are sufficient to derive a MRL proposal of 40 mg/kg (MRL scenario 1); for MRL scenario 2, a MRL proposal of 30 mg/kg was derived. Considering only fosetyl (MRL scenario 3), a MRL at the LOQ of 0.05 mg/kg would be sufficient. However, since the storage of the samples exceeded the period for which fosetyl residues were demonstrated to be stable, the MRL proposal scenario 3 is tentative.

It is noted that the MRL proposal derived by the EMS Italy is higher than the one derived by EFSA because the EMS expressed residues as fosetyl-Al (50 mg/kg vs 40 mg/kg, respectively).

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 (EFSA, 2005). Bare soil was treated with phosphonic acid at amounts corresponding to 15 kg fosetyl-Al/ha. Radishes were sown 32 and 182 days after the soil treatment; lettuce and barley were planted/sown at the plant-back interval (PBI) of 32 days. Only radish root and lettuce leaves (from crops planted at the PBI of 32 days) contained phosphonic acid residues above the LOQ of 0.5 mg/kg, i.e. 0.8 mg/kg and 0.76 mg/kg, respectively (France, 2003). The peer review concluded that a pre-planting period of 30 days is applicable to ensure that succeeding crops do not contain residues of phosphonic acid above the LOQ (EFSA, 2005).

As the seasonal application rate of fosetyl on potatoes is significantly lower (4 kg fosetyl-Al/ha) than the dose rate investigated in the field studies, EFSA concluded that significant phosphonic acid residues are not expected in rotational crops grown after potatoes, provided that fosetyl-Al is applied according to the intended GAP.

1.2.3. Magnitude of residues in processed commodities

New studies investigating the effect of processing on the magnitude of fosetyl and phosphonic acid residues in processed potatoes have not been submitted under the MRL application on the intended use of fosetyl-Al. The submission of processing studies is currently not required considering that the chronic exposure to residues of fosetyl-Al via potatoes was low (< 2% of the acceptable daily intake (ADI)).

In the framework of the MRL applications on potassium phosphonates, the applicant submitted studies where the effect of processing on the magnitude of phosphonic acid residues was investigated in processed commodities of pears (France, 2017a) and peaches (France, 2017c). Pear samples were taken from field trials performed in Poland, France and Spain, and processed into pear juice, pear purée, canned pears, dried pears, wet pomace and dry pomace. Residues of phosphonic acid in raw commodity (RAC) ranged from 28 to 62.8 mg/kg. A concentration of residues due to water loss was observed only in dried pears and dry pomace. In other processed commodities, the concentration of residues was similar to that in the raw commodity indicating no impact of processing on the magnitude of residues. The residue data for pear juice, pear purée and canned pears were disregarded by the EMS France because of insufficient validation of the analytical method. EFSA, however, did not consider this as a significant data gap and derived processing factors for pear juice, purée and canned pears.

Peach samples were taken from two field trials performed in Spain and France (two plots per trial were each treated according to the intended use pattern – drip irrigation or foliar spray). Residues in the raw commodity (whole fruit) ranged from 2.47 to 8.4 mg/kg. Peaches were destoned and processed into jam, purée, nectar and canned peaches. Results indicate that residues of phosphonic acid decrease in jam and purée (50% reduction) and remain stable in nectar and canned fruit. The applicant also provided studies on the storage stability of phosphonic acid in raw peach and in peach jam, purée, nectar and canned peaches. Study results indicate that residues of phosphonic acid are stable in raw commodity for 307 days and in processed peach commodities for 112–114 days (study duration) under deep frozen conditions.

The processing factors derived for dried pears, wet pomace, pear juice, purée and canned pears are proposed for the inclusion in the Annex VI of Regulation (EC) No 396/2005. The derived processing factors for peach processed commodities are not proposed for the inclusion in Annex VI of the above mentioned Regulation as they have been derived from a de-stoned commodity, whereas the existing MRLs are set for the whole fruit (including stone).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposal as well as risk assessment values for all crops under consideration. In Section 3, EFSA assessed whether fosetyl and phosphonic acid residues in the crops under consideration resulting from the intended/authorised use are likely to pose a consumer health risk.

2. Residues in livestock

Potatoes and pome fruit and their by-products can be used as a livestock feed, and therefore, a potential carry-over of fosetyl and phosphonic acid residues into food of animal origin has to be assessed.

The most recent livestock dietary burden for fosetyl and phosphonic acid residues (separately) was calculated in the framework of the MRL review of fosetyl, considering the reported existing European uses of fosetyl-Al on citrus fruit, pome fruit, head cabbage, kale and potatoes (EFSA, 2012a).

In the current assessment, EFSA updated the livestock dietary burden calculated in the MRL review for phosphonic acid with residue data from the new uses on potatoes and pome fruit. The dietary burden of the MRL review was recalculated according to the currently used OECD methodology (OECD, 2013). The updated calculated livestock dietary burdens exceeded the trigger value of 0.1 mg/kg DM for all livestock species. Moreover, the maximum livestock dietary burdens for all livestock species (except poultry) are now significantly above 30% of the maximum feeding levels of livestock feeding studies that have been performed with a mixture of fosetyl and phosphonic acid (France, 2003). However, comparing the results of the dietary burden calculation performed with and without the new uses on potatoes and pome fruit, it becomes evident that overall the contribution of the new use is insignificant. The input values for the two scenarios calculated (with and without the new uses on potatoes and pome fruit) can be found in Appendix D.1.

It should be noted that the conclusions of the MRL review so far have not been implemented and therefore the dietary burden calculation may not fully reflect the uses currently approved in the Member States.[12]

The livestock exposure for the sum of fosetyl and phosphonic acid residues, expressed as fosetyl according to the Regulation (EC) No 396/2005 was not assessed under the current assessment since for the food commodities that can be used as livestock feed and for which the existing MRLs are set above the LOQ (citrus fruits, cabbage, kale) the corresponding risk assessment values are not available. The calculation using MRLs and default processing factors as input values would be a gross overestimation of the actual livestock exposure. Under the current assessment, the livestock exposure to fosetyl (alone) was also not calculated as fosetyl residues in potatoes from the new use of fosetyl-Al were below the LOQ and thus would not affect the existing livestock exposure to fosetyl residues.

EFSA concluded that livestock exposure to phosphonic acid and fosetyl residues and the possible need to revise the existing MRLs for animal products on the basis of appropriate livestock feeding studies has to be re-assessed once the renewal of the approval of fosetyl has been completed and the data on existing uses that result in residues of phosphonic acid in feed commodities are available. For the current application, only an indicative impact assessment was possible, which gave an indication that the new uses on pome fruit and potatoes will not significantly change the dietary exposure of livestock.

[12] Following the MRL review, the approved uses GAPs may have to be revised once the proposed new MRLs are implemented in the EU legislation.

3. Consumer risk assessment

The toxicological reference value for fosetyl-Al (ADI value of 3 mg/kg body weight (bw) per day) was derived in the framework of the EU pesticides peer review (EFSA, 2005) and, as both fosetyl-Al and potassium phosphonates have phosphonic acid as a common metabolite, the peer review proposed to use the toxicological data of fosetyl-Al for the assessment of potassium phosphonates (EFSA, 2012b). The ADI for fosetyl (2.8 mg/kg bw per day) is calculated from the ADI of fosetyl-Al, by applying a molecular weight conversion factor of 0.93. An acute reference dose (ARfD) was deemed unnecessary.

As phosphonic acid is the main component of residues in the plant, a specific toxicological value derived for phosphonic acid (ADI value of 2.25 mg/kg bw day) was proposed to be used as a basis for the risk assessment (EFSA, 2012b). An ARfD was deemed unnecessary for this compound.

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The consumer risk assessment was performed separately for the two scenarios (see Section 1.1.6 – phosphonic acid scenario and fosetyl scenario). The calculations should be considered as tentative since other sources of exposure contributing to the total intake could not be taken into account (e.g. residues resulting from the use of potassium phosphonates and disodium phosphonate), since the MRL review for these substances has not yet been performed.

Fosetyl scenario: The long-term exposure assessment was performed taking into account the STMR values derived for the crops assessed in this application (expressed as fosetyl). For the remaining commodities, the STMR values, where available from the previous EFSA assessments, or the EU MRLs established in Regulation (EC) No 2016/1003[13] were used as input values.

Phosphonic acid scenario: The long-term exposure assessment was performed taking into account the STMR values derived for the crops assessed in this application (expressed as phosphonic acid). For the remaining commodities, the existing EU MRLs in the Commission Regulation (EU) No 2016/1003 were recalculated to phosphonic acid using the molecular weight conversion factor of 0.75 and were used as input values; the MRLs which are set at the LOQ were not recalculated. EFSA is aware that this assumption overestimates the actual consumer exposure, but detailed risk assessment values for phosphonic acid for the existing MRLs are currently not available.

The estimated long-term dietary intake for the fosetyl scenario was in the range of 8–45% of the ADI. The total calculated intake in the phosphonic acid scenario accounted for a maximum 42% of the ADI. The list of input values is presented in Appendix D.2.

EFSA concluded that the long-term intake of residues of phosphonic acid and fosetyl resulting from the existing and the intended uses of fosetyl-Al and potassium phosphonates is unlikely to present a risk to consumer health. EFSA notes that consumer exposure to residues of fosetyl and phosphonic acid from the intake of animal commodities at the current stage is affected by non-standard uncertainties and a refined risk assessment should be performed, taking into account all uses that contribute to the exposure of fosetyl and phosphonic acid; in this comprehensive risk assessment, the expected residues in animal products reflecting livestock exposure to residues related to the use of fosetyl, potassium phosphonates and disodium phosphonate need to be taken into account.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for all crops under consideration.

Based on the tentative risk assessment, EFSA concluded that the proposed use of fosetyl-Al on potatoes and the proposed use of potassium phosphonates on pome fruits and peaches and the authorised use of potassium phosphonates on tree nuts in the United States are unlikely to result in a consumer exposure exceeding the toxicological reference values for phosphonic acid and fosetyl and therefore is unlikely to pose a risk to consumers' health. EFSA notes that consumer exposure to residues of fosetyl and phosphonic acid from the intake of animal commodities at the current stage

[13] 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, benzovindiflupyr, bromoxynil, fludioxonil, fluopicolide, fosetyl, mepiquat, proquinazid, propamocarb, prohexadione and tebuconazole in or on certain products. OJ L 167, 24.6.2016, p. 46–103.

could not be realistically estimated. The consumer exposure has to be reassessed as soon as the renewal of the approval of fosetyl and the review of existing uses of potassium phosphonates and disodium phosphonates is finalised.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MW	molecular weight
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
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SL	soluble concentrate
SMILES	simplified molecular-input line-entry system

STMR	supervised trials median residue
WG	water-dispersible granule
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I[(a)]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s.	Method kind	Range of growth stages and season[(c)]	No min–max	Interval between appl. (min)	kg a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Potassium phosphonates															
Tree nuts (except coconuts)	United States	F	Downy mildew	Liquid	45.5%*	Foliar spray	At onset of disease	6	7–14	0.320–1.620	187–935	3.03 (equivalent to 1.89 phosphonic acid)	kg a.s./ha per appl.	Not specified[(e)]	*648 g/L mono- and di-potassium salts of phosphorous acid equiv. to 405 g/L phosphonic acid
Pome fruits	SEU (FR, EL, IT, ES)	F	Fungal diseases	SC	660 g/L (potassium phosphonate (440 g/L phosphonic acid eq)	Foliar spray	BBCH 09–81	10	–	0.132–0.66 (potassium phosphonates) i.e. 0.088–0.44 (phosphonic acid eq)	300–1,500	1.98 (equivalent to 1.32 phosphonic acid)	kg a.s./ha max. rate per appl.	28	Apply a minimum dose of 333 mL product/ha
	NEU (BE, CZ, DE, PL, NL)	F	Fungal diseases	SC	660	Foliar spray	BBCH 53–81	8	–	0.11–0.55 (potassium phosphonates) i.e. 73–366 (phosphonic acid eq)	300–1,500	1.65 (equivalent to 1.10 phosphonic acid)	kg a.s./ha max. rate per appl.	28	–

Crop and/or situation	NEU, SEU, MS or country	F G or I[(a)]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s.	Method kind	Range of growth stages and season[(c)]	No min–max	Interval between appl. (min)	kg a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Stone fruits	SEU	F	*Phytophthora* spp.	SL	726	Drip irrigation	1st: BBCH 32 2nd: BBCH 35 3rd: BBCH 91	3	14	0.26	1,000	7.26	kg a.s./ha	14	–
	SEU	F	*Phytophthora* spp.	SL	726	Foliar spray	1st: BBCH 32 2nd: BBCH 35 3rd: BBCH 91	3	14	0.484	600	2.904	kg a.s./ha	14	–
Fosetyl-Al															
Peach	SEU	F	*Phytophthora cact.*	WG	800 g/kg	Foliar spraying	BBCH 69–81	1–2	30	0.2	500–1,500	1.0–3.0	kg/ha	28	Max season: 6.0 kg a.i./ha label rate: 0.25%
Potato	SEU	F	*Phytophthora infestans*	WG	298 g/kg	Spray	BBCH 21–69	3	10 days	0.1676	600–800	1.341	kg/ha	40	–

NEU: northern Europe; SEU: southern Europe; MS; Member State; a.s.: active substance; SC: suspension concentrate; SL: soluble concentrate; WG: water-dispersible granule.
(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.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Fosetyl-Al

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling[(a)] (day, DAT)	Comment/source
	Fruit	Oranges	Paintbrush on leaves: 4 × 1 g/15 trees	Whole fruit at maturity (ca. 75 DAT)	Ethyl-labelled fosetyl-Al (France, 2003, 2017b)
		Tangerines	Paintbrush on leaves: 3 × 1 g/15 trees		
		Pineapples	a) Dipping of pineapple crowns (unlabelled a.s.): 1 × 2.4 g/L + micro droplet deposition. Crowns planted b) After 1 year: foliar spray (unlabelled a.s.) 1 × 2.4 g/L + micro droplet deposition	a) 0, 7 14, 28, 56 and 120 DAT b) 115 and 122 DAT_1	Ethyl-labelled fosetyl-Al. Whole fruits sampled (France, 2003, 2017b)
		Tomatoes	Foliar: 2 (14-day interval) × 4,400 g/ha	0 (2 h), 14, 28 and 56 DAT_1	Ethyl-labelled fosetyl-Al (France, 2003)
		Apples	Foliar: 2 (7-day interval) × n.r.	7, 14 DAT_2	Ethyl-labelled fosetyl-Al Fruit and leaves sampled. Data on leaves considered by the peer review for leafy crop group (France, 2003, 2017b; EFSA, 2005)
		Grapes	Microdroplet deposition: 3,024 µg/plant	7,14, 21 DAT	Ethyl-labelled fosetyl-Al. Only leaves sampled. Data on leaves considered by the peer review for leafy crop group (France, 2003; EFSA, 2005)

Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)	Comment/source
	Root/tuber crops	Radish	Bare soil, 4.9 mg phosphonic acid/kg soil, corresponding to 15 kg fosetyl-Al/ha	32, 182	Fosetyl in soil degrades to phosphonic acid. Due to problems radiolabelling phosphonic acid, the study was performed with a non-radiolabelled phosphonic acid (France, 2003)
	Leafy crops	Lettuce		32	
	Cereal (small grain)	Barley		32	
	Other	–	–		

Processed commodities (hydrolysis study)	Conditions	Stable?	Comment/source
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Individual hydrolysis studies performed with fosetyl-Al and phosphonic acid (France, 2003)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	
	Sterilisation (20 min, 120°C, pH 6)	Yes	

PBI: plant-back interval; n.r.: not reported.
(a): DATx: days after treatment x.

Can a general residue definition be proposed for primary crops?	Yes	Due to elementary nature of fosetyl-Al and given similar results obtained on fruits and leafy parts of plant (EFSA, 2005)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2005)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2005)
Plant residue definition for monitoring (RD-Mo)	Peer review (EFSA, 2005, revised in 2013): Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid Regulation (EC) NO 396/2005: Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl MRL review (EFSA, 2012a): 1) Phosphonic acid and 2) Fosetyl (optional)	
Plant residue definition for risk assessment (RD-RA)	Peer review (EFSA, 2005, revised in 2013): Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid MRL review (EFSA, 2012a): 1) Phosphonic acid and 2) Fosetyl (optional)	
	MRL applications (EFSA, 2014, 2015): Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high acid (oranges, grapes), high water (lettuce, cucumber), high oil content (avocado) and high starch content (wheat) : HPLC–MS/MS: LOQ 0.01 mg fosetyl-Al/kg, LOQ 0.1 mg phosphonic acid/kg ILV available The LOQ for fosetyl takes into account that there are 3 molecules of fosetyl in each fosetyl-Al (EFSA, 2012a)	

Potassium phosphonates

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/source**
	No studies due to the simple nature of residue Given the elementary nature of potassium phosphonates, the peer review concluded that, according to available data from the public literature, the main metabolite of potassium phosphonates in plants will be phosphonic acid (EFSA, 2012b)				
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/source**
	No studies due to the simple nature of residue and not triggered The nature of phosphonic acid (because fosetyl-Al degrades rapidly in the soil to phosphonic acid) in rotational crops was investigated in the peer review of fosetyl-Al and indicate phosphonic acid as the main metabolite in rotational crops (EFSA, 2005)				

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	According to studies with fosetyl-Al, the peer review concluded that both fosetyl and phosphonic acid are hydrolytically stable (EFSA, 2005)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	
	Sterilisation (20 min, 120°C, pH 6)	Yes	

DAT: days after treatment; PBI: plant-back interval.

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)	Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012b) According to Regulation (EC) No 396/2005, the residues of potassium phosphonates are currently covered by the enforcement residue definition for fosetyl-Al: sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl	
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)	Matrices with high acid (oranges, grapes), high water (lettuce, cucumber), high oil content (avocado) and high starch content (wheat) : HPLC–MS/MS: LOQ 0.1 mg phosphonic acid/kg ILV available (EFSA, 2012a)	

B.1.1.2. Stability of residues in plants

Fosetyl-Al/potassium phosphonates

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/source**
				Value	**Unit**		
	High water content	Cucumber, lettuce	–18	12	Months	The sum of phosphonic acid and fosetyl	Fosetyl-Al rapidly degrades < 70% recovery within 3–8 months (France, 2003; EFSA, 2012a)
		Cucumber, cabbage	–18	25	Months	The sum of phosphonic acid and fosetyl	Fosetyl-Al rapidly degrades < 70% recovery within 3–8 months (EFSA, 2012a)
			–18	25	Months	Phosphonic acid	EFSA (2012a)
		Apples	–18	12	Months	Phosphonic acid	France (2017a)
		Peaches	–18	307	Days	Phosphonic acid	France (2017c)
	High acid content	Grapes	–18	12	Months	The sum of phosphonic acid and fosetyl	France (2003)
			–18	12	Months	Phosphonic acid	EFSA (2012b)
			–18	25	Months	The sum of phosphonic acid and fosetyl	EFSA (2012a)
						Fosetyl-Al	
						Phosphonic acid	
	High starch content commodities	Potato	–18	12	Months	The sum of phosphonic acid and fosetyl	Fosetyl-Al rapidly degrades < 70% recovery within 3–8 months (France, 2003; EFSA, 2012a)
			–18	25	Months	Phosphonic acid	EFSA (2012a)
	High oil content	Almond	–20	218	Days	Phosphonic acid	France (2017d)
		Pistachio	–20	221	Days	Phosphonic acid	France (2017d)
		Walnut	–20	146	Days	Phosphonic acid	France (2017d)
	Processed commodities	Peach jam, purée, nectar and canned peaches	–18	112–114	Days	Phosphonic acid	Study duration 112–114 days. France (2017c)

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ indoor[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)
Tree nuts (GAP for potassium phosphonates)	USA	1) Phosphonic acid expressed as fosetyl (Reg. 396/2005): Almonds: 0.68; < 0.67; 133.33; 7.44 Walnuts: 71.69; 5.03; 229.8; 89.78 Pistachios: 86.4; 223.11; 226.5; 263.98; 2.41 2) Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012b): Almonds: 0.505; < 0.5; 99.5; 5.55 Walnuts: 53.5; 3.75; 171.5; 67 Pistachios: 64.5; 166.5; 169; 197; 1.8	Residue trials on almonds, walnuts and pistachios combined and extrapolated to the whole group of tree nuts (except coconut) 1) MRL_{OECD} = 509/500 2) MRL_{OECD} = 380/400	1) 500 2) 400	1) 263.98 2) 197	1) 86.43 2) 64.50
Pome fruit (GAP for potassium phosphonates)	NEU	1) Phosphonic acid expressed as fosetyl (Reg. 396/2005): Apples: 23.45; 24.66; 45.83; 51.32; 51.32; 52.26 Pears: 9.65; 59.63 2) Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012b): Apples: 17.50; 18.40; 34.20; 38.30; 38.30; 39.00 Pears: 7.20; 44.50	Residue trials performed with 10 instead of 8 applications, thus not complying with the intended GAP 1) MRL_{OECD} = 119.3/150 2) MRL_{OECD} = 89.03/90.00	–	–	–
	SEU	1) Phosphonic acid expressed as fosetyl (Reg. 396/2005): Apples: 1.18; 12.33; 26.00; 35.91; 41.54; 46.23 Pears: 26.26; 63.38 2) Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012b): Apples: 0.88; 9.20; 19.40; 26.80; 31.00; 34.50; Pears: 19.60; 47.30	GAP-compliant residue trials on apples and pears combined. **Extrapolation to the whole group of pome fruits** 1) MRL_{OECD}=110.14/150 2) MRL_{OECD} = 82.19/90.00	1) 150 2) 90	1) 63.38 2) 47.30	1) 31.09 2) 23.20

Commodity	Region/ indoor[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)
Stone fruit (GAP potassium phosphonates)	SEU (drip irrigation)	1) Phosphonic acid expressed as fosetyl (Reg. 396/2005): Peaches: 1.09; 1.49; 2.20; 3.31; 3.50[(d)]; 3.74[(d)] Nectarines: 6.50; 7.42[(d)] 2) Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012a): Peaches, 0.81; 1.11; 1.64; 2.47; 2.61[(d)]; 2.79[(d)] Nectarines: 4.85; 5.54[(d)]	1) MRL_{OECD} = 12.71/15 2) MRL_{OECD} = 9.48/10	1) 15 2) 10	1) 7.42 2) 5.54	1) 3.40 2) 2.54
	SEU (foliar spray)	1) Phosphonic acid expressed as fosetyl (Reg. 396/2005): Peaches: 5.04; 6.99; 12.73; 20.78; 21.82; 23.22 Nectarines: 11.31; 27.51 2) Phosphonic acid and its salts, expressed as phosphonic acid (EFSA, 2012a): Peaches: 3.76; 5.22; 9.50; 15.51; 16.28; 17.33 Nectarines: 8.44; 20.53	Foliar treatment results in a more critical residue situation and was therefore used for deriving an MRL proposal 1) MRL_{OECD} = 49.13/50 2) MRL_{OECD} = 36.66/40	1) **50** 2) **40**	1) 27.51 2) 20.53	1) 16.76 2) 12.51
Peaches (GAP fosetyl-Al)	SEU (foliar spray)	1) Sum fosetyl, phosphonic acid and their salts, expressed as fosetyl (Reg. 396/2005): 13.48[(d)]; 7.82; 4.61; 17.29; 13.85; 8.45; 8.23; 1.79; 9.16 2) Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid (EFSA, 2005): 10.06[(d)]; 5.85; 3.45; 12.90; 10.34;6.31; 6.15; 1.35; 6.85 3) Fosetyl (optional EFSA 2012a): 0.34[(d)]; 2x < 0.2; 1.21; 0.59; 0.28; 3 x < 0.2 4) Phosphonic acid (EFSA 2012a): 9.8; 5.7; 3.3; 12; 9.9; 6.1; 6.0; 1.2; 6.7	Trials on peaches and nectarines overdosed (3 instead of 2 applications) and therefore not considered	–	–	–

Commodity	Region/ indoor[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)
Potatoes (GAP fosetyl-Al)	SEU	1) Sum fosetyl, phosphonic acid and their salts, expressed as fosetyl (Reg. 396/2005): 11.90; 4.1; 3.23; 16.42; 3.08; 4.18; 19.83; 17.23 2) Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid (EFSA, 2005): 8.88; 3.06; 2.41; 12.26; 2.3; 3.12; 14.8; 12.86 3) Fosetyl (optional EFSA 2012a): 8 x < 0.05[(e)] 4) Phosphonic acid (EFSA 2012a): 8.84; 3.02; 2.37; 12.22; 2.26; 3.08; 14.76; 12.82	Trials on potatoes compliant with the GAP 1) MRL_{OECD} = 38.53/40 2) MRL_{OECD} = 28.76/30 3) MRL_{OECD} = 0.05/0.05 4) MRL_{OECD} = 28.72/30	1) **40** 2) **30** 3) 0.05*[(f)] 4) 30	1) 19.83 2) 14.80 3) < 0.05 4) 14.76	1) 8.04 2) 6.0 3) < 0.05 4) 5.96

MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development; GAP: Good Agricultural Practice.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): 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.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Residue trials on nectarines.
(e): The LOQ values of fosetyl-Al not recalculated to fosetyl as residues below the LOQ.
(f): Tentative MRL proposal due to a possible degradation of fosetyl residues during the storage.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study? Residues in rotational and succeeding crops expected based on field rotational crop study?	For the intended use of fosetyl-Al on potatoes (total seasonal application rate ca 4 kg as/ha), no significant residues of phosphonic acid expected in rotational crops	Following soil treatment with phosphonic acid at amounts corresponding to 15 kg fosetyl-Al/ha, residues of phosphonic acid in the range of the LOQ (0.5 mg/kg) can be present for short-time intervals between applications and planting or sowing of a rotational crop. A preplanting interval of 30 days is recommended (EFSA, 2005)

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[(a)]	Processing factor (PF)		Comment/source
		Individual values	Median PF	
Pears, dried	2	2.28; 3.92	3.10	Studies submitted under the MRL application on potassium phosphonates and refer to the magnitude of phosphonic acid (France, 2017a)
Pears, wet pomace	4	1.0; 1.18; 1.23; 1.06	1.12	
Pears, dry pomace	2	3.19; 4.49	3.84	
Pears, juice	2	0.89; 1.15	1.02	
Pears, purée	2	1.22; 0.88	1.05	
Pears, canned	2	1.0; 0.79	0.90	

MRL: maximum residue level.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

B.2. Residues in livestock

Relevant groups (subgroups)	Dietary burden expressed in				Previous maximum DB calculation[(c)] (mg/kg bw per day)	Most critical subgroup[(a)]	Most critical commodity[(b)]	Trigger exceeded (Y/N)
	mg/kg DM		mg/kg bw per day					
	Median	Maximum	Median	Maximum				
Cattle (all)	480.09	493.71	13.98	14.50	14.23	Dairy cattle	Potato process waste	Y
Cattle (dairy only)	363.42	377.05	13.98	14.50	14.23	Dairy cattle	Potato process waste	Y
Sheep (all)	478.63	491.26	15.95	16.38	16.14	Ram/ewe	Potato process waste	Y
Sheep (ewe only)	478.63	491.26	15.95	16.38	16.14	Ram/ewe	Potato process waste	Y
Swine (all)	252.29	272.69	5.82	6.29	6.02	Swine (breeding)	Potato process waste	Y
Poultry (all)	63.95	67.83	4.51	4.79	4.62	Poultry broiler	Potato dried pulp	Y
Poultry (layer only)	48.91	53.15	3.35	3.64	3.47	Poultry layer	Potato dried pulp	Y

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'.
(c): The previous maximum DB refers to a dietary burden calculated for phosphonic acid in the MRL review for fosetyl (EFSA, 2012a) and now updated according to the OECD methodology.

B.3. Consumer risk assessment

No ARfD has been considered necessary.

ADI **(fosetyl-Al)**	3 mg/kg bw per day (EFSA, 2005) 2.8 mg/kg bw fosetyl (recalculation from fosetyl-Al, using a molecular weight conversion factor of 0.93)
Fosetyl scenario: Highest IEDI, according to EFSA PRIMo	45% ADI (DE child) (tentative risk assessment) Contribution of crops assessed: Potatoes: 1.7% of ADI (NL child diet) Apples: 13% of ADI (DE child diet) Other pome fruit: individually < 1% of the ADI Peaches: 0.3% of ADI (IE adult diet) Tree nuts: individually < 0.3% of the ADI
Assumptions made for the calculations	The calculation is based on the median residue level derived for tree nuts, pome fruit, peaches and potatoes (expressed as fosetyl) from the trials assessed in this application For the remaining commodities, the STMR values derived in previous risk assessments, where available, or the MRLs established in Regulation (EC) No 2016/1003 were used as input values The risk assessment is tentative, since information on the possible contribution of other sources of exposure (e.g. residues resulting from the use of potassium phosphonates and disodium phosphonate) is not available at this stage

ADI **(phosphonic acid)**	2.25 mg/kg bw per day (EFSA, 2012b)
Phosphonic acid scenario: Highest IEDI, according to EFSA PRIMo	42% ADI (DE child) (tentative risk assessment) Contribution of crops assessed: Apples: 12.4% of ADI (DE child diet) Other pome fruit: individually< 1% ADI Tree nuts: individually < 0.3% of ADI Peaches: 0.3% of ADI (IE adult diet) Potatoes: 1.6% of ADI (NL child diet)
Assumptions made for the calculations	The calculation is based on the median residue levels derived for tree nuts, pome fruit, peaches, potatoes (expressed as phosphonic acid) from the trials assessed in this application For the remaining commodities, the existing MRLs set for fosetyl in Regulation (EC) No 2016/1003, recalculated to phosphonic acid (except values at the LOQ), were used as input values The risk assessment is tentative, since information on the possible contribution of other sources of exposure (e.g. residues resulting from the use of potassium phosphonates and disodium phosphonate) is not available at this stage

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL[(a)] (mg/kg)	Proposed EU MRL (mg/kg)			Comment/justification
			(1)	(2)	(3)	
Enforcement residue definitions: 4) Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) 5) Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid 6) Fosetyl (only for crops with intended uses of fosetyl-Al)						
0120010	Almonds	75	500	400	–	The submitted data are sufficient to derive an import tolerance for the US GAP on potassium phosphonates. Based on tentative risk assessment, the risk for consumers is unlikely
0120020	Brazil nuts	2*				
010030	Cashew nuts	75				
0120040	Chestnuts	2*				
0120060	Hazelnuts/cobnuts	75				
0120070	Macadamias	75				
0120080	Pecans	2*				
0120090	Pine nut kernels	2*				
0120100	Pistachios	75				
0120110	Walnuts	75				
013000	Pome fruits	75	150	90	–	The submitted data are sufficient to derive a MRL proposal for the SEU use of potassium phosphonates. Based on tentative risk assessment, the risk for consumers is unlikely
0140030	Peaches	2*	50	40	–	The submitted data are sufficient to derive a MRL proposal for the SEU use of potassium phosphonates. Based on tentative risk assessment, the risk for consumers is unlikely. The submitted data for the intended SEU use of fosetyl-Al were not sufficient to derive a MRL proposal
0211000	Potatoes	30	40	30	0.05*[(b)]	The submitted data are sufficient to derive a MRL proposal for the SEU use of fosetyl-Al. Based on tentative risk assessment, the risk for consumers is unlikely

MRL: maximum residue level; GAP: good agricultural practice; 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.
(b): The MRL proposal is tentative due to a possible degradation of fosetyl residues during the storage of the sample.

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):	**2.25**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2012**	Year of evaluation:	**2015**

All MRLs

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum
7 42

No of diets exceeding ADI: – – –

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
42	DE child	12	Apples	10	Oranges	4	Table grapes	
38	WHO Cluster diet B	10	Tomatoes	6	Wine grapes	2	Peppers	
31	NL child	8	Oranges	7	Apples	3	Table grapes	
26	IE adult	4	Wine grapes	3	Oranges	2	Melons	
22	FR all population	13	Wine grapes	1	Tomatoes	1	Oranges	
21	FR toddler	5	Oranges	3	Apples	3	Tomatoes	
20	PT General population	8	Wine grapes	3	Tomatoes	2	Oranges	
18	WHO cluster diet E	5	Wine grapes	2	Tomatoes	1	Oranges	
17	UK Toddler	5	Oranges	2	Sugar beet (root)	2	Tomatoes	
16	ES child	5	Oranges	3	Tomatoes	1	Apples	
16	WHO regional European diet	4	Tomatoes	1	Oranges	1	Potatoes	
15	DK child	4	Cucumbers	2	Apples	2	Tomatoes	
15	NL general	4	Oranges	2	Wine grapes	1	Tomatoes	
15	WHO cluster diet D	3	Tomatoes	1	Wine grapes	1	Potatoes	
15	SE general population 90th percentile	3	Tomatoes	2	Oranges	1	Mandarins	
14	ES adult	3	Oranges	3	Tomatoes	1	Wine grapes	
14	WHO Cluster diet F	2	Tomatoes	2	Oranges	2	Wine grapes	
14	FR infant	3	Apples	2	Oranges	2	Courgettes	
13	IT kids/toddler	5	Tomatoes	1	Oranges	1	Apples	
12	UK vegetarian	3	Wine grapes	2	Oranges	2	Tomatoes	
12	IT adult	4	Tomatoes	1	Lettuce	1	Oranges	
11	UK Infant	3	Oranges	2	Apples	1	Tomatoes	
11	DK adult	5	Wine grapes	1	Tomatoes	1	Apples	
10	UK Adult	4	Wine grapes	1	Tomatoes	1	Oranges	
9	PL general population	3	Tomatoes	2	Apples	1	Table grapes	
8	FI adult	2	Oranges	1	Tomatoes	1	Wine grapes	
7	LT adult	2	Tomatoes	2	Apples	1	Cucumbers	

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/adults/general population – 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 variabilty factor of 3.

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

Unprocessed commodities

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)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

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

*) 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.

Conclusion:

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

Fosetyl (sum of fosetyl and phosphonic acid, expressed as fosetyl)			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**2.8**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2005**	Year of evaluation:	**2015**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum
8 45

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
45	DE child	13	Apples	10	Oranges	5	Table grapes	
40	WHO Cluster diet B	11	Tomatoes	6	Wine grapes	2	Peppers	
33	NL child	8	Oranges	7	Apples	3	Table grapes	
27	IE adult	4	Wine grapes	3	Oranges	2	Melons	
23	FR all population	14	Wine grapes	2	Tomatoes	1	Oranges	
22	FR toddler	5	Oranges	3	Apples	3	Tomatoes	
21	PT General population	9	Wine grapes	3	Tomatoes	2	Oranges	
19	WHO cluster diet E	6	Wine grapes	2	Tomatoes	1	Oranges	
17	ES child	6	Oranges	4	Tomatoes	1	Apples	
17	UK Toddler	5	Oranges	2	Tomatoes	2	Apples	
17	WHO regional European diet	4	Tomatoes	1	Oranges	1	Potatoes	
16	DK child	4	Cucumbers	3	Apples	2	Tomatoes	
16	NL general	4	Oranges	2	Wine grapes	2	Tomatoes	
16	WHO cluster diet D	4	Tomatoes	1	Wine grapes	1	Potatoes	
16	SE general population 90th percentile	3	Tomatoes	2	Oranges	1	Potatoes	
15	ES adult	3	Oranges	3	Tomatoes	1	Wine grapes	
14	FR infant	3	Apples	2	Oranges	2	Courgettes	
14	WHO Cluster diet F	2	Tomatoes	2	Oranges	2	Wine grapes	
14	IT kids/toddler	5	Tomatoes	1	Oranges	1	Apples	
13	UK vegetarian	3	Wine grapes	2	Oranges	2	Tomatoes	
13	IT adult	4	Tomatoes	1	Lettuce	1	Oranges	
12	DK adult	5	Wine grapes	1	Tomatoes	1	Apples	
11	UK Infant	3	Oranges	2	Apples	1	Tomatoes	
11	UK Adult	4	Wine grapes	2	Tomatoes	2	Oranges	
10	PL general population	3	Tomatoes	2	Apples	1	Table grapes	
9	FI adult	3	Oranges	2	Tomatoes	1	Wine grapes	
8	LT adult	2	Tomatoes	2	Apples	1	Cucumbers	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fosetyl (sum of fosetyl and phosphonic acid, expressed as fosetyl) is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations						Acute risk assessment/adults/general population – 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 variabilty factor of 3.

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

Unprocessed commodities												
	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)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

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

*) 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.

Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of Fosetyl (sum of fosetyl and phosphonic acid, expressed as fosetyl) residues is unlikely to present a pulbic 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
Article 12 MRL review (updated according to OECD 2013): **Risk assessment residue definition:** Phosphonic acid and their salts, expressed as phosphonic acid				
Cabbage	0.20	STMR (EFSA, 2012a)	1.30	HR (EFSA, 2012a)
Kale leaves	2.19	STMR (EFSA, 2012a)	3.68	HR (EFSA, 2012a)
Apple pomace	12.32	STMR (11) × PF (1.12)	–	
Citrus dried pulp[(c)]	120	STMR (12 mg/kg mandarins, lemons, limes) (EFSA, 2012a) × PF (10)[(a)]	–	
Potato	7	STMR (EFSA, 2012a)	10	HR (EFSA, 2012a)
Potato process waste[(b)]	140	STMR × PF (20)[(a)]	–	–
Potato dried pulp[(b)]	266	STMR × PF (38)[(a)]	–	–
Current assessment: **Risk assessment residue definition:** Phosphonic acid and their salts, expressed as phosphonic acid				
Cabbage	0.20	STMR (EFSA, 2012a)	1.30	HR (EFSA, 2012a)
Kale leaves	2.19	STMR (EFSA, 2012a)	3.68	HR (EFSA, 2012a)
Apple pomace	**25.98**	STMR (23.20) × PF (1.12)	–	
Citrus dried pulp[(c)]	120	STMR (12 mg/kg mandarins, lemons, limes) (EFSA, 2012a) × PF (10)[(a)]	–	
Potato	7.0[(d)]	STMR (EFSA, 2012a)	**14.8**	HR
Potato process waste[(b)]	140	STMR × PF (20)[(a)]	–	–
Potato dried pulp[(b)]	266	STMR × PF (38)[(a)]	–	–

MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development; STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

(a): For citrus dried pulp, potato process waste and potato dried pulp in the absence of processing factors supported by data, default processing factors of 10, 20 and 38 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

(b): New feed commodities according of OECD feed item list; not considered in previous EFSA assessments.

(c): New feed commodities according of OECD feed item list; citrus wet pomace considered in previous EFSA assessments.

(d): Residue value higher in the MRL review.

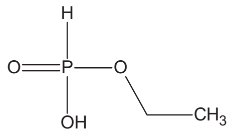
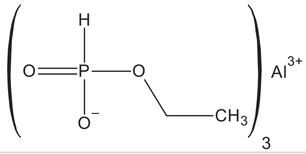
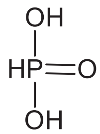
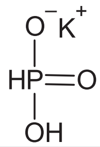
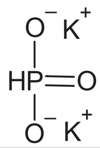
D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl (fosetyl scenario)				
Tree nuts (except coconut)	86.43	STMR	Acute exposure not calculated as the ARfD is not established for fosetyl	
Pome fruit	31.09	STMR		
Peaches	16.76	STMR		
Potatoes	8.04	STMR		
Blackberries, raspberries	16.76	STMR (EFSA, 2015)		
Celeriac	0.21	STMR (EFSA, 2015)		
Kiwi	32.73	STMR (EFSA, 2012b)		
Spices	99.17	STMR (EFSA, 2012b)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Other commodities of plant and animal origin	MRL	Commission Regulation (EU) No 2016/1003		
Risk assessment residue definition: sum of phosphonic acid and their salts, expressed as phosphonic acid (phosphonic acid scenario)				
Tree nuts, except coconut	64.50	STMR	Acute exposure not calculated as the ARfD is not established for phosphonic acid	
Pome fruit	23.20	STMR		
Peaches	12.51	STMR		
Potatoes	7.0	STMR (EFSA, 2012a)		
Blackberries, raspberries	7.5	STMR (EFSA, 2015)		
Celeriac	0.2	STMR (EFSA, 2015)		
Kiwi	23.5	STMR (EFSA, 2012c)		
Spices	74	STMR (EFSA, 2012c)		
Other food commodities of plant and animal origin	MRLs, recalculated to phosphonic acid	Commission Regulation (EU) No 2016/1003		

STMR: supervised trials median residue; ARfD: acute reference dose; MRL: maximum residue level.

Appendix E – Used compound codes

Code/trivial name	Chemical name/SMILES notation[(a)]	Structural formula[(a)]
Fosetyl	Ethyl hydrogen phosphonate	
Fosetyl-Al fosetyl aluminium	Aluminium tris(ethyl phosphonate)	
Phosphonic acid **Phosphorous acid** [PHO(OH)2], (HO)2HPO H3PO3	Phosphonic acid	
Potassium hydrogen phosphonate	Potassium hydrogen phosphonate	
Dipotassium phosphonate	Dipotassium phosphonate	

SMILES: simplified molecular-input line-entry system.
(a): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).