

## STATEMENT OF EFSA

### Statement on the dietary risk assessment for proposed temporary maximum residue levels (t-MRLs) for fosetyl-Al in certain crops<sup>1</sup>

European Food Safety Authority<sup>2</sup>

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#### ABSTRACT

In accordance with Article 43 of Regulation (EC) No 396/2005, the European Commission requested EFSA to perform a dietary risk assessment of the proposed temporary MRLs for fosetyl-Al. These temporary MRLs should accommodate for residues found in different commodities which are according to food business operators most likely resulting from the use of foliar phosphorous fertilizers which could mimic the treatment with fosetyl-Al. The European Commission proposed to raise the existing MRLs as a proportionate risk management measure on a temporary basis to avoid market disruptions, provided that the proposed temporary MRLs do not pose a consumer health risk. EFSA concludes that the overall dietary exposure to fosetyl-Al (sum of fosetyl and phosphonic acid and their salts expressed as fosetyl) linked to the proposed temporary MRLs for the crops under assessment and the existing MRLs for other commodities covered by the EU MRL legislation is not expected to result in a consumer exposure exceeding the toxicological reference values for fosetyl. Considering that the exposure assessment was performed with a conservative approach which is likely to overestimate the real exposure, EFSA concludes that the proposed temporary MRLs are unlikely to pose a consumer health risk. Since the source of the occurrence of the residues in the crops under consideration is not clarified, the conclusions of the risk assessment are restricted to the identified residues of phosphonic acid. EFSA derived several recommendations to be considered by risk managers to identify the source of the contamination aiming to reduce the uncertainties of the risk assessment.

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#### KEY WORDS

fosetyl, phosphonic acid, temporary MRLs, Regulation (EC) No 396/2005

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## SUMMARY

In accordance with Article 43 of Regulation (EC) No 396/2005, the European Commission requested EFSA to perform a dietary exposure assessment for the proposed temporary MRLs for fosetyl-Al in certain crops (nuts, stone fruit, certain berries, certain tropical fruit, legume vegetables and asparagus). These temporary MRLs should accommodate for residues of phosphonic acid found in different commodities. The source of these residues is not clearly identified. Food business operators claim that these residues are most likely resulting from the use of foliar phosphorous fertilizers which could mimic the treatment with fosetyl-Al. The European Commission proposed to raise the existing MRLs as a proportionate risk management measure on a temporary basis to avoid market disruptions, provided that the proposed temporary MRLs do not pose a consumer health risk.

The current residue definition established in Regulation (EC) No 396/2005 for fosetyl-Al comprises the sum of fosetyl, phosphorous acid and their salts, expressed as fosetyl. Phosphorous acid, according to the current IUPAC nomenclature should be renamed to phosphonic acid. The European Commission proposed that the temporary MRLs should refer to this residue definition. For risk assessment purposes, EFSA used the above mentioned residue definition on a provisional basis, noting that in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 a revision of the residue definitions for both risk assessment and enforcement was suggested. The available metabolism studies on fosetyl demonstrated that phosphonic acid is the main metabolite resulting from the use of fosetyl, but also the use of other pesticides leads to the formation of phosphonic acid in treated crops, i.e. potassium phosphonates and disodium phosphonate.

The toxicological profile of fosetyl-Al was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 3 mg/kg bw per day, corresponding to an ADI of 2.8 mg/kg bw per day for fosetyl (molecular weight correction). The setting of an ARfD was not necessary. Phosphonic acid was found to be slightly more toxic (ADI 2.25 mg/kg bw per day); due to its low acute toxicity no ARfD was established. Since the residues present in food occur mainly as phosphonic acid, the ADI value derived for phosphonic acid is the most appropriate toxicological reference value for dietary risk assessment. Thus, the ADI of phosphonic acid was recalculated by applying a molecular weight correction factor to match with the residue definition (residues expressed as fosetyl). The resulting ADI, expressed as fosetyl is 2.52 mg/kg bw per day.

The consumer exposure assessment was performed using the revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The calculated Theoretical Maximum Daily Intake (TMDI) was compared with the ADI for fosetyl which was derived from the ADI for phosphonic acid by applying the appropriate molecular weight correction factor. The estimated long-term exposure accounted for up to 81 % of the ADI (German child diet). Among the crops for which temporary MRLs were proposed, the main contributors were beans with pods (max. 3.3 % of the ADI), peas with pods and peaches (max. 1.7 % of the ADI respectively) and apricots and cherries (1.1 % of the ADI, respectively). No acute consumer exposure was performed due to the low acute toxicity of the active substance. The estimated exposures were then compared with the toxicological reference values derived for fosetyl and phosphonic acid.

The risk assessment focussed on fosetyl and phosphonic acid only. However, since the source of these residues is not unambiguously identified, other possible contaminations linked to the observed unexpected occurrence of phosphonic acid in the crops under consideration cannot be excluded. Further investigations should be performed to elucidate the source of residues and to exclude illegal uses of fosetyl, potassium phosphonates or disodium phosphonate on crops for which no authorisations are granted.

It is noted that the temporary MRLs need to be reconsidered if in the future the residue definition will be amended as proposed by EFSA in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005.

Based on the available information, EFSA concludes that the amendment of the existing MRL as reported in the summary table is not likely to pose a consumer health risk.

### Summary table

Code number <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
<b>Current enforcement residue definition established in Regulation (EC) No 396/2005: Fosetyl-AI (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)</b>				
0120010	Almonds	2*	75	The proposed temporary MRLs are not expected to pose a consumer health risk. It is noted that the risk assessment focussed only on the current residue definition. EFSA also recommends changing the wording of the residue definition to reflect the correct IUPAC nomenclature. This modification has no impact on the existing residue levels.
0120030	Cashews	2*	75	
0120060	Hazelnuts (Filbert)	2*	75	
0120070	Macadamia	2*	75	
0120100	Pistachios	2*	75	
0120110	Walnuts	2*	75	
0140000	Stone fruit (group)	2*	75	
0153000	Cane fruit (subgroup)	2*	75	
0154010	Blueberries	2*	75	
0154030	Currants (red, black and white)	2*	75	
0154040	Gooseberries	2*	75	
0161020	Figs	2*	75	
0161040	Kumquats	2*	75	
0161060	Persimmon	2*	75	
0162030	Passion fruit	2*	75	
0163040	Papaya	2*	75	
0163050	Pomegranate	2*	75	
0220010	Garlic	2*	50	
0260010	Beans (with pods)	2*	75	
0260020	Beans (without pods)	2*	75	
0260030	Peas (with pods)	2*	75	
0260040	Peas (without pods)	2*	75	
0270010	Asparagus	2*	50	

## TABLE OF CONTENTS

Abstract .....	1
Summary .....	2
Table of contents .....	4
Background as provided by European Commission .....	5
Terms of reference as provided by European Commission.....	6
Context of the scientific output .....	7
Assessment .....	8
1. Introduction.....	8
1.1. Fosetyl-Al, fosetyl.....	8
1.2. Potassium phosphonates .....	9
1.3. Disodium phosphonate.....	9
1.4. Fertilisers containing phosphonic acid.....	10
2. Nature of residues in food resulting from the use of pesticides (fosetyl, disodium phosphonate, potassium phosphonates).....	10
3. Mammalian toxicology .....	11
4. Dietary risk assessment .....	12
Conclusions and recommendations .....	14
References .....	15
Appendices .....	16
Appendix A: Dietary risk assessment (results of EFSA PRIMo rev. 2).....	16
Appendix B: Existing EU MRLs established in Regulation (EC) No 396/2005 and proposed MRLs derived in the MRL review .....	17
Abbreviations .....	22

## BACKGROUND AS PROVIDED BY EUROPEAN COMMISSION

Fosetyl-Al<sup>3</sup> is approved as an active substance in plant protection products under Regulation (EC) No 1107/2009<sup>4</sup>. Phosphonic acid (synonymous to phosphorous acid) is a metabolite of fosetyl. Maximum residue levels (MRLs) for fosetyl-Al (residue definition: sum fosetyl + phosphorous acid and their salts, expressed as fosetyl) have been set under Regulation (EC) No 396/2005<sup>5</sup>. Phosphonates (synonymous to phosphites) are the salts of phosphonic acid.

Potassium phosphonates is approved as an active substance in plant protection products under Regulation (EC) No 1107/2009. Maximum residue levels (MRLs) for this substance are set for the same residue definition as for fosetyl-Al.

Disodium phosphonate is approved as an active substance in plant protection products under Regulation (EC) No 1107/2009. Maximum residue levels (MRLs) for this substance are currently set at the default level of 0.01 mg/kg according to Art 18(1)(b) of Regulation (EC) No 396/2005.

Besides their use as active substances in plant protection products, phosphonates are also ingredients to other products of agricultural relevance, notably certain fertiliser products applied to the leaves of plants (foliar fertilisers). It can be reasonably assumed that treatment of plants with such fertiliser products could lead to the detection of phosphonate residues in pertinent agricultural commodities.

The European Commission has been informed by food business operators and Member States that residues of fosetyl, phosphonic acid and their salts have been detected in monitoring samples of various food products to which currently an MRL at the level of determination of 2 mg/kg applies. Frequently, the measured levels exceeded this MRL.

Food business operators and Member States have been investigating the reason(s) for the presence of residues. Given the lack of relevant authorisations for plant protection products containing fosetyl-Al both in the EU and in third countries that are important exporters of the concerned food products into the EU, and the use of phosphonates as ingredient in foliar fertiliser products, the most likely explanation is that residues are a consequence of the application of foliar fertiliser products containing phosphonates. Further investigations are ongoing, and Commission, Member States and food business operators are in discussions regarding measures to generate data for MRL setting and/or prevent the occurrence of phosphonate residues in relevant crops in future growing seasons.

To avoid significant market disruptions in the trade of the concerned products, the Commission considers setting temporary MRLs according to Article 16(1)(a) of Regulation (EC) No 396/2005 on the basis of monitoring data, while the above mentioned measures are implemented.

The European Commission analysed the available monitoring data and considers that it is appropriate to set temporary MRLs for the products and at the levels shown in Table 1, as a proportionate risk management measure on a temporary basis, ensuring a high level of consumer protection in the European Union. Before taking further steps, the European Commission seeks to ascertain whether the proposed temporary MRLs are sufficiently protective for consumers.

A recent discussion in the Standing Committee on the Food Chain and Animal Health – session Pesticide Residues (meeting of 16/17 September 2013, 18/19 November 2013 and 24/25 February 2014) - focussed on the most appropriate residue definition for fosetyl-Al, potassium phosphonates and disodium phosphonate. It was agreed that the European Commission will only present a proposal

<sup>3</sup> Fosetyl-Al is the variant of the active substance fosetyl that is usually used in formulated plant protection products.

<sup>4</sup> 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.

<sup>5</sup> 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, 16.03.2005, p. 1-16.

on the review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 for these substances when an EFSA Reasoned Opinion taking into account uses of all three compounds is available. In contrast, the mandate at hand targets a separate issue related to use of phosphonates in fertiliser products, and aims to obtain the necessary input for a temporary measure, as opposed to the above mentioned issue on the residue definition, which requires additional considerations to find a permanent solution.

### TERMS OF REFERENCE AS PROVIDED BY EUROPEAN COMMISSION

EFSA is requested, according to Article 43 of Regulation (EC) No 396/2005, to assess whether temporary MRLs proposed by the European Commission on the basis of its evaluation of monitoring data on residues of fosetyl, phosphonic acid and their salts are sufficiently protective for consumers in view of their possible exposure to residues of these substances. The monitoring data were already made available to EFSA. The Commission's proposal is to set temporary MRLs for the products and at the level shown in Table 1. The proposed temporary MRLs refer to the unprocessed raw agricultural products.

For the purposes of the requested assessment, the following residue definition should be used: sum fosetyl + phosphorous acid and their salts, expressed as fosetyl.

To obtain the most conservative assessment, residue data underlying document SANCO/10057/2014 on MRLs for fosetyl in kiwi, potatoes and spices should be taken into account. The document was based on the EFSA Reasoned Opinion on the modification of the existing MRLs for fosetyl in potato, kiwi and certain spices (EFSA, 2012c) but proposed setting MRLs in spices for entire (sub-) groups, instead of in single spice crops only. This proposal received a positive opinion of the Standing Committee on the Food Chain and Animal Health – section Pesticide Residues on 25 February 2014 but has not yet been adopted.

**Table 1:** Current and proposed MRLs for Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl) in certain products

Code	Commodity	Current MRL (mg/kg)	Proposed t-MRL (mg/kg)
0120010	Almonds	2*	75
0120030	Cashews	2*	75
0120060	Hazelnuts (Filbert)	2*	75
0120070	Macadamia	2*	75
0120100	Pistachios	2*	75
0120110	Walnuts	2*	75
0140000	Stone fruit (group)	2*	75
0153000	Cane fruit (subgroup)	2*	75
0154010	Blueberries	2*	75
0154030	Currants (red, black and white)	2*	75
0154040	Gooseberries	2*	75
0161020	Figs	2*	75
0161040	Kumquats	2*	75
0161060	Persimmon	2*	75
0162030	Passion fruit	2*	75
0163040	Papaya	2*	75
0163050	Pomegranate	2*	75
0220010	Garlic	2*	50
0260010	Beans (with pods)	2*	75

0260020	Beans (without pods)	2*	75
0260030	Peas (with pods)	2*	75
0260040	Peas (without pods)	2*	75
0270010	Asparagus	2*	50

## CONTEXT OF THE SCIENTIFIC OUTPUT

According to Article 43 of Regulation (EC) No 396/2005 the European Commission may request from EFSA a scientific opinion on any measure related to the assessment of risks under the referenced Regulation.

On 28 April 2014 EFSA received a request of the European Commission for a dietary exposure assessment of proposed temporary maximum residue levels (t-MRLs) of fosetyl-Al. The European Commission asked EFSA to assess whether t-MRLs proposed by the European Commission, on the basis of an evaluation of monitoring data on residues of fosetyl, phosphorous acid and their salts provided by food business operators, are sufficiently protective for consumers in view of their possible exposure to residues of these substances. The monitoring data were made available by Commission services.

The deadline proposed for the statement is 16 May 2014.

EFSA accepted the mandate and included it in the EFSA Register of Questions with the reference number EFSA-Q-2014-00358 and the following subject:

*Fosetyl-Al - Request to assess consumer health risks for proposed temporary MRLs.*

In Regulation (EC) No 396/2005 the residue definition for fosetyl-Al is set as “Fosetyl-Al (sum of fosetyl and phosphorous acid and their salts expressed as fosetyl)”.

In order to avoid confusions, it is highlighted that phosphorous acid, which is the main metabolite of fosetyl, should be referred to as phosphonic acid according to the current chemical nomenclature (IUPAC). Thus, in this statement the metabolite is referred to as phosphonic acid, unless reference is made to legal texts where phosphorous acid is explicitly mentioned.



## ASSESSMENT

EFSA bases its assessment on the conclusion on the peer review of the pesticide risk assessment of the active substance fosetyl (EFSA, 2005), the previous reasoned opinion on fosetyl (EFSA, 2009, 2012b, 2012c) as well as the EFSA conclusions on potassium phosphonates (EFSA, 2012a) and on disodium phosphonate (EFSA, 2013).

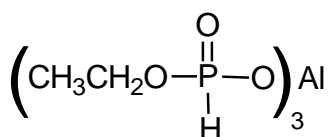
Food business operators submitted monitoring data and results of self-control programmes to the European Commission to substantiate the request to modify the current MRLs. These data were the basis for the European Commission to derive the proposed temporary MRLs. The results of the monitoring analysis were reported in different formats and not all of the results reflected the current residue definition which is defined as fosetyl-Al (sum of fosetyl and phosphorous acid and their salts expressed as fosetyl). The European Commission shared these data with EFSA but explicitly noted that current mandate does not require EFSA to verify that the proposed temporary MRLs are sufficient to cover the residue levels found in monitoring and self-control programmes. Thus, information in the submitted data files is purely for information purpose and is therefore not subject to the assessment presented in the framework of the current statement.

### 1. Introduction

In the following sections possible sources of contamination are discussed.

#### 1.1. Fosetyl-Al, fosetyl

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 for which the structural formula is depicted below.



Molecular weight for fosetyl is 110; for fosetyl aluminium it is 354.1.

Fosetyl was evaluated in the framework of Directive 91/414/EEC<sup>6</sup> with France being the designated rapporteur Member State (RMS). Following the peer review, which was carried out by EFSA (EFSA, 2005), a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2006/64/EC<sup>7</sup>, entering into force on 01 May 2007. According to Regulation (EU) No 540/2011<sup>8</sup>, fosetyl is approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as fungicide only.

The EU MRLs for fosetyl are established in Annex IIIA of Regulation (EC) No 396/2005. In the framework of assessments of MRL applications, EFSA recommended the modification of existing MRLs (EFSA, 2009, 2012c) which were subsequently implemented in the EU MRL legislation; the latest amendments regarding kiwi and spices are not yet published in the Official Journal. All existing EU MRLs, which are established for the sum of fosetyl, phosphorous acid and their salts, expressed as fosetyl, are summarized in Appendix B to this document. For the crops under consideration the existing MRLs are set at the limit of quantification (LOQ). In the framework of the MRL review, no GAPs or import tolerances were reported for the crops under consideration. CXLs for fosetyl or its

<sup>6</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

<sup>7</sup> 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, 27/07/2006, p. 107-111.

<sup>8</sup> Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1-186.



metabolite phosphonic acid are not available. Thus EFSA concludes that the residues found in the crops under considerations do not reflect approved uses of fosetyl.

In 2012, EFSA issued a reasoned opinion on the review of the existing MRLs for fosetyl under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2012b). EFSA recommended setting the residue definition for enforcement as phosphonic acid. Optionally, a separate enforcement residue definition comprising fosetyl only was proposed. In addition, EFSA proposed to modify the MRLs to reflect the revised residue definitions and the actually approved uses. The proposed MRLs are also reported in Appendix B. These proposed MRLs have not yet been implemented in the EU MRL legislation since the European Commission is of the opinion that the MRL review of potassium phosphonates and disodium phosphonate, two approved active substances that lead to residues of phosphonic acid in treated crops, should be completed before the existing fosetyl MRLs are amended.

### 1.2. Potassium phosphonates

Potassium phosphonates (formerly potassium phosphate) is an active substance that was assessed in the framework of Directive 91/414/EEC with France being the designated rapporteur Member State. The structural formula is depicted below.



Molecular weight for monopotassium phosphonate: 120.1; for dipotassium phosphonate: 158.2.

Following the peer review, which was carried out by EFSA (EFSA, 2012a), a decision on the approval of the active substance was published by means of Commission Regulation (EU) No 369/2013<sup>9</sup>, entering into force on 1 October 2013.

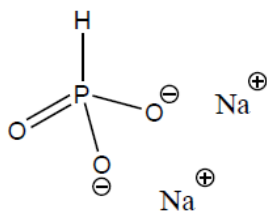
No specific MRLs are established for potassium phosphonates, but the EU MRLs set for fosetyl are applicable.

Since the MRL review under Article 12 of Regulation (EC) No 396/2005 has not yet been performed, EFSA has no overview on the approved uses and the required MRLs for this active substance at EU level. In case the use of this active substance is authorised in one of the EU Member States or in a third country, and it becomes evident that the existing EU MRL is not sufficient, an MRL application needs to be submitted in accordance with Article 6 of Regulation (EC) No 396/2005. For potassium phosphonate the possibility of approved uses which are not sufficiently covered by EU MRLs cannot be excluded at the moment.

### 1.3. Disodium phosphonate

Disodium phosphonate is an active substance that was assessed in the framework of Directive 91/414/EEC with France being the designated rapporteur Member State. The structural formula is depicted below.

<sup>9</sup> 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, 23/04/2013, p. 39–42 .



Molecular weight for disodium phosphonate is 125.96.

Following the peer review, which was carried out by EFSA (EFSA, 2013), a decision on the approval of the active substance was published by means of Commission Regulation (EU) No 832/2013<sup>10</sup>, entering into force on 1 February 2014.

No specific MRLs are established for disodium phosphonate; instead the default MRL of 0.01 mg/kg according to Article 18(1)(b) of Regulation (EC) No 396/2005 is applicable.

The MRL review under Article 12 of Regulation (EC) No 396/2005 has not yet been performed. Thus, considering disodium phosphonate as possible source of the contamination, the same conclusion as for potassium phosphonates is derived.

#### 1.4. Fertilisers containing phosphonic acid

It was claimed that residues of phosphonic acid in the crops concerned may result from the use of phosphorous fertilisers and some organic products used for foliar fertilisation. This possible source of residues of phosphonic acid was discussed during the peer review of potassium phosphonates. The experts were of the opinion that for fertilising purposes, only phosphorous (V) and not phosphorous (III) is relevant. Thus, phosphonic acid was not expected to result from fertilisers/products that were applied as plant nutrient (EFSA, 2012a).

From the available information it is concluded that the residues found in the crops under considerations are not originating from approved uses of fosetyl; since currently no comprehensive overview is available on the approved uses of disodium phosphonate and potassium phosphonates in the EU and in third countries the use of these pesticide products might be a possible explanation. The use of fertilisers containing phosphonic acid is rather questionable, since phosphorous (III) is according to experts' opinion not a plant nutrient. It is most likely that the residues that were reported by food business operators do not refer to fosetyl, but consist of phosphonic acid. No information is available whether the samples contain additional, non-identified compounds/contaminants which could give an indication of the source of the residues or which might give raise to consumer health concerns. Further investigations on the source of the contamination would therefore be strongly recommended.

## 2. Nature of residues in food resulting from the use of pesticides (fosetyl, disodium phosphonate, potassium phosphonates)

Metabolism studies which were performed with fosetyl-Al in primary crops (foliar application on fruits and fruiting vegetables: oranges, tangerines, apples, pineapples and tomatoes) were assessed in the framework of the peer review and the MRL review (EFSA, 2005, 2012b). The studies demonstrate that the major plant metabolites are phosphonic acid and ethanol. Ethanol, when not lost by volatilisation, is further incorporated into natural products such as D-glucose, starch, lignin, cellulose or fatty acids. Phosphonic acid is considered to be toxicologically relevant and its concentration is generally higher than that of parent fosetyl (EFSA, 2012b).

<sup>10</sup> Commission Implementing Regulation (EU) No 832/2013 of 30 August 2013 approving the active substance disodium phosphonate, 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 Implementing Regulation (EU) No 540/2011. OJ L 233, 31/08/2013, p. 3–6.

To address the metabolism of disodium phosphonate and potassium phosphonates, scientific publications on the uptake, translocation and distribution of phosphonates and phosphonic acid in plants were submitted in the framework of the peer review. EFSA concluded that, upon application to leaves or the root system, phosphonates are rapidly absorbed, vertically translocated into different plant parts and accumulated in sink organs like fruits or roots. Further, the studies suggest that phosphonates are not readily oxidised to phosphate in plants. Having regard to the peer review of potassium phosphonates and disodium phosphonate, it has been concluded that, given the elementary nature of phosphonate salts, only transformation into phosphonic acid is expected in plants (EFSA, 2012a, 2013).

The proposed residue definition for monitoring and risk assessment for disodium phosphonate and potassium phosphonates in plant commodities was phosphonic acid and its salts, expressed as phosphonic acid.

The current residue definition established in Regulation (EC) No 396/2005 reflects the recommendation of the peer review derived of fosetyl<sup>11</sup> proposing the residue definitions for risk assessment and enforcement purpose “Fosetyl-Al: sum of fosetyl, phosphorous acid<sup>12</sup> and their salts, expressed as fosetyl”. For risk assessment purposes EFSA proposes to use on a provisional basis the same residue definition. The contribution of fosetyl to the total residues is expected to be low, taking into account the results of the metabolism studies.

In the framework of the Article 12 MRL review, it was agreed that the residue definition for both risk assessment and monitoring should be set as phosphonic acid only and that risk managers should consider if a separate residue definition for fosetyl should be established to enforce residues that are specific to the use of fosetyl-Al (EFSA, 2012b).

### 3. Mammalian toxicology

The toxicological properties of fosetyl-Al and its metabolite phosphonic acid were peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA (EFSA, 2005). Both compounds have the same mechanism of toxicity. These toxicological reference values and a calculated value derived for fosetyl are summarized in Table 2-1.

In the framework of the peer review of potassium phosphonates and disodium phosphonate, the ADI value derived for phosphonic acid and the conclusion regarding the ARfD were confirmed (EFSA, 2012a, 2013).

**Table 3-1: Overview of the toxicological reference values derived in the peer review**

	Source	Year	Value	Study relied upon	Safety factor
<b>Fosetyl-Al</b>					
ADI	EFSA	2005	3 mg/kg bw per d	2 year rat and dog	100
ARfD	EFSA	2005	Not necessary.		
<b>Fosetyl</b>					
ADI	-	-	2.8 mg/kg bw per d	Calculated, from the fosetyl-Al ADI using an appropriate molecular weight conversion	-
ARfD	-	-	Not necessary.		

<sup>11</sup> It is noted that the residue definition was revised when the corrigendum to the EFSA conclusion on fosetyl was issued in June 2013. However, the current residue definition in Regulation (EC) No 396/2005 reflects the originally proposed residue definition derived in the peer review.

<sup>12</sup> IUPAC name: phosphonic acid.

	Source	Year	Value	Study relied upon	Safety factor
<b>Phosphonic acid</b>					
ADI	EFSA	2005, 2012, 2013	2.25 mg/kg bw per d <sup>(a)</sup>	117 week rat	100
ARfD	EFSA	2005, 2012, 2013	Not necessary.		

(a) In June 2013, a corrigendum to the EFSA conclusion on fosetyl was published. The ADI for phosphonic acid has been amended to include a correction for the water content of the material tested in the 117-week rat study, and to account for the different molecular weights of the tested material and phosphonic acid.

Assuming that the residues present in food occur mainly as phosphonic acid, EFSA is of the opinion that the ADI value derived for phosphonic acid would be the most appropriate toxicological reference value for dietary risk assessment. However, since according to the current residues definition in Regulation (EC) No 396/2005 the residues are expressed as fosetyl, the ADI derived for phosphonic acid needs to be corrected, applying the molecular weight correction factor<sup>13</sup>. Thus, the recalculated ADI of phosphonic acid, expressed as fosetyl is 2.52 mg/kg bw per day<sup>14</sup>.

#### 4. Dietary risk assessment

EFSA calculated the Theoretical Maximum Daily Intake (TMDI) in accordance with the methodology derived by JMPR (FAO, 2009), using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population<sup>15</sup> (EFSA, 2007). The residue definition for risk assessment is assumed to be identical with the current residue definition for enforcement. The residue concentrations used for the calculation of the dietary intake correspond to the temporary MRLs and the existing EU MRLs, except for kiwi and spices where the recently voted MRLs were used for the exposure calculation. The input values are summarised in the table below (Table 4-1). It is noted that none of the proposed temporary MRLs refers to commodities that are used as animal feed. Thus, the proposed temporary MRLs do not impact the currently established MRLs for food of animal origin. Further refinements of the intake calculations were not performed at this stage.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with an active substance that leads to residues of fosetyl or phosphonic acid. If this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure, a consumer health risk can be excluded with a high probability.

An acute consumer exposure was not performed due to the low acute toxicity of fosetyl and its metabolite phosphonic acid.

**Table 4-1:** Input values for the consumer dietary exposure assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
<b>Residue definition for risk assessment:</b> Fosetyl-AI (sum of fosetyl and phosphorous acid and their salts, expressed as fosetyl)		

<sup>13</sup> Molecular Weight correction factor =  $MW_{\text{fosetyl}}/MW_{\text{phosphonic acid}}$  ( $110/98 = 1.12$ )

<sup>14</sup>  $ADI_{\text{phosphonic acid}} * MW_{\text{correction factor}}$  ( $2.25 * 1.12$ ) = 2.52 mg/kg bw per day

<sup>15</sup> The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Almonds	75	proposed temporary MRL
Cashews	75	proposed temporary MRL
Hazelnuts (Filbert)	75	proposed temporary MRL
Macadamia	75	proposed temporary MRL
Pistachios	75	proposed temporary MRL
Walnuts	75	proposed temporary MRL
Stone fruit (group)	75	proposed temporary MRL
Cane fruit (subgroup)	75	proposed temporary MRL
Blueberries	75	proposed temporary MRL
Currants (red, black and white)	75	proposed temporary MRL
Gooseberries	75	proposed temporary MRL
Figs	75	proposed temporary MRL
Kumquats	75	proposed temporary MRL
Persimmon	75	proposed temporary MRL
Passion fruit	75	proposed temporary MRL
Papaya	75	proposed temporary MRL
Pomegranate	75	proposed temporary MRL
Garlic	50	proposed temporary MRL
Beans (with pods)	75	proposed temporary MRL
Beans (without pods)	75	proposed temporary MRL
Peas (with pods)	75	proposed temporary MRL
Peas (without pods)	75	proposed temporary MRL
Asparagus	50	proposed temporary MRL
Kiwi	150	MRL voted in SCFCAH on 25 February 2014 (SANCO/10057/2014 rev. 2)
Spices	400	MRL voted in SCFCAH on 25 February 2014 (SANCO/10057/2014 rev. 2)
Other food of plant or animal origin	existing MRLs	See Appendix B

The estimated exposure was then compared with the ADI value derived for fosetyl (2.52 mg/kg bw per day, see Section 3). The results of the intake calculation are presented in Appendix A to this reasoned opinion.

The total calculated long-term intake accounted for up to 81 % of the ADI (German diet for children). Among the crops for which temporary MRLs were proposed, the main contributors were beans with pods (max. 3.3 % of the ADI), peas with pods and peaches (max. 1.7 % of the ADI respectively) and apricots and cherries (1.1 % of the ADI, respectively).

## CONCLUSIONS AND RECOMMENDATIONS

Based on the results of the dietary risk assessment, which focussed on the occurrence of fosetyl and phosphonic acid only, EFSA concludes that the temporary MRLs proposed for the crops listed in the table below are not likely to pose a public health concern.

### Summary table

Code number <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
<b>Current enforcement residue definition established in Regulation (EC) No 396/2005: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)</b>				
0120010	Almonds	2*	75	The proposed temporary MRLs are not expected to pose a consumer health risk. It is noted that the risk assessment focussed only on the current residue definition.
0120030	Cashews	2*	75	
0120060	Hazelnuts (Filbert)	2*	75	
0120070	Macadamia	2*	75	
0120100	Pistachios	2*	75	
0120110	Walnuts	2*	75	
0140000	Stone fruit (group)	2*	75	
0153000	Cane fruit (subgroup)	2*	75	
0154010	Blueberries	2*	75	
0154030	Currants (red, black and white)	2*	75	
0154040	Gooseberries	2*	75	
0161020	Figs	2*	75	
0161040	Kumquats	2*	75	
0161060	Persimmon	2*	75	
0162030	Passion fruit	2*	75	
0163040	Papaya	2*	75	
0163050	Pomegranate	2*	75	
0220010	Garlic	2*	50	
0260010	Beans (with pods)	2*	75	
0260020	Beans (without pods)	2*	75	
0260030	Peas (with pods)	2*	75	
0260040	Peas (without pods)	2*	75	
0270010	Asparagus	2*	50	

EFSA would also recommend changing the wording of the residue definition to reflect the correct IUPAC nomenclature. This modification has no impact on the existing residue levels.

Since the source of these residues is not unambiguously identified, other possible contaminations linked to the occurrence of fosetyl/phosphonic acid in the crops under consideration cannot be excluded. Further investigations should be performed to elucidate the source of residues, to identify if other compounds are linked to the presence of phosphonic acid/fosetyl in the crops under assessment and to exclude illegal uses of fosetyl, potassium phosphonates or disodium phosphonate on crops for which no authorisations are granted. For chemical analysis aiming at identifying the source of the contamination analytical methods should be used that are able to differentiate between phosphonic

acid and fosetyl, and possible also cover aluminium ion, to exclude the possibility of illegal uses of fosetyl.

Once the source of the unexpected residues in the crops mentioned in the summary table is identified, further risk management measures need to be considered.

It is noted that the temporary MRLs need to be reconsidered if in the future the residue definition will be amended as proposed by EFSA in the framework of the MRL review (EFSA, 2012b).

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- EFSA (European Food Safety Authority), 2012c. Reasoned opinion on the modification of the existing MRLs for fosetyl in potato, kiwi and certain spices. *EFSA Journal* 2012;10(12):3019, 43 pp. doi:10.2903/j.efsa.2012.3019
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APPENDICES

APPENDIX A: DIETARY RISK ASSESSMENT (RESULTS OF EFSA PRIMO REV. 2)

Fosetyl										
Status of the active substance:			Code no.:							
LOQ (mg/kg bw):			proposed LOQ:							
Toxicological end points										
ADI (mg/kg bw/day):			2.52			ARfD (mg/kg bw):			n.n.	
Source of ADI:			EFSA			Source of ARfD:			EFSA	
Year of evaluation:			2012, 2013			Year of evaluation:			2012, 2013	
<p>The ADI for fosetyl was calculated from the ADI for phosphonic acid (2.25 mg/kg bw per day), multiplied with the molecular weight correction factor (MW fosetyl: 110, MW phosphonic acid: 98; CF = 1.12).            The toxicological assessment of phosphonic acid can be found in the EFSA conclusions on disodium phosphonate and potassium phosphonates (EFSA, 2012, 2013).</p>										
Chronic risk assessment										
TMDI (range) in % of ADI										
minimum - maximum										
12 81										
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	pTMRs at LOQ (in % of ADI)		
80.6	DE child	35.9	Apples	11.3	Oranges	5.0	Table grapes			
59.5	NL child	18.8	Apples	9.3	Oranges	7.0	Potatoes			
54.0	WHO Cluster diet B	12.2	Tomatoes	7.1	Wine grapes	3.2	Potatoes			
42.6	IE adult	5.0	Wine grapes	3.1	Oranges	2.7	Potatoes			
38.8	FR toddler	7.8	Apples	6.0	Potatoes	6.0	Oranges			
33.3	PT General population	9.9	Wine grapes	6.3	Potatoes	3.6	Tomatoes			
30.2	WHO cluster diet E	6.4	Wine grapes	4.6	Potatoes	2.5	Apples			
29.3	FR all population	15.9	Wine grapes	1.7	Tomatoes	1.4	Apples			
28.1	FR infant	7.4	Apples	4.9	Potatoes	2.7	Oranges			
27.5	UK Toddler	5.9	Oranges	5.1	Apples	4.2	Potatoes			
26.7	WHO regional European diet	4.8	Potatoes	4.4	Tomatoes	2.0	Apples			
26.4	DK child	6.9	Apples	4.9	Cucumbers	2.9	Potatoes			
26.3	SE general population 90th percentile	5.0	Potatoes	3.1	Apples	3.0	Tomatoes			
25.5	ES child	6.5	Oranges	3.9	Tomatoes	3.4	Apples			
25.1	NL general	4.4	Oranges	3.5	Apples	3.3	Potatoes			
24.5	WHO cluster diet D	4.8	Potatoes	4.0	Tomatoes	2.0	Apples			
21.7	ES adult	3.8	Oranges	3.1	Tomatoes	2.3	Apples			
21.5	WHO Cluster diet F	4.1	Potatoes	2.7	Tomatoes	2.6	Oranges			
21.4	UK Infant	4.7	Apples	3.9	Potatoes	3.9	Oranges			
20.8	IT Kids/toddler	5.7	Tomatoes	2.6	Apples	1.4	Oranges			
19.6	PL general population	6.1	Apples	4.1	Potatoes	3.5	Tomatoes			
18.9	IT adult	4.6	Tomatoes	2.4	Apples	1.1	Lettuce			
17.7	UK vegetarian	3.2	Wine grapes	2.6	Oranges	2.5	Tomatoes			
16.6	DK adult	5.5	Wine grapes	2.3	Apples	1.7	Potatoes			
15.3	LT adult	5.6	Apples	3.8	Potatoes	2.5	Tomatoes			
15.1	UK Adult	4.3	Wine grapes	1.7	Tomatoes	1.7	Oranges			
12.0	FI adult	2.9	Oranges	1.7	Tomatoes	1.5	Potatoes			
<p><b>Conclusion:</b>            The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.            A long-term intake of residues of Fosetyl is unlikely to present a public health concern.</p>										

**APPENDIX B: EXISTING EU MRLs ESTABLISHED IN REGULATION (EC) No 396/2005 AND PROPOSED MRLs DERIVED IN THE MRL REVIEW**

Code number	Groups and examples of individual products to which the MRLs apply	Existing MRLs	MRLs proposed in MRL review (Art. 12 of Reg. 396/2005)	
		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
100000	1. FRUIT FRESH OR FROZEN; NUTS			
110000	(j) Citrus fruit	75		
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	75	20	2
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	75	20	2
110030	Lemons ( Citron, lemon )	75	50	4
110040	Limes	75	50	4
110050	Mandarins (Clementine, tangerine and other hybrids)	75	50	4
110990	Others	75		
120000	(ii) Tree nuts (shelled or unshelled)	2*		
120010	Almonds	2*		
120020	Brazil nuts	2*		
120030	Cashew nuts	2*		
120040	Chestnuts	2*		
120050	Coconuts	2*		
120060	Hazelnuts (Filbert)	2*		
120070	Macadamia	2*		
120080	Pecans	2*		
120090	Pine nuts	2*		
120100	Pistachios	2*		
120110	Walnuts	2*		
120990	Others	2*		
130000	(iii) Pome fruit	75	40	0.6
130010	Apples (Crab apple)	75		
130020	Pears (Oriental pear)	75		
130030	Quinces	75		
130040	Medlar	75		
130050	Loquat	75		
130990	Others	75		
140000	(iv) Stone fruit	2*		

Code number	Groups and examples of individual products to which the MRLs apply	Existing MRLs	MRLs proposed in MRL review (Art. 12 of Reg. 396/2005)	
		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
140010	Apricots	2*		
140020	Cherries (sweet cherries, sour cherries)	2*		
140030	Peaches (Nectarines and similar hybrids)	2*		
140040	Plums (Damson, greengage, mirabelle)	2*		
140990	Others	2*		
150000	(v) Berries & small fruit			
151000	(a) Table and wine grapes	100	70	2
151010	Table grapes	100		
151020	Wine grapes	100		
152000	(b) Strawberries	75	60	3
153000	(c) Cane fruit	2*		
153010	Blackberries	2*		
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	2*		
153030	Raspberries (Wineberries )	2*	2	0.2
153990	Others	2*		
154000	(d) Other small fruit & berries	2*		
154010	Blueberries (Bilberries cowberries (red bilberries))	2*		
154020	Cranberries	2*		
154030	Currants (red, black and white)	2*		
154040	Gooseberries (Including hybrids with other ribes species)	2*		
154050	Rose hips	2*		
154060	Mulberries (arbutus berry)	2*		
154070	Azarole (mediteranean medlar)	2*		

Code number	Groups and examples of individual products to which the MRLs apply	Existing MRLs	MRLs proposed in MRL review (Art. 12 of Reg. 396/2005)	
		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries)	2*		
154990	Others	2*		
160000	(vi) Miscellaneous fruit			
161000	(a) Edible peel	2*		
161010	Dates	2*		
161020	Figs	2*		
161030	Table olives	2*		
161040	Kumquats (Marumi kumquats, nagami kumquats)	2*		
161050	Carabobola (Bilimbi)	2*		
161060	Persimmon	2*		
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	2*		
161990	Others	2*		
162000	(b) Inedible peel, small	2*		
162010	Kiwi	2*/300 (a)		
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	2*		
162030	Passion fruit	2*		
162040	Prickly pear (cactus fruit)	2*		
162050	Star apple	2*		
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and	2*		

Code number	Groups and examples of individual products to which the MRLs apply	Existing MRLs	MRLs proposed in MRL review (Art. 12 of Reg. 396/2005)	
		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
	mamme sapote)			
162990	Others	2*		
163000	(c) Inedible peel, large			
163010	Avocados	50	40	1.5
163020	Bananas (Dwarf banana, plantain, apple banana)	2*		
163030	Mangoes	2*		
163040	Papaya	2*		
163050	Pomegranate	2*		
163060	Chirimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	2*		
163070	Guava	2*		
163080	Pineapples	50	15	0.05
163090	Bread fruit (Jackfruit)	2*		
163100	Durian	2*		
163110	Soursop (guanabana)	2*		
163990	Others	2*		
200000	2. VEGETABLES FRESH OR FROZEN			
210000	(i) Root and tuber vegetables			
211000	(a) Potatoes	30	20	0.4
212000	(b) Tropical root and tuber vegetables	2*		
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	2*		
212020	Sweet potatoes	2*		
212030	Yams (Potato bean (yam bean), Mexican yam bean)	2*		
212040	Arrowroot	2*		
212990	Others	2*		
213000	(c) Other root and tuber vegetables except sugar beet			
213010	Beetroot	2*		
213020	Carrots	2*		
213030	Celeriac	2*		
213040	Horseradish	2*		

Code number	Groups and examples of individual products to which the MRLs apply	Existing MRLs	MRLs proposed in MRL review (Art. 12 of Reg. 396/2005)	
		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
213050	Jerusalem artichokes	2*		
213060	Parsnips	2*		
213070	Parsley root	2*		
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	25	20	0.2
213090	Salsify (Scorzoner, Spanish salsify (Spanish oysterplant))	2*		
213100	Swedes	2*		
213110	Turnips	2*		
213990	Others	2*		
220000	(ii) Bulb vegetables			
220010	Garlic	2*		
220020	Onions (Silverskin onions)	50	30	0.5
220030	Shallots	2*		
220040	Spring onions (Welsh onion and similar varieties)	30		
220990	Others	2*		
230000	(iii) Fruiting vegetables			
231000	(a) Solanacea			
231010	Tomatoes (Cherry tomatoes, )	100	60	4
231020	Peppers (Chilli peppers)	130	90	0.5
231030	Aubergines (egg plants) (Pepino)	100	60	4
231040	Okra, lady's fingers	2*		
231990	Others	2*		
232000	(b) Cucurbits - edible peel	75	70	4
232010	Cucumbers	75		
232020	Gherkins	75		
232030	Courgettes (Summer squash, marrow (patisson))	75		
232990	Others	75		
233000	(c) Cucurbits-inedible peel	75	50	5
233010	Melons (Kiwano )	75		
233020	Pumpkins (Winter	75		

Code number	Groups and examples of individual products to which the MRLs apply	Existing MRLs	MRLs proposed in MRL review (Art. 12 of Reg. 396/2005)	
		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
	squash)			
233030	Watermelons	75		
233990	Others	75		
234000	(d) Sweet corn	5		
239000	(e) Other fruiting vegetables	5		
240000	(iv) Brassica vegetables	10		
241000	(a) Flowering brassica	10	1.5	0.4
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	10		
241020	Cauliflower	10		
241990	Others	10		
242000	(b) Head brassica	10	1.5	0.4
242010	Brussels sprouts	10		
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	10		
242990	Others	10		
243000	(c) Leafy brassica	10		
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	10	0.2	0.01*
243020	Kale (Borecole (curly kale), collards)	10	6	5
243990	Others	10		
244000	(d) Kohlrabi	10	4	0.01*
250000	(v) Leaf vegetables & fresh herbs			
251000	(a) Lettuce and other salad plants including Brassicacea	75	150	1
251010	Lamb's lettuce (Italian cornsalad)	75		
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	75		
251030	Scarole (broad-leaf	75		

Code number	Groups and examples of individual products to which the MRLs apply	Existing MRLs	MRLs proposed in MRL review (Art. 12 of Reg. 396/2005)	
		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
	endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)			
251040	Cress	75		
251050	Land cress	75		
251060	Rocket, Rucola (Wild rocket)	75		
251070	Red mustard	75		
251080	Leaves and sprouts of Brassica spp (Mizuna)	75		
251990	Others	75		
252000	(b) Spinach & similar (leaves)			
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	75	30	0.2
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	2*		
252030	Beet leaves (chard) (Leaves of beetroot)	15	15	0.2
252990	Others	2*		
253000	(c) Vine leaves (grape leaves)	2*		
254000	(d) Water cress	2*		
255000	(e) Witloof	75	90	1.5
256000	(f) Herbs	75	30	0.2
256010	Chervil	75		
256020	Chives	75		
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	75		
256040	Parsley	75		
256050	Sage (Winter savory, summer savory, )	75		
256060	Rosemary	75		
256070	Thyme ( marjoram,	75		

Code number	Groups and examples of individual products to which the MRLs apply	Existing MRLs	MRLs proposed in MRL review (Art. 12 of Reg. 396/2005)	
		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
	oregano)			
256080	Basil (Balm leaves, mint, peppermint)	75		
256090	Bay leaves (laurel)	75		
256100	Tamagon (Hyssop)	75		
256990	Others	75		
260000	(vi) Legume vegetables (fresh)	2*		
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	2*		
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	2*		
260030	Peas (with pods) (Mangetout (sugar peas))	2*		
260040	Peas (without pods) (Garden pea, green pea, chickpea)	2*		
260050	Lentils	2*		
260990	Others	2*		
270000	(vii) Stem vegetables (fresh)			
270010	Asparagus	2*		
270020	Cardoons	2*		
270030	Celery	2*		
270040	Fennel	2*		
270050	Globe artichokes	50	100	0.5
270060	Leek	30	30	3
270070	Rhubarb	2*		
270080	Bamboo shoots	2*		
270090	Palm hearts	2*		
270990	Others	2*		
280000	(viii) Fungi	2*		
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	2*		
280020	Wild (Chanterelle, Truffle, Morel, )	2*		
280990	Others	2*		

Code number	Groups and examples of individual products to which the MRLs apply	Existing MRLs	MRLs proposed in MRL review (Art. 12 of Reg. 396/2005)	
		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
290000	(ix) Sea weeds	2*		
300000	3. PULSES, DRY	2*		
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	2*		
300020	Lentils	2*		
300030	Peas (Chickpeas, field peas, chickling vetch)	2*	2	0.2
300040	Lupins	2*		
300990	Others	2*		
400000	4. OILSEEDS AND OILFRUITS	2*		
401000	(j) Oilseeds	2*		
401010	Linseed	2*		
401020	Peanuts	2*		
401030	Poppy seed	2*		
401040	Sesame seed	2*		
401050	Sunflower seed	2*		
401060	Rape seed (Bird rapeseed, turnip rape)	2*		
401070	Soya bean	2*		
401080	Mustard seed	2*		
401090	Cotton seed	2*		
401100	Pumpkin seeds	2*		
401110	Safflower	2*		
401120	Borage	2*		
401130	Gold of pleasure	2*		
401140	Hempseed	2*		
401150	Castor bean	2*		
401990	Others	2*		
402000	(ii) Oilfruits	2*		
402010	Olives for oil production	2*		
402020	Palm nuts (palmoil kernels)	2*		
402030	Palmfruit	2*		
402040	Kapok	2*		
402990	Others	2*		
500000	5. CEREALS	2*		
500010	Barley	2*		
500020	Buckwheat	2*		
500030	Maize	2*		
500040	Millet (Foxtail millet,	2*		

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		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
	teff)			
500050	Oats	2*		
500060	Rice	2*		
500070	Rye	2*		
500080	Sorghum	2*		
500090	Wheat (Spelt Triticale)	2*		
500990	Others	2*		
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA			
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i> )	5*		
620000	(ii) Coffee beans	5*		
630000	(iii) Herbal infusions (dried)	500	500	50
631000	(a) Flowers	500		
631010	Camomile flowers	500		
631020	Hybiscus flowers	500		
631030	Rose petals	500		
631040	Jasmine flowers	500		
631050	Lime (linden)	500		
631990	Others	500		
632000	(b) Leaves	500		
632010	Strawberry leaves	500		
632020	Rooibos leaves	500		
632030	Maté	500		
632990	Others	500		
633000	(c) Roots	500		
633010	Valerian root	500		
633020	Ginseng root	500		
633990	Others	500		
639000	(d) Other herbal infusions	500		
640000	(iv) Cocoa (fermented beans)	2*		
650000	(v) Carob (st.johns bread)	2*		
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	1500	800	30

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		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
800000	8. SPICES	5*/400 (a)		
810000	(i) Seeds	5*/400 (a)		
810010	Anise	5*/400 (a)		
810020	Black caraway	5*/400 (a)		
810030	Celery seed (Lovage seed)	5*/400 (a)		
810040	Coriander seed	5*/400 (a)		
810050	Cumin seed	5*/400 (a)		
810060	Dill seed	5*/400 (a)		
810070	Fennel seed	5*/400 (a)		
810080	Fenugreek	5*/400 (a)		
810090	Nutmeg	5*/400 (a)		
810990	Others	5*/400 (a)		
820000	(ii) Fruits and berries	5*/400 (a)		
820010	Allspice	5*/400 (a)		
820020	Anise pepper (Japan pepper)	5*/400 (a)		
820030	Caraway	5*/400 (a)		
820040	Cardamom	5*/400 (a)		
820050	Juniper berries	5*/400 (a)		
820060	Pepper, black and white (Long pepper, pink pepper)	5*/400 (a)		
820070	Vanilla pods	5*/400 (a)		
820080	Tamarind	5*/400 (a)		
820990	Others	5*/400 (a)		
830000	(iii) Bark	5*/400 (a)		
830010	Cinnamon (Cassia)	5*/400 (a)		
830990	Others	5*/400 (a)		
840000	(iv) Roots or rhizome	5*/400 (a)		
840010	Liquorice	5*/400 (a)		
840020	Ginger	5*/400 (a)		
840030	Turmeric (Curcuma)	5*/400 (a)		
840040	Horseradish (b)			
840990	Others	5*/400 (a)		
850000	(v) Buds	5*/400 (a)		
850010	Cloves	5*/400 (a)		
850020	Capers	5*/400 (a)		
850990	Others	5*/400 (a)		
860000	(vi) Flower stigma	5*/400 (a)		
860010	Saffron	5*/400 (a)		
860990	Others	5*/400 (a)		
870000	(vii) Aril	5*/400 (a)		
870010	Mace	5*/400 (a)		

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		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
870990	Others	5*/400 (a)		
900000	9. SUGAR PLANTS			
900010	Sugar beet (root)	2*		
900020	Sugar cane	2*		
900030	Chicory roots	75	60	1.5
900990	Others	2*		
100000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS			
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,5*		
1011000	(a) Swine	0,5*		
1011010	Meat	0,5*	0,5*	-
1011020	Fat free of lean meat	0,5*	0,5*	-
1011030	Liver	0,5*	0,5*	-
1011040	Kidney	0,5*	0,6	-
1011050	Edible offal	0,5*		
1011990	Others	0,5*		
1012000	(b) Bovine	0,5*		
1012010	Meat	0,5*	0,5*	-
1012020	Fat	0,5*	0,5*	-
1012030	Liver	0,5*	0,5*	-
1012040	Kidney	0,5*	0,7	-
1012050	Edible offal	0,5*		
1012990	Others	0,5*		
1013000	(c) Sheep	0,5*		
1013010	Meat	0,5*	0,5*	-
1013020	Fat	0,5*	0,5*	-
1013030	Liver	0,5*	0,5*	-
1013040	Kidney	0,5*	0,7	-
1013050	Edible offal	0,5*		
1013990	Others	0,5*		
1014000	(d) Goat	0,5*		
1014010	Meat	0,5*	0,5*	-

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		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
1014020	Fat	0,5*	0,5*	-
1014030	Liver	0,5*	0,5*	-
1014040	Kidney	0,5*	0,7	-
1014050	Edible offal	0,5*		
1014990	Others	0,5*		
1015000	(e) Horses, asses, mules or hinnies	0,5*		
1015010	Meat	0,5*		
1015020	Fat	0,5*		
1015030	Liver	0,5*		
1015040	Kidney	0,5*		
1015050	Edible offal	0,5*		
1015990	Others	0,5*		
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,5*		
1016010	Meat	0,5*	0,5*	-
1016020	Fat	0,5*	0,5*	-
1016030	Liver	0,5*	0,5*	-
1016040	Kidney	0,5*		
1016050	Edible offal	0,5*		
1016990	Others	0,5*		

Code number	Groups and examples of individual products to which the MRLs apply	Existing MRLs	MRLs proposed in MRL review (Art. 12 of Reg. 396/2005)	
		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,5*		
1017010	Meat	0,5*		
1017020	Fat	0,5*		
1017030	Liver	0,5*		
1017040	Kidney	0,5*		
1017050	Edible offal	0,5*		
1017990	Others	0,5*		
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,1*		
1020010	Cattle	0,1*	0,1*	-
1020020	Sheep	0,1*	0,1*	-
1020030	Goat	0,1*	0,1*	-
1020040	Horse	0,1*		
1020990	Others	0,1*		
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried,	0,1*	0,5*	-

Code number	Groups and examples of individual products to which the MRLs apply	Existing MRLs	MRLs proposed in MRL review (Art. 12 of Reg. 396/2005)	
		Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Phosphonic acid	Fosetyl (c)
	cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter			
1030010	Chicken	0,1*		
1030020	Duck	0,1*		
1030030	Goose	0,1*		
1030040	Quail	0,1*		
1030990	Others	0,1*		
1040000	(iv) Honey (Royal jelly, pollen)	0,5*		
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,5*		
1060000	(vi) Snails	0,5*		
1070000	(vii) Other terrestrial animal products	0,5*		

- (\*) Indicates lower limit of analytical determination
- (a) MRL voted in SCFCAH on 25 February 2014, but not yet adopted.
- (b) 0840040 Horseradish: The applicable maximum residue level for horseradish (*Armoracia rusticana*) in the spice group is the one set for horseradish (*Armoracia rusticana*) in the Vegetables category, root and tuber vegetables group (code 0213040) taking into account changes in the levels by processing (drying) according to Art. 20 (1) of Regulation (EC) No 396/2005.
- (c) Optional residue definition proposed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005.

## ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
EFSA	European Food Safety Authority
EU	European Union
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MW	molecular weight
PRIMo	(EFSA) Pesticide Residues Intake Model
RD	residue definition
TMDI	theoretical maximum daily intake