

REASONED OPINION

Modification of the existing MRL for fosetyl-Al in radishes¹

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SUMMARY

According to Article 6(2) of the Regulation (EC) No 396/2005, the Netherlands have received an application from Bayer CropScience BV to modify the existing MRL for fosetyl-Al in radishes. In order to accommodate the intended pesticide use in the Netherlands, the applicant proposed to raise the existing MRL of 2 mg/kg (equivalent to the limit of quantification) to 20 mg/kg. The Netherlands as the Evaluating Member State (EMS) have drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 29 March 2009.

Taking into account the evaluation presented by the EMS, the Draft Assessment Report prepared by France and the EFSA conclusion prepared in the framework of the peer review under Directive 91/414/EEC the following conclusions are reached.

The toxicological profile of fosetyl-Al was assessed in the framework of the peer review under Directive 91/414/EEC. The data were sufficient to conclude on an ADI of 3 mg/kg bw/day. Because of the low acute toxicity of the active substance and the major metabolite, no ARfD values were established.

The metabolism of fosetyl-Al was elucidated in fruit and fruiting vegetables. The only toxicologically relevant compound identified in significant concentrations was phosphorous acid. Given the elementary nature of fosetyl-Al and the similar results obtained on fruits and leaves, the metabolic pattern is expected to be similar in all crops. Thus, a general residue definition was established as fosetyl-Al (sum of fosetyl, phosphorous acid and their salts, expressed as fosetyl) for both risk assessment and enforcement purpose. An analytical method based on GC/FPD is available to control compliance with MRLs established for this residue definition.

The submitted residue trials were sufficient to derive an MRL proposal of 25 mg/kg.

The possible presence of fosetyl-Al related residues in succeeding crops was addressed in the peer review. Taking into account the intended application rate for radishes, no significant residues of fosetyl or phosphorous acid are expected in succeeding crops.

1 On request from the European Commission, Question No EFSA-Q-2009-00639, issued on 14 September 2009.

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The consumer risk assessment based on the existing MRLs and the STMR derived for the intended use in radishes was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). The total calculated dietary intake ranged from 10 to 63% of the ADI for the different diets included in the model. Thus, it is concluded that no long-term consumer health risk is associated with the intended use of fosetyl-Al in radishes. No acute risk assessment was necessary because the toxicological profile of the active substance did not require the setting of an acute reference dose.

In conclusion, EFSA recommends amending the temporary MRLs for fosetyl-Al in radishes as summarised in the table below:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Radishes	2(*)	25	The MRL proposal is sufficiently supported by data and no consumer health risk was identified regarding the expected residues on radishes.

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

It is also noted that phosphorous acid in plants does not only result from the use of fosetyl-Al, but also other pesticides like potassium phosphonate, foliar P fertilizers and some organic products used for foliar fertilization can be a source of phosphorous acid which could mimic a treatment with fosetyl-Al. Therefore, in the framework of the MRL review under Article 12(2) of Regulation EC (No) 396/2005 the current residue definition and the MRLs established of should be reconsidered, taking into account other sources of phosphorous acid.

KEY WORDS

Fosetyl, radishes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, organophosphorous fungicide, phosphorous acid

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

The Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from the company Bayer CropScience BV³ to modify the existing MRL for the active substance fosetyl-Al in radishes. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 May 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00639 and the following subject:

Fosetyl - Application to modify the existing MRL for fosetyl-al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl) in radishes from 2 mg/kg to 20 mg/kg*

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

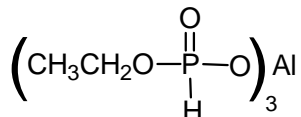
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 29 August 2009.

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THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Fosetyl is the ISO common name for ethyl hydrogen phosphonate (IUPAC). In 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 and fosetyl aluminium, respectively belong to the class of organophosphorous fungicides. The mode of action is explained by inhibiting the germination of spores or by blocking development of mycelium and sporulation. Fosetyl has systemic properties and is rapidly absorbed through the plant leaves or roots with translocation both acropetally and basipetally. Fosetyl is used on a variety of crops to control, among others, diseases caused by *Phytophthora*, *Pythium*, *Plasmopara*, *Bremia* spp.

Fosetyl-Al was evaluated in the framework of Directive 91/414/EEC with France being the designated Rapporteur Member State (RMS). The representative uses supported in the peer review comprised foliar spraying in citrus, cucumber and grapes at application rates between 2 kg (grapes) up to 7 kg (citrus). On the basis of the EFSA conclusion (EFSA, 2005), the active substance was included in Annex I of Directive 91/414/EEC by Directive 2006/64/EC which entered into force on 1 May 2007.

Before September 2008, MRLs for fosetyl-Al were established at national level only. These values were included in Annex III of Regulation (EC) No 396/2005 as temporary MRLs after the consumer risk assessment performed by EFSA (EFSA, 2007) demonstrated that the national MRLs do not pose an unacceptable consumer health risk. The currently valid MRLs are summarised in Appendix C. Since fosetyl-Al has not been evaluated by the JMPR, no CXLs have been established.

The Netherlands have received an application for a new use of fosetyl-Al in radishes grown in glasshouses. The product should be used against *Peronospora* by foliar application with an application rate of 0.775 kg/ha 14 days before harvest. In Appendix A the intended GAP is presented in the standard format. According to the evaluation performed by the EMS it would be necessary to raise the MRL for radishes from 2 mg/kg (equivalent to the limit of quantification) to 20 mg/kg.

EFSA bases its assessment on the evaluation report submitted by the Netherlands (2008), the Draft Assessment Report (France, 2003) and the EFSA conclusion (EFSA, 2005).

ASSESSMENT

1. Methods of analysis

1.1. Methods for enforcement of residues in food of plant origin

In the framework of the peer review under Directive 91/414/EEC analytical methods suitable for routine MRL enforcement purposes were assessed. Fosetyl-Al and phosphorous acid can be quantified in plant matrices with high water and high acid content after extraction with acetonitrile/water, clean-up and methylation by means of GC/FPD. For both analytes a LOQ of at least 0.5 mg/kg respectively could be achieved. In lettuce even lower concentrations of 0.2 mg/kg were achievable.

No multi-residue methods are applicable for the determination of fosetyl-Al and phosphorous acid in plant material.

EFSA concludes that sufficiently validated methods for fosetyl-Al and phosphorous acid are available which can be applied also for radishes, a crop belonging to crop group with high water content.

1.2. Methods for enforcement of residues in food of animal origin

Analytical methods for products of animal origin are not relevant in the framework of the current application because radishes are normally not used as animal feeding stuff.

2. Mammalian toxicology

The toxicological properties of fosetyl-Al and its metabolite phosphorous acid were investigated in the peer review. ADI values have been established at very similar levels for fosetyl-Al and its metabolite. ARfD values were not established because of the low acute toxicity. The information is summarised in Table 2-1.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Fosetyl-Al					
ADI	EFSA	2005	3	2 yr rat and dog	100
ARfD	EFSA	2005		Not necessary	
Phosphorous acid					
ADI	EFSA	2005	3.9	117 week rat	100
ARfD	EFSA	2005		Not necessary	

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

In the peer review, plant metabolism of fosetyl-Al was investigated in fruit (citrus, apples and pineapples) and fruiting vegetables (tomatoes). In addition a translocation study on grapes was evaluated which demonstrated that penetration and translocation of parent fosetyl-Al is limited.

The initial step of fosetyl-Al metabolism proceeds through the hydrolytic cleavage of the ethyl ester bond with phosphorous acid and ethanol as the major plant metabolites. The metabolism of ethanol, when not lost by volatilisation, further consists in incorporation into natural products such as D-glucose, starch, lignin, cellulose or fatty acids (EFSA, 2005).

No metabolism studies are available for root or tuber vegetables. However, the peer review concluded that, due to the elementary nature of fosetyl-Al, and given similar results obtained on fruits and leafy parts of the plant, the metabolic pattern is expected to be similar in all crop groups. Thus, no further metabolism studies are required for the given application on radishes.

Phosphorous acid is considered to be toxicologically relevant and its level is generally higher than that of parent compound. Therefore it was concluded that the residue definition for monitoring and for risk assessment should be established, taking into account also the analytical methods for enforcement, as *fosetyl-Al* (*sum of fosetyl, phosphorous acid and their salts, expressed as fosetyl*). The monitoring residue definition established in Regulation (EC) No. 396/2005 is identical with this residue definition derived in the peer review.

It is noted that phosphorous acid in plants does not only result from the use of fosetyl-Al, but also the use of pesticides containing potassium phosphonate, foliar P fertilizers and some organic products used for foliar fertilization can be a source of phosphorous acid which could mimic a treatment with fosetyl-Al (Malusà et al. 2005). Since phosphorous acid is not a specific marker substance for the use of fosetyl-Al, the residue definition established in the peer review should be reconsidered in the framework of the MRL-review under Article 12(2) of Regulation 396/2005.

3.1.1.2. Magnitude of residues

In support of the intended uses on radishes the applicant provided four supervised field trials in radishes performed in the Netherlands in spring and autumn 2006 under glass. The trials were performed in accordance with the intended GAP regarding the number of applications, the application rate and the PHI. All trials were performed as residue decline studies measuring the residues of fosetyl and H₃PO₃ separately between 0 and 21 days. In two trials the interval between the treatments was shorter than the intended GAP (4 days instead of 7 to 10 days). Also the growth stage of the crop at the last application was different compared with the intended use. The trials were performed with a final treatment in growth stage BBCH 42 or 43 (20 or 30% of the expected root diameter reached), whereas the intended GAP foresees a last treatment at BBCH 12 (2nd true leaf unfolded). However, EFSA is of the opinion that the residue trials are acceptable although they might slightly overestimate the residue in the crop. But considering the differences of the radish varieties summarised in Annex I of Regulation 396/2005 in terms of size and vegetation period (Code 0213080, *Raphanus sativus* var. *sativus*- black radish, Japanese radish, small radish and similar varieties), this deviation from the intended GAP is expected to contribute to a variation of the residue levels which might occur also under real conditions in the different radish varieties.

Since the results of the supervised field trials were reported as fosetyl and phosphorous acid, EFSA recalculated the phosphorous acid to fosetyl by applying a molecular weight correction factor of 1.34 (MW fosetyl: 110; phosphorous acid: 82). The fosetyl residues were in all cases below the LOQ of 0.2 mg/kg.

EFSA concludes that a sufficient amount of acceptable residue trials were provided which allow to derive a MRL proposal for the intended use on radishes. The intended GAP on radishes would require to set a MRL of 25 mg/kg. Other possible sources of phosphorous acid which may lead to residues of phosphorous acid (e.g. foliar treatment with P fertilizers, treatment with potassium phosphonate) are not considered. It is recommended that this aspect is assessed in detail in the framework of the MRL-review under Article 12(2) of Regulation 396/2005.

Storage stability was studied in grapes, cucumbers, potatoes and lettuce, all these crops belonging to the group with high water content. Phosphorous acid, which is the degradation product of fosetyl, has been found to be stable during 12 months under storage conditions at a temperature of -18°C. Since the radish samples have been stored not more than 120 days, the trials can be considered as reliable in terms of storage stability.

Table 3-1. Overview of the available residues trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement Fosetyl-Al (sum of fosetyl, phosphorous acid and their salts expressed as fosetyl)	Risk assessment Fosetyl-Al (sum of fosetyl, phosphorous acid and their salts expressed as fosetyl)					
Radishes	EU	Indoor	Fosetyl/H ₃ PO ₃	<0.2/6.4 <0.2/7.3 <0.2/7.7 <0.2/9.2	10.25	12.53	25	1	The results for phosphorous acid were recalculated to fosetyl applying the CF of 1.34. R _{ber} = 24.1 R _{max} = 18.5
			Fosetyl + 1.34*H ₃ PO ₃	8.78 9.98 10.52 12.53					

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

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

3.1.1.3. Effect of industrial processing and/or household preparation

Studies are available on the effect of processing on the nature and the level of residues in processed commodities. Fosetyl-Al and phosphorous acid are hydrolytically stable under conditions representative for pasteurisation, baking, brewing, boiling and sterilisation.

Specific processing studies for radishes are not necessary because of the low contribution to the dietary intake and because radishes are consumed raw.

3.1.2. Rotational crops

Fosetyl-Al degrades in soil very rapidly to its metabolite, phosphorous acid which has the potential to accumulate in soil (DT_{90} can be longer than 1 year). Rotational crop studies were performed with radishes, lettuce and barley investigating the amount of residues of phosphorous acid grown one month after soil was treated with 15 kg /ha of fosetyl-Al, corresponding to 4.9 mg phosphorous acid /kg soil. Since the levels of phosphorous acid in the harvested products were slightly above the LOQ of 0.5 mg/kg, the peer review concluded that a pre-planting interval for rotational crops of 30 days would be a suitable measure to ensure that succeeding crops do not contain residues above the LOQ.

Considering the significantly lower application rate in radishes (1.5 kg/ha per growing season), no significant fosetyl-related residues are expected in succeeding crops.

3.2. Nature and magnitude of residues in livestock

Radishes are not typical livestock feed items. Thus, the nature and magnitude of fosetyl-Al residues in livestock is not further discussed in the framework of this assessment.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). For the chronic intake assessment EFSA used the existing MRLs as established in Annex III of Regulation (EC) No. 396/2005 and the STMR value derived for the intended use of fosetyl-Al on radishes as input values. Since no ARfD was derived for the active substance fosetyl-Al, no acute intake calculation was performed. The input values for the exposure calculation are summarised in table 4-1.

Table 4-1. Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Fosetyl-Al (sum of fosetyl, phosphorous acid and their salts expressed as fosetyl)				
Radishes	10.25	STMR	Not relevant	
Other plant commodities	MRL	See Appendix C		
Food of animal origin	MRL	See Appendix C		

Since the ADI as reported in section 2.1 is expressed as fosetyl-Al, the value had to be recalculated to fosetyl taking into account the molecular weight ratio of fosetyl and fosetyl-Al. The molecular weight correction factor applied was 0.97. Thus, for the chronic risk assessment the exposure of fosetyl was compared with the corrected toxicological reference value of 2.91.

The intake assessment indicates no consumer concern for any of the European diets. The total calculated intake values range from 9.9 to 63% of the ADI. The contribution of radishes to the total dietary intake is insignificant; in all diets it was less than 0.1% of the ADI.

Consequently, EFSA comes to the conclusion that the intended use of fosetyl-Al on radishes is acceptable with regard to consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of fosetyl-Al was assessed in the framework of the peer review under Directive 91/414/EEC. The data were sufficient to conclude on an ADI of 3 mg/kg bw/day. Because of the low acute toxicity of the active substance and the major metabolite, no ARfD values were established.

The metabolism of fosetyl-Al was elucidated in fruit and fruiting vegetables. The only toxicologically relevant compound identified in significant concentrations was phosphorous acid. Given the elementary nature of fosetyl-Al and the similar results obtained on fruits and leaves, the metabolic pattern is expected to be similar in all crops. Thus, a general residue definition was established as fosetyl-Al (sum of fosetyl, phosphorous acid and their salts, expressed as fosetyl) for both risk assessment and enforcement purpose. An analytical method based on GC/FPD is available to control compliance with MRLs established for this residue definition.

The submitted residue trials were sufficient to derive an MRL proposal of 25 mg/kg.

The possible presence of fosetyl-Al related residues in succeeding crops was addressed in the peer review. Taking into account the intended application rate on radishes, no significant residues of fosetyl or phosphorous acid are expected in succeeding crops.

The consumer risk assessment based on the existing MRLs and the STMR derived for the intended use in radishes was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). The total calculated dietary intake ranged from 10 to 63% of the ADI for the different diets included in the model. Thus, it is concluded that no long-term consumer health risk is associated with the intended use of fosetyl-Al in radishes. No acute risk assessment was necessary because the toxicological profile of the active substance did not require the setting of an acute reference dose.

RECOMMENDATIONS

EFSA recommends amending the temporary MRLs for fosetyl-Al in radishes as summarised in the table below:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Radishes	2(*)	25	The MRL proposal is sufficiently supported by data and no consumer health risk was identified regarding the expected residues.

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

It is also noted that phosphorous acid in plants does not only result from the use of fosetyl-Al, but also other pesticides like potassium phosphonate, foliar P fertilizers and some organic products used for foliar fertilization can be a source of phosphorous acid which could mimic a treatment with fosetyl-Al. Therefore, in the framework of the MRL review under Article 12(2) of Regulation EC (No) 396/2005 the current residue definition and the MRLs established should be reconsidered, taking into account other sources of phosphorous acid.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

1	2	3	4	5	6			7			8	9
Crop and / or situation	F, G or I	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
			Type	Conc. of a.i.	method, kind	growth stage	number (range)	kg a.i./hl	water l/ha	kg a.i./ha		
(a)	(b)	(c)	(d - f)	(i)	(f - h)			(j)			(k)	(l)
Radish	G	Peronospora spp.	SL	530	Foliar spraying	BBCH 0-12	1-2	0.077-0.155	500-1000	0.775	14	7-10 d

- Remarks:
- (a) In case of group of crops the Codex classification should be used
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and sucking insects, soil born insects, foliar fungi
 - (d) e.g. wettable powder (WP), emulsifiable concentration (EC), granule (GR)
 - (e) Use CIPAC/FAO Codes where appropriate
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment
 - (k) PHI = Pre-harvest interval
 - (l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Fosetyl			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	2	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	2,91	ARfD (mg/kg bw):	n.n.
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2005	Year of evaluation:	2005

The ADI of 3 mg/kg bw/d as derived in the EFSA opinion for fosetyl-AI was recalculated to fosetyl by applying the molecular weight correction factor of 0.97.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).

The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		10	63						
		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)	
63,2	DE child	31,1	Apples	9,8	Oranges	4,4	Table grapes		63,2
45,7	NL child	16,3	Apples	8,0	Oranges	6,1	Potatoes		45,7
41,7	WHO Cluster diet B	10,6	Tomatoes	6,2	Wine grapes	2,8	Potatoes		41,7
29,3	FR toddler	6,8	Apples	5,2	Apples	5,2	Potatoes		29,3
28,6	IE adult	4,3	Wine grapes	2,7	Oranges	2,4	Potatoes		28,6
26,2	PT General population	8,6	Wine grapes	5,5	Potatoes	3,1	Tomatoes		26,2
23,9	FR all population	13,7	Wine grapes	1,5	Tomatoes	1,2	Apples		23,9
21,8	DK child	6,0	Apples	4,2	Cucumbers	2,5	Potatoes		21,8
21,8	WHO cluster diet E	5,5	Wine grapes	4,0	Potatoes	2,2	Apples		21,8
21,7	UK Toddler	5,1	Oranges	4,4	Apples	3,6	Potatoes		21,7
21,1	FR infant	6,4	Apples	4,3	Potatoes	2,3	Oranges		21,1
20,1	SE general population 90th percentile	4,3	Potatoes	2,7	Apples	2,6	Tomatoes		20,1
20,1	ES child	5,6	Oranges	3,4	Tomatoes	2,9	Apples		20,1
20,0	WHO regional European diet	4,1	Potatoes	3,8	Tomatoes	1,7	Apples		20,0
19,5	NL general	3,8	Oranges	3,0	Apples	2,8	Potatoes		19,5
19,3	WHO cluster diet D	4,2	Potatoes	3,5	Tomatoes	1,7	Apples		19,3
17,2	WHO Cluster diet F	3,5	Potatoes	2,3	Tomatoes	2,2	Oranges		17,2
16,3	ES adult	3,3	Oranges	2,7	Tomatoes	2,0	Apples		16,3
15,9	UK Infant	4,0	Apples	3,4	Potatoes	3,3	Oranges		15,9
15,7	PL general population	5,3	Apples	3,5	Potatoes	3,0	Tomatoes		15,7
15,5	IT kids/toddler	4,9	Tomatoes	2,3	Apples	1,2	Oranges		15,5
14,2	UK vegetarian	2,8	Wine grapes	2,2	Oranges	2,1	Tomatoes		14,2
13,8	IT adult	4,0	Tomatoes	2,0	Apples	1,0	Lettuce		13,8
13,6	DK adult	4,8	Wine grapes	2,0	Apples	1,5	Potatoes		13,6
12,9	LT adult	4,8	Apples	3,3	Potatoes	2,1	Tomatoes		12,9
12,2	UK Adult	3,7	Wine grapes	1,5	Tomatoes	1,4	Oranges		12,2
9,9	FI adult	2,5	Oranges	1,5	Tomatoes	1,3	Potatoes		9,9

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Fosetyl is unlikely to present a public health concern.

APPENDIX C – EXISTING EC MRLS

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	75
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	75
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	75
110030	Lemons (Citron, lemon)	75
110040	Limes	75
110050	Mandarins (Clementine, tangerine and other hybrids)	75
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
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*
140010	Apricots	2*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
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
151010	Table grapes	100
151020	Wine grapes	100
152000	(b) Strawberries	75
153000	(c) Cane fruit	2*
153010	Blackberries	2*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	2*
153030	Raspberries (Wineberries)	2*
153990	Others	2*
154000	(d) Other small fruit & berries	2*
154010	Blueberries (Bilberries cowberries (red bilberries))	2*
154020	Cranberries	2*
154030	Curants (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 (mediterranean medlar)	2*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	2*
154990	Others	2*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	2*
161010	Dates	2*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
161020	Figs	2*
161030	Table olives	2*
161040	Kumquats (Marumi kumquats, nagami kumquats)	2*
161050	Carambola (Bilimbi)	2*
161060	Persimmon	2*
161070	Jambolan (java plum) (Java apple (water apple), pomeac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	2*
161990	Others	2*
162000	(b) Inedible peel, small	2*
162010	Kiwi	2*
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 mammeiy sapote)	2*
162990	Others	2*
163000	(c) Inedible peel, large	
163010	Avocados	50
163020	Bananas (Dwarf banana, plantain, apple banana)	2*
163030	Mangoes	2*
163040	Papaya	2*
163050	Pomegranate	2*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	2*
163070	Guava	2*
163080	Pineapples	50
163090	Bread fruit (Jackfruit)	2*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
163100	Durian	2*
163110	Soursava (guanabana)	2*
163990	Others	2*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	30
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	2*
213010	Beetroot	2*
213020	Carrots	2*
213030	Celeriac	2*
213040	Horseradish	2*
213050	Jerusalem artichokes	2*
213060	Parsnips	2*
213070	Parsley root	2*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	2*
213090	Salsify (Scorzoneria, 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
220030	Shallots	2*
220040	Spring onions (Welsh onion and	30

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
	similar varieties)	
220990	Others	2*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	100
231020	Peppers (Chilli peppers)	130
231030	Aubergines (egg plants) (Pepino)	100
231040	Okra, lady's fingers	2*
231990	Others	2*
232000	(b) Cucurbits - edible peel	75
232010	Cucumbers	75
232020	Gherkins	75
232030	Courgettes (Summer squash, marrow (patisson))	75
232990	Others	75
233000	(c) Cucurbits-inedible peel	75
233010	Melons (Kiwano)	75
233020	Pumpkins (Winter squash)	75
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
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	10
241020	Cauliflower	10
241990	Others	10
242000	(b) Head brassica	10
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
243020	Kale (Borecole (curly kale), collards)	10
243990	Others	10

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
244000	(d) Kohlrabi	10
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	75
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 endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	75
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
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	2*
252030	Beet leaves (chard) (Leaves of beetroot)	15
252990	Others	2*
253000	(c) Vine leaves (grape leaves)	2*
254000	(d) Water cress	2*
255000	(e) Witloof	75
256000	(f) Herbs	75
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

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
256060	Rosemary	75
256070	Thyme (marjoram, oregano)	75
256080	Basil (Balm leaves, mint, peppermint)	75
256090	Bay leaves (laurel)	75
256100	Tarragon (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
270060	Leek	30
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*
290000	(ix) Sea weeds	2*
300000	3. PULSES, DRY	2*
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans,	2*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
	cowpeas)	
300020	Lentils	2*
300030	Peas (Chickpeas, field peas, chickling vetch)	2*
300040	Lupins	2*
300990	Others	2*
400000	4. OILSEEDS AND OILFRUITS	2*
401000	(i) 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, teff)	2*
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	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
	INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	5*
620000	(ii) Coffee beans	5*
630000	(iii) Herbal infusions (dried)	500
631000	(a) Flowers	500
631010	Camomille 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
800000	8. SPICES	5*
810000	(i) Seeds	5*
810010	Anise	5*
810020	Black caraway	5*
810030	Celery seed (Lovage seed)	5*
810040	Coriander seed	5*
810050	Cumin seed	5*
810060	Dill seed	5*
810070	Fennel seed	5*
810080	Fenugreek	5*
810090	Nutmeg	5*
810990	Others	5*
820000	(ii) Fruits and berries	5*
820010	Allspice	5*
820020	Anise pepper (Japan pepper)	5*
820030	Caraway	5*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
820040	Cardamom	5*
820050	Juniper berries	5*
820060	Pepper, black and white (Long pepper, pink pepper)	5*
820070	Vanilla pods	5*
820080	Tamarind	5*
820990	Others	5*
830000	(iii) Bark	5*
830010	Cinnamon (Cassia)	5*
830990	Others	5*
840000	(iv) Roots or rhizome	5*
840010	Liquorice	5*
840020	Ginger	5*
840030	Turmeric (Curcuma)	5*
840040	Horseradish	5*
840990	Others	5*
850000	(v) Buds	5*
850010	Cloves	5*
850020	Capers	5*
850990	Others	5*
860000	(vi) Flower stigma	5*
860010	Saffron	5*
860990	Others	5*
870000	(vii) Aril	5*
870010	Mace	5*
870990	Others	5*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	2*
900020	Sugar cane	2*
900030	Chicory roots	75
900990	Others	2*
100000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
101000	(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*
101100	(a) Swine	0,5*
101101	Meat	0,5*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
0		
101102	Fat free of lean meat	0,5*
101103	Liver	0,5*
101104	Kidney	0,5*
101105	Edible offal	0,5*
101199	Others	0,5*
101200	(b) Bovine	0,5*
101201	Meat	0,5*
101202	Fat	0,5*
101203	Liver	0,5*
101204	Kidney	0,5*
101205	Edible offal	0,5*
101299	Others	0,5*
101300	(c) Sheep	0,5*
101301	Meat	0,5*
101302	Fat	0,5*
101303	Liver	0,5*
101304	Kidney	0,5*
101305	Edible offal	0,5*
101399	Others	0,5*
101400	(d) Goat	0,5*
101401	Meat	0,5*
101402	Fat	0,5*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
101403	Liver	0,5*
101404	Kidney	0,5*
101405	Edible offal	0,5*
101499	Others	0,5*
101500	(e) Horses, asses, mules or hinnies	0,5*
101501	Meat	0,5*
101502	Fat	0,5*
101503	Liver	0,5*
101504	Kidney	0,5*
101505	Edible offal	0,5*
101599	Others	0,5*
101600	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,5*
101601	Meat	0,5*
101602	Fat	0,5*
101603	Liver	0,5*
101604	Kidney	0,5*
101605	Edible offal	0,5*
101699	Others	0,5*
101700	(g) Other farm animals (Rabbit, Kangaroo)	0,5*
101701	Meat	0,5*
101702	Fat	0,5*
101703	Liver	0,5*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
101704 0	Kidney	0,5*
101705 0	Edible offal	0,5*
101799 0	Others	0,5*
102000 0	(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*
102001 0	Cattle	0,1*
102002 0	Sheep	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
102003 0	Goat	0,1*
102004 0	Horse	0,1*
102099 0	Others	0,1*
103000 0	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,1*
103001 0	Chicken	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
103002 0	Duck	0,1*
103003 0	Goose	0,1*
103004 0	Quail	0,1*
103099 0	Others	0,1*
104000 0	(iv) Honey (Royal jelly, pollen)	0,5*
105000 0	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,5*
106000 0	(vi) Snails	0,5*
107000	(vii) Other terrestrial animal	0,5*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)
0	products	

(*) Indicates lower limit of analytical determination

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
DTU	Danish Technical University
dw	dry weight
EC	European Community
ECD	electron capture detection
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FPD	flame photometric detector
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization

IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K _{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10 ⁻⁶)
PRIMo	Pesticide Residues Intake Model
RMS	rapporteur Member State
SEU	Southern European Union
SL	soluble concentrate
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WG	water dispersible granule
WHO	World Health Organisation
WP	wettable powder