

**Art. 51**  
**Extension of authorisation for minor uses**

**REGISTRATION REPORT**

**Part A**

**Risk Management**

**Product code: Aliette WG**

**Active Substances:**

**Fosetyl 746 g/kg**

**COUNTRY: Germany**

**Central Zone**

**Zonal Rapporteur Member State: Germany**

**CORE ASSESSMENT**

**Applicant: Landesanstalt für Landwirtschaft, Forsten  
und Gartenbau - LLFG Dezernat Pflanzenschutz**

**Date: 04/01/2013**

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## PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of Aliette WG containing Fosetyl in Germany.

The risk assessment conclusions are based on the already existing registration of the PPP. The following sections of Registration Report, Part B were prepared on basis of new data:

- Section 4.

Assessments for the safe use of Aliette WG have been made using endpoints agreed in the EU reviews of Fosetyl.

Appendix 1 of this document provides a copy of the final product authorisation in Germany (will be included in the final registration report).

### 1 Details of the application

Application to extend the authorisation of a plant protection product (PPP) already authorised in Germany to minor uses not yet covered by that authorisation.

The application is intended for use in Germany only.

#### 1.1 Application background

##### Details on applicant and application

Plant protection product	<b>Aliette WG</b>
Type of application	Zonal application according to Article 51, ZRMS=DE, first application (GV1)
Registration number	043099-00/05
Applicant	Landesanstalt für Landwirtschaft, Forsten und Gartenbau - LLFG Dezernat Pflanzenschutz, Strenzfelder Allee 22, 06406 Bernburg, Germany
Authorisation holder	Bayer CropScience Deutschland GmbH, Registrierung & PGA, Elisabeth-Selbert-Straße 4a, 40764 Langenfeld, Germany
Function	Fungicide
Type of formulation	Water dispersible granule
Expiration of authorisation	2015-12-31

## 1.2 Annex I inclusion

The active substances included in the plant protection product are approved according Regulation (EC) No 1107/2009. The present application is in line with the provisions of the approvals.

Active substance (BVL Number)

**Fosetyl (0522)**

Content in PPP	746 g/kg
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	30/04/2017

## 1.3 Regulatory approach

The PPP is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI. Therefore the evaluation of the current application is limited to the points not covered by the existing registration.

### 1.3.1 Uses applied for and registration decision

Number of use	Plant/commodity/object	Harmful organism/purpose	decision
001	Fresh herbs	downy mildew (Peronosporaceae)	Authorise

### 1.3.2 Public interest and minor use

According to Article 51 (2) a and c of the Regulation (EC) No 1107/2009 extensions of authorisation are only possible if the intended use applied for is minor in nature and in public interest.

In Germany the cultivated area of fresh herbs is about 3566 ha, of which approx. 1426 ha need to be controlled. Calculation shows that authorisation holder will not profit from an authorisation of the requested use(s). All data are valid for open field.

Upon this calculation and the examination of available alternative measures for the applied use(s) it can be stated that the applied use(s) is minor in nature and the authorisation is in the public interest.

## 1.4 Data protection claims

The applicant is owner of the new studies submitted and claims data protection.

## 1.5 Letters of Access

The applicant is owner of the new studies submitted.

Authorisation holder agrees to the current application to extend the authorisation.

## 2 Details of the authorisation

### 2.1 Product identity

Product name	Aliette WG
Authorisation number	043099-00
Composition	Fosetyl 746 g/kg
Type of formulation	Water dispersible granule (WG)
Function	Fungicide
Authorisation holder	Bayer CropScience Deutschland GmbH, Registrierung & PGA, Elisabeth-Selbert-Straße 4a, 40764 Langenfeld, Germany

### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling under Directive 99/45/EC or Regulation (EC) No 1272/2008

Xi	Irritant
RK052	R 52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
RX036	R 36: Irritating to eyes
SX002	S 2: Keep out of the reach of children
SX035	S 35: This material and its container must be disposed of in a safe way.
SX039	S 39: Wear eye/face protection.
SX046	S 46: If swallowed, seek medical advice immediately and show this container or label
SP001	To avoid risk to man and the environment, comply with the instructions for use.

#### 2.2.2 R and S phrases under Regulation (EC) No 547/2011

EO001	SPo1: After contact with skin, first remove product with dry cloth and then wash with plenty of water.
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#### 2.2.3 Other phrases

##### 2.2.3.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

##### Operator protection

SB001 Avoid any unnecessary contact with the product. Misuse can lead to health damage.

##### Ecosystem protection

NW262 The product is toxic for algae.

NW468 Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This

also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

#### **Integrated Pest Management (IPM)**

- NN333 The product is classified as harmful for populations of the species *Phytoseiulus persimilis* (predatory mite).
- NN334 The product is classified as harmful for populations of the species *Typhlodromus pyri* (predatory mite).

#### **Active substance**

none

The authorization of the PPP is linked to the following conditions (voluntary labelling):

#### **Honeybee**

- NB6641 The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)

#### **Integrated Pest Management (IPM)**

- NN160 The product is classified as harmless for populations of the species *Aleochara bilineata* (staphylinid beetle).
- NN161 The product is classified as harmless for populations of the species *Coccinella septempunctata* (seven-spotted ladybird).
- NN165 The product is classified as harmless for populations of the species *Poecilus cupreus* (ground beetle).
- NN170 The product is classified as harmless for populations of the species *Chrysoperla carnea* (lacewing).
- NN183 The product is classified as harmless for populations of the species *Encarsia formosa* (chalcid wasp).
- NN1842 The product is classified as harmless for populations of the species *Aphidius rhopalosiphii* (braconid wasp).

### **2.2.3.2 Specific restrictions linked to the intended uses**

Some of the authorized uses are linked to the following conditions (mandatory labelling):  
See 2.3 (Product uses)

#### **Ecosystem protection**

- NW642 The product is not authorised for use in or in the immediate vicinity of surface waters or coastal waters (§ 6 (2) 'PflschG' [Plant Protection Act]). Irrespective of this fact, the binding minimum buffer zone to be kept from surface waters, provided for by state law, must be observed. Violations may be punished by fines of up to Euro 50.000.

## 2.3 Product uses

PPP (product name/code) **Aliette WG (043099-00)** Formulation type: **WG**  
active substance **Fosetyl** Conc. of as 1: **746 g/kg**

Applicant: **Landesanstalt für Landwirtschaft, Forsten und Gartenbau - LLFG Dezernat Pflanzenschutz** professional use   
Zone(s): **central EU** non professional use

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:  e.g. safener/synergist per ha  e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
001	DE	Fresh herbs, utilisation as fresh herbage	F	Downy mildew (Peronosporaceae)	spraying	at beginning of infestation and/or when first symptoms become visible	a) 2 (10 to 14 days) b) 2	a) 3 kg/ha b) 6 kg/ha	a) 2.238 kg as/ha  b) 4.476 kg as/ha	200 - 800	21	Restrictions (see 2.2.3.2) NW 642

### **3 Risk management**

#### **3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles**

##### **3.1.1 Physical and chemical properties**

Not relevant for extension of authorisation according article 51.

##### **3.1.2 Methods of analysis**

###### **3.1.2.1 Analytical method for the formulation**

Not relevant for extension of authorisation according article 51.

###### **3.1.2.2 Analytical methods for residues**

Analytical methods for commodities of high water such as fresh herbs are available and acceptable for enforcing all compounds given in the residue definition.

##### **3.1.3 Mammalian Toxicology**

The PPP is already registered in Germany according to Directive 91/414/EEC.

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

##### **3.1.4 Residues and Consumer Exposure**

The residue behaviour of the active substances Fosetyl has been evaluated within the EU review process. Information about metabolism is sufficient to evaluate the intended use in fresh herbs.

###### **3.1.4.1 Residues**

The available residue information is sufficient to perform an adequate assessment. Residues that are expected from the intended use of the plant protection product will not exceed the MRL set in Regulation (EC) No 396/2005 for Fosetyl (75 mg/kg herbs).

###### **3.1.4.2 Consumer exposure**

An assessment of residue uptake by consumers (TMDI calculation, EFSA PRIMo) results in the following maximum ADI consumptions:

Fosetyl (3 mg/kg bw/d) – 62 % (DE children)

Long-term dietary intake of residues of Fosetyl is unlikely to present a public health concern for European consumers.

No acute risk is expected from the consumption of fresh herbs treated according to the intended use.

##### **3.1.5 Environmental fate and behaviour**

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 043099-00 according the uniform principles of directive 91/414/EEC.

No specific risk mitigation is necessary to avoid harmful effects on the Groundwater.



### 3.1.6 Ecotoxicology

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 043099-00 according the uniform principles of directive 91/414/EEC.

The PPP Aliette WG and the active substance Fosetyl are toxic to the aquatic environment (*Scenedesmus subspicatus*:  $E_b C_{50(3d,sta.,real)} = 5900 \mu\text{g a.i./L}$ ). Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practise are acceptable. Therefore the safety phrases and conditions of use NW262, NW468 and NW 642 are assigned, see also 2.2.

#### Risk Assessment for Honeybees

The honeybee risk assessment for the main application covers the use(s) in accordance with Article 51 of regulation (EC) No 1107/2009 (see also point 2.2).

### 3.1.7 Efficacy

Labelling in accordance with the requirements of ANNEX III General principles of integrated pest management under directive 2009/128/EC (see also point 2.2):

-The classification of effects on beneficial arthropods for the main application covers the use(s) applied for under the terms of Article 51 of regulation (EC) No 1107/2009.

According to Article 51 of the regulation (EC) No 1107/2009 the requirements for approval concerning the sufficient effect and any unacceptable effects on plants and plant products not need to be checked.

### 3.2 Conclusions

PPP Aliette WG is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI.

The intended use is minor in nature and the extension of authorisation is in public interest. Effects on bees and other beneficials were evaluated in the frame of the already authorised uses. No additional effects are anticipated because of the extension of uses(s).

The intended use in fresh herbs will not result in residues above the MRLs set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food with these residues of Fosetyl is not expected. There is no special risk mitigation necessary which deviate from the existing registration.

Considering an application in accordance with the evaluated use pattern and good agricultural practise as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

### 3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

None

#### Appendix 1 – Copy of the product authorisation

Will be inserted in final registration report

#### Appendix 2 – Copy of the product label

No product label available. Not mandatory according to Article 51 (5)

### **Appendix 3 – Letter of Access**

No letter of access necessary. The applicant is owner of the new studies submitted. Authorisation holder agrees to the current application to extend the authorisation.



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IHR ZEICHEN  
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22200.043099-00/05.66832  
(bitte bei Antwort angeben)

DATUM 10. Januar 2013

**GV1 043099-00/05**

**Aliette WG**

**Verfahren zur Erweiterung einer Zulassung nach Artikel 51 Abs. 1 der Verordnung (EG)  
Nr. 1107/2009**

Bescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit dem Wirkstoff: 746 g/kg Fosetyl (als Aluminium-Salz 800 g/kg)

Zulassungsnummer: 043099-00

Versuchsbezeichnung: BAY-16590-F-3-WG

Antrag vom: 2. Mai 2012

wird wie in Anlage 1 beschrieben auf der Grundlage von Art. 51 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (Abl. L 309 vom 24.11.2009, S. 1) um folgende Anwendungsgebiete bzw. Anwendungen erweitert:

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
043099-00/05-001	Falsche Mehltaupilze (Peronosporaceae)	frische Kräuter	

### **Festgesetzte Anwendungsbestimmungen**

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281) festgesetzt:

- keine -

### **Auflagen**

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:  
Siehe Anlage 1, jeweils unter Nr. 2.

### **Vorbehalt**

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

### **Abgelehnte Anwendungsgebiete bzw. Anwendungen**

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

- keine -

### **Weitere Hinweise und Bemerkungen**

Zu den Anwendungen 043099-00/05-001

Bestimmbare Rückstände (>0.5 mg/kg) von Phosphoriger Säure in Kulturen, die innerhalb von 30 Tagen nachgebaut werden, können nicht sicher ausgeschlossen werden. Es ist jedoch nicht zu erwarten, dass dabei die derzeit für Fosetyl+Phosphorige Säure geltenden Rückstandshöchstgehalte von mind. 2 mg/kg überschritten werden.

Aus diesem Grunde wird von einer Beschränkung des Nachbaus abgesehen.

### **Rechtsbehelfsbelehrung**

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen  
im Auftrag

gez. Dr. Hans-Gerd Nolting  
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

**Anlage**

## Anlage 1 zugelassene Anwendung: 043099-00/05-001

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Falsche Mehltaupilze (Peronosporaceae)

Pflanzen/-erzeugnisse/Objekte: frische Kräuter

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

- Erläuterungen:

Anwendung im Haus- und

Kleingartenbereich: Nein

Erläuterung zum Schadorganismus:

Stadium des Schadorganismus:

- Erläuterungen:

Erläuterung zur Kultur: Nutzung als frisches Kraut

Stadium der Kultur:

- Erläuterungen:

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

- Erläuterungen:

Maximale Zahl der Behandlungen

- in dieser Anwendung: 2

- für die Kultur bzw. je Jahr: 2

- Abstand: 10 bis 14 Tage

- Erläuterungen Anzahl

Behandlungen:

Mischungspartner:

- Erläuterungen:

Anwendungstechnik: spritzen

- Erläuterungen:

Aufwand:

- 3 kg/ha in 200 bis 800 l Wasser/ha

- Erläuterungen:

Sonstige Ergänzungen und Hinweise: - keine -

#### 2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

### **2.3 Wartezeiten**

21 Tage

Freiland: frische Kräuter

### **3 Anwendungsbezogene Anwendungsbestimmungen**

- keine -

**REGISTRATION REPORT**  
**Part B**

**Section 4: Metabolism and Residues**  
**Detailed summary of the risk assessment**

**Product code: Aliette WG**  
**Active Substance: 746 g/L Fosetyl**

**Central Zone**  
**Zonal Rapporteur Member State: Germany**

**CORE ASSESSMENT**

**Applicant: LLG Bernburg**  
**Date: 04/01/2013**



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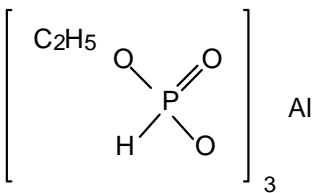
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## IIIA 8 METABOLISM AND RESIDUES DATA

### IIIA 8.1 Evaluation of the active substances

#### IIIA 8.1.1 Fosetyl-Al

**Table IIIA 8.1-1: Identity of the active substance**

Structural formula	
Common Name	Fosetyl-Al
CAS number	39148-24-8

##### IIIA 8.1.1.1 Storage stability

A brief summary of the storage stability data on fosetyl is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the corresponding DAR ([ASB2010-10342](#)) and in EFSA's Conclusion on the Peer-Review ([ASB2012-3677](#)).

**Table IIIA 8.1-2: Stability of residues (Annex IIA, point 6.1)**

Stability of fosetyl and phosphorous acid	<p>Fosetyl was stable during 12 months at – 18°C in grapes, but instable in cucumbers, potatoes and lettuce concurrently forming increasing amounts of phosphorous acid.</p> <p>The sum of phosphorous acid and fosetyl was stable during 12 months at – 18°C in grapes, cucumbers, potatoes and lettuce.</p>
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##### IIIA 8.1.1.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of fosetyl in plants is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the corresponding DAR ([ASB2010-10342](#)) and in EFSA's Conclusion on the Peer-Review ([ASB2012-3677](#)).

**Table IIIA 8.1-3: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)**

Plant groups covered	<p>Citrus, pineapple, grapes, apples and tomatoes, <sup>14</sup>C-fosetyl</p> <p>The chemical structure of fosetyl-Al determines its metabolic fate in plants and animals. The initial step is the hydrolysis of the ethyl ester bond with phosphorous acid and ethanol resulting as the major plant metabolites. Ethanol further dissipates by volatilisation or is degraded and incorporated into natural constituents of plant and animal tissues.</p> <p>See EFSA conclusion for details.</p>
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Rotational crops	<p>Confined study, outdoors, incorporation of phosphorous acid (no radio-label) into bare soil, rotational crops radish, lettuce and barley, PBI 1 month</p> <p>Fosetyl-AI degrades in soil very rapidly to its metabolite phosphorous acid. For that reason a study has been conducted to investigate the potential for phosphorous acid residues to occur in succeeding crops. Application rate was 4.9 mg/kg soil thus representing the concentration resulting from the application of 15 kg/ha of fosetyl-AI (maximum dose applied during one growing season). Radishes, lettuce and barley were sown/planted 1 month after soil treatment.</p> <p>Phosphorous acid levels above the natural background were observed, but only slightly above the validated LOQ (0.5 mg/kg) for monitoring of products of plant origin.</p> <p>See EFSA conclusion for details.</p>
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	yes
Distribution of the residue in peel/ pulp	Not applicable
Processed commodities (nature of residue)	Both fosetyl and phosphorous acid were hydrolytically stable under simulated conditions of pasteurisation, baking, brewing, boiling and sterilisation.
Residue pattern in raw and processed commodities similar? (yes/no)	yes
Plant residue definition for monitoring	<p>Sum of fosetyl, phosphorous acid and their salts, expressed as fosetyl</p> <p>This is in line with Reg. (EC) No 396/2005.</p>
Plant residue definition for risk assessment	Sum of fosetyl, phosphorous acid and their salts, expressed as fosetyl
Conversion factor(s) (monitoring to risk assessment)	Not applicable

### III A 8.1.1.3 *Metabolism in livestock and animal residue definition(s)*

A brief summary of the metabolism of fosetyl in livestock is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the corresponding DAR ([ASB2010-10342](#)) and in EFSA's Conclusion on the Peer-Review ([ASB2012-3677](#)).

**Table III A 8.1-4: Metabolism in livestock (Annex II A, point 6.2.2 to 6.2.5 and 6.7.1)**

Animals covered	<p>Lactating goats, <sup>14</sup>C-fosetyl:</p> <ul style="list-style-type: none"> <li>- 10 mg/kg feed, 7 days (<a href="#">RIP2003-385</a>, <a href="#">RIP2003-386</a>, <a href="#">RIP2003-387</a>)</li> <li>- 30 mg/kg feed, 7 days (<a href="#">RIP2003-388</a>)</li> </ul> <p>Fosetyl was detected in urine/faeces only. Radioactive residues in tissues/organs and in milk were attributed to natural compounds. Parent has been metabolised to phosphorous acid and ethanol and <sup>14</sup>C building blocks have been introduced in biosynthetic pathways. Large parts of applied radioactivity have not been recovered and probably left via respiration (<sup>14</sup>CO<sub>2</sub>).</p>
Time needed to reach a plateau concentration in milk and eggs	Milk: up to 2 days

Animal residue definition for monitoring	Sum of fosetyl, phosphorous acid and their salts, expressed as fosetyl  This is in line with Reg. (EC) No 396/2005.
Animal residue definition for risk assessment	Sum of fosetyl, phosphorous acid and their salts, expressed as fosetyl
Conversion factor(s) (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

#### *IIIA 8.1.1.4 Residues in rotational crops*

A brief summary of the field rotational crop studies on fosetyl is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the corresponding DAR ([ASB2010-10342](#)) and in EFSA's Conclusion on the Peer-Review ([ASB2012-3677](#)).

**Table IIIA 8.1-5: Residues in rotational crops (Annex IIA, point 6.6.3)**

Field studies	Residues of phosphorous acid in the range of the LOQ (0.5 mg/kg) can be present in plants following short time intervals between application and planting or sowing of a rotational crop. A pre-planting interval of 30 days is recommended.
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#### *IIIA 8.1.1.5 Residues in livestock*

Residues of fosetyl in commodities of animal origin were not assessed, since the crops under consideration (herbs) are not used as animal feed.

### **IIIA 8.2 Evaluation of the intended use(s)**

#### **IIIA 8.2.1 Selection of critical use and justification**

The critical GAP used for consumer intake and risk assessment is presented in Table IIIA 8.2-1.

**Table IIIA 8.2-1: Critical Use (worst case) used for consumer intake and risk assessment**

1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)  (a)	F G or I  (b)	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)  (c)	Application			Application rate			PHI (days) (i)	Remarks:  e.g. safener/synergist per ha  e.g. recommended or mandatory tank mixtures  (j)
					Method / Kind  (d-f)	Timing / Growth stage of crop & season  (g)	Max. number (min. interval between applications) a) per use b) per crop/ season (h)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
1		Fresh herbs (utilisation as fresh herbage)	F	Downy mildew of cucurbits ( <i>Peronosporacea</i> )	spraying	At beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (10-14 days)	a) 3 b) 6	a) 2.2 b) 4.5	200 / 800	21	

- Remarks:
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
  - (d) All abbreviations used must be explained
  - (e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
  - (f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

- (g) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (h) The minimum and maximum number of application possible under practical conditions of use must be provided
- (i) PHI - minimum pre-harvest interval
- (j) Remarks may include: Extent of use/economic importance/restrictions

### IIIA 8.2.2 Fresh herbs

#### IIIA 8.2.2.1 Residues in primary crops

The following table gives a brief overview of the supervised residue trials selected for the assessment of fosetyl in fresh herbs. For the detailed evaluation of new/additional residue trials it is referred to Appendix 2.

**Table IIIA 8.2-2: Overview of the selected supervised residue trials for fosetyl in fresh herbs**

Commodity	Region <sup>(a)</sup>	Outdoor/ Indoor	Individual trial results (mg/kg)		STM <sub>R</sub> (mg/kg) <sup>(b)</sup>	HR (mg/kg) <sup>(c)</sup>	Median CF <sup>(d)</sup>
			Enforcement (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)	Risk assessment (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)			
Fresh herbs	NEU	Outdoor	2.3, 3.2, 5.4, 6.6, 45	2.3, 3.2, <u>5.4</u> , 6.6, 45	5.4	45	not applicable

Underline median value from trial results (based on DoR for risk assessment)

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

Analytical methods for commodities of high water such as fresh herbs are available and acceptable for enforcing all compounds given in the residue definition.

#### IIIA 8.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

#### IIIA 8.2.2.3 Residues in processed commodities

No data available.

#### IIIA 8.2.2.4 Proposed pre-harvest intervals, withholding periods

See GAP table.

### IIIA 8.3 Consumer intake and risk assessment

The consumer intake and risk assessment is based on the appropriate input values given in Table IIIA 8.3-1 and the toxicological reference values stated in Table IIIA 8.3-2. For the detailed calculation results it is referred to Appendix 3.

**Table IIIA 8.3-1: Residue input values for the consumer risk assessment**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Fresh herbs	75	MRL	Not required	No ARfD allocated
other commodities	various	MRL	--	--

**Table IIIA 8.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)**

ADI	3 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	62 % (based on 2-4 years old DE children, mean body weight)
NTMDI (% ADI) according to German NVS II model	65 % (2-4 years old DE children, individual body weight)
IEDI (% ADI) according to EFSA PRIMo	Not required
NEDI (% ADI) according to German NVS II model	Not required
Factors included in IEDI and NEDI	None
ARfD	Not necessary
IESTI (EFSA PRIMo) (% ARfD)	Not necessary
NESTI (German NVS II model) (% ARfD)	Not necessary
Factors included in IESTI and NESTI	None

#### **IIIA 8.4 Proposed maximum residue levels (MRLs)**

No new MRLs are required.

#### **IIIA 8.5 Conclusion**

The data available is considered sufficient for risk assessment. An exceedance of the current MRL of 75 mg/kg for fosetyl (sum of fosetyl and phosphorous acid and their salts, expressed as fosetyl) as laid down in Reg. (EU) 396/2005 is not expected.

The submitted supervised field trials cover crops with multiple cuttings per year (e.g. parsley) and crops with only one cutting/harvest. Additional field trials data were reported in the context of Art. 12(2) of Reg. (EC) No 396/2005 on spinach and lettuce grown in NEU, partly with more critical GAPs as applied for. Residues found in these trials also comply with the established MRL for fosetyl in fresh herbs of 75 mg/kg.

The chronic and the short-term intake of fosetyl residues is unlikely to present a public health concern.

As far as consumer health protection is concerned, Germany agrees with the authorization of the intended use. A pre-planting interval of 30 days is recommended.

## Appendix 1 List of data submitted in support of the evaluation

**Table A 1: List of data submitted in support of the evaluation**

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR*
OECD: KIIA 6.3	Bacher R.	2012	Magnitude of FOSETYL-AI (Fosetyl-AI and its metabolite Phosphonic Acid) residues in herbs ID P 2430 G GLP: yes not published <a href="#">ASB2012-8355</a>	yes	LSA	Y
All	France	2003	Fosetyl (Draft Assessment Report) <a href="#">ASB2010-10342</a>			used
All	EFSA	2005	Conclusion regarding the peer review of the pesticide risk assessment of the active substance fosetyl, EFSA Scientific Report (2005) 54, 1-79 <a href="#">ASB2012-3677</a>			used

\* Y: Yes, relied on  
 N: No, not relied on  
 Add: Relied on, study not submitted by applicant but necessary for evaluation

## Appendix 2 Detailed evaluation of the additional studies relied upon

### A 2.1 Storage stability

No further study on storage stability submitted.

### A 2.2 Residues in primary crops

#### A 2.2.1 Nature of residues

No further study on nature of residues submitted.



### A 2.2.2 Magnitude of residues in fresh herbs

Reference:	OECD KIIA 6.3
Report	Magnitude of FOSETYL-Al (Fosetyl-Al and its metabolite Phosphonic Acid) residues in herbs; Bacher, R.; 2012; ID P 2430 G; <a href="#">ASB2012-8355</a>
Guideline(s):	Guidance to Dir. 91/414/EEC
Deviations:	no
GLP:	yes
Acceptability:	yes

**Table A 2: Residues of fosetyl in garden parsley**

<b>RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)</b> (Application on agricultural and horticultural crops)		Active ingredient	: Fosetyl
Federal Institute for Risk Assessment, Berlin Federal Republic of Germany		Crop / crop group	: Garden Parsley
Content of a.i. (g/kg or g/l) : 777 g/kg		Submission date	: 2012-06-05
Formulation (e.g. WP) : WG		Indoors / outdoors	: Outdoors (European North)
Commercial product (name) : (submitted to GV1 <b>043099-00/05</b> ) treated with Aliette WG (actual 777 g/kg Fosetyl-Al)		Other a.i. in formulation (content and common name)	:
Applicant : Landesanstalt für Landwirtschaft, Forsten und Gartenbau Sachsen-Anhalt, LSA		Residues calculated as	: 8.1 Phosphorous acid, calculated as Fosetyl 8.2 Fosetyl-Al (Aluminium tris-O-ethylphosphonate), calculated as Fosetyl 8.3 Fosetyl (sum Fosetyl-Al+Phosphorous acid and their salts)

1	2	3	4			5	6	7	8.1	8.2	8.3	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residue s (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl								
	(a)	(b)				(c)		(a)				(d)	(e)
PTRL Europe ID P 2430 G, 1LFSPE0111/03, trial LR-K-11-FK- F-05-ST-01  Germany 06406 Bernburg  2012-02-27	Mooskrause	1) 2011-04-08 (sowing) 2) 3) 2011-06-21- 2011-07-09	2.4 2.4	408 407	0.58 0.58	2011-07-12 2011-07-19 <sup>4)</sup>	BBCH 42	plant, fresh	5.4 5.1	<0.10 <0.10	<u>5.4</u> 5.1	21 28	4) spraying after 1 <sup>st</sup> cutting  analytical method: PTRL Bericht B 2430 G (HPLC- MS/MS), LOQ's: Fosetyl-Al 0.10 mg/kg, Phosphorous acid 0.20 mg/kg, max. sample storage: 5 months  <a href="#">ASB2012-8355</a>

- Remarks: (a) According to CODEX Classification / Guide  
(b) Only if relevant  
(c) Year must be indicated  
(d) Days after last application (Label pre-harvest interval, PHI, underline)  
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

Comments of zRMS:	Acceptable.
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**Table A 3: Residues of fosetyl in garden parsley**

**RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)**

(Application on agricultural and horticultural crops)

Active ingredient : Fosetyl  
 Crop / crop group : Garden Parsley

Federal Institute for Risk Assessment, Berlin  
 Federal Republic of Germany

Submission date : 2012-06-05

Content of a.i. (g/kg or g/l) : 746 g/kg  
 Formulation (e.g. WP) : WG  
 Commercial product (name) : (submitted to GV1 **043099-00/05**)  
 treated with Aliette WG (actual 746 g/kg Fosetyl-Al)

Indoors / outdoors : Outdoors (European North)  
 Other a.i. in formulation (content and common name) :

Applicant : Landesanstalt für Landwirtschaft, Forsten und Gartenbau  
 Sachsen-Anhalt, LSA

Residues calculated as : 8.1 Phosphorous acid, calculated as Fosetyl  
 8.2 Fosetyl-Al (Aluminium tris-O-ethylphosphonate), calculated as Fosetyl  
 8.3 Fosetyl (sum Fosetyl-Al+Phosphorous acid and their salts)

1 Report-No. Location incl. Postal code and date	2 Commodity/ Variety	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest	4 Application rate per treatment			5 Dates of treatments or no. of treatments and last date	6 Growth stage at last treatment or date	7 Portion analysed	8.1 Residues (mg/kg)	8.2 Residue s (mg/kg)	8.3 Residues (mg/kg)	9 PHI (days)	10 Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl								
	(a)	(b)				(c)		(a)				(d)	(e)
PTRL Europe ID P 2430 G, trial LR-K-11-FK- F-05-NRW-01  Germany 48147 Münster  2012-02-27	Gigante de Italia	1) 2011-04-22 (sowing) 2) 3) 2011-07-09	2.2 2.2	600 600	0.37 0.37	2011-07-18 2011-08-01 <sup>4)</sup>	BBCH 42-43	plant, fresh	6.6 4.1	<0.10 <0.10	<u>6.6</u> 4.1	21 28	4) spraying after 1 <sup>st</sup> cutting  analytical method: PTRL Bericht B 2430 G (HPLC- MS/MS), LOQ's: Fosetyl-Al 0.10 mg/kg, Phosphorous acid 0.20 mg/kg, max. sample storage: 5 months  <a href="#">ASB2012-8355</a>

Comments of zRMS:	Acceptable.
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**Table A 4: Residues of fosetyl in sage, common**

**RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)**  
 (Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin  
 Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 777 g/kg  
 Formulation (e.g. WP) : WG  
 Commercial product (name) : (submitted to GV1 **043099-00/05**)  
 treated with Aliette WG (actual 777 g/kg Fosetyl-Al)  
 Applicant : Landesanstalt für Landwirtschaft, Forsten und Gartenbau  
 Sachsen-Anhalt, LSA

Active ingredient : Fosetyl  
 Crop / crop group : Sage, Common

Submission date : 2012-06-05

Indoors / outdoors : Outdoors (European North)  
 Other a.i. in formulation (content and common name) :

Residues calculated as : 8.1 Phosphorous acid, calculated as Fosetyl  
 8.2 Fosetyl-Al (Aluminium tris-O-ethylphosphonate), calculated as Fosetyl  
 8.3 Fosetyl (sum Fosetyl-Al+Phosphorous acid and their salts)

1 Report-No. Location incl. Postal code and date	2 Commodity/ Variety	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest	4 Application rate per treatment			5 Dates of treatments or no. of treatments and last date	6 Growth stage at last treatment or date	7 Portion analysed	8.1 Residues (mg/kg)	8.2 Residues (mg/kg)	8.3 Residues (mg/kg)	9 PHI (days)	10 Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl								
	(a)	(b)				(c)		(a)			(d)	(e)	
PTRL Europe ID P 2430 G, R-WZ-2011- 21, trial LR-K- 11-FK-F-04- WET-01  Germany 35516 Münzenberg  2012-02-27	Unknown	1) 2011-05-24 (planting) 2) 3) 2011-08-16	2.4 2.4	600 600	0.39 0.40	2011-07-19 2011-07-26 <sup>4)</sup>	BBCH 45	plant, fresh	2.3 1.0	<0.10 <0.10	2.3 1.0	21 28	4) spraying  analytical method: PTRL Bericht B 2430 G (HPLC- MS/MS), LOQ's: Fosetyl-Al 0.10 mg/kg, Phosphorous acid 0.20 mg/kg, max. sample storage: 5 months  <a href="#">ASB2012-8355</a>

Comments of zRMS: Acceptable.

**Table A 5: Residues of fosetyl in sage, common**

**RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)**  
 (Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin  
 Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 746 g/kg  
 Formulation (e.g. WP) : WG  
 Commercial product (name) : (submitted to GV1 **043099-00/05**)  
 treated with Aliette WG (actual 746 g/kg Fosetyl-AI)  
 Applicant : Landesanstalt für Landwirtschaft, Forsten und Gartenbau  
 Sachsen-Anhalt, LSA

Active ingredient : Fosetyl  
 Crop / crop group : Sage, Common

Submission date : 2012-06-05

Indoors / outdoors : Outdoors (European North)  
 Other a.i. in formulation (content and common name) :

Residues calculated as : 8.1 Phosphorous acid, calculated as Fosetyl  
 8.2 Fosetyl-AI (Aluminium tris-O-ethylphosphonate), calculated as Fosetyl  
 8.3 Fosetyl (sum Fosetyl-AI+Phosphorous acid and their salts)

1 Report-No. Location incl. Postal code and date	2 Commodity / Variety	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest	4 Application rate per treatment			5 Dates of treatments or no. of treatments and last date	6 Growth stage at last treatment or date	7 Portion analysed	8.1 Residues (mg/kg)	8.2 Residues (mg/kg)	8.3 Residues (mg/kg)	9 PHI (days)	10 Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl								
	(a)	(b)				(c)		(a)			(d)	(e)	
PTRL Europe ID P 2430 G, R-WZ-2011-21, trial LR-K-11- FK-F-04-SN-01  Germany 01705 Freital/OT Wurgwitz  2012-02-27	Unknown	1) 2009-04-24 (planting) 2) 3) 2011-07-15	2.2 2.2	400 400	0.56 0.56	2011-04-29 2011-06-24 <sup>4)</sup>	BBCH 47-49	plant, fresh	3.2	<0.1	<u>3.2</u>	21	4) spraying  analytical method: PTRL Bericht B 2430 G (HPLC-MS/MS), LOQ's: Fosetyl-AI 0.10 mg/kg, Phosphorous acid 0.20 mg/kg, max. sample storage: 6 months  <a href="#">ASB2012-8355</a>

Comments of zRMS:	Acceptable
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**Table A 6: Residues of fosetyl in thyme, garden**

**RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)**

(Application on agricultural and horticultural crops)

Active ingredient : Fosetyl  
 Crop / crop group : Thyme, Garden

Federal Institute for Risk Assessment, Berlin  
 Federal Republic of Germany

Submission date : 2012-06-05

Content of a.i. (g/kg or g/l) : 777 g/kg  
 Formulation (e.g. WP) : WG  
 Commercial product (name) : (submitted to GV1 **043099-00/05**)  
 treated with Aliette WG (actual 777 g/kg Fosetyl-Al)

Indoors / outdoors : Outdoors (European North)  
 Other a.i. in formulation (content and common name) :

Applicant : Landesanstalt für Landwirtschaft, Forsten und Gartenbau  
 Sachsen-Anhalt, LSA

Residues calculated as : 8.1 Phosphorous acid, calculated as Fosetyl  
 8.2 Fosetyl-Al (Aluminium tris-O-ethylphosphonate), calculated as Fosetyl  
 8.3 Fosetyl (sum Fosetyl-Al+Phosphorous acid and their salts)

1 Report-No. Location incl. Postal code and date	2 Commodity/ Variety	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest	4 Application rate per treatment			5 Dates of treatments or no. of treatments and last date	6 Growth stage at last treatment or date	7 Portion analysed	8.1 Residues (mg/kg)	8.2 Residues (mg/kg)	8.3 Residues (mg/kg)	9 PHI (days)	10 Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl								
	(a)	(b)				(c)		(a)			(d)	(e)	
PTRL Europe ID P 2430 G, 1LFSTH0111/02, trial LR-K-11-FK-F- 06-ST-01  Germany 06406 Bernburg  2012-02-27	Deutscher Winter	1) 2010-04-08 (sowing) 2) 2011-05-06 3) 2011	2.5 2.3	421 396	0.58 0.58	2011-05-02 2011-05-09 <sup>4)</sup>	BBCH 48-61	plant, fresh	45.0 37.0	<0.10 <0.10	45.0 37.0	21 28	4) spraying  analytical method: PTRL Bericht B 2430 G (HPLC- MS/MS), LOQ's: Fosetyl-Al 0.10 mg/kg, Phosphorous acid 0.20 mg/kg, max. sample storage: 8 months  <a href="#">ASB2012-8355</a>

Comments of zRMS: Acceptable

**A 2.3            Residues in processed commodities**

No new study on residues in processed commodities has been submitted.

**A 2.4            Residues in rotational crops**

No new study on residues in rotational crops has been submitted.

**A 2.5            Residues in livestock**

No new study on residues in livestock has been submitted.

**A 2.6            Other studies/information**

None

### Appendix 3 Pesticide Residue Intake Model (PRIMo)

<b>Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)</b>				<b>Prepare workbook for refined calculations</b>	
Status of the active substance:		Code no.:			
LOQ (mg/kg bw):		proposed LOQ:			
<b>Toxicological end points</b>					
ADI (mg/kg bw/day):		3		ARfD (mg/kg bw):	
Source of ADI:		EFSA		n.n.	
Year of evaluation:		2008		Source of ARfD:	
				EFSA	
Year of evaluation:		2008		Year of evaluation:	
				2008	

Main choice of toxicological reference values.

➤ 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).

➤ pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment									
		TMDI (range) in % of ADI							
		minimum - maximum							
		10		61					
		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 LOC (in % of ADI)	
61,5	DE child	31,8	Pome fruit	11,5	Citrus fruit	4,2	Table and wine grapes		
44,3	NL child	16,9	Pome fruit	10,2	Citrus fruit	5,9	Potatoes		
40,5	WHO Cluster diet B	10,3	Tomatoes	7,1	Table and wine grapes	3,9	Citrus fruit		
28,5	FR toddler	7,2	Pome fruit	5,8	Citrus fruit	5,1	Potatoes		
28,6	IE adult	6,7	Citrus fruit	3,9	Table and wine grapes	3,7	Pome fruit		
26,5	PT General population	9,2	Table and wine grapes	5,3	Potatoes	3,5	Pome fruit		
23,2	FR all population	13,7	Table and wine grapes	1,6	Citrus fruit	1,5	Pome fruit		
21,4	SE general population 90th percentile	4,2	Potatoes	3,5	Pome fruit	3,5	Citrus fruit		
21,4	WHO cluster diet E	6,0	Table and wine grapes	3,8	Potatoes	2,6	Pome fruit		
21,3	UK Toddler	5,8	Citrus fruit	4,7	Pome fruit	3,5	Potatoes		
21,2	DK child	7,5	Pome fruit	4,1	Cucurbits - edible peel	2,4	Potatoes		
20,5	FR infant	7,0	Pome fruit	4,1	Potatoes	2,6	Citrus fruit		
19,6	WHO regional European diet	4,0	Potatoes	3,7	Tomatoes	2,1	Pome fruit		
19,5	ES child	5,9	Citrus fruit	4,1	Pome fruit	3,3	Tomatoes		
18,8	WHO cluster diet D	4,1	Potatoes	3,4	Tomatoes	2,2	Cucurbits - inedible peel		
18,7	NL general	4,6	Citrus fruit	3,4	Pome fruit	2,9	Table and wine grapes		
16,8	WHO Cluster diet F	3,4	Potatoes	2,8	Citrus fruit	2,4	Table and wine grapes		
15,9	ES adult	3,6	Citrus fruit	2,8	Pome fruit	2,6	Tomatoes		
15,6	UK Infant	4,5	Pome fruit	3,4	Citrus fruit	3,3	Potatoes		
15,2	PL general population	5,8	Pome fruit	3,4	Potatoes	2,9	Tomatoes		
15,1	IT kids/toddler	4,8	Tomatoes	3,1	Pome fruit	1,8	Citrus fruit		
13,9	UK vegetarian	3,0	Table and wine grapes	2,6	Citrus fruit	2,1	Tomatoes		
13,5	DK adult	4,9	Table and wine grapes	2,5	Pome fruit	1,5	Potatoes		
13,4	IT adult	3,9	Tomatoes	2,6	Pome fruit	1,4	Citrus fruit		
12,5	LT adult	5,1	Pome fruit	3,2	Potatoes	2,1	Tomatoes		
11,9	UK Adult	3,8	Table and wine grapes	1,7	Citrus fruit	1,5	Tomatoes		
9,6	FI adult	2,8	Citrus fruit	1,4	Tomatoes	1,2	Potatoes		

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Fosetyl-AI (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl) is unlikely to present a public health concern.