

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

**REGISTRATION REPORT**

**Part A**

**Risk Management**

**Product code: Betasana SC**  
**Active Substance: Phenmedipham 160 g/L**

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

**NATIONAL ASSESSMENT**

**Applicant: Pflanzenschutzdienst der  
Landwirtschaftskammer Nordrhein-Westfalen**

**Date: 01/07/2014**

## Table of Contents

<b>PART A – Risk Management</b> .....	<b>3</b>
<b>1 Details of the application</b> .....	<b>3</b>
1.1 Application background .....	3
1.2 Annex I inclusion .....	4
1.3 Regulatory approach .....	4
1.3.1 Uses applied for and registration decision .....	4
1.3.2 Public interest and minor use .....	4
1.4 Data protection claims .....	4
1.5 Letters of Access.....	4
<b>2 Details of the authorisation</b> .....	<b>5</b>
2.1 Product identity .....	5
2.2 Classification and labelling.....	5
2.2.1 Classification and labelling under Directive 99/45/EC or Regulation (EC) No 1272/2008.....	5
2.2.2 R and S phrases under Regulation (EC) No 547/2011 .....	5
2.2.3 Other phrases.....	5
2.2.3.1 Restrictions linked to the PPP.....	5
2.2.3.2 Specific restrictions linked to the intended uses .....	6
2.3 Product uses .....	8
<b>3 Risk management</b> .....	<b>9</b>
3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles .....	9
3.1.1 Physical and chemical properties .....	9
3.1.2 Methods of analysis.....	9
3.1.2.1 Analytical method for the formulation .....	9
3.1.2.2 Analytical methods for residues .....	9
3.1.3 Mammalian Toxicology .....	9
3.1.4 Residues and Consumer Exposure .....	9
3.1.4.1 Residues.....	9
3.1.4.2 Consumer exposure .....	9
3.1.5 Environmental fate and behaviour .....	9
3.1.6 Ecotoxicology .....	10
3.1.7 Efficacy .....	10
3.2 Conclusions.....	10
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 .....	11
<b>Appendix 1 – Copy of the product authorisation</b> .....	<b>11</b>
<b>Appendix 2 – Copy of the product label</b> .....	<b>11</b>
<b>Appendix 3 – Letter of Access</b> .....	<b>11</b>

## PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of Betasana SC containing Phenmedipham 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 Betasana SC have been made using endpoints agreed in the EU reviews of Phenmedipham.

Appendix 1 of this document provides a copy of the final product authorisation in Germany.  
See below

### 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>Betasana SC</b>
Type of application	Zonal application according to Article 51, ZRMS=DE, first application (GV1)
Registration number	005328-00/04
Applicant	Pflanzenschutzdienst der Landwirtschaftskammer Nordrhein-Westfalen, Siebengebirgsstraße 200, 53229 Bonn, Deutschland
Authorisation holder	United Phosphorus Ltd. The Centre, Birchwood Park, WA3 6YN Warrington, UK
Function	Herbicide
Type of formulation	Suspension concentrate
Expiration of authorisation	2014-12-31

## 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)

### **Phenmedipham (0233)**

Content in PPP	160 g/l
Approval status	Approved according to Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	31/07/2017

## 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

<b>Number of use</b>	<b>Plant/commodity/object</b>	<b>Harmful organism/purpose</b>	<b>decision</b>
001	spinach and related species, beta beets (red, yellow, white beet)	annual bluegrass, annual dicotyledonous weeds	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 spinach and related species, beta beets (red, yellow, white beet) is about 200 ha, of which approx. 160 ha need to be controlled. Calculation shows that authorisation holder will not profit from an authorisation of the requested use.

Upon this calculation and the examination of available alternative measures for the applied use it can be stated that the applied use 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	Betasana SC
Authorisation number	005328-00
Composition	Phenmedipham 160 g/L
Type of formulation	Suspension concentrate (SC)
Function	Herbicide
Authorisation holder	United Phosphorus Ltd.

### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling under Directive 99/45/EC

N	Dangerous for the environment
Xi	Irritant
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R36	Irritating to eyes
R43	May cause sensitisation by skin contact
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S2	Keep out of the reach of children
S24	Avoid contact with skin
S35	This material and its container must be disposed of in a safe way.
S46	If swallowed, seek medical advice immediately and show this container or label
S57	Use appropriate container to avoid environmental contamination.
SP001	To avoid risks to man and the environment, comply with the instructions for use.

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

None.

#### 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.
SE110	Wear tight fitting eye protection when handling the undiluted product.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.

SS2101 Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.

SS610 Wear a rubber apron when handling the undiluted product.

#### **Ecosystem protection**

NW262 The product is toxic for algae.

NW264 The product is toxic for fish and aquatic invertebrates.

NW265 The product is toxic for higher aquatic plants.

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.

NW604 The direction for use which determined a certain distance to protect surface waters does not apply in areas which are specifically identified by the designated authority, as long as the authority has authorised the application there.

#### **Honeybee**

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

Mode of action (HRAC-Group): C1

#### **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)**

NN164 The product is classified as harmless for populations of the species *Bembidion lampros* (ground beetle).

NN135 The product is classified as harmless for populations of the species *Erigone atra* (erigonid spider).

### **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**

NW605-1 When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all

times for drift reduction classes marked with "\*".

50 %: 19 m, 75 %: 5 m, 90 %: 5 m

NW606 The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro.

15 m.

## 2.3 Product uses

**PPP (product name/code) active substance 1**      **Betasana SC (005328-00) Phenmedipham**      **Formulation type:**      **SC**  
**Conc. of as 1:**      **160 g/L**  
  
**safener**      -      **Conc. of safener:**      -  
**synergist**      -      **Conc. of synergist:**      -  
  
**Applicant:**      **Pflanzenschutzdienst der Landwirtschaftskammer Nordrhein-Westfalen**      **professional use**        
**Zone(s):**      **central EU**      **non professional use**        
  
**Verified by MS:** y

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	spinach and related species (NNNSA), beta beets (red, yellow, white beet) (BEAVX)	F	annual bluegrass (POAAN), annual dicotyledonous weeds (TTTDS),	spraying	after emergence	a) 1 b) 1	a) 1 L/ha b) 1 L/ha	a) 160 g as/ha  b) 160 g as/ha	200 - 400	28	Restrictions (see 2.2.3.2) N605-1, NW606 utilisation as baby leaf salat ..

### **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**

Leaves of spinach and related species and beta beets belong to the group of high water content commodities. Acceptable analytical methods in babyleaf salads are available for enforcing phenmedipham residues.

##### **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 phenmedipham has been evaluated within the EU review process. Information about metabolism is sufficient to evaluate the intended use in babyleaf salads.

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

The intended use was assigned to baby leaf plants to be utilized as salad, i.e. up to the 8 true-leaf stage. In ten supervised field trials on spinach treated at exaggerated application rates in comparison to the intended use, no quantifiable residues of phenmedipham were determined at a PHI of 28 days. An exceedance of the current MRLs of 0.05\* mg/kg for phenmedipham in leaves and sprouts of brassica and of 0.5 mg/kg in spinach as laid down in Reg. (EU) 396/2005 are not expected.

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

Long-term exposure:

The assessment of uptake of phenmedipham residues by consumers (TMDI calculation, EFSA PRIMo and NTMDI calculation, German NVS II) results in the following maximum ADI (0.03 mg/kg bw/d) consumptions:

TMDI = 15.5 % (UK toddler)

NTMDI = 15.8 % (DE child)

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

Short-term exposure:

Based on the acute toxicity of phenmedipham no ARfD has been allocated. Therefore, no acute risk is expected from the consumption of babyleaf salads 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 005328-00/00 according the uniform principles of directive 91/414/EEC.

According to modelling results considering use patterns as laid down in 2.3 entries into groundwater of the active substance above 0.1 µg/L can be excluded. Special risk mitigation measures to protect the environment are not necessary.

### 3.1.6 Ecotoxicology

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 005328-00/00 according the uniform principles of directive 91/414/EEC.

The PPP Betasana SC and the active substance phenmedipham are toxic to the aquatic environment (PPP: *Daphnia magna* EC<sub>50</sub>(2 d): 87 µg/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, NW264, NW265, NW468, NW605-1 and NW606 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 applied for under the terms of Article 51 of regulation (EC) No 1107/2009.
- The categories and labelling for mode of action for the main application cover the use 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 Betasana SC 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 use.

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 MRLs of 0.05\* mg/kg in leaves and sprouts of Brassica spp. and of 0.5 mg/kg in spinach set in Regulation (EC) No 396/2005 for phenmedipham. The chronic and the short-term intake of phenmedipham residues are unlikely to present a public health concern. As far as consumer health protection is concerned, it is agreed with the authorisation of the intended use. 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.

**An authorisation can be granted.**

### **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**

See below

#### **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 200.22200.005328-00/04.83124  
(bitte bei Antwort angeben)

DATUM 9. Juli 2014

**GV1 005328-00/04**

**Betasana SC**

**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: 160 g/l Phenmedipham

Zulassungsnummer: 005328-00

Versuchsbezeichnung: CHD-02001-H-0-SC

Antrag vom: 6. Mai 2013

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
005328-00/04-001	Einjährige zweikeimblättrige Unkräuter	Beten (Rote, Gelbe, Weiße Bete), Spinat und verwandte Arten	

### **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), zuletzt geändert durch Artikel 4 Absatz 87 des Gesetzes vom 7. August 2013 (BGBl. I S. 3154) festgesetzt:

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

### **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 -

## **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: 005328-00/04-001

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einjährige zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Beten (Rote, Gelbe, Weiße Bete), Spinat und verwandte Arten

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und Kleingartenbereich: Nein

Erläuterung zur Kultur: Nutzung als baby leaf - Salate

Anwendungszeitpunkt: Nach dem Auflaufen

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 1

Anwendungstechnik: spritzen

Aufwand:

- 1 l/ha in 200 bis 400 l Wasser/ha

#### 2.2 Sonstige Kennzeichnungsauflagen

- keine -

#### 2.3 Wartezeiten

28 Tage Freiland: Beten (Rote, Gelbe, Weiße Bete)

28 Tage Freiland: Spinat und verwandte Arten

### 3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "\*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in

jedem Fall zu beachten.

reduzierte Abstände: 50 % 10 m, 75 % 5 m, 90 % 5 m

Begründung:

Das o.g. Pflanzenschutzmittel bzw. der darin enthaltene Wirkstoff Phenmedipham besitzt ein hohes Gefährdungspotenzial für aquatische Organismen. Bewertungsbestimmend ist hier die EC50 (2 d, stat) von 87 µg/l an Daphnia magna mit dem Präparat. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 100 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von Gewässerorganismen zu gewährleisten.

(NW606)

Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

15 m

Begründung:

Siehe NW605-1.

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

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

**Product code: Betasana SC**  
**Active Substance: 160 g/L Phenmedipham**

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

**CORE ASSESSMENT**

**Applicant: Landwirtschaftskammer NRW**  
**Date: 01/07/2014**

## Table of Contents

4	METABOLISM AND RESIDUES DATA .....	3
4.1	Evaluation of the active substances .....	3
4.2	Evaluation of the intended use(s) .....	3
4.2.1	Selection of critical use and justification .....	3
4.2.2	Baby leaf salad (extrapolated from spinach) .....	5
4.2.2.1	Residues in primary crops .....	5
4.2.2.2	Distribution of the residue in peel/pulp .....	5
4.2.2.3	Residues in processed commodities .....	5
4.2.2.4	Proposed pre-harvest intervals, withholding periods.....	5
4.3	Consumer intake and risk assessment.....	5
4.4	Proposed maximum residue levels (MRLs).....	6
4.5	Conclusion .....	6
Appendix 1	List of data submitted in support of the evaluation .....	7
Appendix 2	Detailed evaluation of the additional studies relied upon.....	7
A 2.1	Storage stability .....	7
A 2.2	Residues in primary crops .....	7
A 2.2.1	Nature of residues .....	7
A 2.2.2	Magnitude of residues in Spinach.....	8
A 2.3	Residues in processed commodities .....	15
A 2.4	Residues in rotational crops.....	15
A 2.5	Residues in livestock .....	15
A 2.6	Other studies/information .....	15
Appendix 3	Pesticide Residue Intake Model (PRIMo) .....	16

## **4 METABOLISM AND RESIDUES DATA**

### **4.1 Evaluation of the active substances**

Not detailed in the context of this assessment. Data on phenmedipham has been previously evaluated at EU level and described in detail in the DAR by Finland ([ASB2010-10239](#)).

### **4.2 Evaluation of the intended use(s)**

#### **4.2.1 Selection of critical use and justification**

The critical GAP used for consumer intake and risk assessment is presented in Table 4.2-1.

**Table 4.2-1: 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)	L 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		
001	DE	Beta beets (red, yellow, white beet), spinach and similar  <b>utilization as baby leaf salad</b>	F	Annual dicotyledonous weeds	spraying	after emergence	a) 1 b) 1	a) 1.0 L/ha b) 1.0 L/ha	a) 0.16 kg/ha b) 0.16 kg/ha	200-400	28	baby leaf salad harvested up to 8 true leaf stage (Code 0251080)

- 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

## 4.2.2 Baby leaf salad (extrapolated from spinach)

### 4.2.2.1 Residues in primary crops

The following table gives a brief overview of the supervised residue trials selected for the assessment of phenmedipham in spinach, harvested at baby leaf stage. For the detailed evaluation of new/additional residue trials, it is referred to Appendix 2.

**Table 4.2-2: Overview of the selected supervised residue trials for phenmedipham in baby leaf crops**

Commodity	Region <sup>(a)</sup>	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) <sup>(b)</sup>	HR (mg/kg) <sup>(c)</sup>	Median CF <sup>(d)</sup>
			Enforcement (phenmedipham)	Risk assessment (phenmedipham)			
Spinach, harvested at baby leaf stage	NEU	Outdoor	5 x <0.05	5 x <0.05	0.05	0.05	1

(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.

Two studies were available ([ASB2013-10282](#), [RIP2006-327](#)), each reporting the results of various trials on the magnitude of phenmedipham residues in spinach leaves. Plots received treatments that were unexceptionally overdosed in terms of application rates (0.32 to 0.63 kg as/ha). Moreover, some plots were treated twice (interval of 5-6 days) instead of a single treatment as outlined in the proposed use conditions of the GAP. Despite the more critical conditions, observed phenmedipham residues in leaf were consistently below the analytical LOQ of 0.05 mg/kg at 28 DAA.

On the other hand, not all plots can be considered to represent a sufficient degree of spatial and temporal variability. Depending on stringency of criteria of independence, a varying number of trials can be interpreted as sufficiently independent. In the end five trials were selected for evaluation of the use and check for compliance with the existing legal limit.

Analytical methods for commodities of high water content such as leaves and sprouts of Brassica are available and acceptable for enforcing all compounds given in the residue definition. Storage stability studies in sugar beet roots and tops were demonstrating that phenmedipham residues are stable for up to two years when stored under deep freeze conditions (DAR by FIN, [ASB2010-10239](#)). Specimens were not stored for longer than that period prior to analysis.

### 4.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

### 4.2.2.3 Residues in processed commodities

No residue data were available or necessary.

### 4.2.2.4 Proposed pre-harvest intervals, withholding periods

The suggested pre-harvest interval (PHI) of 28 days is acceptable and sufficiently supported by the field residue studies.

## 4.3 Consumer intake and risk assessment

The consumer intake and risk assessment is based on the appropriate input values given in Table 4.3-1 and the toxicological reference values stated in Table 4.3-2. For the detailed calculation results it is referred to Appendix 3.

**Table 4.3-1: 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
Leaves and sprouts of Brassica spp. (0251080)	0.05	MRL	ARFD not allocated, not necessary	
other commodities in annex I to Regulation (EC) No 396/2005	various	MRLs as set out in Regulation (EU) No 149/2008		

**Table 4.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)**

ADI	0.03 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	15.5 % (based on UK toddler, 14.5 kg mean body weight)
NTMDI (% ADI) according to DE NVS II model	15.8 % (based on children 2-4 years, individual consumption/body weight ratio)
IEDI (EFSA PRIMo) (% ADI)	Not necessary
NEDI (DE NVS II model) (% ADI)	Not necessary
Factors included in IEDI and NEDI	Not applicable
ARfD	Not necessary, due to low acute toxicity (no ARfD is allocated)
IESTI (EFSA PRIMo) (% ARfD)	
NESTI (DE NVS II model) (% ARfD)	
Factors included in IESTI and NESTI	

#### **4.4 Proposed maximum residue levels (MRLs)**

No new MRLs are required.

#### **4.5 Conclusion**

The intended use was assigned to baby leaf plants utilized as salad, i.e. up to the 8 true-leaf stage (coded 0251080 in Commission Regulation (EUC) No 600/2010). In ten supervised field trials on spinach treated at exaggerated application rates in comparison to the intended use, no quantifiable residues of phenmedipham were determined at a PHI of 28 day. Since baby leaf is a minor crop, four trials are deemed sufficient to meet the minimum requirements of the EU guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (SANCO 7525/VI/95 revision 9).

An exceedance of the current MRL of 0.05 mg/kg for phenmedipham in leaves and sprouts of brassica (code 0251080) as laid down in Reg. (EU) 396/2005 is not expected.

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

As far as consumer health protection is concerned, the BfR/Germany agrees with the authorization of the intended use.

## 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 Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
All	Finland	1999	phenmedipham (Monograph) December 1999 GLP: Open Published: Yes <a href="#">ASB2010-10239</a>	Open		Add
KIIA 6.3	Moede, J.	1996	Phenmedipham Betanal, emulsifiable concentrate 157 g/l Code: CQ 532 Residues of Phenmedipham in spinach, Germany 1995 Field trial no.: GR 503, 504, 505, 506 CR 96/004 ! PMP R180 GLP: Yes Published: No BVL-2466022, <a href="#">ASB2013-10282</a>	Yes	BAY	Y
KIIA 6.3	Wienhold, C.	1983	Residues of Phenmedipham in spinach from Netherlands R48 ! II/83, R+S 43/83-PA 38 584.64/9 GLP: Yes Published: No BVL-2466046, <a href="#">RIP2006-327</a>	Yes	BAY	Y
	Anonym	2013	Phenmedipham / Betasana SC: Zusammenfassung der Guten Landwirtschaftlichen Praxis nach Anwendung von Pflanzenschutzmitteln - Spinat und verwandte Arten, Beten (Rote, Weiße, Gelbe) <a href="#">ASB2013-10281</a>		GO1	Add

Y        yes  
 Add    additional

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

### A 2.1 Storage stability

No further study on storage stability submitted/needed.

### A 2.2 Residues in primary crops

#### A 2.2.1 Nature of residues

No further study on nature of residues submitted/needed.

### A 2.2.2 Magnitude of residues in Spinach

Reference:	OECD KIIA 6.3
Report	<a href="#">ASB2013-10282</a>
Guideline(s):	BBA Richtlinien für die Prüfung von Pflanzenschutzmitteln im Zulassungsverfahren – Allgemeine Hinweise zur Planung, Anlage und Durchführung von Rückstandsversuchen BBA Rückstandsuntersuchungen – Richtlinie für Feldversuche und Probenahme, Merkblatt 41 IVA Richtlinien, Rückstandsversuche Teil I: Prüfungen an Pflanzen, A: Allgemeiner und spezieller Teil
Deviations:	No
GLP:	Yes
Acceptability:	Yes

#### Table A 2: Residues of phenmedipham in spinach

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

Active ingredient : Phenmedipham  
Crop / crop group : Spinach

Federal Institute for Risk Assessment, Berlin  
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 157 g/L  
Formulation (e.g. WP) : EC (Emulsifiable concentrate)  
Commercial product (name) : Betanal  
Applicant : Landwirtschaftskammer Nordrhein-Westfalen

Indoors / Outdoors : Outdoors (European North)  
Other a.i. in formulation (content and common name) :  
Residues calculated as : 8.1 Phenmedipham  
8.2 MHPC

Betasana SC - 005328-00/04  
Part B – Section 4 - Core Assessment  
zRMS version

1	2	3	4			5	6	7	8.1	8.2	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)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
Doc.No. PMP R180, study CR 96/004, trial GR 503  Germany 46359 Heiden (Borken)  1996-04-03	spinach / Correnta	1) 1995-05-06 (sowing) 2) 3) 1995-06-19	0.31	200	0.16	1995-05-22 <sup>4)</sup>	BBCH 10	whole plant  leaf	26.0 0.23 <0.050 <b>&lt;0.050</b>	0.36 <0.050 <0.050 <0.050	0 7 21 28	4) spraying  analytical method: Schering method PF-R 93 080 (HPLC-UV), LOQ: 0.05 mg/kg, max. sample storage time in month(s):7  <a href="#">ASB2013-10282</a>
Doc.No. PMP R180, study CR 96/004, trial GR 504  Germany 46359 Heiden (Borken)  1996-04-03	spinach / Correnta	1) 1995-05-06 (sowing) 2) 3) 1995-06-19	0.31	200	0.16	1995-05-22 <sup>4)</sup>	BBCH 10	whole plant  leaf	15.0 0.18 <0.050 <b>&lt;0.050</b>	0.21 <0.050 <0.050 <0.050	0 7 21 28	4) spraying  analytical method: Schering method PF-R 93 080 (HPLC-UV), LOQ: 0.05 mg/kg, max. sample storage time in month(s):7  <a href="#">ASB2013-10282</a>
Doc.No. PMP R180, study CR 96/004, trial GR 505  Germany 46359 Heiden (Borken)  1996-04-03	spinach / Bolero	1) 1995-08-10 (sowing) 2) 3) 1995-09-28	0.31	300	0.10	1995-08-31 <sup>4)</sup>	BBCH 14-15	whole plant  leaf	32.0 <0.050 0.090 <b>&lt;0.050</b>	0.44 0.080 <0.050 <0.050	0 7 21 28	4) spraying  analytical method: Schering method PF-R 93 080 (HPLC-UV), LOQ: 0.05 mg/kg, max. sample storage time in month(s):2  <a href="#">ASB2013-10282</a>

1	2	3	4			5	6	7	8.1	8.2	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)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
Doc.No. PMP R180, study CR 96/004, trial GR 506  Germany 46359 Heiden (Borken)  1996-04-03	spinach / Bolero	1) 1995-08-10 (sowing) 2) 3) 1995-09-28	0.31	300	0.10	1995-08-31 <sup>4)</sup>	BBCH 14-15	whole plant  leaf	18.0 0.90 0.060 <u>&lt;0.050</u>	0.37 0.060 <0.050 <0.050	0 7 21 28	4) spraying  analytical method: Schering method PF-R 93 080 (HPLC-UV), LOQ: 0.05 mg/kg, max. sample storage time in month(s):2  <a href="#">ASB2013-10282</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:	The trials are acceptable although they represent a situation worse than indicated by the GAP.
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Reference: OECD KIIA 6.3  
 Report [RIP2006-327](#)  
 Guideline(s): Not stated  
 Deviations: Not applicable  
 GLP: No  
 Acceptability: No

**Table A 3: Residues of phenmedipham in spinach**

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

Active ingredient : Phenmedipham  
Crop / crop group : Spinach

Federal Institute for Risk Assessment, Berlin  
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 157 g/L  
Formulation (e.g. WP) : EC (Emulsifiable concentrate)  
Commercial product (name) : Betanal  
Applicant : Bayer CropScience

Indoors / Outdoors : Outdoors (European North)  
Other a.i. in formulation (content and common name) :  
Residues calculated as : Phenmedipham

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 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)	
study R 48, trial 1983/326-1, plot 1 Harvest trial  The Netherlands Geesburg  1983-10-31	spinach / Mediana	1) 1983-04-18 (sowing) 2) 3) 1983	0.39	300	0.13	1983-05-10 <sup>4)</sup>	BBCH 12	leaf	0.20 0.10 <b>&lt;0.050</b> <0.050	14 20 27 34	4) spraying  analytical method: A61343, M- 144899-01-1 (GC-ECD), LOQ: 0.05 mg/kg, max. sample storage time in month(s): 5  <b>exaggerated application rates</b>  <a href="#">RIP2006-327</a>
study R 48, trial 1983/326-2, plot 2 Harvest trial  The Netherlands Geesburg  1983-10-31	spinach / Mediana	1) 1983-04-18 (sowing) 2) 3) 1983	0.39 0.39	300 300	0.13 0.13	1983-05-10 <sup>4)</sup> 1983-05-16 <sup>4)</sup>	BBCH 12	leaf	0.53 0.34 0.064 <b>&lt;0.050</b>	8 14 21 28	4) spraying  analytical method: A61343, M- 144899-01-1 (GC-ECD), LOQ: 0.05 mg/kg, max. sample storage time in month(s): 5  <b>exaggerated application rates</b>  <a href="#">RIP2006-327</a>

Betasana SC - 005328-00/04  
Part B – Section 4 - Core Assessment  
zRMS version

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study R 48, trial 1983/326-3, plot 3 Harvest trial  The Netherlands Geesburg  1983-10-31	spinach / Mediana	1) 1983-04-18 (sowing) 2) 3) 1983	0.63	300	0.21	1983-05-10 <sup>4)</sup>	BBCH 12	leaf	0.29 0.14 <b>&lt;0.050</b> <b>&lt;0.050</b>	14 20 27 34	4) spraying  analytical method: A61343, M- 144899-01-1 (GC-ECD), LOQ: 0.05 mg/kg, max. sample storage time in month(s): 5  <b>exaggerated application rates</b>  <a href="#">RIP2006-327</a>
study R 48, trial 1983/338-1, plot 1 Harvest trial  The Netherlands Geesburg  1983-10-31	spinach / Mediana	1) 1983-05-10 (sowing) 2) 3) 1983	0.39	300	0.13	1983-06-06 <sup>4)</sup>	BBCH 12	leaf  <b>controls &gt; LOQ</b> leaf	1.6 0.30  0.12	10 16  10	4) spraying  analytical method: A61343, M- 144899-01-1 (GC-ECD), LOQ: 0.05 mg/kg, max. sample storage time in month(s): 6  <b>intended PHI not documented, controls &gt; LOQ</b>  <a href="#">RIP2006-327</a>
study R 48, trial 1983/338-2, plot 2 Harvest trial  The Netherlands Geesburg  1983-10-31	spinach / Mediana	1) 1983-05-10 (sowing) 2) 3) 1983	0.39 0.39	300 300	0.13 0.13	1983-06-06 <sup>4)</sup> 1983-06-10 <sup>4)</sup>	BBCH 14	leaf  <b>controls &gt; LOQ</b> leaf	6.0 0.94  0.13	6 12  6	4) spraying  analytical method: A61343, M- 144899-01-1 (GC-ECD), LOQ: 0.05 mg/kg, max. sample storage time in month(s): 6  <b>intended PHI not documented, controls &gt; LOQ</b>  <a href="#">RIP2006-327</a>

Betasana SC - 005328-00/04  
Part B – Section 4 - Core Assessment  
zRMS version

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study R 48, trial 1983/338-3, plot 3 Harvest trial  The Netherlands Geesburg  1983-10-31	spinach / Mediana	1) 1983-05-10 (sowing) 2) 3) 1983	0.63	300	0.21	1983-06-06 <sup>4)</sup>	BBCH 12	leaf	1.7 0.35	10 16	4) spraying  analytical method: A61343, M- 144899-01-1 (GC-ECD), LOQ: 0.05 mg/kg, max. sample storage time in month(s): 6  <b>intended PHI not documented</b>  <a href="#">RIP2006-327</a>
study R 48, trial 1983/341-1, plot 1 Harvest trial  The Netherlands De Krim  1983-10-31	spinach / Norvak	1) 1983-06-18 (sowing) 2) 3) 1983	0.39	300	0.13	1983-06-25 <sup>4)</sup>	BBCH 12	leaf  controls > LOQ leaf	0.21 <0.050 <b>&lt;0.050</b> 0.094	12 19 25 12	4) spraying  analytical method: A61343, M- 144899-01-1 (GC-ECD), LOQ: 0.05 mg/kg, max. sample storage time in month(s): 5  <b>controls &gt; LOQ</b>  <a href="#">RIP2006-327</a>
study R 48, trial 1983/341-2, plot 2 Harvest trial  The Netherlands De Krim  1983-10-31	spinach / Norvak	1) 1983-06-18 (sowing) 2) 3) 1983	0.39 0.39	300 300	0.13 0.13	1983-06-25 <sup>4)</sup> 1983-06-30 <sup>4)</sup>	BBCH 12	leaf	1.1 0.087 <b>&lt;0.050</b>	7 14 20	4) spraying  analytical method: A61343, M- 144899-01-1 (GC-ECD), LOQ: 0.05 mg/kg, max. sample storage time in month(s): 5  <b>intended PHI not documented</b>  <a href="#">RIP2006-327</a>

Betasana SC - 005328-00/04

Part B – Section 4 - Core Assessment

zRMS version

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study R 48, trial 1983/341-3, plot 3 Harvest trial  The Netherlands De Krim  1983-10-31	spinach / Norvak	1) 1983-06-18 (sowing) 2) 3) 1983	0.63	300	0.21	1983-06-25 <sup>4)</sup>	BBCH 12	leaf  controls > LOQ leaf	0.26 <0.050 <b>&lt;0.050</b> 0.11	12 19 25 12	4) spraying  analytical method: A61343, M- 144899-01-1 (GC-ECD), LOQ: 0.05 mg/kg, max. sample storage time in month(s): 5  <b>controls &gt; LOQ</b>  <a href="#">RIP2006-327</a>

Comments of zRMS:	Not acceptable due to various deviations concerning relevant key parameters of the GAP like application rate, treatment frequency and/or PHI. Furthermore, the study was not conducted in compliance with GLP.
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**A 2.3**            **Residues in processed commodities**

No new study on residues in processed commodities has been submitted/(and) none is needed due to low residues at harvest.

**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>Phenmedipham (R)</b>	
Status of the active substance:	Code no.
LOQ (mg/kg bw):	proposed LOQ:
<b>Toxicological end points</b>	
ADI (mg/kg bw/day):	ARfD (mg/kg bw):
Source of ADI:	Source of ARfD:
Year of evaluation:	Year of evaluation:
	n.n. SANCO 2004

Explain choice of toxicological reference values.  
 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.

		<b>Chronic risk assessment</b>						
		TMDI (range) in % of ADI minimum - maximum						
		No of diets exceeding ADI: 2 ----- 16						
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)
15.5	UK Toddler	7.6	Sugar beet (root)	3.4	Milk and cream,	0.9	Oilseeds	
13.7	UK Infant	6.5	Milk and cream,	3.4	Sugar beet (root)	0.8	CEREALS	
12.5	FR toddler	6.6	Milk and cream,	1.2	Spinach & similar (leaves)	0.8	Potatoes	
11.7	NL child	4.9	Milk and cream,	1.1	Pome fruit	1.0	Potatoes	
10.4	DE child	2.4	Milk and cream,	2.1	Herbs	1.0	Herbs	
9.5	WHO Cluster diet B	2.0	CEREALS	1.1	Herbs	1.0	Fruiting vegetables	
8.2	FR Infant	4.3	Milk and cream,	0.7	Spinach & similar (leaves)	0.7	Potatoes	
7.6	IE adult	1.1	CEREALS	1.0	Herbs	0.6	Tropical root and tuber vegetables	
7.0	SE general population 90th percentile	2.1	Milk and cream,	0.8	CEREALS	0.7	Meat, preparations of meat, offals,	
6.8	DK child	2.1	Milk and cream,	1.7	CEREALS	0.7	Meat, preparations of meat, offals,	
6.5	WHO cluster diet E	1.2	Herbs	1.0	CEREALS	0.6	Potatoes	
6.5	WHO cluster diet D	1.6	Herbs	1.4	CEREALS	0.6	Meat, preparations of meat, offals,	
6.3	ES child	2.1	Milk and cream,	0.9	CEREALS	0.7	Milk and cream,	
5.5	WHO regional European diet	0.8	Herbs	0.8	CEREALS	0.7	Meat, preparations of meat, offals,	
4.6	WHO Cluster diet F	0.9	CEREALS	0.7	Milk and cream,	0.6	Potatoes	
4.2	PT General population	0.9	CEREALS	0.9	Potatoes	0.5	Table and wine grapes	
4.0	UK Adult	1.3	Sugar beet (root)	0.5	Milk and cream,	0.4	Oilseeds	
4.0	NL general	1.1	Milk and cream,	0.5	CEREALS	0.5	Potatoes	
3.7	UK vegetarian	1.3	Sugar beet (root)	0.5	Milk and cream,	0.5	CEREALS	
3.6	ES adult	0.8	Milk and cream,	0.5	Milk and cream,	0.4	CEREALS	
3.5	IT kids/toddler	1.4	CEREALS	0.5	Herbs	0.4	Meat, preparations of meat, offals,	
3.3	FR all population	0.7	Table and wine grapes	0.6	CEREALS	0.4	Fruiting vegetables	
3.0	IT adult	0.8	CEREALS	0.6	Herbs	0.4	Milk and cream,	
3.0	DK adult	0.9	Milk and cream,	0.6	CEREALS	0.4	Spinach & similar (leaves)	
2.7	LT adult	0.7	Milk and cream,	0.5	CEREALS	0.3	Meat, preparations of meat, offals,	
2.5	FI adult	0.9	Milk and cream,	0.3	Potatoes	0.5	CEREALS	
1.9	PL general population	0.6	Potatoes	0.4	Pome fruit	0.2	Potatoes	
<p><b>Conclusion:</b>                  The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs, were below the ADI.                  A long-term intake of residues of Phenmedipham (R) is unlikely to present a public health concern.</p>								