

## REASONED OPINION OF EFSA

### Modification of the existing MRLs for boscalid in gherkins and courgettes<sup>1</sup>

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00643)

Issued on 20 July 2009

#### SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, Belgium, hereafter referred to as the Evaluating Member State (EMS), compiled an application to modify the existing MRLs for boscalid in courgettes and gherkins. In order to accommodate for a new uses of boscalid in Belgium, it is proposed to raise the existing MRL of 0.2 mg/kg for gherkins and courgettes to 2.0 mg/kg. Belgium also intends to authorize the use on kohlrabi, but no MRL proposal was made since the intended use does not require raising of the existing MRL of 0.5 mg/kg.

Belgium drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 29 May 2009. EFSA derives the following conclusions regarding the application, based on the above mentioned evaluation report as well as the Draft Assessment Report prepared by Germany.

The toxicological profile of boscalid was investigated in the peer review and the data were sufficient to conclude in an ADI value of 0.04 mg/kg bw/d. ARfD value was not established as boscalid does not possess acute toxicological properties.

The metabolism of boscalid in primary crops is elucidated in fruits and fruiting vegetables, leafy vegetables, pulses and oilseeds and the risk assessment and enforcement residue definition is established as parent boscalid. Consequently, the MRL application does not require additional metabolism studies. Adequate analytical methods are available to enforce the proposed MRLs.

Boscalid is known to be persistent in the soil and therefore boscalid residues might occur in succeeding crops in amounts exceeding 0.01 mg/kg. Taking that into account, the MRL setting for boscalid in annual crops requires consideration of possible boscalid residues in crop when it is grown as a primary crop and when it is grown as a rotational crop. Submitted supervised residue trials data on gherkins and courgettes indicate that a higher MRL of 3.0 mg/kg than requested by the EMS (2.0 mg/kg) would be necessary to accommodate the intended GAP in Belgium. The MRL proposal is expected to cover also the residues originating in these crops when they are grown as rotational crops. Supervised residue trials

<sup>1</sup> For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRLs for boscalid in gherkins and courgettes. *EFSA Scientific Report* (2009) 335, 1-28

data on kohlrabi would not require amendment of the existing MRL 0.5 mg/kg which was set in the peer review as a default value to cover possible occurrence of boscalid residues in rotational crops in cases where no specific residue trials or rotational crop study data are available. Submitted residue trials on kohlrabi indicate that an MRL of 0.1 mg/kg would be sufficient when kohlrabi is grown as a primary crop. However, no information is available to EFSA concerning the most critical GAPs in primary crops to make a realistic estimation of boscalid residues occurring in kohlrabi when it is grown as a rotational crop. EFSA will assess this aspect in detail in the framework of the review of the existing MRLs for boscalid according to Article 12 (2) of Regulation 396/2005.

Residues in commodities of animal origin were not assessed in the framework of this application considering that the crops under consideration are not used as livestock feed.

Consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annexes III of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use of boscalid on courgettes and gherkins. For kohlrabi the existing MRL was used as an input value. In addition, for several crops the STMR values were used as reported in the framework of setting the temporary EC MRL for boscalid. No acute risk assessment was undertaken since no ARfD value has been established.

No long term intake concerns were identified for any of European diets. The total calculated intake values ranged from 14.5-77.5% of the ADI. The contribution of gherkins and courgettes to the total dietary intake is insignificant being 0.4 % of the ADI for gherkins (WHO Cluster diet B) and 1.24% of the ADI for courgettes (French infant diet).

EFSA concludes that the intended use of boscalid on courgettes, gherkins and kohlrabi is sufficiently supported by data and no risk for consumer health was identified.

EFSA notes that inconsistencies with regard to MRLs for animal commodities (incompatibility of general MRL set under code 1010000 with specific commodity MRLs) have been identified in Regulation (EC) No 839/2008 as well as in the online EU Pesticides database which should be corrected when amendments to boscalid MRLs are made.

### Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: boscalid			
Gherkins, courgettes	0.2	3.0	MRL proposal is supported by data and no risk for consumers was identified for the proposed uses.
Kohlrabi	0.5	No modification necessary	Intended use is supported by data and would not require raising of the existing MRL. The existing MRL is set as a default value to cover possible residues in the crop when it is grown as a rotational crop. According to residue trials the MRL of 0.1 mg/kg for kohlrabi grown as primary crop would be sufficient. No information is available to EFSA concerning the most critical GAPs in primary crops to make a realistic estimation of boscalid residues occurring in kohlrabi when it is grown as a rotational crop.

**Key words: Boscalid, gherkins, courgettes, kohlrabi, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, carboxamide fungicide**

## TABLE OF CONTENTS

Background .....	5
Terms of reference.....	5
The active substance and its use pattern.....	6
Assessment .....	7
1. Methods of analysis.....	7
1.1. Methods for enforcement of residues in food of plant origin .....	7
1.2. Methods for enforcement of residues in food of animal origin .....	7
2. Mammalian toxicology.....	7
3. Residues.....	8
3.1. Nature and magnitude of residues in plant.....	8
3.1.1. Primary crops.....	8
3.1.1.1. Nature of residues .....	8
3.1.1.2. Magnitude of residues.....	8
3.1.1.3. Effect of industrial processing and/or household preparation .....	11
3.1.2. Rotational crops.....	11
3.1.2.1. Preliminary considerations.....	11
3.1.2.2. Nature of residues .....	11
3.1.2.3. Magnitude of residues.....	11
3.2. Nature and magnitude of residues in livestock .....	12
4. Consumer risk assessment .....	12
Conclusions and recommendations .....	15
Documentation provided to EFSA .....	16
References .....	16
Appendix A – Good Agricultural Practices (GAPs) .....	17
Appendix B – Existing EC MRLs.....	18
Appendix C – Pesticide Residues Intake Model (PRIMo).....	25
Glossary / Abbreviations.....	27

## **BACKGROUND**

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that where a Member State considers that the modification of an MRL is necessary, that Member State may compile and evaluate an application to modify the MRL in accordance with the provisions of Article 7 of that regulation.

In particular, Belgium, hereafter referred to as the Evaluating Member State (EMS), compiled an application to modify the existing MRL for boscalid in courgettes, gherkins and kohlrabi. This application was notified to the European Commission and EFSA and subsequently evaluated in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 May 2009. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2009-00643 and the following subject:

*Boscalid - Application to modify the existing MRL for boscalid in courgettes and gherkins from 0.2 mg/kg to 2 mg/kg.*

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

## **TERMS OF REFERENCE**

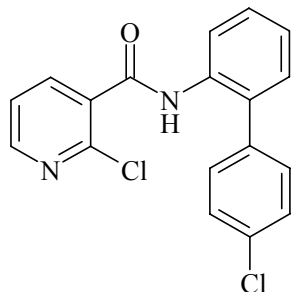
According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the Evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

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

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

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Boscalid is the ISO common name for 2-chloro-*N*-(4'-chlorobiphenyl-2-yl) nicotinamide (IUPAC).



Boscalid is a fungicide belonging to the chemical class of carboxamides. Boscalid is fat soluble. It effectively controls several fungal pathogens belonging to the four major classes of plant pathogenic fungi. Boscalid is envisaged to be used as a fungicide on several agricultural and horticultural, ornamentals and viticulture. Boscalid has preventative and curative properties. It inhibits spore germination, germ tube elongation, mycelial growth and sporulation.

Boscalid was peer reviewed under Directive 91/414/EEC with Germany being the designated Rapporteur Member State. Boscalid is included in Annex I to the Directive 91/414/EEC by the Commission Directive 2008/44/EC which entered into force on 1 August 2008. The representative uses evaluated under the peer review were foliar application on grapes, oilseed rape, beans and peas. Boscalid was not peer reviewed by EFSA.

In the European Community the temporary MRLs for boscalid are established in Annex III of Regulation (EC) No 396/2005 (Appendix B). The current MRLs for courgettes and gherkins are established at 0.2 mg/kg and for kohlrabi at 0.5 mg/kg. The existing MRL for kohlrabi is most likely set as a default MRL to cover the residues in rotational crops according to the decision taken in the peer review. Codex Alimentarius has established CXLs for a range of commodities but no CXLs are set for the crops under consideration.

The GAP for which an authorization is requested in Belgium refers to an indoor and outdoor application of boscalid on gherkins and courgettes once or twice at an application rate of 0.4 kg a.s./ha. The minimum waiting period is 1 day. The intended GAP on kohlrabi refers to an outdoor application of boscalid for a maximum of three times at an application rate of 0.267 kg a.s./ha with the PHI of 14 days. The GAPs are summarized in Appendix A.

EFSA notes that inconsistencies with regard to MRLs for animal commodities (incompatibility of general MRL set under code 1010000 with specific commodity MRLs) have been identified in Regulation (EC) No 839/2008 as well as in the online EU Pesticides database which should be corrected when amendments to boscalid MRLs are made.

## ASSESSMENT

### 1. Methods of analysis

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

Analytical enforcement methods for the determination of boscalid residues in the foodstuffs of plant origin were evaluated in the framework of the peer review of Directive 91/414/EEC (Germany, 2002). Several analytical methods are sufficiently validated for the determination of boscalid residues in plant matrices:

- 1) GC-MS method with the LOQ of 0.01 mg/kg for matrices with high water, high acid content and for dry matrices and with the LOQ of 0.02 mg/kg for high oil content matrices;
- 2) LC-MS-MS method with the LOQ of 0.05 mg/kg for matrices with high water, high acid high oil content and for dry matrices;
- 3) GC-MS method with the LOQ of 0.01 mg/kg for matrices with high water content, with the LOQ of 0.02 mg/kg for matrices with high oil content and with the LOQ of 0.05 mg/kg for dry commodities.

EFSA concludes that adequate analytical methods are available for the determination of boscalid residues in gherkins, courgettes and kohlrabi.

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

The availability of analytical methods for enforcement of residues in the foodstuffs of animal origin was not investigated because crops under consideration are not used as livestock feed.

### 2. Mammalian toxicology

The toxicological reference values for boscalid have been investigated under the peer review (European Commission, 2008) and are summarized in the Table 2-1.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Boscalid					
ADI	COM	2008	0.04	2 yr rat	100
ARfD	COM	2008	n.n.		

n.n. – not necessary

### **3. Residues**

#### **3.1. Nature and magnitude of residues in plant**

##### **3.1.1. Primary crops**

###### **3.1.1.1. Nature of residues**

Under the peer review of Directive 91/414/EEC the metabolism of boscalid was investigated in fruits and fruiting vegetables, leafy vegetables, pulses and oilseeds (Germany, 2002):

-grapes: foliar application 3 x 0.8 kg a.s./ha

-lettuce: foliar application 3 x 0.7 kg a.s./ha

-beans: foliar application 3 x 0.5 kg a.s./ha

Metabolism studies were performed with [diphenyl-U-<sup>14</sup>C]-boscalid and [pyridine-3-<sup>14</sup>C]-boscalid. In grapes (fruits) 92.7% of the TRR was unchanged parent boscalid; in stalks and leaves parent boscalid amounted for up to 95- 98% of the TRR. In lettuce boscalid was almost no metabolised. The residues in beans (edible part) were much lower compared to the rest of the plant. When separating greens beans into pods and seeds, the major part of radioactivity was found in pods rather than seeds. Parent boscalid (both labels) was identified as the major compound of the TRR in bean leaves and forage (>98%), in green beans and green pods (97%), in bean straw (≥94%), in dry pods (80-95%) and in dry seeds (72%). In green beans and seeds (both labels) also the cleavage products M510F62 (chlorophenylaminobenzene) and M510F47 (chloronicotinic acid) were identified in low concentrations.

In the peer review it was concluded that unchanged parent compound was the major component of the residue in metabolism studies and that all other metabolites were of minor toxicological importance. Therefore the residue in all commodities of plant origin for risk assessment and enforcement should be defined as parent boscalid.

Consequently, EFSA concludes that metabolic pattern in crops under consideration is sufficiently addressed and no additional metabolism studies are required.

###### **3.1.1.2. Magnitude of residues**

In support of the proposed GAP on courgettes and gherkins Belgium reported four outdoor trials on courgettes and four indoor trials on cucumbers with sampling done at day 1 and 3 after the last treatment. In two trials residue values were higher with a longer PHI. These values were included in the database for deriving the MRL proposal.

In support of the intended GAP in kohlrabi, Belgium reported four residue trials.

Residue trials data are summarized in Table 3-1.

The storage stability of residues in treated crops has been evaluated under the peer review of Directive 91/414/EEC (Germany, 2002). Studies demonstrated storage stability of boscalid under frozen conditions for at least 24 months in dry commodities(wheat grain, wheat straw), matrices with high oil content (oilseed rape seed) and matrices with high water content (white cabbage, peaches and peas). Supervised residue trial samples prior analysis where stored deep frozen for a maximum of 13-14 months, meaning that the demonstrated storage stability period of boscalid was not exceeded.



According to the EMS, analytical methods used for analysing supervised residues trials samples are considered sufficiently validated and fit for purpose.

From the submitted supervised field trials data it is concluded that:

- 1) a higher MRL of 3.00 mg/kg for gherkins and courgettes as proposed by the EMS (2 mg/kg) would be necessary to accommodate the intended GAP in Belgium;
- 2) the intended use on kohlrabi would not require amendment of the existing MRL. The current MRL of 0.5 mg/kg for kohlrabi was set in the peer review by risk managers as a default value to cover possible occurrence of boscalid residues in rotational crops (see section 3.1.2.3.). The supervised residue field trials on kohlrabi (grown as primary crop) indicate that an MRL of 0.1 mg/kg would be sufficient. However, no information is available to EFSA concerning the most critical GAPs in primary crops to make a realistic estimation of residue occurrence in kohlrabi when they are grown as rotational crops. EFSA will assess this aspect in detail in the framework of the review of the existing MRLs for boscalid according to Article 12 (2) of Regulation 396/2005.

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

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement	Risk assessment					
Enforcement residue definition : boscalid									
Courgette, gherkins	NEU	Outdoor	0.108*; 0.158; 0.16; 0.191;	0.108*; 0.158; 0.16; 0.191;	0.16	0.19	0.5	1.0	Outdoor trials were performed on courgettes but indoor trials were performed on cucumbers. Residues data can be extrapolated to gherkins and courgettes. Indoor use is more critical therefore these values were used to derive the MRL proposal (indicated in bold). R <sub>ber (outdoor)</sub> =0.37 mg/kg R <sub>max(outdoor)</sub> =0.33 mg/kg R <sub>ber(indoor)</sub> =2.1 mg/kg R <sub>max(indoor)</sub> =2.29 mg/kg
	EU	Indoor	0.415; 0.654; 0.816; 1.128*	0.415; 0.654; 0.816; 1.128*	<b>0.74</b>	<b>1.128</b>	<b>3.0</b>	<b>1.0</b>	
Kohlrabi	NEU	Outdoor	<0.02; 0.02; 0.029; 0.038	<0.02; 0.02; 0.029; 0.038	0.025	0.038	0.1	1.0	R <sub>ber</sub> =0.07 mg/kg R <sub>max</sub> =0.07 mg/kg

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

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

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

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

(\*): Indicates that residue value is obtained from a longer PHI of 3 days

### 3.1.1.3. Effect of industrial processing and/or household preparation

Under the peer review of Directive 91/414/EEC the effects of processing on the nature of boscalid was investigated in hydrolysis study by stimulating pasteurization, baking, brewing, boiling and sterilisation processes (Germany, 2002). The studies demonstrate that boscalid was not degraded during processing.

The effect of processing on the magnitude of boscalid residues was also investigated under the peer review and various processing factors were obtained.

Under the current application, the applicant has not submitted any processing studies. Such, however, are not considered necessary, taking into account the low contribution of crops under consideration to the total dietary intake.

## 3.1.2. Rotational crops

### 3.1.2.1. Preliminary considerations

All crops under consideration can be grown in crop rotation. Under the peer review the rate of degradation of boscalid in soil was investigated in field and laboratory studies (Germany, 2002). The studies indicate that  $DT_{90lab}$  amounts for a maximum of 442 days and  $DT_{90f}$  exceeds 1 year. In this case a special consideration should be given to boscalid residues in rotational crops.

### 3.1.2.2. Nature of residues

The metabolism of boscalid in rotational crops was investigated in the peer review in radish, lettuce and wheat (Germany, 2002) following the application of  $^{14}C$ -boscalid (pyridine and diphenyl- label). Studies indicate that generally higher residues are identified with pyridine labelled boscalid. Apart from parent boscalid which was the major component of the TRR in all crops except wheat grain, metabolite M510F61 (sugar conjugate of boscalid) was identified at levels exceeding the trigger value of 10% in radish leaf (11.2% - 15.5 % 365 DAT and 21.2% (diphenyl label) 270 DAT) and in wheat forage (18.1% (diphenyl label) 270 DAT).

The proposed metabolic pathway in succeeding crops involves hydroxylation and conjugation reactions. Part of residues was also incorporated and/or associated into/with natural products, such as starch, cellulose and lignin. In the peer review it was decided that that parent boscalid is the only substance of concern in rotational crops, meaning that metabolic pathway of primary and rotational crops is similar. No metabolites of concern in soil were identified.

### 3.1.2.3. Magnitude of residues

In a *confined* rotational crop study  $^{14}C$ -boscalid was applied on a bare soil at an application rate equivalent to 2.1 kg a.s./ha. After aging of the soil for 30 (simulating an emergency plant back), 120 (simulating a fall plant back), 270 (simulating a plant back for vegetables) and 365 days, radish, lettuce and wheat were planted or sowed.

A *field* study on rotational crops was conducted by applying boscalid to either vegetables (lettuce 2 x 0.3 kg a.s./ha; green beans 3 x 0.5 kg a.s./ha; carrots 3 x 0.3 kg a.s./ha) or winter rape (1 x 0.5 kg a.s./ha). In both cases wheat was sown as a succeeding crop.

Results from *confined* study indicate that concentrations of boscalid are relatively low in lettuce leaves (0.014 - 0.072 mg/kg) and radish root (0.009-0.09 mg/kg). Higher residues were found in radish leaves (0.09 - 0.3 mg/kg) and wheat forage (0.19 - 1.47 mg/kg). Very high residues were identified in wheat straw (0.81 mg/kg (270 DAT) - 7.99 mg/kg (30 DAT)). In wheat grain the concentration of parent was low ( $\leq$  0.028 mg/kg (30 DAT)) since the largest part of radioactivity was not extractable and a part of TRR was detected in starch fraction.

Results from the *field* study indicate, that no boscalid residues were found above the LOQ in wheat grain. Boscalid residues were found in a wheat straw (0.75 mg/kg) when planted after vegetables, but no residues were found in wheat straw when rape was sown as a primary crop.

Summarizing the above mentioned, available studies on rotational crops indicate that there is a potential for accumulation of boscalid residues in crops grown in crop rotation. Taking into account the persistent nature of boscalid in soil as well as its ability to be acropetally transported in plants, it was concluded in the peer review that the parent compound boscalid may occur in crops grown in rotation. As a result, a default MRL of 0.5 mg/kg was set for all annual crops in order to cover possible boscalid residues in crop when it is grown in rotation in cases where no specific residue trails or rotational crop study data are available.

With regard to the current application, EFSA concludes that:

- the use of boscalid on gherkins and courgettes most likely will not result in residue levels exceeding the default value of 0.5 mg/kg in rotational crops. The MRL proposal of 3 mg/kg in gherkins and courgettes is expected to cover also the residues originating in these crops when they are grown as rotational crops;
- the MRL of 0.5 mg/kg for kohlrabi was established by risk managers to cover possible residues in the crop when it is grown as a rotational crop. The current MRL for kohlrabi should be reconsidered since specific supervised residue field trials on kohlrabi grown as primary crop is now available which indicate that an MRL of 0.1 mg/kg would be sufficient. However, no information is available to EFSA concerning the most critical GAPs in primary crops to make a realistic estimation of residues occurring in kohlrabi when it is grown as a rotational crop.

### **3.2. Nature and magnitude of residues in livestock**

Since crops under consideration are not used as a livestock feed, nature and magnitude of boscalid in livestock is not of relevance for the current application.

## **4. Consumer risk assessment**

Consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). For the chronic intake assessment EFSA used the existing MRLs as established in Annexes III of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use of boscalid on gherkins and courgettes. For kohlrabi the existing MRL was used as an input value. In addition, for several crops the STMR values were used as reported by various EC MS in the framework of setting the temporary EC MRLs for boscalid.

No acute risk assessment was undertaken since no ARfD value has been established.

Input values are summarized in Table 4-1.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: boscalid				
Courgettes, gherkins	0.74	STMR	Acute risk assessment was not undertaken since no ARfD value is established.	
Kohlrabi	0.5	MRL		
Pome fruit	0.34	STMR (Germany, 2009)		
Stone fruit	0.14	STMR (Greece, 2007)		
Cane fruit	2.5	STMR (Germany, 2009)		
Other small fruits and berries	0.39	STMR (Germany, 2009)		
Kiwi	1.24	STMR (Germany, 2009)		
Celeriac	0.34	STMR (Germany, 2009)		
Radishes	0.28	STMR (Germany, 2007)		
Onions	0.2	STMR (Germany, 2009)		
Tomatoes	0.32	STMR (Germany, 2007)		
Peppers	0.51	STMR (Germany, 2007)		
Flowering brassica	0.05	STMR (Germany, 2009)		
Leafy brassica	1.10	STMR (Germany, 2009)		
Lamb`s lettuce	14	STMR (Germany, 2009)		
Lettuce and other salad plants inc. Brassicacea (excluding lamb`s lettuce)	2.40	STMR (Germany, 2007)		
Beans (with pods)	0.50	STMR (France, 2007)		
Peas (without pods)	0.35	STMR (France, 2007)		
Celery	2.00	STMR (Germany, 2009)		
Barley, oats	0.92	STMR (Germany, 2007)		
Other commodities	MRL	Appendix B		
Animal commodities	Individual MRLs*	Appendix B		

\*- excluding values as set under the following codes: 1010000, 1011000, 1012000, 1013000, 1014000, 1015000, 1016000, 1017000 as they are in contradiction with MRLs set for individual commodities belonging to this group

The summary of intake calculations can be found in Appendix C.

No long term intake concerns were identified for any of European diets. The total calculated intake values ranged from 14.5-77.5% of the ADI. The contribution of gherkins and courgettes to the total dietary intake is insignificant being 0.4 % of the ADI for gherkins (WHO Cluster diet B) and 1.24% of the ADI for courgettes (French infant diet). The contribution of kohlrabi (with the existing MRL of 0.5 mg/kg) to the total dietary intake amounts for a maximum of 0.12% of the ADI (WHO Cluster diet D).

EFSA concludes that the intended use of boscalid on courgettes, gherkins and kohlrabi is sufficiently supported by data and no risk for consumer health was identified.

## CONCLUSIONS AND RECOMMENDATIONS

The toxicological profile of boscalid was investigated in the peer review and the data were sufficient to conclude in an ADI value of 0.04 mg/kg bw/d. ARfD value was not established as boscalid does not possess acute toxicological properties.

The metabolism of boscalid in primary crops is elucidated in fruits and fruiting vegetables, leafy vegetables, pulses and oilseeds and the risk assessment and enforcement residue definition is established as parent boscalid. Consequently, the MRL application does not require additional metabolism studies. Adequate analytical methods are available to enforce the proposed MRLs.

Boscalid is known to be persistent in the soil and therefore boscalid residues might occur in succeeding crops in amounts exceeding 0.01 mg/kg. Taking that into account, the MRL setting for boscalid in annual crops requires consideration of possible boscalid residues in crop when it is grown as a primary crop and when it is grown as a rotational crop. Submitted supervised residue trials data on gherkins and courgettes indicate that a higher MRL of 3.0 mg/kg than requested by the EMS (2.0 mg/kg) would be necessary to accommodate the intended GAP in Belgium. The MRL proposal is expected to cover also the residues originating in these crops when they are grown as rotational crops. Supervised residue trials data on kohlrabi would not require amendment of the existing MRL 0.5 mg/kg which was set in the peer review as a default value to cover possible occurrence of boscalid residues in rotational crops in cases where no specific residue trials or rotational crop study data are available. Submitted residue trials on kohlrabi indicate that an MRL of 0.1 mg/kg would be sufficient when kohlrabi is grown as a primary crop. However, no information is available to EFSA concerning the most critical GAPs in primary crops to make a realistic estimation of boscalid residues occurring in kohlrabi when it is grown as a rotational crop. EFSA will assess this aspect in detail in the framework of the review of the existing MRLs for boscalid according to Article 12 (2) of Regulation 396/2005.

Residues in commodities of animal origin were not assessed in the framework of this application considering that the crops under consideration are not used as livestock feed.

Consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annexes III of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use of boscalid on courgettes and gherkins. For kohlrabi the existing MRL was used as an input value. In addition, for several crops the STMR values were used as reported in the framework of setting the temporary EC MRL for boscalid. No acute risk assessment was undertaken since no ARfD value has been established.

No long term intake concerns were identified for any of European diets. The total calculated intake values ranged from 14.5-77.5% of the ADI. The contribution of gherkins and courgettes to the total dietary intake is insignificant being 0.4 % of the ADI for gherkins (WHO Cluster diet B) and 1.24% of the ADI for courgettes (French infant diet).

EFSA concludes that the intended use of boscalid on courgettes, gherkins and kohlrabi is sufficiently supported by data and no risk for consumer health was identified.

EFSA notes that inconsistencies with regard to MRLs for animal commodities (incompatibility of general MRL set under code 1010000 with specific commodity MRLs) have been identified in Regulation (EC) No 839/2008 as well as in the online EU Pesticides database which should be corrected when amendments to boscalid MRLs are made.

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: boscalid			
Gherkins, courgettes	0.2	3.0	MRL proposal is supported by data and no risk for consumers was identified for the proposed uses.
Kohlrabi	0.5	No modification necessary	Intended use is supported by data and would not require raising of the existing MRL. The existing MRL is set as a default value to cover possible residues in the crop when it is grown as a rotational crop. According to residue trials the MRL of 0.1 mg/kg for kohlrabi grown as primary crop would be sufficient. No information is available to EFSA concerning the most critical GAPs in primary crops to make a realistic estimation of boscalid residues occurring in kohlrabi when it is grown as a rotational crop.

#### DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRL for boscalid in courgettes, gherkins and kohlrabi prepared by Belgium under Regulation (EC) No 396/2005. Submitted to EFSA on 29 May 2009. Updated by the EMS on 15 July 2009.

#### REFERENCES

- Germany, 2002. Draft Assessment Report on boscalid prepared by Germany under Directive 91/414/EEC. November 2002. Addendum 2 (revised) to the DAR. 24 May 2006.
- European Commission, 2008. Review report for the active substance boscalid. SANCO 3919/2007-rev.4. 21 January 2008.
- Germany, 2009. Pesticide Residues Overview File (PROFile) for boscalid as submitted by Germany to EFSA according to Article 12(2) of Regulation (EC) No 396/2005. 22 June 2009.
- Germany, 2007. Refinement of the EFSA-evaluation for boscalid according to MRL setting in Regulation (EC) no 396/2005.
- France, 2007. Data from France on the GAPs for boscalid in the framework of setting temporary MRLs for boscalid in Regulation (EC) No 396/2005.
- Greece, 2007. Data from Greece on the GAPs for boscalid in the framework of setting temporary MRLs for boscalid in Regulation (EC) No 396/2005.



**APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)**

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	
Courgette, gherkin	Belgium (NEU)	F/ G	Powdery mildew Leaf mould	WG	26.7%	Spray		1-2	2 weeks			0.4	1 day
Kohlrabi	Belgium (NEU)	F	Alternaria	WG	26.7%	Spray		1-3	2 weeks			0.1	14 days

(a) For crops, the EU and Codex classifications (both) should be used; where

(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) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of relevant, the use situation should be described (e.g. fumigation of a structure) equipment used must be indicated

(i) g/kg or g/l

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell)

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

**APPENDIX B – EXISTING EC MRLs**

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid (R)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon)	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	1
120010	Almonds	1
120020	Brazil nuts	1
120030	Cashew nuts	1
120040	Chestnuts	1
120050	Coconuts	1
120060	Hazelnuts (Filbert)	1
120070	Macadamia	1
120080	Pecans	1
120090	Pine nuts	1
120100	Pistachios	1
120110	Walnuts	1
120990	Others	1
130000	(iii) Pome fruit	2
130010	Apples (Crab apple)	2
130020	Pears (Oriental pear)	2
130030	Quinces	2
130040	Medlar	2
130050	Loquat	2
130990	Others	2
140000	(iv) Stone fruit	3
140010	Apricots	3
140020	Cherries (sweet cherries, sour cherries)	3

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid (R)
140030	Peaches (Nectarines and similar hybrids)	3
140040	Plums (Damson, greengage, mirabelle)	3
140990	Others	3
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	5
151010	Table grapes	5
151020	Wine grapes	5
152000	(b) Strawberries	10
153000	(c) Cane fruit	10
153010	Blackberries	10
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	10
153030	Raspberries (Wineberries)	10
153990	Others	10
154000	(d) Other small fruit & berries	10
154010	Blueberries (Bilberries cowberries (red bilberries))	10
154020	Cranberries	10
154030	Currants (red, black and white)	10
154040	Gooseberries (Including hybrids with other ribes species)	10
154050	Rose hips	10
154060	Mulberries (arbutus berry)	10
154070	Azarole (mediteranean medlar)	10
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries)	10
154990	Others	10
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid ) (R)
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomegranate, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	
162010	Kiwi	5
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,3
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid ) (R)
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,5
212000	(b) Tropical root and tuber vegetables	0,5
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,5
212020	Sweet potatoes	0,5
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,5
212040	Arrowroot	0,5
212990	Others	0,5
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,5
213020	Carrots	1
213030	Celeriac	1
213040	Horseradish	1
213050	Jerusalem artichokes	0,5
213060	Parsnips	1
213070	Parsley root	3
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	1
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	1
213100	Swedes	0,5
213110	Turnips	0,5
213990	Others	0,5
220000	(ii) Bulb vegetables	
220010	Garlic	0,5
220020	Onions (Silverskin onions)	3
220030	Shallots	0,5
220040	Spring onions (Welsh onion and similar varieties)	0,5
220990	Others	0,5
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid (R)
231010	Tomatoes (Cherry tomatoes, )	1
231020	Peppers (Chilli peppers)	2
231030	Aubergines (egg plants) (Pepino)	1
231040	Okra, lady's fingers	0,5
231990	Others	0,5
232000	(b) Cucurbits - edible peel	0,2
232010	Cucumbers	0,2
232020	Gherkins	0,2
232030	Courgettes (Summer squash, marrow (patisson))	0,2
232990	Others	0,2
233000	(c) Cucurbits-inedible peel	0,5
233010	Melons (Kiwano )	0,5
233020	Pumpkins (Winter squash)	0,5
233030	Watermelons	0,5
233990	Others	0,5
234000	(d) Sweet corn	0,5
239000	(e) Other fruiting vegetables	0,5
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	1
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	1
241020	Cauliflower	1
241990	Others	1
242000	(b) Head brassica	
242010	Brussels sprouts	2
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	2
242990	Others	1
243000	(c) Leafy brassica	10
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	10
243020	Kale (Borecole (curly kale), collards)	10
243990	Others	10

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid (R)
244000	(d) Kohlrabi	0,5
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb's lettuce (Italian cornsalad)	40
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	10
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	10
251040	Cress	10
251050	Land cress	10
251060	Rocket, Rucola (Wild rocket)	10
251070	Red mustard	10
251080	Leaves and sprouts of Brassica spp (Mizuna)	10
251990	Others	10
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	10
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,5
252030	Beet leaves (chard) (Leaves of beetroot)	5
252990	Others	0,5
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	10
255000	(e) Witloof	0,5
256000	(f) Herbs	10
256010	Chervil	10
256020	Chives	10

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid ) (R)
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	10
256040	Parsley	10
256050	Sage (Winter savory, summer savory)	10
256060	Rosemary	10
256070	Thyme ( marjoram, oregano)	10
256080	Basil (Balm leaves, mint, peppermint)	10
256090	Bay leaves (laurel)	10
256100	Tarragon (Hyssop)	10
256990	Others	10
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	2
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	2
260030	Peas (with pods) (Mangetout (sugar peas))	2
260040	Peas (without pods) (Garden pea, green pea, chickpea)	1
260050	Lentils	0,5
260990	Others	0,5
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,05*
270020	Cardoons	0,5
270030	Celery	7
270040	Fennel	0,5
270050	Globe artichokes	0,5
270060	Leek	5
270070	Rhubarb	0,5
270080	Bamboo shoots	0,5
270090	Palm hearts	0,5
270990	Others	0,5
280000	(viii) Fungi	0,5

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid ) (R)
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,5
280020	Wild (Chanterelle, Truffle, Morel ,)	0,5
280990	Others	0,5
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,5
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,5
300020	Lentils	0,5
300030	Peas (Chickpeas, field peas, chickling vetch)	0,5
300040	Lupins	0,5
300990	Others	0,5
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,5
401020	Peanuts	0,5
401030	Poppy seed	0,5
401040	Sesame seed	0,5
401050	Sunflower seed	0,5
401060	Rape seed (Bird rapeseed, turnip rape)	0,2
401070	Soya bean	0,5
401080	Mustard seed	0,5
401090	Cotton seed	0,5
401100	Pumpkin seeds	0,5
401110	Safflower	0,5
401120	Borage	0,5
401130	Gold of pleasure	0,5
401140	Hempseed	0,5
401150	Castor bean	0,5
401990	Others	0,5
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	3
500020	Buckwheat	0,5
500030	Maize	0,5

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid ) (R)
500040	Millet (Foxtail millet, teff)	0,5
500050	Oats	3
500060	Rice	0,5
500070	Rye	0,5
500080	Sorghum	0,5
500090	Wheat (Spelt Triticale)	0,5
500990	Others	0,5
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,5
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i> )	0,5
620000	(ii) Coffee beans	0,5
630000	(iii) Herbal infusions (dried)	0,5
631000	(a) Flowers	0,5
631010	Camomille flowers	0,5
631020	Hybiscus flowers	0,5
631030	Rose petals	0,5
631040	Jasmine flowers	0,5
631050	Lime (linden)	0,5
631990	Others	0,5
632000	(b) Leaves	0,5
632010	Strawberry leaves	0,5
632020	Rooibos leaves	0,5
632030	Maté	0,5
632990	Others	0,5
633000	(c) Roots	0,5
633010	Valerian root	0,5
633020	Ginseng root	0,5
633990	Others	0,5
639000	(d) Other herbal infusions	0,5
640000	(iv) Cocoa (fermented beans)	0,5
650000	(v) Carob (st johns bread)	0,5
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	35
800000	8. SPICES	0,5
810000	(i) Seeds	0,5
810010	Anise	0,5
810020	Black caraway	0,5
810030	Celery seed (Lovage	0,5

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid ) (R)
	seed)	
810040	Coriander seed	0,5
810050	Cumin seed	0,5
810060	Dill seed	0,5
810070	Fennel seed	0,5
810080	Fenugreek	0,5
810090	Nutmeg	0,5
810990	Others	0,5
820000	(ii) Fruits and berries	0,5
820010	Allspice	0,5
820020	Anise pepper (Japan pepper)	0,5
820030	Caraway	0,5
820040	Cardamom	0,5
820050	Juniper berries	0,5
820060	Pepper, black and white (Long pepper, pink pepper)	0,5
820070	Vanilla pods	0,5
820080	Tamarind	0,5
820990	Others	0,5
830000	(iii) Bark	0,5
830010	Cinnamon (Cassia )	0,5
830990	Others	0,5
840000	(iv) Roots or rhizome	0,5
840010	Liquorice	0,5
840020	Ginger	0,5
840030	Turmeric (Curcuma)	0,5
840040	Horseradish	0,5
840990	Others	0,5
850000	(v) Buds	0,5
850010	Cloves	0,5
850020	Capers	0,5
850990	Others	0,5
860000	(vi) Flower stigma	0,5
860010	Saffron	0,5
860990	Others	0,5
870000	(vii) Aril	0,5
870010	Mace	0,5
870990	Others	0,5
900000	9. SUGAR PLANTS	0,5
900010	Sugar beet (root)	0,5
900020	Sugar cane	0,5
900030	Chicory roots	0,5
900990	Others	0,5
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid ) (R)
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,5
1011000	(a) Swine	0,5
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,1
1011030	Liver	0,1
1011040	Kidney	0,1
1011050	Edible offal	0,1
1011990	Others	0,05*
1012000	(b) Bovine	0,5
1012010	Meat	0,05*
1012020	Fat	0,3
1012030	Liver	0,2
1012040	Kidney	0,3
1012050	Edible offal	0,3
1012990	Others	0,05*
1013000	(c) Sheep	0,5
1013010	Meat	0,05*
1013020	Fat	0,3
1013030	Liver	0,2
1013040	Kidney	0,3
1013050	Edible offal	0,3
1013990	Others	0,05*
1014000	(d) Goat	0,5
1014010	Meat	0,05*
1014020	Fat	0,3
1014030	Liver	0,2
1014040	Kidney	0,3
1014050	Edible offal	0,3
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,5
1015010	Meat	0,05*
1015020	Fat	0,3
1015030	Liver	0,2
1015040	Kidney	0,3
1015050	Edible offal	0,3
1015990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid ) (R)
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,5
1016010	Meat	0,05*
1016020	Fat	0,1
1016030	Liver	0,1
1016040	Kidney	0,05
1016050	Edible offal	0,1
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,5
1017010	Meat	0,05*
1017020	Fat	0,3
1017030	Liver	0,2
1017040	Kidney	0,3
1017050	Edible offal	0,3
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	0,5

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid ) (R)
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*
*-Indicates limit of analytical quantification ( R) = The residue definition differs for the following combinations pesticide-code number:		

Code number	Groups and examples of individual products to which the MRLs apply (a)	Boscalid ) (R)
code 1000000: Sum of boscalid and M 510F01 including its conjugates		



## APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

<b>Boscalid</b>			
Status of the active substance:	<b>Included</b>	Code no.	<b>20</b>
Default MRL (mg/kg bw):	0.5	proposed LOQ:	
<b>Toxicological end points</b>			
ADI (mg/kg bw/day):	<b>0.04</b>	ARfD (mg/kg bw):	<b>n.n.</b>
Source of ADI:	<b>COM</b>	Source of ARfD:	<b>COM</b>
Year of evaluation:	<b>2008</b>	Year of evaluation:	<b>2008</b>

**Chronic risk assessment - refined calculations**

		TMDI (range) in % of ADI minimum - maximum						
		15      78						
		<b>No of diets exceeding ADI: ---</b>						
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)
77.5	WHO Cluster diet B	22.4	Wine grapes	10.7	Wheat	4.3	Table grapes	34.0
75.9	FR toddler	17.7	Spinach	15.6	Strawberries	9.0	Leek	22.6
71.6	IE adult	15.6	Wine grapes	6.2	Strawberries	4.4	Sweet potatoes	23.0
70.1	DE child	15.9	Table grapes	12.2	Strawberries	10.3	Apples	28.0
68.6	FR all population	50.0	Wine grapes	4.1	Wheat	2.3	Strawberries	9.2
66.1	NL child	9.5	Table grapes	9.3	Spinach	7.4	Potatoes	30.1
59.5	UK Toddler	28.6	Sugar beet (root)	5.0	Strawberries	4.9	Wheat	46.6
56.8	PT General population	31.1	Wine grapes	6.7	Potatoes	4.9	Wheat	17.4
56.1	WHO cluster diet E	20.1	Wine grapes	4.9	Wheat	4.8	Potatoes	19.5
52.9	FR infant	12.2	Strawberries	11.1	Spinach	6.6	Carrots	15.1
44.0	UK Infant	12.6	Sugar beet (root)	5.5	Strawberries	4.8	Milk and cream,	32.0
37.6	WHO cluster diet D	8.1	Wheat	5.1	Potatoes	4.5	Wine grapes	21.5
36.1	NL general	7.9	Wine grapes	3.5	Spinach	3.4	Potatoes	11.6
35.2	WHO Cluster diet F	7.5	Wine grapes	4.5	Wheat	4.3	Potatoes	16.3
34.6	DK child	6.9	Wheat	5.5	Rye	3.4	Carrots	22.8
33.7	WHO regional European diet	5.0	Potatoes	3.7	Wheat	2.9	Wine grapes	15.7
33.6	SE general population 90th percentile	5.2	Potatoes	4.1	Strawberries	4.0	Wheat	16.8
30.8	UK vegetarian	10.2	Wine grapes	4.7	Sugar beet (root)	2.6	Wheat	13.0
30.6	UK Adult	13.5	Wine grapes	5.0	Sugar beet (root)	2.1	Wheat	11.8
30.3	DK adult	17.4	Wine grapes	2.5	Wheat	1.8	Potatoes	8.3
26.8	IT kids/toddler	8.3	Wheat	3.0	Strawberries	1.9	Other cereal	15.6
26.4	ES child	5.5	Wheat	2.5	Lettuce	2.3	Potatoes	16.9
25.6	ES adult	5.2	Wine grapes	3.2	Lettuce	2.9	Wheat	9.3
22.4	IT adult	5.2	Wheat	2.4	Spinach	2.3	Lettuce	10.6
17.3	PL general population	4.3	Potatoes	4.0	Table grapes	1.8	Head cabbage	8.1
15.3	LT adult	4.0	Potatoes	2.0	Head cabbage	1.6	Apples	10.7
14.5	FI adult	3.8	Wine grapes	1.9	Strawberries	1.5	Potatoes	6.5

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

## GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
L	litre
LC	liquid chromatography

LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
PF	processing factor
PHI	pre harvest interval
ppm	parts per million ( $10^{-6}$ )
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water dispersible granule