

## REASONED OPINION

### Reasoned opinion on the modification of the existing maximum residue levels (MRLs) for boscalid in beans and peas with pods<sup>1</sup>

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

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#### ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, France, hereafter referred to as the evaluating Member State (EMS), received an application from BASF France SAS to modify the existing maximum residue levels (MRLs) for the active substance boscalid in beans and peas with pods. In order to accommodate for the intended use of boscalid, France proposed to raise the existing MRL from the value of 3 mg/kg to 6 mg/kg. France drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA. According to EFSA, the data are sufficient to derive a MRL proposal of 5 mg/kg for the intended field use on beans and peas with pods. Adequate analytical enforcement methods are available to control the residues of boscalid. Based on the risk assessment results, EFSA concludes that the proposed use of boscalid on beans and peas with pods will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk

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#### KEY WORDS

boscalid, beans and peas with pods, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, carboxamide fungicide

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<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2014-00931, approved on 10 March 2015.

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Suggested citation: EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing maximum residue levels (MRLs) for boscalid in beans and peas with pods. EFSA Journal 2015;13(3):4045, 19 pp. doi:10.2903/j.efsa.2015.4045

Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

## SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, France, hereafter referred to as the evaluating Member State (EMS), received an application from BASF France SAS to modify the existing maximum residue levels (MRLs) for the active substance boscalid in beans and peas with pods. In order to accommodate for the intended use of boscalid, France proposed to raise the existing MRL from the value of 3 mg/kg to 6 mg/kg. France drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 19 December 2014.

EFSA bases its assessment on the Evaluation report, the Draft Assessment Report (DAR) and its addendum, the Commission Review Report on boscalid, the JMPR Evaluation reports as well as the conclusions from previous EFSA opinions on boscalid, including the EFSA reasoned opinion on the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of boscalid was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.04 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of boscalid was investigated after foliar applications in the fruit, leafy and oilseeds/pulses crop groups. The residue definition for enforcement and risk assessment in plants has been defined as parent boscalid. For the uses on beans and peas with pods, EFSA concludes that the metabolism of boscalid is sufficiently addressed and the residue definition for enforcement and risk assessment as parent compound is applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 5 mg/kg for the intended field use on beans and peas with pods. Adequate analytical enforcement methods are available to control the residues of boscalid at the validated LOQ of 0.01 mg/kg.

The peer review concluded that boscalid is hydrolytically stable under standard hydrolysis conditions and the same residue definition as for raw agricultural commodities (RAC) is applicable. Numerous processing factors (PF) for different processed commodities have been proposed in the framework of the Article 12 MRL review, of which an indicative PF for cooked/canned peas. Additional processing data on beans or peas have not been submitted but are not strictly necessary according to the MRL review.

The occurrence of boscalid residues in rotational crops was investigated in the framework of the peer review. It was concluded that the residue definition proposed for primary crops is also applicable to rotational crops. Boscalid is a very persistent compound and residues may potentially be present in rotational crops, but variations in the residue uptake between different crop groups were observed. Based on a preliminary estimation performed by EFSA, the impact on the overall residues on beans and peas due to possible additional uptake from the soil is insignificant, provided that the compound is used on these crops according to the proposed Good Agricultural Practice (GAP). Since an official guideline for the setting of MRLs in rotational crops is not available and considering the uncertainty and limitations of the calculation performed, Member States are recommended to consider establishing appropriate risk mitigation measures in order to avoid the accumulation of residues in soil as well as the presence in rotational crops.

Residues of boscalid in commodities of animal origin were not assessed in the framework of this application, since fresh beans and peas with pods are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for boscalid according to Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account the existing uses of boscalid at the EU level and the Codex maximum residue limits (CXLs) set for certain commodities. EFSA now updates this risk assessment with the

supervised trials median residue (STMR) value derived for the crops under consideration. No acute consumer exposure assessment was performed as the setting of an ARfD was not necessary for boscalid.

Under the assumption that the MRLs will be amended as proposed in the Article 12 review, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 53 % of the ADI (Irish adult). The contribution of residues to the total consumer exposure accounted for a maximum of 1.8 % and 0.4 % of the ADI for beans and peas with pods, respectively.

EFSA concludes that the proposed use of boscalid on beans and peas with pods will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

Thus, EFSA proposes to amend the existing MRLs as reported in the summary table.

#### SUMMARY TABLE

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
<b>Enforcement residue definition: Boscalid (F) (R)</b>				
0260010	Beans (with pods)	3	5	Supported by a combined dataset of NEU and SEU outdoor trials.
0260030	Peas (with pods)	3	5	Extrapolation from data on beans with pods.

(a): According to Annex I of Regulation (EC) No 396/2005.

(F): Fat-soluble.

(R): The residue definition differs for the following combinations pesticide-code number:

Boscalid – code 1000000: Sum of boscalid and M 510F01, including its conjugates expressed as boscalid.

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## BACKGROUND

Regulation (EC) No 396/2005<sup>3</sup> establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC,<sup>4</sup> repealed by Regulation (EC) No 1107/2009,<sup>5</sup> shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

France, hereafter referred to as the EMS, received an application from the company BASF France SAS<sup>6</sup> to modify the existing MRL for the active substance boscalid in beans and peas with pods. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 19 December 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00931 and the following subject:

*Boscalid – Application to set new MRLs in beans and peas with pods*

France proposed to raise the existing MRL of boscalid in beans and peas with pods from the value of 3 mg/kg to 6 mg/kg.

Following a clarification from the EMS on the minimum interval between applications of the intended GAP (ten days) and the interval time actually used in the selected residue trials (six-seven days), EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

## TERMS OF REFERENCE

In accordance with 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.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) 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 deadline for providing the reasoned opinion is 19 March 2015.

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<sup>3</sup> Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

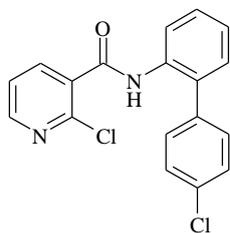
<sup>4</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

<sup>5</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

<sup>6</sup> BASF France SAS Agro Division, 21 Chemin de la Sauvegarde, 69134 Ecully Cedex, France.

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Boscalid is the ISO common name for 2-chloro-*N*-(4'-chlorobiphenyl-2-yl)nicotinamide (IUPAC). The chemical structure of the compound is reported below.



Boscalid is a fungicide belonging to the group of carboxamide class of compounds. Boscalid exerts preventive and curative action by altering spore germination, germ tube elongation, mycelial growth and sporulation of a wide range of fungal pathogens in several agricultural crops.

Boscalid was evaluated in the framework of Council Directive 91/414/EEC with Germany designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission Directive 2008/44/EC<sup>7</sup> which entered into force on 01 August 2008 for use as fungicide. In accordance with Commission Implementing Regulation (EU) No 540/2011,<sup>8</sup> boscalid is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated in the peer review were foliar applications on grapes, oilseed rape, beans and peas at a rate between 200 and 600 g a.s./ha, both in northern and southern Europe. The Draft Assessment Report (DAR) of boscalid was not peer reviewed by EFSA, therefore no EFSA conclusion is available.

The EU MRLs for boscalid are established in Annex IIIA of Regulation (EC) No 396/2005. EFSA recommendations to modify the existing MRLs on various crops (EFSA, 2009, 2010a, 2010b, 2011) have been implemented in three Regulations adopted between 2010 and 2012. In 2014, EFSA issued a reasoned opinion on the review of the existing MRLs for boscalid according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014), which reviewed all uses authorised at the EU level and the maximum residue limits (CXLs) adopted by Codex Alimentarius. Modifications of the existing MRLs were proposed for several crops; these modifications have not yet been discussed by the Standing Committee on Plants, Animals, Food and Feed (SCPAFF). The existing EU MRL for boscalid on beans and peas with pods is set at 3 mg/kg. Codex Alimentarius has established CXLs for a wide range of commodities, including beans and peas with pods for which the CXL is set at 3 mg/kg.

The details of the intended GAP for boscalid on beans and peas with pods are given in Appendix A.

## ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (France, 2014), the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Germany, 2002, 2006), the Commission Review Report on boscalid (EC, 2008), the JMPR Evaluation reports (FAO, 2006, 2008, 2009b, 2010) as well as the conclusions from previous EFSA reasoned opinions on boscalid (EFSA, 2009, 2010a, 2014) and scientific reports (EFSA, 2010b, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation

<sup>7</sup> Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthialicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* and prothioconazole as active substances. OJ L 94, 05.04.2008, p. 13–20.

<sup>8</sup> Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.06.2011, p. 1–186.

(EU) No 546/2011<sup>9</sup> and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

## 1. Method of analysis

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

Analytical methods for the determination of residues in plant commodities were assessed in the framework of the peer review and the review of the existing MRLs for boscalid under Article 12 of Regulation (EC) No 396/2005. EFSA concluded that validated analytical methods are available to enforce boscalid residues in high water, high acidic and high oil content and in dry commodities at the lowest LOQ of 0.01 mg/kg (EFSA, 2014).

Since the commodities under consideration belong to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for boscalid are available.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since fresh peas and beans are normally not fed to livestock.

## 2. Mammalian toxicology

The toxicological profile of the active substance boscalid was assessed in the framework of the peer review under Council Directive 91/414/EEC (EC, 2008). The data were sufficient to derive toxicological reference values for boscalid which are compiled in Table 2-1.

**Table 2-1:** Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Boscalid					
<b>ADI</b>	EC	2008	0.04 mg/kg bw per day	Rat, 2-yr oral feed	100
<b>ARfD</b>	EC	2008	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

The metabolism of boscalid was investigated in the fruit (grape), pulses and oilseeds (beans) and leafy (lettuce) crop groups following foliar applications and assessed during the peer review and in the framework of the Article 12 MRL review (Germany, 2002; EFSA, 2014). The details of the metabolism study results are reported in a previous EFSA reasoned opinion (EFSA, 2014). The characteristics of these studies are summarised in Table 3-1.

<sup>9</sup> Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

**Table 3-1:** Summary of available metabolism studies in plants

Crop group	Crops	Application <sup>(a)</sup>	Sampling <sup>(b)</sup>	Comments
Fruit	Grapes	Foliar, 3× 800 g/ha, F	75 DALA	–
Leafy crop	Lettuce	Foliar, 3× 700 g/ha, G	18 DALA	–
Pulse/Oilseed	Beans	Foliar, 3× 500 g/ha, G	0 (whole plant), 14 (forage, pods, seeds), 53 (straw, pods, seeds) DALA	–

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G).

(b): DALA: days after last application.

The residue definition for both enforcement and risk assessment as boscalid was confirmed during the MRL review (EFSA, 2014). The current residue definition set in Regulation (EC) No 396/2005 in plants is identical to the residue definition derived in the peer review.

### 3.1.1.2. Magnitude of residues

In support of the intended outdoor uses, eight NEU and nine SEU residue trials conducted on beans over more than two seasons were submitted. The trials were performed at a dose rates in accordance with the 25 % tolerance rule. The interval between applications was shorter (6 and 7 days) than specified in the GAP (10 days). This deviation is not expected to have major impact on the level of residue. The extrapolation from beans with pods to peas with pod is acceptable as the GAPs are the same and the number of trials is sufficient (EC, 2011). Based on the outcome of the Mann-Whitney U-Test (FAO, 2009a), a MRL proposal of 5 mg/kg was derived combining the two sets of NEU and SEU trials.

The results of the residue trials, the related risk assessment input values (HR, STMR) and the MRL proposal are summarised in Table 3-2.

The storage stability of boscalid in primary crops was investigated in the DAR under Council Directive 91/414/EEC (Germany, 2002). Residues of boscalid were found to be stable at  $\leq -18^{\circ}\text{C}$  for up to 16 months in matrices with high acid content and 24 months in matrices with high water and high oil content and in dry commodities. As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated (up to 356 days), it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical method used to analyse the supervised residue trial samples has been sufficiently validated and was proven to be fit for the purpose (France, 2014).

EFSA concludes that the data are sufficient to derive a MRL proposal of 5 mg/kg<sup>10</sup> for the intended NEU and SEU use on beans and peas with pods.

<sup>10</sup> The EMS proposed a MRL of 6 mg/kg derived from the single set of NEU residue trials (France, 2014).

**Table 3-2:** Overview of the available residues trials data

<b>Crop</b>	<b>Region/ Indoor</b> (a)	<b>Residue levels (mg/kg)</b> (b)	<b>Recommendations/comments</b> (c)	<b>MRL proposals</b> (mg/kg)	<b>HR</b> (mg/kg) (d)	<b>STMR</b> (mg/kg) (e)
<b>Beans with pods</b>	NEU	0.07; <u>0.34</u> ; <u>0.45</u> ; <u>1.17</u> ; 1.4; <u>1.46</u> ; 2.23; <u>3.17</u>	<u>Underlined</u> : values measured at a longer PHI (13-14 days). NEU and SEU datasets similar (U-test, 5 %). MRL, STMR and HR derived from the merged data. <b>Extrapolation to peas with pods.</b> MRL <sub>OECD</sub> : 4.3/5	<b>5</b>	3.17	0.66
	SEU	0.38; 0.4; 0.49; 0.5; 0.6; 0.66; 1.1; 1.49; <u>1.8</u>				

(a): **NEU**: Outdoor trials conducted in northern Europe; **SEU**: Outdoor trials conducted in southern Europe; **Indoor**: indoor EU trials or **Country code**: if non-EU trials (EC, 2011).

(b): Individual residue levels considered for MRL calculation are reported in ascending order.

(c): Any information/comment supporting the decision and OECD MRL, unrounded/rounded value.

(d): **STMR**: Median value of the individual trial results according to residue definition for risk assessment.

(e): **HR**: Highest value of the individual trial results according to the residue definition for risk assessment.

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

The effect of processing on the nature of boscalid was investigated under standard hydrolysis conditions. The studies were reported in the DAR (Germany, 2002). Since boscalid showed to be hydrolytically stable during pasteurisation, baking/boiling/brewing and sterilisation, EFSA confirmed that the same residue definition as for RAC is applicable (EFSA, 2014).

Several processing studies are available in different processed commodities. From the results of a single study on cooked and canned peas an indicative processing factor (PF) of <0.36 was derived during the MRL review (EFSA, 2014). No additional processing studies on beans or peas were provided in this application but are not strictly necessary unless a more robust PF is required for enforcement.

## 3.1.2. Rotational crops

### 3.1.2.1. Preliminary considerations

Beans and peas can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The field soil degradation studies demonstrated that the degradation rate of boscalid is slow; the maximum DT<sub>90</sub> was over one year (EC, 2008), which is above the trigger value of 100 days. Thus, the nature and magnitude of the compound uptake in rotational crops was investigated (EC, 1997c).

### 3.1.2.2. Nature of residues

The metabolism of boscalid in rotational crops (lettuce, radish, wheat) was assessed in the DAR prepared under Council Directive 91/414/EEC and in the MRL review (Germany, 2002; EFSA, 2014). The details of the metabolism studies are reported in the previous EFSA reasoned opinion (EFSA, 2014). The metabolism in rotational crops was shown to be similar to the primary crop metabolism and it was therefore concluded that the residue definition proposed for primary crops is also applicable to rotational crops (EFSA, 2014).

### 3.1.2.3. Magnitude of residues

Due to its persistent nature in soil and its ability to be transported systemically in plants, the parent compound boscalid may occur in crops grown in rotation and appropriate risk mitigating measures are recommended in the inclusion Directive. Although variations in the residue uptake between different crop groups were observed, a default MRL of 0.5 mg/kg has been established at European level for all annual crops, in order to cover possible boscalid residues in crops where the use of boscalid is not authorised but which may be grown in rotation with a crop where boscalid was legally applied (EFSA, 2014).

No official guidance defining an approach for the setting of MRLs in rotational crops to take into account the uptake of residues from previously treated soil is currently in place. Based on a preliminary estimation<sup>11</sup> EFSA performed, it was not considered necessary to correct the existing MRL on the crops under consideration to accommodate for additional uptake from the soil (EFSA, 2014). Similarly, provided that the compound is used on beans and peas with pods according to the proposed GAP, no significant uptake (>25 % of the highest residue observed on the treated crop) of boscalid residue from the soil is expected and would contribute to the overall boscalid residues in these crops.

Considering the uncertainty of the calculations, mainly due to the limitations regarding the predicted plateau of boscalid concentration in soil, and that no guidance on the setting of MRLs in rotational crops is available, further information addressing these uncertainties would be required. Furthermore,

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<sup>11</sup> The assessment was based on the data from available field studies and the methodology applied by the JMPR (FAO, 2009b). Details are reported in the previous reasoned opinion (EFSA, 2014).

residue trials after repeated applications in permanent crops were considered as desirable by the MRL review (EFSA, 2014). Hence, Member States are recommended to consider the need for appropriate risk mitigation measures when granting authorisations for boscalid in order to avoid the accumulation of residues in soil as well as the presence in rotational crops.

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

Since fresh beans and peas with pods are normally not fed to livestock, the nature and magnitude of boscalid residues in livestock is not assessed in the framework of this application (EC, 1996).

## 4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population<sup>12</sup> (EFSA, 2007).

In the framework of the review of the existing MRLs for boscalid according to Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account the existing uses of boscalid at the EU level and the CXLs set for certain commodities (EFSA, 2014). EFSA now updates this risk assessment for the crops under consideration with the STMR derived from the residue trials. Those food commodities, for which no uses were reported in the framework of the Article 12 review were excluded from the exposure calculation, assuming that there is no use of boscalid on these crops.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that the food consumed will contain residues at the STMR identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

No acute consumer exposure assessment was performed as the setting of an ARfD was not necessary for boscalid.

The input values used for the dietary exposure calculation are summarised in Table 4-1.

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

Commodity	Chronic exposure assessment	
	Input value (mg/kg)	Comment
<b>Risk assessment residue definition:</b> Boscalid		
Beans with pods	0.66	STMR (outdoor, NEU/SEU)
Peas with pods	0.66	STMR (outdoor, beans)
Other plant and animal origin commodities	STMR/ STMR-P/ MRL	See Table 4.1 of the EFSA Reasoned opinion on the review of the existing maximum residue levels for boscalid according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014)

<sup>12</sup> The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

The estimated exposure was then compared with the toxicological reference value derived for boscalid (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

Under the assumption that the MRLs will be amended as proposed in the Article 12 review, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 53 % of the ADI (Irish adult). The contribution of residues in beans and peas with pods to the total consumer exposure accounted for a maximum of 1.8 % (French toddler) and 0.4 % (WHO regional European diet) of the ADI for beans and peas with pods, respectively.

EFSA concludes that the intended use of boscalid on beans and peas with pods will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The toxicological profile of boscalid was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.04 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of boscalid was investigated after foliar applications in the fruit, leafy and oilseeds/pulses crop groups. The residue definition for enforcement and risk assessment in plants has been defined as parent boscalid. For the uses on beans and peas with pods, EFSA concludes that the metabolism of boscalid is sufficiently addressed and the residue definition for enforcement and risk assessment as parent compound is applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 5 mg/kg for the intended field use on beans and peas with pods. Adequate analytical enforcement methods are available to control the residues of boscalid at the validated LOQ of 0.01 mg/kg.

The peer review concluded that boscalid is hydrolytically stable under standard hydrolysis conditions and the same residue definition as for raw agricultural commodities (RAC) is applicable. Numerous processing factors (PF) for different processed commodities have been proposed in the framework of the Article 12 MRL review, of which an indicative PF for cooked/canned peas. Additional processing data on beans or peas have not been submitted but are not strictly necessary according to the MRL review.

The occurrence of boscalid residues in rotational crops was investigated in the framework of the peer review. It was concluded that the residue definition proposed for primary crops is also applicable to rotational crops. Boscalid is a very persistent compound and residues may potentially be present in rotational crops, but variations in the residue uptake between different crop groups were observed. Based on a preliminary estimation performed by EFSA, the impact on the overall residues on beans and peas due to possible additional uptake from the soil is insignificant, provided that the compound is used on these crops according to the proposed Good Agricultural Practice (GAP). Since an official guideline for the setting of MRLs in rotational crops is not available and considering the uncertainty and limitations of the calculation performed, Member States are recommended to consider establishing appropriate risk mitigation measures in order to avoid the accumulation of residues in soil as well as the presence in rotational crops.

Residues of boscalid in commodities of animal origin were not assessed in the framework of this application, since fresh beans and peas with pods are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for boscalid according to

Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account the existing uses of boscalid at the EU level and the Codex maximum residue limits (CXLs) set for certain commodities. EFSA now updates this risk assessment with the supervised trials median residue (STMR) value derived for the crops under consideration. No acute consumer exposure assessment was performed as the setting of an ARfD was not necessary for boscalid.

Under the assumption that the MRLs will be amended as proposed in the Article 12 review, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 53 % of the ADI (Irish adult). The contribution of residues to the total consumer exposure accounted for a maximum of 1.8 % and 0.4 % of the ADI for beans and peas with pods, respectively.

EFSA concludes that the proposed use of boscalid on beans and peas with pods will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

## RECOMMENDATIONS

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
<b>Enforcement residue definition:</b> Boscalid (F) (R)				
0260010	Beans (with pods)	3	5	Supported by a combined dataset of NEU and SEU outdoor trials.
0260030	Peas (with pods)	3	5	Extrapolation from data on beans with pods.

(a): According to Annex I of Regulation (EC) No 396/2005.

(F): Fat-soluble.

(R): The residue definition differs for the following combinations pesticide-code number:

Boscalid – code 1000000: Sum of boscalid and M 510F01, including its conjugates expressed as boscalid.

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## APPENDICES

### Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. a.s. (i)	Method kind (f-h)	Growth stage & season (j)	number min-max (k)	interval min-max	kg as/hL min-max	Water L/ha min-max	g a.s./ha min-max		
Beans with pods	NEU	F	<i>Botrytis</i> spp., <i>Sclerotinia</i> spp., <i>Uromyces</i> spp.	WG	267 g/kg	spraying	BBCH 15-89	2	10	0.04-0.1	400-1000	400	7	
	SEU													
Peas with pods	NEU	F	<i>Ascochyta pisi</i> , <i>Erysiphe</i> spp., <i>Peronospora</i> spp., <i>Sclerotinia</i> spp.	WG	267 g/kg	spraying	BBCH 15-89	2	10	0.04-0.1	400-1000	400	7	
	SEU													

#### Remarks:

- (a) For crops, EU or other classifications, e.g. Codex, 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 sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Technical Monograph No 2, 4<sup>th</sup> Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2<sup>nd</sup> Ed., 2001), including where relevant, information on season at time of application
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

## Appendix B. Pesticide Residue Intake Model (PRIMO)

<b>Boscalid</b>										
Status of the active substance: <b>Approved</b>					Code no.:					
LOQ (mg/kg bw):					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>EC</b>					Source of ARfD: <b>EC</b>					
Year of evaluation: <b>2008</b>					Year of evaluation: <b>2008</b>					
<b>Chronic risk assessment - refined calculations</b>										
		TMDI (range) in % of ADI minimum - maximum								
		10                      53								
<b>No of diets exceeding ADI: ---</b>										
Highest calculated TMDI values in % of ADI		Highest contributor to MS diet (in % of ADI)			2nd contributor to MS diet (in % of ADI)			3rd contributor to MS diet (in % of ADI)		pTMRs at LOQ (in % of ADI)
MS Diet		Commodity / group of commodities			Commodity / group of commodities			Commodity / group of commodities		
53.3	IE adult	5.2	Rhubarb	4.4	Wine grapes	3.3	Barley			
52.2	NL child	5.8	Apples	5.2	Spinach	4.5	Potatoes			
52.0	WHO Cluster diet B	6.4	Wine grapes	5.0	Lettuce	4.3	Onions			
44.8	DE child	11.0	Apples	4.5	Table grapes	2.9	Spinach			
38.2	FR toddler	9.9	Spinach	4.2	Leek	3.9	Potatoes			
33.7	WHO cluster diet E	5.7	Wine grapes	2.9	Potatoes	2.2	Barley			
32.4	FR all population	14.2	Wine grapes	3.0	Witloof	2.7	Other lettuce and other salad			
30.8	WHO regional European diet	5.3	Lettuce	3.1	Potatoes	2.4	Onions			
29.2	FR infant	6.2	Spinach	3.2	Potatoes	2.5	Leek			
28.6	WHO cluster diet D	3.1	Potatoes	2.8	Onions	2.8	Wheat			
27.8	NL general	3.2	Witloof	2.2	Wine grapes	2.1	Potatoes			
25.8	SE general population 90th percentile	3.2	Potatoes	2.5	Onions	1.8	Chinese cabbage			
23.4	PT General population	8.8	Wine grapes	4.1	Potatoes	1.9	Onions			
23.0	WHO Cluster diet F	4.2	Lettuce	2.6	Potatoes	2.1	Wine grapes			
22.8	ES adult	7.5	Lettuce	1.5	Wine grapes	1.3	Barley			
22.4	IT adult	5.3	Lettuce	2.2	Other lettuce and other salad plants	1.8	Wheat			
21.7	DK child	3.0	Cucumbers	2.3	Wheat	2.1	Apples			
21.1	ES child	5.8	Lettuce	1.9	Wheat	1.4	Potatoes			
20.8	IT kids/toddler	4.1	Lettuce	2.8	Wheat	1.5	Other lettuce and other salad			
20.3	UK Toddler	2.9	Sugar beet (root)	2.7	Potatoes	1.7	Wheat			
17.0	UK Infant	2.5	Potatoes	1.4	Apples	1.3	Sugar beet (root)			
16.2	UK vegetarian	2.9	Wine grapes	2.0	Lettuce	1.2	Onions			
13.7	PL general population	2.6	Potatoes	1.9	Apples	1.8	Onions			
13.6	UK Adult	3.8	Wine grapes	1.6	Lettuce	1.1	Potatoes			
13.2	DK adult	4.9	Wine grapes	1.1	Potatoes	0.9	Onions			
10.4	LT adult	2.4	Potatoes	1.7	Apples	1.1	Head cabbage			
9.8	FI adult	1.1	Lettuce	1.1	Wine grapes	0.9	Potatoes			
<p><b>Conclusion:</b> The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Boscalid is unlikely to present a public health concern.</p>										

## ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CXL	Codex Maximum Residue Limit (Codex MRL)
DALA	days after last application
DAR	Draft Assessment Report
DT <sub>90</sub>	period required for 90 % dissipation (define method of estimation)
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
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
HR	highest residue
i.e.	that is (id est, <i>Latin</i> )
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RAC	raw agricultural commodity
RMS	rapporteur Member State

SCPAFF	Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH)
SEU	Southern European Union
STMR	supervised trials median residue
STMR-P	STMR, processed commodity
TMDI	theoretical maximum daily intake
WG	water dispersible granule
WHO	World Health Organization
yr	year