Modication of the existing maximum residue level for boscalid in honey

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF SE submitted a request to the competent national authority in Germany to modify the existing maximum residue level (MRL) for the active substance boscalid in honey and other apiculture products. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for honey from field studies. This MRL proposal covers residues measured in honey samples analysed in the framework of EU National Monitoring Programmes. Adequate analytical methods for enforcement are available to control the residues of boscalid in honey at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that residues concentrations in honey at the level of the proposed MRL are unlikely to present a risk to consumer health.

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Keywords: boscalid, honey, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2018-00322

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Suggested citation: EFSA (European Food Safety Authority), Anastassiou M, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2019. Reasoned opinion on the modification of the existing maximum residue level for boscalid in honey. EFSA Journal 2019;17(11):5897, 25 pp. https://doi.org/10.2903/j.efsa.2019.5897

ISSN: 1831-4732

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in Germany (evaluating Member State (EMS)) to modify the existing maximum residue level (MRL) for the active substance boscalid in honey and other apiculture products. The EMS 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 the European Food Safety Authority (EFSA) on 26 April 2018. To accommodate for the intended uses of boscalid, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 0.15 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 6 February 2019, the EMS submitted the requested information in a revised evaluation report (Germany, 2018), which replaced the previously submitted evaluation report.

The information provided by the applicant, the data evaluated by EFSA under previous MRL assessments and the information from pesticide monitoring programmes have been used to derive the following conclusions.

The nature of boscalid residues in primary crops following foliar applications has been investigated in three crop groups (fruits, pulses/oilseeds and leafy crops). Boscalid (parent compound) was the major residue in the different parts of the plants investigated.

Similarly, in rotational crop metabolism studies in wheat, lettuce and radish, parent boscalid was identified as the major residue.

Studies investigating the effect of processing on the nature of boscalid (standard hydrolysis studies) demonstrated that boscalid is stable under conditions representative of pasteurisation, boiling/brewing/baking and sterilisation.

It is expected that residues in floral nectar resulting from the use of boscalid in primary crops also consists mainly of parent boscalid. The nectar is processed by bees following a process of regurgitation and then the honey is stored under specific conditions in the beehives, before harvesting. Since there is limited information available whether the enzymatic processes occurring in the bee gut involved in the production of honey or the storage in the beehive have an impact on the nature of residues, it would be desirable to further investigate these aspects.

Considering results of metabolism studies (primary crops, rotational crops) and the standard hydrolysis studies, the residue definitions for honey (both enforcement and risk assessment) are proposed as ‘boscalid’ parent compound. These residue definitions are the same as the ones applicable to primary crops and the one implemented in Regulation (EC) No 396/2005.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available to quantify residues of boscalid in honey. The methods allow quantification of residues at or above the LOQ of 0.01 mg/kg.

For investigating the magnitude of the residues of boscalid in honey, a sufficient number of supervised residue trials were provided (field and semi-field trials); in these trials, beehives were placed near oilseed rape fields treated with boscalid during flowering. Residues of boscalid were determined in honey at different timepoints after the treatment of the crop. The study design of the trials was considered appropriate to use the results of the trials for deriving an MRL proposal of 0.15 mg/kg. In addition, EFSA assessed the monitoring data from official EU National control programmes conducted by several Member States during 2013–2017, to check the plausibility of the residues found in the supervised residue trials. The highest boscalid residue measured in more than 1,500 honey samples was 0.082 mg/kg.

Honey bees may be exposed to boscalid residues not only by foraging primary crops treated with boscalid, but also via residues in rotational crops which are grown in fields where boscalid was previously applied and where residues are taken up from the soil. Although several data gaps have been identified at the time of the MRL review related to the rotational and succeeding crops, it is likely that the scenario tested in the residue trials would cover this source of exposure of bees, which could also contribute to the overall residues in honey.

Specific studies investigating the magnitude of boscalid residues in processed commodities have not been submitted and are not required, considering the low contribution of residues in honey to the total calculated consumer exposure and the stability of boscalid under processing conditions.

Residues of boscalid in other commodities of animal origin (swine, ruminant and other farmed animals) were not assessed since honey is normally not a feed item to livestock.
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 body weight (bw) per day. No acute reference dose (ARfD) was deemed necessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). A comprehensive long-term exposure assessment was performed taking into account the residue concentrations in crops for which the European Union (EU) MRLs were established, residues in animal products, as well as the contribution of the residues of boscalid expected in honey. No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total chronic calculated intake accounted for approximately 51.2% of the ADI (Dutch, children); the contribution of the residues in honey to the total exposure accounted for a maximum of 0.04% of the ADI (German, children).

EFSA concluded that the possible occurrence of boscalid residues in honey at the proposed MRL will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers’ health.

The peer review of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---|---|---|---|---|
| 01040000 | Honey and other apiculture products\(^{(b)}\) | 0.05\(^{*}\) | 0.15 | The available data are sufficient to derive an MRL proposal for honey. The MRL proposal is higher than the boscalid residues found in EU pesticide monitoring programmes (1,583 samples analysed between 2013 and 2017).
Since boscalid is a fat-soluble compound, residues are expected to accumulate in lipophilic matrices, such as beeswax. Thus, the MRL proposal might not cover honey that contains honeycombs.
The proposed MRL for honey is unlikely to pose a risk for EU consumers. |

\(^{*}\): Indicates that the MRL is set at the limit of analytical quantification (LOQ).
\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
\(^{(b)}\): Currently, MRLs set for honey are not applicable to other apicultural products (Commission Regulation (EU) 2018/62).
(F): Fat soluble.

MRL: maximum residue level.

It must be noted that the investigation of possible risk to honey bees related to the use of boscalid in oilseed rape or in any other crop is outside the scope of this reasoned opinion. The risk to honey bees is currently under assessment in the framework of the peer-review process of the renewal of the first approval of boscalid. Additionally, national competent authorities at Member State level have to pay attention to the bee health and bee protection when granting authorisations for plant protection products.
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Assessment

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in Germany (hereafter referred to as evaluating Member State (EMS)) to modify the existing MRL for the active substance boscalid in honey and other apiculture products. The EMS 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 the European Food Safety Authority (EFSA) on 26 April 2018.

Boscalid is the ISO common name for 2-chloro-N-(4′-chlorobiphenyl-2-yl)nicotinamide (IUPAC). The chemical structure of the active substance is reported in Appendix E.

Boscalid was evaluated in the framework of Council Directive 91/414/EEC1 with Germany designated as rapporteur Member State (RMS); the representative uses assessed were foliar treatments on grapes, oilseed rape, beans and peas. The draft assessment report (DAR) of boscalid was not peer reviewed by EFSA; therefore, no EFSA conclusion is available. Boscalid was approved2 for the use as fungicide on 1 August 2008. National authorisations have been granted for a wide range of crops, including crops that are foraged by bees. The process of renewal of the first approval is currently ongoing.

The European Union (EU) MRLs for boscalid are established in Annexes II of Regulation (EC) No 396/2005.3 The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014) and the proposed modifications have been implemented in the MRL legislation. As a result of the MRL review, the MRL for honey has been lowered from 0.5 mg/kg to the limit of quantification (LOQ) of 0.05* mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2018), the draft assessment report (DAR) (and its addendum) (Germany, 2002, 2006) prepared under Council Directive 91/414/EEC, the Commission review report on boscalid (European Commission, 2008), as well as the conclusions from previous EFSA opinions on boscalid (EFSA, 2014, 2015).

For this application, the data requirements established in Regulation (EU) No 544/20114 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011). In its assessment, EFSA also considered some aspects of the technical guidelines on honey (European Commission, 2018) recently published. 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 (EU) No 546/2011.5

As the EU peer review for the renewal of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application, including the end points of relevant studies assessed previously, are presented in Appendix B.

The evaluation report submitted by the EMS (Germany, 2018) and the exposure calculations performed with the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthiazacilcarb, boscalid, carvone, fludioxonil, Paecilomyces lilacinus and prothioconazole as active substances. OJ L 94, 5.4.2008, p. 13–20.
3 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, 16.3.2005, p. 1–16.
4 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
5 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, 11.6.2011, p. 127–175.
1. Residues in plants/honey

1.1. Nature of residues and methods of analysis in plants/honey

1.1.1. Nature of residues in primary crops

The nature of boscalid residues in primary crops following foliar applications has been investigated in three crop groups (fruits, pulses/oilseeds and leafy crops). These studies were assessed in the framework of the MRL review of the active substance (EFSA, 2014). The available metabolism studies indicated that the metabolic pathway of boscalid is similar in all crops investigated and that unchanged parent boscalid was the main component in all plant parts.

Honey is a product originated from sugary secretions of plants (floral nectar mainly). Based on these studies, EFSA expects that residues in floral nectar resulting from the use of boscalid in primary crops also consists mainly of parent boscalid. The nectar is processed by bees following a process of regurgitation and then the honey is stored under specific conditions in the beehives before harvesting. Further information, whether enzymatic processes occurring in the bee gut involved in the production of honey or the storage in the beehive have an impact on the nature of residues is not available.

1.1.2. Nature of residues in rotational crops

According to the soil degradation studies evaluated in the framework of the peer review, the DT$_{90}$ value is greater than the trigger value of 100 days (European Commission, 2008).

Residues in nectar collected by bees may occur not only due to treatment of the primary crop, but due to the persistence of boscalid in soil, residues are also expected in nectar of rotational crops grown on fields previously treated with boscalid.

A confined rotational crop study has been evaluated during the MRL review (EFSA, 2014). It was concluded that based on the information provided in the study on lettuce, radish and wheat, boscalid is the main expected residue in the rotational and succeeding crops.

Considering the information above, EFSA concluded that it is likely that in rotational crops residues in pollen and nectar resulting from the uptake of residues via roots might primarily consist of boscalid parent compound.

1.1.3. Nature of residues in processed commodities

Standard hydrolysis studies simulating the effect on the nature of boscalid residues under processing conditions representative of pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6) were assessed during the MRL review (EFSA, 2014) and it was concluded that the compound is hydrolytically stable under the representative conditions. Thus, for processed commodities, the same residue definition as for raw agricultural commodities (RAC) is applicable (EFSA, 2014).

The process of converting nectar to honey does not involve hydrolytic conditions at elevated temperature; however, honey may be used as an ingredient in processed products that are heat treated. Considering the stability of boscalid under hydrolytic conditions representative for food processing, it is unlikely that in processed honey products residues of boscalid are degraded to other compounds.

1.1.4. Methods of analysis in plants/honey

Several enforcement methods have been previously assessed which were validated for different plant matrices (EFSA, 2014).

For honey, the multi-residue QuEChERS method in combination with high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS), as described by CEN (2008), was suggested by the EMS (Germany, 2018). This analytical method was sufficiently validated for honey at the LOQ of 0.01 mg/kg. Thus, for honey a sufficiently validated analytical method is available that can be used for MRL enforcement.

1.1.5. Storage stability of residues in plants/honey

The storage stability of boscalid has been demonstrated for a period of 24 months at −18°C in high water commodities (cabbages, peaches, peas), high oil content commodities (rapeseeds) and dry/high
starch commodities (wheat grain, cereals straw) and for a period of 16 months at −18°C in high acid content commodities (grapes) (EFSA, 2014).

No particular storage stability studies are available for honey. Given the demonstrated stability of boscalid over at least 16 months in the different plant matrices, EFSA agrees with the EMS that it can be reasonable assumed that boscalid residues in honey are stable for at least 16 months.

1.1.6. Proposed residue definitions

Boscalid was the main residue found in primary and rotational crops. In previous assessments, parent compound boscalid was proposed as the residue definition for enforcement and risk assessment. The same residue definition applies to processed products due to the stability of the residues of boscalid under conditions representative of pasteurisation, boiling/brewing/baking and sterilisation.

In the case of boscalid, the residue definitions derived for primary crops might be appropriate for honey, since it is a product originated mainly from floral nectar. This is in line with the current risk management practice that establishes by default the same residue definition for honey as for primary crops. Although the available data do not give indications that metabolites are likely to occur in honey, in general, further investigations would be desirable whether enzymatic processes that occur during the transformation of nectar to honey and the storage of honey in the beehives have an impact on the nature of residues, considering the limited experimental data on this subject.

The residue definition implemented in Regulation (EC) No 396/2005 is parent boscalid.

1.2. Magnitude of residues in plants/honey

1.2.1. Magnitude of residues in honey

Residue trials investigating the magnitude of residues in honey were conducted in Germany, which were used to derive the MRL proposal. Detailed information is available in Section 1.2.1.1. In addition, EFSA assessed the monitoring data from official EU National control programmes conducted by several Member States during 2013–2017, to verify the plausibility of the MRL proposal derived from the residue trials (Section 1.2.1.2).

1.2.1.1. Magnitude of residues from field trials conducted on rapeseed

The EMS proposes to derive the MRL for honey from field trials and semi-field trials conducted during the growing seasons 2003 and 2004 in Germany.

- Design and results of a study performed under field conditions (the study contains 4 trials on different locations in Germany):

  Boscalid was applied on oilseed rape once at a rate of 250 g/ha during flowering (BBCH 60–69). The size of the oilseed rape fields ranged from 6.1 to 14.2 ha. Beehives were placed close to the treated fields before the application. Samples of the aerial parts of the rape plants were taken after the boscalid application and analysed for boscalid residues. Honey samples were taken from the beehives placed next to the treated fields 20–26 days after the treatment of the crop. Pollen was gathered with pollen traps installed at the entrance of the beehives and analysed in order to check the bee flight to ensure that bees visited the treated rape seed fields. As result, 82.7–88.3% of the pollen was identified as rape type.

  The residue concentration in the four trials ranged from 0.01 to 0.08 mg/kg.

- Design and results of study performed under semi-field conditions (the study was conducted in Germany):

  One residue trial was conducted under semi-field conditions, i.e. using tunnel tents. Three different scenarios were tested: in the first one, boscalid (500 g/ha) was applied before flowering (BBCH 59). In the second scenario, the crop was treated at full flowering (BBCH 65) and the bee colonies were placed in the tunnels the day after the treatment. In the third scenario, the crop was also treated at full flowering, with the bee colonies being present in the tunnels already during the application of boscalid. From all scenarios, honey samples were taken twice after the start of the bee exposure. The first sampling was carried out 21, 8 or 7 days after the respective treatment, the second one after the end of flowering period which was 26, 13 and 12 days after application (Germany, 2018).
In the first and second scenario, boscalid residues in honey were all below the LOQ (0.05 mg/kg). Only in scenario three (treatment of oilseed rape during foraging activity of the bees) quantifiable residues were determined (i.e. 0.064 mg/kg) seven days after the treatment.

Overall both studies (field and semi-field studies) were considered sufficient in terms of quality and number to derive an MRL proposal for honey. It should be noted that currently, MRLs set for honey are not applicable to other apicultural products following Commission Regulation (EU) 2018/62.

The analytical methods used to analyse the residue trial samples have been sufficiently validated and were proven to be fit for purpose (Germany, 2018). Prior to analysis, honey samples were stored for up to 14 months under frozen conditions. It is expected that boscalid residues were stable for the storage period (see also Section 1.1.5). The results of the residue trials considered for deriving the MRL proposal for honey and pertinent risk assessment values are summarised in Appendix B.1.2.1.

The applicant provided six additional residue trials performed in Germany in which beehives were located near fields of oilseed rape which was treated with boscalid during flowering (application rate 200–250 g/ha). Honey samples were taken 15–42 days after the application of boscalid. In none of the trials, quantifiable residues of boscalid were found in honey. These studies were conducted in open field. No information was provided whether in vicinity other attractive crops for bees were grown and whether these crops were also treated with boscalid. Information from pollen samples was not available. Thus, these studies were considered not fully representative for MRL setting. However, the studies can be used as supporting data, similar to the monitoring data reported in Section 1.2.1.2, confirming that the MRL proposal derived from the valid residue trials (field and semi-field studies) covers the scenario tested in the trials.

### 1.2.1.2. Magnitude of residues from EU national monitoring program

In the framework of Article 32 of Regulation (EC) No 396/2005 (official national control programmes), monitoring data were submitted to EFSA. A total of 1,590 samples of honey were analysed for boscalid residues in the reference period from 2013 to 2017. Samples originated from 25 different EU Member States and from 15 non-EU countries; most of the samples (61%, 972 samples) were from Germany. For 11% of the samples, the origin was unknown. The validated LOQs for the analytical methods used in the analysis ranged from 0.002 to 0.5 mg/kg.

Overall, 27 samples (2%) contained quantifiable boscalid residues (residues above the LOQ); only one sample contained a residue concentration greater than the current MRL of 0.05 mg/kg (i.e. 0.08 mg/kg). The highest boscalid residue measured in honey in the reference period accounted for 0.082 mg/kg.

The results of the statistical assessment of the monitoring data are presented in Appendix B.1.2.2.

The data demonstrated that the MRL proposal derived from the valid residue trials (see Section 1.2.1.1) is higher than the highest residue found in market samples of honey.

### 1.2.2. Magnitude of residues in rotational crops

Regarding the magnitude of boscalid residues in crops that can grow in rotation, insufficient information has been presented during the MRL review to quantify the accumulation of boscalid residues in soils and in rotational crops after a long period of time (EFSA, 2014). The data gaps were identified as follows:

- Further data to confirm the plateau level in soil that served as a basis for performing the rotational crop field trials;
- Further rotational crop field trials to address residues in strawberries, fruiting vegetables, stem vegetables, leafy vegetables, etc.);
- Residue trials after repeated application in permanent crops.

The data gaps identified have been implemented in Regulation (EU) 2016/156. The information is not essential for the current application. However, once the requested studies are available, they will...
complement the current information in order to get a better understanding of the residue situation in rotational crops, the related exposure of honey bees and the final magnitude of residues in honey.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the effect of processing on the magnitude of boscalid residues in honey have not been submitted and are not required, considering the hydrolytic stability of boscalid (see Section 1.1.3), the low contribution of residues in honey to the total calculated consumer exposure and the stability of boscalid under processing conditions.

1.2.4. Additional consideration on the magnitude of the residues in other apiculture products (wax, pollen, royal jelly)

There is evidence that residues of certain active substances used as pesticides may be transferred not only to honey, but also to other bee products (e.g. bee bread, pollen, beeswax) (Chauzat and Faucon, 2007; Wilmart et al., 2016; Calatayud-Vernich et al., 2018; Lozano et al., 2019; Shimshoni et al., 2019).

Since boscalid is a fat-soluble compound (log P<sub>OW</sub> 2.96 at 21°C, pH 7.1), residues are expected to accumulate in lipophilic matrices, such as beeswax. Thus, it is likely that honey containing honeycombs in a certain amount may present higher residue concentrations than the residues measured in the residue trials, which refer only to honey samples.

For other apiculture products, no data are available to estimate the magnitude of boscalid residues. However, since an MRL set for honey does not currently apply to other apicultural products, no further recommendations are derived in the framework of this application.

1.2.5. Proposed MRLs

Based on the available residue trials, an MRL proposal of 0.15 mg/kg is derived for honey, using the OECD MRL calculator. The MRL proposal derived from the valid residue trials is higher than the highest residue reported for honey from the EU pesticide monitoring programmes for the reference period of 2013–2017. In Section 3, EFSA assessed the possible risk to EU consumers from being exposed to boscalid residues in honey at the level of the proposed MRL.

2. Residues in livestock

Not relevant for the current assessment.

3. 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 subgroups of the EU population<sup>9</sup> (EFSA, 2007).

The estimated long-term (chronic) exposure was compared with the Acceptable Daily Intake (ADI) derived for boscalid in the framework of the inclusion of boscalid in Annex I of Directive 91/414/EEC (European Commission, 2008). No short-term (acute) exposure assessment has been calculated since the setting of an ARfD has not been considered necessary.

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 EU level supported by data. 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 on these crops (EFSA, 2014). EFSA updated the chronic risk assessment performed under the Article 12 review, considering the MRL proposals taken over in the EU Regulation by Reg. (EU) 2016/156 and including the MRL<sup>10</sup> value derived for honey in

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<sup>9</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, 2007a).

<sup>10</sup> EFSA has considered a conservative approach using the MRL instead of the STMR considering the limited experience in the setting of MRLs for honey.
the framework of the current application. The input values used for the dietary exposure calculation are summarised in Appendix D.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total chronic calculated intake accounted for approximately 51.2% of the ADI (Dutch, children); the contribution of the residues in honey to the total exposure accounted for a maximum of 0.04% of the ADI (German, children).

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

EFSA concluded that the MRL proposal for honey derived from field residue studies will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a health risk to consumers.

4. Conclusions and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for honey based on field and semi-field residue trials where bees were exposed to boscalid by placing the honey bee hives next to oilseed rape fields treated with boscalid. It should be noted that the MRL proposal might not cover honey placed in the market that contains honeycombs.

EFSA concluded that the residues expected in honey at the level of the proposed MRL will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers’ health.

It must be noted that the investigation of possible risk to bees related to the use of boscalid in oilseed rape or other crops is outside the scope of this reasoned opinion. The evaluation of the risk to honey bees is currently on-going in the framework of the renewal of the approval of boscalid at EU level. National competent authorities at Member State level should pay attention to the bee health and bee protection when granting authorisations for plant protection products.

Taking into account experiences gained in using the EU technical guidelines for the MRL setting in honey (European Commission, 2018), EFSA recommends that in a future revision of the EU guidance document further details should be elaborated particularly to consider the following aspects:

A. Design of residue trials representative for the uses under assessment:

- More guidance should be provided on the selection of the geographical location and distribution of residue trials with regard to the authorised uses across Europe. EFSA recommends that field residue trials for honey should be performed in the different European regulatory zones if Good Agricultural Practices (GAPs) are authorised or intended for crops attractive to bees in Northern and Southern Europe;
- Further guidance should be developed on the design of field residue trials in the crops under consideration or surrogate crops like oilseed rape or phacelia to ensure realistic results for honey reflecting the intended/authorised uses (e.g. dose rate, timing and frequency of the applications);
- Further information on the landscape composition of the field residue trials should be given (i.e. typology of vegetation in vicinity to the beehive that may contribute to or dilute the final residues in honey);
- EFSA recommends that pollen composition is always reported in the field residue trials in order to verify whether the bees forage in the treated crop or in other non-treated crops;

B. Information related to the nature of the residues in honey to which consumers might be exposed to:

- Further guidance should be given how to interpret available information from metabolism studies in primary crops and rotational crops (e.g. representative for oilseed and pulses/fruits/leafy crops/root crops/cereals) in the different parts of the plants with regard to the nature of residues in honey.
- Further guidance should be given on how to decide whether an active substance and/or relevant metabolite(s) may pose systemic properties. According to the technical guidelines (European Commission 2018), in several scenarios of the decision-making scheme, the investigation of residues in honey is triggered by this characteristic and therefore further clarification is necessary with this regard;
• Information on the potential enzymatic processes occurring in the bee gut involved in the production of honey have an impact on the nature of the pesticide residues in honey. This information might elucidate if the processing by bees and in-hive processing might impact the nature of the residues to which final consumers might be exposed to;

• Further investigation on the behaviour of the residues in the honey bee combs would be desirable in particular for active substances and metabolites that might accumulate in beeswax in order to guarantee that the MRL proposal covers also honey with honey bee combs placed in the market or other apicultural products.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CEN European Committee for Standardisation (Comité Européen de Normalisation)
DAR draft assessment report
DAT days after treatment
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC–MS gas chromatography with mass spectrometry
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
InChiKey International Chemical Identifier Key
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LOQ limit of quantification
MRL maximum residue level
MS Member States
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
P<sub>ow</sub> partition coefficient between n-octanol and water
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern Europe
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
WHO World Health Organization
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Not relevant.\textsuperscript{11} In the framework of the review of existing MRLs according to Art. 12 of EU Regulation 396/2005 (EFSA, 2014), numerous GAPs were reported for crops that might be attractive to bees for food foraging and that might contribute to the final residues of boscalid in honey. However, since the MRL application is not linked to one specific GAP and applies to honey as food item for consumers, this Appendix is not relevant for the given application.

\textsuperscript{11} A GAP was reported in the MRL application and in the ER (Germany, 2018); the GAP authorised in oilseed rape was used to assess the reliability and appropriateness of the residue trials for honey (see Section 1.2.1.1).
### Appendix B – List of end points

#### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

#### B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|----------------------------------|-------------|---------|---------------|----------------|----------------|
| Fruit crops | Grapes | Foliar (F) | 3 × 800 g/ha | 45 | Radiolabelled active substance: U-14C-diphenyl-boscalid and 3-14C-pyridine-boscalid (EFSA, 2014) |
| Leafy crops | Lettuces | Foliar (G), 3 × 700 g/ha | 18 | Radiolabelled active substance: U-14C-diphenyl-boscalid and 3-14C-pyridine-boscalid (EFSA, 2014) |
| Pulses/oilseeds | Beans | Foliar (G), 3 × 500 g/ha | 0(a), 14(b), 53(c) | Radiolabelled active substance: U-14C-diphenyl-boscalid and 3-14C-pyridine-boscalid (a): whole plant (b): forage, green beans, pods and seeds (c): bean straw, bean dry pods and dry seeds (EFSA, 2014) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|---------------|-----------|----------------|
| Root/tuber crops | Radishes | Bare soil (G) | 1 × 2,100 g/ha | 30, 120, 370, 365 | Radiolabelled active substance: U-14C-diphenyl-boscalid and 3-14C-pyridine-boscalid (EFSA, 2014) |
| Leafy crops | Lettuces | | | | |
| Cereal (small grain) | Wheat | | | | |
| other | | | | | |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4) | Yes | EFSA (2014) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | EFSA (2014) |
| Sterilisation (20 min, 120°C, pH 6) | Yes | EFSA (2014) |
| Other processing conditions | – | – |
Can a general residue definition be proposed for primary crops?  
Yes  
EFSA (2014)

Rotational crop and primary crop metabolism similar?  
Yes  
EFSA (2014)

Residue pattern in processed commodities similar to residue pattern in raw commodities?  
Yes  
EFSA (2014)

Plant residue definition for monitoring (RD-Mo)  
Boscalid  
According to current risk management practice, the residue definition for plant products is extrapolated to honey

Plant residue definition for risk assessment (RD-RA)  
Boscalid  
According to current risk management practice, the residue definition for plant products is extrapolated to honey

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)  
Matrices with high water content, high acid content and dry matrices: GC-MS, LOQ 0.01 mg/kg  
Matrices with high oil content: GC-MS, LOQ 0.02 mg/kg  
Matrices with high water content, high acid content and high oil content matrices: HPLC-MS/MS, LOQ 0.01 mg/kg  
Matrices with high water content, high acid content, high oil content matrices and dry/starch commodities: multi-residue QuEChERS method in combination with HPLC-MS/MS, LOQ 0.01 mg/kg (EFSA, 2014)  
Honey: multi-residue QuEChERS method in combination with HPLC-MS/MS, LOQ 0.01 mg/kg (Germany, 2018)

DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; GC–MS: gas chromatography with mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; LOQ: limit of quantification.

### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|-----------------|-------------------|----------------|
|                                   | High water content | Cabbages, Peaches, Peas | −18 | 24 Months | Boscalid | EFSA (2014) |
|                                   | High oil content | Rapeseeds | −18 | 24 Months | Boscalid | EFSA (2014) |
|                                   | Dry/High starch | Wheat grain cereals straw | −18 | 24 Months | Boscalid | EFSA (2014) |
|                                   | High acid content | Grapes | −18 | 16 Months | Boscalid | EFSA (2014) |
|                                   | Others | | | | | |

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B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

| Commodity | Region/Indoor(a) | Residue levels observed in supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR (c) (mg/kg) |
|-----------|-----------------|------------------------------------------------|----------------|------------------------|--------------|------------------|
| Honey     | NEU             | 0.01, 0.02, 0.06, 0.064, 0.08                      | Field trials for estimating residue concentration in honey: Oilseed rape was treated at BBCH between 60 and 69 with 250 g/ha. Beehives were placed close to the treated fields. Samples of honey were taken at different times. For further information, see Section 1.2.1.1. Samples were analysed for parent boscalid (LOQ 0.01 mg/kg). MRL was calculated using the OECD MRL calculator (OECD, 2011) | 0.15        | 0.08          | 0.06            |

MRL: maximum residue level; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; BBCH: growth stages of mono- and dicotyledonous plants; LOQ: limit of quantification.

(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.

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity.

B.1.2.2. Summary of residues in honey found in EU pesticide monitoring

| EU monitoring data submitted to EFSA under Art. 32 of Reg. 396/2005 |
|---------------------------------------------------------------|
| Total number of samples | 1,583(a) |
| Number of samples per year | 2013 420 |
| | 2014 221 |
| | 2015 333 |
| | 2016 204 |
| | 2017 405 |
| Number of samples with residues > LOQ (% of samples > LOQ) | 27 (1.7%) |
| Number of samples with residues > current MRL (0.05 mg/kg) | 1(a) |
| Mean(b) | 0.0082 mg/kg |
| Standard deviation(b) | 0.0096 mg/kg |
| Median(c) | 0.01 mg/kg |
| Maximum | 0.082 mg/kg |
| P90(c) | 0.01 mg/kg |
| P95(c) | 0.02 mg/kg |
| P97.5(c) | 0.05 mg/kg |

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EU monitoring data submitted to EFSA under Art. 32 of Reg. 396/2005

| pgg(c) | 0.05 mg/kg |

P: percentile; MRL: maximum residue level; LOQ: limit of quantification.
(a): Seven additional samples were reported where the LOQ of the analytical method was greater than the current MRL of 0.05 mg/kg; these samples were excluded for the statistical analysis.
(b): Upper bound approach: For samples with residues below or at the LOQ, the calculation was performed assuming the residues were equal to the numerical value of the LOQ.
(c): Percentiles calculated using Microsoft Excel.

B.1.2.3. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Inconclusive | Data gaps identified in MRL review
| Residues in rotational and succeeding crops expected based on field rotational crop study? | – | Not relevant for the current assessment

MRL: maximum residue level.

B.1.2.4. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant for the current assessment.

B.3. Consumer risk assessment

Not relevant since no ARfD has been considered necessary (European Commission, 2008).

| ADI | 0.04 mg/kg bw per day (European Commission, 2008) |
| Highest IEDI, according to EFSA PRIMo | 51.2% ADI (Dutch, children) |
| Contribution of crops assessed: Honey and other apiculture products: 0.04% of ADI (German, children) |
| Assumptions made for the calculations | The risk assessment was performed using EFSA PRIMo rev.2 |
| | EFSA updated the chronic risk assessment performed under the Article 12 review, considering the STMR values corresponding to the MRLs implemented in the EU Regulation by Reg. (EU) 2016/156 and the MRL for honey derived from the field residue trials |
| | The food commodities for which no uses were reported were excluded from the exposure calculation assuming that there is no use on these crops (EFSA, 2014) |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; MRL: maximum residue level.
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|------------|-------------------------|-------------------------|------------------------|
| 01040000 | Honey and other apiculture products<sup>(b)</sup> | 0.05<sup>*</sup> | 0.15 | The available data are sufficient to derive an MRL proposal for honey. The MRL proposal is higher than the boscalid residues found in EU pesticide monitoring programmes (1,583 samples analysed between 2013 and 2017). Since boscalid is a fat-soluble compound, residues are expected to accumulate in lipophilic matrices, such as beeswax. Thus, the MRL proposal might not cover honey that contains honeycombs. The proposed MRL for honey is unlikely to pose a risk for EU consumers. |

<sup>(a)</sup> Commodity code number according to Annex I of Regulation (EC) No 396/2005.<br><sup>(b)</sup> Currently, MRLs set for honey are not applicable to other apicultural products (Commission Regulation (EU) 2018/62.<br><sup>(F)</sup> Fat soluble.

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**Enforcement residue definition:** Boscalid<sup>(F)</sup>
Appendix C – Pesticide Residue Intake Model (PRIMo)

### Boscald

| Status of the active substance: | Approved |
|---------------------------------|----------|
| Code no.                         | 0.01     |
| LOD (mg/kg bw)                   | Proposed LOD |

#### Toxicological end points

- **ADI (mg/kg bw per day):** 0.04
  - Source of ADI: EC
- **ARfD (mg/kg bw):** n.n.
  - Source of ARfD: EC

| Year of evaluation | ADI | Year of evaluation | ADI |
|--------------------|-----|--------------------|-----|
| 2008               | 0.04| 2008               | 0.04|

| No of diets exceeding ADI | TMDI (range) in % of ADI |
|---------------------------|--------------------------|
|                           | minimum – maximum        |
|                           |                          |

#### Chronic risk assessment – refined calculations

| Highest calculated TMDI values in % of ADI | High contributor to MS diet (in % of ADI) | Commodity/group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity/group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity/group of commodities | pTMRLs at LOQ (in % of ADI) |
|-------------------------------------------|-------------------------------------------|--------------------------------|-----------------------------------------|--------------------------------|----------------------------------------|--------------------------------|---------------------------|
| 51.2 NL child                             | 5.6 Apples                                |                                | 5.2 Spinach                             |                                | 4.5 Potatoes                           |                                | 0.0                       |
| 48.4 WHO Cluster diet B                   | 6.4 Wine grapes                           |                                | 5.0 Lettuce                             |                                | 4.3 Oranges                            |                                | 0.0                       |
| 43.9 DE child                             | 11.0 Apples                               |                                | 4.5 Table grapes                        |                                | 2.9 Spinach                            |                                | 0.0                       |
| 43.5 IE adult                             | 4.4 Wine grapes                           |                                | 3.3 Barley                              |                                | 2.7 Sweet potatoes                     |                                | 0.0                       |
| 37.9 FR toddler                           | 9.9 Spinach                               |                                | 4.2 Leaf                                |                                | 3.9 Potatoes                           |                                | 0.0                       |
| 32.6 WHO cluster diet E                   | 5.7 Wine grapes                           |                                | 2.9 Potatoes                            |                                | 2.2 Barley                             |                                | 0.0                       |
| 30.9 FR all population                    | 14.2 Wine grapes                          |                                | 3.0 Witloof                             |                                | 2.7 Other lettuce and other salad     |                                | 0.0                       |
| 28.6 FR infant                            | 6.2 Spinach                               |                                | 3.2 Potatoes                            |                                | 2.5 Leaf                               |                                | 0.0                       |
| 27.4 WHO regional European diet           | 5.3 Lettuce                               |                                | 3.1 Potatoes                            |                                | 2.4 Onion                              |                                | 0.0                       |
| 27.3 WHO cluster diet D                   | 3.1 Potatoes                              |                                | 2.8 Onion                               |                                | 2.8 Wheat                              |                                | 0.0                       |
| 27.0 NL general                           | 3.2 Witloof                               |                                | 2.2 Wine grapes                         |                                | 2.1 Potatoes                           |                                | 0.0                       |
| 23.6 SE general population 9th percentile | 3.2 Potatoes                              |                                | 2.5 Onion                               |                                | 1.8 Chinese cabbage                    |                                | 0.0                       |
| 23.4 PT General population                | 6.8 Wine grapes                           |                                | 4.1 Potatoes                            |                                | 1.9 Onion                              |                                | 0.0                       |
| 22.9 WHO Cluster diet F                   | 4.2 Lettuce                               |                                | 2.6 Potatoes                            |                                | 2.1 Wine grapes                        |                                | 0.0                       |
| 21.5 DK child                             | 3.0 Cucumbers                             |                                | 2.3 Wheat                               |                                | 2.1 Apples                             |                                | 0.0                       |
| 21.0 IT adult                             | 5.3 Lettuce                               |                                | 2.2 Other lettuce and other salad plants |                                | 1.8 Wheat                              |                                | 0.0                       |
| 21.0 ES adult                             | 7.5 Lettuce                               |                                | 1.5 Wine grapes                         |                                | 1.3 Barley                             |                                | 0.0                       |
| 20.1 IT kids/toddler                     | 4.1 Lettuce                               |                                | 2.8 Wheat                               |                                | 1.5 Other lettuce and other salad     |                                | 0.0                       |
| 19.9 ES child                             | 5.6 Lettuce                               |                                | 1.9 Wheat                               |                                | 1.4 Potatoes                           |                                | 0.0                       |
| 19.5 UK Toddler                           | 2.9 Sugar beet (root)                     |                                | 2.7 Potatoes                            |                                | 1.7 Wheat                              |                                | 0.0                       |
| 16.4 UK infant                            | 2.5 Potatoes                              |                                | 1.4 Apples                              |                                | 1.3 Sugar beet (root)                  |                                | 0.0                       |
| 15.1 UK vegetarian                       | 2.9 Wine grapes                           |                                | 2.0 Lettuce                             |                                | 1.2 Onion                              |                                | 0.0                       |
| 13.7 PL general population                | 2.6 Potatoes                              |                                | 1.9 Apples                              |                                | 1.8 Onion                              |                                | 0.0                       |
| 13.2 UK Adult                             | 3.6 Wine grapes                           |                                | 1.6 Lettuce                             |                                | 1.1 Potatoes                           |                                | 0.0                       |
| 13.0 DK adult                             | 4.9 Wine grapes                           |                                | 1.1 Potatoes                            |                                | 0.9 Onion                              |                                | 0.0                       |
| 10.4 LT adult                             | 2.4 Potatoes                              |                                | 1.7 Apples                              |                                | 1.1 Heart cabbages                     |                                | 0.0                       |
| 9.7 FI adult                              | 1.1 Lettuce                               |                                | 1.1 Wine grapes                         |                                | 0.9 Potatoes                           |                                | 0.0                       |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
### Acute risk assessment/children – refined calculations

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|---|---|---|---|
| --- | --- | --- | --- |

| Commodities | pTMRL/threshold MRL (mg/kg) | Commodities | pTMRL/threshold MRL (mg/kg) |
|---|---|---|---|
| Unprocessed commodities | --- | --- | --- |

### Acute risk assessment/adults/general population – refined calculations

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

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| No of commodities for which ARfD/ADI is exceeded | No of critical MRLs (IEST 1) | No of critical MRLs (IEST 2) |
|--------------------------------------------------|-----------------------------|-----------------------------|
| Highest % of ARfD/ADI Processed commodities pTMRL/ threshold MRL (mg/kg) | --- | --- |
| Highest % of ARfD/ADI Processed commodities pTMRL/ threshold MRL (mg/kg) | --- | --- |

1) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**pTMRL**: provisional temporary MRL.

Conclusion:
As no ARfD was considered necessary, it is concluded that the short-term intake of Boscalid residues is unlikely to present a public health concern.

As no ARfD was considered necessary, it is concluded that the short-term intake of Boscalid residues is unlikely to present a public health concern.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Not relevant for the current application.

D.2. Consumer risk assessment

| Commodity                                           | Chronic risk assessment |
|-----------------------------------------------------|-------------------------|
|                                                     | Input value (mg/kg)     |
| Honey and other apiculture products(a)              | 0.15 MRL (Table in section B.1.2.1) |
| Citrus fruits                                       | 0.07 STMR-P (EFSA, 2014) |
| Tree nuts                                           | 0.27 STMR (EFSA, 2014)  |
|                                                     | Highest of the group    |
| Apples                                              | 0.37 STMR (EFSA, 2014)  |
| Pears, Quinces                                      | 0.42 STMR (EFSA, 2014)  |
| Apricots, peaches                                   | 0.77 STMR (EFSA, 2014)  |
| Cherries                                            | 1.51 STMR (EFSA, 2014)  |
| Plums                                               | 1.21 STMR (EFSA, 2014)  |
| Table and wine grapes                               | 1.42 STMR (EFSA, 2014)  |
| Strawberries                                        | 1.95 STMR (EFSA, 2014)  |
| Cane fruits                                         | 2.53 STMR (EFSA, 2014)  |
| Other small fruits and berries                      | 3.60 STMR (EFSA, 2014)  |
| Bananas                                             | 0.05 STMR-P (EFSA, 2014) |
| Kiwis                                               | 0.08 STMR-P (EFSA, 2014) |
| Potatoes                                            | 0.31 STMR (EFSA, 2014)  |
| Root and tuber vegetables except beetroots          | 0.31 STMR (EFSA, 2014)  |
| Beetroots                                           | 0.38 STMR (EFSA, 2014)  |
| Bulb vegetables                                     | 2.30 STMR (EFSA, 2014)  |
| Tomatoes, aubergines                                | 0.4 STMR (EFSA, 2014)   |
| Peppers and other solanaceae                        | 0.57 STMR (EFSA, 2014)  |
| Cucurbits – edible peel                             | 0.73 STMR (EFSA, 2014)  |
| Cucurbits – inedible peel                           | 0.40 STMR (EFSA, 2014)  |
| Flowering brassica and head brassica except head cabbage | 1.52 STMR (EFSA, 2014) |
| Head cabbage                                        | 1.10 STMR (EFSA, 2014)  |
| Leafy brassica                                      | 3.65 STMR (EFSA, 2014)  |
| Kohlrabi                                            | 1.52 STMR (EFSA, 2014)  |
| Lettuce and other salad plants including brassicaceae including spinach | 5.60 STMR (EFSA, 2014) |
| Purslane, beet leaves (chards), vine leaves and water cress? | 3.65 STMR (EFSA, 2014) |
| Herbs                                               | 14.45 STMR (EFSA, 2014) |
| Beans (with pods)                                   | 0.66 STMR (EFSA, 2015)  |
| Beans (without pods)                                | 0.50 STMR (EFSA, 2014)  |
| Peas (with pods)                                    | 0.66 STMR (EFSA, 2015)  |
| Peas (without pods)                                 | 0.50 STMR (EFSA, 2014)  |
| Lentils (fresh)                                     | 3.00 STMR (EFSA, 2014)  |
| Asparagus                                           | 0.10 STMR (EFSA, 2014)  |
| Cardoons                                            | 0.10 STMR (EFSA, 2014)  |
| Celery                                              | 2.18 STMR (EFSA, 2014)  |
| Fennel                                              | 2.18 STMR (EFSA, 2014)  |
| Globe artichokes                                    | 1.23 STMR (EFSA, 2014)  |
| Commodity                                           | Input value (mg/kg) | Comment                        |
|-----------------------------------------------------|---------------------|--------------------------------|
| Leek                                                | 2.35                | STMR (EFSA, 2014)              |
| Rhubarb                                             | 0.10                | STMR (EFSA, 2014)              |
| Dry pulses                                          | 0.13                | STMR (EFSA, 2014)              |
| Oilseeds                                            | 0.15                | STMR (EFSA, 2014)              |
| Barley, oats                                        | 1.07                | STMR (EFSA, 2014)              |
| Rye, wheat                                          | 0.17                | STMR (EFSA, 2014)              |
| Buckwheat, maize, millet, rice, sorghum, other cereals | 0.05                | STMR (EFSA, 2014)              |
| Coffee beans                                        | 0.05                | STMR (EFSA, 2014)              |
| Herbal infusions except herbal infusions from dried roots | 0.9                | STMR (EFSA, 2014)              |
| Herbal infusions from dried roots                   | 3                   | STMR (EFSA, 2014)              |
| Hops                                                | 24.51               | STMR (EFSA, 2014)              |
| Spices                                              | 0.05                | STMR (EFSA, 2014)              |
| Sugar cane                                          | 0.21                | STMR (EFSA, 2014)              |
| Swine meat\(^{(d)}\)                                | 0.03                | STMR (EFSA, 2014)              |
| Swine fat                                           | 0.03                | STMR (EFSA, 2014)              |
| Ruminants meat\(^{(d)}\)                           | 0.05                | STMR (EFSA, 2014)              |
| Ruminants fat                                       | 0.12                | STMR (EFSA, 2014)              |
| Poultry meat\(^{(d)}\)                             | 0.03                | STMR (EFSA, 2014)              |
| Poultry fat                                         | 0.06                | STMR (EFSA, 2014)              |
| Ruminants’ milk                                     | 0.02                | STMR (EFSA, 2014)              |
| Birds’ eggs                                         | 0.01                | STMR (EFSA, 2014)              |
| Swine kidney\(^{(b)}\)                              | 0.05                | STMR (EFSA, 2014)              |
| Ruminants’ kidney\(^{(b)}\)                         | 0.09                | STMR (EFSA, 2014)              |
| Poultry liver\(^{(b)}\)                             | 0.06                | STMR (EFSA, 2014)              |
| Swine liver\(^{(c)}\)                               | 0.08                | STMR (EFSA, 2014)              |
| Ruminants’ liver\(^{(c)}\)                          | 0.11                | STMR (EFSA, 2014)              |

STMR: supervised trials median residue; MRL: maximum residue level.

(a): The proposed MRL in honey has been considered as chronic input values for PRiMo taking into consideration a conservative approach due to the limited experience in the setting of MRLs in honey.

(b): Risk assessment residue definition for these commodities is as follows: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugate), expressed as boscalid.

(c): Risk assessment residue definition for these commodities is as follows: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugate) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid.

(d): For food items of animal origin: Consumption figures in the EFSA PRiMo are expressed as meat. Since the a.s. is a fat-soluble pesticide, STMR and HR residue values were calculated considering an 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|----------------------------------|-------------------------------------------------|---------------------------------|
| Boscalid                         | 2-chloro-N-(4’-chlorobiphenyl-2-yl)nicotinamide  | ![Structural formula](image)    |
|                                 | O=C(Nc1ccccccc1ccc(c)(c)c1cccnc1Cl)             |                                 |
|                                 | WYEMYLFITZORAB-UHFFFAOYSA-N                     |                                 |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup> ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(c)</sup> ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).