Modification of the existing maximum residue level for boscalid in pomegranates

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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 Greece to modify the existing maximum residue level (MRL) for the active substance boscalid in granate apples/pomegranates. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for pomegranates. Adequate analytical methods for enforcement are available to control the residues of boscalid in the commodity under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of boscalid according to the reported agricultural practice is unlikely to present a risk to consumer health. The reliable end points, appropriate for use in regulatory risk assessment are presented.

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Keywords: Boscalid, Pomegranate, Fungicide, MRL, consumer risk assessment

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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 Greece (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance boscalid in granate apples/pomegranates. 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 16 September 2019. To accommodate for the intended uses of boscalid, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.01 mg/kg to 2.0 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which was requested from the EMS. On 21 July 2020, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

The draft assessment report (DAR) prepared by the rapporteur Member State (RMS), Germany, in the framework of the approval of the active substance boscalid under Council Directive 91/414/EEC was not peer reviewed by EFSA, and therefore, no EFSA conclusion is available. Based on the conclusions derived in the EU Commission Review Report in support of the Commission Directive 2008/44/EC concerning the inclusion of boscalid in Annex I to Directive 91/414/EEC, the data evaluated by EFSA under previous MRL assessments, and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of boscalid following foliar application was investigated in crops belonging to the groups of fruit crops (grapes), leafy crops (lettuce) and oilseeds (beans). As the proposed use of boscalid is on permanent crops, investigations of residues in rotational crops are not required.

Studies investigating the effect of processing on the nature of boscalid (hydrolysis studies) demonstrated that the active substance is stable. Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and/or degradation products and the capabilities of enforcement analytical methods, the residue definition for plant products was proposed as boscalid only for enforcement and risk assessment. This residue definition is applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in this application, metabolism of boscalid in primary and in rotational crops, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definition is applicable.

Sufficiently validated analytical methods based on GC and high-performance liquid chromatography (HPLC) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive an MRL proposal of 2 mg/kg for pomegranate. From the results of six studies on apple juice (representative for pomegranate juice), a processing factor (PF) of 0.08 was derived during the MRL review.

Residues of boscalid in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of boscalid was assessed under Directive 91/414/EEC and an acceptable daily intake (ADI) of 0.04 mg/kg body weight (bw) per day was derived. An acute reference dose (ARfD) was deemed unnecessary.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required. The estimated long-term dietary intake accounted for 75% of the ADI (NL toddler). The contribution of residues expected in pomegranates to the overall long-term consumer exposure accounted for a maximum of 0.2% of the ADI (GEMS/Food G08).

EFSA concluded that the proposed use of boscalid on granate apples/pomegranates will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers’ health.

The EU pesticides 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.

EFSA proposes to amend the existing MRL as reported in the summary table below.
Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code\(^{(a)}\) | Commodity                  | ExistingEU MRL (mg/kg) | ProposedEU MRL (mg/kg) | Comment/justification                                                                 |
|----------------|---------------------------|------------------------|------------------------|---------------------------------------------------------------------------------------|
| 0163050        | Granate apples/pomegranates | 0.01*                  | 2                      | The submitted data are sufficient to derive an MRL proposal. Risk for consumers unlikely |

**Modification of the existing MRL for boscalid in pomegranates**

MRL: maximum residue level.

*: 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.

\(^{(F)}\): Fat soluble.
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for boscalid in granate apples/pomegranates. The detailed description of the intended uses of boscalid in SEU, which is the basis for the current MRL application, is reported in Appendix A.

Boscalid is the ISO common name for 2-chloro-N-(4’-chlorobiphenyl-2-yl)pyridine-3-carboxamide (IUPAC). The chemical structure of the active substance is reported in Appendix E.

Boscalid was evaluated in the framework of Directive 91/414/EEC1 with Germany designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on grapes, lettuce and beans. The draft assessment report (DAR) prepared by the RMS was not peer reviewed by EFSA, and therefore, no EFSA conclusion is available. Boscalid was approved2 for the use as fungicide on 1 January 2008.

The process of renewal of the first approval of the active substance is currently ongoing.

The EU maximum residue levels (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.4 After the completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for boscalid and these reasoned opinions have been considered in recent MRL regulations.5 Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.6

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance boscalid in granate apples/pomegranates. 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 16 September 2019. To accommodate for the intended uses of boscalid, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.01 mg/kg to 2.0 mg/kg.

EFSA identified points which needed further clarification, which was requested from the EMS. On 21 July 2020, the EMS submitted a revised evaluation report (Greece, 2019), which replaced the previously submitted evaluation report. EFSA based its assessment on the evaluation report submitted by the EMS (Greece, 2019), 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, 2019b).

For this application, the data requirements established in Regulation (EU) No 544/20117 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). 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 546/2011.8

1 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.
2 Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, Paecilomyces lilacinus and prothioconazole as active substances (Text with EEA relevance) 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, 16.03.2005, p. 1–16.
4 Commission Regulation (EC) No 216/156 of 18 January 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for boscalid, clothianidin, thiamethoxam, folpet and tolclofos-methyl in or on certain products.
5 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides.eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN.
6 Commission Regulation (EU) No 441/2012 of 24 May 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrin, bifenazate, boscalid, cadusafos, chlorantraniliprole, chlorothalonil, clothianidin, cyproconazole, deltamethrin, dicamba, difenoconazole, dinocap, etoxazole, fenpyroximate, fluembendiamide, fludioxonil, glyphosate, metalaxyl-M, meptyldinocap, novaluron, thiamethoxam and triazophos in or on certain products OJ L 135, 25.5.2012, p. 4–56.
7 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.
8 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.
As the EU pesticides peer review of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion may 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 (Greece, 2019) and the exposure calculations using 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.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of boscalid in primary crops belonging to the group of fruit crops (grapes), leafy crops (lettuce) and oilseeds (beans) has been investigated in the framework of the MRL review and EU pesticides peer review (Germany, 2002; EFSA, 2014).

In the crops tested, parent compound was the main residue and the only one considered relevant for the animal and human health risk assessment.

For the intended use, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

As the proposed use of boscalid is on a permanent crop, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of boscalid was investigated in the framework of the EU pesticides peer review (Germany, 2002) and MRL review (EFSA, 2014). These studies showed that the boscalid is hydrolytically stable under standard processing conditions.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of boscalid residues were assessed during the EU pesticides peer review (Germany, 2002) and MRL review (EFSA, 2014).

The methods are sufficiently validated for residues of boscalid in the crops under consideration. The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg for the total residue (boscalid only) in high water content, high acid content and dry matrices.

1.1.5. Storage stability of residues in plants

The storage stability of boscalid in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (Germany, 2002) and MRL review (EFSA, 2014).

It was demonstrated that in crops assessed in the framework of this application, residues were stable for at least 16 months in matrices with high acid content when stored at \(-18^\circ\text{C}\).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products and the capabilities of enforcement analytical methods, the following residue definition was proposed:

- residue definition for risk assessment: boscalid;
- residue definition for enforcement: boscalid.

The same residue definitions are applicable to processed products.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.
Taking into account the proposed use assessed in this application, EFSA concluded that this residue definition is appropriate, and no modification is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted four residue decline trials performed on pomegranate in Greece, Italy and Spain in 2017 (Greece, 2019). Trials were performed with spray application (nominal rate 500 g a.s./ha, two applications, interval of 4 days (one trial) or 5 days (three trials), 7-day PHI) and are sufficiently compliant with the proposed use GAP. EFSA requested clarification regarding the independence of two trials performed in Greece with similar application dates and on the same variety. The EMS provided the localities of the trials and the distance between sites was considered sufficient to confirm that the trials are geographically independent. The slightly higher residue value at 14-day PHI in one trial was selected for use in the risk assessment and MRL calculation.

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated. The samples were analysed for the parent compound. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose.

1.2.2. Magnitude of residues in rotational crops

As the proposed use of boscalid is on a permanent crop, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crops under assessment are not available. Numerous processing factors (PF) for different processed commodities have been evaluated in the framework of the Article 12 MRL review (EFSA, 2014). From the results of six studies on apple juice (representative for pomegranate juice), a processing factor (PF) of 0.08 was derived. Residues in peel and pulp (seeds) in addition to whole fruits were analysed within the residue trials study in pomegranate.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposal as well as risk assessment values for the commodity under evaluation. The number and quality of the trials are sufficient to derive an MRL proposal of 2 mg/kg for granate apples/pomegranates. In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as pomegranates are normally not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for boscalid used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the approval of the active substance (European Commission, 2008).

Short-term (acute) dietary risk assessment

Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required.
Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2014). EFSA updated the calculation with the relevant supervised trial median residue (STMR) values derived from the residue trials submitted in support of this MRL application for pomegranates; in addition, STMRs derived in EFSA opinions published after the MRL review (EFSA, 2015, 2019b). The input values used in the exposure calculations are summarised in Appendix D.2.

The estimated long-term dietary intake accounted for 75% of the ADI (NL toddler). The contribution of residues expected in pomegranates to the overall long-term consumer exposure accounted for a maximum of 0.2% of the ADI (GEMS/Food G08) and is presented in Appendix B.3.

EFSA concluded that the long-term intake of residues of boscalid resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for pomegranates.

EFSA concluded that the proposed use of boscalid on granate apples/pomegranates will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

- a.s. active substance
- ADI acceptable daily intake
- ARfD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- bw body weight
- CAC Codex Alimentarius Commission
- CAS Chemical Abstract Service
- CF conversion factor for enforcement to risk assessment residue definition
- CIRCA (EU) Communication & Information Resource Centre Administrator
- CS capsule suspension
- CV coefficient of variation (relative standard deviation)
- CXL Codex maximum residue limit
- DAR draft assessment report
- DAT days after treatment
- DM dry matter
- DP dustable powder
- DS powder for dry seed treatment
- EC emulsifiable concentrate
- EDI estimated daily intake
- EMS evaluating Member State
- eq residue expressed as a.s. equivalent
- FAO Food and Agriculture Organization of the United Nations
- FID flame ionisation detector
- GAP Good Agricultural Practice
- GC gas chromatography
- GC-FID gas chromatography with flame ionisation detector
- GC-MS gas chromatography with mass spectrometry
- GC-MS/MS gas chromatography with tandem mass spectrometry
- GS growth stage
- HPLC high-performance liquid chromatography
- HPLC-MS high-performance liquid chromatography with mass spectrometry
- HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
- HR highest residue
| Abbreviation | Description |
|--------------|-------------|
| IEDI         | international estimated daily intake |
| ISO          | International Organisation for Standardisation |
| IUPAC        | International Union of Pure and Applied Chemistry |
| LC           | liquid chromatography |
| LOQ          | limit of quantification |
| MRL          | maximum residue level |
| MS           | Member States |
| MS/MS        | mass spectrometry detector |
| MW           | molecular weight |
| NEU          | northern Europe |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant back interval |
| PF           | processing factor |
| PHI          | preharvest interval |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| PROFile      | (EFSA) Pesticide Residues Overview File |
| 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 |
| SL           | soluble concentrate |
| SP           | water-soluble powder |
| STMR         | supervised trials median residue |
| STMR-P       | supervised trials median residue for a processed commodity |
| TAR          | total applied radioactivity |
| UV           | ultraviolet (detector) |
| WG           | water-dispersible granule |
| WHO          | World Health Organization |
| WP           | wettable powder |
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | Preparations and Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|--------------------------------------------|-------------|-------------|-------------------------------|---------------|---------|
| Granate apples/ pomegranates | SEU | F | Botrytis spp. (BOTRSP); Alternaria spp. (ALSTESP) | WG | 500.0 g/kg | Foliar treatment – broadcast spraying | 60–87 | 2 | 5 | 700–2000 | 500 | g a.i./ha | 7 |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WG: water-dispersible granule.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI – minimum preharvest interval.
## 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<sup>(a)</sup>, 14<sup>(b)</sup>, 53<sup>(c)</sup> | Radiolabelled active substance: U-14C-diphenyl-boscalid and 3-14C-pyridine-boscalid<br>(a): whole plant<br>(b): forage, green beans, pods and seeds<br>(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 × 2100 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; GC-MS: gas chromatography with mass spectrometry; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); LOQ: limit of quantification.

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

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period Value Unit | 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 the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|--------------|--------------------------|------------------------------------------------------------------|-----------------|------------------------|----------------------|-------------------------|-------------|
| Pomegranates | SEU                      | Whole fruit: 0.37, 0.46†, 0.53, 0.82 (Pulp/seed: < 0.01, 0.14, < 0.01, 0.072) | Residue trials on pomegranate compliant with GAP. † Higher residue value at 14-day PHI selected. | 2                     | 0.82                 | 0.50                    | –           |

**MRL**: maximum residue level; GAP: Good Agricultural Practice.

\(^{(a)}\): 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 and not to the edible portion.

\(^{(c)}\): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

\(^{(d)}\): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in rotational crops

| Question                                                                 | Answer                                                                 |
|--------------------------------------------------------------------------|------------------------------------------------------------------------|
| Residues in rotational and succeeding crops expected based on confined   | Inconclusive Data gaps identified in MRL review (EFSA, 2014)            |
| rotational crop study?                                                    |                                                                        |
| Residues in rotational and succeeding crops expected based on field       | -- Not applicable for the current assessment since pomegranate is a     |
| rotational crop study?                                                   | permanent crop.                                                        |

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application. Processing studies available in the MRL Review (EFSA, 2014) for apple juice are considered applicable to pomegranate juice.

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | CF_p(b) | Comment/Source                                      |
|---------------------|----------------------------|------------------------|---------|----------------------------------------------------|
| Apples, juice       | 6                          | See (EFSA, 2014)       | 0.08    | Details on the processing conditions not available (PROFile) (EFSA, 2014). |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

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

| Parameter                                      | Value                                                                 |
|------------------------------------------------|-----------------------------------------------------------------------|
| ADI                                            | 0.04 mg/kg bw per day (European Commission, 2008)                     |
| Highest IEDI, according to EFSA PRImo          | 75% of the ADI (NL toddler) Contribution of crops assessed: Granate/Pomegranate: 0.2 % of ADI (GEMS/FoodG08) |
| Assumptions made for the calculations          | The risk assessment was performed using EFSA PRImo rev. 3.1. (EFSA, 2018, 2019a). The calculation is based on the median residue levels derived for raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. EFSA updated the chronic risk assessment performed under the Article 12 review (EFSA, 2014), considering the STMR values corresponding to the MRLs implemented in the EU Regulation 2016/156, the STMRs derived in EFSA opinions published after the MRL review (EFSA, 2015, 2019b), and median residue levels for pomegranates observed in the residue trials presented for this MRL application. The food commodities for which no uses were reported in the context of the MRL review were excluded from the exposure calculation assuming that there is no use on these crops. |

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

| Code<sup>(a)</sup> | Commodity                  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|----------------------------|-------------------------|-------------------------|-----------------------|
| 0163050           | Granate apples/pomegranates | 0.01*                   | 2                       | The submitted data are sufficient to derive an MRL proposal. Risk for consumers unlikely |

**Enforcement residue definition:** Boscalid<sup>(F)</sup>

MRL: maximum residue level.

*: 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.

(F): Fat soluble.
Appendix C – Pesticide Residue Intake Model (PRIMo)

| Commodity/group of commodities | MRLs set at the LOQ (% of ADI) | commodities not under assessment (% of ADI) |
|--------------------------------|--------------------------------|--------------------------------------------|
| Witloofs/Belgian endives       | 75%                            | ---                                        |
| Spinaches                      | 50%                            | ---                                        |
| Spinaches                      | 40%                            | ---                                        |
| Onions                         | 36%                            | ---                                        |
| Spinaches                      | 35%                            | ---                                        |
| Tomatoes                       | 35%                            | ---                                        |
| Potatoes                       | 34%                            | ---                                        |
| Wheat                          | 32%                            | ---                                        |
| Onions                         | 30%                            | ---                                        |
| Head cabbages                  | 29%                            | ---                                        |
| Other lettuce and other salad plants | 27%                        | ---                                        |
| Wine grapes                    | 26%                            | ---                                        |
| Leeks                          | 24%                            | ---                                        |
| Barley                         | 23%                            | ---                                        |
| Cucumbers                      | 22%                            | ---                                        |
| Wheat                          | 21%                            | ---                                        |
| Lettuces                       | 20%                            | ---                                        |
| Sweet potatoes                 | 18%                            | ---                                        |
| Strawberries                   | 17%                            | ---                                        |
| Onions                         | 15%                            | ---                                        |
| Onions                         | 14%                            | ---                                        |
| Onions                         | 13%                            | ---                                        |
| Potatoes                       | 12%                            | ---                                        |
| Apples                         | 11%                            | ---                                        |
| Potatoes                       | 10%                            | ---                                        |
| Potatoes                       | 9%                             | ---                                        |
| Potatoes                       | 8%                             | ---                                        |
| Barley                         | 7%                             | ---                                        |
| Potatoes                       | 6%                             | ---                                        |
| Potatoes                       | 5%                             | ---                                        |
| Spinaches                      | 4%                             | ---                                        |
| Spinaches                      | 3%                             | ---                                        |
| Spinaches                      | 2%                             | ---                                        |
| Spinaches                      | 1%                             | ---                                        |
| Onions                         | 0%                             | ---                                        |

**Details – acute risk assessment/adults**

**Details – acute risk assessment/children**

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

**Conclusion:**

No estimated long-term dietary intake (TMDI/IEDI) was below the ADI.

The long-term intake of residues of Boscalid is unlikely to present a public health concern.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Acute risk assessment/children

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | IESTI |
|-----------------------|-------------|--------------------------|---------------------|-------|

### Acute risk assessment/adults/general population

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | IESTI |
|-----------------------|-------------|--------------------------|---------------------|-------|

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### Show results for all crops

#### Unprocessed commodities

| Results for children | No of commodities for which ARfD/ADI is exceeded (IESTI): | Results for adults | No of commodities for which ARfD/ADI is exceeded (IESTI): |
|----------------------|-----------------------------------------------------------|---------------------|----------------------------------------------------------|
| IESTI                |                                                           |                     |                                                          |

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | IESTI |
|-----------------------|-------------|--------------------------|---------------------|-------|

#### Processed commodities

| Results for children | No of processed commodities for which ARfD/ADI is exceeded (IESTI): | Results for adults | No of processed commodities for which ARfD/ADI is exceeded (IESTI): |
|----------------------|-------------------------------------------------------------------|---------------------|-------------------------------------------------------------------|
| IESTI                |                                                                  |                     |                                                                  |

| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | IESTI |
|-----------------------|-----------------------|--------------------------|---------------------|-------|

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**Conclusion:**

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

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**Details – acute risk assessment/children**

**Details – acute risk assessment/adults**

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Modification of the existing MRL for boscalid in pomegranates
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                                                                 | Input value (mg/kg) | Comment                     |
|--------------------------------------------------------------------------|---------------------|-----------------------------|
| Granate apples/pomegranates                                              | 0.50                | STMR (Greece, 2019)         |
| Citrus fruits                                                            | 0.07                | STMR-P (EFSA, 2014)         |
| Tree nuts, except pistachios                                             | 0.05                | STMR (EFSA, 2014)           |
| Pistachios                                                               | 0.27                | STMR (EFSA, 2014)           |
| Apples, 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)           |
| Blueberries, cranberries, currants, gooseberries, azarole/               | 3.60                | STMR (EFSA, 2014)           |
| Mediterranean medlars, elderberries and other small fruits and berries  |                     |                             |
| Rose hips, mulberries and elderberries                                   | 2.60                | STMR (EFSA, 2014)           |
| Kiwis                                                                    | 0.07                | STMR-P (EFSA, 2014)         |
| Bananas                                                                  | 0.05                | STMR-P (EFSA, 2014)         |
| Potatoes                                                                 | 0.31                | STMR (EFSA, 2014)           |
| Root and tuber vegetables, except beetroots and Jerusalem artichokes    | 0.31                | STMR (EFSA, 2014)           |
| Beetroots                                                                | 0.38                | STMR (EFSA, 2014)           |
| Jerusalem artichokes                                                    | 2                   | EU MRL                      |
| Garlic, onions, shallots                                                | 2.20                | STMR (EFSA, 2014)           |
| Spring onions                                                           | 2.30                | STMR (EFSA, 2014)           |
| Tomatoes, aubergines                                                    | 0.40                | STMR (EFSA, 2014)           |
| Peppers                                                                  | 0.57                | STMR (EFSA, 2014)           |
| Okra/lady's fingers and other solanaceae                                | 0.57                | STMR (EFSA, 2014)           |
| Cucurbits with edible peel                                              | 0.73                | STMR (EFSA, 2014)           |
| Cucurbits with 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 plantsincluding Brassicaceae and spinaches     | 5.60                | STMR (EFSA, 2014)           |
| Purslanes, chards/beet leaves, grape leaves and watercress             | 3.65                | STMR (EFSA, 2014)           |
| Witloofs/Belgian endives                                                | 8.55                | STMR (EFSA, 2014)           |
| Herbs and edible flowers                                                | 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)           |
| Commodity | Chronic risk assessment |
|-----------|-------------------------|
| 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) |
| Celeries | 2.18 STMR (EFSA, 2014) |
| Florence fennels | 2.18 STMR (EFSA, 2014) |
| Globe artichokes | 1.23 STMR (EFSA, 2014) |
| Leeks | 2.35 STMR (EFSA, 2014) |
| Rhubarbs | 0.10 STMR (EFSA, 2014) |
| Dry pulses, except lupins/lupini beans | 0.13 STMR (EFSA, 2014) |
| Lupins/lupini beans | 0.12 STMR (EFSA, 2014) |
| Oilseeds, except soyabeans | 0.15 STMR (EFSA, 2014) |
| Soyabeans | 0.12 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 from dried flowers and dried leaves | 0.05 STMR (EFSA, 2014) |
| Herbal infusions from dried roots | 0.95 STMR (tentative) (EFSA, 2014) |
| Hops | 24.51 STMR (EFSA, 2014) |
| Spices | 0.05 STMR (EFSA, 2014) |
| Sugar canes | 0.21 STMR (EFSA, 2014) |
| Swine meat(a) | 0.03 STMR (EFSA, 2014) |
| Swine fat | 0.03 STMR (EFSA, 2014) |
| Ruminants meat(a) | 0.05 STMR (EFSA, 2014) |
| Ruminants fat | 0.12 STMR (EFSA, 2014) |
| Poultry meat(a) | 0.03 STMR (EFSA, 2014) |
| Poultry fat | 0.03 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) |
| Honey and other apiculture products(d) | 0.15 Proposed MRL (EFSA, 2019b) |

STMR: supervised trials median residue; STMR-P: supervised trials median residue for a processed commodity.

(a): 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).

(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): 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.
### 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)pyridine-3-carboxamide  
                                 | O=C(Nc1ccccc1c1ccc(Cl)cc1)c1cccnc1Cl  
                                 | WYEMLYFITZORAB-UHFFFAOYSA-N        |

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

<sup>(b)</sup> ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 Jul 2019).

<sup>(c)</sup> ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 Jul 2019).