Evaluation of confirmatory data following the Article 12 MRL review for pyraclostrobin

European Food Safety Authority (EFSA), Alba Brancato, Daniela Brocca, Luis Carrasco Cabrera, Chloe De Lentdecker, Zoltan Erdos, Lucien Ferreira, Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Alfonso Lostia, Christopher Lythgo, Paula Medina, Ileana Miron, Tünde Molnár, Ragnor Pedersen, Hermine Reich, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, Jose Tarazona, Anne Theobald, Benedicte Vagenende and Laura Villamar-Bouza

Abstract

The applicant BASF SE submitted a request to the competent national authority in Germany to evaluate the confirmatory data that were identified for pyraclostrobin in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps, residues trials supporting the existing use of pyraclostrobin on table grapes authorised in southern EU Member States and an analytical method for analysing residues of pyraclostrobin in coffee beans were submitted. The data gap for coffee beans was considered satisfactorily addressed. The new residue trials in table grapes give an indication that the existing MRL for table grapes should be raised. However, since a potential acute consumer health risk for table grapes could not be excluded, EFSA recommend the lowering of the existing MRL.

© 2018 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: pyraclostrobin, confirmatory data, pesticide, MRL review, risk assessment

Requestor: European Commission
Question numbers: EFSA-Q-2018-00331
Correspondence: pesticides.mrl@efsa.europa.eu
Evaluation of confirmatory data for pyraclostrobin to address data gaps identified in the MRL review
Summary

In 2011, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) Eight residues trials complying with the import tolerance GAP on cotton seed;
2) Eight trials supporting the southern FR GAP on grapes (data gap resulting from a fall back GAP);
3) Four residues trials complying with the import tolerance GAP on celery;
4) A validated method for enforcement of pyraclostrobin in coffee beans.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 668/2013, including footnotes related to data gaps number 2 (related to table grapes), 3 and 4, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 13 July 2015. Data gap number 1 was not implemented in the MRL regulation, because risk managers decided to set an alternative MRL that was sufficiently supported by data. The footnote related to data gap number 3 was deleted by Commission Regulation (EU) No 2017/1016, since the requested confirmatory data were provided in the framework of a MRL application and were found to be sufficient to address the data gap (EFSA, 2017).

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, BASF SE submitted an application to the competent national authority in the Germany (rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 26 April 2018. When assessing the evaluation report, EFSA identified points which needed further clarifications. On 13 September 2018, the evaluating Member State (EMS) submitted a revised evaluation report which addressed the points for clarification.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

| Code(a) | Commodity        | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|------------------|-----------------|--------------|---------------------------|
| 0151010 | Table grapes     | 1 (ft.1)        | 0.01*        | A sufficient number of residue trials representative for the SEU use were submitted, providing evidence that the existing MRL needs to be raised to 1.5 mg/kg. However, since an acute consumer health risk could not be excluded, EFSA suggests lowering the MRL to the LOQ. Data for alternative GAPs that would allow deriving a safe fall-back MRL are not available to EFSA |
| 0620000 | Coffee beans     | 0.3 (ft.2)      | 0.3          | The data submitted were sufficient to address the data gap identified in the framework of the MRL review. The footnote related to the existing MRL for coffee beans can be deleted. The risk assessment performed for coffee beans in the framework of the MRL review is still valid |

MRL: maximum residue level; SEU: southern Europe; LOQ: limit of quantification; GAP: Good Agricultural Practice.
*: 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): Existing EU MRL and corresponding footnote on confirmatory data.
Ft.1: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 13 July 2015, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap No 1).
Ft.2: The European Food Safety Authority identified some information on analytical methods as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 13 July 2015, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap No 4).
(F): Fat-soluble.
Assessment

The review of existing maximum residue levels (MRLs) for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed in 2011 (EFSA, 2011). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The list of Good Agricultural Practices (GAPs) assessed in the framework of the MRL review that were not fully supported by data and for which confirmatory data were requested are listed in Appendix A.

Following the MRL review, MRLs have been modified by Commission Regulation (EU) No 668/2013, including footnotes that specified for the relevant MRLs the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 13 July 2015.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2016), the applicant, BASF SE, submitted an application to the competent national authority in Germany (designated rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided (i) residues trials supporting the GAP on grapes (south EU) and (ii) a validated method for enforcement of pyraclostrobin in coffee beans.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 26 April 2018 (Germany, 2018). EFSA proceeded with the assessment of the application as requested by the European Commission in accordance with Article 9 of the Regulation. During the detailed assessment, EFSA identified points which needed further clarifications. On 13 September 2018, the RMS submitted a revised evaluation report which addressed the points for clarification (Germany, 2018).

EFSA based its assessment on the evaluation report submitted by the RMS (Germany, 2018), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 and additional assessments of pyraclostrobin performed after the MRL review (EFSA, 2011, 2012, 2013, 2014a,b, 2016, 2017, 2018).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 668/2013 are applicable. 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.

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B.

The process on the renewal of the approval of the active substance pyraclostrobin in accordance with Regulation (EC) No 1107/2009 is ongoing; thus, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

The evaluation report submitted by the RMS (Germany, 2018) is considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document 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

Not relevant for the current assessment.

---

1 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.
2 Commission Regulation (EU) No 668/2013 of 12 July 2013 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 2,4-DB, dimethomorph, indoxacarb, and pyraclostrobin in or on certain products. OJ L 192, 13.7.2013, p. 39–71.
3 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.
4 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.
1.1.2. Nature of residues in rotational crops

Not relevant for the current assessment.

1.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4. Methods of analysis in plants

In order to address data gap number 4, the applicant provided a validated analytical method, including independent laboratory validation, for enforcement of pyraclostrobin in coffee beans. Details on the analytical method are presented in Appendix B.1.1.1.

EFSA concluded that the data gap identified in the framework of the MRL review was addressed.

1.1.5. Stability of residues in plants

Not relevant for the current assessment.

1.1.6. Proposed residue definitions

The previously derived residue definitions are still applicable (EFSA, 2011).

1.2. Magnitude of residues in plants

In order to address data gap number 2, the applicant provided 26 residue trials performed in grapes. Among the submitted trials, 10 outdoor trials on grapes compliant with the southern Europe (SEU) GAP (3 × 100 g/ha, preharvest interval (PHI) 35 days) were identified. The number of the studies is sufficient for the purpose of MRL setting in table grapes. All samples were analysed for the parent compound, using sufficiently validated analytical methods. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (Germany, 2018).

Based on the GAP-compliant residue trials, a MRL proposal of 1.5 mg/kg was calculated using the OECD calculator, hence, suggesting that the existing MRL which was derived from residue trials that reflected a more critical GAP (i.e. 4 × 160 g/ha, PHI 35 days) should be raised. The applicant and the RMS did not provide any further explanations for the unexpected result of the residue trials.

Furthermore, the trials were used to derive the risk assessment values; while the highest residue (HR) derived from the GAP-compliant residue trials was higher than the HR derived from the overdosed trials, the supervised trials median residue (STMR) value comparable. The results of the risk assessment are presented in Section 3.

2. Residues in livestock

The confirmatory data assessed in this evaluation do not have an impact on pesticide residues expected in livestock. Thus, the previous assessment of residues in livestock (EFSA, 2018) is still valid.

3. Consumer risk assessment

EFSA updated the previous risk assessment for table grapes, taking into account the new data submitted under this application.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for table grapes in accordance with the internationally agreed methodology. The calculation was based on the HR derived from the GAP-compliant residue trials submitted as confirmatory data (Appendix D.1).

The calculated short-term exposure exceeded the ARFD (113.9% of the ARFD) for table grapes assessed in this application (see Appendix B.3). Based on these results, EFSA concluded that for the existing SEU use in table grapes a potential short-term intake concern cannot be excluded.

Long-term (chronic) dietary risk assessment

EFSA updated the chronic risk assessment, including the STMR value derived from the residue trials submitted in support of this MRL application for table grapes; in addition, STMR values derived in EFSA opinions published after the MRL review (2011, 2012, 2013, 2014a, 2014b, 2016, 2017, 2018) were
included in the dietary exposure assessment (scenario 1). The input values used in the exposure calculations are summarised in Appendix D.1. In scenario 1, the estimated long-term dietary intake was in the range of 1.8–14% of the acceptable daily intake (ADI).

In scenario 2 of the chronic risk assessment, table grapes were excluded; taking into account that for the critical SEU use in table grapes an acute intake concern was identified. In this scenario, the estimated long-term dietary intake was in the range of 1.8–12.5% of the ADI. EFSA concluded that the long-term intake of residues of pyraclostrobin resulting from the existing and the intended uses in table grapes is unlikely to present a risk to consumer health.

4. Conclusion and Recommendations

To address data gaps identified in the framework of the MRL review (EFSA, 2011), the applicant provided GAP-compliant residues trials supporting the SEU GAP (France) on table grapes and a validated method for enforcement of pyraclostrobin in coffee beans. The data gaps were sufficiently addressed.

The submitted residue trials in grapes led to a higher MRL (1.5 mg/kg) than the tentative one (1 mg/kg) which was derived from overdosed residue trials; furthermore, the risk assessment values derived from these residue trials suggest that the residue trials had a higher HR value. However, EFSA does not recommend raising the current tentative MRL since a risk to consumer health cannot be excluded for short-term dietary exposure to table grapes. The calculated short-term exposure exceeded the ARfD (113.9% of the ARfD).

The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix B.4.

References

EFSA (European Food Safety Authority), 2011. Review of the existing maximum residue levels for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(8):2344, 92 pp. https://doi.org/10.2903/j.efsa.2011.2344

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the modification of the existing MRLs for pyraclostrobin in leafy brassica and various cereals. EFSA Journal 2012;10(3):2606, 36 pp. https://doi.org/10.2903/j.efsa.2012.2606

EFSA (European Food Safety Authority), 2013. Reasoned opinion on the modification of the existing MRLs for pyraclostrobin in cucumbers and Jerusalem artichokes. EFSA Journal 2013;11(2):3109, 27 pp. https://doi.org/10.2903/j.efsa.2013.3109

EFSA (European Food Safety Authority), 2014a. Reasoned opinion on the modification of the existing MRL for pyraclostrobin in chicory roots. EFSA Journal 2014;12(5):3685, 23 pp. https://doi.org/10.2903/j.efsa.2014.3685

EFSA (European Food Safety Authority), 2014b. Reasoned opinion on the modification of the existing MRLs for pyraclostrobin in Swedes and turnips. EFSA Journal 2014;12(10):3872, 19 pp. https://doi.org/10.2903/j.efsa.2014.3872

EFSA (European Food Safety Authority), 2016. Reasoned opinion on the modification of the existing maximum residue level for pyraclostrobin in beet leaves (chards). EFSA Journal 2016;14(8):4552, 14 pp. https://doi.org/10.2903/j.efsa.2016.4552

EFSA (European Food Safety Authority), 2017. Reasoned opinion on the modification of the existing maximum residue levels for pyraclostrobin in various crops. EFSA Journal 2017;15(1):4686, 19 pp. https://doi.org/10.2903/j.efsa.2017.4686

EFSA (European Food Safety Authority), 2018. Reasoned opinion on the modification of the existing maximum residue levels for pyraclostrobin in soyabean. EFSA Journal 2018;16(11):5466, 28 pp. https://doi.org/10.2903/j.efsa.2018.5466

European Commission, 2016. Commission staff working document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 17 June 2016. SANTE/E4/VW 10235/2016 - Rev. 2, 3pp., Brussels, 17 June 2016.

Germany, 2018. Evaluation report on confirmatory data to be considered for the review of the existing MRL for pyraclostrobin. February 2018, 24 pp.

Abbreviations

a.s. pyraclostrobin
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
Evaluation of confirmatory data for pyraclostrobin to address data gaps identified in the MRL review

bw  body weight
CF  conversion factor for enforcement to risk assessment residue definition
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
HPLC-UVD  high performance liquid chromatography with ultra-violet detector
HR  highest residue
IEDI  international estimated daily intake
IESTI  international estimated short-term intake
ILV  independent laboratory validation
InChiKey  International Chemical Identifier Key.
ISO  International Organisation for Standardisation
IUPAC  International Union of Pure and Applied Chemistry
LC  liquid chromatography
LOQ  limit of quantification
Mo  monitoring
MRL  maximum residue level
MS  Member States
MS/MS  tandem mass spectrometry detector
NEU  northern Europe
OECD  Organisation for Economic Co-operation and Development
PBI  plant-back interval
PHI  preharvest interval
PRIMo  (EFSA) Pesticide Residues Intake Model
RA  risk assessment
RD  residue definition
RMS  rapporteur Member State
SE  Suspo-emulsion
SEU  southern Europe
SMILES  simplified molecular-input line-entry system
STMR  supervised trials median residue
WG  water-dispersible granule
## Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

| Crop and/or situation | NEU, SEU, MS or country | F, G or T(8) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|--------------|------------------------------------|-------------|-------------|--------------------------------|
|                       |                         |              |                                    | Type(b)     | Conc. a.s.  | Method kind        | Range of growth stages and season(c) | Number min-max | Interval between application (min) | kg a.s./hl min-max | Water L/ha min-max | Rate | Unit | PHI (days)(d) | Remarks                  |
|                       |                         |              |                                    | Range of growth stages and season(c) | Number min-max | Interval between application (min) | kg a.s./hl min-max | Water L/ha min-max | Rate | Unit | PHI (days)(d) | Remarks                  |
|                       |                         |              |                                    | Range of growth stages and season(c) | Number min-max | Interval between application (min) | kg a.s./hl min-max | Water L/ha min-max | Rate | Unit | PHI (days)(d) | Remarks                  |
|                       |                         |              |                                    | Range of growth stages and season(c) | Number min-max | Interval between application (min) | kg a.s./hl min-max | Water L/ha min-max | Rate | Unit | PHI (days)(d) | Remarks                  |
| Critical SEU GAP assessed in the framework of the MRL review (EFSA, 2011) | | | | | | | | | | | | | | | | | |
| Table grapes           | SEU                     | F            | Fungal diseases                     | SE          | 40 g/L       | Foliar treatment – spraying n.d. | 3 | n.d. | n.d. | n.d. | 100 g a.s./ha | 35 |
| Additional GAPs reported in ER (Germany, 2018) | | | | | | | | | | | | | | | | | |
| Grapes                 | IT, ES                  | F            | Fungal diseases                     | WG          | 50 g/kg      | Spraying BBCH 09-83            | 3 | 8–12 days | 8.3–50 | 200–1,200 | 100 g a.s./ha | 35 |
| Grapes                 | BG                      | F            | Fungal diseases                     | WG          | 50 g/kg      | Spraying BBCH 09-83            | 2 | 7–10 days | 8.3–50 | 200–1,200 | 100 g a.s./ha | 28 |
| Grapes                 | FR                      | F            | Fungal diseases                     | WG          | 50 g/kg      | Spraying BBCH 09-83            | 2 | 10 days | 25–75 | 100–300 | 75 g a.s./ha | 35 |
| Grapes                 | PT                      | F            | Fungal diseases                     | WG          | 50 g/kg      | Spraying BBCH 09-83            | 2 | 12 days | 6.25–37.5 | 200–1,200 | 75 g a.s./ha | 56 |
| Grapes                 | ES, GR, IT             | F            | Fungal diseases                     | 67 g/kg     | Spraying BBCH 15-81 | 3 | 12 days | 10–20 | 500–1,000 | 100 g a.s./ha | 35 |
| Grapes                 | ES, IT                 | F            | Fungal diseases                     | 250 g/kg    | Spraying BBCH 53-83 | 3 | 12 days | 8.3–100 | 100–1,200 | 100 g a.s./ha | 35 |
| Crop and/or situation | NEU, SEU, MS or country | F, G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-------------|----------------------------------|-------------|-------------|-------------------------------|----------------|---------|
|                       |                         |             |                                  | Type(b)     | Conc. a.s.  | Method kind                  | Range of growth stages and season(c) | Number min–max | Interval between application (min) | kg a.s./ha | Water L/ha | Rate | Unit |               |               |               |
| Grapes               | FR                      | F           | Fungal diseases                  | 40 g/kg     | Spraying    | BBCH 09-83                  | 1               | n.a.                          | 20–66.7 | 150 – 500 | 100   | g a.s./ha | 35               | No application later than BBCH 69 in table grapes |

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WG: water-dispersible granule; SE: Suspo-emulsion.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. 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                      |             |         |                |                | No new information provided. The residue definitions derived in the framework of the MRL review (EFSA, 2011) are still applicable |
| Root crops                       |             |         |                |                |               |
| Leafy crops                      |             |         |                |                |               |
| Cereals/grass                    |             |         |                |                |               |
| Pulses/oilseeds                  |             |         |                |                |               |
| Miscellaneous                    |             |         |                |                |               |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|-------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                    |             |         |                |           | No new information provided. The residue definitions derived in the framework of the MRL review (EFSA, 2011) are still applicable |
| Leafy crops                         |             |         |                |           |               |
| Cereal (small grain)                |             |         |                |           |               |
| Other                               |             |         |                |           |               |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/source |
|-----------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)     | No new information provided under the current application. The residue definitions derived in the framework of the MRL review (EFSA, 2011) are still applicable |
| Baking, brewing and boiling (60 min, 100°C, pH 5) |               |         |
| Sterilisation (20 min, 120°C, pH 6)     |               |         |
| Other processing conditions             |               |         |
Can a general residue definition be proposed for primary crops?
Rotational crop and primary crop metabolism similar?
Residue pattern in processed commodities similar to residue pattern in raw commodities?
Plant residue definition for monitoring (RD-Mo)
Plant residue definition for risk assessment (RD-RA)
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

| Yes | EFSA (2011) |
|-----|-------------|
| Yes | EFSA (2011) |
| Yes | EFSA (2011) |

Pyraclostrobin (EFSA, 2011)

Coffee beans:
- analytical method based on LC–MS/MS;
- LOQ of 0.02 mg/kg;
- ILV available: (LC–MS/MS), LOQ of 0.02 mg/kg
  (Germany, 2018)

Matrices with high water content, high oil content, high acid content and dry/high starch content matrices and hops:
- LC–MS/MS, LOQ 0.02 mg/kg;
- Confirmatory method available using HPLC-UV;
- ILV available

High water content, acidic and dry/high starch content commodities:
- Higher sensible method for with a
- LOQ of 0.01 mg/kg
  (EFSA, 2011)

DAT: days after treatment; PBI: plant-back interval; LC-MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; HPLC-UV: high-performance liquid chromatography with ultraviolet detection.

B.1.1.2. Stability of residues in plants

No new information has been submitted under the current application.
## 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) |
|-----------|------------------|----------------------------------------------------------------|----------------|------------------------|---------------|----------------|-------|
| Table grapes (0151010) | SEU | 0.11, 0.17, 0.22, 0.23, 0.30, 0.40, 0.42, 0.44, 0.85, 0.87, 0.13, 2 × 0.14, 0.16, 0.18, 0.2, 0.21, 2 × 0.23, 0.27, 0.28, 0.34, 0.37, 0.38, 0.39, 0.4, 0.45, 0.47, 0.48, 0.56, 2 × 0.59, 2 × 0.72 | GAP-compliant residue trials on grapes (3 × 100 g/ha, PHI 35 days). Overdosed residues trials assessed in the framework of MRL review GAP (4 × 160 g/ha) (EFSA, 2011) | 1.5 | 0.87 | 0.35 | – |

MRL: maximum residue level; GAP: Good Agricultural Practice; PHI: preharvest interval.

(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

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No | EFSA (2011) |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not required | EFSA (2011) |

B.1.2.3. Processing factors

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

B.2. Residues in livestock

The submitted information does not trigger the re-assessment of the livestock dietary burden.

B.3. Consumer risk assessment

| ARfD | 0.03 mg/kg bw (EFSA, 2011) |
| Highest IESTI, according to EFSA PRIMO | Table grapes: 113.9% of ARfD |
| Assumptions made for the calculations | The calculation is performed only on table grapes, considering the highest residue levels derived from the GAP-compliant residue trials submitted in support of the MRL application. An empirically derived variability factor of 3 was used instead of the default one of 5 (EFSA, 2011) |
| ADI | 0.03 mg/kg bw (EFSA, 2011) |
| Highest IEDI, according to EFSA PRIMO | Scenario 1: 14% ADI (diet), Scenario 2: 12.5% ADI (diet) |
| Assumptions made for the calculations | Scenario 1: The calculation is performed for the crop under assessment considering the median residue level derived from the trials provided with this application together with the STMR values derived from previous assessments and from MRL review. Scenario 2: same assumptions as for scenario 1, excluding table grapes |

ARfD: acute reference dose; IESTI: international estimated short-term intake; PRIMO: (EFSA) Pesticide Residues Intake Model; bw: body weight; GAP: Good Agricultural Practice; MRL: maximum residue level; ADI: acceptable daily intake; IEDI: international estimated daily intake; STMR: supervised trials median residue.
# B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity       | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation                                                                                                                                                                                                 |
|-------------------|-----------------|-----------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0151010           | Table grapes    | 1 (ft.1)                    | 0.01*        | A sufficient number of residue trials representative for the SEU use were submitted, providing evidence that the existing MRL needs to be raised to 1.5 mg/kg. However, since an acute consumer health risk could not be excluded, EFSA suggests lowering the MRL to the LOQ. Data for alternative GAPs that would allow deriving a safe fall-back MRL are not available to EFSA. |
| 0620000           | Coffee beans    | 0.3 (ft.2)                  | 0.3          | The data submitted were sufficient to address the data gap identified in the framework of the MRL review. The footnote related to the existing MRL for coffee beans can be deleted. The risk assessment performed for coffee beans in the framework of the MRL review is still valid. |

MRL: maximum residue level; SEU: southern Europe; LOQ: limit of quantification; GAP: Good Agricultural Practice.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

<sup>(a)</sup>: Commodity code number according to Annex I of Regulation (EC) No 396/2005.

<sup>(b)</sup>: Existing EU MRL and corresponding footnote on confirmatory data.

<sup>ft.1</sup>: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 13 July 2015, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap No 2).

<sup>ft.2</sup>: The European Food Safety Authority identified some information on analytical methods as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 13 July 2015, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap No 4).

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

### Pyraclostrobin

| Status of the active substance | LOQ (mg/kg) | Proposed LOQ |
|-------------------------------|------------|--------------|
| Code no.                      | 0.03       |              |

**Toxicological end points**

- **ADI (mg/kg bw per day):** 0.03
- **ARfD (mg/kg bw):** 0.03
- **Source of ADI:** EFSA 2011
- **Source of ARfD:** EFSA 2011

**Year of evaluation: 2011**

**No of diets exceeding ADI:** ---

**Highest calculated TMDI values in % of ADI**

| Commodity/group of commodities | MS Diet |
|--------------------------------|---------|
| Commodity/group of commodities | MS Diet |
| Approximate contribution (%)   |         |
| 16.0  DE child                | 5.8     | 5.8 Table grapes | 9.3 Orange |
| 10.4  NL child                | 3.0     | 3.0 Apples       | 3.0 Apples |
| 7.7   WHO Cluster diet B      | 1.0     | 1.0 Tomatoes     | 1.0 Tomatoes |
| 7.4   IE adult                | 1.4     | 1.4 Berry        | 1.4 Berry |
| 7.3   UK Toddler              | 3.0     | 3.0 Sugar beet (root) | 3.0 Apple |
| 6.4   FR toddler              | 1.2     | 1.2 Apples       | 1.2 Apples |
| 5.7   FR infant               | 1.2     | 1.2 Apples       | 1.2 Apples |
| 5.3   DK child                | 1.1     | 1.1 Apples       | 1.1 Apple |
| 5.3   UK Infant               | 1.3     | 1.3 Sugar beet (root) | 1.3 Apple |
| 4.9   WHO cluster diet E      | 0.9     | 0.9 Berry        | 0.9 Berry |
| 4.4   WHO cluster diet D      | 0.4     | 0.4 Tomato       | 0.4 Tomato |
| 4.4   ES child                | 0.5     | 0.5 Apples       | 0.5 Apples |
| 4.4   WHO regional European diet | 0.4 | 0.4 Tomato       | 0.4 Tomato |
| 4.2   SE general population 90th percentile | 0.5 | 0.5 Apples | 0.5 Apples |
| 4.1   WHO Cluster diet F      | 0.7     | 0.7 Berry        | 0.7 Berry |
| 3.9   NL general              | 0.8     | 0.8 Apple        | 0.8 Apple |
| 3.7   ES adult                | 0.6     | 0.6 Berry        | 0.6 Berry |
| 3.1   IT child/adolescent     | 0.5     | 0.5 Tomato       | 0.5 Tomato |
| 3.0   PT General population   | 0.5     | 0.5 Apples       | 0.5 Potatoes |
| 2.8   PL general population   | 1.0     | 1.0 Apples       | 1.0 Table grapes |
| 2.8   IT adult                | 0.4     | 0.4 Tomato       | 0.4 Tomato |
| 2.6   UK vegetarian           | 0.5     | 0.5 Sugar beet (root) | 0.5 Apple |
| 2.6   LT adult                | 0.9     | 0.9 Apple        | 0.9 Tomato |
| 2.4   FI all population       | 0.2     | 0.2 Tomato       | 0.2 Tomato |
| 2.1   UK Adult                | 0.5     | 0.5 Sugar beet (root) | 0.5 Apple |
| 1.9   DK adult                | 0.4     | 0.4 Apple        | 0.4 Apple |
| 1.8   FI adult                | 0.2     | 0.2 Tomato       | 0.2 Tomato |

**Chronic risk assessment – refined calculations**

| Commodity/group of commodities | MS Diet |
|--------------------------------|---------|
| Approximate contribution (%)   |         |
| 14.0  DE child                | 5.8     | 5.8 Table grapes | 9.3 Orange |
| 10.4  NL child                | 3.0     | 3.0 Apples       | 3.0 Apples |
| 7.7   WHO Cluster diet B      | 1.0     | 1.0 Tomatoes     | 1.0 Tomatoes |
| 7.4   IE adult                | 1.4     | 1.4 Berry        | 1.4 Berry |
| 7.3   UK Toddler              | 3.0     | 3.0 Sugar beet (root) | 3.0 Apple |
| 6.4   FR toddler              | 1.2     | 1.2 Apples       | 1.2 Apples |
| 5.7   FR infant               | 1.2     | 1.2 Apples       | 1.2 Apples |
| 5.3   DK child                | 1.1     | 1.1 Apples       | 1.1 Apple |
| 5.3   UK Infant               | 1.3     | 1.3 Sugar beet (root) | 1.3 Apple |
| 4.9   WHO cluster diet E      | 0.9     | 0.9 Berry        | 0.9 Berry |
| 4.4   WHO cluster diet D      | 0.4     | 0.4 Tomato       | 0.4 Tomato |
| 4.4   ES child                | 0.5     | 0.5 Apples       | 0.5 Apples |
| 4.4   WHO regional European diet | 0.4 | 0.4 Tomato       | 0.4 Tomato |
| 4.2   SE general population 90th percentile | 0.5 | 0.5 Apples | 0.5 Apples |
| 4.1   WHO Cluster diet F      | 0.7     | 0.7 Berry        | 0.7 Berry |
| 3.9   NL general              | 0.8     | 0.8 Apple        | 0.8 Apple |
| 3.7   ES adult                | 0.6     | 0.6 Berry        | 0.6 Berry |
| 3.1   IT child/adolescent     | 0.5     | 0.5 Tomato       | 0.5 Tomato |
| 3.0   PT General population   | 0.5     | 0.5 Apples       | 0.5 Potatoes |
| 2.8   PL general population   | 1.0     | 1.0 Apples       | 1.0 Table grapes |
| 2.8   IT adult                | 0.4     | 0.4 Tomato       | 0.4 Tomato |
| 2.6   UK vegetarian           | 0.5     | 0.5 Sugar beet (root) | 0.5 Apple |
| 2.6   LT adult                | 0.9     | 0.9 Apple        | 0.9 Tomato |
| 2.4   FI all population       | 0.2     | 0.2 Tomato       | 0.2 Tomato |
| 2.1   UK Adult                | 0.5     | 0.5 Sugar beet (root) | 0.5 Apple |
| 1.9   DK adult                | 0.4     | 0.4 Apple        | 0.4 Apple |
| 1.8   FI adult                | 0.2     | 0.2 Tomato       | 0.2 Tomato |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Pyraclostrobin is unlikely to pose a public health concern.
### Acute risk assessment/children – refined calculations

The acute risk assessment is based on 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.

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.

#### Highest % of ARfD/ADI Commodities

| Commodity | pTMRL/Threshold MRL (mg/kg) |
|-----------|----------------------------|
| Table grapes | 0.87/0.76 |

#### No of critical MRLs (IESTI 1): 1

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

| Commodity | pTMRL/Threshold MRL (mg/kg) |
|-----------|----------------------------|
| Table grapes | 0.87/0.76 |

#### No of critical MRLs (IESTI 2): 1

### Evaluation of confirmatory data for pyraclostrobin to address data gaps identified in the MRL review

**Conclusion:**

For Pyraclostrobin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. The estimated short term intake (ESTI 1) exceeded the ARfD/ADI for 1 commodities. Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities. For processed commodities, no exceedance of the ARfD/ADI was identified.
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Pyraclostrobin is unlikely to present a public health concern.
The acute risk assessment is based on 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.

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 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 processed commodities, no exceedance of the ARfD/ADI was identified. Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.

### Table: Highest % of ARfD/ADI Commodities

| Processed commodities | No of critical MRLs (IESTI 1) | 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): |
|-----------------------|-------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|
| | 1 | 1 | 1 | 1 | 1 |
| Highest % of ARfD/ADI commodities | Threshold MRL | pTMRL | threshold MRL | pTMRL | threshold MRL |
| Table grapes | 0.87 / 0.76 | 0.87 / 0.76 | 0.87 / 0.76 | 0.87 / - | 0.87 / - |

Conclusion:

For Pyraclostrobin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. The estimated short-term intake (ESTI 1) exceeded the ARfD/ADI for 1 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.

No of commodities for which ARfD/ADI is exceeded: 1

No of critical MRLs (IESTI 1): 1

No of critical MRLs (IESTI 2): 1

### Table: Highest % of ARfD/ADI Commodities

| Unprocessed commodities | No of critical MRLs (IESTI 1) | 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): |
|-------------------------|-------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|
| | 1 | 1 | 1 | 1 | 1 |
| Highest % of ARfD/ADI commodities | Threshold MRL | pTMRL | threshold MRL | pTMRL | threshold MRL |
| Table grapes | 0.87 / 0.76 | 0.87 / 0.76 | 0.87 / 0.76 | 0.87 / - | 0.87 / - |

Conclusion:

For Pyraclostrobin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. The estimated short-term intake (ESTI 1) exceeded the ARfD/ADI for 1 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.

No of commodities for which ARfD/ADI is exceeded: 1

No of critical MRLs (IESTI 1): 1

No of critical MRLs (IESTI 2): 1

### Table: Highest % of ARfD/ADI Commodities

| Processed commodities | No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|-----------------------|--------------------------------------------------|--------------------------------------------------|
| | --- | --- |
| Highest % of ARfD/ADI commodities | Threshold MRL | pTMRL |
| Table grapes | 0.87 / 0.76 | 0.87 / 0.76 |

Conclusion:

For Pyraclostrobin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. The estimated short-term intake (ESTI 1) exceeded the ARfD/ADI for 1 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.

No of commodities for which ARfD/ADI is exceeded: 1

No of critical MRLs (IESTI 1): 1

No of critical MRLs (IESTI 2): 1

### Table: Highest % of ARfD/ADI Commodities

| Unprocessed commodities | No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|-------------------------|--------------------------------------------------|--------------------------------------------------|
| | --- | --- |
| Highest % of ARfD/ADI commodities | Threshold MRL | pTMRL |
| Table grapes | 0.87 / 0.76 | 0.87 / 0.76 |

Conclusion:

For Pyraclostrobin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. The estimated short-term intake (ESTI 1) exceeded the ARfD/ADI for 1 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.

No of commodities for which ARfD/ADI is exceeded: 1

No of critical MRLs (IESTI 1): 1

No of critical MRLs (IESTI 2): 1
## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

| Commodity              | Chronic risk assessment | Acute risk assessment |
|------------------------|-------------------------|-----------------------|
|                        | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| **Risk assessment residue definition:** Pyraclostrobin          |                         |                       |
| Table grapes           | 0.35                    | Scenario 1: STMR (see Table B.1.2.1) | 0.87 | Scenario 1: HR (see Table B.1.2.1) |
|                        | –                       | Scenario 2: No input value included, assuming that the use of table grapes is withdrawn | – | Scenario 2: No input value included, assuming that the use of table grapes is withdrawn |
| Other commodities      | See input values derived during the Article 12 MRL review (EFSA, 2011) and the latest MRL applications under Art 10 of the EU regulation 396/2005 (EFSA, 2011, 2012, 2013, 2014a,b, 2016, 2017, 2018) | – | Acute risk assessment is performed only for crop for which confirmatory data were requested |
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-----------------------------------------------|----------------------------------|
| Pyraclostrobin                | methyl 2-[1-(4-chlorophenyl)-1H-pyrazol-3-yloxymethyl]-N-methoxycarbanilate<br>\[\text{O}=\text{C}(\text{OC})\text{N}(\text{OC})\text{c1ccccc1COc1ccn(n1)c1ccc(Cl)cc1}\]<br>HZRSNVGNWUDEFX-UHFFFAOYSA-N | ![Structural formula](image-url) |

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).