Modification of the existing maximum residue levels and setting of import tolerances for pyraclostrobin in various crops

European Food Safety Authority (EFSA), Maria Anastassiadou, 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, Tunde Molnar, Stefanie Nave, Ragnar Pedersen, Hermine Reich, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, Jose Tarazona, Anne Theobald, Benedicte Vagenende and Laura Villamar-Bouza

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF SE submitted two requests to the competent national authority in Germany. The first one, to modify the existing maximum residue levels (MRL) for the active substance pyraclostrobin in various crops and to set import tolerances for sugar canes and American persimmons; the second one to set import tolerances for pineapples and passion fruits/maracujas. The data submitted in support of the requests were found to be sufficient to derive MRL proposals for mandarins, grapefruits, lemons, limes, passion fruits/maracujas, pineapples, flowering brassica, head cabbages, lamb’s lettuce, cresses and other sprouts, land cresses, rucola, red mustards, baby leaf crops, globe artichokes and leeks. For oranges, American persimmons, spinach and similar leaves and sugar canes, data gaps were identified which precluded the derivation of MRL proposals. The data submitted did not provide evidence that the existing MRLs for crops belonging to the group of lettuces and maize have to be modified to accommodate for the intended uses. For escaroles, no MRL was proposed as the intended use was found to lead to residues for which a potential consumer health risk cannot be excluded. EFSA concluded that the short-term intake of residues resulting from the uses of pyraclostrobin according to the reported agricultural practices assessed is unlikely to present a risk to consumer health, except for escaroles, where the expected intake was found to exceed the toxicological reference value. Taking into account the existing and the proposed new MRLs, a long-term intake concern for consumers was not identified.

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

Keywords: pyraclostrobin, various crops, import tolerance, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question numbers: EFSA-Q-2017-00584, EFSA-Q-2017-00282

Correspondence: pesticides.mrl@efs.europa.eu
Suggested citation: European Food Safety Authority (EFSA), Anastassiadou M, Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Nave S, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B and Villamar-Bouza L, 2018. Reasoned opinion on the modification of the existing maximum residue levels and setting of import tolerances for pyraclostrobin in various crops. EFSA Journal 2018;16(11):5488, 38 pp. https://doi.org/10.2903/j.efsa.2018.5488

ISSN: 1831-4732

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

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted two applications to the competent national authority in Germany (evaluating Member State (EMS)). The first one to modify the existing maximum residue levels (MRL) for the active substance pyraclostrobin in various crops and to set import tolerances in sugar canes and American persimmons. The second one to set import tolerances for pineapples and passion fruits/maracujas. The details of the applications are outlined below. Germany drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA). The MRL proposals derived by the EMS are also reported in the table below.

| EFSA Question number | Date of submission of the evaluation reports to EFSA | Crops | EMS MRL proposals |
|----------------------|------------------------------------------------------|-------|-------------------|
| Q-2017-00282         | 7 April 2017                                         | Pineapples | 0.3 mg/kg (import tolerance (IT) for Brazil) |
|                      |                                                      | Passion fruits/maracujas | 0.2 mg/kg (IT for Brazil) |
| Q-2017-00584         | 17 July 2017                                         | Citrus fruits | 2 mg/kg |
|                      |                                                      | Flowering brassica | 0.5 mg/kg |
|                      |                                                      | Head cabbages | 0.4 mg/kg |
|                      |                                                      | Lettuces and salad plants (except lettuces and escarole) | 10 mg/kg |
|                      |                                                      | Lettuces | 2 mg/kg |
|                      |                                                      | Escarole | 0.9 mg/kg |
|                      |                                                      | Spinaches and chards | 0.5 mg/kg |
|                      |                                                      | Purslane | 0.2 mg/kg |
|                      |                                                      | Globe artichokes | 3 mg/kg |
|                      |                                                      | Leeks | 0.8 mg/kg |
|                      |                                                      | Maize | 0.02* mg/kg |
|                      |                                                      | Sugar canes | 0.02 mg/kg (IT for USA) |
|                      |                                                      | American persimmons | 0.02 mg/kg (IT for USA) |

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification for both applications, which were requested from the EMS. On 8 February 2018, the EMS submitted revised evaluation reports, which replaced the previously submitted evaluation reports.

The metabolism of pyraclostrobin following a foliar application was sufficiently investigated in crops belonging to the groups of fruit, and leafy crops, root and tuber vegetables and cereals. The metabolism of pyraclostrobin in rotational crops was found to be similar to the one depicted in the primary crops. Under representative conditions for food processing (standard hydrolysis studies), pyraclostrobin was stable.

Based on the metabolic pattern identified in the metabolism studies, in the hydrolysis studies and the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed as pyraclostrobin for enforcement and risk assessment. The residue definitions are applicable to primary crops, rotational crops and processed products.

Sufficiently validated analytical methods based on high-performance liquid chromatography (HPLC) are available to quantify pyraclostrobin residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.02 mg/kg in the crops assessed (limit of quantification (LOQ)). For high water content, acidic and dry commodities, the CEN QuEChERS method is validated to a LOQ of 0.01 mg/kg.

The submitted data was sufficient to derive MRL proposals for all crops assessed except for American persimmons, spinaches and similar leaves, and sugar canes. For oranges, lettuce and maize, the information provided did not provide evidence that the existing MRLs have to be changed.
For a number of processed products derived from the crops assessed in this application, processing factors (PF) were derived that can be used for enforcement purposes and should be included in Annex VI of Regulation (EC) No 396/2005 as follows:

- Mandarin, peel
  - Existing EU MRL (mg/kg): 3.02
  - Proposed EU MRL (mg/kg): 1.41
  - Comment/justification: The submitted data did not provide evidence that the existing MRL has to be modified.

- Orange, peel
  - Existing EU MRL (mg/kg): 3.78
  - Proposed EU MRL (mg/kg): 0.62
  - Comment/justification: The submitted residue trials are sufficient to derive a MRL proposal for the intended SEU use. Risk for consumers unlikely (based on exposure assessment including a peeling factor).

- Mandarin, pulp
  - Existing EU MRL (mg/kg): 0.13
  - Proposed EU MRL (mg/kg): 0.13
  - Comment/justification: No modification needed.

- Orange, pulp
  - Existing EU MRL (mg/kg): 0.10
  - Proposed EU MRL (mg/kg): 1.10

- Orange juice
  - Existing EU MRL (mg/kg): 0.05
  - Proposed EU MRL (mg/kg): 1.43

- Orange juice, pasteurised
  - Existing EU MRL (mg/kg): 0.08
  - Proposed EU MRL (mg/kg): 0.36

- Orange marmalade
  - Existing EU MRL (mg/kg): 0.19
  - Proposed EU MRL (mg/kg): 0.27

- Pineapple pulp
  - Proposed EU MRL (mg/kg): 0.27

The occurrence of pyraclostrobin residues in rotational crops was investigated in the framework of the European Union (EU) pesticides peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

As the crops under consideration and their by-products are used as feed products, a potential carry-over into food of animal origin was assessed. However, the contribution of pyraclostrobin residues in the crops under consideration in this MRL application to the total livestock exposure was found to be insignificant and therefore a modification of the existing MRLs for commodities of animal origin was considered unnecessary.

The toxicological profile of pyraclostrobin was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.03 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.03 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). EFSA concluded that the proposed use of pyraclostrobin on escaroles could result in an acute consumer exposure exceeding the toxicological reference value and therefore did not propose a MRL. For the remaining crops for which a need to modify the existing MRLs was identified (i.e. mandarins, grapefruits, lemons, limes, passion fruits/maracuja, pineapples, flowering brassica, head cabbages, globe artichokes, leeks), the acute risk assessment did not identify a consumer exposure exceeding the ARfD. Although the residue data submitted do not require a modification of the existing MRL for lettuce, the risk assessment indicated a potential acute intake concern for the intended southern European (SEU) GAP.

Based on the results of the chronic risk assessment, EFSA concluded that residues resulting from the GAPs assessed in the framework of this application are unlikely to pose a risk to consumers’ health.

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

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

It is noted that the renewal of the approval for pyraclostrobin under Regulation (EC) No 1107/2009 is currently ongoing; the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of this process.

| Code(a) | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|---------|-----------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0110020 | Oranges         | 2.0                     | No modification needed  | The submitted data did not provide evidence that the existing MRL has to be modified. |
| 0110050 | Mandarins       | 1.0                     | 2.0                     | The submitted residue trials are sufficient to derive a MRL proposal for the intended SEU use. Risk for consumers unlikely (based on exposure assessment including a peeling factor). |

Enforcement residue definition: pyraclostrobin
| Code(a) | Commodity                        | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                 |
|--------|----------------------------------|-------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0110010 | Grapefruit, lemons, limes        | 1.0                     | 2                       | Data are sufficient (combined data set in oranges and mandarins) to derive a MRL proposal for the remaining citrus crops. A risk for consumers is unlikely (based on exposure assessment including peeling factors) |
| 0110030 | Passion fruits/ maracujas        | 0.02*                   | 0.2                     | The submitted residue trials are sufficient to derive an import tolerance (Brazilian GAP). Risk for consumers unlikely. The proposed MRL is at lower than the existing MRL in Brazil (i.e. 0.5 mg/kg) |
| 0162030 | American persimmons              | 0.02*                   | No MRL proposal         | The submitted residue trials are not sufficient to derive an import tolerance for the USA GAP                                                                 |
| 0163080 | Pineapples                       | 0.02*                   | 0.3                     | The submitted residue trials are sufficient to derive an import tolerance (Brazilian GAP). Risk for consumers unlikely. The proposed MRL is lower than the existing MRL in Brazil (i.e. 0.5 mg/kg) |
| 0241000 | Flowering brassica               | 0.1                     | 0.5                     | The submitted residue trials are sufficient to derive a MRL proposal for the intended SEU use. Risk for consumers unlikely                                                                                     |
| 0242020 | Head cabbages                    | 0.2                     | 0.4                     | The submitted residue trials are sufficient to derive a MRL proposal for the intended SEU use. Risk for consumers unlikely                                                                                     |
| 0251010 | Lamb's lettuces                  | 10.0                    | 10 or 15 Further risk management considerations needed | Taking into account the residue trials in lamb's lettuce reflecting the SEU GAP, a MRL proposal of 15 mg/kg is derived. Considering also data from lettuce (open leaf varieties) a lower MRL of 10 mg/kg is considered sufficient. Risk for consumers unlikely |
| 0251020 | Lettuces                         | 2.0                     | No modification needed; further risk management considerations needed | The data set submitted in support of the NEU GAP lead to a MRL proposal of 0.9 mg/kg. From the SEU data set, a MRL proposal of 2 mg/kg was derived. Although this GAP would not require a modification of the existing MRL, it was noted that the highest residue (HR) measured in the supporting data set lead to an exceedance of the ARfD. No intake concern was identified for the HR reflecting the indoor GAP which is the basis for the existing MRL. Before granting a new authorisation in lettuce, Member States should verify that the acute risk assessment performed in the framework of the MRL review under Article 12 is still valid, even if the existing MRL does not have to be modified. Alternatively, the lowering of the existing MRL to the level of 0.9 mg/kg could be considered; this MRL proposal reflects the NEU GAP. For this GAP, a risk for consumers is unlikely |
| 0251030 | Escarole                         | 0.4                     | No MRL proposal         | Although sufficient data are available to derive a MRL proposal of 0.9 mg/kg for the intended NEU use, EFSA did not recommend a modification of the existing MRL since an acute consumer health risk could not be excluded |
| Code<sup>a</sup> | Commodity                      | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-----------------|--------------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0251040         | Cresses and other sprouts      | 10                      | 10 or 15                | Further risk management considerations needed Taking into account the residue trials in lamb’s lettuce reflecting the SEU GAP, a MRL proposal of 15 mg/kg is derived by extrapolation. Considering also data from lettuce (open leaf varieties), a lower MRL of 10 mg/kg is considered sufficient. Risk for consumers unlikely |
| 0251050         | Land cresses                   |                         |                         |                                                                                       |
| 0251060         | Roman rocket/ rucola           |                         |                         |                                                                                       |
| 0251070         | Red mustards                   |                         |                         |                                                                                       |
| 0251080         | Baby leaf crops                |                         |                         |                                                                                       |
| 0252000         | Spinaches and similar leaves   | 0.6 spinaches 0.02* purslanes 1.5 chard | No MRL proposal         | The submitted residue trials are not sufficient to derive an MRL proposal for the intended SEU uses |
| 0270050         | Globe artichokes               | 2.0                     | 3.0                     | The submitted residue trials are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely |
| 0270060         | Leeks                          | 0.7                     | 0.8                     | The submitted residue trials are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely |
| 0500030         | Maize                          | 0.02*                   | No modification needed  | The submitted data did not provide evidence that the existing MRL has to be modified     |
| 0900020         | Sugar canes                    | 0.02*                   | No MRL proposal         | The submitted residue trials are not sufficient to derived a MRL for import tolerance (USA GAP) |

MRL: maximum residue level; SEU: southern Europe; GAP: Good Agricultural Practice; NEU: northern Europe; ARfD: acute reference dose.

*: 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.
## Table of contents

Abstract .......................................................................................................................... 1
Summary ......................................................................................................................... 3
Assessment ..................................................................................................................... 8
1. Residues in plants ....................................................................................................... 9
   1.1. Nature of residues and methods of analysis in plants ............................................ 9
      1.1.1. Nature of residues in primary crops ................................................................. 9
      1.1.2. Nature of residues in rotational crops .............................................................. 9
      1.1.3. Nature of residues in processed commodities ............................................... 10
      1.1.4. Methods of analysis in plants .......................................................................... 10
      1.1.5. Stability of residues in plants ........................................................................... 10
      1.1.6. Proposed residue definitions ........................................................................... 10
      1.2. Magnitude of residues in plants ......................................................................... 10
      1.2.1. Magnitude of residues in primary crops ......................................................... 10
         1.2.1.1. Citrus .............................................................................................................. 11
         1.2.1.2. Passion fruits ................................................................................................. 11
         1.2.1.3. American persimmons .................................................................................. 11
         1.2.1.4. Pineapples .................................................................................................... 11
         1.2.1.5. Flowering brassica (broccoli, cauliflower) ...................................................... 12
         1.2.1.6. Head cabbages ............................................................................................. 12
         1.2.1.7. Lettuces (code 0251020) .............................................................................. 12
         1.2.1.8. Lamb’s lettuces (code 0251010) ................................................................. 12
         1.2.1.9. Escaroles (code 0251030) ............................................................................ 12
         1.2.1.10. Other lettuce crops (cresses, land cresses, Roman rocket, red mustards, baby leaf crops) ........................................................................................................ 12
         1.2.1.11. Spinaches and similar leaves ....................................................................... 12
         1.2.1.12. Globe Artichokes ........................................................................................ 13
         1.2.1.13. Leeks ............................................................................................................. 13
         1.2.1.14. Maize ............................................................................................................ 13
         1.2.1.15. Maize forage ............................................................................................... 13
         1.2.1.16. Sugar canes ................................................................................................. 13
      1.2.2. Magnitude of residues in rotational crops ...................................................... 13
      1.2.3. Magnitude of residues in processed commodities ......................................... 14
      1.2.4. Proposed MRLs ............................................................................................... 14
2. Residues in livestock ................................................................................................ 14
3. Consumer risk assessment ....................................................................................... 14
4. Conclusion and Recommendations ......................................................................... 15
References ..................................................................................................................... 16
Abbreviations ............................................................................................................... 17
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs ................................................................. 19
Appendix B – List of end points .................................................................................... 22
Appendix C – Pesticide Residue Intake Model (PRIMo) .................................................. 32
Appendix D – Input values for the exposure calculations ............................................. 36
Appendix E – Used compound codes ........................................................................ 38
Assessment

The detailed descriptions of the intended European Union (EU) uses of pyraclostrobin in various crops for which an amendment of the existing maximum residue level (MRL) was requested, the existing uses authorised on sugar cane and persimmons in the USA and the existing uses on pineapples and passion fruits authorised in Brazil for which the setting of import tolerances were requested, are reported in Appendix A.

Pyraclostrobin is the ISO common name for methyl 2-[1-(4-chlorophenyl)pyrazol-3-yloxymethyl]-N-methoxycarbanilate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Pyraclostrobin was evaluated in the framework of Directive 91/414/EEC1 with Germany designated as rapporteur Member State (RMS); the representative use assessed was a foliar application on grapes. The draft assessment report (DAR) prepared by the RMS was not peer reviewed by the European Food Safety Authority (EFSA). Therefore, no EFSA conclusion is available. Pyraclostrobin was approved2 for the use as a fungicide on 1 June 2004. In 2009, the approval for pyraclostrobin was extended to be used as a plant growth regulator.3 The process of renewal of the approval of the active substance under Regulation (EC) No 1107/20094 is ongoing.

The review of existing MRLs according to Article 12 of Regulation (EC) No 396/20055 (MRL review) has been performed (EFSA, 2011b) and EU MRLs for pyraclostrobin are now established in Annex II of Regulation (EC) No 396/2005. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for pyraclostrobin (EFSA, 2012, 2013, 2014a,b, 2016, 2017, 2018a, b,c). The proposals from these reasoned opinions have been implemented in recent regulations6 for EU MRL legislation, except for the proposals derived in the most recent assessments published in 2018.

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in Germany (evaluating Member State (EMS)) to set import tolerances for the active substance pyraclostrobin in pineapple and passion fruit. Germany drafted the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 7 April 2017. The EMS proposed to establish an MRL for pineapple imported from Brazil at the level of 0.3 mg/kg and for passion fruit from Brazil of 0.2 mg/kg. In the country of origin, the MRLs for pineapples and passion fruits are set at the level of 0.5 mg/kg.

Furthermore, BASF SE submitted a second application to the German competent national authority to modify the existing MRLs for pyraclostrobin in citrus fruits, lettuce, spinach, flowering brassica, head cabbage, globe artichoke, leeks and maize and to set import tolerances for pyraclostrobin in sugar cane and persimmon to accommodate for the authorised uses in the USA.7 The evaluation report prepared by Germany was submitted to the European Commission and forwarded to EFSA on 17 July 2017. The EMS proposed the following MRLs for the crops under assessment:

- citrus fruits (except oranges): 2 mg/kg (NB: for oranges no modification of the existing MRL was considered necessary since the existing MRL is set at 2 mg/kg);
- flowering brassica: 0.5 mg/kg;
- head cabbage: 0.4 mg/kg;
- lettuces and salad plants (except lettuces and escarole): 10 mg/kg;
- lettuces: 2 mg/kg;
- escarole: 0.9 mg/kg;

---

1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Directive 2004/30/EC of 10 March 2004 amending Council Directive 91/414/EEC to include benzoic acid, flazasulfuron and pyraclostrobin as active substances, OJ L 77, 13.3.2004, p. 50–53.
3 Commission Directive 2009/25/EC of 2 April 2009 amending Council Directive 91/414/EEC as regards an extension of the use of the active substance pyraclostrobin. OJ L 91, 3.4.2009, p. 20–22.
4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
5 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.
6 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
7 The original version of the Evaluation Report submitted in 2017 contained a request to modify the MRL for table olives and olives for oil production. However, olives have been withdrawn by the applicant in the revised evaluation report submitted in February 2018 (Germany 2017b).
• spinach and chards: 0.5 mg/kg;
• purslane: 0.2 mg/kg;
• globe artichoke: 3 mg/kg;
• leeks: 0.8 mg/kg.

No modifications were considered appropriate (or needed) by the EMS for oranges, spinach, chards, maize, American persimmons and sugar cane.

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested from the EMS. On 8 February 2018, the EMS submitted revised evaluation reports (Germany, 2017a,b), which replaced the previously submitted evaluation reports.

EFSA based its assessment on the evaluation reports submitted by the EMS (Germany, 2017a,b), the DAR and its addenda (Germany, 2001, 2003) prepared under Council Directive 91/414/EEC, the Commission review report on pyraclostrobin (European Commission, 2004), the JMPR evaluation reports (FAO, 2006, 2011), the conclusions from previous EFSA reasoned opinions on pyraclostrobin under Article 10 (EFSA, 2011a, 2012, 2013, 2014a,b, 2016, 2017, 2018a,b,c) as well as the review of the existing MRLs for pyraclostrobin under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011b).

For this application, the data requirements established in Regulation (EU) No 544/20118 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, 2013). 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 546/20119.

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

The evaluation reports submitted by the EMS (Germany, 2017a,b) 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.

As for pyraclostrobin the renewal of the approval under Regulation (EC) No 1107/2009 is currently ongoing, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of this process.

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 pyraclostrobin following foliar applications was investigated in fruit crops (grapes), root crops (potatoes) and in cereals (wheat and paddy rice) (EFSA, 2011b, 2018c). The metabolic pathway was found to be similar in all crop groups investigated where the predominant compound of the total residues in the crops investigated was the parent pyraclostrobin; the desmethoxy metabolite (500M07) was found in smaller amounts compared to the parent pyraclostrobin (Germany, 2001, 2003; EFSA, 2018c).

1.1.2. **Nature of residues in rotational crops**

Some of the intended EU uses of pyraclostrobin are on crops that can be grown in rotation with other crops (i.e. flowering brassica, head cabbages, lettuces, spinach, leeks and maize). Therefore, it is necessary to investigate the nature of residues in succeeding crops resulting from the uses on primary crops. In the framework of the EU pesticides peer review, it was concluded that pyraclostrobin and the metabolites 500M06 and 500M07 are highly persistent in soil (DT90field pyraclostrobin: 83–230 days; DT90lab500M06: 428–552 days; DT90lab500M07: 372–529 days) (European Commission, 2004).

---

8 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.

9 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 L155, 11.6.2011, p. 127–175.
The available rotational crops metabolism studies showed no accumulation of pyraclostrobin or its metabolites (including 500M07) in the edible parts of the rotational crops. The metabolism of pyraclostrobin in rotational crops was considered to be similar to the metabolic pathway depicted in primary crops (EFSA, 2011b).

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of pyraclostrobin was investigated in the framework of the peer review. A study was conducted simulating pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6) which demonstrated the stability of pyraclostrobin under these conditions (Germany, 2001, 2003).

1.1.4. Methods of analysis in plants

An analytical method and its independent laboratory validation (ILV), using liquid chromatography with tandem mass spectrometry (LC–MS/MS) were sufficiently validated at a limit of quantification (LOQ) of 0.02 mg/kg for the determination of pyraclostrobin in high oil content, high water content, high acid content and dry/high starch content commodities (EFSA, 2011b).

In a previous EFSA reasoned opinion (EFSA, 2014a,b), the QuEChERS extraction procedure in combination with LC–MS/MS (CEN, 2008) was proposed as the analytical method to determine pyraclostrobin residues in high water content, acidic and dry/high starch content commodities at a LOQ of 0.01 mg/kg.

Overall, it is concluded that sufficiently validated analytical methods for enforcement of pyraclostrobin residues in high oil-, high water-, high acid- and dry/high starch content commodities are available.

1.1.5. Stability of residues in plants

Storage stability under frozen conditions (below −10°C) of pyraclostrobin and compound 500M07 residues was demonstrated for at least 18 months in high water-, high oil- and dry/high starch content commodities (Germany, 2001).

1.1.6. Proposed residue definitions

Based on the metabolism studies submitted in primary crops, rotational crops and the studies addressing the nature of residues in processed commodities, the residue definition for risk assessment and for enforcement in primary crops, rotational crops and processed commodities was set as parent ‘pyraclostrobin’ (EFSA, 2011b).

The current residue definition set in Regulation (EC) No 396/2005 also comprises only the parent compound pyraclostrobin.

The previously derived residue definitions are appropriate for the crops under assessment.

If in the framework of the ongoing peer review residue definitions will be revised, the existing MRLs, including the MRLs proposed in this assessment, will have to be reconsidered.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL applications, the applicant submitted residue trials in citrus (oranges, mandarins), flowering brassica, head cabbages, lettuces and similar, spinaches and similar, artichokes, leeks, maize and the import tolerances on persimmons, sugar cane, pineapples and passion fruits/maracuja. The samples were analysed for the parent compound and the main metabolite 500M07.

According to the EMS, the analytical methods used in the residue trials to analyse for pyraclostrobin and the metabolite 500M07 have been sufficiently validated and were proven to be fit for purpose. The samples of residue trials, except the samples of sugar cane (see Section 1.2.1.16), were stored for a period and temperature for which integrity of the samples was demonstrated (Germany, 2017a,b).
1.2.1.1. Citrus

Oranges

In total, 12 GAP-compliant residue trials on oranges and sweet oranges were provided. Out of these, 10 trials (5 duplicate trials) were not fully independent; they were performed on different varieties but in the same location at the same time. From these duplicate trials, the highest residue concentration was used for calculating the MRL proposal. Therefore, overall, only seven independent trials were available. Since oranges are a major crop, one additional residue trial would be required to derive a MRL proposal. EFSA calculated an indicative MRL proposal from the seven trials which is identical with the current EU MRL (i.e. 2 mg/kg).

Additional four overdosed residue trials in sweet oranges were provided (4 applications of 1.1 kg a.i./ha instead of 0.225 kg a.i./ha). These trials with residues ranging from 0.94 to 2.7 mg/kg cannot be used to derive the MRL proposal since the calculated scaling factor exceeds the acceptable limit of 4, but they were used to derive peeling and processing factors (see Section B.1.2.3).

Mandarins

The applicant submitted 14 GAP-compliant residue trials on mandarins, performed in southern Europe (SEU). Out of these 14 trials, 8 trials (4 duplicate trials) were not fully independent since they were performed in the same locations at the same time. From these duplicate trials, the highest residue concentration was used for calculating the MRL proposal. Therefore, overall, 10 independent trials were used to derive the MRL proposal.

In four of the residue trials, the distribution of the residue in pulp and peel was investigated to derive a peeling factor (see Section B.1.2.3).

Other citrus fruits (grapefruits, lemons, limes)

According to the information provided by the EMS, the GAP reported in Appendix A is intended for all citrus fruits. According to the EU guidance document for extrapolation (European Commission, 2017), at least eight trials on oranges and eight trials in mandarins would be required to derive a MRL proposal for all crops belonging to the group of citrus fruits. Thus, one additional trial in oranges would be required to fulfil these requirements. However, considering that a sufficient number of mandarin trials (10 trials) are available and usually mandarins are expected to be the crop in which higher residues are expected, EFSA considered the data sufficient to derive a MRL proposal for the remaining citrus crops derived from the combined data set. The calculated MRL proposal for grapefruit, lemons and limes is similar to the MRL proposal for mandarins and the existing MRL for oranges.

1.2.1.2. Passion fruits

Four residue trials compliant with the existing GAP in Brazil were provided. The trials were sufficient to derive a MRL proposal of 0.2 mg/kg. The MRL set in Brazil for passion fruits is 0.5 mg/kg (Indice Monografico Piroclorstrobin – P4610).

1.2.1.3. American persimmons

In support of the US import tolerance request, the applicant provided three US residue trials approximating the USA GAP. Since for persimmons at least four residue trials are required according to the EU data requirements, the data are considered insufficient and therefore no MRL proposal is derived for this crop.

1.2.1.4. Pineapples

Nine GAP-compliant residue trials performed in Brazil were provided. The trials were sufficient to derive a MRL proposal of 0.3 mg/kg. The MRL set in Brazil for pineapples is 0.5 mg/kg (Indice Monografico Piroclorstrobin – P4610).

Studies investigating the distribution between pulp and peel were used to derive peeling factors (see B.1.2.3).

10 Agência Nacional de Vigilância Sanitária. D.O.U de 08/06/2016. http://portal.anvisa.gov.br/registros-e-autorizacoes/agrotxic os/produtos/monografia-de-agrotxicicos/autorizadas
1.2.1.5. Flowering brassica (broccoli, cauliflower)

In support of the southern Europe (SEU) outdoor use, eight GAP-compliant residue trials (four trials on cauliflower and four trials on broccoli) were provided. Based on the combined data set, a MRL proposal of 0.5 mg/kg is derived.

1.2.1.6. Head cabbages

Eight GAP-compliant residue trials were provided; the trials were conducted in south of France, Italy, Greece and Spain. A MRL proposal of 0.4 mg/kg was calculated.

1.2.1.7. Lettuces (code 0251020)

In support of the northern Europe (NEU) GAP, eight residue trials on lettuces (open leaf varieties) were submitted; the trials were conducted in Belgium, Germany, the Netherlands, northern France and the United Kingdom. The trials were sufficient to derive a MRL of 0.9 mg/kg.

In addition, the applicant provided 12 residue trials performed in different lettuce varieties that comply with the SEU GAP. The information available did not allow verifying whether the varieties used in the trials were head forming or open leaf varieties. In the absence of a confirmation that the trials were performed in open leaf varieties, EFSA considered the trials were in head forming varieties; thus, they can be used to derive an MRL proposal for lettuce (code 0251020). However, the trials were not used to derive MRL proposals for other crops by extrapolation for which trials in open leaf varieties would be required. Based on the SEU residue trials, a MRL proposal of 2 mg/kg was calculated with the OECD calculator. It is noted that this MRL proposal is identical with the current MRL in place for this crop.

1.2.1.8. Lamb’s lettuces (code 0251010)

The applicant provided four GAP-compliant residue trials on lamb’s lettuce; the trials reflect the SEU GAP. Based on these trials, a MRL proposal of 15 mg/kg is derived using the OECD MRL calculator.

However, based on expert judgement, taking into account the highest result found in lamb’s lettuce trials (4.16 mg/kg) and the results in other open leaf lettuce varieties (up to 0.59 mg/kg), EFSA is of the opinion that a MRL of 10 mg/kg would be sufficient. This MRL proposal is in line with the conclusions of the EMS. It is noted that the current MRL for lamb’s lettuce is 10 mg/kg.

1.2.1.9. Escaroles (code 0251030)

No residue trials were provided on escaroles. In accordance with the extrapolation guidance (European Commission, 2017), trials on lettuce (open leaf varieties) can be used to derive an MRL proposal by extrapolation for escaroles/broad-leaved endives. Thus, based on the NEU residue trials in lettuce, a MRL proposal of 0.9 mg/kg is derived for escaroles.

To support the SEU GAP in escaroles, no appropriate residue data on open leaf lettuce varieties are available. Since the lettuce trials did not provide the information whether they were performed in open leaf varieties (see also comments on SEU residue trials in lettuce), EFSA does not recommend using the trials to derive the MRL proposal for escaroles.

1.2.1.10. Other lettuce crops (cresses, land cresses, Roman rocket, red mustards, baby leaf crops)

No specific residue trials performed on one of the above-mentioned crops were provided by the applicant. However, according to the guidance document (European Commission, 2017), an MRL can be derived by extrapolation from residue trials in open leaf varieties of lettuces (extrapolation to the whole group) or from lamb’s lettuce to Roman rocket, red mustards and baby leaf crops (extrapolation to individual minor crops).

Thus, using these options, a MRL proposal for the three crops mentioned reflecting the NEU uses can be derived from the residue trials in leaf lettuce (i.e. 0.9 mg/kg); for the SEU GAP, the extrapolation from trials in lamb’s lettuce data would suggest a MRL of 15 mg/kg; taking into account the results of residue trials in open leaf varieties, a MRL of 10 mg/kg seems to be sufficient.

It is noted that the current MRL for these three crops is set at the level of 10 mg/kg.

1.2.1.11. Spinaches and similar leaves

No SEU Residue trials on spinaches were provided by the applicant (only four German trials are reported). Since these trials were not representative for SEU, they were not used to derive the MRL proposal. According to the EU guidance document on extrapolation (European Commission, 2017),
residue trials in lettuces (open leaf varieties) can be used to derive a MRL for spinaches and similar leaves. However, for the SEU GAP, no appropriate residue trials are available and therefore no MRL proposal could be derived (see Section 1.2.1.7, comments on the SEU lettuce trials).

1.2.1.12. Globe Artichokes

In support of the SEU GAP, five residue trials were provided conducted in south of France, Italy and Spain. As globe artichokes are a minor crop, these residue trials are sufficient to derive a MRL of 3.0 mg/kg.

1.2.1.13. Leeks

In support of the SEU GAP, four GAP-compliant residue trials performed on leeks in Greece, Italy and Spain were provided. As leek is a minor crop in the southern zone, these residue trials are sufficient to derive a MRL of 0.8 mg/kg.

1.2.1.14. Maize

In support of the NEU and SEU GAPs on maize grain, four residue trials for the NEU GAP and four trials for the SEU GAP were provided. In all trials, the residues were below the LOQ (0.01 mg/kg). Maize is a major crop in NEU and SEU, and therefore at least eight residue trials for the NEU and SEU zone would be required. However, considering that in none of the trials quantifiable residues were observed, the available trials are sufficient to derive a MRL proposal at the LOQ. It is noted that the current MRL for maize is set at the LOQ of 0.02 mg/kg.

1.2.1.15. Maize forage

Sufficient residue trials on maize forage compliant with the NEU and SEU intended uses in maize are available to estimate the residues that are expected in this feed item.

1.2.1.16. Sugar canes

In support of the import tolerance request, eight USA trials in sugar cane were provided that were performed in three different locations in the USA in 2008 in compliance with the reported GAP. Two additional overdosed trials were provided that are not relevant for the application. Within the different sites, the trials only differed in the varieties tested while the date of the treatment was the same. In addition, the EMS noted deficiencies of the trials as regards the storage conditions (the samples were stored at −5°C, one of the trials for a period longer than investigated in storage stability studies).

EFSA agrees with the EMS that the number of independent, valid residue trials is insufficient to derive a MRL proposal for sugar cane.

1.2.2. Magnitude of residues in rotational crops

No rotational crop field studies have been submitted with this application.

During the peer review and the MRL review, experts concluded that based on two rotational crop metabolism studies covering three representative crop groups, all relevant label positions and the entire interval of major soil metabolite formation, no residues of toxicological and quantitative relevance are transferred from soil to crops at the representative GAP conditions (Germany, 2001, 2003; EFSA, 2012). These rotational crops metabolism studies that were conducted following bare soil application of pyraclostrobin at a dose rate of 900 g a.s./ha, the total radioactive residues in the edible parts of succeeding crops decreased along with the plant-back intervals (PBIs) suggesting that accumulation of pyraclostrobin and its degradation products in crops grown in rotation is not expected (Germany, 2001, 2003). The highest total residues accounted for 0.04 mg/kg in radish root (30-day PBI), 0.017 mg/kg in lettuce (365-day PBI), 0.114 and 0.089 mg/kg in wheat straw (30-day PBI) and grain (120-day PBI), respectively.

Since the maximum annual application rates for the crops under consideration in this application are lower than the application rate tested in the rotational crop study, and the fact that in the confined rotational crop study pyraclostrobin was applied directly to bare soil whilst interception by crop foliage is expected in practice, it is concluded that the previously derived conclusion is still valid, provided that the active substance is applied according to the proposed GAP.

If in the framework of the ongoing peer review, residues in rotational crops will be re-assessed. Depending on the outcome, this conclusion may have to be reconsidered.
1.2.3. Magnitude of residues in processed commodities

Processing studies in mandarins, oranges, spinaches, pineapple and maize were provided in this assessment, demonstrating that peeling, juicing and cooking leads to a reduction of the pyraclostrobin residues in the processed commodities (Germany, 2017a,b). The number and quality of the processing studies is sufficient to derive a number of robust processing factors which are recommended to be included in Annex VI of Regulation (EC) No 396/2005.

1.2.4. Proposed MRLs

EFSA concluded that the submitted residue trials are sufficient to derive MRL proposals of 2.0 mg/kg for mandarins, grapefruit, lemons and limes (SEU GAP), 0.5 mg/kg for flowering brassica (SEU GAP), 0.4 mg/kg for head cabbages (SEU GAP), 0.9 mg/kg for escaroles (NEU GAP), 3.0 mg/kg for globe artichokes (SEU GAP) and 0.8 mg/kg for leeks (SEU GAP). For lamb's lettuce, cresses, land cresses, Roman rocket, red mustards and baby leaf crops, EFSA derived two MRL proposals for further risk management consideration (10 or 15 mg/kg).

The data provided did not give evidence that the existing MRLs for lettuces (2 mg/kg) and for maize grain (current MRL set at the LOQ of 0.02 mg/kg) need to be changed.

For the crops where import tolerances were requested, an MRL of 0.2 mg/kg is proposed for passion fruits/maracujas and 0.3 mg/kg for pineapples; both MRL proposals are lower than the MRLs set in the country of origin (0.5 mg/kg for both crops).

For American persimmons, spinaches and similar leaves and sugar canes, the data were not sufficient to derive a MRL proposal. The same was true for oranges. For oranges, an indicative MRL was calculated based on seven trials (instead of eight trials) which is identical with the current MRL in place (i.e. 2 mg/kg).

In Section 3, EFSA describes the results of the risk assessment performed for the calculated MRL proposals derived from the supervised field trials.

2. Residues in livestock

Head cabbage, maize and dried citrus pulp may be used as feed items. Therefore, it was necessary to update the previous dietary burden calculations for livestock (EFSA, 2018c) to estimate whether the intended uses of pyraclostrobin on the crops under consideration in this reasoned opinion would have an impact on the residues expected in food of animal origin.

The updated dietary burden calculation was performed according to the currently used OECD methodology (OECD, 2013). The input values for the exposure calculation for livestock are presented in Appendix D.1. The results of the dietary burden calculation presented in Appendix B.2 show that the estimated exposure of cattle, swine and poultry to pyraclostrobin residues exceeded the trigger values.

Comparing the dietary burden calculation that was calculated in the framework of the previous assessment (EFSA, 2018c) with the calculation presented above, including the commodities assessed in this reasoned opinion demonstrated that the overall exposure to residues of pyraclostrobin to the total livestock, did not change significantly. Therefore, EFSA concluded that the previously derived MRL proposals for products of animal origin (EFSA, 2018a) do not have to be revised.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different sub-groups 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 pyraclostrobin used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticide peer review (European Commission, 2004).

The short-term (acute) dietary exposure assessment was performed for the commodities assessed in this application. The complete list of input values can be found in Appendix D.2. For citrus fruits\textsuperscript{11} it is noted that the EMS proposed to use a variability factor (VF) of 2.6 for citrus fruits (derived from a study in pome fruit investigating the unit-to-unit variability) instead of using the default VF of 7. Considering that there is no general agreement on the possible extrapolation of unit-to-unit variability factors from pome fruit to citrus, and since no acute intake concern was identified for citrus fruit using the default variability factor, EFSA did not follow the approach proposed by the EMS.
(mandarins, grapefruits, lemons and lime) and pineapples, peeling factors were used to perform a more realistic exposure assessment. For crops where no change of the MRL was proposed, the calculations were performed with the HR value derived from the trials derived in this assessment (lettuce) or with the more critical highest residue/supervised trials median residue (HR/STMR) value derived in a previous assessment (i.e. cresses, land cress, Roman rocket, red mustard baby leaf crops and maize). The crops for which the data were not sufficient to derive MRL proposals were not included in the acute risk assessment (i.e. oranges, American persimmons, spinaches and similar leaves and sugar canes).

The results of this calculation showed an exceedance of the ARfD for escaroles (172% of the ARfD) and for lettuce (144% of the ARfD); for the remaining crops, the estimated exposure was below the ARfD (96% for globe artichokes, 74% for Roman rocket, 57% for leeks and 42% for cauliflower). The short-term exposure for the remaining crops was below 40% of the ARfD.

In scenario 2 of the acute risk assessment, the HR value for lettuce and escarole were replaced with the HR values derived in the framework of the MRL review, reflecting the current MRLs in place. In this scenario, for none of the crops an exceedance of the ARfD was noted.

In the framework of Article 12 MRL review, a comprehensive long-term exposure assessment was performed taking into account the existing uses at the EU level and the acceptable CXLs (EFSA, 2011b). EFSA updated this risk assessment with the median residue levels (STMRs) derived from the residue trials submitted in support of this MRL application for mandarins, grapefruits, lemons, limes, passion fruits, pineapples, flowering brassica, globe artichokes and leeks (Table B.1.2.1 in Appendix B) and the STMRs reported in the previous EFSA reasoned opinions and the Article 12 MRL review (EFSA 2011a,b, 2012, 2013, 2014a,b, 2016, 2017, 2018a,b,c). For citrus fruit and pineapples, the peeling factors were considered. For the crops for which no need for an amendment of the existing MRL was identified or where the previously derived STMR values were higher, the STMR values derived in previous assessment were used. The food commodities, for which no uses were reported in the framework of the Article MRL 12 review or in subsequent EFSA opinions, were excluded from the exposure calculation, assuming that there is no use of pyraclostrobin on these crops. The complete list of input values can be found in Appendix D.2.

The estimated long-term dietary intake was in the range of 2–17.5% of the ADI. The highest contribution of residues expected from the commodities assessed in this application is on leeks (0.6% of ADI). The contribution of the single commodities to the overall long-term exposure is presented in the Appendix C.

In scenario 2, the chronic exposure was calculated where the STMR values for escaroles and lettuce were replaced with the STMR values derived for the MRL review (EFSA, 2011b). This modification did not have an impact on the result of the chronic risk assessment.

Overall, EFSA concluded that the long-term intake of residues of pyraclostrobin resulting from the intended uses for the crops under consideration is unlikely to present a chronic risk to consumer health.

4. Conclusion and Recommendations

EFSA concludes that the submitted residue trials are sufficient to derive MRL proposals of 2.0 mg/kg for mandarins, grapefruit, lemons and limes (SEU GAP), 0.5 mg/kg for flowering brassica (SEU GAP), 0.4 mg/kg for head cabbages (SEU GAP), 3.0 mg/kg for globe artichokes (SEU GAP) and 0.8 mg/kg for leeks (SEU GAP). For passion fruits/maracujas and pineapples, the data were found to be sufficient to derive import tolerances which are comparable with the MRLs in place in the country of origin (i.e. 0.2 mg/kg for passion fruits and 0.3 mg/kg for pineapples). For none of the proposed MRLs, consumer intake concerns were identified.

For lamb’s lettuce, cresses, land cresses, Roman rocket, red mustards and baby leaf crops, EFSA derived two MRL proposals for further risk management consideration (10 or 15 mg/kg).

The data provided does not give evidence that the existing MRLs for lettuces (2 mg/kg) and for maize grain (current MRL set at the LOQ of 0.02 mg/kg) need to be changed. Although for lettuce a modification of the existing MRL was not deemed necessary, the short-term risk assessment performed with the highest residue found in supervised residue trials submitted in support of the MRL application revealed a potential intake concern. The short-term exposure calculated with the HR derived from the data set submitted previously which reflected a less critical GAP (indoor use), but lead to the same MRL, did not exceed the ARfD. Thus, before granting a new authorisation in lettuce, Member States should verify that the acute risk assessment performed in the framework of the MRL review under Article 12 is still valid, even if the existing MRL does not have to be modified.
For American persimmons, spinach leaves and sugar canes, the data were not sufficient to derive a MRL proposal. The same was true for oranges. For oranges, an indicative MRL proposal of 2 mg/kg was calculated based on seven trials (instead of eight trials), which is identical with the current MRL in place.

EFSA identified a short-term intake concern for the use in escaroles/broad-leaved endives. Therefore no modification of the existing MRL was proposed by EFSA.

The MRL recommendations are summarised in Appendix B.4.

References

CEN (European Committee for Standardization), 2008a. Foods of plant origin – Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE. QuEChERS-method. EN 15662, November 2008.

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers’ health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. https://doi.org/10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2011a. Reasoned opinion on the modification of the existing MRLs for pyraclostrobin in various crops. EFSA Journal 2011;9(3):2120. https://doi.org/10.2903/j.efsa.2011.2120

EFSA (European Food Safety Authority), 2011b. Review of the existing maximum residue levels (MRLs) for pyraclostrobin according to MRL review 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 MRLs 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 MRLs 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), 2018a. Reasoned opinion on the modification of the existing MRL for pyraclostrobin in soyabean. EFSA Journal 2018;15(1):5466, 29 pp. https://doi.org/10.2903/j.efsa.2018.5466

EFSA (European Food Safety Authority), 2018b. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for pyraclostrobin. EFSA Journal 2018;5472, 29 pp. https://doi.org/10.2903/j.efsa.2018.5472

EFSA (European Food Safety Authority), 2018c. Setting of an import tolerance for pyraclostrobin in rice. EFSA Journal 2018;16(11):5483, 23 pp. https://doi.org/10.2903/j.efsa.2018.5483

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals.7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.
European Commission, 2004. Review report for the active substance pyraclostrobin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 November 2003 in view of the inclusion of pyraclostrobin in Annex I of Council Directive 91/414/EEC. SANCO/1420/2001-Final, 8. September 2004.

European Commission, 2004a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.

FAO (Food and Agriculture Organization of the United Nations), 2006. Pyraclostrobin. In: Pesticide residues in food – 2006. Evaluations. Part I – Residues. Joint meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper 189/1, 821–866.

FAO (Food and Agriculture Organization of the United Nations), 2011. Pyraclostrobin. In: Pesticide residues in food – 2011. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 211, 223–237.

FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.

Germany, 2001. Draft assessment report on the active substance pyraclostrobin prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, August 2001.

Germany, 2003. Addendum to the draft assessment report on the active substance pyraclostrobin prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, October 2003.

Germany, 2017a. Evaluation report on the setting of import tolerance for pyraclostrobin in pineapples and passion fruits/maracuja. January 2017 as revised in February 2018, 33 pp.

Germany, 2017b. Evaluation report on the setting/modification of MRLs for pyraclostrobin in various crops. April 2017 as revised in February 2018, 109 pp.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 4 September 2013.

Abbreviations

| Abbreviation | Description |
|--------------|-------------|
| a.i.         | active ingredient |
| a.s.         | active substance |
| ADI          | acceptable daily intake |
| AR           | applied radioactivity |
| ARfD         | acute reference dose |
| BBCH         | growth stages of mono- and dicotyledonous plants |
| bw           | body weight |
| CEN          | European Committee for Standardisation (Comité Européen de Normalisation) |
| cGAP         | critical GAP |
| CXL          | Codex maximum residue limit |
| DAR          | draft assessment report |
| DAT          | days after treatment |
| DM           | dry matter |
| DT90         | period required for 90% dissipation (define method of estimation) |
| EC           | emulsiifiable concentrate |
| EMS          | evaluating Member State |
| FAO          | Food and Agriculture Organization of the United Nations |
| GAP          | Good Agricultural Practice |
| HPLC-MS/MS   | high performance liquid chromatography with tandem mass spectrometry |
| HPLC-UVD     | high performance liquid chromatography with ultra-violet detector |
| HR           | highest residue |
| IEDI         | international estimated daily intake |
| IESTI        | international estimated short-term intake |
| InChiKey     | International Chemical Identifier Key |
| ILV          | independent laboratory validation |
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LC liquid chromatography
LOQ limit of quantification
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
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern Europe
SL soluble concentrate
SMILES simplified molecular-input line-entry system
SP water-soluble powder
STMR supervised trials median residue
WG water-dispersible granule
WHO World Health Organization
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------------------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
| Citrus – oranges and mandarins<sup>(1)</sup> | SEU | F | Alternaria spp. | WG 200 g/kg | Foliar spray BBCH 31-85 | 4 | 7.5–15 1,500–3,000 225 g/ha 7 | 7-day PHI cGAP for GR and FR. Less cGAP for ES, IT, PT (21-day PHI) |
| American Persimmons | USA | F | Not available | WG 128 g/kg | Foliar with ground equipment, aerial equipment, or sprinkler irrigation N/A | 3 | 7–14 Not available Not available 166–206 g/ha 0 | Max. seasonal application rate 550 g ai/ha |
| Passion fruits/ maracujas | Brazil | F | Colletotrichum | WG 50 g/kg | Spray Preventively or when first symptoms occur | 4 | 10 12.5–15 1,000 125–150 g/ha 7 | – |
| Pineapples | Brazil | F | Ceratocystis paradoxa | WG 50 g/kg | Spray Preventively or when first symptoms occur | 4 | 8–10 42–50 200–300 125–150 g/ha 3 | – |
| Flowering brassica (broccoli, cauliflower) | SEU | F | Peronospora parasitica, Alternaria brassicae | EC 40 g/kg | High volume spraying BBCH 11-49 | 1–3 | Not specified 8–50 200–1,000 80–100 g/ha 7 | Intended uses in IT, PT, ES, GR |
| Head cabbages | SEU | F | Peronospora parasitica, Alternaria brassicae | EC 40 g/kg | High volume spraying BBCH 11-49 | 1–3 | Not specified 8–50 200–1,000 80–100 g/ha 3 | Intended uses in IT, ES, GR, PT |
| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|-----------------------------------|-------------|-------------|-----------------------------|------------|---------|
| **Lettuces and similar** | NEU SEU | Bremia lactucae | EC 40 g/kg, High volume spraying | BBCH 10-49 | 1-3 Not specified | 10-50 | 200-1,000 | g/ha | 7 | Intended uses in FR, DK, EE, FI, LT, LV, NO, SE, PL, GR (only lettuce and escaroles), ES (only lettuce) |
| **Spinaches & similar leaves** (Spinach, purslane, chards) | SEU | Peronospora spp. (farinosa, etc.) | EC 40 g/kg, High volume spraying | BBCH 11-49 | 1-3 Not specified | 8-50 | 200-1,000 | g/ha | 7 | Intended uses in ES, GR, IT, PT |
| **Globe artichokes** | SEU | Bremia lactucae | EC 40 g/kg, High volume spraying | BBCH 50-85 | 1-3 Not specified | 8-50 | 200-1,000 | g/ha | 3 | Intended uses in ES, GR, PT, IT |
| **Leeks** | SEU | Phytophthora porri | EC 40 g/kg, High volume spraying | BBCH 11-49 | 1-3 Not specified | 8-50 | 200-1,000 | g/ha | 3 | Intended uses in ES, PT, IT |
| **Maize** | NEU SEU | Exserohilum turcicum | EC 200 g/kg, Spraying | BBCH 30-65 (Summer) | 1 | N/A | 100-400 | g/ha | N/A | PHI defined by growth stage at application Intended uses in BG, UK, ES, GR, IT, PT, DK, SE |
| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|------------------------------------|-------------|-------------|-------------------------------|
|                       |                         |                                    | Type(b) Conc. a.s. Method kind | Range of growth stages & season(c) | Number min–max | Interval between application (min) (days) | g a.s./hL/min–max | Water L/ha/min–max | Rate Unit | PHI (days)(d) | Remarks(e) |
| Maize (forage and grain) | NEU SEU | F | *Setosphaeria turcica, Puccinia sorghum, Kabatiella zeae* | EC 200 g/kg | Spraying 30–65 (Summer) | 1 | N/A | 200–400 | 200 g/ha N/A | Including physiological effects PHI defined by growth stage at application Intended uses in BG, UK, ES, GR, IT, PT, DK, SE |
| Sugar canes | US F | Puccinia kuehni, Puccinia melanocephala | EC 250 g/kg | Spraying Preventative/first symptoms | 4 | Not specified | N/A | – | 225 g/ha 14 | Max. two sequential applications. Maximum per season: 890 g F500/ha |

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

(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.
(e): The intended uses were reported in the Appendix A of the Evaluation Report (Germany, 2017b); this information was used to retrieve the geographical zone reported in the second column of this table.
(f): EMS provided a clarification on 12 July 2018 by email that the GAP is intended for all citrus fruit.
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                            | Grapes      | Foliar: 6 × 130 to 480 g a.s./ha, from BBCH 53-55 to 81 | 40 DAT<sub>6</sub> | Radiolabelled active substance: [tolyl-U-<sup>14</sup>C]-pyraclostrobin and [chlorophenyl-U-<sup>14</sup>C]-pyraclostrobin (EFSA, 2011b) |
| Root                             | Potatoes    | Foliar: 6 × 300 g a.s./ha, from BBCH 31 to maturity | 7 DAT<sub>3</sub> and 7 DAT<sub>6</sub> (maturity) | &nbsp; |
| Cereals/grass                    | Wheat       | Foliar: 2 × 300 g a.s./ha, from BBCH 32 to 61 | 0 DAT<sub>1</sub>, 31 DAT<sub>1</sub>, 41 DAT<sub>2</sub> 63/65 DAT (forage) 74/6 DAT (hay) 103/104 DAT (grain, straw) | &nbsp; |
| Paddy rice                       |            | Foliar: 3 × 130 g a.s./ha, from BBCH 39 to 69 | -1 DAT<sub>2</sub> (forage), 57 DAT<sub>3</sub> (straw, grain) | EFSA (2018c) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Radishes    | 900 g a.s./ha | 30, 120, 365 | Radiolabelled active substance: [tolyl-U-<sup>14</sup>C]-pyraclostrobin and [chlorophenyl-U-<sup>14</sup>C]-pyraclostrobin (EFSA, 2011b) |
| Leafy crops                         | Lettuces    | 30, 120, 365 | 30, 120, 365 | &nbsp; |
| Cereal (small grain)                | Wheat       | 30, 120, 365 | &nbsp; | &nbsp; |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)     | Yes        | EFSA (2011b) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | EFSA (2011b) |
| Sterilisation (20 min, 120°C, pH 6)     | Yes        | EFSA (2011b) |
Can a general residue definition be proposed for primary crops?
Yes EFSA (2011b)

Rotational crop and primary crop metabolism similar?
Yes EFSA (2011b)

Residue pattern in processed commodities similar to residue pattern in raw commodities?
Yes For standard processing types (pasteurisation, baking, brewing, boiling and sterilisation)

Plant residue definition for monitoring (RD-Mo)
Pyraclostrobin

Plant residue definition for risk assessment (RD-RA)
Pyraclostrobin

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
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. Higher sensible method for high water content, acidic and dry/high starch content commodities with a LOQ of 0.01 mg/kg is also available
Confirmatory method available using HPLC-UV
ILV available (EFSA, 2011b)

BBCH: growth stages of mono- and dicotyledonous plants; DATx, days after treatment x (e.g. DAT2: day after 2nd treatment); a.s.: active substance; 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

| Plant products (available studies) | Category                  | Commodity            | T (°C) | Stability period | Compounds covered | Comment/source |
|-----------------------------------|---------------------------|----------------------|--------|------------------|-------------------|---------------|
|                                    |                           |                      | < – 10 | 96%              | 18 months Pyraclostrobin | Germany (2001) |
|                                    | High water content        | Tomatoes             | < – 10 | 92%              | 18 months         |               |
|                                    |                           | Sugar beet tops      | < – 10 | 98%              | 18 months Pyraclostrobin |               |
|                                    |                           | Sugar beet roots     | < – 10 | 99%              | 18 months         |               |
|                                    | High starch content       | Sugar beet roots     | < – 10 | 91%              | 18 months Pyraclostrobin |               |
|                                    |                           | Peanut nutmeat       | < – 10 | 88%              | 18 months Pyraclostrobin |               |
|                                    | High oil content          | Peanut oil            | < – 10 | 84%              | 18 months         |               |
|                                    |                           | Wheat grain           | < – 10 | 88%              | 18 months Pyraclostrobin |               |
|                                    | Dry/high starch content   | Grape juice           | < – 10 | 88%              | 18 months Pyraclostrobin |               |
|                                    | Others                    | Wheat straw           | < – 10 | 99%              | 18 months Pyraclostrobin |               |
### B.1.2. Magnitude of residues in plants

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

| Commodity          | Region/ indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|--------------------|-------------------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------------------|---------------------------|
| Oranges            | SEU                           | Oranges: 0.33, 0.34, 0.39, 0.60, 0.64, 0.69, 1.30               | Residue trials on oranges compliant with GAP. Since the number of trials is not fully compliant with the data requirements, only an indicative MRL proposal was calculated (2 mg/kg). The indicative calculated MRL is identical with the current MRL | 2 (indicative)         | 1.3 (indicative)          | 0.60 (indicative)         |
| Mandarins          | SEU                           | Mandarins: 0.25, 0.25, 0.37, 0.51, 0.52, 0.54, 0.70, 0.76, 0.87, 1.20 | Residue trials on mandarins compliant with GAP                                | 2                      | 1.2                      | 0.53                      |
| Citrus (grapefruits, lemons, limes) | SEU               | Oranges and mandarins: See above                               | From the merged data set, an indicative MRL proposal for all citrus fruit is derived. Although the number of trials in oranges is not fully compliant with the data requirement for extrapolation, but considering that a sufficient number of mandarin trials are available and usually mandarins are expected to be the crop in which higher residues are expected, EFSA considered the data sufficient to derive a MRL proposal for the remaining citrus crops from the combined data set in oranges and mandarins | 2                      | 1.3                      | 0.54                      |
| Passion fruits/ maracujas | Brazil                  | 0.03, 0.04, 0.05, 0.10                                          | Residue trials compliant with the GAP                                           | 0.2                    | 0.10                     | 0.05                      |
| American persimmons | USA                         | 0.092, 0.44, 1.15                                               | Residue trials compliant with the GAP. Number of trials not sufficient to derive a MRL | No MRL proposal        | –                        | –                         |
| Pineapples         | Brazil                       | 2 × 0.02, 0.03, 0.04, 0.05, 2 × 0.07, 0.09, 0.19               | Residue trials compliant with the GAP                                           | 0.3                    | 0.19                     | 0.05                      |

<sup>(a)</sup> Indoor (a)
| 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) |
|-----------------------------------|------------------|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|---------------|
| Flowering brassica                | SEU              | Cauliflower: $2 \times 0.010, 0.020, 0.040$                       | Combined data set on cauliflower (4) and broccoli (4) compliant with GAP are used to derive MRL by extrapolation for the whole group of flowering brassica | 0.5                    | 0.19         | 0.05          |
| Head cabbages                     | SEU              | $5 \times 0.01, 0.02, 0.03, 0.22$                                | Residue trials compliant with the GAP on head cabbage                                                                   | 0.4                    | 0.22         | 0.01          |
| Lettuces                          | NEU              | Lettuces (open leaf varieties) $0.01, 0.07, 0.11, 2 \times 0.12, 0.17, 0.22, 0.59 | Residue trials on lettuce (open leaf varieties) compliant with the NEU GAP                                          | 0.9                    | 0.59         | 0.12          |
|                                   | SEU              | Lettuces: $< 0.01, 0.02, 0.05, 2 \times 0.21, 0.22, 0.24, 0.27, 0.28, 0.30, 0.59, 1.60$ | Residue trials on lettuce compliant with the SEU GAP. Not clear whether trials were performed in open leaf varieties or head forming varieties | 2                      | 1.6          | 0.23          |
| Lamb’s lettuce                    | NEU              | Lettuces (open leaf varieties) $0.01, 0.07, 0.11, 2 \times 0.12, 0.17, 0.22, 0.59 | Residue trials on lettuce (open leaf varieties) compliant with the NEU GAP can be used to derive MRL proposal by extrapolation | 0.9                    | 0.59         | 0.12          |
|                                   | SEU              | $0.11, 0.73, 3.89, 4.16$                                        | Residue trials on lamb’s lettuce compliant with the SEU GAP. The MRL proposal derived with the OECD calculator is 15 mg/kg; alternative MRL proposal 10 mg/kg (expert judgement, taking into account residue data in NEU open leaf varieties) | 15 or 10               | 4.16         | 2.31          |
| Escarole                          | NEU              | Lettuces (open leaf varieties): $0.01, 0.07, 0.11, 2 \times 0.12, 0.17, 0.22, 0.59 | Residue trials on lettuce (open leaf varieties) compliant with the NEU GAP                                          | 0.9                    | 0.59         | 0.12          |
|                                   | SEU              | –                                                               | No appropriate residue trials are available                                                                             | –                      | –            | –             |
| Other crops belonging to crop group of lettuces and salad plants (cresses, land cresses, Roman rocket, red mustards, baby leaf crops) | NEU              | Lettuces (open leaf varieties): $0.01, 0.07, 0.11, 2 \times 0.12, 0.17, 0.22, 0.59 | MRL proposal derived from residue trials on lettuce (open leaf varieties) compliant with the NEU GAP by extrapolation | 0.9                    | 0.59         | 0.12          |
|                                   | SEU              | Lamb’s lettuce: $0.11, 0.73, 3.89, 4.16$                        | Residue trials on lamb’s lettuce compliant with the SEU GAP, extrapolation to other lettuces                           | 15 or 10               | 4.16         | 2.31          |
| 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) |
|----------------------------------------------|------------------|------------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|--------------|
| Spinaches and similar leaves (spinach, purslane, chards) | SEU              | 0.19, 0.22, 0.25, 0.34, 1.44                                      | No SEU residue trials on spinaches available                                    |                        |              |              |
|                                              |                  |                                                                  | Extrapolation from lettuces is also not possible since no SEU residue trials in open leaf varieties are available |                        |              |              |
|                                              |                  |                                                                  |                                                                                 |                        |              |              |
| Globe Artichokes                             | SEU              | 0.21, 0.25, 0.26, 0.29                                           | Residue trials on artichokes compliant with SEU GAP                             | 3.0                    | 1.44         | 0.25         |
| Leeks                                        | SEU              | 0.21, 0.25, 0.26, 0.29                                           | Leek is a minor crop in the south EU. Residue trials (4) compliant with the GAP | 0.8                    | 0.29         | 0.26         |
| Maize (grain)                                | SEU              | 4 × < 0.01                                                       | Residue trials on maize compliant with GAP. Reduced numbers of trials are sufficient as in none of the trials residues above the LOQ were measured | 0.01*                  | 0.01         | 0.01         |
|                                              | NEU              | 4 × < 0.01                                                       | The information was sufficient to derive input values for the dietary burden calculation. Since the NEU and SEU data are similar (Mann-Whitney U-test), the data sets were merged to derive the HR and STMR |                        |              |              |
| Maize (forage)                               | NEU              | 0.22, 0.33, 0.36, 0.44, 0.47                                     | The information was sufficient to derive input values for the dietary burden calculation. Since the NEU and SEU data are similar (Mann-Whitney U-test), the data sets were merged to derive the HR and STMR |                        | 0.76         | 0.36         |
|                                              | SEU              | 0.20, 0.21, 0.22, 0.76                                           |                                                                                 |                        |              |              |
| Sugar canes                                  | USA              | 0.048, 0.059, 0.097                                              | Residue trials compliant with the GAP but number of trials is not sufficient to derive a MRL; limited validity of residue trials due to storage conditions not covered by storage stability studies |                        |              |              |

MRL: maximum residue level; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; LOQ: limit of quantification.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity 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.
B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on **confined** rotational crop study?

|                |                |
|----------------|----------------|
| No             | Germany (2001) |

Residues in rotational and succeeding crops expected based on **field** rotational crop study?

|                |                |
|----------------|----------------|
| No             | Germany (2001) |

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | Median PF | Comment/source |
|---------------------|----------------------------|------------------------|-----------|----------------|
| Individual values   |                            |                        |           |                |
|                     |                            | **Processing Factor (PF)** |           |                |
| Mandarin, peel      | 8                          | 1.96, 1.96, 2.71, 2.97, 3.06, 3.57, 3.78, 5.14 | 3.02      | Germany (2017b) |
| Mandarin, pulp      | 8                          | 0.02, 0.06, 0.08, 0.11, 0.14, 0.14, 0.16, 0.27 | 0.13      | Germany (2017b) |
| Orange, peel        | 12                         | 1.74, 2.32, 2.52, 3.11, 3.6, 3.74, 3.82, 4.0, 4.0, 4.78, 5.21, 6.36 | 3.78      | Germany (2017b) |
| Orange, pulp        | 12                         | 0.03, 0.05, 0.05, 0.06, 0.06, 0.09, 0.11, 0.13, 0.14, 0.15, 0.22, 0.45 | 0.10      | Germany (2017b) |
| Orange juice        | 4                          | 0.03, 0.04, 0.05, 0.13 | 0.05      | Germany (2017b) |
| Orange juice, pasteurised | 4                  | 0.04, 0.04, 0.11, 0.13 | 0.08      | Germany (2017b) |
| Orange marmalade    | 4                          | 0.06, 0.18, 0.19, 0.25 | 0.19      | Germany (2017b) |
| Orange pomace, wet  | 4                          | 1.07, 1.31, 1.5, 1.81 | 1.41      | Germany (2017b) |
| Orange pomace, dried | 4                        | 5.44, 6.5, 7.34, 9.89 | 6.92      | Germany (2017b) |
| Spinaches, cooked   | 4                          | 0.39, 0.50, 0.74, 1.7 | 0.62      | Germany (2017b) |
| Maize, chopped fodder | 4                       | 1.05, 1.10, 1.10, 1.12 | 1.10      | Germany (2017b) |
| Maize silage (from whole plant) | 4           | 0.94, 1.32, 1.53, 1.80 | 1.43      | Germany (2017b) |
| Maize refined oil, flour, meal, starch, gluten, bran, middling, germs, press cake | 4 | $< 0.01, < 0.02, < 0.023, < 0.027, < 0.045, < 0.05, < 0.05, < 0.05$ | $< 0.36$ | Germany (2017b) |
| Pineapple pulp      | 4                          | $< 0.15, < 0.21, < 0.33, < 0.48$ | 0.27      | Germany (2017a) |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

(b): A tentative PF is derived based on a limited data set.
### B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|-----------------------------|----------------------------|---------------------------|---------------------------|------------------------|
|                             | mg/kg bw per day | mg/kg DM |                         |                         |                        |
| Cattle (all)                | Median 0.084     | Maximum 0.133            | Median 2.53               | Maximum 3.85           | Dairy cattle            | Barley straw | Yes                   |
| Cattle (dairy only)         | 0.084            | 0.133                   | 2.20                      | 3.47                   | Dairy cattle            | Barley straw | Yes                   |
| Sheep (all)                 | 0.127            | 0.232                   | 3.61                      | 6.00                   | Lamb                    | Barley straw | Yes                   |
| Sheep (ewe only)            | 0.120            | 0.200                   | 3.61                      | 6.00                   | Ram/Ewe                 | Barley straw | Yes                   |
| Swine (all)                 | 0.023            | 0.034                   | 1.02                      | 1.47                   | Swine (breeding)        | Potato process waste | Yes                   |
| Poultry (all)               | 0.028            | 0.061                   | 0.41                      | 0.89                   | Poultry layer           | Wheat straw | Yes                   |
| Poultry (layer only)        | 0.028            | 0.061                   | 0.41                      | 0.89                   | Poultry layer           | Wheat straw | Yes                   |
| Fish                        | N/A              |                         |                          |                        |                         |                        |                        |

bw: body weight; DM: dry matter.
The highest dietary burden expressed in mg/kg DM result from sheep.

(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

(c): The highest dietary burden expressed in mg/kg DM result from sheep.

### B.2.1. Nature of residues and methods of analysis in livestock

Since the contribution of the residues of pyraclostrobin in the crops under consideration to the total livestock dietary intake is insignificant, the previous assessment of residues in livestock is still valid (EFSA, 2018c).
### B.3. Consumer risk assessment

| ARfD | 0.03 mg/kg bw (European Commission, 2004) |
|------|------------------------------------------|
|      | **Highest IESTI, according to EFSA PRIMo** |
|      | Escarole (broad-leaf endive): 172% of ARfD (scenario 1), 82% (scenario 2) |
|      | Lettuce: 144% of ARfD (scenario 1), 73% (scenario 2) |
|      | Globe artichokes: 96% of ARfD |
|      | Rocket, Rucola: 74% of ARfD |
|      | Leek: 57% of ARfD |
|      | Cauliflower 42% of ARfD |
|      | Lamb's lettuce: 39% of ARfD |
|      | Grapefruit: 39% of ARfD |
|      | Head cabbage: 39% of ARfD |
|      | Broccoli: 37% of ARfD |
|      | Mandarins: 29% of ARfD |
|      | Pineapples: 17% of ARfD |
|      | Lemons: 15% of ARfD |
|      | Limes: 8% of ARfD |
|      | Cress: 7% of ARfD |

| Assumptions made for the calculations |
|---------------------------------------|
| **Scenario 1:** HR/STMR derived from trials provided with this application except for cresses, land cress, Roman rocket, red mustard baby leaf crops and maize (more critical HR/STMR value derived in a previous assessment). PF for citrus fruit and pineapples |
| The crops for which the data were not sufficient to derive MRL proposals were not included in the acute risk assessment (i.e. oranges, American persimmons, spinach and similar leaves and sugar canes) |
| **Scenario 2:** for lettuce and escaroles, the HR values derived in the Art. 12 MRL review were used (reflecting the existing uses) instead of the HR values derived from residue trials submitted in this application |

| ADI | 0.03 mg/kg bw (European Commission, 2004) |
|-----|------------------------------------------|
|     | **Highest IEDI, according to EFSA PRIMo** |
|     | Scenario 1: 17.5% ADI (DE child diet) |
|     | The highest contribution of crops assessed: leeks (0.6% of ADI) |
|     | **Scenario 2:** Same results as for scenario 1 |

| Assumptions made for the calculations |
|---------------------------------------|
| **Scenario 1:** The calculation is based on the median residue levels derived for raw agricultural commodities derived from the trials provided with this application or the higher STMR values derived in previous assessments (i.e. head cabbage, lettuces, lamb's lettuce, cresses, land cress, Roman rocket, red mustards, Baby leaf crops, spinach and similar crops, beet leaves, maize); for citrus fruit and pineapples, PF were used |
| **Scenario 2:** Same assumptions as scenario 1; fall-back STMR for escaroles and lettuces |

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

| Code(a) | Commodity                  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                                                                                 |
|--------|-----------------------------|-------------------------|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0110020| Oranges                     | 2.0                     | No modification needed  | The submitted data did not provide evidence that the existing MRL has to be modified                                                                                                                                  |
| 0110050| Mandarin                    | 1.0                     | 2.0                     | The submitted residue trials are sufficient to derive a MRL proposal for the intended SEU use. Risk for consumers unlikely (based on exposure assessment including a peeling factor)                                        |
| 0110010| Grapefruit,                | 1.0                     | 2                       | Data are sufficient (combined data set in oranges and mandarins) to derive a MRL proposal for the remaining citrus crops. A risk for consumers is unlikely (based on exposure assessment including peeling factors) |
| 0110030| Grapes,                     |                          |                          |                                                                                                                                                                                                                     |
| 0110040|                           |                          |                          |                                                                                                                                                                                                                     |
| 0162030| Passion fruits/             | 0.02*                   | 0.2                     | The submitted residue trials are sufficient to derive an import tolerance (Brazilian GAP). Risk for consumers unlikely. The proposed MRL is at lower than the existing MRL in Brazil (i.e. 0.5 mg/kg) |
|        | maracujas                   |                          |                          |                                                                                                                                                                                                                     |
| 0162060| American persimmons        | 0.02*                   | No MRL proposal         | The submitted residue trials are not sufficient to derive an import tolerance for the USA GAP                                                                                                                           |
| 0163080| Pineapples                 | 0.02*                   | 0.3                     | The submitted residue trials are sufficient to derive an import tolerance (Brazilian GAP). Risk for consumers unlikely. The proposed MRL is lower than the existing MRL in Brazil (i.e. 0.5 mg/kg) |
| 0241000| Flowering brassica         | 0.1                     | 0.5                     | The submitted residue trials are sufficient to derive a MRL proposal for the intended SEU use. Risk for consumers unlikely                                                                                                 |
| 0242020| Head cabbages              | 0.2                     | 0.4                     | The submitted residue trials are sufficient to derive a MRL proposal for the intended SEU use. Risk for consumers unlikely                                                                                                 |
| 0251010| Lamb’s lettuce             | 10.0                    | 10 or 15 Further risk management considerations needed | Taking into account the residue trials in lamb’s lettuce reflecting the SEU GAP, a MRL proposal of 15 mg/kg is derived. Considering also data from lettuce (open leaf varieties) a lower MRL of 10 mg/kg is considered sufficient. Risk for consumers unlikely |

*Enforcement residue definition: pyraclostrobin(F)*

---

www.efsa.europa.eu/efsajournal 30 EFSA Journal 2018;16(11):5488
| Code\(^{(a)}\) | Commodity                  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                 |
|----------------|----------------------------|-------------------------|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| 0251020        | Lettuces                   | 2.0                     | No modification needed; further risk management considerations needed | The data set submitted in support of the NEU GAP lead to a MRL proposal of 0.9 mg/kg. From the SEU data set, a MRL proposal of 2 mg/kg was derived. Although this GAP would not require a modification of the existing MRL, it was noted that the highest residue (HR) measured in the supporting data set lead to an exceedance of the ARfD. No intake concern was identified for the HR reflecting the indoor GAP which is the basis for the existing MRL. Before granting a new authorisation in lettuce, Member States should verify that the acute risk assessment performed in the framework of the MRL review under Article 12 is still valid, even if the existing MRL does not have to be modified. Alternatively, the lowering of the existing MRL to the level of 0.9 mg/kg could be considered; this MRL proposal reflects the NEU GAP. For this GAP, a risk for consumers is unlikely. |
| 0251030        | Escarole                   | 0.4                     | No MRL proposal          | Although sufficient data are available to derive a MRL proposal of 0.9 mg/kg for the intended NEU use, EFSA did not recommend a modification of the existing MRL since an acute consumer health risk could not be excluded. |
| 0251040        | Cresses and other sprouts  | 10                      | 10 or 15 Further risk management considerations needed | Taking into account the residue trials in lamb’s lettuce reflecting the SEU GAP, a MRL proposal of 15 mg/kg is derived by extrapolation. Considering also data from lettuce (open leaf varieties), a lower MRL of 10 mg/kg is considered sufficient. Risk for consumers unlikely. |
| 0251050        | Land cresses               |                         |                         |                                                                                                                                                    |
| 0251060        | Roman rocket/ rucola       |                         |                         |                                                                                                                                                    |
| 0251070        | Red mustards               |                         |                         |                                                                                                                                                    |
| 0251080        | Baby leaf crops            |                         |                         |                                                                                                                                                    |
| 0252000        | Spinaches and similar leaves | 0.6 spinach 0.02* purslanes 1.5 chard | No MRL proposal | The submitted residue trials are not sufficient to derive an MRL proposal for the intended SEU uses.                                                                                                      |
| 0270050        | Globe artichokes           | 2.0                     | 3.0                     | The submitted residue trials are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely.                                                                                         |
| 0270060        | Leeks                      | 0.7                     | 0.8                     | The submitted residue trials are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely.                                                                                         |
| 0500030        | Maize                      | 0.02*                   | No modification needed  | The submitted data did not provide evidence that the existing MRL has to be modified                                                                                                                              |
| 0900020        | Sugar canes                | 0.02*                   | No MRL proposal         | The submitted residue trials are not sufficient to derived a MRL for import tolerance (USA GAP)                                                                                            |

MRL: maximum residue level; SEU: southern Europe; GAP: Good Agricultural Practice; NEU: northern Europe; ARfD: acute reference dose.

*: 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)

#### PYRACLOSTROBIN

| Toxicological end points | ADI (mg/kg bw per day) | Proposed LOQ (mg/kg bw) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD | Year of evaluation | Year of evaluation |
|--------------------------|------------------------|-------------------------|-----------------|---------------|---------------|-------------------|-------------------|
|                          | 0.03                   | 0.03                    |                 | EC            | EC            | 2004              | 2004              |

#### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) |
|--------------------------------|---------------------------------------------|
|                                |                                             |

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) |
|--------------------------------|---------------------------------------------|
|                                |                                             |

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) |
|--------------------------------|---------------------------------------------|
|                                |                                             |

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) |
|--------------------------------|---------------------------------------------|
|                                |                                             |

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) |
|--------------------------------|---------------------------------------------|
|                                |                                             |

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) |
|--------------------------------|---------------------------------------------|
|                                |                                             |

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) |
|--------------------------------|---------------------------------------------|
|                                |                                             |

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) |
|--------------------------------|---------------------------------------------|
|                                |                                             |

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) |
|--------------------------------|---------------------------------------------|
|                                |                                             |

### 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 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 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 residues level which would lead to an exposure equivalent to 100% of the ARfD.

For processed commodities, no exceedance of the ARfD/ADI was identified.

The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 2 commodities. Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodity.

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

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

### Acute risk assessment/children – refined calculations

| Commodity | pTMRL/ADI (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ADI (mg/kg) | Highest % of ARfD/ADI Commodities |
| --- | --- | --- | --- | --- |
| Scarole (broad-leaf) | 0.59 | 171.9 | 58.6 | Lettuce |
| Lettuce | 1.6 | 143.5 | 86.1 | Lettuce |
| Globe artichokes | 1.44 | 96.4 | 26.1 | Lamb's lettuce |
| Rocket, Rucola | 7.2 | 74.3 | 23.3 | Head cabbage |
| Leek | 0.25 | 57.0 | 20.1 | Cauliflower |
| Cauliflower | 0.19 | 41.9 | 0.19 | Cauliflower |
| Lettuce | 1.6 | 39.0 | 18.5 | Lettuce |
| Lamb's lettuce | 4.16 | 38.7 | 13.5 | Broccoli |
| Processed commodities | 0.13 | 38.6 | 26.3 | Broccoli |
| Broccoli | 0.19 | 36.9 | 9.1 | Cress |
| Mandarin | 0.156 | 28.9 | 7.0 | Cress |
| Pineapples | 0.0513 | 17.3 | 3.9 | Pineapples |
| Lemons | 0.13 | 14.9 | 3.0 | Lemons |
| Limes | 0.13 | 8.7 | 2.8 | Limes |
| Cress | 7.2 | 7.0 | 0.5 | Passion fruit |

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

| Commodity | pTMRL/ADI (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ADI (mg/kg) | Highest % of ARfD/ADI Commodities |
| --- | --- | --- | --- | --- |
| Scarole (broad-leaf) | 0.59 | 171.9 | 58.6 | Lettuce |
| Lettuce | 1.6 | 143.5 | 86.1 | Lettuce |
| Globe artichokes | 1.44 | 96.4 | 26.1 | Lamb's lettuce |
| Rocket, Rucola | 7.2 | 74.3 | 23.3 | Head cabbage |
| Leek | 0.25 | 57.0 | 20.1 | Cauliflower |
| Cauliflower | 0.19 | 41.9 | 0.19 | Cauliflower |
| Lettuce | 1.6 | 39.0 | 18.5 | Lettuce |
| Lamb's lettuce | 4.16 | 38.7 | 13.5 | Broccoli |
| Processed commodities | 0.13 | 38.6 | 26.3 | Broccoli |
| Broccoli | 0.19 | 36.9 | 9.1 | Cress |
| Mandarin | 0.156 | 28.9 | 7.0 | Cress |
| Pineapples | 0.0513 | 17.3 | 3.9 | Pineapples |
| Lemons | 0.13 | 14.9 | 3.0 | Lemons |
| Limes | 0.13 | 8.7 | 2.8 | Limes |
| Cress | 7.2 | 7.0 | 0.5 | Passion fruit |

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

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.

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

### Processed commodities

| Commodity | pTMRL/ADI (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ADI (mg/kg) | Highest % of ARfD/ADI Commodities |
| --- | --- | --- | --- | --- |
| Scarole (broad-leaf) | 0.59 | 171.9 | 58.6 | Lettuce |
| Lettuce | 1.6 | 143.5 | 86.1 | Lettuce |
| Globe artichokes | 1.44 | 96.4 | 26.1 | Lamb's lettuce |
| Rocket, Rucola | 7.2 | 74.3 | 23.3 | Head cabbage |
| Leek | 0.25 | 57.0 | 20.1 | Cauliflower |
| Cauliflower | 0.19 | 41.9 | 0.19 | Cauliflower |
| Lettuce | 1.6 | 39.0 | 18.5 | Lettuce |
| Lamb's lettuce | 4.16 | 38.7 | 13.5 | Broccoli |
| Processed commodities | 0.13 | 38.6 | 26.3 | Broccoli |
| Broccoli | 0.19 | 36.9 | 9.1 | Cress |
| Mandarin | 0.156 | 28.9 | 7.0 | Cress |
| Pineapples | 0.0513 | 17.3 | 3.9 | Pineapples |
| Lemons | 0.13 | 14.9 | 3.0 | Lemons |
| Limes | 0.13 | 8.7 | 2.8 | Limes |
| Cress | 7.2 | 7.0 | 0.5 | Passion fruit |

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

* 2) pTMRL: provisional temporary MRL for unprocessed commodity.

* 3) pTMRL: provisional temporary MRL for unprocessed commodity.
# PYRACLOSTROBIN

| Toxicological end points | ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD | Year of evaluation | Year of evaluation |
|-------------------------|------------------------|----------------|---------------|---------------|-------------------|-------------------|
| | | | EC | EC | 2004 | 2004 |

## Limit of quantitation (LOQ)

**LOQ (mg/kg):**

- Proposed LOQ: 0.03 mg/kg bw

## ADI (mg/kg bw per day)

- ADI: 0.03 mg/kg bw per day

## ARfD (mg/kg bw)

- ARfD: 0.03 mg/kg bw

## Source of ADI, ARfD

- Source of ADI: EC
- Source of ARfD: EC

## Year of evaluation

- Year of evaluation: 2004

## No of diets exceeding ADI

- No of diets exceeding ADI: ---

## Calculation of Theoretical Maximum Daily Intakes (TMDI)

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.

## Commodity/group of commodities

- Milk and cream
- Apples
- Sugar beet (root)
- Barley
- Cucumbers
- Oranges
- Lettuce
- Wheat
- Tomatoes
- Table grapes
- Gooseberries
- Carrots
- Apples
- Potatoes
- Cucumbers
- Tomatoes
- Lettuce
- Tomatoes
- Apples
- Potatoes

## TMDI values in % of ADI

- Minimum: 5.0
- Maximum: 17.5

## Commodity/group of commodities

**Highest contributor to MS diet (in % of ADI):**

- 1.7: Milk and cream
- 1.6: Apples
- 1.5: Milk and cream

**2nd contributor to MS diet (in % of ADI):**

- 1.4: Milk and cream
- 1.3: Sugar beet (root)
- 1.2: Milk and cream

**3rd contributor to MS diet (in % of ADI):**

- 1.1: Apples
- 1.0: Apples
- 1.0: Milk and cream

### TMDI values in % of ADI

| Commodity/group of commodities | Minimum | Maximum |
|-------------------------------|---------|---------|
| Milk and cream                | 5.0     | 17.5    |
| Apples                        | 1.7     | 1.6     |
| Sugar beet (root)             | 1.5     | 1.4     |
| Milk and cream                | 1.3     | 1.2     |
| Apples                        | 1.1     | 1.0     |
| Milk and cream                | 1.0     | 1.0     |
| Milk and cream                | 0.9     | 0.8     |
| Sugar beet (root)             | 0.7     | 0.6     |
| Apples                        | 0.6     | 0.5     |
| Milk and cream                | 0.5     | 0.4     |
| Apples                        | 0.4     | 0.3     |
| Milk and cream                | 0.4     | 0.3     |
| Apples                        | 0.3     | 0.2     |
| Milk and cream                | 0.2     | 0.2     |
| Apples                        | 0.1     | 0.1     |

### 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 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 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.

### No of critical MRLs (ESTI 1)

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

| 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): |
|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|

| Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) |
|----------------------------------|------------------------------|----------------------------------|------------------------------|----------------------------------|------------------------------|----------------------------------|------------------------------|
| 96.4 Globe artichokes 1.44/-     |                              | 81.6 Scallion (broccoli) 0.28/-  |                              | 74.3 Rocket, Rucola 7.2/-        |                              | 72.6 Lettuce 0.81/-              |                              |
| 81.6 Scallion (broccoli) 0.28/-  |                              | 74.3 Rocket, Rucola 7.2/-        |                              | 68.8 Globe artichokes 1.44/-     |                              | 43.6 Lettuce 0.81/-              |                              |
| 72.6 Lettuce 0.81/-              |                              | 41.9 Cauliflower 0.15/-         |                              | 40.7 Leek 0.29/-                |                              | 23.3 Head cabbage 0.22/-         |                              |
| 57.0 Leek 0.25/-                 |                              | 41.9 Cauliflower 0.15/-         |                              | 18.5 Leek 0.29/-                |                              | 14.0 Head cabbage 0.22/-         |                              |
| 41.9 Cauliflower 0.19/-         |                              | 39.0 Leek 0.29/-                |                              | 13.5 Broccoli 0.19/-            |                              | 14.0 Head cabbage 0.22/-         |                              |
| 39.0 Leek 0.29/-                |                              | 38.7 Grapefruit 0.13/-          |                              | 9.1 Cress 7.2/-                 |                              | 13.5 Broccoli 0.19/-            |                              |
| 38.7 Grapefruit 0.13/-          |                              | 36.2 Broccoli 0.19/-           |                              | 8.7 Grapefruit 0.13/-           |                              | 9.1 Cress 7.2/-                 |                              |
| 36.2 Broccoli 0.19/-           |                              | 26.3 Broccoli 0.18/-          |                              | 8.7 Grapefruit 0.13/-           |                              | 6.5 Grapefruit 0.13/-           |                              |
| 28.9 Mandarins 0.156/-         |                              | 21.8 Mandarins 0.156/-         |                              | 7.0 Mandarins 0.156/-           |                              | 5.4 Mandarins 0.156/-           |                              |
| 17.3 Pineapples 0.0513/-     |                              | 17.3 Pineapples 0.0513/-       |                              | 3.9 Pineapples 0.0513/-         |                              | 3.9 Pineapples 0.0513/-         |                              |
| 14.9 Lemons 0.13/-             |                              | 11.1 Lemons 0.13/-             |                              | 3.0 Lemons 0.13/-               |                              | 2.2 Lemons 0.13/-               |                              |
| 8.7 Limes 0.13/-               |                              | 7.0 Cress 7.2/-                 |                              | 2.8 Limes 0.13/-                |                              | 2.0 Limes 0.13/-                |                              |
| 7.0 Cress 7.2/-                |                              | 6.2 Limes 0.15/-                | 0.5 Passion fruit 0.1/-        | 0.5 Passion fruit 0.1/-         |                              | 0.5 Passion fruit 0.1/-         |                              |

### modifier of existing MRLs and setting of import tolerances for pyraclostrobin in various crops

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

For PYRACLOSTROBIN, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

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.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

### Conclusion:

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity         | Median dietary burden | Maximum dietary burden |
|------------------------|-----------------------|------------------------|
|                        | Input value (mg/kg)   | Comment                |
|                        |                       | Input value (mg/kg)    | Comment                |
|                        |                       |                         |                        |
| Risk assessment residue definition: Pyraclostrobin |
| Citrus dried pulp      | 3.73                  | STMR (0.54) × PF (6.9) |
| Head cabbage           | 0.02                  | STMR (EFSA, 2011b)     |
| Maize forage/silage    | 0.51                  | STMR × PF (1.43)       |
| Maize, field grain     | 0.02                  | STMR                   |
| Maize, pop grain       | 0.02                  | STMR                   |
| Other feed items       |                       | STMR, HR (EFSA 2012, 2014b, 2018a,c) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

D.2. 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 |
| Risk assessment residue definition for livestock: sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin |
| Oranges                 | 0.07                    | STMR (CXL) × PF (0.14) (EFSA, 2011a) |
|                         |                         | –                      |
|                         |                         | Not assessed since no MRL proposal was derived |
| Mandarins               | 0.069                   | STMR × PF<sub>peeling</sub> (0.13) |
|                         |                         | 0.16                   |
|                         |                         | HR × PF<sub>peeling</sub> (0.13) |
| Grapefruit              | 0.052                   | STMR × PF<sub>peeling</sub> (0.1) |
|                         |                         | 0.13                   |
|                         |                         | HR × PF<sub>peeling</sub> (0.1) |
| Lemons                  | 0.053                   | STMR × PF<sub>peeling</sub> (0.1) |
|                         |                         | 0.13                   |
|                         |                         | HR × PF<sub>peeling</sub> (0.1) |
| Limes                   | 0.053                   | STMR × PF<sub>peeling</sub> (0.1) |
|                         |                         | 0.13                   |
|                         |                         | HR × PF<sub>peeling</sub> (0.1) |
| Table grapes            | 0.44<sup>(a)</sup>      | STMR (EFSA, 2011b)     |
|                         |                         | –                      |
|                         |                         | Not relevant for current application |
| Passion fruits/maracuja | 0.05                    | STMR                   |
|                         |                         | 0.10                   |
|                         |                         | HR                     |
| Pineapples              | 0.014                   | STMR × PF<sub>peeling</sub> (0.27) |
|                         |                         | 0.05                   |
|                         |                         | HR × PF<sub>peeling</sub> (0.27) |
| Flowering brassica     | 0.05                    | STMR                   |
|                         |                         | 0.19                   |
|                         |                         | HR                     |
| Head cabbage            | 0.02                    | STMR (EFSA, 2011b)     |
|                         |                         | 0.22                   |
|                         |                         | HR                     |
| Lettuces               | Scenario 1              | 0.26                   |
|                         |                         | STMR (indoor GAP, EFSA, 2011b) |
|                         |                         | 1.6                    |
|                         |                         | HR (SEU GAP)           |
|                         | Scenario 2              | 0.26                   |
|                         |                         | STMR (indoor GAP, EFSA, 2011b) |
|                         |                         | 0.81                   |
|                         |                         | HR (indoor GAP, EFSA, 2011b) |
| Lamb's lettuce         | 2.5                     | STMR (EFSA, 2011b)     |
|                         |                         | 4.16                   |
|                         |                         | HR                     |
| Escarole               | Scenario 1              | 0.12                   |
|                         |                         | STMR                   |
|                         |                         | 0.59                   |
|                         |                         | HR                     |
|                         | Scenario 2              | 0.04                   |
|                         |                         | STMR (EFSA, 2011b)     |
|                         |                         | 0.28                   |
|                         |                         | HR (EFSA, 2011b)       |
| Cresses                | 2.5                     | STMR (EFSA, 2011b)     |
|                         |                         | 7.2                    |
|                         |                         | HR (EFSA, 2011b)       |
| Land cress             | 2.5                     | STMR (EFSA, 2011b)     |
|                         |                         | 7.2                    |
|                         |                         | HR (EFSA, 2011b)       |
| Roman rocket           | 2.5                     | STMR (EFSA, 2011b)     |
|                         |                         | 7.2                    |
|                         |                         | HR (EFSA, 2011b)       |
| Red mustard            | 2.5                     | STMR (EFSA, 2011b)     |
|                         |                         | 7.2                    |
|                         |                         | HR (EFSA, 2011b)       |
| Baby leaf crops        | 2.5                     | STMR (EFSA, 2011b)     |
|                         |                         | 7.2                    |
|                         |                         | HR (EFSA, 2011b)       |

www.efsa.europa.eu/efsajournal 36 EFSA Journal 2018;16(11):5488
| Commodity               | Chronic risk assessment | Acute risk assessment |
|------------------------|-------------------------|-----------------------|
|                        | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Spinaches and similar leaves | 0.05 STMR (EFSA, 2011b) | –                     | Not assessed since no MRL proposal was derived |
| Beet leaves            | 0.26 STMR (EFSA, 2011b) | –                     |                       |
| Globe artichokes       | 0.25 STMR               | 1.44 HR               |                       |
| Leeks                  | 0.26 STMR               | 0.29 HR               |                       |
| Maize                  | 0.02 STMR (EFSA, 2011b) | 0.02 STMR (EFSA, 2011b) |                       |

Chronic risk assessment undertaken considering all authorised uses identified during the Article 12 MRL review (EFSA, 2011b) and the latest MRL applications under Art 10 of the EU regulation 396/2005 (EFSA, 2011a, 2012, 2013, 2014a,b, 2016, 2017, 2018a,b,c) and Acute risk assessment undertaken only with regard to the crop under consideration.

STMR: supervised trials median residue; CXL: Codex maximum residue limit; MRL: maximum residue level; HR: highest residue; PF: processing factor; GAP: Good Agricultural Practice; SEU: southern Europe.

(a): Pending the decision of the revision on the existing MRL for table grapes, the previously derived STMR (EFSA, 2011a,b) was still included in the calculation.
## Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| Pyraclostrobin      | methyl 2-[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl-N-methoxycarbanilate  
O=C(OC)N(OC)c1cccc1COc1ccn(n1)c1ccc(cc1)cc1  
HZRSNVGNWUFEX-UHFFFAOYSA-N | ![Pyraclostrobin structural formula](image)  |
| Desmethoxy metabolite (500M07, BF 500-3) | methyl 2-([(1-(4-chlorophenyl)-1H-pyrazol-3-yl)oxy]methyl)phenyl)carbamate  
O=C(OC)Nc1cccc1COc1ccn(n1)c1ccc(cc1)cc1  
SEUOYURJKYAPC-UHFFFAOYSA-N | ![Desmethoxy metabolite structural formula](image)  |
| 500M04              | 1-(4-chlorophenyl)-1H-pyrazol-3-ol  
Clc1cccc1cccn(O)n1  
DRENHOMDLNJDUG-UHFFFAOYSA-N | ![500M04 structural formula](image)  |
| 500M49              | methyl [2-(hydroxymethyl)phenyl]carbamate  
O=C(OC)Nc1cccc1CO  
QNCPWLXCDKFGK-EUHFFFAOYSA-N | ![500M49 structural formula](image)  |
| 500M06              | 1-(4-chlorophenyl)-3-[[2-[(methoxycarbonyl)amino]benzoyl]oxy]-1H-pyrazol-4-yl β-D-glucopyranosiduronic acid  
O=C(OC)Nc1cccc1COc1ccn(cc1O[C@@H](O)[C@@H][O][C@@H]1O)c(-O)c1ccc(cc1)cc1  
AKGNRMGSEIHMP-BPDMSXLESA-N | ![500M06 structural formula](image)  |
| 500M72 (L-tryptophan) | L-tryptophan  
O=C(O)[C@@H][N]Cc1c[NH]c2cccc21  
QIVBCDIJAIAPQS-VIFPVQBESA-N | ![500M72 structural formula](image)  |

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