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# Setting of import tolerance for pyraclostrobin in papayas

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## Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF SE submitted a request to the competent national authority in Germany to set an import tolerance for the active substance pyraclostrobin in papayas imported from Brazil. The data submitted in support of the request were found to be sufficient to derive a maximum residue level (MRL) proposal for papayas. Adequate analytical methods for enforcement are available to control the residues of pyraclostrobin on the commodity under consideration at or above the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of pyraclostrobin on papayas imported from Brazil according to the reported agricultural practices is unlikely to present a risk to consumer health.



**Keywords:** pyraclostrobin, papayas, fungicide, MRL, consumer risk assessment

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## Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in Germany (rapporteur Member State, EMS) to set an import tolerance for the active substance pyraclostrobin in papayas.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 13 July 2021. The appointed EMS Germany assessed the dossier and declared its admissibility on 24 March 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by the European Food Safety Authority (EFSA), and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies, and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 18 October 2022 to 8 November 2022. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting 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 February 2023. The EMS proposed to establish maximum residue level (MRL) for papayas imported from Brazil at the level of 0.6 mg/kg. The MRL in place for pyraclostrobin on papayas in Brazil is 0.5 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS. On 3 March 2023, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the EMS who submitted a revised evaluation report to EFSA on 27 March 2023, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments, and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of pyraclostrobin following foliar application was investigated in crops belonging to the groups of root vegetables (potatoes), fruits (grapes) and cereals (wheat, paddy rice). Studies investigating the effect of processing on the nature of pyraclostrobin (hydrolysis studies) demonstrated that the active substance is stable. As the proposed use of pyraclostrobin is on imported and permanent crops, investigations of residues in rotational crops are not required. Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the general residue definitions for plant products were proposed as pyraclostrobin for enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops, and processed products. EFSA concluded that for the crops assessed in this application, metabolism of pyraclostrobin in primary crops and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) are available to quantify residues in papayas according to the enforcement residue definition. The methods enable the quantification of residues at or above 0.01 mg/kg in the crops assessed (limit of quantification – LOQ). According to the EMS, extraction efficiency of the analytical enforcement method has been sufficiently demonstrated according to the guidance SANTE/2017/10632 in the context of the renewal assessment report (Germany, 2001), and remains relevant for this application. EFSA would recommend that data on extraction efficiency for all types of matrices are further considered and confirmed in the framework of the ongoing peer review for the renewal of the active substance.

The available residue trials are sufficient to derive an MRL proposal for papayas. A risk management decision is required on whether to set the MRL at the level established in Brazil (0.5 mg/kg) or as calculated applying the OECD methodology (0.6 mg/kg).

Specific studies investigating the magnitude of pyraclostrobin residues in processed commodities were not submitted and are not required, considering the low individual contribution of the processed products prepared from the crop under consideration to the overall dietary consumer exposure. Residues of pyraclostrobin in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of 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 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The acute exposure calculation performed on the crop under consideration did not identify acute consumer intake concerns related to the notified use of pyraclostrobin on papayas in Brazil (maximum 35.3% of the ARfD). For the calculation of the chronic exposure, EFSA used the median residue values (STMR) as derived from the residue trials submitted and the STMRs available from previously issued EFSA opinions. The existing MRL was used for table grapes and for the products of animal origin. No long-term consumer intake concerns were identified for any of the European diets incorporated in EFSA PRIMo. The estimated long-term dietary intake accounted for a maximum of 32% of the ADI (NL toddler diet). The contribution of residues expected in papayas to the overall long-term exposure was low and accounted for a maximum of 0.002% of ADI (SE general diet).

EFSA concluded that the use of pyraclostrobin on papayas authorised in Brazil assessed in this MRL application will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The EU peer review of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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

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

| Code[(a)] | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---|---|---|---|---|
| **Enforcement residue definition:** Pyraclostrobin[(F)] | | | | |
| 0163040 | Papayas | 0.07 | 0.5 or 0.6<br>Further risk management considerations required | The submitted data are sufficient to derive an import tolerance (Brazilian GAP).<br>Based on the residue trials on papayas submitted an MRL of 0.6 mg/kg is derived with the OECD calculator. The MRL set in Brazil for papayas is lower, 0.5 mg/kg. In the residue trials on papayas, the highest residue level was 0.25 mg/kg, which is half the Brazilian MRL.<br>Risk management decision is required on whether to set the MRL at the level established in Brazil (0.5 mg/kg) or as calculated applying the OECD methodology (0.6 mg/kg).<br>Risk for consumers is unlikely. |

MRL: maximum residue level; GAP: Good Agricultural Practice.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

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## Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for the active substance pyraclostrobin in papayas. The detailed description of the use of pyraclostrobin authorised in Brazil in papayas, which is the basis for the import tolerance application, is reported in Appendix A.

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

Pyraclostrobin was evaluated in the framework of Directive 91/414/EEC[1] with Germany designated as rapporteur Member State (RMS) for the representative uses as a foliar application on grapes. The draft assessment report (DAR) prepared by the RMS was not peer reviewed by EFSA. Therefore, no EFSA conclusion is available. Pyraclostrobin was approved[2] for the use as 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 first approval is currently ongoing.

The EU MRLs for pyraclostrobin are established in Annex II of Regulation (EC) No 396/2005[4]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011b) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for pyraclostrobin (EFSA, 2011a, 2012a, 2013, 2014a,b, 2016, 2017, 2018a,c,d, 2019a). Furthermore, the evaluation of the MRL review confirmatory data on pyraclostrobin was performed in 2018 (EFSA 2018b). The proposals from these reasoned opinions have been considered in recent MRL regulations.[5] In addition, certain Codex maximum residue limits (CXLs) from pyraclostrobin have been taken over in the EU MRL legislation taking into account EFSA recommendations (EFSA, 2011, 2019b, 2021).

In accordance Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[6], the applicant BASF SE submitted on 13 July 2021 an application to the competent national authority in Germany, alongside the dossier containing the supporting data using the IUCLID format.

The appointed EMS Germany assessed the dossier and declared its admissibility on 24 March 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies, and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 18 October 2022 to 8 November 2022. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting 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 February 2023. The EMS proposed to increase the MRL for papayas to the level of 0.6 mg/kg. The MRL in place for pyraclostrobin on papayas in Brazil is 0.5 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS. On 3 March 2023, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the EMS who submitted a revised

[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 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.
[5] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as
[6] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

evaluation report to EFSA on 27 March 2023, which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2023), the DAR (and its addendum) (Germany, 2001, 2003) prepared under Council Directive 91/414/EEC, the Commission review report on pyraclostrobin (European Commission, 2004), as well as the conclusions from previous EFSA opinions on pyraclostrobin (EFSA, 2011a, 2012a, 2013, 2014a,b, 2016, 2017, 2018a,b,c), including the review of the existing MRLs for pyraclostrobin under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011b), the assessment of confirmatory data following the MRL review for pyraclostrobin (EFSA, 2018b) as well as, EFSA outputs on the Scientific support for preparing an EU position for the 44th, 51st and 52nd Sessions of the CCPR (EFSA, 2012b, 2019b, 2021).

For this application, the data requirements established in Regulation (EU) No 544/2011[7] and the guidance documents applicable at the date of submission of the IUCLID application are applicable (European Commission, 1997a,b,c,d,e,f,g, 2010, 2017, 2020, 2021; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[8].

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

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

The evaluation report submitted by the EMS (Germany, 2023) 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.[9]

# 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 in primary crops belonging to the group of fruit crops (grapes), root crops (potatoes) and cereals (wheat) has been assessed in the framework of Directive 91/414/EEC and reassessed by EFSA during the MRL review (Germany, 2001; EFSA, 2011b). An additional study on paddy rice was assessed in a reasoned opinion issued after the MRL review (EFSA, 2018c). The metabolic pathway was found to be similar in all crop groups investigated. After foliar application, the predominant compound of the total residues in the crops investigated was the parent pyraclostrobin; the desmethoxy metabolite (500 M07) occurred in small amounts compared to the parent pyraclostrobin (Germany, 2001; EFSA, 2011b).

Since the crops under consideration belong to the fruit crop group, EFSA concluded that the metabolic behaviour in primary crops is sufficiently addressed, and further studies are not required.

### 1.1.2. Nature of residues in rotational crops

As the use of pyraclostrobin under assessment is on permanent, imported crops, investigations of residues in rotational crops are not required. However, metabolism studies in rotational crops are available and are reported in Appendix B for completeness.

### 1.1.3. Nature of residues in processed commodities

Standard hydrolysis studies simulating processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the framework of Directive 91/414/EEC and reassessed by

[7] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

[9] Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00184

EFSA during the MRL review (Germany, 2001; EFSA, 2011b). From these studies, it was concluded that processing by pasteurisation, baking/brewing/boiling and sterilisation is not expected to have a significant impact on the composition of residues in matrices of plant origin.

#### 1.1.4. Analytical methods for enforcement purposes in plant commodities

An analytical method using liquid chromatography with tandem mass spectrometry (LC–MS/MS) and its independent laboratory validation (ILV) 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 commodities. For confirmatory purposes, a second MS/MS transition was validated. In addition, the multi-residue quick, easy, cheap, effective, rugged, and safe (QuEChERS) method in combination with high-performance chromatography with tandem mass spectrometry (HPLC–MS/MS) is reported for the routine analysis of pyraclostrobin in high water content, acidic content, and dry commodities with an LOQ of 0.01 mg/kg (EFSA, 2011b). A validated analytical method, including its ILV, for enforcement of pyraclostrobin in coffee beans is also available (EFSA, 2018c).

EFSA concluded that pyraclostrobin can be enforced in food of plant origin by LC–MS/MS with an LOQ of at least 0.02 mg/kg in in crops belonging to the group of high-water content commodities, to which papayas belong (EFSA, 2011b, 2018b). The analytical multi-residue QuEChERS method for routine monitoring achieves a lower LOQ of 0.01 mg/kg. According to the EMS, extraction efficiency of the LC–MS/MS analytical enforcement method 421/0 has been sufficiently demonstrated according to the guidance SANTE/2017/10632 in the context of the renewal assessment report (Germany, 2001). It remains relevant for this application.

EFSA would recommend that data on extraction efficiency for all types of matrices are further considered and confirmed in the framework of the ongoing peer review for the renewal of the active substance.

#### 1.1.5. Storage stability of residues in plants

The storage stability of pyraclostrobin in high water, high acid, high oil content and dry commodities was assessed in the framework of the of Directive 91/414/EEC and reassessed during the MRL review (Germany, 2001; EFSA, 2011b). In the high-water content matrices, to which group the crop under assessment belongs, pyraclostrobin residues were stable for at least 18 months when stored at −10°C.

#### 1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the following residue definitions were proposed during the MRL review (EFSA, 2011b):

- residue definition for risk assessment: pyraclostrobin
- residue definition for enforcement: pyraclostrobin

The same residue definitions are applicable to rotational crops and processed products (EFSA, 2011b). The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

For the use assessed in this application, EFSA concluded that these residue definitions are appropriate and no further information is required.

### 1.2. Magnitude of residues in plants

#### 1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted Good Agricultural Practice (GAP)-compliant residue trials performed in Brazil on papayas (six trials). The trials were performed over two seasons in Brazil and half of them were designed as decline trials. The samples were analysed for the parent compound in accordance with the residue definition for enforcement and risk assessment and for the metabolite 500 M07. In all the trials, residues of pyraclostrobin were measured in the whole fruit. Residue decline data show that residues of pyraclostrobin and its metabolite (500 M07) decline in papaya fruits with increasing PHIs. According to the EMS, the methods used were sufficiently validated and fit for purpose (Germany, 2023). EFSA notes that the solvent system used for the analytical

method (L0076/09) to assess the residue trials is comparable with the one used for the enforcement method (421/0), therefore extraction efficiency is considered sufficiently proven according to the guidance SANTE/2017/10632 for the crop under assessment. The samples of these residue trials were stored for a maximum storage interval of 166 days prior to analyses under conditions for which the integrity of the samples has been demonstrated for pyraclostrobin.

The number of trials is sufficient to derive an MRL proposal in support of the reported Brazilian use of pyraclostrobin on papayas.

### 1.2.2. Magnitude of residues in rotational crops

As the use of pyraclostrobin assessed in this application is on permanent and imported crops, investigations on the magnitude of residues in rotational crops are not required.

### 1.2.3. Magnitude of residues in processed commodities

No studies were submitted in the context of this MRL application are not available and are not necessary because the theoretical maximum daily intake (TMDI) for the individual crops under assessment is expected to be less than 10% of the acceptable daily intake (ADI).

Papayas are fruits with inedible peel, however information of the distribution of residues between peel and pulp was not investigated in the residue trials submitted.

### 1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for the commodity under evaluation (see Appendix B.4). The MRL proposal derived using the OECD calculator and the results of the submitted residue trials is of 0.6 mg/kg, which is higher than the MRL set in Brazil for papayas (0.5 mg/kg). In the residue trials on papayas, the highest residue level was 0.25 mg/kg, which is equal to half the Brazilian MRL. According to the applicant, the MRL value was originally established in Brazil by extrapolation from residue trials on mangos (Germany, 2023). Extrapolation from mangos to papayas is not foreseen at the EU level (European Commission, 2020). In Section B.3, EFSA assessed whether residues on papayas resulting from the use reported to be authorised in Brazil are likely to pose a consumer health risk.

## 2. Residues in livestock

Not relevant as papayas are not used for feed purposes. Hence, investigations on residues in livestock are not further considered in the framework of the current evaluation.

## 3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018e, 2019c). 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. ADI and ARfD values) were derived in the framework of the EU pesticide peer review (European Commission, 2004).

*Short-term (acute) dietary risk assessment*

The short-term exposure assessment for papayas was performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016). The calculation was based on the highest residue (HR) level expected in the raw agricultural commodity derived from supervised field trials. The input value can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD (exposure accounted for 35.3% of the ARfD for NL children diet, see Appendix B.3).

*Long-term (chronic) dietary risk assessment*

In the framework of the MRL review a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level, existing import tolerances and the acceptable CXLs (EFSA, 2011b). EFSA updated these calculations several times after the MRL review. The chronic risk assessments were updated again by including the STMR value derived for papayas.

For the remaining commodities covered by the MRL regulation, the STMR derived in the framework of the MRL review and the STMR values derived in EFSA opinions issued after the MRL review were selected as input values (EFSA, 2011a, 2012a, 2013, 2014a,b, 2016, 2017, 2018a,c,d, 2019a). For table grapes, the existing MRL was used as the related STMR could not be retrieved. Available peeling factors were also considered to refine the calculations in certain products with inedible peel. The commodities of animal origin are all set at the LOQ, and, as worst scenario exposure, the conversion factor of 4 derived for liver, of 1 for tissues of swine and ruminants in the framework of the MRL review and of 6.8 for milks derived during a previous EFSA reasoned opinion (EFSA, 2018a) were used to take into consideration the metabolites included in the residue definition for risk assessment of products of animal origin. The STMR for the Codex MRLs (CXLs) implemented in the EU MRL regulation were also included in the calculation (FAO, 2011, 2019, 2021). The complete list of input values used in the exposure calculations is presented Appendix D.1.

The estimated long-term dietary intake was in the range up to 32% of the ADI. The contribution of residues expected in the commodity assessed in this application to the overall long-term exposure is low and presented in more detail in Appendix B.3.

EFSA concluded that the long-term intake of residues of pyraclostrobin resulting from the existing and the use in papayas under assessment is unlikely to present a risk to consumer health.

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

## 4. Conclusion and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for papayas. A risk management decision is required on whether to set the MRL at the level established in Brazil (0.5 mg/kg) or as calculated applying the OECD methodology (0.6 mg/kg). In the residue trials on papayas submitted, the highest residue level was 0.25 mg/kg, which is half the Brazilian MRL.

EFSA concluded that the use of pyraclostrobin on papayas authorised in Brazil will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The EU peer review of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

The MRL recommendations are summarised in Appendix B.4.

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## Abbreviations

| | |
|---|---|
| a.s. | active substance |
| ADI | acceptable daily intake |
| AR | applied radioactivity |
| ARfD | acute reference dose |
| BBCH | growth stages of mono- and dicotyledonous plants |
| bw | body weight |
| CCPR | Codex Committee on Pesticide Residues |
| CF | conversion factor for enforcement to risk assessment residue definition |
| CXL | Codex maximum residue limit |
| DAR | draft assessment report |
| DAT | days after treatment |
| FAO | Food and Agriculture Organization of the United Nations |
| GAP | Good Agricultural Practice |
| HPLC–MS/MS | high-performance liquid chromatography with tandem mass spectrometry |
| HR | highest residue |
| IEDI | international estimated daily intake |
| IESTI | international estimated short-term intake |
| ILV | independent laboratory validation |
| InChiKey | International Chemical Identifier Key |
| ISO | International Organization for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| JMPR | Joint FAO/WHO Meeting on Pesticide Residues |
| LC–MS/MS | liquid chromatography with tandem mass spectrometry |
| LOQ | limit of quantification |
| MRL | maximum residue level |
| MS | Member States |
| NEU | northern Europe |
| OECD | Organisation for Economic Co-operation and Development |
| PF | processing factor |
| PHI | preharvest interval |
| PRIMo | (EFSA) Pesticide Residues Intake Model |
| RA | risk assessment |
| RAC | raw agricultural commodity |
| RD | residue definition |
| RMS | rapporteur Member State |

| | |
|---|---|
| SC | suspension concentrate |
| SEU | southern Europe |
| SMILES | simplified molecular-input line-entry system |
| STMR | supervised trials median residue |
| TMDI | theoretical maximum daily intake |
| WHO | World Health Organization |

## Appendix A – Summary of intended notified GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I[a] | Pests or Group of pests controlled | Preparation | | Application | | | | Application rate per treatment | | | | PHI (days)[d] | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Type[b] | Conc. a.s. (g/L) | Method kind | Range of growth stages and season[c] | Number min–max | Interval between application (days) min–max | g a.s./hL min–max | Water (L/ha) min–max | Rate min–max | Unit | | |
| Papayas | BR | F | Anthracnose, powdery mildew | SC | 333 | Foliar treatment - broadcast spraying on foliage | Initiate applications at onset of 1st symptoms or preventively | 1–4 | 7–14 | 0.004–0.027 | 500–1,000 | 42–133 | g a.i./ha | 7 | Max annual rate: 533 g a.i./ha |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; BR: Brazil; a.s.: active substance; SC: Suspension concentrate.

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

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

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

(d): PHI – minimum pre-harvest interval.

# Appendix B – List of end points

## B.1. Residues in plants

### B.1.1. Nature of residues and analytical methods for enforcement purposes in plant commodities

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

| **Primary crops** (available studies) | **Crop groups** | **Crops** | **Applications** | **Sampling (DAT)** | **Comment/Source** |
|---|---|---|---|---|---|
| | Fruit crops | Grapes | Foliar: 6 × 130 to 480 g a.s./ha, from BBCH 53–55 to 81 | 40 | Radiolabelled active substance: [tolyl-U-$^{14}$C]-pyraclostrobin and [chlorophenyl-U-$^{14}$C]-pyraclostrobin (EFSA, 2011b) |
| | Root crops | Potatoes | Foliar: 6 × 300 to 400 g a.s./ha, from BBCH 31 to maturity | 7 | |
| | Cereals/grass | Wheat | Foliar: 2 × 300 g a.s./ha, from BBCH 32 to 61 | 0, 31, 41, 63/65 (forage), 74/76 (hay) and 103/104 (grain, straw) | |
| | | Paddy rice | Foliar: 3 × 130 g a.s./ha, from BBCH 39 to 69 | –1 (forage) and 57 (straw, grain) | Radiolabelled active substance: [tolyl-U-$^{14}$C]-pyraclostrobin and [chlorophenyl-U-$^{14}$C]-pyraclostrobin (FAO, 2018) |
| **Rotational crops** (available studies) | **Crop groups** | **Crops** | **Application** | **PBI (DAT)** | **Comment/Source** |
| | Root/tuber crops | Radishes | Bare soil, 1 × 900 g a.s./ha | 30, 120, 365 | Radiolabelled active substance: [tolyl-U-$^{14}$C]-pyraclostrobin and [chlorophenyl-U-$^{14}$C]-pyraclostrobin (EFSA, 2011b) |
| | Leafy crops | Lettuces | | | |
| | Cereal (small grain) | Wheat | | | |
| | Other | | | | |
| **Processed commodities** (hydrolysis study) | **Conditions** | | **Stable?** | | **Comment/Source** |
| | Pasteurisation (20 min, 90°C, pH 4) | | Yes | | EFSA (2011b) |
| | Baking, brewing and boiling (60 min, 100°C, pH 5) | | Yes | | EFSA (2011b) |
| | Sterilisation (20 min, 120°C, pH 6) | | Yes | | EFSA (2011b) |
| | Other processing conditions | | | | |

| | | |
|---|---|---|
| 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 | EFSA (2018b) |
| 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, dry commodities (EFSA, 2011b):<br>• LC–MS/MS, LOQ 0.02 mg/kg.<br>• Confirmatory method available using HPLC–UV.<br>• ILV available.<br>• Extraction efficiency verified<br><br>Matrices with high water content, high acidic content and dry commodities EFSA, 2011b).<br>• QuEChERS HPLC–MS/MS LOQ of 0.01 mg/kg<br>• ILV available<br>Difficult matrices: hops (EFSA, 2011b) and coffee (EFSA, 2018b)<br>• LC–MS/MS, LOQ 0.02 mg/kg.<br>• ILV available for coffee | |

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; LC–MS/MS: liquid chromatography with tandem mass spectrometry; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

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

| **Plant products** (available studies) | **Category** | **Commodity** | **T (°C)** | **Stability period** | | **Compounds covered** | **Comment/ Source** |
|---|---|---|---|---|---|---|---|
| | | | | **Value** | **Unit** | | |
| | High water content | Tomatoes | < −10 | 18 | Months | Pyraclostrobin/ 500 M07 | Germany (2001) |
| | High water content | Sugar beet tops | | | | | |
| | High oil content | Peanut nutmeat | | | | | |
| | Dry/High starch | Wheat grain | | | | | |
| | High acid content | Grape juice | | | | | |
| | Others | Wheat straw | | | | | |

## B.1.2. Magnitude of residues in plants

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

| Commodity | Region[(a)] | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR[(b)] (mg/kg) | STMR[(c)] (mg/kg) | CF[(d)] |
|---|---|---|---|---|---|---|---|
| Papayas | BR | 3 × < 0.01, 0.06, 0.24, 0.25 | Residue trials on papayas compliant with reported Brazilian GAP.<br>500 M07: 3 × < 0.01, 0.06, 0.02, 0.05 mg 500 M07/kg | 0.6 | 0.25 | 0.035 | N/A |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment; N/A: not applicable.
*: 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, EU: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. N/A, not applicable.

#### B.1.2.2. Residues in rotational crops

| | | |
|---|---|---|
| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Not triggered | Not required (import tolerance on permanent crops) |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered | Not required (import tolerance on permanent crops) |

#### B.1.2.3. Processing factors

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

## B.2. Residues in livestock

Not relevant as papayas are not used for feed purposes.

## B.3. Consumer risk assessment

| | |
|---|---|
| ARfD | 0.03 mg/kg bw per day (European Commission, 2004) |
| Highest IESTI, according to EFSA PRIMo | Papayas: 35.3% ARfD (NL child) |
| Assumptions made for the calculations | Calculations performed with PRIMo revision 3.1<br><br>The calculation is based on the highest residue level expected in papayas from the use authorised in Brazil.<br><br>For commodities not included in the present MRL application, the short-term exposure assessment was performed using the risk assessment input values (HR or STMR) derived in previous EFSA reasoned opinions and the existing MRL (table grapes, products of animal origin). An empirical unit-to-unit variability factor of 3 was used in apples and pears risk assessment (EFSA, 2011b).<br>EFSA confirms the slight exceedance of the ARfD in lettuces (103% of the ARfD) and wine grapes (100.4% of ARfD) previously observed (EFSA, 2018d, 2019a). Recommendations for a possible refinement of the calculation performed according to the agreed methodologies are not available. To be noted is that the standard assumptions used in the calculation are quite conservative and do not consider possible reduction by washing for lettuces and that in wine pyraclostrobin residues are less than 5% of the residues observed in unprocessed grapes (PF for wine of 0.03, EFSA, 2011b). |
| ADI | 0.03 mg/kg bw (European Commission, 2004) |
| Highest IEDI, according to EFSA PRIMo | 32% ADI (NL toddler diet)<br>Contribution of crops assessed:<br>Papayas: 0.002% of ADI (SE general diet) |
| Assumptions made for the calculations | Calculations performed with PRIMo revision 3.1. |

| | |
|---|---|
| | The calculation is based on the median residue level for raw agricultural commodity (papayas) derived from the submitted trials and the median residues derived by EFSA in previous assessments (EFSA, 2011a, 2012a, 2013, 2014a,b, 2016, 2017, 2018a,c,d, 2019a). The STMR for the Codex MRLs (CXLs) implemented in the EU MRL regulation were also included in the calculation (FAO, 2011, 2019, 2021). Peeling factors were considered to refine the calculations for citrus, pineapples, and cucurbits with inedible peel. A conversion factor of 4 for swine and ruminant liver, 1 for the other tissues (EFSA, 2011b) and 6.8 for milks (EFSA, 2018a) was applied to take into consideration the metabolites included in the residue definition for risk assessment in animal commodities.<br><br>The contributions of commodities where no GAP was reported in the framework of the MRL review and in the opinions issued after the MRL review and no CXL was implemented in the MRL legislation were not included in the calculation. |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit; HR: highest residue; GAP: Good Agricultural Practice.

## B.4. Recommended MRLs

| Code[(a)] | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---|---|---|---|---|
| **Enforcement residue definition:** Pyraclostrobin[(F)] | | | | |
| 0163040 | Papayas | 0.07 | 0.5 or 0.6<br>Further risk management considerations required | The submitted data are sufficient to derive an import tolerance (Brazilian GAP).<br>Based on the residue trials on papayas submitted an MRL of 0.6 mg/kg is derived with the OECD calculator. The MRL set in Brazil for papayas is lower, 0.5 mg/kg. In the residue trials on papayas, the highest residue level was 0.25 mg/kg, which is half the Brazilian MRL.<br>Risk management decision is required on whether to set the MRL at the level established in Brazil (0.5 mg/kg) or as calculated applying the OECD methodology (0.6 mg/kg).<br>Risk for consumers is unlikely. |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

# Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

## Pyraclostrobin (F)

LOQs (mg/kg) range from: 0.01 to: 0.10

**Toxicological reference values**

| | | | |
|---|---|---|---|
| ADI (mg/kg bw per day): | 0.03 | ARfD (mg/kg bw): | 0.03 |
| Source of ADI: | European | Source of ARfD: | European Commmision |
| Year of evaluation: | 2004 | Year of evaluation: | 2004 |

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

**Refined calculation mode**

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

No of diets exceeding the ADI : ---

| | Calculated exposure (% of ADI) | MS Diet | Exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | Exposure resulting from: MRLs set at the LOQ (in % of ADI) | Exposure resulting from: commodities not under assessment (in % of ADI) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| TMDI/NEDI/IEDI calculation (based on average food consumption) | 32% | NL toddler | 9.53 | 14% | Milk: Cattle | 5% | Apples | 2% | Pears | 0.1% | 32% |
| | 19% | DE child | 5.72 | 6% | Apples | 4% | Milk: Cattle | 1% | Table grapes | 0.3% | 19% |
| | 17% | NL child | 4.98 | 6% | Milk: Cattle | 3% | Apples | 1% | Sugar beet roots | 0.2% | 17% |
| | 13% | UK infant | 4.03 | 9% | Milk: Cattle | 0.7% | Apples | 0.5% | Carrots | 0.3% | 13% |
| | 13% | FR child 3 15 yr | 3.88 | 5% | Milk: Cattle | 0.9% | Other lettuce and other salad plants | 0.9% | Oranges | 0.3% | 13% |
| | 13% | FR toddler 2 3 yr | 3.85 | 7% | Milk: Cattle | 1% | Apples | 0.4% | Sugar beet roots | 0.2% | 13% |
| | 10% | GEMS/Food G07 | 3.10 | 2% | Wine grapes | 1% | Milk: Cattle | 0.7% | Barley | 0.2% | 10% |
| | 10% | GEMS/Food G11 | 3.08 | 2% | Milk: Cattle | 2% | Wine grapes | 0.9% | Barley | 0.2% | 10% |
| | 10% | DE women 14-50 yr | 2.99 | 3% | Milk: Cattle | 1% | Wine grapes | 1% | Apples | 0.1% | 10% |
| | 10% | DE general | 2.97 | 3% | Milk: Cattle | 1% | Wine grapes | 1% | Apples | 0.1% | 10% |
| | 10% | GEMS/Food G08 | 2.96 | 2% | Wine grapes | 1% | Milk: Cattle | 1% | Barley | 0.2% | 10% |
| | 10% | RO general | 2.94 | 3% | Wine grapes | 3% | Milk: Cattle | 0.7% | Apples | 0.2% | 10% |
| | 10% | UK toddler | 2.94 | 5% | Milk: Cattle | 0.8% | Apples | 0.5% | Oranges | 0.2% | 10% |
| | 10% | GEMS/Food G15 | 2.87 | 2% | Wine grapes | 2% | Milk: Cattle | 0.9% | Barley | 0.2% | 10% |
| | 9% | IE adult | 2.70 | 2% | Wine grapes | 1.0% | Milk: Cattle | 0.4% | Other other small fruit & berries | 0.1% | 9% |
| | 9% | DK child | 2.70 | 3% | Milk: Cattle | 1% | Apples | 0.8% | Cucumbers | 0.2% | 9% |
| | 9% | FR adult | 2.63 | 4% | Wine grapes | 1% | Other lettuce and other salad plants | 1% | Milk: Cattle | 0.1% | 9% |
| | 9% | GEMS/Food G10 | 2.57 | 1% | Milk: Cattle | 0.7% | Barley | 0.7% | Wine grapes | 0.2% | 9% |
| | 8% | GEMS/Food G06 | 2.52 | 1% | Tomatoes | 1% | Table grapes | 0.6% | Milk: Cattle | 0.1% | 8% |
| | 8% | SE general | 2.37 | 3% | Milk: Cattle | 0.7% | Bovine: Muscle/meat | 0.5% | Apples | 0.1% | 8% |
| | 7% | ES child | 2.21 | 3% | Milk: Cattle | 0.5% | Oranges | 0.5% | Apples | 0.3% | 7% |
| | 7% | NL general | 2.18 | 2% | Milk: Cattle | 0.9% | Wine grapes | 0.7% | Apples | 0.1% | 7% |
| | 7% | PT general | 2.16 | 4% | Wine grapes | 0.5% | Apples | 0.4% | Potatoes | | 7% |
| | 7% | FR infant | 2.15 | 4% | Milk: Cattle | 0.8% | Apples | 0.4% | Carrots | 0.1% | 7% |
| | 6% | ES adult | 1.70 | 1% | Milk: Cattle | 0.7% | Wine grapes | 0.6% | Barley | 0.2% | 6% |
| | 5% | DK adult | 1.53 | 2% | Wine grapes | 1% | Milk: Cattle | 0.4% | Apples | 0.1% | 5% |
| | 5% | FI 3 yr | 1.46 | 0.7% | Oat | 0.5% | Raspberries (red and yellow) | 0.5% | Cucumbers | | 5% |
| | 4% | IT adult | 1.29 | 1% | Other lettuce and other salad plants | 0.4% | Tomatoes | 0.4% | Apples | | 4% |
| | 4% | UK vegetarian | 1.29 | 1% | Wine grapes | 0.7% | Milk: Cattle | 0.3% | Apples | 0.1% | 4% |
| | 4% | UK adult | 1.28 | 2% | Wine grapes | 0.7% | Milk: Cattle | 0.2% | Apples | 0.1% | 4% |
| | 4% | IT toddler | 1.26 | 0.9% | Other lettuce and other salad plants | 0.5% | Tomatoes | 0.4% | Wheat | | 4% |
| | 4% | LT adult | 1.07 | 0.9% | Milk: Cattle | 0.9% | Apples | 0.2% | Potatoes | 0.1% | 4% |
| | 3% | FI 6 yr | 1.03 | 0.4% | Raspberries (red and yellow) | 0.4% | Oat | 0.4% | Cucumbers | | 3% |
| | 3% | FI adult | 0.88 | 0.5% | Wine grapes | 0.5% | Coffee beans | 0.3% | Apples | | 3% |
| | 3% | PL general | 0.84 | 1.0% | Apples | 0.3% | Table grapes | 0.3% | Tomatoes | | 3% |
| | 2% | IE child | 0.49 | 0.8% | Milk: Cattle | 0.2% | Apples | 0.1% | Currants (red, black and white) | 0.1% | 2% |

**Conclusion:**
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Pyraclostrobin (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

| Acute risk assessment /children | Acute risk assessment/adults/general population |
|---|---|
| Details – acute risk assessment/children | Details – acute risk assessment/adults |

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

**Show results for all crops**

**Unprocessed commodities**

**Results for children**
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

**IESTI**

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|
| 103% | Lettuces | 2/0.81 | 31 |
| 92% | Mangoes | 0.6/0.35 | 28 |
| 90% | Cucumbers | 0.5/0.41 | 27 |
| 89% | Kales | 1.5/0.61 | 27 |
| 84% | Globe artichokes | 3/1.44 | 25 |
| 80% | Oranges | 2/0.18 | 24 |
| 76% | Celeries | 1.5/0.61 | 23 |
| 75% | Chinese cabbages/pe-tsai | 1.5/0.7 | 22 |
| 73% | Apricots | 1/0.63 | 22 |
| 73% | Melons | 0.5/0.15 | 22 |
| 73% | Table grapes | 0.3/0.3 | 22 |
| 64% | Cherries (sweet) | 3/1.57 | 19 |
| 60% | Sweet peppers/bell peppers | 0.5/0.3 | 18 |
| 59% | Watermelons | 0.5/0.15 | 18 |
| 57% | Pears | 0.5/0.29 | 17 |

Expand/collapse list

**Results for adults**
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

**IESTI**

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|
| 100% | Wine grapes | 2/1.27 | 30 |
| 74% | Red mustards | 10/4.16 | 22 |
| 63% | Blueberries | 4/2.08 | 19 |
| 62% | Globe artichokes | 3/1.44 | 19 |
| 59% | Chinese cabbages/pe-tsai | 1.5/0.7 | 18 |
| 52% | Cherries (sweet) | 3/1.57 | 16 |
| 51% | Chards/beet leaves | 1.5/0.81 | 15 |
| 46% | Currants (red, black and | 3/2.1 | 14 |
| 39% | Kales | 1.5/0.61 | 12 |
| 38% | Cucumbers | 0.5/0.41 | 11 |
| 38% | Florence fennels | 1.5/0.61 | 11 |
| 36% | Blackberries | 3/1.32 | 11 |
| 34% | Table grapes | 0.3/0.3 | 10 |
| 33% | Lettuces | 2/0.81 | 9.8 |
| 33% | Celeries | 1.5/0.61 | 9.8 |

**Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)** 2

**Processed commodities**

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

**IESTI**

| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|
| 95% | Oranges/juice | 2/0.54 | 28 |
| 92% | Florence fennels/boiled | 1.5/0.61 | 28 |
| 90% | Currants (red, black and white | 3/0.94 | 27 |
| 86% | Pumpkins/boiled | 0.5/0.29 | 26 |
| 84% | Chards/beet leaves/boiled | 1.5/0.81 | 25 |
| 62% | Escaroles/broad-leaved endiv | 0.4/0.28 | 19 |
| 56% | Kales/boiled | 1.5/0.61 | 17 |
| 55% | Leeks/boiled | 0.8/0.29 | 17 |
| 50% | Elderberries/juice | 3/0.94 | 15 |
| 50% | Broccoli/boiled | 0.5/0.19 | 15 |
| 44% | Cauliflowers/boiled | 0.5/0.19 | 13 |
| 34% | Raspberries/juice | 3/0.87 | 10 |
| 32% | Courgettes/boiled | 0.5/0.27 | 9.6 |
| 30% | Parsnips/boiled | 0.5/0.18 | 9.1 |
| 26% | Pineapples/canned | 0.3/0.19 | 7.8 |

Expand/collapse list

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

**IESTI**

| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|
| 69% | Celeries/boiled | 1.5/0.61 | 21 |
| 53% | Pumpkins/boiled | 0.5/0.29 | 16 |
| 40% | Currants (red, black and | 3/0.94 | 12 |
| 39% | Florence fennels/boiled | 1.5/0.61 | 12 |
| 34% | Chards/beet leaves/boiled | 1.5/0.81 | 10 |
| 29% | Elderberries/juice | 3/0.94 | 8.6 |
| 27% | Oranges/juice | 2/0.54 | 8.2 |
| 26% | Cauliflowers/boiled | 0.5/0.19 | 7.9 |
| 21% | Courgettes/boiled | 0.5/0.27 | 6.2 |
| 20% | Grapefruits/juice | 2/0.54 | 5.9 |
| 19% | Onions/boiled | 1.5/0.62 | 5.8 |
| 19% | Escaroles/broad-leaved | 0.4/0.28 | 5.7 |
| 17% | Leeks/boiled | 0.8/0.29 | 5.1 |
| 16% | Apples/juice | 0.5/0.14 | 4.7 |
| 15% | Broccoli/boiled | 0.5/0.19 | 4.6 |

**Conclusion:**
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 2 commodities.

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

# Appendix D – Input values for the exposure calculations

## D.1. Consumer risk assessment

| Commodity | Existing/ proposed MRL (mg/kg) | Source | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|---|---|
| | | | Input value[a] (mg/kg)[d] | Comment[b] | Input value[a] (mg/kg)[d] | Comment[b] |
| **Risk assessment residue definition:** Pyraclostrobin | | | | | | |
| Grapefruits | 2 | EFSA (2018d) | 0.054 | STMR-RAC*PeF | 0.13 | HR-RAC*PeF |
| Oranges | 2 | EFSA (2018d) | 0.0756 | STMR-RAC*PeF | 0.182 | HR-RAC*PeF |
| Lemons | 2 | EFSA (2018d) | 0.054 | STMR-RAC*PeF | 0.13 | HR-RAC*PeF |
| Limes | 2 | EFSA (2018d) | 0.054 | STMR-RAC*PeF | 0.13 | HR-RAC*PeF |
| Mandarins | 2 | EFSA (2018d) | 0.0689 | STMR-RAC*PeF | 0.156 | HR-RAC*PeF |
| Other citrus fruit | 2 | EFSA (2018d) | 0.0054 | STMR-RAC*PeF | | |
| Almonds | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Brazil nuts | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Cashew nuts | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Chestnuts | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Coconuts | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Hazelnuts/cobnuts | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Macadamia | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Pecans | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Pine nut kernels | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Pistachios | 1 | EFSA (2011b) | 0.22 | STMR-RAC | 0.45 | HR-RAC |
| Walnuts | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Other tree nuts | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | | |
| Apples | 0.5 | EFSA (2011b) | 0.14 | STMR-RAC | 0.29 | HR-RAC |
| Pears | 0.5 | EFSA (2011b) | 0.14 | STMR-RAC | 0.29 | HR-RAC |
| Quinces | 0.5 | EFSA (2011b) | 0.14 | STMR-RAC | 0.29 | HR-RAC |
| Medlar | 0.5 | EFSA (2011b) | 0.14 | STMR-RAC | 0.29 | HR-RAC |
| Loquats/Japanese medlars | 0.5 | EFSA (2011b) | 0.14 | STMR-RAC | 0.29 | HR-RAC |
| Other pome fruit | 0.5 | EFSA (2011b) | 0.14 | STMR-RAC | | |
| Apricots | 1 | EFSA (2011b) | 0.43 | STMR-RAC | 0.63 | HR-RAC |
| Cherries (sweet) | 3 | FAO (2011) | 0.51 | STMR-RAC | 1.57 | HR-RAC |
| Peaches | 0.3 | FAO (2011) | 0.065 | STMR-RAC | 0.13 | HR-RAC |
| Plums | 0.8 | FAO (2011) | 0.09 | STMR-RAC | 0.4 | HR-RAC |
| Table grapes | 0.3 | Existing MRL | 0.3 | MRL | 0.3 | MRL |
| Wine grapes | 2 | EFSA (2011b) | 0.48 | STMR-RAC | 1.27 | HR-RAC |
| Strawberries | 1.5 | FAO (2011) | 0.2 | STMR-RAC | 0.75 | HR-RAC |
| Blackberries | 3 | FAO (2011) | 0.87 | STMR-RAC | 1.32 | HR-RAC |
| Dewberries | 2 | EFSA (2011b) | 0.87 | STMR-RAC | 1.32 | HR-RAC |
| Raspberries (red and yellow) | 3 | FAO (2011) | 0.87 | STMR-RAC | 1.32 | HR-RAC |
| Other cane fruit | 2 | EFSA (2011b) | 0.87 | STMR-RAC | | |
| Blueberries | 4 | FAO (2011) | 0.78 | STMR-RAC | 2.08 | HR-RAC |
| Cranberries | 3 | EFSA (2011b) | 0.94 | STMR-RAC | 2.1 | HR-RAC |
| Currants (red, black and white) | 3 | EFSA (2011b) | 0.94 | STMR-RAC | 2.1 | HR-RAC |

| Commodity | Existing/ proposed MRL (mg/kg) | Source | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|---|---|
| | | | Input value[a] (mg/kg)[d] | Comment[b] | Input value[a] (mg/kg)[d] | Comment[b] |
| Gooseberries (green, red and yellow) | 3 | EFSA (2011b) | 0.94 | STMR-RAC | 2.1 | HR-RAC |
| Rose hips | 3 | EFSA (2011b) | 0.94 | STMR-RAC | 2.1 | HR-RAC |
| Mulberries (black and white) | 3 | EFSA (2011b) | 0.94 | STMR-RAC | 2.1 | HR-RAC |
| Azarole/ Mediterranean medlar | 3 | EFSA (2011b) | 0.94 | STMR-RAC | 2.1 | HR-RAC |
| Elderberries | 3 | EFSA (2011b) | 0.94 | STMR-RAC | 2.1 | HR-RAC |
| Other small fruit & berries | 3 | EFSA (2011b) | 0.94 | STMR-RAC | | |
| Passion fruits/ maracujas | 0.2 | FAO (2019) | 0.045 | STMR-RAC | 0.1 | HR-RAC |
| Avocados | 0.2 | FAO (2019) | 0.053 | STMR-RAC | 0.104 | HR-RAC |
| Bananas | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Mangoes | 0.6 | FAO (2019) | 0.11 | STMR-RAC | 0.35 | HR-RAC |
| Papayas | | Intended use | 0.035 | STMR-RAC | 0.25 | HR-RAC |
| Pineapples | 0.3 | EFSA (2018d) | 0.0135 | STMR-RAC*PeF | 0.0513 | HR-RAC*PeF |
| Potatoes | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Cassava roots/ manioc | 0.02 | FAO (2019) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Sweet potatoes | 0.02 | FAO (2019) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Yams | 0.02 | FAO (2019) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Arrowroots | 0.02 | FAO (2019) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Other tropical root and tuber vegetables | 0.02 | FAO (2019) | 0.02 | STMR-RAC | | |
| Beetroots | 0.5 | EFSA (2011b) | 0.03 | STMR-RAC | 0.06 | HR-RAC |
| Carrots | 0.5 | EFSA (2011b) | 0.12 | STMR-RAC | 0.24 | HR-RAC |
| Celeriacs/turnip rooted celeries | 0.5 | EFSA (2017) | 0.16 | STMR-RAC | 0.23 | HR-RAC |
| Horseradishes | 0.5 | EFSA (2011b) | 0.08 | STMR-RAC | 0.18 | HR-RAC |
| Jerusalem artichokes | 0.06 | EFSA (2013) | 0.02 | STMR-RAC | 0.05 | HR-RAC |
| Parsnips | 0.5 | EFSA (2011b) | 0.08 | STMR-RAC | 0.18 | HR-RAC |
| Parsley roots/ Hamburg roots parsley | 0.5 | EFSA (2011b) | 0.03 | STMR-RAC | 0.06 | HR-RAC |
| Radishes | 0.5 | EFSA (2011b) | 0.08 | STMR-RAC | 0.3 | HR-RAC |
| Salsifies | 0.5 | EFSA (2011b) | 0.03 | STMR-RAC | 0.06 | HR-RAC |
| Swedes/rutabagas | 0.5 | EFSA (2011b) | 0.02 | STMR-RAC | 0.06 | HR-RAC |
| Turnips | 0.5 | EFSA (2011b) | 0.02 | STMR-RAC | 0.06 | HR-RAC |
| Garlic | 0.3 | EFSA (2011b) | 0.02 | STMR-RAC | 0.21 | HR-RAC |
| Onions | 1.5 | FAO (2011) | 0.06 | STMR-RAC | 0.62 | HR-RAC |
| Shallots | 0.3 | EFSA (2011b) | 0.02 | STMR-RAC | 0.21 | HR-RAC |
| Spring onions/ green onions and Welsh onions | 1.5 | FAO (2011) | 0.42 | STMR-RAC | 0.6 | HR-RAC |

| Commodity | Existing/ proposed MRL (mg/kg) | Source | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|---|---|
| | | | Input value[a] (mg/kg)[d] | Comment[b] | Input value[a] (mg/kg)[d] | Comment[b] |
| Tomatoes | 0.3 | EFSA (2011b) | 0.1 | STMR-RAC | 0.26 | HR-RAC |
| Sweet peppers/bell peppers | 0.5 | EFSA (2011b) | 0.13 | STMR-RAC | 0.3 | HR-RAC |
| Aubergines/egg plants | 0.3 | EFSA (2011b) | 0.1 | STMR-RAC | 0.26 | HR-RAC |
| Cucumbers | 0.5 | EFSA (2013) | 0.15 | STMR-RAC | 0.41 | HR-RAC |
| Gherkins | 0.5 | EFSA (2011b) | 0.17 | STMR-RAC | 0.27 | HR-RAC |
| Courgettes | 0.5 | EFSA (2011b) | 0.17 | STMR-RAC | 0.27 | HR-RAC |
| Other cucurbits - edible peel | 0.5 | EFSA (2011b) | 0.17 | STMR-RAC | | |
| Melons | 0.5 | EFSA (2011b) | 0.055 | STMR-RAC*PeF | 0.145 | HR-RAC*PeF |
| Pumpkins | 0.5 | EFSA (2011b) | 0.055 | STMR-RAC*PeF | 0.145 | HR-RAC*PeF |
| Watermelons | 0.5 | EFSA (2011b) | 0.055 | STMR-RAC*PeF | 0.145 | HR-RAC*PeF |
| Other cucurbits - inedible peel | 0.5 | EFSA (2011b) | 0.055 | STMR-RAC*PeF | | |
| Sweet corn | 0.04 | EFSA (2019a) | 0.016 | STMR-RAC | 0.021 | HR-RAC |
| Broccoli | 0.5 | EFSA (2018d) | 0.05 | STMR-RAC | 0.19 | HR-RAC |
| Cauliflowers | 0.5 | EFSA (2018d) | 0.05 | STMR-RAC | 0.19 | HR-RAC |
| Other flowering brassica | 0.5 | EFSA (2018d) | 0.05 | STMR-RAC | | |
| Brussels sprouts | 0.3 | EFSA (2011b) | 0.03 | STMR-RAC | 0.14 | HR-RAC |
| Head cabbages | 0.4 | EFSA (2018d) | 0.01 | STMR-RAC | 0.22 | HR-RAC |
| Chinese cabbages/ pe-tsai | 1.5 | EFSA (2012a) | 0.19 | STMR-RAC | 0.7 | HR-RAC |
| Kales | 1.5 | EFSA (2011b) | 0.19 | STMR-RAC | 0.61 | HR-RAC |
| Other leafy brassica | 1.5 | EFSA (2012a) | 0.19 | STMR-RAC | | |
| Kohlrabies | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Lamb's lettuce/corn salads | 10 | EFSA (2018d) | 2.31 | STMR-RAC | 4.16 | HR-RAC |
| Lettuces | 2 | EFSA (2011b) | 0.26 | STMR-RAC | 0.81 | HR-RAC |
| Escaroles/broad-leaved endives | 0.4 | EFSA (2011b) | 0.04 | STMR-RAC | 0.28 | HR-RAC |
| Cress and other sprouts and shoots | 10 | EFSA (2018d) | 2.31 | STMR-RAC | 4.16 | HR-RAC |
| Land cress | 10 | EFSA (2018d) | 2.5 | STMR-RAC | 4.16 | HR-RAC |
| Roman rocket/ rucola | 10 | EFSA (2018d) | 2.5 | STMR-RAC | 4.16 | HR-RAC |
| Red mustards | 10 | EFSA (2018d) | 2.5 | STMR-RAC | 4.16 | HR-RAC |
| Baby leaf crops (including brassica species) | 10 | EFSA (2018d) | 2.5 | STMR-RAC | 4.16 | HR-RAC |
| Other lettuce and other salad plants | 10 | EFSA (2018d) | 2.5 | STMR-RAC | | |
| Spinaches | 0.6 | FAO (2021) | 0.071 | STMR-RAC | 0.31 | HR-RAC |
| Chards/beet leaves | 1.5 | EFSA (2016) | 0.26 | STMR-RAC | 0.81 | HR-RAC |
| Witloofs/Belgian endives | 0.09 | FAO (2019) | 0.03 | STMR-RAC | 0.04 | HR-RAC |
| Chervil | 2 | EFSA (2011b) | 0.26 | STMR-RAC | 0.81 | HR-RAC |
| Chives | 2 | EFSA (2011b) | 0.26 | STMR-RAC | 0.81 | HR-RAC |

| Commodity | Existing/ proposed MRL (mg/kg) | Source | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|---|---|
| | | | Input value[a] (mg/kg)[d] | Comment[b] | Input value[a] (mg/kg)[d] | Comment[b] |
| Celery leaves | 2 | EFSA (2011b) | 0.26 | STMR-RAC | 0.81 | HR-RAC |
| Parsley | 2 | EFSA (2011b) | 0.26 | STMR-RAC | 0.81 | HR-RAC |
| Sage | 2 | EFSA (2011b) | 0.26 | STMR-RAC | 0.81 | HR-RAC |
| Rosemary | 2 | EFSA (2011b) | 0.26 | STMR-RAC | 0.81 | HR-RAC |
| Thyme | 2 | EFSA (2011b) | 0.26 | STMR-RAC | 0.81 | HR-RAC |
| Basil and edible flowers | 2 | EFSA (2011b) | 0.26 | STMR-RAC | 0.81 | HR-RAC |
| Laurel/bay leaves | 2 | EFSA (2011b) | 0.26 | STMR-RAC | 0.81 | HR-RAC |
| Tarragon | 2 | EFSA (2011b) | 0.26 | STMR-RAC | 0.81 | HR-RAC |
| Other herbs | 2 | EFSA (2011b) | 0.26 | STMR-RAC | | |
| Beans (with pods) | 0.6 | EFSA (2017) | 0.13 | STMR-RAC | 0.37 | HR-RAC |
| Beans (without pods) | 0.3 | EFSA (2011b) | 0.01 | STMR-RAC | 0.27 | HR-RAC |
| Peas (with pods) | 0.6 | EFSA (2017) | 0.13 | STMR-RAC | 0.37 | HR-RAC |
| Peas (without pods) | 0.15 | EFSA (2017) | 0.01 | STMR-RAC | 0.07 | HR-RAC |
| Asparagus | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | HR-RAC |
| Celeries | 1.5 | FAO (2019) | 0.15 | STMR-RAC | 0.61 | HR-RAC |
| Florence fennels | 1.5 | EFSA (2017) | 0.4 | STMR-RAC | 0.61 | HR-RAC |
| Globe artichokes | 3 | EFSA (2018d) | 0.25 | STMR-RAC | 1.44 | HR-RAC |
| Leeks | 0.8 | EFSA (2018d) | 0.26 | STMR-RAC | 0.29 | HR-RAC |
| Beans | 0.3 | EFSA (2011b) | 0.04 | STMR-RAC | 0.04 | STMR-RAC |
| Lentils | 0.5 | EFSA (2011b) | 0.13 | STMR-RAC | 0.13 | STMR-RAC |
| Peas | 0.3 | EFSA (2011b) | 0.04 | STMR-RAC | 0.04 | STMR-RAC |
| Lupins/lupini beans | 0.05 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | STMR-RAC |
| Other pulses | 0.3 | EFSA (2011b) | 0.04 | STMR-RAC | | |
| Linseeds | 0.2 | EFSA (2011a) | 0.04 | STMR-RAC | 0.04 | STMR-RAC |
| Peanuts/groundnuts | 0.04 | EFSA (2011a) | 0.02 | STMR-RAC | 0.02 | STMR-RAC |
| Poppy seeds | 0.2 | EFSA (2011a) | 0.04 | STMR-RAC | 0.04 | STMR-RAC |
| Sesame seeds | 0.2 | EFSA (2011a) | 0.04 | STMR-RAC | 0.04 | STMR-RAC |
| Sunflower seeds | 0.3 | EFSA (2011a) | 0.053 | STMR-RAC | 0.053 | STMR-RAC |
| Rapeseeds/canola seeds | 0.2 | EFSA (2011a) | 0.035 | STMR-RAC | 0.035 | STMR-RAC |
| Soya beans | 0.2 | EFSA (2018a) | 0.02 | STMR-RAC | 0.02 | STMR-RAC |
| Mustard seeds | 0.2 | EFSA (2011a) | 0.04 | STMR-RAC | 0.04 | STMR-RAC |
| Cotton seeds | 0.3 | EFSA (2011a) | 0.03 | STMR-RAC | 0.03 | STMR-RAC |
| Safflower seeds | 0.2 | EFSA (2011a) | 0.04 | STMR-RAC | 0.04 | STMR-RAC |
| Borage seeds | 0.2 | EFSA (2011a) | 0.04 | STMR-RAC | 0.04 | STMR-RAC |
| Gold of pleasure seeds | 0.2 | EFSA (2011a) | 0.04 | STMR-RAC | 0.04 | STMR-RAC |
| Castor beans | 0.2 | EFSA (2011a) | 0.04 | STMR-RAC | 0.04 | STMR-RAC |
| Barley | 1 | FAO (2011) | 0.345 | STMR-RAC | 0.345 | STMR-RAC |
| Maize/corn | 0.02 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | STMR-RAC |
| Oat | 1 | FAO (2011) | 0.345 | STMR-RAC | 0.345 | STMR-RAC |
| Rice | 0.09 | EFSA (2018c) | 0.02 | STMR-RAC | 0.02 | STMR-RAC |
| Rye | 0.2 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | STMR-RAC |
| Sorghum | 0.5 | FAO (2011) | 0.025 | STMR-RAC | 0.025 | STMR-RAC |
| Wheat | 0.2 | EFSA (2011b) | 0.02 | STMR-RAC | 0.02 | STMR-RAC |

| Commodity | Existing/ proposed MRL (mg/kg) | Source | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|---|---|
| | | | Input value[a] (mg/kg)[d] | Comment[b] | Input value[a] (mg/kg)[d] | Comment[b] |
| Coffee beans | 0.3 | EFSA (2011b) | 0.025 | STMR-RAC | 0.025 | STMR-RAC |
| Hops (dried) | 15 | EFSA (2011b) | 3.45 | STMR-RAC | 7.4 | HR-RAC |
| Sugar beet roots | 0.2 | EFSA (2011b) | 0.04 | STMR-RAC | 0.11 | HR-RAC |
| Sugar canes | 0.08 | FAO (2019) | 0.027 | STMR-RAC | 0.045 | HR-RAC |
| Chicory roots | 0.5 | EFSA (2014a) | 0.03 | STMR-RAC | 0.08 | HR-RAC |
| Swine: Muscle/ meat[c] | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Swine: Fat tissue | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Swine: Liver | 0.05 | Existing MRL | 0.2 | LOQ*CF | 0.2 | LOQ*CF |
| Swine: Kidney | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Swine: Edible offals (other than liver and kidney) | 0.05 | Existing MRL | 0.2 | LOQ*CF | 0.2 | LOQ*CF |
| Bovine: Muscle/ meat[c] | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Bovine: Fat tissue | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Bovine: Liver | 0.05 | Existing MRL | 0.2 | LOQ*CF | 0.2 | LOQ*CF |
| Bovine: Kidney | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Bovine: Edible offals (other than liver and kidney) | 0.05 | Existing MRL | 0.2 | LOQ*CF | 0.2 | LOQ*CF |
| Sheep: Muscle/ meat[c] | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Sheep: Fat tissue | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Sheep: Liver | 0.05 | Existing MRL | 0.2 | LOQ*CF | 0.2 | LOQ*CF |
| Sheep: Kidney | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Sheep: Edible offals (other than liver and kidney) | 0.05 | Existing MRL | 0.2 | LOQ*CF | 0.2 | LOQ*CF |
| Goat: Muscle/ meat[c] | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Goat: Fat tissue | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Goat: Liver | 0.05 | Existing MRL | 0.2 | LOQ*CF | 0.2 | LOQ*CF |
| Goat: Kidney | 0.05 | Existing MRL | 0.05 | LOQ*CF | 0.05 | LOQ*CF |
| Goat: Edible offals (other than liver and kidney) | 0.05 | Existing MRL | 0.2 | LOQ*CF | 0.2 | LOQ*CF |
| Poultry: Muscle/ meat[c] | 0.05 | Existing MRL | 0.05 | LOQ | 0.05 | LOQ |
| Poultry: Fat tissue | 0.05 | Existing MRL | 0.05 | LOQ | 0.05 | LOQ |
| Poultry: Liver | 0.05 | Existing MRL | 0.05 | LOQ | 0.05 | LOQ |
| Poultry: Kidney | 0.05 | Existing MRL | 0.05 | LOQ | 0.05 | LOQ |
| Poultry: Edible offals (other than liver and kidney) | 0.05 | Existing MRL | 0.05 | LOQ | 0.05 | LOQ |
| Milk: Cattle | 0.01 | Existing MRL | 0.068 | STMR-RAC*CF | 0.068 | STMR-RAC*CF |
| Milk: Sheep | 0.01 | Existing MRL | 0.068 | STMR-RAC*CF | 0.068 | STMR-RAC*CF |
| Milk: Goat | 0.01 | Existing MRL | 0.068 | STMR-RAC*CF | 0.068 | STMR-RAC*CF |
| Milk: Horse | 0.01 | Existing MRL | 0.068 | STMR-RAC*CF | 0.068 | STMR-RAC*CF |

| Commodity | Existing/ proposed MRL (mg/kg) | Source | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|---|---|
| | | | Input value[a] (mg/kg)[d] | Comment[b] | Input value[a] (mg/kg)[d] | Comment[b] |
| Milk: Others | 0.01 | Existing MRL | 0.068 | STMR-RAC*CF | 0.068 | STMR-RAC*CF |
| Eggs: Chicken | 0.05 | Existing MRL | 0.05 | LOQ | 0.05 | LOQ |
| Eggs: Duck | 0.05 | Existing MRL | 0.05 | LOQ | 0.05 | LOQ |
| Eggs: Goose | 0.05 | Existing MRL | 0.05 | LOQ | 0.05 | LOQ |
| Eggs: Quail | 0.05 | Existing MRL | 0.05 | LOQ | 0.05 | LOQ |
| Eggs: Others | 0.05 | Existing MRL | 0.05 | LOQ | | |

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor; CF: conversion factor for enforcement to risk assessment residue definition; ARfD: acute reference dose.

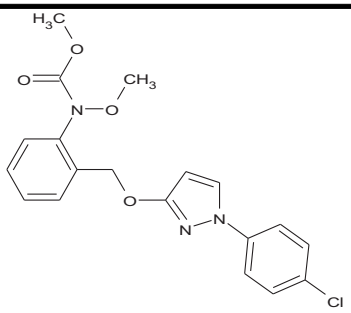
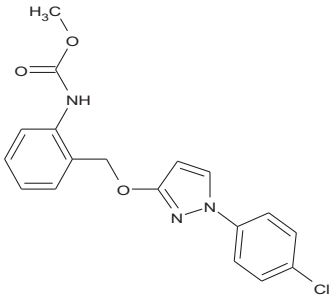
(a): Figures in the table are rounded to 2 digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

(b): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

(c): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticide, STMR and HR residue values were calculated considering an 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).

(d): The use of peeling factors was implemented for the calculation of input values in the following commodities: grapefruits (0.100), oranges (0.140), lemons (0.100), limes (0.100), mandarins (0.130), other citrus fruit (0.100), pineapple (0.270), melons (0.500), pumpkins (0.500), watermelons (0.500), other cucurbits with inedible peel (0.500).

## Appendix E – Used compound codes

| Code/trivial name[a] | IUPAC name/SMILES notation/InChiKey[b] | Structural formula[c] |
|---|---|---|
| Pyraclostrobin | methyl 2-[1-(4-chlorophenyl)-1*H*-pyrazol-3-yloxymethyl]-*N*-methoxycarbanilate<br>O=C(OC)N(OC)c1ccccc1COc1ccn(n1)c1ccc(Cl)cc1<br>HZRSNVGNWUDEFX-UHFFFAOYSA-N |  |
| Desmethoxy metabolite (500 M07, BF 500–3) | methyl [2-({[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy}methyl)phenyl]carbamate<br>O=C(OC)Nc1ccccc1COc1ccn(n1)c1ccc(Cl)cc1<br>SEUOYURJKYLAPC-UHFFFAOYSA-N |  |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).