Setting of an import tolerance for pyraclostrobin in rice

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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 rice. The data submitted in support of the request were found to be sufficient to derive a maximum residue level (MRL) proposal for rice. Based on the risk assessment results, EFSA concluded that the short-term intake of residues resulting from the use of pyraclostrobin according to the reported agricultural practices is unlikely to present a risk to consumer health. Taking into account the proposed new MRL, a long-term intake concern for consumers was not identified.

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Keywords: pyraclostrobin, rice, import tolerance, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2017-00476

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in Germany (evaluating Member State (EMS)) to set an import tolerance for the active substance pyraclostrobin in rice. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 1 June 2017. The EMS proposed to raise the existing European Union maximum residue level (EU MRL) for pyraclostrobin in rice from the limit of quantification (LOQ) of 0.02 to 0.09 mg/kg. The MRL in the country of origin was not reported.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

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

The metabolism of pyraclostrobin following a foliar application was assessed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 and was found to be sufficiently investigated for crops belonging to the groups of fruits, leafy crops, root and tuber vegetables and cereals. In the current application, a new metabolism study representative for rice was submitted, which showed a similar metabolic pattern compared with the previously assessed metabolism studies.

Pyraclostrobin was shown to be stable under conditions representative for food processing (standard hydrolysis studies).

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.

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 (LOQ). For high water content, acidic and dry commodities, the CEN QuEChERS method is validated to a LOQ of 0.01 mg/kg.

For a number of processed products derived from the crop 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:

- Rice bran 5.3
- Rice parboiled white milled rice 0.9
- Rice flour 0.16
- Rice, polished 0.16
- Rice sake 0.012

As the crop under consideration and their by-products are used as feed product, a potential carry-over into food of animal origin was assessed. It was found that the contribution of pyraclostrobin residues in rice and its by-products to the total livestock exposure was insignificant and therefore a modification of the previously derived 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). The short-term exposure related to residues of pyraclostrobin in rice following the treatment with pyraclostrobin in accordance with the Good Agricultural Practice (GAP) authorised in Indonesia did not exceed the ARfD (0.8% of the ARfD). The estimated long-term dietary intake was in the range of 2–17.4% of the ADI. Thus, residues of pyraclostrobin 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 endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------------|------------|------------------------|-------------------------|------------------------|
| 0500060          | Rice       | 0.02*                  | 0.09                    | The submitted residue trials are sufficient to derive an import tolerance request (Indonesian GAP). Information on the authorisation of the use of pyraclostrobin in rice in Indonesia was provided, however, not the legal limit. Therefore, risk management considerations are required regarding the acceptability of the derived MRL proposal. Risk for consumers unlikely. |

MRL: maximum residue level; 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.
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Assessment

The detailed descriptions of the existing use of pyraclostrobin authorised in Indonesia for rice, for which an import tolerance was requested, is reported in Appendix A. The maximum residue level (MRL) in the country of origin was not reported.

Pyraclostrobin is the ISO common name for methyl 2-[(4-chlorophenyl)pyrazol-3-yl(oxy)methyl]-N-methoxy-carbanilate (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) for the representative uses as foliar applications 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, 2011) 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). The proposals from these reasoned opinions have been implemented in recent regulations6 for European Union (EU) MRL legislation, except 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 an import tolerance for the active substance pyraclostrobin in rice. 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 1 June 2017. The EMS proposed to establish an MRL for rice imported from Indonesia at the level of 0.09 mg/kg EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation.

EFSA based its assessment on the evaluation reports submitted by the EMS (Germany, 2017), 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, 2012, 2013, 2014a,b, 2016, 2017, 2018a,b) as well as the review of the existing MRLs for pyraclostrobin under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011).

For this application, the data requirements established in Regulation (EU) No 544/20117 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 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 546/20118.

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Directive 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/eur-pesticides-database/public/?event=pesticide.residue.selection&language=EN
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 L155, 11.6.2011, p. 127–175.
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, 2017) 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 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

Under the MRL review, metabolism of pyraclostrobin following foliar applications was investigated in fruit crops (grapes), root crops (potatoes) and in cereals (wheat) (EFSA, 2011). In the evaluation report (Germany, 2017), further metabolism studies investigating foliar applications in leafy crops (cabbage) and cereals/grass crop (paddy rice) were provided.

In the metabolism study in rice, which is the study most relevant for the import tolerance request, the predominant compounds of the total residues were the parent compound pyraclostrobin together with its desmethoxy metabolite (500M07). In addition, hydroxylation in the tolyl and the chlorophenyl rings and cleavage between both ring systems were observed, but these routes were less pronounced. The hydroxylation reaction is followed by glucosylation or methylation, whereas the intermediates of the cleavage reaction are further transformed by conjugation or the shikimate pathway. The transformation according to shikimate pathway resulted in the formation of the natural amino acid L-tryptophan in potato tubers and wheat grains (Germany, 2017).

Metabolism in rice was qualitatively and quantitatively comparable with the previously assessed studies in fruit crops, root crops and cereals. Thus, for the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Not relevant for the import tolerance request under assessment.

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 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6) 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, 2011).

In a previous EFSA reasoned opinion (EFSA, 2014a), 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 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, 2011, 2014b). The results of the metabolism study in paddy rice submitted under the current assessment were consistent with the previously assessed metabolism studies and therefore do not trigger a modification of the residue definition for rice. Considering that metabolite 500M07 was observed in primary crop metabolism studies, including rice, in significant amounts, a revision of residue definition for risk assessment should be discussed in the framework of the renewal of the approval.

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

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Rice

In support of the import tolerance (Indonesia) for rice, in total, 17 residue trials from different parts of the world (Brazil, Vietnam, Indonesia, Philippines, Thailand, Taiwan, China and India) were provided, which complied with the Good Agricultural Practice (GAP) authorised in Indonesia. The samples were analysed for the parent compound and the main metabolite 500M07. According to the EMS, the analytical methods used to analyse for pyraclostrobin and the metabolite 500M07 in the residue trial samples have been sufficiently validated and were proven to be fit for purpose. The samples were stored for a period for which integrity of the samples was demonstrated (Germany, 2017).

Only two of the trials were performed in Indonesia, additional eight trials were performed in Asia and seven trials from Brazil. EFSA decided to pool all the data from the different geographical regions after conducting a statistical analysis (Mann-Whitney U test, FAO, 2016) that demonstrated that trials from Indonesia and outside of Indonesia belong to a similar population.

A MRL of 0.09 mg/kg is proposed for brown rice (husked rice).

Additional studies were provided to derived processing factors (see Section B.1.2.3).

1.2.2. Magnitude of residues in rotational crops

The investigation of residues in rotational crops is of no relevance for the import tolerance application under assessment.

1.2.3. Magnitude of residues in processed commodities

Processing studies in rice were provided in this assessment, demonstrating that boiling and milling leads to a reduction of the pyraclostrobin residues in the processed commodities (Germany, 2017). 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

In support of the import tolerance for rice from Indonesia, a MRL of 0.09 mg/kg is proposed.

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

2. Residues in livestock

Rice may be used as feed item. Therefore, it was necessary to update the previous dietary burden calculations for livestock (EFSA, 2018a) to estimate whether the residues in rice and its by-products 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 are presented in Appendix B.2. The estimated exposure of cattle, swine and poultry to pyraclostrobin residues exceeded the trigger values.

Including the STMR derived for rice bran in the dietary burden calculation, the overall exposure of livestock did not change significantly compared with the calculation performed in the framework of the previous assessment (EFSA, 2018a). Therefore, EFSA concluded that the previously derived MRL proposals for products of animal origin 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 subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for pyraclostrobin used in the risk assessment (i.e. daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticide peer review (European Commission, 2004).

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, 2011). EFSA updated this risk assessment with the median residue level (STMR) derived from the residue trials submitted in support of this MRL application for rice (Table B.1.2.1 in Appendix B) and the STMRs reported in the previous EFSA reasoned opinions carried out after the Article 12 MRL review (EFSA, 2012, 2013, 2014a,b, 2016, 2017, 2018a). 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 2–17.4% of the ADI. The contribution of residues expected in rice accounts for maximum 0.05% of ADI. The results of short-term (acute) dietary exposure assessment for rice showed no exceedance of the ARfD (0.8% of the ARfD).

Overall, EFSA concluded that the long-term and short-term intake of residues of pyraclostrobin resulting from the use of pyraclostrobin in rice is unlikely to present a chronic risk to consumer health.

4. **Conclusion and Recommendations**

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal of 0.09 mg/kg for rice.

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

The MRL recommendations are summarised in Appendix B.4.

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### Abbreviations

| Abbreviation | Description |
|--------------|-------------|
| 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) |
| CS           | capsule suspension |
| CXL          | Codex maximum residue limit |
| DAT          | days after treatment |
| DM           | dry matter |
| EMS          | evaluating Member State |
| FAO          | Food and Agriculture Organization of the United Nations |
| GAP          | Good Agricultural Practice |
| HPLC         | high performance liquid chromatography |
| HPLC-UVD     | high performance liquid chromatography with ultra-violet detector |
| HR           | highest residue |
| IEDI         | international estimated daily intake |
| IESTI        | international estimated short-term intake |
| ILV          | independent laboratory validation |
| InChIKey     | International Chemical Identifier Key |
| ISO          | International Organisation for Standardisation |
| IUPAC        | International Union of Pure and Applied Chemistry |
| JMPR         | Joint FAO/WHO Meeting on Pesticide Residues |
| LC           | liquid chromatography |
| LOQ          | limit of quantification |
| MRL          | maximum residue level |
| 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 |
| SEU          | southern Europe |
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| UV           | ultraviolet (detector) |
| 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 | F G or I(a) | Pests or group of pests controlled | Preparation Type(b) | Conc. a.s. | Method kind | Range of growth stages and 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) |
|----------------------|--------------------------|------------|-----------------------------------|---------------------|-----------|------------|----------------------------------|---------------|---------------------------------|----------------|----------------|----------|-------------|------------|
| Rice (Oryza sativa)  | Indonesia                | F          | Rice blast (Pyricularia oryzae)   | CS                  | 100 g/kg | Spray      | BBCH 43-65                       | 2             | 10                              | –              | –              | 100 g/ha  | Fixed by latest growth stage BBCH 65 | Critical GAP; less critical GAPs reported in ER for Colombia, Dominican Republic, Guatemala and Panama |

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; MRL: maximum residue level; a.s.: active substance; CS: capsule suspension.

(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, 2017); this information was used to retrieve the geographical zone reported in the second column of this table.
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 DAT₆         | Radiolabelled active substance: [tolyl-U-¹⁴C]-pyraclostrobin and [chlorophenyl-U-¹⁴C]-pyraclostrobin (EFSA, 2011) |
| Root                              | Potatoes    | Foliar: 6 × 300 g a.s./ha, from BBCH 31 to maturity | 7 DAT₃ and 7 DAT₆ (maturity) | |
| Cereals/ grass                    | Wheat       | Foliar: 2 × 300 g a.s./ha, from BBCH 32 to 61 | 0 DAT₁, 31 DAT₁, 41 DAT₂ 63/65 DAT (forage) 74/76 DAT (hay) 103/104 DAT (grain, straw) | |
| Paddy rice                        |             | Foliar: 3 × 130 g a.s./ha, from BBCH 39 to 69 | -1 DAT₂ (forage), 57 DAT₃ (straw, grain) | (Germany, 2017) |

| 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-¹⁴C]-pyraclostrobin and [chlorophenyl-U-¹⁴C]-pyraclostrobin (EFSA, 2011) |
| Leafy crops                         | Lettuces    |         | 30, 120, 365 |           |               |
| Cereal (small grain)                | Wheat       |         | 30, 120, 365 |           |               |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/source |
|------------------------------------------|------------|---------|----------------|
|                                         | Pasteurisation (20 min, 90°C, pH 4) | Yes | EFSA (2011) |
|                                         | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | EFSA (2011) |
|                                         | Sterilisation (20 min, 120°C, pH 6) | Yes | EFSA (2011) |
B.1.1.2. Stability of residues in plants

Can a general residue definition be proposed for primary crops?
Yes
EFSA (2011)

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

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 (2011)

BBCH: growth stages of mono- and dicotyledonous plants; DATx: days after treatment x (e.g. DAT2: day after 2nd treatment); PBI: plant-back interval; LC-MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; HPLC-UV: high performance liquid chromatography with ultraviolet detector; ILV: independent laboratory validation.

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

| Plant products (available studies) | Category | Commodity          | T (°C) | Stability period | Value | Unit | Compounds covered | Comment/source |
|-----------------------------------|----------|--------------------|--------|------------------|-------|------|-------------------|----------------|
| High water content                | Tomatoes | < -10              | 96%    | 18 months        |       |      | Pyraclostrobin    | Germany (2001) |
|                                  |          | < -10              | 92%    | 18 months        |       |      |                   |                 |
|                                  | Sugar beet tops | < -10              | 98%    | 18 months        |       |      | Pyraclostrobin    |                 |
|                                  |          | < -10              | 99%    | 18 months        |       |      |                   |                 |
| High starch content              | Sugar beet roots | < -10              | 91%    | 18 months        |       |      | Pyraclostrobin    |                 |
|                                  |          | < -10              | 91%    | 18 months        |       |      |                   |                 |
| High oil content                 | Peanut nutmeat | < -10              | 88%    | 18 months        |       |      | Pyraclostrobin    | 500M07          |
|                                  |          | < -10              | 84%    | 18 months        |       |      |                   |                 |
|                                  | Peanut oil | < -10              | 106%   | 18 months        |       |      | Pyraclostrobin    | 500M07          |
|                                  |          | < -10              | 120%   | 18 months        |       |      |                   |                 |
| Dry/high starch content          | Wheat grain | < -10              | 88%    | 18 months        |       |      | Pyraclostrobin    | 500M07          |
|                                  |          | < -10              | 89%    | 18 months        |       |      |                   |                 |
| High acid content                | Grape juice | < -10              | 88%    | 18 months        |       |      | Pyraclostrobin    |                 |
|                                  |          | < -10              | 93%    | 18 months        |       |      |                   |                 |
| Others                            | Wheat straw | < -10              | 99%    | 18 months        |       |      | Pyraclostrobin    | 500M07          |
|                                  |          | < -10              | 97%    | 18 months        |       |      |                   |                 |
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) |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|------------------------|-------------------------|--------------------------|
| Rice      | Indonesia                   | 6 × < 0.01, 2 × 0.01, 2 × 0.02, 2 × 0.03, 4 × 0.04, 0.06      | Residue trials on rice compliant with the Indonesian GAP | 0.09                   | 0.06                    | 0.02                     |

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

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
B.1.2.2. Residues in rotational crops

Not relevant for the import tolerance application.

B.1.2.3. Processing factors

| Processed commodity                  | Number of valid studies<sup>a</sup> | Processing Factor (PF) | Comment/source |
|-------------------------------------|-------------------------------------|------------------------|----------------|
|                                     |                                     | Individual values      | Median PF      |                |
| Rice bran                           | 3                                   | Individual values: 4.90, 5.29, 5.73 | 5.3            | Germany (2017) |
| Rice parboiled white milled rice    | 3                                   | Individual values: 0.756, 0.889, 1.17 | 0.9            | Germany (2017) |
| Rice flour                          | 3                                   | Individual values: 0.10, 0.163, 0.416 | 0.16           | Germany (2017) |
| Rice, polished                      | 3                                   | Individual values: 0.14, 0.16, 0.416 | 0.16           | Germany (2017) |
| Rice sake                           | 3                                   | Individual values: 0.10, 0.116, 0.416 | 0.012          | Germany (2017) |

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

<sup>b</sup>: A tentative PF is derived based on a limited data set.

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Dietary burden expressed in mg/kg DM | Most critical subgroup<sup>a</sup> | Most critical commodity<sup>b</sup> | Trigger exceeded (Y/N) |
|----------------------------|----------------------------------------------|-------------------------------------|-----------------------------------|-----------------------------------|-----------------------|
|                            | Median | Maximum | Median | Maximum | Dairy cattle | Barley straw | Yes |
| Cattle (all)               | 0.084  | 0.133   | 2.53   | 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)                | 0.021  | 0.032   | 0.90   | 1.40     | Swine (breeding) | Kale | 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.

<sup>a</sup>: 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’.

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

<sup>c</sup>: 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 residue of pyraclostrobin in the crop under consideration to the total livestock dietary intake is insignificant, the previous assessment of residues in livestock is still valid (EFSA, 2018a).
B.3. Consumer risk assessment

| ARfD                  | 0.03 mg/kg bw (COM, 2004) |
|-----------------------|---------------------------|
| Highest IESTI, according to EFSA PRIMO | Rice: 0.8% of ARfD |
| Assumptions made for the calculations | IESTI calculation using the STMR derived from trials provided on rice |

| ADI                  | 0.03 mg/kg bw (COM, 2004) |
|----------------------|---------------------------|
| Highest IEDI, according to EFSA PRIMO | 17.4% ADI (DE child diet) |
| Assumptions made for the calculations | Contribution of rice: 0.05% of the ADI |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMO: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; ADI: acceptable daily intake; IEDI: international estimated daily intake.

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|-------------------------|-------------------------|-----------------------|
| 0500060 | Rice      | 0.02*                   | 0.09                    | The submitted residue trials are sufficient to derive an import tolerance request (Indonesian GAP). Information on the authorisation of the use of pyraclostrobin in rice in Indonesia was provided however not the legal limit. Therefore, risk management considerations are required regarding the acceptability of the derived MRL proposal. Risk for consumers unlikely. |

MRL: maximum residue level; 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)

### PYRACLOSTROBIN

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

### Status of the active substance:
- Included

| Code no. | LOQ (mg/kg) | Proposed LOQ (mg/kg) |
|----------|-------------|----------------------|
|          |             |                      |

### Chronic risk assessment – refined calculations

#### pTMRLs at LOQ in % of ADI

| Commodity/group of commodities | 1.9 | 1.1 | 0.5 |
|-------------------------------|-----|-----|-----|
| Table grapes                  |     |     |     |
| Apples                        |     |     |     |

| Commodity/group of commodities | 0.6 |
|-------------------------------|-----|
| Carrots                       |     |

| Commodity/group of commodities | 0.3 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 0.4 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 0.5 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 0.6 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 0.7 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 0.8 |
|-------------------------------|-----|
| Carrots                       |     |

| Commodity/group of commodities | 0.9 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 1.0 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 1.1 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 1.2 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 1.3 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 1.4 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 1.5 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 1.6 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 1.7 |
|-------------------------------|-----|
| Apples                        |     |

| Commodity/group of commodities | 1.8 |
|-------------------------------|-----|
| Apples                        |     |

### 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.
### Acute risk assessment/children – refined calculations

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

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002) for lettuce; a variability factor of 5 was used. In the IESTI 2 calculation, 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.

| Commodity | pTMRL/threshold MRL (mg/kg) |
|-----------|-----------------------------|
| Rice      | 0.02                        |

| Commodity | pTMRL/threshold MRL (mg/kg) |
|-----------|-----------------------------|
| Rice      | 0.02                        |

| Commodity | pTMRL/threshold MRL (mg/kg) |
|-----------|-----------------------------|
| Rice      | 0.02                        |

| Commodity | pTMRL/threshold MRL (mg/kg) |
|-----------|-----------------------------|
| Rice      | 0.02                        |

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

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

For processed commodities, no exceedance of the ARfD was identified.
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 for plants: Pyraclostrobin |
| Rice bran/pollard    | 0.11                  | STMR × PF (5.3, see Table B.1.2.3) | 0.11                  | STMR × PF (5.3, see Table B.1.2.3) |
| Other feed items     | STMR, HR (EFSA 2012, 2014b, 2018a) |

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 for plants: 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 |
| Rice                          | 0.02                    | STMR                  | 0.02                  | STMR                  |
| Swine: meat, fat, kidney      | 0.05                    | STMR                  |                        |                      |
| Swine: liver                  | 0.20                    | STMR                  |                        |                      |
| Bovine: meat, fat, kidney     | 0.05                    | STMR                  |                        |                      |
| Bovine: liver                 | 0.20                    | STMR                  |                        |                      |
| Sheep: meat, fat, kidney      | 0.05                    | STMR                  |                        |                      |
| Sheep: liver                  | 0.20                    | STMR                  |                        |                      |
| Milk: cattle, sheep and goat  | 0.07                    | STMR                  |                        |                      |
| Other commodities             | See previous assessments (EFSA, 2011, 2012, 2013, 2014a,b, 2016, 2017, 2018a,b(a)) |                      |

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

| Code/trivial name                  | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup>                                                                 | Structural formula<sup>(b)</sup>                                      |
|-----------------------------------|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| Pyraclostrobin                    | methyl 2-[1-(4-chlorophenyl)-1H-pyrazol-3-yl氧基甲基]-N-甲氧基尿素酸甲酯<br>\[O=C(OC)N(OC)c1cccccc1COc1ccn(n1)c1ccc(Cl)cc1<br>HZRSVGNWUDEFX-UHFFFAOYSA-N] | ![Pyraclostrobin Structural Formula](attachment:pyraclostrobin_structural_formula.png) |
| Desmethoxy metabolite (500M07, BF 500-3) | methyl [2-\{1-(4-chlorophenyl)-1H-pyrazol-3-yl\}氧基\{\methyl\}对苯二甲酸甲酯<br>\[O=C(OC)c1cccccc1COc1ccn(n1)c1ccc(Cl)cc1<br>SEUOYURKYLAPC-UHFFFAOYSA-N] | ![Desmethoxy Metabolite Structural Formula](attachment:desmethoxy_metabolite_structural_formula.png) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.<br>
<sup>(a)</sup>: ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).<br>
<sup>(b)</sup>: ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).