Modification of the existing maximum residue levels for pyraclostrobin in soyabean

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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 France to modify the existing maximum residue level (MRL) for the active substance pyraclostrobin in soyabean. The data submitted in support of the request were found to be sufficient to derive MRL proposals for soyabean. The applicant provided a new validated analytical method to control residues of pyraclostrobin on the commodity under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg, which is a value lower than the one currently in use. Adequate analytical methods for enforcement in animal matrices at the validated LOQ of 0.01 mg/kg are available. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of pyraclostrobin according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Keywords: pyraclostrobin, soyabean, pesticide, 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 France (evaluating Member State (EMS)) to modify the existing maximum residue level (MRL) for the active substance pyraclostrobin in soyabean. 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 2018. To accommodate for the intended uses of pyraclostrobin, the EMS proposed to raise the existing MRL from 0.05 mg/kg to 0.2 mg/kg.

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

Based on the conclusions derived 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 fruit crops, root crops, and cereals.

Studies investigating the effect of processing on the nature of pyraclostrobin (hydrolysis studies) demonstrated that the active substance is stable. At very high temperatures (above 190°C) the parent compound was found to degrade to metabolites 500M04 and 500M49.

In rotational crops, the major residue identified was the parent compound.

Based on the metabolic pattern identified in metabolism studies, 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. These residue definitions are applicable to primary crops, rotational crops and processed products.

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC-MS/MS) are available to quantify residues in the crop assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crop assessed (limit of quantification (LOQ)).

The available residue trials are sufficient to derive a MRL proposal of 0.2 mg/kg for soyabean.

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

As the crop under consideration and its by-products are used as feed products, a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant species/animal species.

Therefore, the possible occurrence of pyraclostrobin residues in commodities of animal origin was investigated. The nature of pyraclostrobin residues in livestock has been investigated during the MRL review of pyraclostrobin and the residue definition for enforcement was proposed as ‘pyraclostrobin’; while for risk assessment, as the ‘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’, with a conversion factor of 4 on ruminant liver and 1 on all other commodities.

The contribution of pyraclostrobin residues in the crop under consideration in this MRL application to the total livestock exposure was insigniﬁcant and therefore a modiﬁcation of the existing MRLs for commodities of animal origin was considered unnecessary.

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

The consumer risk assessment was performed with revision 3 of the EFSA Pesticide Residues Intake Model (PRIMO). The short-term exposure did not exceed the ARfD for the crop assessed in this application. The estimated long-term dietary intake was in the range of 2.0–32% of the ADI.

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

The peer review of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet ﬁnalised and therefore the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the peer review.

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

| Code\(^{(a)}\) | Commodity            | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|---------------|----------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0401070       | Soybean              | 0.05                    | 0.2                     | The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely |
| 1011010, 1011020, 1011030, 1011040 | Swine: muscle, fat, liver kidney | 0.05*                   | 0.05                     | The applicant submitted a new validated method with an LOQ of 0.01 mg/kg. Therefore it is proposed to lower the LOQ related to the MRL for animal commodities |
| 1012010, 1012020, 1012030, 1012040 | Bovine: muscle, fat, liver kidney | 0.05*                   | 0.05                     |                                                                                        |
| 1013010, 1013020, 1013030, 1013040 | Sheep: muscle, fat, liver kidney | 0.05*                   | 0.05                     |                                                                                        |
| 1014010, 1014020, 1014030, 1014040 | Goat: muscle, fat, liver kidney | 0.05*                   | 0.05                     |                                                                                        |
| 1016010, 1016020, 1016030, 1016040 | Poultry: muscle, fat, liver kidney | 0.05*                   | 0.05                     |                                                                                        |

**Enforcement residue definition:** pyraclostrobin\(^{(F)}\)

| MRL: maximum residue level; SEU: southern Europe; LOQ: limit of quantification. |
|*: 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. |
Assessment

The detailed description of the intended use of pyraclostrobin which is the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Pyraclostrobin is the ISO common name for methyl 2-[1-(4-chlorophenyl)pyrazol-3-yl oxy]methyl]-N-methoxy carbamate (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/EEC with Germany designated as rapporteur Member State (RMS) for the representative use as 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 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. The process of renewal of the first approval is currently ongoing.

The European Union (EU) MRLs for pyraclostrobin are established in Annexes II of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011) 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. The proposals from these reasoned opinions have been considered in recent regulations for EU MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in France (EMS) to modify the MRL for the active substance pyraclostrobin in soyabean. 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 EFSA on 1 June 2018. To accommodate for the intended uses of pyraclostrobin, the EMS proposed to raise the existing MRL from 0.05 to 0.2 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2018), 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, 2011, 2012, 2013, 2014a,b, 2016, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011 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 546/2011.

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 might 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, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation report submitted by the EMS (France, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1 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: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
6 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.
7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
1. 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, root crops and cereals has been investigated in the framework of Directive 91/414/EEC and the EU MRL review (Germany, 2001; EFSA, 2011).

The metabolic pathway was found to be similar in all crop groups investigated. The predominant compound of the total residues in the crops investigated was the parent pyraclostrobin; the desmethoxy metabolite (500M07) was found in small amounts compared to the parent pyraclostrobin (Germany, 2001; EFSA, 2011).

For the intended use in soyabeans, plant metabolism is considered to be sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Soyabean can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review (European Commission, 2004), pyraclostrobin and the metabolites 500M06 and 500M07 are highly persistent in soil (DT\textsubscript{90,\textit{field}} pyraclostrobin: 83–230 days, DT\textsubscript{90,\textit{lab}}500M06: 428–552 days, DT\textsubscript{90,\textit{lab}}500M07: 372–529 days).

Metabolism studies in rotational crops were assessed in the framework of the peer review and the MRL review (Germany, 2001; EFSA, 2011). No accumulation of pyraclostrobin or its metabolites (including 500M07) in the edible parts of the rotational crops were found. The metabolism of pyraclostrobin in rotational crops was considered to be similar to the metabolic pathway depicted in primary crops (EFSA, 2011).

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 the peer review and the MRL review (Germany, 2001; EFSA, 2011). It was concluded that pyraclostrobin is hydrolytically stable under the representative conditions.

In the framework of this MRL application, a study investigating the nature of pyraclostrobin residues under more drastic processing conditions which simulates raffination of olive oil at high temperatures (190°C and 240°C, 30 min) was provided. In the study, a mixture of olive oil and aqueous sodium chloride solution (ratio 2:1) was heated up to 190°C and 240°C. At 190°C, a significant degradation of pyraclostrobin into 500M07 (41%) was observed. At this temperature, the parent compound (23%) and the metabolite 500M04 (19%) were also detected. At 240°C the amount of parent accounted for only 5% applied radioactivity (AR) and the metabolite 500M04 (76%) and 500M07 (16%) were the major compounds detected (France, 2018).

Considering that the process of the peer review is ongoing; once a final decision on the toxicological relevance of the degradation products is taken, a separate residue definition for processed products might be considered.

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 LOQ of 0.02 mg/kg for the determination of pyraclostrobin in matrices with high water content, high oil content, high acid content and dry/high starch content matrices and hops. In addition, a more sensitive method for high water content, acidic and dry/high starch content commodities with a LOQ of 0.01 mg/kg was provided (EFSA, 2011).

Thus, for soyabeans, sufficiently validated analytical methods are available for enforcing the proposed MRL for pyraclostrobin.

1.1.5. Stability of residues in plants

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

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

The residue definitions may need to be reconsidered, once the renewal process for the approval of pyraclostrobin is completed.

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 16 residue trials performed in soyabean (8 SEU trials and 8 NEU trials). All samples were analysed for the parent and metabolite 500M07. According to the assessment of the EMS, the analytical methods used to analyse the residue trial samples were sufficiently validated and fit for purpose (France, 2018).

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

For the purpose of the current MRL application on soyabean, only trials conducted in southern zone of Europe have been considered. All eight SEU trials are compliant with the intended GAP. The available studies are sufficient to derive a MRL proposal for soyabean.

1.2.2. Magnitude of residues in rotational crops

In the metabolism studies in rotational crops which were conducted with pyraclostrobin applied at a dose rate of 900 g a.s./ha on the bare soil, the total radioactive residues in the edible parts of succeeding crops planted at different plant back intervals were analysed. Overall, an accumulation of pyraclostrobin and its degradation products in crops grown in rotation was not observed (EFSA, 2011). The highest total residues accounted for 0.04 mg/kg in radish root (30-day plant-back interval (PBI)), 0.017 mg/kg in lettuce (365-day PBI), 0.114 and 0.089 mg/kg in wheat straw (30-day PBI) and grain (120-day PBI), respectively.

Considering that the studies were performed with a higher application rate than the intended use in soyabeans (seasonal application rate of 250 g/ha) and the fact that in the confined rotational crop study pyraclostrobin was applied directly to bare soil whilst interception by crop foliage is expected in practice, the previously derived conclusion in the framework of the MRL review is also valid for the intended use in soyabeans, i.e. residues of pyraclostrobin resulting from soil uptake will not exceed 0.01 mg/kg (EFSA, 2011). Specific plant-back restrictions are currently not considered necessary provided that the active substance is applied according to the proposed GAP.

1.2.3. Magnitude of residues in processed commodities

In the framework of this MRL application, a new processing study on processed rape seeds has been submitted by the applicant (France, 2018). From this study, a processing factor (PF) of 2.91 was derived for crude oil; for other processed products derived from rape seed (i.e. meal, refined oil, soapstock and press cake), the residues were lower compared with the residues in the unprocessed raw agricultural product (PF < 1) (France, 2018).

Considering that the oil content of rape seed is significantly higher (38–44%) compared to soyabeans (13–24%) (OECD, 2008), the PFs of rape seed should not be extrapolated to soyabeans. However, this data gives an indication that the residues are likely to accumulate in the oil fraction.

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). In Section 3, EFSA assessed whether residues on this crop resulting from the intended use are likely to pose a consumer health risk.
2. Residues in livestock

Since soyabean and its by-products are used as feed item, it is necessary to assess whether the intended use of pyraclostrobin in soyabean would require a modification of the MRLs set for animal commodities. EFSA calculated the dietary burden\(^8\) using the OECD methodology (OECD, 2013) and the dietary burden differed from the previous assessment (EFSA, 2014b). The difference however is mainly due to the different calculation methodologies used: while the previous dietary burden calculation (EFSA, 2014b) was performed in accordance with the methodology applicable at the time the current dietary burden calculation was performed according to the revised 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.

2.1. Nature of residues and methods of analysis in livestock

Metabolism studies in goat and hen have been assessed previously in the framework of the peer review and the MRL review (Germany, 2001; EFSA, 2011).

The residue definition for enforcement was defined as ‘pyraclostrobin’ in all commodities of animal origin.

The residue definition for risk assessment was defined as the ‘sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1\(^H\)-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1\(^H\)-pyrazole moiety, expressed as pyraclostrobin’ (EFSA, 2011).

The applicant provided sufficiently validated analytical methods, including ILV, to be used for enforcement purpose in milk, egg, fat, liver, kidney and muscle and LOQ of 0.01 mg/kg was achieved. It is noted that this method has a lower LOQ than the LOQ established in the MRL legislation (0.05 mg/kg).

In the framework of the peer review, the proposed residue definitions were considered to be fat soluble.

EFSA concluded that the metabolism of pyraclostrobin in livestock was sufficiently elucidated.

2.2. Magnitude of residues in livestock

Feeding studies with lactating cows were assessed previously in the framework of the peer review and MRL review (Germany, 2001; EFSA, 2011). Considering the expected dietary burden for ruminants, EFSA concluded that a modification of the level of the existing MRLs is not required. However, since the new analytical method provided with the current application has a lower LOQ, EFSA proposes to remove the label (*) denoting the MRL as an LOQ.

Since no feeding study is available for poultry, the metabolism study in laying hens (EFSA, 2011) was used to estimate whether a revision of the existing MRLs for poultry products is required. The metabolism study was performed at dose levels of approximately 0.7 and 0.88 mg/kg bw per day, which represents 10 times the maximum calculated dietary intake. EFSA concluded that the intended uses do not have a significant impact on the residues expected in poultry. Therefore, there is no need to modify the existing EU MRLs in poultry except for the EFSA’s proposal to remove the label (*) denoting the MRL as an LOQ.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3 of the EFSA PRIMo.

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 MRL review (EFSA, 2011). The metabolites included in the risk assessment residue definition for animal commodities were considered to be not more toxic than the parent compound.

Short-term (acute) dietary risk assessment

The short-term exposure assessment for soyabeans was performed in accordance with the internationally agreed methodology. The calculation was based on the STMR derived from MRL review (EFSA, 2011) since this value was higher than the one derived from supervised field trials submitted in the current application (Appendix D.2).

\(^8\) The STMR for soyabean from the MRL review (EFSA, 2011) was used because it was higher than the one derived from the supervised field trials performed for the intended GAP in the framework of this application.
The short-term exposure did not exceed the ARfD for any of the crops assessed in this application (see Appendix C).

**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 approved in the EU and sufficiently supported import tolerances or Codex MRLs (EFSA 2011). In addition, STMR values derived in EFSA opinions published after the MRL review (EFSA, 2012, 2013, 2014a,b, 2016, 2017) were included in the dietary exposure assessment. For soyabeans, the STMR derived in the framework of the MRL review (EFSA, 2011) was used since this value was higher than the one derived from supervised field trials submitted in the current application. The complete list of input values used in the exposure calculations is presented Appendix D.2.

The estimated long-term dietary intake was in the range of 2.0–32% of the ADI. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix C.

EFSA concluded that the long-term intake of residues of pyraclostrobin resulting from the existing and the intended uses is unlikely to present a 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 for soyabeans.

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

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement to risk assessment residue definition
DAR draft assessment report
DAT days after treatment
DM dry matter
DT₉₀ period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
GAP Good Agricultural Practice
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS/MS 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
RA  risk assessment
RAC  raw agricultural commodity
RD  residue definition
RMS  rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC  suspension concentrate
SEU  southern Europe
STMR supervised trials median residue
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 | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|-------------------------|-------------|------------------------------------|-------------|----------------|-------------------------------|---------------|---------|
| Soyabean, SEU F       |                         | SC          | Septoria glycines SEPTGL Botrytis cinerea BOTRCI Peronospora manshurica PEROMA Sclerotinia sclerotiorum SCLESC | 250 g/L     | Spraying BBCH 51-75 a) Max. number per use: 1 (2 in case of split application) b) Max. number per crop/ season: 1 (2 in case of split application) | 14 60-250 100-400 | 0.25 F | Dose rate range of 0.6-1 L/ha per application favoured Max. 1 L/ha and season, split application 2 × 0.5 L/ha possible, 14–21 days interval within application window |

NEU: northern European Union; SEU: southern European Union; MS: Member State; 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, 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.

(F): The PHI is covered by the vegetation period remaining between the application of the plant protection product and the use of the product (e.g. harvest) or the setting of a PHI in days is not required, respectively.
Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/source |
|----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                      |            | Grapes  | Foliar: 6 × 130 to 480 g a.s./ha (1 × 480, 2 × 240, 3 × 180, 4 × 130, 5 × 240, 6 × 240); from BBCH 53-55 to 81 | 40 DAT₆ | Radiolabelled active substance: [tolyl-U-¹⁴C]-pyraclostrobin and [chlorophenyl-U-¹⁴C]-pyraclostrobin (EFSA, 2011) |
| Root crops                       |            | 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 DAT₁, 63/65 DAT (forage) 74/6 DAT (hay) 103/104 DAT (grain, straw) | |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                     | Radishes    | Bare soil, 0.9 kg a.s./ha | 30, 120, 365 | Radiolabelled active substance: [tolyl-U-¹⁴C]-pyraclostrobin and [chlorophenyl-U-¹⁴C]-pyraclostrobin (EFSA, 2011) |
| Leafy crops                          | Lettuces    | Bare soil, 0.9 kg a.s./ha | 30, 120, 365 | |
| Cereal (small grain)                 | Wheat       | Bare soil, 0.9 kg a.s./ha | 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) |
|                                         | Olive oil raffination (30 min, 190°C and 240°C) | No | Pyrclostrobin degraded significantly to 500M04 and 500M07 (France, 2018) |
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)
Considering the outcome of the renewal of the active substance, the need to derive a specific residue definition for processed products involving conditions like oil raffination might be considered

Plant residue definition for monitoring (RD-Mo)

Plant residue definition for risk assessment (RD-RA)

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

| 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 | 500M07 |
| | Sugar beet tops | < −10 | 98% | 18 months | Pyraclostrobin |
| | | < −10 | 99% | 18 months | 500M07 |
| High starch content | Sugar beet roots | < −10 | 91% | 18 months | Pyraclostrobin |
| | | < −10 | 91% | 18 months | 500M07 |
| High oil content | Peanut nutmeat | < −10 | 88% | 18 months | Pyraclostrobin |
| | | < −10 | 84% | 18 months | 500M07 |
| | Peanut oil | < −10 | 106% | 18 months | Pyraclostrobin |
| | | < −10 | 120% | 18 months | 500M07 |
| Dry/high starch content | Wheat grain | < −10 | 88% | 18 months | Pyraclostrobin |
| | | < −10 | 89% | 18 months | 500M07 |
| High acid content | Grape juice | < −10 | 88% | 18 months | Pyraclostrobin |
| | | < −10 | 93% | 18 months | 500M07 |
| Others | Wheat straw | < −10 | 99% | 18 months | Pyraclostrobin |
| | | < −10 | 97% | 18 months | 500M07 |

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; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants
B.1.2. Magnitude of residues in plants

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

| Commodity | Region/indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|-----------|-------------------------|---------------------------------------------------------------|----------------|------------------------|-------------------|---------------------|---------|
| Soyabean  | SEU                     | 7 × < 0.01, 0.12                                               | Residue trials on soybeans compliant with GAP | 0.2                  | 0.12              | 0.01                | –       |

MRL: maximum residue level; GAP: Good Agricultural Practice.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in rotational crops

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

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

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | Comment/source |
|---|---|---|---|
| | | Individual values | Median PF |
| Rape seeds (crude oil) | 3 | 2.53, 2.91, 1.45 | 2.91 | France (2018) |
| Other processed commodities were assessed in MRL review | | | | EFSA (2011) |

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

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|---|---|---|---|---|
| | Median | Maximum | Median | Maximum | | |
| Cattle (all) | 0.084 | 0.133 | 2.53 | 3.85 | Dairy cattle | Barley straw | Y |
| Cattle (dairy only) | 0.084 | 0.133 | 2.20 | 3.47 | Dairy cattle | Barley straw | Y |
| Sheep (all) | 0.127 | 0.232 | 3.61 | 6.00 | Lamb | Barley straw | Y |
| Sheep (ewe only) | 0.120 | 0.200 | 3.61 | 6.00 | Ram/Ewe | Barley straw | Y |
| Swine (all) | 0.021 | 0.032 | 0.90 | 1.40 | Swine (breeding) | Kale leaves | Y |
| Poultry (all) | 0.028 | 0.061 | 0.41 | 0.89 | Poultry layer | Wheat straw | Y |
| Poultry (layer only) | 0.028 | 0.061 | 0.41 | 0.89 | Poultry layer | Wheat straw | Y |
| Fish | N/A | | | | |

bw: body weight; DM: dry matter.

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

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.
B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal                  | Dose (mg/kg bw per day) | Duration (days) | Comment/source                      |
|-------------------------------|--------------------------|--------------------------|-----------------|------------------------------------|
|                               | Laying hen              | 0.70                     | 7               | ^14^C-chlorophenyl pyraclostrobin (EFSA, 2011) |
|                               |                          | 0.88                     | 7               | ^14^C-tolyl pyraclostrobin (EFSA, 2011) |
|                               | Lactating ruminants (goat) | 0.9–10 (low dose); 2.72 (high dose) | 5               | ^14^C-chlorophenyl pyraclostrobin (EFSA, 2011) |
|                               |                          | 0.65–0.75 (low dose); 1.37 (high dose) | 5               | ^14^C-tolyl pyraclostrobin (EFSA, 2011) |

bw: body weight.

Time needed to reach a plateau concentration in milk and eggs (days)

| Commodity | Milk | Eggs |
|-----------|------|------|
|           | 3    | 5    |

Metabolism in rat and ruminant similar

Yes EFSA (2011)

Can a general residue definition be proposed for animals?

Yes EFSA (2011)

Animal residue definition for monitoring (RD-Mo)

Pyraclostrobin (EFSA, 2011)

Animal residue definition for risk assessment (RD-RA)

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 (EFSA, 2011)

Fat soluble residues

Yes EFSA (2011)

Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)

Validated LC–MS/MS analytical method is available to enforce pyraclostrobin in milk, eggs, muscle, fat, kidney and liver with an LOQ of 0.01 mg/kg. ILV available (France 2018)

LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal                  | Commodity       | T (°C) | Stability period (Value, Unit) | Compounds covered                                                                 | Comment/source |
|-------------------------------------|--------------------------|-----------------|--------|-------------------------------|----------------------------------------------------------------------------------|----------------|
| Hen                                 | Muscle, fat, liver, Eggs | −18             | 8      | Months                        | Pyraclostrobin                                                                   | EFSA (2011)    |
| Goat                                | Muscle, fat, liver, kidney, Milk | −18             | 8      | Months                        | Pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety | EFSA (2011)    |
### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF<sup>(c)</sup> |
|------------------|---------------------------------------------|------------------------|----------------------|------------------|
|                  | Mean | Highest | STMR<sup>(a)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) |                  |
| Cattle (all)     |      |         |                          |                      |                  |
| Closest feeding level (0.22 mg/kg bw; 1.6 N rate)<sup>(d)</sup> |      |         |                          |                      |                  |
| Muscle           | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Fat              | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Liver            | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Kidney           | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Cattle (dairy only) |      |         |                          |                      |                  |
| Closest feeding level (0.22 mg/kg bw; 1.6 N rate)<sup>(d)</sup> |      |         |                          |                      |                  |
| Milk             | 0.01 | 0.01    | 0.01                     | 0.01                | 0.01*            |
| Sheep (all)<sup>(e)</sup> |      |         |                          |                      |                  |
| Closest feeding level (0.22 mg/kg bw; 0.9 N rate)<sup>(d)</sup> |      |         |                          |                      |                  |
| Muscle           | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Fat              | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Liver            | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Kidney           | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Sheep (ewe only)<sup>(e)</sup> |      |         |                          |                      |                  |
| Closest feeding level (0.22 mg/kg bw; 1.1 N rate)<sup>(d)</sup> |      |         |                          |                      |                  |
| Milk             | 0.01 | 0.01    | 0.01                     | 0.01                | 0.01*            |
| Swine (all)<sup>(e)</sup> |      |         |                          |                      |                  |
| Closest feeding level (0.22 mg/kg bw; 6.8 N rate)<sup>(d)</sup> |      |         |                          |                      |                  |
| Muscle           | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Fat              | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Liver            | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Kidney           | 0.05 | 0.05    | 0.05                     | 0.05                | 0.05             |
| Poultry (all)    |      |         |                          |                      |                  |

MRL proposals were derived from metabolism study.

MRL: maximum residue level; bw: body weight.

*: Indicates that the MRL is proposed at the limit of quantification.

n.a.: not applicable.

n.r.: not reported.

(a): Mean residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

(c): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

(d): Closest feeding level and N dose rate related to the maximum dietary burden.

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
B.3. Consumer risk assessment

**ARfD**

Highest IESTI, according to EFSA PRIMo: Soyabens: 28% of ARfD

Assumptions made for the calculations:
The calculation is performed only for the crop under assessment, considering the median residue level derived from the MRL review (EFSA 2011); the median value from MRL review was used because it was higher than the one derived from the supervised field trials performed for the intended GAP in the framework of this application.

The contribution of animals’ commodities was also considered, by considering HR values, to take into account the calculation performed with the new version of the Animal Intake model.

**ADI**

Highest IEDI, according to EFSA PRIMo: 32% ADI (NL toddler)

Assumptions made for the calculations:
The calculation is performed for the crop under assessment, considering the median residue level derived from the MRL review (EFSA 2011); the median value from MRL review was used because it was higher than the one derived from the supervised field trials performed for the intended GAP in the framework of this application.

Furthermore, all the median residue levels for the crops assessed in previous reasoned opinions and MRL review were considered.

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; GAP: Good Agricultural Practice; HR: highest residue.

B.4. Recommended MRLs

| Code<sup>a</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-----------------|-----------|------------------------|-------------------------|-----------------------|
| 0401070         | Soybean   | 0.05                   | 0.2                     | The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely. |
| 1011010, 1011020, 1011030, 1011040 | Swine: muscle, fat, liver kidney | 0.05<sup>*</sup> | 0.05 | The applicant submitted a new validated method with an LOQ of 0.01 mg/Kg. Therefore it is proposed to lower the LOQ related to the MRL for animal commodities. |
| 1012010, 1012020, 1012030, 1012040 | Bovine: muscle, fat, liver kidney | 0.05<sup>*</sup> | 0.05 | |
| 1013010, 1013020, 1013030, 1013040 | Sheep: muscle, fat, liver kidney | 0.05<sup>*</sup> | 0.05 | |

Enforcement residue definition: pyraclostrobin<sup>f</sup>
| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|------------|------------------------|-------------------------|------------------------|
| 1014010, 1014020, 1014030, 1014040 | Goat: muscle, fat, liver kidney | 0.05* | 0.05 | |
| 1016010, 1016020, 1016030, 1016040 | Poultry: muscle, fat, liver kidney | 0.05* | 0.05 | |

MRL: maximum residue level; SEU: southern Europe; LOQ: limit of quantification.
*: 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 (F)

| LOQs (mg/kg) range from | 0.02 to: 0.02 |
|------------------------|----------------|

#### Toxicological reference values

| ADI (mg/kg bw per day) | 0.03 |
|------------------------|------|
| ARfD (mg/kg bw)        | 0.03 |

**Source of ADI:** EFSA PRIMo revision 3.0; 2017/12/11

**Year of evaluation:**

#### Calculated exposure (% of ADI)

| MS Diet | Exposure (%) | highest contributor to MS Diet (in % of ADI) |
|---------|--------------|---------------------------------------------|
|         |              | Commodity/group of commodities               |
|         |              | MRLs set at the LOQ (in % of ADI)            |
|         |              | commodities not under assessment (in % of ADI) |

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
|-------------------------------|----------------------------------|-----------------------------------------------|
| Table grapes                  | 0.0%                             | 18%                                           |
| Sugar beet roots              | 0.0%                             | 5%                                            |
| Apples                        | 0.0%                             | 11%                                           |
| Carrots                       | 4%                               | 5%                                            |
| Sugar beet roots              | 0.0%                             | 5%                                            |
| Apples                        | 0.0%                             | 5%                                            |
| Barley                        | 6%                               | 4%                                            |
| Milk: Cattle                  | 0.0%                             | 3%                                            |
| Lamb's lettuce/corn salads    | 0.0%                             | 6%                                            |
| Table grapes                  | 0.0%                             | 6%                                            |
| Apples                        | 0.0%                             | 5%                                            |
| Cress and other sprouts and shoots | 0.0%                         | 6%                                            |
| Lettuce                       | 0.0%                             | 4%                                            |
| Tomatoes                      | 0.0%                             | 3%                                            |
| Cucumbers                     | 0.0%                             | 4%                                            |
| Sugar beet roots              | 0.0%                             | 4%                                            |
| Blackberries                  | 0.0%                             | 5%                                            |
| Lettuce                       | 0.0%                             | 3%                                            |
| Oranges                       | 0.0%                             | 5%                                            |
| Cucumbers                     | 0.0%                             | 3%                                            |
| Apple: 2 yr                   | 0%                               | 5%                                            |
| Carrots                       | 2%                               | 4%                                            |
| Apples                        | 0.0%                             | 2%                                            |
| Barrett                       | 0.0%                             | 7%                                            |
| Tomatoes                      | 0.0%                             | 2%                                            |
| Cucumbers                     | 0%                               | 3%                                            |

#### 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.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Acute risk assessment/children

| Commodities | MRL/ADI | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------|---------|---------------------|-----------------------|
| Milk: Cattle | 0.07/0.07 | 8.4 | 28% |
| Milk: Goat | 0.07/0.07 | 1.6 | 5% |
| Bovine: Liver | 0.05/0.2 | 1.6 | 1% |
| Bovine: Liver | 0.05/0.2 | 2.0 | 0.9% |
| Sheep: Muscle/meat | 0.05/0.05 | 0.85 | 0.7% |
| Swine: Muscle/meat | 0.05/0.05 | 0.81 | 0.6% |
| Bovine: Kidney | 0.05/0.05 | 0.19 | 0.5% |
| Bovine: Muscle/meat | 0.05/0.05 | 0.36 | 0.5% |
| Bovine: Muscle | 0.05/0.05 | 0.28 | 0.4% |
| Swine: Muscle/meat | 0.05/0.05 | 0.23 | 0.4% |
| Swine: Kidney | 0.05/0.05 | 0.09 | 0.2% |
| Swine: Fat tissue | 0.05/0.05 | 0.11 | 0.1% |

### Acute risk assessment/adults/general population

| Commodities | MRL/ADI | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------|---------|---------------------|-----------------------|
| Soyabean/soy milk | 0.02 | 0.08 | 0.3% |
| Soyabean/boiled | 0.01 | 0.03 | 0.1% |

### Details – acute risk assessment/children

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

### Details – acute risk assessment/adults/general population

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

### Conclusion

No exceedance of the toxicological reference value was identified for any expressed commodity. A last term value of residue of pyraclostrobin (r) is unlikely to pose a risk for processed commodities, no exceedance of the ARfD/ADI 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**          |
| Barley straw         | 3.38 STMR (EFSA, 2011) | 6.92 HR (EFSA, 2011)   |
| Sugar beet tops      | 0.07 STMR (EFSA, 2011) | 0.18 HR (EFSA, 2011)   |
| Cabbage head         | 0.02 STMR (EFSA, 2011) | 0.09 HR (EFSA, 2011)   |
| Kale                 | 0.19 STMR (EFSA, 2012) | 0.70 HR (EFSA, 2012)   |
| Oat straw            | 3.38 STMR (EFSA, 2011) | 6.92 HR (EFSA, 2011)   |
| Rye straw            | 1.85 STMR (EFSA, 2011) | 5.68 HR (EFSA, 2011)   |
| Wheat straw          | 1.85 STMR (EFSA, 2011) | 5.68 HR (EFSA, 2011)   |
| Triticale straw      | 1.85 STMR (EFSA, 2011) | 5.68 HR (EFSA, 2011)   |
| Potato               | 0.02 STMR (EFSA, 2011) | 0.06 HR (EFSA, 2011)   |
| Swede                | 0.02 STMR (EFSA, 2014b)| 0.06 STMR (EFSA, 2014b)|
| Turnip               | 0.02 STMR (EFSA, 2014b)| 0.06 STMR (EFSA, 2014b)|
| Barley grain         | 0.07 STMR (EFSA, 2011) | 0.07 STMR (EFSA, 2011) |
| Maize grain          | 0.02 STMR (EFSA, 2011) | 0.02 STMR (EFSA, 2011) |
| Bean seed            | 0.04 STMR (EFSA, 2011) | 0.04 STMR (EFSA, 2011) |
| Oat grain            | 0.07 STMR (EFSA, 2011) | 0.04 STMR (EFSA, 2011) |
| Pea seed             | 0.04 STMR (EFSA, 2011) | 0.07 STMR (EFSA, 2011) |
| Rye grain            | 0.02 STMR (EFSA, 2011) | 0.02 STMR (EFSA, 2011) |
| Triticale grain      | 0.02 STMR (EFSA, 2011) | 0.02 STMR (EFSA, 2011) |
| Wheat grain          | 0.02 STMR (EFSA, 2011) | 0.02 STMR (EFSA, 2011) |
| Soybean seed         | 0.02 STMR (EFSA, 2011) | 0.02 STMR (EFSA, 2011) |
| Apple pomace wet(a)  | 0.35 STMR × 2.5 PF (EFSA, 2011) | 0.35 STMR × 2.5 PF (EFSA, 2011) |
| Beet sugar dried pulp(b) | 0.04 STMR × 18 PF (EFSA, 2011) | 0.04 STMR × 18 PF (EFSA, 2011) |
| Beet sugar ensiled pulp(b) | 0.04 STMR × 3 PF (EFSA, 2011) | 0.04 STMR × 3 PF (EFSA, 2011) |
| Beet sugar molasses(b) | 0.04 STMR × 28 PF (EFSA, 2011) | 0.04 STMR × 28 PF (EFSA, 2011) |
| Brewer's grain dried(b) | 0.07 STMR × 3.3 PF (EFSA, 2011) | 0.07 STMR × 3.3 PF (EFSA, 2011) |
| Citrus dried pulp(a) | 0.5 STMR × 2.5 PF (EFSA, 2011) | 0.5 STMR × 2.5 PF (EFSA, 2011) |
| Distiller's grain dried(b) | 0.07 STMR × 3.3 PF (EFSA, 2011) | 0.07 STMR × 3.3 PF (EFSA, 2011) |
| Peanut meal(b)       | 0.04 STMR × 2 PF (EFSA, 2011) | 0.04 STMR × 2 PF (EFSA, 2011) |
| Potato process waste(b) | 0.02 STMR × 20 PF (EFSA, 2011) | 0.02 STMR × 20 PF (EFSA, 2011) |
| Potato dried pulp(b) | 0.04 STMR × 38 PF (EFSA, 2011) | 0.04 STMR × 38 PF (EFSA, 2011) |
| Soybean meal(b)      | 0.03 STMR × 1.3 PF (EFSA, 2011) | 0.03 STMR × 1.3 PF (EFSA, 2011) |
| Soybean hulls(b)     | 0.26 STMR × 13 PF (EFSA, 2011) | 0.26 STMR × 13 PF (EFSA, 2011) |
| Sunflower meal(b)    | 0.08 STMR × 2.0 PF (EFSA, 2011) | 0.08 STMR × 2.0 PF (EFSA, 2011) |
| Wheat gluten meal(b) | 0.04 STMR × 1.8 PF (EFSA, 2011) | 0.04 STMR × 1.8 PF (EFSA, 2011) |
| Wheat milled by-products(b) | 0.14 STMR × 7 PF (EFSA, 2011) | 0.14 STMR × 7 PF (EFSA, 2011) |

Risk assessment residue definition: Pyraclostrobin
STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): For apple pomace wet and citrus dried pulp, a processing factor of 2.5 was included in the calculation to consider the potential concentration of residues in these commodities.
(b): For beet sugar dried pulp, beet sugar ensiled pulp, brewer’s grain dried, distiller’s grain dried, peanut meal, potato process waste, potato dried pulp, soybean meal, soybean hulls, sunflower meal, wheat gluten meal and wheat milled-by-products, in the absence of processing factors supported by data, default processing factors of 18, 3, 28, 3.3, 3.3, 2, 20, 38, 1.3, 13, 2, 1.8 and 7 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

D.2. Consumer risk assessment

| Commodity                           | Chronic risk assessment | Acute risk assessment |
|-------------------------------------|-------------------------|-----------------------|
|                                     | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Soyabean                            | 0.02                    | STMR (EFSA, 2011)     | 0.02                | STMR (EFSA, 2011)     |
| Swine, Bovine, Sheep, Goat: meat    | 0.05                    | STMR (see Table B.2.2.1) | 0.05               | HR (see Table B.2.2.1) |
| Swine, Bovine, Sheep, Goat: fat     | 0.05                    | STMR (see Table B.2.2.1) | 0.05               | HR (see Table B.2.2.1) |
| Swine, Bovine, Sheep, Goat: kidney  | 0.05                    | STMR (see Table B.2.2.1) | 0.05               | HR (see Table B.2.2.1) |
| Swine, Bovine, Sheep, Goat: liver   | 0.2                     | STMR (see Table B.2.2.1) | 0.2                | HR (see Table B.2.2.1) |
| Poultry: meat, fat, liver, kidney   | 0.05                    | MRL (Regulation (EU) 2017/1016) | 0.05               | MRL (Regulation (EU) 2017/1016) |
| Milk                                | 0.07                    | STMR (see Table B.2.2.1) | 0.07               | STMR (see Table B.2.2.1) |
| Egg                                 | 0.05                    | MRL (Regulation (EU) 2017/1016) | 0.05               | MRL (Regulation (EU) 2017/1016) |
| Other commodities                   | See previous assessments (EFSA, 2011, 2012, 2013, 2014a,b, 2016, 2017) | –                     | Acute risk assessment performed only for the commodities under assessment |
## 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-yloxymethyl]-N-methoxycarbanilate | ![Structural formula](image1) |
|                                       | O=\text{C}(\text{OC})\text{N}(\text{OC})c1cccc1COc1ccn(n1)c1ccc(Cl)cc1 |                                  |
|                                       | HZRSNVGNWUDEFX-UHFFFAOYSA-N                     |                                  |
| Desmethoxy metabolite (500M07, BF 500-3) | methyl [2-[(4-chlorophenyl)-1H-pyrazol-3-yl oxy]methyl]phenyl[carbamate | ![Structural formula](image2) |
|                                       | O=\text{C}(\text{OC})\text{Nc1cccc1COc1ccn(n1)c1ccc(Cl)cc1 |                                  |
|                                       | SEUOYURJKYLAPC-UHFFFAOYSA-N                     |                                  |
| 500M04                                | 1-(4-chlorophenyl)-1H-pyrazol-3-ol               | ![Structural formula](image3) |
|                                       | Clc1ccc(cc1)n1ccc(O)n1                          |                                  |
|                                       | DRENHOMDLNJD0G-UHFFFAOYSA-N                     |                                  |
| 500M49                                | methyl [2-(hydroxymethyl)phenyl]carbamate         | ![Structural formula](image4) |
|                                       | O=\text{C}(\text{OC})\text{Nc1cccc1CO}         |                                  |
|                                       | QNCPLXCDKFGEK-UHFFFAOYSA-N                     |                                  |
| Pyraclostrobin                        | methyl 2-[1-(4-chlorophenyl)-1H-pyrazol-3-yloxymethyl]-N-methoxycarbanilate | ![Structural formula](image5) |
|                                       | O=\text{C}(\text{OC})\text{Nc1cccc1COc1ccn(n1)c1ccc(Cl)cc1 |                                  |
|                                       | HZRSNVGNWUDEFX-UHFFFAOYSA-N                     |                                  |

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

<sup>(a)</sup>: ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(b)</sup>: ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).