Setting of import tolerances for mandestrobin in strawberries and table and wine grapes

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Sumitomo Chemical Agro Europe SAS submitted a request to the competent national authority in Austria to set an import tolerance for the active substance mandestrobin in strawberries, table grapes and wine grapes. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposals for the crops under consideration. Adequate analytical methods for enforcement are available to control the residues of mandestrobin in plant matrices under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of mandestrobin according to the reported agricultural practices is unlikely to present a risk to consumer health.

Keywords: mandestrobin, strawberry, grapes, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Sumitomo Chemical Agro Europe SAS submitted an application to the competent national authority in Austria (evaluating Member State (EMS)) to set import tolerances for the active substance mandestrobin in rapeseeds, strawberries and table and wine grapes. 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 23 January 2017. The EMS proposed to raise the existing European Union maximum residue levels (EU MRLs) for mandestrobin in all commodities under consideration.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On 26 March 2018, the EMS submitted a final revised evaluation report (Austria, 2017), which replaced the previously submitted evaluation report. Since missing information was still identified for specific parts of the application, the applicant took the decision to take forward only those uses that were fully supported by data, therefore on 2 May 2018 the applicant informed EMS and EFSA as regards the wish to withdraw the MRL request for rapeseeds, maintaining the MRL request for strawberries and grapes.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessment and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of mandestrobin following foliar application was investigated in crops belonging to the pulses/oilseeds (oilseed rape), cereals/grasses (wheat) and leafy (lettuces) crop groups.

Studies investigating the effect of processing on the nature of mandestrobin (hydrolysis studies) demonstrated that the active substance is stable. Studies on the effects of processing on the nature of the metabolites De-Xy-S-2200, 4-OH-S-2200 and 2-CH₂OH-S-2200 have not been submitted and are currently not required, considering low residues of metabolites in raw commodities and low consumer exposure to mandestrobin residues.

For the import tolerance requests on the crops under consideration, the investigation of residues in rotational crops and livestock is not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites, the residue definitions for plant products were proposed as mandestrobin for enforcement and sum of mandestrobin, De-Xy-S-2200, 4-OH-S-2200 conjugate, 2-CH₂OH-S-2200 conjugate, expressed as mandestrobin for risk assessment. These residue definitions are applicable to primary crops.

EFSA concluded that for the crops assessed in this application, metabolism of mandestrobin in primary crops has been sufficiently addressed and that the previously derived residue definitions are applicable.

A sufficiently validated analytical method based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) is available to quantify residues in the crops 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 crops assessed (limit of quantification (LOQ)).

The available residue trials are sufficient to derive an MRL proposal for mandestrobin at 5 mg/kg in table and wine grapes and at 3 mg/kg in strawberries.

The derived processing factors for grape juice and raisins were based on one study only for which processing details were not provided and therefore processing factors are not proposed. A concentration of residues was observed in both processed commodities.

The toxicological profile of mandestrobin was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.19 mg/kg body weight (bw) per day. An acute reference dose (ARDF) was deemed not necessary on the basis of the low acute toxicity profile of mandestrobin. The toxicological properties of the metabolites included in the residue definition for risk assessment were assessed in the framework of the EU pesticides peer review and the metabolites De-Xy-S-2200 and 4-OH-S-2200 are covered by the toxicological profile of the parent mandestrobin. The metabolite 2-CH₂OH-S-2200 is not covered by the toxicological properties of the parent compound; however, this metabolite was not detected at levels at or above the LOQ in the supervised crop field trials for the commodities under consideration. In case the metabolite 2-CH₂OH-S-2200 is detected in commodities assessed in future MRL applications, then additional studies addressing the toxicological properties of this metabolite may be required.
The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The long-term exposure assessment was performed using for table and wine grapes the supervised trials median residue (STMR) value derived according to the risk assessment residue definition, whereas for strawberries a conversion factor (CF) from enforcement to risk assessment was applied to the STMR value which was derived for the enforcement residue definition. For several stone fruits, the risk assessment values from the previous EFSA assessment were used to refine the exposure calculation. For the remaining commodities, the existing EU MRLs were selected as input values. A CF for enforcement to risk assessment was not necessary because currently all existing EU MRLs are set at the LOQ. The highest estimated long-term dietary intake was 3.2% of the ADI (FR all population diet). The contribution of residues in wine grapes accounted for 2.9% of the ADI (FR all population diet).

Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of mandestrobin according to the reported agricultural practices is unlikely to present a risk to consumer 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\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|------------|-------------------------|-------------------------|-----------------------|
| 0151000        | Grapes     | 0.01*                   | 5.0                     | The submitted data are sufficient to derive an import tolerance (CAN GAP). Risk for consumers unlikely |
| 0152000        | Strawberries | 0.01*                  | 3.0                     |                       |

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.
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Assessment

The detailed description of the existing use of mandestrobin authorised in Canada on strawberries and table and wine grapes, which is the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Mandestrobin is the ISO common name for (RS)-2-methoxy-N-methyl-2-[a-(2,5-xylyloxy)-o-toly] acetamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Mandestrobin is a new active substance that was evaluated in the framework of Regulation (EC) No 1107/2009 with Austria designated as rapporteur Member State (RMS) for the representative use as a spray application on oilseed rape. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2015). Mandestrobin was approved for the use as a fungicide on 9 December 2015.

The EU MRLs for mandestrobin are established in Annex II of Regulation (EC) No 396/2005. The MRL review required under Article 12 of Regulation (EC) No 396/2005 was addressed by the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance mandestrobin (EFSA, 2015). Currently, Codex MRLs have not been established for mandestrobin. EFSA has issued one reasoned opinion on the modification of MRLs for mandestrobin in apricots, cherries, peaches/nectarines and plums (EFSA, 2018). The proposals from this reasoned opinion have been recently implemented in EU MRL legislation. The current MRL for grapes applicable in Canada is 5 mg/kg; for strawberries, the Canadian MRL is 3 mg/kg.

In accordance with Article 6 of Regulation (EC) No 396/2005, Sumitomo Chemical Agro Europe SAS submitted an application to the competent national authority in Austria (evaluating Member State, EMS) to set import tolerances for the active substance mandestrobin in rapeseeds, strawberries and table and wine grapes. 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 23 January 2017. The EMS proposed to raise the existing EU MRLs for mandestrobin in all commodities under consideration.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On 26 March 2018, the EMS submitted a final revised evaluation report (Austria, 2017), which replaced the previously submitted evaluation report. Since missing information was still identified for specific parts of the application, the applicant took the decision to take forward only those uses that were fully supported by data, therefore on 2 May 2018 the applicant informed EMS and EFSA as regards the wish to withdraw the MRL request for rapeseeds, maintaining the MRL request for strawberries and grapes.

EFSA based its assessment on the updated evaluation report submitted by the EMS (Austria, 2017), the DAR (and its addendum) (Austria, 2014, 2015) prepared under Regulation (EC) 1107/2009, the Commission review report on mandestrobin (European Commission, 2015), the conclusion on the peer review of the pesticide risk assessment of the active substance mandestrobin (EFSA, 2015), as well as the conclusions from a previous EFSA opinion on mandestrobin (EFSA, 2018).

For this application, the data requirements established in Regulation (EU) No 283/2013 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). 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 546/2011⁶.

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 (Austria, 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.

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 mandestrobin in primary crops was assessed in the EU pesticides peer review on the basis of studies performed with foliar application in crops belonging to the pulses/oilseeds (oilseed rapes), cereals/grasses (wheat) and leafy (lettuce) crop groups (EFSA, 2015).

Mandestrobin was a major component of the residue in all crops. The R/S ratio of mandestrobin remained approximately 1:1 indicating no R/S isomerisation in all tested crops. Major metabolites (>10% total radioactive residue (TRR)) were identified as 4-OH-S-2200 (conjugated), 2-CH2OH-S-2200 (conjugated) and De-Xy-S-2200. No additional studies on crop metabolism were submitted within the present application.

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 effects of processing on the nature of mandestrobin residues were assessed in the EU pesticides peer review. Studies showed that mandestrobin was stable under conditions representing pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2015). Studies on the effects of processing on the nature of metabolites De-Xy-S-2200, 4-OH-S-2200 and 2-CH2OH-S-2200 have not been submitted and are currently not required, considering low residues of metabolites in raw commodities and the low consumer exposure to mandestrobin residues.

1.1.4. Methods of analysis in plants

Methods of analysis for monitoring of residues in plants were assessed in the EU pesticide peer review and the liquid chromatography with tandem mass spectrometry (LC–MS/MS) method is validated for quantification of residues in the crops assessed (high acid content matrices) and in matrices with high water and high starch content at the limit of quantification (LOQ) of 0.01 mg/kg. For the determination of residues in high oil content matrices, a DFG S19 method using gas chromatography with mass spectrometry (GC–MS) is applicable at the validated LOQ of 0.01 mg/kg (EFSA, 2015).

1.1.5. Stability of residues in plants

Studies on the storage stability of mandestrobin and the metabolites De-Xy-S-2200, 4-OH-S-2200, 2-CH2OH-S-2200 performed on rapeseeds (high oil content commodity), lettuces (high water content commodity), barley grain (high starch content commodity) and straw were assessed in the EU pesticides peer review and acceptable storage stability was demonstrated for all compounds for at least 12 months when stored at <−18°C (EFSA, 2015).

⁶ 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.
Additional storage stability data on oranges (high acid content commodity) and dried bean (high protein content commodity) was submitted and assessed in the previous EFSA reasoned opinion (EFSA, 2018). The same study was submitted under the current MRL application with longer storage intervals investigated. Results indicated that mandestrobin and its metabolite De-XY-S-2200 are stable in both matrices for 12 months when stored at T°< −18°C. The freezer storage stability of metabolites 4-OH-S-2200 and 2-CH2OH-S-2200 was demonstrated in high protein content matrices for 12 months and in high acid content matrices for 26 months (Austria, 2017).

In addition, the storage stability of incurred residues of mandestrobin and De-XY-S-2200 was investigated in trial samples of strawberries, grapes, grape juice and raisins when stored at −20°C (Austria, 2018). In strawberries and grapes, the stability of both compounds was demonstrated for a period up to ca. 19 and 18 months, respectively. Mandestrobin and De-XY-S-2200 were stable for 7 months in juice and for ca. 13 and 15 months, respectively, in raisins. An increase of De-XY-S-2,200 residues in raisins over time was observed.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in plant metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products, and the capabilities of enforcement analytical methods, the following residue definitions were proposed in the EU pesticides peer review (EFSA, 2015):

- residue definition for enforcement: mandestrobin
- residue definition for risk assessment: sum of mandestrobin, De-XY-S-2200, 4-OH-S-2200 conjugate, 2-CH2OH-S-2200 conjugate, expressed as mandestrobin.

The toxicological properties of the metabolites included in the residue definition for risk assessment were assessed in the framework of the EU pesticides peer review and the metabolites De-XY-S-2200 and 4-OH-S-2200 are covered by the toxicological profile of the parent mandestrobin. The metabolite 2-CH2OH-S-2200 is not covered by the toxicological properties of the parent compound; however, this metabolite was not detected at levels at or above the LOQ in the supervised crop field trials for the commodities under consideration. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition. Taking into account the uses assessed in this application, EFSA concluded that these residue definitions are appropriate for the crops under assessment and no modification is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Table and wine grapes

In support of the authorised Good Agricultural Practice (GAP) in Canada, the applicant submitted in total 16 residue trials on table and wine grapes, which were performed in 2011 and 2012 in the United States (12 trials) and Canada (4 trials). One Canadian trial was disregarded as in compliant in terms of application rate and number of applications. In four trials from the USA, a parallel plot was treated with an exaggerated application rate and data from one plot were used to obtain information for processing studies (juice, raisins).

Residue trial samples were analysed for mandestrobin and its metabolites De-XY-S-2200, 4-OH-S-2200 conjugate and 2-CH2OH-S-2200 conjugate. The analytical methods have been sufficiently validated at the LOQ of 0.02 mg/kg for the determination of each compound individually (Austria, 2017). The residue data for risk assessment were expressed as total parent mandestrobin, applying the molecular weight factors.

Residues of mandestrobin ranged from 0.47 to 3.46 mg/kg, De-XY-S-2200 and 4-OH-S-2200 ranged from < 0.02 to 0.04 mg/kg and residues of 2-CH2OH-S-2200 were below the LOQ of 0.02 mg/kg.

The residue trial samples of grapes before analysis were stored frozen for 9 months (12 USA trials) to 17 months (3 CAN trials) for analysis of mandestrobin and De-XY-S-2200 and for 15 months (12 USA trials) to 26 months (3 CAN trials) for the analysis of 4-OH-S-2200 and 2-CH2OH-S-2200 conjugates. The sample storage intervals are covered by available storage stability studies.

The residue data are sufficient to derive an MRL proposal of 5 mg/kg for mandestrobin in table and wine grapes in support of the authorised use in Canada.
Strawberries

In support of the authorised GAP in Canada, the applicant submitted in total 10 GAP-compliant residue trials on strawberries, which were performed in 2011 and 2012 in the USA (8 trials) and Canada (2 trials). In two trials, a parallel plot was treated with double the authorised application rate to provide information on the magnitude of relevant metabolites in the crop when treated at higher application rates of the active substance.

Residue trial samples were analysed for mandestrobin and its metabolites De-Xy-S-2200 in all 10 trials and in two trials for residues of 4-OH-S-2200 conjugate and 2-CH2OH-S-2200 conjugate. The analytical methods have been sufficiently validated at the LOQ of 0.02 mg/kg for the determination of each compound individually (Austria, 2017).

Residues of mandestrobin ranged from 0.45 to 2.01 mg/kg, metabolite De-Xy-S-2200 accounted for < 0.02 to 0.02 mg/kg and metabolites 2-CH2OH-S-2200 and 4-OH-S-2200 were below the LOQ of 0.02 mg/kg.

The residue trial samples of strawberries before analysis were stored frozen for 13 months (8 USA trials) to 19 months (2 CAN trials) for the analysis of mandestrobin and De-Xy-S-2200, and for 16 months for the analysis of metabolites CH2OH-S-2200 and 4-OH-S-2200. The sample storage intervals are covered by available storage stability studies.

It is noted that only two trials on strawberries provide information on the occurrence of metabolites 2-CH2OH-S-2200 and 4-OH-S-2200, whereas such data should have been provided for all trials to derive the input residue values for risk assessment. The average conversion factor (CF) of 1.10 from enforcement to risk assessment was derived from these two trials and it is supported by the CF derived for grapes, which is within the same range (1.06) and reflects similar proportion between parent and metabolites at a longer (more critical in terms of metabolite burden) preharvest interval (PHI) of 10 days. In addition, strawberry samples taken from the overdosed trial plots demonstrated residues of these metabolites to be at or below the LOQ. Therefore, EFSA accepted the lack of a full residue data set. To derive values for the risk assessment, the CF of 1.10 will be applied.

The residue data are sufficient to derive an MRL proposal of 3 mg/kg for mandestrobin in strawberries in support of the authorised use in Canada.

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

In the framework of the current application, the applicant submitted data on residues in grape juice and raisins (Austria, 2017). In one trial, grapes were treated three times at an exaggerated application rate of ca. 2 kg/ha and fruits were processed into juice and raisins. A concentration of residues was observed both in juice (processing factor (PF) 1.4) and raisins (PF 1.9). Since data were derived from one study only and no details on the technological processes were provided, the derived processing factors are not proposed for enforcement.

1.2.4. Proposed MRLs

In support of the authorised use of mandestrobin in Canada, an MRL of 5 mg/kg is derived for table and wine grapes and an MRL of 3 mg/kg is derived for strawberries.

2. Residues in livestock

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

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).
The toxicological reference value for mandestrobin used in the risk assessment (i.e. acceptable daily intake (ADI) value of 0.19 mg/kg body weight (bw) per day) was derived in the framework of the EU pesticides peer review (EFSA, 2015). The derivation of an acute reference dose (ARfD) was deemed not necessary on the basis of the low acute toxicity profile of mandestrobin. The toxicological properties of the metabolites included in the residue definition for risk assessment were assessed in the framework of the EU pesticides peer review. The metabolites De-Xy-S-2200 and 4-OH-S-2200 conjugate are covered by the toxicological profile of the parent active substance. It was concluded that the metabolite 2-CH₂OH-S-2200 (also included as a conjugate in the residue definition for risk assessment) is not covered by the toxicological studies (EFSA, 2015). However, the metabolite 2-CH₂OH-S-2200 was not detected at levels at or above the LOQ in the supervised crop field trials of grapes and in two trials of strawberries (including data from an overdosed plot) and therefore further consideration is not required in the framework of the current MRL application. In case the metabolite 2-CH₂OH-S-2200 is detected in commodities assessed in future MRL applications, then additional studies addressing the toxicological properties of this metabolite may be required.

The long-term exposure assessment was performed taking into account the STMR values derived for grapes and strawberries assessed in this application. For grapes, the STMR value derived according to the risk assessment residue definition was used as an input value, whereas for strawberries the CF from enforcement to risk assessment of 1.1 was applied to the STMR value derived for the enforcement residue definition. For several stone fruits, the risk assessment values from the previous EFSA assessment were available and thus used as input values for refined exposure calculation (EFSA, 2018).

For the remaining commodities covered by the Commission Regulation (EU) 2016/486, the existing EU MRLs were selected as input values. A CF for enforcement to risk assessment was not necessary because currently all existing EU MRLs are set at the LOQ. The complete list of input values is presented in Appendix D.1.

The highest estimated long-term dietary intake accounted for 3.2% of the ADI (FR all population diet). 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 B.3. The residues of mandestrobin in wine grapes account for up to 2.9% of the ADI (FR all population diet).

EFSA concluded that the long-term intake of residues of mandestrobin in table and wine grapes and strawberries resulting from the authorised uses in Canada 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 strawberries and grapes to accommodate the authorised uses of mandestrobin in Canada. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of mandestrobin according to the reported agricultural practices is unlikely to present a risk to consumer health.

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 |
| CF | conversion factor for enforcement to risk assessment residue definition |
| CS | capsule suspension |
| CV | coefficient of variation (relative standard deviation) |
| DAR | draft assessment report |
| DAT | days after treatment |
| EMS | evaluating Member State |
| FAO | Food and Agriculture Organization of the United Nations |
| GAP | Good Agricultural Practice |
| GC-MS | gas chromatography with mass spectrometry |
| HR | highest residue |
| IEDI | international estimated daily intake |
| InChIKey | International Chemical Identifier Key |
| ISO | International Organisation for Standardisation |
| IUPAC | International Union of Pure and Applied Chemistry |
| LC | liquid chromatography |
| Acronym | Description |
|---------|-------------|
| 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 |
| RD      | residue definition |
| RMS     | rapporteur Member State |
| SANCO   | Directorate-General for Health and Consumers |
| SC      | suspension concentrate |
| SEU     | southern Europe |
| SMILES  | simplified molecular-input line-entry system |
| STMR    | supervised trials median residue |
| TRR     | total radioactive residue |
## 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 | Remarks |
|-----------------------|-------------------------|-----------------|-----------------------------------|-------------|-----------------|-------------------------------|---------|
|                       |                         |                 |                                   | Type\(^{(b)}\) Conc. a.s. Method kind | Range of growth stages and season\(^{(c)}\) Number min–max | Interval between application (min) | g a.s./hl min–max | Water L/ha min–max | Rate Unit | PHI (days)\(^{(d)}\) | |
| Table and wine grapes | Canada                  | F               | Botrytis bunch rot/ grey mould (Botrytis cinerea) | SC 479.3   Foliar spray | n.a 3               | 10 days                       | 420 g/ha 10 |
| Strawberries          | Canada                  | F               | Botrytis grey mould (Botrytis cinerea) | SC 479.3   Foliar spray | n.a 4               | 7–14 days                     | 420 g/ha 0  |

**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 pre-harvest interval.
### Appendix B – List of end points

#### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Leafy crops                       | Lettuces    | Foliar; 2 × 800 g a.s./ha | 5 DAT₁, 5 DAT₂ | [phenoxy-¹⁴C]- and [benzyl-¹⁴C]-mandestrobin EFSA (2015) |
| Cereals/grass                     | Wheat       | Foliar; 1 × 300 g a.s./ha | 7, 14, 104 | [phenoxy-¹⁴C]- and [benzyl-¹⁴C]-mandestrobin EFSA (2015) |
| Pulses/oilseeds                  | Oilseed rapeseeds | Foliar; 2 × 400 g a.s./ha | 14, 40 14, 54 | [phenoxy-¹⁴C]- and [benzyl-¹⁴C]-mandestrobin EFSA (2015) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|--------------------------------------|-------------|---------|----------------|----------|----------------|
| Root/tuber crops                    | Carrot      | Bare soil; 1 × 1.6 kg a.s./ha | 30, 120, 365 | [phenoxy-¹⁴C]- and [benzyl-¹⁴C]-mandestrobin EFSA (2015) |
| Leafy crops                         | Lettuce     | Bare soil; 1 × 1.6 kg a.s./ha | 30, 120, 365 | [phenoxy-¹⁴C]- and [benzyl-¹⁴C]-mandestrobin EFSA (2015) |
| Cereal (small grain)                | Wheat       | Bare soil; 1 × 1.6 kg a.s./ha | 30, 120, 365 | [phenoxy-¹⁴C]- and [benzyl-¹⁴C]-mandestrobin EFSA (2015) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/source |
|------------------------------------------|------------|--------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)     | Yes        |        | [phenoxy-¹⁴C]- mandestrobin (EFSA, 2015) Metabolites 2-CH₂OH-S-2200, 4-OH-S-2200 and De-Xy-S-2,200 not investigated |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes        |        | [phenoxy-¹⁴C]- mandestrobin (EFSA, 2015) Metabolites 2-CH₂OH-S-2200, 4-OH-S-2200 and De-Xy-S-2,200 not investigated |
| Sterilisation (20 min, 120°C, pH 6)     | Yes        |        | [phenoxy-¹⁴C]- mandestrobin (EFSA, 2015) Metabolites 2-CH₂OH-S-2200, 4-OH-S-2200 and De-Xy-S-2,200 not investigated |
Can a general residue definition be proposed for primary crops?  
Yes  EFSA (2015)

Rotational crop and primary crop metabolism similar?  
Yes  EFSA (2015)

Residue pattern in processed commodities similar to residue pattern in raw commodities?  
Yes  EFSA (2015)

Plant residue definition for monitoring (RD-Mo)  
Mandestrobin

Plant residue definition for risk assessment (RD-RA)  
Sum of mandestrobin, De-Xy-S-2200, 4-OH-S-2200 conjugate, 2-CH₂OH-S-2200 conjugate, expressed as mandestrobin

Conversion factor (monitoring to risk assessment) for oilseed rape: 4 (EFSA, 2015)  
Conversion factor for strawberries: 1.1 (Austria, 2017)

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)  
Matrices with high oil content (oilseed rape seeds): GC-MS (DFG S19), LOQ 0.01 mg/kg  
Matrices with high water (peaches), high acid (grapes) and high starch content (cereal grain): LC-MS/MS (QuEChERS), LOQ 0.01 mg/kg  
(EFSA, 2015)
### Stability of residues in plants

| Plant products (available studies) | Category                     | Commodity     | T (°C) | Stability period Value | Compounds covered | Comment/source |
|------------------------------------|------------------------------|---------------|--------|------------------------|-------------------|---------------|
|                                    | High water content           | Lettuces      | –18    | 12 Months              | Mandestrobin, De-Xy-S-2200, 4-OH-S-2200, 2-CH2OH-S-2200 | EFSA (2015)     |
|                                    | High oil content             | Rapeseeds     | –18    | 12 Months              | Mandestrobin, De-Xy-S-2200 |               |
|                                    | High starch                  | Barley grain  | –18    | 12 Months              | 4-OH-S-2200, 2-CH2OH-S-2200 |               |
|                                    | High acid                    | Oranges       | –18    | 12 Months              | Mandestrobin, De-Xy-S-2200 | Austria (2017) |
|                                    |                              |              | –18    | 26 Months              | 4-OH-S-2200, 2-CH2OH-S-2200 |               |
|                                    |                              | Strawberries  | –20    | 19 Months              | Mandestrobin and De-Xy-S-2200 (incurred residues) |               |
|                                    |                              | Grapes        | –20    | 18 Months              | Mandestrobin and De-Xy-S-2200 (incurred residues) |               |
|                                    | High protein                 | Beans         | –18    | 12 Months              | Mandestrobin De-Xy-S-2200, 4-OH-S-2200, 2-CH2OH-S-2200 | Austria (2017) |
|                                    | Others                       | Barley straw  | –18    | 12 Months              | Mandestrobin, De-Xy-S-2200, 4-OH-S-2200, 2-CH2OH-S-2200 | EFSA (2015)     |
|                                    |                              | Grape juice   | –20    | 7 Months               | Mandestrobin and De-Xy-S-2200 (incurred residues) | Austria (2017) |
|                                    |                              | Raisins       | –20    | 13 Months              | Mandestrobin (incurred residues) |               |
|                                    |                              |              | –20    | 15 Months              | De-Xy-S-2200 (incurred residues) |               |
### 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) | CF<sup>(e)</sup> |
|------------------------|-------------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------------------|---------------------------|----------------|
| Table and wine grapes  | USA/CAN                       | Mo: 2.43; 0.74; 3.46; 1.86; 1.35; 1.31; 0.79; 1.21; 1.45; 1.42; 1.0; 1.96; 0.47; 1.04; 1.08 RA: 2.50; 0.81; 3.58; 1.95; 1.44; 1.39; 0.86; 1.28; 1.52; 1.49; 1.07; 2.03; 0.54; 1.11; 1.15 De-Xy-S-2200: 7 × < 0.02; 7 × 0.02; 0.04 mg/kg 2-CH<sub>2</sub>OH-S-2200: 15 × < 0.02 mg/kg 4-OH-S-2200: 8 × < 0.02, 3 × 0.02; 0.03; 3 × 0.04 mg/kg | Residue trials on table and wine grapes compliant with GAP | 5.0                    | Mo: 3.46                 | RA: 3.58                  | Mo: 1.31 |
|                        |                               |                                                              |                                                                                  |                        |                          |                           | 1.06            |
| Strawberries           | USA/CAN                       | Mo: 0.48; 2.04; 0.70; 0.45; 1.18; 0.81; 0.91; 1.21; 1.00; 0.62 RA: - - - - 0.52; 1.25; - - - - - - De-Xy-S-2200: 9 × < 0.02; 0.02 CH<sub>2</sub>OH-S-2200: 2 × < 0.02 4-OH-S-2200: 2 × < 0.02 | Residue trials on strawberries compliant with the GAP In two overdosed plots (4 × ca. 840 g/ha), residues of metabolites were: De-Xy-S-2200: 2 × < 0.02 2-CH<sub>2</sub>OH-S-2200: 2 × < 0.02 4-OH-S-2200: < 0.02; 0.02 | 3.0                    | Mo: 2.04                 | Mo: 0.86                  | 1.10            |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.

(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): Supervised trials median residue according to the residue definition for monitoring.

(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2. Residues in rotational crops

Not relevant for the import tolerance application.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies | Processing Factor (PF) | CF<sub>P</sub><sup>(a)</sup> | Comment/source |
|---------------------|-------------------------|------------------------|------------------|----------------|
| Grapes, juice       | 1                       | 1.40                   | na               | 1.01 Tentative<sup>(b)</sup> |
| Grapes, raisins     | 1                       | 1.93                   | na               | 1.02 Tentative<sup>(b)</sup> |

(a): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.
(b): A tentative PF is derived based on a limited data set.

B.2. Residues in livestock

Not relevant for the import tolerance application for the crops under consideration.

B.3. Consumer risk assessment

An acute exposure was not calculated since the setting of an ARfD has been considered unnecessary by the EU pesticides peer review (EFSA, 2015).

| Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-----------|-------------------------|-------------------------|-----------------------|
| Table grapes | 0.9 % of ADI (DE child diet) | 3.2 % ADI (FR all population diet) | Contribution of crops assessed: Table grapes: 0.9 % of ADI (DE child diet) Wine grapes: 2.9 % of ADI (FR all population diet) Strawberries: 0.3 % of ADI (FR toddler) |

Assumptions made for the calculations

The calculation is based on the median residue levels derived for grapes and strawberries from the supervised residue trials and reflecting the residue situation according to the risk assessment residue definition. For apricots, peaches, cherries and plums the risk assessment values were as derived in the previous EFSA assessment (EFSA, 2018). For the remaining food commodities the existing EU MRLs set in Regulation (EU) 2016/486 were used as input values. A conversion factor (CF) for enforcement to risk assessment was not necessary because currently all existing EU MRLs are set at the LOQ.

B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------------------|------------|-------------------------|-------------------------|-----------------------|
| 0151000             | Grapes     | 0.01*                   | 5.0                     | The submitted data are sufficient to derive an import |
| 0152000             | Strawberries | 0.01*                 | 3.0                     | Tolerance (CAN GAP). 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.
### Appendix C – Pesticide Residue Intake Model (PRIMo)

#### Mandestrobin

| Status of the active substance: | Approved |
|--------------------------------|----------|
| Code no.                       | LOQ (mg/kg bw): Proposed LOQ |
| Toxological end points         | ADI (mg/kg bw per day): 0.19 ARfD (mg/kg bw): n.n. |
| Source of ADI:                 | EFSA Source of ARfD: EFSA |
| Year of evaluation:            | 2015 Year of evaluation: 2015 |

#### Toxicological end points

- **ADI (mg/kg bw per day):** 0.19
- **ARfD (mg/kg bw):** n.n.
- **Source of ADI:** EFSA
- **Year of evaluation:** 2015

#### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI values in % of ADI |
|--------------------------------|-------------------------|
|                                | Minimum – Maximum       |

| Commodity/group of commodities | 1st contributor to MS diet (in % of ADI) |
|--------------------------------|-----------------------------------------|
|                                | Commodity/group of commodities         |

| Commodity/group of commodities | 2nd contributor to MS diet (in % of ADI) |
|--------------------------------|-----------------------------------------|
|                                | Commodity/group of commodities         |

| Commodity/group of commodities | 3rd contributor to MS diet (in % of ADI) |
|--------------------------------|-----------------------------------------|
|                                | Commodity/group of commodities         |

| Commodity/group of commodities | TMDI at LOQ (in % of ADI) |
|--------------------------------|--------------------------|
|                                | Minimum – Maximum        |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs, were below the ADI. A long-term intake of residues of mandestrobin is unlikely to present a public health concern.

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**Setting of import tolerances for mandestrobin in strawberries and grapes**

www.efsa.europa.eu/efsajournal 19 EFSA Journal 2018;16(8):5395
Acute risk assessment/children – refined calculations  

Acute risk assessment is not necessary.  
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

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

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

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

Highest % of ARfD/ADI Commodities

| IESTI 1 |    |    | IESTI 2 |    |    |
|--------|----|----|--------|----|----|
| Highest % of ARfD/ADI Commodities | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/threshold MRL (mg/kg) |

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

Processed commodities

| IESTI 1 |    |    | IESTI 2 |    |    |
|--------|----|----|--------|----|----|
| Highest % of ARfD/ADI commodities | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI commodities | pTMRL/threshold MRL (mg/kg) |

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

* The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
** pTMRL: provisional temporary MRL.
*** pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:
As no ARfD was considered necessary, it is concluded that the short-term intake of Mandestrobin residues is unlikely to present a public health concern.
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

| Commodity                          | Chronic risk assessment | Comment                        |
|------------------------------------|-------------------------|--------------------------------|
| **Risk assessment residue definition**: sum of mandestrobin, De-Xy-S-2200, 4-OH-S-2200 conjugate, 2-CH_2OH-S-2200 conjugate, expressed as mandestrobin |                         |                                |
| Table and wine grapes              | 1.39                    | STMR RA                        |
| Strawberries                       | 0.95                    | STMR Mo * CF (1.1)             |
| Apricots, peaches/nectarines       | 0.53                    | STMR (EFSA, 2018)             |
| Cherries                           | 0.58                    | STMR (EFSA, 2018)             |
| Plums                              | 0.13                    | STMR (EFSA, 2018)             |
| Other commodities of plant and animal origin | MRL | Regulation (EU) 2016/486 |

STMR: supervised trials median residue; Mo: monitoring; CF: conversion factor for enforcement to risk assessment residue definition.
### Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|---------------------------------------|-----------------------|
| **mandestrobin** (R-isomer of mandestrobin) S-2167 | \([R]-2\text{-methoxy}\text{-N-methyl-2-}\text{[\(\alpha\)-2,5-xyloxy-0-toly]}\text{] acetamide CNC(=O)[C@H](OC)c2cccc2COc1cc(c)c1C} | ![Structural formula](image1) |
| **mandestrobin** (S-isomer of mandestrobin) S-2354 | \([S]-2\text{-methoxy}\text{-N-methyl-2-}\text{[\(\alpha\)-2,5-xyloxy-0-toly]}\text{] acetamide CNC(=O)[C@H](OC)c2cccc2COc1cc(c)c1C} | ![Structural formula](image2) |
| **2-CH\(_2\)OH-S-2200** | \((2RS)-2\text{-[2-(2-hydroxymethyl-5-methylphenoxy)methyl]phenyl]-2-methoxy-N-methylacetamide CNC(=O)C(OC)c2cccc2COc1cc(c)c1C} | ![Structural formula](image3) |
| **4-OH-S-2200** | \((2RS)-2\text{-[2-(4-hydroxy-2,5-dimethylphenoxy)methyl]phenyl]-2-methoxy-N-methylacetamide CNC(=O)C(OC)c2cccc2COc1cc(c)c1C} | ![Structural formula](image4) |
| **De-Xy-S-2200** | \((2RS)-2\text{-[2-(2-hydroxymethylphenyl]-2-methoxy-N-methylacetamid OCc1cccc1C(OC)(=O)NC} | ![Structural formula](image5) |

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).