Modification of the existing maximum residue levels for mandestrobin in apricots, cherries, peaches/nectarines and plums

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Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Sumitomo Chemical Agro Europe S.A.S. submitted a request to the competent national authority in France, to modify the existing maximum residue levels (MRL) for the active substance mandestrobin in apricots, cherries, peaches/nectarines and plums. The data submitted in support of the request were found to be sufficient to derive MRL proposals for apricots, cherries, peaches/nectarines and plums. Adequate analytical methods for enforcement are available to control the residues of mandestrobin in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. A short-term dietary risk assessment was not required. Based on the long-term risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of mandestrobin according to the agricultural practices reported in the good agricultural practice (GAP) for applications at growth stages BBCH 77–87 is unlikely to present a risk to consumer health. The GAP for applications at growth stages BBCH 57–69 is not adequately supported by residue trials data. The reliable end points appropriate for use in regulatory risk assessment are presented.

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Keywords: mandestrobin, apricot, cherry, nectarine, peach, plum, 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 S.A.S. submitted an application to the competent national authority in France (evaluating Member State, EMS), to modify the existing maximum residue levels (MRLs) for the active substance mandestrobin in apricots, cherries, peaches/nectarines and plums. France 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 29 August 2017. To accommodate the intended uses of mandestrobin, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 mg/kg for apricots and peaches, 3 mg/kg for cherries and 0.5 mg/kg for plums.

EFSA assessed the application and the evaluation report as required by Article 10 of Regulation 396/2005. Taking into account the conclusions derived by EFSA in the framework of the European Union (EU) pesticide peer review of the active substance mandestrobin under Regulation (EC) No 1107/2009 and the additional data provided by the EMS in the framework of the present 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 (lettuce) 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. As the proposed uses of mandestrobin are on permanent crops and the possible degradation in processed products have been sufficiently addressed and that the previously derived residue definitions are applicable.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and/or degradation products, 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 and processed products.

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

A sufficiently validated analytical method based on liquid chromatography-tandem mass spectrometry detector (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 (LOQ).

The available residue trials are sufficient to derive MRL proposals of 3 mg/kg for cherries, 0.5 mg/kg for plums and a common MRL proposal of 2 mg/kg for apricots and peaches/nectarines, on the basis of the good agricultural practice (GAP) for applications at growth stages BBCH 77–87. The GAP for applications at growth stages BBCH 57–69 is not adequately supported by residue trials data.

Specific processing factors (PFs) for the crops under assessment are not available. Specific studies investigating the magnitude of mandestrobin residues in processed commodities are not required in this case because the contribution of mandestrobin residues in the commodities under consideration to the theoretical maximum daily intake (TMDI) is less than 10% of the acceptable daily intake (ADI), and the metabolite 2-CH₂OH-S-2200 (not covered by the toxicological studies) was at levels below the LOQ. If processing factors were to be required by risk managers, in particular for enforcement purposes, then additional processing studies would be needed.

Residues of mandestrobin in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

The toxicological profile of mandestrobin was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an ADI of 0.19 mg/kg body weight (bw) per day. 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 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 (also included as conjugate in the residue definition for risk assessment) is not covered by the toxicological studies; 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-CH\textsubscript{2}OH-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 taking into account the supervised trials median residue (STMR) values derived for the commodities assessed in this application; for the remaining commodities covered by the MRL regulation, the existing EU MRLs were selected as input values. The highest estimated long-term dietary intake was 0.6% of the ADI.

EFSA concluded that the proposed uses of mandestrobin on apricots, cherries, peaches/nectarines and plums will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers’ health.

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

| Code\(^{(a)}\) | Commodity           | Existing EU MRL\(^{(b)}\) (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|---------------|---------------------|----------------------------------|-------------------------|-------------------------------------------------------------------------------------|
| 140010        | Apricots            | 0.01\(^{*}\)                     | 2                       | The combined submitted data on apricots and peaches are sufficient to derive a common MRL proposal for apricots and peaches/nectarines on the basis of the SEU GAP for applications at growth stages BBCH 77–87. The GAP for applications at growth stages BBCH 57–69 was not supported by sufficient data to derive an MRL proposal. Risk for consumers unlikely. |
| 140020        | Cherries            | 0.01\(^{*}\)                     | 3                       | The MRL proposal reflects the SEU GAP for applications at growth stages BBCH 77–87. The GAP for applications at growth stages BBCH 57–69 was not supported by sufficient data to derive an MRL proposal. Risk for consumers unlikely. |
| 140030        | Peaches/nectarines  | 0.01\(^{*}\)                     | 2                       | The combined submitted data on apricots and peaches are sufficient to derive a common MRL proposal for apricots and peaches/nectarines on the basis of the SEU GAP for applications at growth stages BBCH 77–87. The GAP for applications at growth stages BBCH 57–69 was not supported by sufficient data to derive an MRL proposal. Risk for consumers unlikely. |
| 140040        | Plums               | 0.01\(^{*}\)                     | 0.5                     | The MRL proposal reflects the SEU GAP for applications at growth stages BBCH 77–87. The GAP for applications at growth stages BBCH 57–69 was not supported by sufficient data to derive an MRL proposal. Risk for consumers unlikely. |

\(^{*}\): 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.
\(^{(b)}\): Existing EU MRLs established in Commission Regulation (EU) 2016/486.
Table of contents

Abstract................................................................................................................................................... 1
Summary................................................................................................................................................. 3
Assessment.............................................................................................................................................. 6
1. Residues in plants ........................................................................................................................ 6
   1.1. Nature of residues and methods of analysis in plants.............................................................. 6
   1.1.1. Nature of residues in primary crops ....................................................................................... 6
   1.1.2. Nature of residues in rotational crops .................................................................................... 7
   1.1.3. Nature of residues in processed commodities........................................................................... 7
   1.1.4. Methods of analysis in plants................................................................................................... 7
   1.1.5. Stability of residues in plants.................................................................................................. 7
   1.1.6. Proposed residue definitions................................................................................................... 7
   1.2. Magnitude of residues in plants ................................................................................................. 7
      1.2.1. Magnitude of residues in primary crops.............................................................................. 7
      1.2.2. Magnitude of residues in rotational crops .......................................................................... 8
      1.2.3. Magnitude of residues in processed commodities............................................................... 8
      1.2.4. Proposed MRLs .................................................................................................................... 9
2. Residues in livestock..................................................................................................................... 9
3. Consumer risk assessment ............................................................................................................. 9
4. Conclusion and Recommendations................................................................................................. 10
References............................................................................................................................................... 10
Abbreviations ........................................................................................................................................... 10
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs.............. 12
Appendix B – List of end points ............................................................................................................. 13
Appendix C – Pesticide Residue Intake Model (PRIMo) ................................................................ 19
Appendix D – Input values for the exposure calculations................................................................. 21
Appendix E – Used compound codes ............................................................................................... 22
Assessment

The detailed description of the intended uses of mandestrobin in apricots, cherries, peaches/nectarines and plums, which are 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-[α-(2,5-xylyloxy)-o-tolyl]acetamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Mandestrobin is a new active substance and was evaluated in the framework of Regulation (EC) No 1107/20091 with Austria designated as rapporteur Member State (RMS) for the representative use as a spray application to oilseed rape. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by European Food Safety Authority (EFSA) (EFSA, 2015).

Mandestrobin was approved2 for use as a fungicide on 9 December 2015.

The European Union (EU) MRLs for mandestrobin are established in Annexes II of Regulation (EC) No 396/2005.3 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 based its assessment on the evaluation report submitted by the evaluating Member State (EMS; France, 2017), the DAR and its revision (Austria, 2014, 2015) prepared under Regulation (EC) 1107/2009, and the EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance mandestrobin (EFSA, 2015).

For this application, the data requirements established in Regulation (EU) No 283/20134 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 546/20115.

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, 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 peer review on the basis of studies performed with foliar application in crops belonging to the pulses/oilseeds (oilseed rape), 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-

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1 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
2 Commission Implementing Regulation (EU) 2015/2085 of 18 November 2015 approving the active substance mandestrobin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 302, 19.11.2015, p. 93–9.
3 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 302, 19.11.2015, p. 93–9.
4 Regulation (EC) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 70, 16.03.2005, p. 1–16.
5 Commission Regulation (EC) 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.
2200. No additional studies on crop metabolism were submitted in 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

As the proposed uses of mandestrobin are on permanent crops, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

The effects of industrial processing and/or household preparation were assessed in the EU peer review. Studies on the nature of the residue during processing 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 the metabolites De-Xy-S-2200, 4-OH-S-2200 and 2-CH2OH-S-2200 have not been submitted.

1.1.4. Methods of analysis in plants

Methods of analysis for monitoring of residues in plants were assessed in the EU peer review and the liquid chromatography-tandem mass spectrometry detector (LC-MS/MS) method is validated for quantification of residues in the crops assessed (high water content matrices) with a limit of quantification (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 oilseed rape seed (high oil content commodity), lettuce (high water content commodity), barley grain (dry commodity) and straw were assessed in the EU peer review and stability was demonstrated to be at least 12 months when stored at < −18°C (EFSA, 2015). Additional storage stability studies on orange (whole fruit; high acid commodity) and dried bean (white seeds; high protein commodity) have been submitted in the present MRL application and the stability of mandestrobin and the metabolites De-Xy-S-2200, 4-OH-S-2200 and 2-CH2OH-S-2200 were demonstrated to be at least 9 months in samples stored at < −18°C (France, 2017).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in 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 EFSA Conclusion on the EU 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 same residue definitions are applicable to processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition. Taking into account the proposed use 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

The proposed uses on apricot, cherry, peach/nectarine and plum are based on two common Good Agricultural Practices (GAPs) for distinct use patterns, by application of the pesticide product during the growth stage range of either BBCH 57 – 69 or BBCH 77 – 87. In support of the MRL application, the applicant submitted residue trials performed in apricot, cherry, peach and plum during the 2015 growing season. For apricot, cherry and peach, the residue trials were conducted for each crop at five geographically independent sites located in southern France, Greece, Italy and Spain. For plum, 10 residue trials were conducted at geographically independent sites in southern France, Greece, Italy and
Spain. All trials were performed with two foliar spray applications of a suspension concentrate formulation with an interval of 6 or 7 days.

The submitted residue trials were performed with applications in apricot at BBCH 78-85 and 85-87, in cherry at BBCH 81-85 and 85-87, in peach at BBCH 77-85 and 85-87 and in plum at BBCH 81-87 and 85-87 and are sufficiently compliant with the southern Europe (SEU) GAP for applications in the growth stage range BBCH 77–87 (2 × 262.5 g a.s./ha). The samples in all the submitted residue trials are reported to have been stored under the conditions, for which integrity of residues has been demonstrated. The portion analysed was the flesh after removal of the stone and residues were calculated as whole fruit assuming no residue in stone, in accordance with the parts of the products to which the EU MRLs for stone fruit apply.6 In all submitted residue trials, the samples were analysed for the parent compound, in accordance with the residue definition for enforcement, and for the metabolites De-Xy-S-2200, 4-OH-S-2200 conjugate, 2-CH2OH-S-2200 conjugate, which are included in the residue definition for risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose, with individual LOQs of 0.01 mg/kg for each component of the residue definition.

The metabolite 4-OH-S-2200 was present at levels at or above the LOQ in all trials performed on cherry, in one trial on apricot (at all five preharvest intervals (PHIs)), and in one trial on plum (at two PHIs); this metabolite was at levels below the LOQ in all other trials on apricot and plum and in all trials on peach. Metabolite De-Xy-S-2200 was present at the level of the LOQ in samples from two trials on cherry (at four distinct PHIs); the levels of this metabolite were below the LOQ in all other submitted residue trials. Metabolite 2-CH2OH-S-2200 was at levels below the LOQ in all submitted residue trials. Where peak residues were detected after the GAP minimum PHI, the highest residue value was selected for the purpose of MRL calculation, and the highest summed residue value was selected for the purpose of risk assessment.

The GAP for applications at earlier growth stages (BBCH 57-69; 2 × 225 g a.s./ha) is not supported by the residue trials. It may be expected that the GAP for applications of the active substance at earlier growth stages, before the formation of fruit and at a lower application rate than performed in the submitted residues trials would likely lead to lower residues of the parent mandestrobin in the fruit at time of harvest; however, for longer PHIs (i.e. for applications at growth stages earlier than BBCH 77), the potential for the metabolite 2-CH2OH-S-2200 (included in the risk assessment residue definition but not covered by the toxicological studies; see also Section 3) to be present at levels higher the LOQ in the fruit at time of harvest cannot be excluded on the basis of the available residue trials data. It therefore cannot be concluded that the GAP for applications at earlier growth stage would lead to the less critical residues situation with regard to residue levels of the metabolite 2-CH2OH-S-2200 and the potential risk to consumer health.

1.2.2. Magnitude of residues in rotational crops

As the proposed uses of mandestrobin are on permanent crops, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Specific processing factors (PFs) for the crops under assessment are not available. Processing studies in plum (juice, puree, canned and dried) were submitted in the present MRL application and gave an indication that residue levels are reduced; but the studies did not allow for the derivation of robust processing factors because the analytical method used has not been validated for the processed commodities (France, 2017). Processing of stone fruit by cooking, canning, juicing and pureeing is not expected to lead to a concentration of residues of mandestrobin or a significant increase in the levels of the metabolites De-Xy-S-2200, 4-OH-S-2200 conjugate, 2-CH2OH-S-2200 conjugate. However, the processing of stone fruits to dried fruits and jamming may result in a concentration of the residues resulting from loss of water in the processed product. Nevertheless, specific processing studies are not required in this case because the contribution of mandestrobin residues in the commodities under consideration to the theoretical maximum daily intake (TMDI) is less than 10% of the acceptable daily intake (ADI) and the metabolite 2-CH2OH-S-2200 (not covered by the toxicological studies) was at

6 Commission Regulation (EU) No 752/2014 of 24 June 2014 amending Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards additions and modification of the examples of related varieties or other products to which the same MRL applies. OJ L 208, 15.7.2014, p. 1–71.
levels below the LOQ. If processing factors were to be required by risk managers, in particular for enforcement purposes, then additional processing studies would be needed.

1.2.4. Proposed MRLs

The available data are sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation on the basis of the GAP for applications at growth stages BBCH 77–87 (see Appendix B.4). It is proposed to derive a common MRL for apricots and peaches/nectarines on the basis of the combined residues data from trials performed on apricot and peach, in accordance with the guidance (European Commission, 2017).

The GAP for applications at growth stages BBCH 57–69 is not supported by residue trials data and the information available was not sufficient to derive MRL proposals or risk assessment values on the basis of this GAP.

In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses in accordance with the GAP for applications at growth stages BBCH 77–87 are likely to pose a consumer health risk.

2. Residues in livestock

The assessment of potential residues in livestock is not required because the crops under consideration in this MRL application are normally used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues.

The toxicological reference value for mandestrobin used in the risk assessment (i.e. ADI value) 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 are covered by the toxicological profile of the parent active substance. It was concluded that the metabolite 2-CH2OH-S-2200 (also included as 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 for the commodities under consideration in the present application (compliant with the GAP for applications at growth stages BBCH 77–87), 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.

A short-term dietary risk assessment was not required considering the toxicological profile of the active substance mandestrobin and the metabolites De-Xy-S-2200 and 4-OH-S-2200, and considering that the metabolite 2-CH2OH-S-2200 (included in the residue definition for risk assessment but not covered by the toxicological studies) was not found at or above the LOQ in the supervised crop field trials for the commodities under consideration.

The long-term exposure assessment was performed taking into account the supervised trials median residue (STMR) values derived for the commodities assessed in this application; for the remaining commodities covered by the MRL regulation, the existing EU MRLs were selected 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. The complete list of input values is presented in Appendix D.2.

The highest estimated long-term dietary intake was 0.6% 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 B.3. EFSA concluded that the long-term intake of residues of mandestrobin resulting from 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 MRL proposals for cherries and plums and to derive a common MRL proposal for apricots and peaches/nectarines.

EFSA concluded that the proposed uses of mandestrobin on apricots, cherries, peaches/nectarines and plums will not result in a consumer exposure exceeding the toxicological reference value and therefore are 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
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
EMS evaluating Member State
GAP Good Agricultural Practice
GC gas chromatography
GC-MS gas chromatography with mass spectrometry
IEDI international estimated daily intake
IESTI international estimated short-term intake
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 mass spectrometry detector
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
STMR supervised trials median residue
TAR total applied radioactivity
TMDI theoretical maximum daily intake
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 | Unit | PHI (days)\(^{(d)}\) | Remarks |
|-----------------------|-------------------------|-------------------|-----------------------------------|-------------|-------------|--------------------------------|------|------------------|---------|
| Stone fruits (peach, nectarine, apricot, plum, cherry) | SEU | F | Monilinia laxa | SC 250 g/L Foliar spray | 57–69 | 2 | 7 | Max. 15 | 500–1500 | 225 g a.s./ha | n.a. | At flowering |
| Stone fruits (peach, nectarine, apricot, plum, cherry) | SEU | F | Monilinia sp. | SC 250 g/L Foliar spray | 77–87 | 2 | 7 | Max. 17.5 | 500–1500 | 262.5 g a.s./ha | 1 | Preharvest |

NEU: northern European Union; SEU: southern European Union; MS: Member State; n.a.: not applicable.

\(^{(a)}\): 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.
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 | Lettuce | Foliar; 2 × 800 g a.s./ha | 5 DAT₁, 5 DAT₂ | [phenoxy-¹⁴C]-mandestrobin EFSA, 2015 |
|                                  | Cereals/grass | Wheat | Foliar; 1 × 300 g a.s./ha | 7, 14, 104 | [phenoxy-¹⁴C]-mandestrobin [benzyl-¹⁴C]-mandestrobin EFSA, 2015 |
|                                  | Pulses/oilseeds | Oilseed rape | Foliar; 2 × 400 g a.s./ha | 14, 40 | [phenoxy-¹⁴C]-mandestrobin [benzyl-¹⁴C]-mandestrobin EFSA, 2015 |

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

As the proposed uses of mandestrobin in the present MRL application are on permanent crops, investigations of residues in rotational crops are not required.
| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|----------------------------------------|------------|--------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)    | Yes        | Parent mandestrobin only. Metabolites 2-CH$_2$OH-S-2200, 4-OH-S-2200 and De-Xy-S-2200 not investigated. EFSA, 2015 |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes        | Parent mandestrobin only. Metabolites 2-CH$_2$OH-S-2200, 4-OH-S-2200 and De-Xy-S-2200 not investigated. EFSA, 2015 |
| Sterilisation (20 min, 120°C, pH 6)    | Yes        | Parent mandestrobin only. Metabolites 2-CH$_2$OH-S-2200, 4-OH-S-2200 and De-Xy-S-2200 not investigated. EFSA, 2015 |

DAT$_1$: Days after first treatment; DAT$_2$: Days after second treatment.

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-CH$_2$OH-S-2200 conjugate, expressed as mandestrobin |
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | Barley grain (dry), grape (acidic), peach (high water): LC–MS/MS, QuEChERS LOQ = 0.01 mg/kg Oilseed rape seeds (high oil): GC–MS, DFG S19 LOQ = 0.01 mg/kg (EFSA, 2015) |
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity               | T (°C) | Stability period | Compounds covered                                                                 | Comment/Source |
|-----------------------------------|-------------------|-------------------------|--------|------------------|-----------------------------------------------------------------------------------|----------------|
|                                   | High water content| Lettuce                 | 18     | 12 month         | Mandestrobin De-Xy-S-2200 4-OH-S-2200 2-CH₂OH-S-2200                           | EFSA, 2015     |
|                                   | High oil content  | Oilseed rape seed       | 18     | 12 month         | Mandestrobin De-Xy-S-2200 4-OH-S-2200 2-CH₂OH-S-2200                           | EFSA, 2015     |
|                                   | High protein content| Dried bean, white seeds| 18     | 9 month          | Mandestrobin De-Xy-S-2200 4-OH-S-2200 2-CH₂OH-S-2200                           | France, 2017   |
|                                   | Dry/High starch   | Barley grain            | 18     | 12 month         | Mandestrobin De-Xy-S-2200 4-OH-S-2200 2-CH₂OH-S-2200                           | EFSA, 2015     |
|                                   | High acid content | Orange                  | 18     | 9 month          | Mandestrobin De-Xy-S-2200 4-OH-S-2200 2-CH₂OH-S-2200                           | France, 2017   |
|                                   | Others            | Straw                   | 18     | 12 month         | Mandestrobin De-Xy-S-2200 4-OH-S-2200 2-CH₂OH-S-2200                           | EFSA, 2015     |
### 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)(b) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|--------------------------------|------------------|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|---------------|-----------------|-------|
| Apricots, peaches/nectarines   | SEU              | Mo: 0.11, 0.25, 0.35(e), 0.48, 1.11(e)                                 | Residue trials compliant with the GAP for applications at BBCH growth stages 77–87 only. The trials on apricot and peach were combined to derive a common MRL for apricots and peaches/nectarines. The metabolite 4-OH-S-2200 was present at levels at or above the LOQ of 0.01 mg/kg in one trial on apricot (at all five PHIs) and below the LOQ in all other trials. Metabolites 2-CH$_2$OH-S-2200 and De-Xy-S-2200 were below the LOQs of 0.01 mg/kg in all trials on apricot and peach. | 2                      | Mo: 1.20       | RA: 1.23         | 1.13  |
|                                |                  | RA: 0.14, 0.28, 0.39(e), 0.51, 1.13(e)                                |                                                                                                                                                                                                               |                        |               |                 |       |
|                                |                  | Peaches                                                             |                                                                                                                                                                                                               |                        |               |                 |       |
|                                |                  | Mo: 0.41, 0.51, 0.64, 0.83, 1.2 RA: 0.44, 0.54, 0.67, 0.86, 1.23       |                                                                                                                                                                                                               |                        |               |                 |       |
| Cherries                       | SEU              | Mo: 0.38, 0.45, 0.52, 1.1, 1.4 RA: 0.41, 0.49, 0.58, 1.16, 1.43       | Residue trials compliant with the GAP for applications at BBCH growth stages 77–87 only. The metabolite 4-OH-S-2200 was present at levels at or above the LOQ of 0.01 mg/kg in all trials. Metabolite De-Xy-S-2200 was present at the level of the LOQ of 0.01 mg/kg in samples from two trials (at four distinct PHIs) and below the LOQ in all other trials. Metabolite 2-CH$_2$OH-S-2200 was below the LOQ of 0.01 mg/kg in all trials. | 3                      | Mo: 1.40       | RA: 1.43         | 1.09  |
|                                |                  |                                                                     |                                                                                                                                                                                                               |                        |               |                 |       |
| Plums                          | SEU              | Mo: 0.06, 0.07, 0.07(e), 0.08, 0.09, 0.11(e), 0.17, 0.20, 0.20, 0.29(e), 0.19(e) | Residue trials compliant with the GAP for applications at BBCH growth stages 77–87 only. The metabolite 4-OH-S-2200 was present at levels at or above the LOQ of 0.01 mg/kg in one trial (at two PHIs) and below the LOQ in all other trials. Metabolites 2-CH$_2$OH-S-2200 and De-Xy-S-2200 were below the LOQs of 0.01 mg/kg in all trials. | 0.5                    | Mo: 0.29       | RA: 0.32         | 1.40  |
|                                |                  | RA: 0.09, 0.10, 0.10(e), 0.11, 0.12, 0.14(e), 0.20, 0.23, 0.23, 0.32(e), 0.32(e) |                                                                                                                                                                                                               |                        |               |                 |       |

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

(e): Peak residue detected after the GAP minimum PHI.

(f): Value identified as an outlier according to Dixon test but included in the MRL and risk assessment calculations since no further explanation is given in study reports.
B.1.2.2. Residues in rotational crops

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

| Not applicable. | As the proposed uses of mandestrobin are on permanent crops, investigations of residues in rotational crops are not required |

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

| Not applicable. | As the proposed uses of mandestrobin are on permanent crops, investigations of residues in rotational crops are not required |

B.1.2.3. Processing factors

Processing studies submitted in the framework of the present MRL application did not allow for the derivation of robust processing factors.

B.2. Residues in livestock

Not relevant as stone fruits are not used for feed purposes.

B.3. Consumer risk assessment

ARfD

Not required (EFSA, 2015)

Highest IESTI, according to EFSA PRIMo

A short-term (acute) dietary risk assessment is not necessary because (1) an ARfD for the active substance mandestrobin has been considered not required due to the toxicological profile, and (2) the metabolite 2-CH₂OH-S-2200 (included in the risk assessment residue definition but not covered by the toxicological studies) was not found at levels at or above the LOQ in the supervised crop field trials for the commodities under consideration.

ADI

0.19 mg/kg bw per day (EFSA, 2015)

Highest IEDI, according to EFSA PRIMo

0.6% ADI (DE child)

Contribution of crops assessed:

- Cherries: 0.1% of ADI
- Apricots: 0.1% of ADI
- Peaches: 0.1% of ADI

Assumptions made for the calculations

The calculation is based on the median residue levels derived for raw agricultural commodities. The risk assessment is based on the available information which indicates that the metabolite 2-CH₂OH-S-2200 (included in the risk assessment residue definition but not covered by the toxicological studies) was not found at significant levels (above the LOQ) in the commodities under consideration. For the remaining commodities covered by the MRL regulation, the existing EU MRLs were selected 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<sup>(b)</sup> (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------------|----------------------------|--------------------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 140010            | Apricots                   | 0.01*                                | 2                       | The combined submitted data on apricots and peaches are sufficient to derive a common MRL proposal for apricots and peaches/nectarines on the basis of the SEU GAP for applications at growth stages BBCH 77-87. The GAP for applications at growth stages BBCH 57-69 was not supported by sufficient data to derive an MRL proposal. Risk for consumers unlikely. |
| 140020            | Cherries                   | 0.01*                                | 3                       | The MRL proposal reflects the SEU GAP for applications at growth stages BBCH 77-87. The GAP for applications at growth stages BBCH 57-69 was not supported by sufficient data to derive an MRL proposal. Risk for consumers unlikely. |
| 140030            | Peaches/nectarines         | 0.01*                                | 2                       | The combined submitted data on apricots and peaches are sufficient to derive a common MRL proposal for apricots and peaches/nectarines on the basis of the SEU GAP for applications at growth stages BBCH 77-87. The GAP for applications at growth stages BBCH 57-69 was not supported by sufficient data to derive an MRL proposal. Risk for consumers unlikely. |
| 140040            | Plums                      | 0.01*                                | 0.5                     | The MRL proposal reflects the SEU GAP for applications at growth stages BBCH 77-87. The GAP for applications at growth stages BBCH 57-69 was not supported by sufficient data to derive an MRL proposal. Risk for consumers unlikely. |

**Enforcement residue definition:** mandestrobin

* MRL: maximum residue level; SEU: southern Europe; BBCH: growth stages of mono- and dicotyledonous plants.
* *: 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.
* (b): Existing EU MRLs established in Commission Regulation (EU) 2016/486.
Appendix C – PESTICIDE Residue Intake Model (PRIMo)

| Commodity/group of commodities | pTMRLs at LOQ (in % of ADI) |
|-------------------------------|-----------------------------|
| Milk and cream                | 0.3                         |
| Potatoes                      | 0.3                         |
| Wheat                         | 0.2                         |
| Cherries                      | 0.2                         |
| Apricots                      | 0.1                         |
| Peaches                       | 0.1                         |
| Sugar beet                    | 0.1                         |

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

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|
| Highest % of ARfD/ADI Commodity | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodity | pTMRL/threshold MRL (mg/kg) |
| --- | --- | --- | --- |
| --- | --- | --- | --- |

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

| No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|-------------------------------------------------|-------------------------------------------------|
| Highest % of ARfD/ADI Processed commodity | pTMRL/threshold MRL (mg/kg) |
| --- | --- |
| --- | --- |

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

** pTMRL: provisional temporary MRL.

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

Conclusion:

As no ARD 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. Livestock dietary burden calculations

Not relevant as apricots, cherries, peaches, nectarines and plums are not used for feed purposes.

D.2. Consumer risk assessment

| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|--------------------------|-----------------------|
|           | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition: sum of mandestrobin, De-Xy-S-2200, 4-OH-S-2200 conjugate, 2-CH₂OH-S-2200 conjugate, expressed as mandestrobin |
| 140010 Apricots | 0.53 | STMR RA (apricot, peach) | | |
| 140020 Cherries | 0.58 | STMR RA | | |
| 140030 Peaches | 0.53 | STMR RA (apricot, peach) | A short-term dietary risk assessment was not required due to the toxicological profile of the active substance mandestrobin and because the metabolite 2-CH₂OH-S-2200 (included in the risk assessment residue definition but not covered by the toxicological studies) was not detected at levels at or above the LOQ in the supervised crop field trials for the commodities under consideration. |
| 140040 Plums | 0.13 | STMR RA | | |
| Other commodities | MRL | MRLs in Commission Regulation (EU) 2016/486 (a) A conversion factor (CF) for enforcement to risk assessment was not necessary because all MRLs are set at the LOQ. | | |

MRL: maximum residue level; LOQ: limit of quantification; STMR: supervised trials median residue; RA: risk assessment.
(a): Commission Regulation (EU) 2016/486 of 29 March 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, fluopyrafurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl- M, pendimethalin and tefluthrin in or on certain products. C/2016/1707. OJ L 90, 6.4.2016, p. 1–66.
## Appendix E – Used compound codes

| Code/trivial name | Chemical name/SMILES notation (a) | Structural formula (a) |
|------------------|----------------------------------|------------------------|
| **mandestrobin** (R-isomer of mandestrobin) | \((R)-2\text{-methoxy-N-methyl-2-[}\alpha\text{-}(2,5\text{-xylyloxy})\text{-o-tolyl}]\text{acetamide}\) | ![Structural formula for (R)-mandestrobin] |
| S-2167 | CNC(\(=\)O)(C@\(\text{H}\))(OC)c2cccccc2COc1cc(C)ccc1C |  |
| **mandestrobin** (S-isomer of mandestrobin) | \((S)-2\text{-methoxy-N-methyl-2-[}\alpha\text{-}(2,5\text{-xylyloxy})\text{-o-tolyl}]\text{acetamide}\) | ![Structural formula for (S)-mandestrobin] |
| S-2354 | CNC(\(=\)O)(C@\(\text{H}\))(OC)c2cccccc2COc1cc(C)ccc1C |  |
| **2-CH\(_2\)OH-S-2200** | \((2\text{RS})\text{-2-[}2\text{-}(2\text{-hydroxymethyl-5\text{-methylphenoxymethyl}})\text{phenyl}\text{-2-methoxy-N-methylacetamide}\) | ![Structural formula for 2-CH\(_2\)OH-S-2200] |
| | CNC(\(=\)O)C(OC)c2cccccc2COc1cc(C)ccc1CO |  |
| **4-OH-S-2200** | \((2\text{RS})\text{-2-[}2\text{-}(4\text{-hydroxy-2,5\text{-dimethylphenoxymethyl}})\text{phenyl}\text{-2-methoxy-N-methylacetamide}\) | ![Structural formula for 4-OH-S-2200] |
| | CNC(\(=\)O)C(OC)c2cccccc2COc1cc(C)c(O)cc1C |  |
| **De-Xy-S-2200** | \((2\text{RS})\text{-2-[}2\text{-}(2\text{-hydroxymethylphenyl}\text{-2-methoxy-N-methylacetamide}\) | ![Structural formula for De-Xy-S-2200] |
| | OCC1cccccc1C(OC)(\(=\)O)NC |  |

(a): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).