Setting of import tolerance for azoxystrobin in sugar beet roots

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Crop Protection AG submitted a request to the competent national authority in Austria to set an import tolerance for the active substance azoxystrobin in sugar beet roots. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposals for sugar beet roots. However, robust processing factors for Annex VI in view of monitoring of residues in processed commodities could not be derived. Adequate analytical methods for enforcement are available to control the residues of azoxystrobin in plant and animal matrices at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of azoxystrobin according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Keywords: azoxystrobin, sugar beet roots, molasses, fungicide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Austria (evaluating Member State, EMS) to set an import tolerance for the active substance azoxystrobin in sugar beet roots. 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 14 May 2020. The EMS proposed to establish MRLs for sugar beet roots imported from the USA at the level of 5 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested from the EMS. On 6 October 2020, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

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

The metabolism of azoxystrobin following foliar application was investigated in crops belonging to the group of fruit crops (grapes), cereals/grass (wheat) and pulses/oilseeds (peanuts). The use under assessment is a post-harvest treatment on sugar beet roots. Considering that azoxystrobin was applied close to harvest in the foliar metabolism studies, the results of the available studies were deemed applicable to cover the post-harvest good agricultural practice (GAP).

Studies investigating the effect of processing on the nature of azoxystrobin (hydrolysis studies) demonstrated that the active substance is hydrolytically stable.

As the use under assessment is a post-harvest application for imported commodities, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies and on the results of hydrolysis studies, the residue definition for enforcement and risk assessment in all plant commodities following foliar application was proposed as azoxystrobin. This residue definition is also deemed appropriate for the post-harvest use on sugar beet roots.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectroscopy (HPLC-MS/MS) are available to quantify residues in the commodities with high water content 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 an MRL proposal of 5 mg/kg for sugar beet roots.

However, it was noted that the imported commodities are not expected to be the sugar beet roots as such as the applicant informed EFSA that the intended commodities for import are refined sugar and molasses, which are processed commodities.

Processing factors (PF) for sugar beet roots processed commodities could not be derived from processing studies provided since only one trial was available. The study indicates a reduction of residue concentration in different processed commodities. Nevertheless, only indicative PFs were derived, which cannot be recommended to be included in Annex VI of Regulation (EC) No 396/2005.

Consequently, although an MRL proposal can be derived in the present opinion, the enforcement of azoxystrobin residues in the imported processed commodities may require additional processing trials on the effect of processing on the magnitude of residues in refined sugar and its by-products (e.g. molasses, dried pulp, ensiled pulp).

The calculated livestock dietary burden resulted to be the same as the previous assessment. Consequently, the outcome of the previous assessment remains valid. EFSA highlights that for all animal commodities except milk and poultry commodities, the current EU MRLs were derived from CXLs (e.g. mammalian liver, kidney, edible offal (0.07 mg/kg) and fat (0.05 mg/kg)). EFSA could not reassess the calculations of the JMPR but notes that the EU livestock dietary burden indicates that lower MRLs would be sufficient to accommodate the existing EU uses of azoxystrobin. The EU livestock dietary burden leads to MRL values at the LOQ in all animal matrices. Furthermore, a risk management decision still needs to be taken on the data gap on general toxicity of the livestock metabolites L1, L4 an L9 and on their impact on current MRLs for fat, liver, kidney and other edible offals of swine and ruminants.
The toxicological profile of azoxystrobin was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.2 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The estimated chronic exposures were compared with the ADI of azoxystrobin. The estimated long-term dietary intake was up to 22% of the ADI (Dutch toddler). The contribution of residues expected in the sugar beet roots does not exceed 5.7% of the ADI. A short-term (acute) risk assessment was not required since no ARfD has been considered necessary for azoxystrobin.

EFSA concluded that the consumer intake of residues of azoxystrobin resulting from the existing uses and the import of commodities resulting from the US authorised use on sugar beet roots is unlikely to present a risk to consumer health.

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

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|------------|------------------------|-------------------------|-----------------------|
| 0900010 | Sugar beet roots | 0.2 | 5 | The submitted data are sufficient to derive an import tolerance MRL proposal on the basis of the US authorised use. No consumer health risk was identified. The MRL proposal is derived for raw sugar beet roots. However, the imported commodities are expected to be refined sugar and molasses (processed commodities). A robust processing factor (PF) for these commodities could not be derived. Therefore, enforcement of azoxystrobin residues in the imported processed commodities is uncertain. Risk managers may require additional data on the effect of processing on the magnitude of residues in refined sugar and its by-products (e.g. molasses, dried pulp, ensiled pulp) in order to derive a robust PF for inclusion in Annex VI in view of monitoring of residues in imported commodities. |

MRL: maximum residue level.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Assessment

The European Food Safety Authority (EFSA) received an application to set an import tolerance for azoxystrobin in sugar beet roots. The detailed description of the existing use of azoxystrobin authorised in the USA in sugar beet roots, which is the basis for the current application, is reported in Appendix A.

Azoxystrobin is the ISO common name for methyl (2E)-2-(2-[[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy]phenyl)-3-methoxyacrylate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Azoxystrobin was evaluated for renewal of the approval in the framework Directive 91/414/EEC1 with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on cereals and brassica vegetables. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2010). The decision on the renewal of azoxystrobin entered into force on 1 January 2012.2 The approval is restricted to uses as fungicide only. The EU MRLs for azoxystrobin are established in Annex II of Regulation (EC) No 396/20053. The review of existing MRLs for azoxystrobin are established in Annex II of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2013) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for azoxystrobin. The proposals from these reasoned opinions have been considered in recent MRL regulations.4

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Austria (evaluating Member State, EMS) to set an import tolerance for the active substance azoxystrobin in sugar beet roots. 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 14 May 2020. The EMS proposed to establish MRLs for sugar beet roots imported from the USA at the level of 5 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 6 October 2020, the EMS submitted a revised evaluation report (Austria, 2020), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Austria, 2020), the draft assessment report (DAR) (and its addendum) (United Kingdom, 2009a,b) prepared under Council Directive 91/414/EEC, the Commission review report on azoxystrobin (European Commission, 2015), the conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin (EFSA, 2010), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2013), as well as the conclusions from previous EFSA opinions on azoxystrobin (EFSA, 2016a,b, 2020).

For this application, the data requirements established in Regulation (EU) No 544/20115 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a-g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.6

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Implementing Regulation (EU) No 703/2011 of 20 July 2011 approving the active substance azoxystrobin, 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 190, 21.7.2011, p. 33–37.
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 70, 16.3.2005, p. 1–16.
4 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/pesticides-database/public/?event=pesticide.residue.selection&language=EN
5 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
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.
A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously is presented in Appendix B. The evaluation report submitted by the EMS (Austria, 2020) 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 azoxystrobin in primary crops belonging to the groups of fruit crops (grapes), cereals/grass (wheat) and pulses/oilseeds (peanuts) has been investigated in the framework of the EU pesticides peer review (EFSA, 2010). All metabolism studies assessed in this framework were performed with foliar applications.

The metabolism pattern was similar in all plant groups and consequently the residue definition for enforcement and risk assessment in all plant commodities following foliar application was proposed as azoxystrobin (EFSA, 2010, 2013).

The use under assessment in the present opinion is a post-harvest treatment on sugar beet roots. Considering that azoxystrobin was applied close to harvest in the foliar metabolism studies, the results of the available studies were deemed applicable to cover the post-harvest GAPs during the MRL review (EFSA, 2013). Therefore, further data were not required to support the intended use.

1.1.2. Nature of residues in rotational crops

As the use under assessment is a post-harvest application for imported commodities, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of azoxystrobin was investigated in the framework of the EU pesticides peer review (EFSA, 2010). These studies showed that azoxystrobin is hydrolytically stable under standard processing conditions.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of azoxystrobin residues in plant commodities were assessed during the peer review for the renewal of the approval of azoxystrobin and during the MRL review (EFSA, 2010, 2013).

An analytical method using high-performance liquid chromatography with tandem mass spectrometry detection (HPLC-MS/MS) was concluded to be sufficiently validated for the determination of azoxystrobin in dry, high acid-, high water- and high oil-content matrices and hops, with a limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2010, 2013).

The crop under consideration belongs to the high-water content commodity group. Therefore, sufficiently validated analytical methods are available to control azoxystrobin residues in sugar beet roots. New data submitted in the current MRL application have been assessed by the EMS and confirm this conclusion (Austria, 2020).

1.1.5. Storage stability of residues in plants

The storage stability of azoxystrobin in plant matrices stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2010).

In all investigated high-water content commodities (bananas, peaches, tomatoes, cucumbers, lettuce, carrots), azoxystrobin was found to be stable for at least 24 months when stored at –18°C. This result also applies to sugar beet roots.
1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies and on the results of hydrolysis studies, the residue definition for enforcement and risk assessment in all plant commodities following foliar application was proposed as azoxystrobin (EFSA, 2010, 2013).

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

Although the available metabolism studies were all performed with foliar applications, EFSA concluded that these results also cover post-harvest uses (EFSA, 2013). Therefore, this residue definition is deemed appropriate for the post-harvest use on sugar beet roots.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the import tolerance application, the applicant submitted six residue trials performed on sugar beet roots. All trials were performed in the USA, in accordance with the GAP (post-harvest treatment). Sugar beets per sample were collected from the field at maturity (BBCH 49). The sugar beet tops were removed before application. Azoxystrobin was applied to sugar beet roots as a flowable suspension concentrate (SC). One single post-harvest application was made as a direct spray to the roots, as a nominal rate equivalent to 4.25 g azoxystrobin per 2,000 lb sugar beet roots. Following post-harvest treatment, the sugar beet roots were allowed to dry for 2–3 h (with the exception of trial 04, where the roots were collected immediately), prior to collection.

The samples were analysed for the parent compound in line with the residue definition for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Austria, 2020).

It is noted that although sugar beet is a major crop worldwide, a minimum of four trials are required for post-harvest treatments according to Regulation (EU) No 544/2011. Therefore, the six trials submitted in order to support the post-harvest GAP were considered enough and no additional trials were required.

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

1.2.2. Magnitude of residues in rotational crops

As the use under assessment is a post-harvest application for imported commodities, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

One processing trial performed with sugar beet roots was submitted in the present application. The study investigates the effect of the industrial sugar processing on the magnitude of azoxystrobin residues in refined sugar and several intermediate products (e.g. raw sugar) and by-products (e.g. molasses, dried pulp, ensiled pulp).

The trial indicates that industrial sugar processing leads to a reduction of the residues in the processed products and by-products investigated (Austria, 2020). It is noted that the industrial process applied in the experiment starts with a cleaning step with brush and water, and removal of loose leaves and foreign matter. Considering that azoxystrobin residues after a post-harvest treatment are mainly on the external part of sugar beet roots, this cleaning step is expected to play a role in the reduction of residues observed in the processed commodities. Although indicative (only one trial), the derived processing factors indicate a reduction of residues in refined sugar (PF = 0.017) and by-products (max. PF = 0.47 for dried pulp).

The quality of the processing study is acceptable, but the number of trials is not sufficient to derive robust processing factors and therefore is not recommended for inclusion in Annex VI of Regulation (EC) No 396/2005. If risk managers wish to derive robust processing factors, which allow enforcement of azoxystrobin residues in imported sugar, further processing trials would be required.
1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for sugar beet roots (see Appendix B.1.2.1).

It is noted that the MRL derived for this import tolerance is on sugar beet roots. However, the imported commodities are not expected to be the sugar beet roots as such. Upon request for clarification, the applicant informed EFSA that the intended commodities for import are the following processed commodities: refined sugar and molasses. In the absence of a robust data set (only 1 processing trial), EFSA was not in a position to derive robust PF for inclusion in Annex VI in view of monitoring of residues in these commodities. Consequently, although an MRL proposal can be derived in the present opinion, the enforcement of azoxystrobin residues in the imported processed commodities may require additional data on the effect of processing on the magnitude of residues in refined sugar and its by-products (e.g. molasses, dried pulp, ensiled pulp).

In Section 3, EFSA assessed whether residues in sugar beet roots (and processed commodities) resulting from the post-harvest use authorised in the USA is likely to pose a consumer health risk.

2. Residues in livestock

Sugar beet roots and by-products of the sugar production process (molasses, dried pulp, ensiled pulp) may be used for feed purposes. Hence, it was necessary to update the previous dietary burden calculation for livestock to estimate whether the import tolerance under evaluation would have an impact on the residues expected in food of animal origin. EFSA updated the calculations performed in the previous assessment (EFSA, 2020), adding the input values for sugar beet molasses, dried pulp and ensiled pulp. As the indicative PF derived for these processed commodities indicate a reduction of azoxystrobin concentrations in sugar beet molasses, dried pulp and ensiled pulp, the default processing factors for these by-products (respectively, 28, 18 and 3) were not considered in the calculations.

The input values for the exposure calculations for livestock are presented in Appendix D.1. The results of the dietary burden calculation are presented in Section B.2.

EFSA highlights that for all animal commodities except milk and poultry commodities, the current EU MRLs were derived from CXLs (e.g. mammalian liver, kidney, edible offal (0.07 mg/kg) and fat (0.05 mg/kg)). EFSA could not reassess the calculations of the JMPR, but notes that the EU livestock dietary burden calculated in the confirmatory data assessment (which is equal to the one calculated in the current assessment; see Appendix B.2) indicates that lower MRLs would be sufficient to accommodate the existing EU uses of azoxystrobin (see Appendix B.2.2). The EU livestock dietary burden leads to MRL values at the LOQ in all animal matrices (EFSA, 2020). Furthermore, a risk management decision still needs to be taken on the data gap on general toxicity of the livestock metabolites L1, L4 an L9 and on their impact on current MRLs for fat, liver, kidney and other edible offals of swine and ruminants (EFSA, 2020).

3. Consumer risk assessment

In the framework of the assessment of confirmatory data following the MRL review (EFSA, 2020), a comprehensive consumer risk assessment for azoxystrobin was performed by EFSA taking into account the input values previously considered for the consumer risk assessment of azoxystrobin, the updated risk assessment values assessed as confirmatory data (for lettuce and other salad plants), the CXLs and associated risk assessment values (for prickly pears/cactus fruits and sugar cane; FAO, 2017). This consumer risk assessment was performed with the most recent version of the EFSA Pesticide Residues Intake Model (PRIMo Rev. 3.1; EFSA, 2018, 2019).

This previous consumer risk assessment was updated considering the risk assessment values derived from the residue trials submitted in support of this MRL import tolerance application for sugar beet roots. The input values used to perform the consumer risk assessment are reported in Appendix D.2.

The toxicological reference value for acceptable daily intake (ADI) of 0.2 mg/kg bw per day assessed in the framework of the EU pesticides peer review is applicable (European Commission, 2015). The derivation of an acute reference dose (ARfD) was considered not necessary (EFSA, 2010).
The estimated chronic exposures were compared with the ADI of azoxystrobin. The outcome of the calculations is reported in Appendix B.3. The estimated long-term dietary intake was up to 22% of the ADI (Dutch toddler). The contribution of residues expected in the sugar beet roots (intended import tolerance) to the overall long-term exposure is presented in more detail in Appendix B.3. A short-term (acute) risk assessment was not required since no ARfD has been considered necessary for azoxystrobin.

EFSA concluded that the consumer intake of residues of azoxystrobin resulting from the existing uses and the import of commodities resulting from the US authorised use on sugar beet roots is unlikely to present a risk to consumer health.

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for sugar beet roots.

EFSA concluded that the US authorised use of azoxystrobin on sugar beet roots will not result in a consumer exposure exceeding the toxicological reference value (ADI) and therefore is unlikely to pose a risk to consumers’ health.

The MRL recommendations are summarised in Appendix B.4.

EFSA noted that the MRL derived for this import tolerance is on sugar beet roots (raw commodity). However, the imported commodities are expected to be refined sugar and molasses, which are processed commodities. In the absence of a robust PF for inclusion in Annex VI in view of monitoring of residues in these commodities, the enforcement of azoxystrobin residues in the imported processed commodities is uncertain. Therefore, although an MRL proposal can be derived in the present opinion, risk managers may require additional data on the effect of processing on the magnitude of residues in refined sugar and its by-products (e.g. molasses, dried pulp, ensiled pulp) in order to derive a robust PF for Annex VI in view of monitoring of residues in imported commodities.

Furthermore, the imported by-products of sugar production processes might be fed to livestock. The effect of these feed items on the calculated dietary burden was assessed and it was concluded that the outcome of the Article 12 confirmatory data assessment regarding residues in livestock commodities remains valid. However, a risk management decision is still pending on the data gap on general toxicity of livestock metabolites L1, L4 an L9 and on its impact on current MRLs for liver, kidney, fat and other edible offals (EFSA, 2020).

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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

CAC Codex Alimentarius Commission

CAS Chemical Abstract Service

CF conversion factor for enforcement to risk assessment residue definition
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F or G or I (a) | Pest(s) or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|-------------------------|----------------|-------------------------------------|-------------|-------------|--------------------------------|---------------|---------|
| Sugar beet roots      | USA                     | 1              | **Fusarium spp., Botrytis spp., Penicillium spp., Rhizoctonia spp.** | SC          | 1.99 lb/gallon (239 g/L) | Post-harvest treatment Application on harvested roots | 0.6 fl oz/2,000 lb of roots (17.74 mL/2000 lb of roots) | 0.5 gallons/ton | 0.0093 1 lb a.s./2,000 lb of roots | 4.23 4.66 g a.s./tonne (metric ton) | 0 Direct spray to root. |

MRL: maximum residue level; GAP: Good Agricultural Practice; 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, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

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

(d): PHI – minimum 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 |
|----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                      | Grape       | Foliar: 250 + 1,000 + 1,000 + 250 g/ha | 21             | Radiolabelled azoxystrobin: $^{14}$C-pyrimidinyl, $^{14}$C-cyanophenyl, $^{14}$C-phenylacrylate (EFSA, 2010) |
| Cereals/grass                    | Wheat       | Foliar: 2 × 500 g/ha; BBCH 30-31 and 59-61 Forage: 13 Grain and straw: 61–62 | 28             | Radiolabelled azoxystrobin: $^{14}$C-pyrimidinyl, $^{14}$C-cyanophenyl, $^{14}$C-phenylacrylate (EFSA, 2010) |
| Pulses/oilseeds                 | Peanut      | Foliar: 850 + 850 + 300 g/ha | 10             | Radiolabelled azoxystrobin: $^{14}$C-pyrimidinyl, $^{14}$C-cyanophenyl, $^{14}$C-phenylacrylate (EFSA, 2010) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Radish      | Bare soil: 2.2 kg/ha | 30, 200, 365 | Radiolabelled azoxystrobin: $^{14}$C-pyrimidinyl, $^{14}$C-cyanophenyl, $^{14}$C-phenylacrylate (EFSA, 2010) |
| Leafy crops                        | Lettuce     |         |                |           |                |
| Cereal (small grain)                | Wheat       |         |                |           |                |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|-----------------------------------------|------------|--------|----------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4) | Yes    | EFSA (2010)   |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes    |                |
|                                        | Sterilisation (20 min, 120°C, pH 6) | Yes    |                |
Can a general residue definition be proposed for primary crops?
Yes (EFSA, 2010)

Rotational crop and primary crop metabolism similar?
Yes (EFSA, 2010)

Residue pattern in processed commodities similar to residue pattern in raw commodities?
Yes (EFSA, 2010)

Plant residue definition for monitoring (RD-Mo)
Azoxystrobin

Plant residue definition for risk assessment (RD-RA)
Azoxystrobin

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
Matrices with high water content, high oil content, high acid content, dry matrices and hops: HPLC–MS/MS, LOQ 0.01 mg/kg (EFSA, 2010, 2013).
As HPLC–MS/MS using two mass transitions is a highly specific detection technique, a confirmatory method is not required.
ILV available (Austria, 2020).

DAT: days after treatment; BBCH: growth stages of mono- and dicotyledonous plants; PBI: plant-back interval; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

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

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|-----------------|-------------------|---------------|
|                                   |          |           |        | Value | Unit |                          |               |
| High water content                | Banana   | –18       | 24     | Months | Azoxystrobin | EFSA (2010)    |
|                                  | Peach    | –18       | 24     | Months | Azoxystrobin | EFSA (2010)    |
|                                  | Tomato   | –18       | 24     | Months | Azoxystrobin | EFSA (2010)    |
|                                  | Cucumber | –18       | 24     | Months | Azoxystrobin | EFSA (2010)    |
|                                  | Lettuce  | –18       | 24     | Months | Azoxystrobin | EFSA (2010)    |
|                                  | Carrot   | –18       | 24     | Months | Azoxystrobin | EFSA (2010)    |
| High oil content                 | Oilseed rape | –18   | 24     | Months | Azoxystrobin | EFSA (2010)    |
|                                  | Pecans   | –18       | 24     | Months | Azoxystrobin | EFSA (2010)    |
|                                  | Peanut   | –18       | 24     | Months | Azoxystrobin | EFSA (2010)    |
| Dry/High starch                  | Cereal grain | –18 | 24     | Months | Azoxystrobin | EFSA (2010)    |
| High acid content                | Grape    | –18       | 24     | Months | Azoxystrobin | EFSA (2010)    |
|                                  | Apple    | –18       | 24     | Months | Azoxystrobin | EFSA (2010)    |
|                                  | Orange   | –18       | 24     | Months | Azoxystrobin | EFSA (2010)    |
| Others                            | Cereal straw | –18 | 24     | Months | Azoxystrobin | EFSA (2010)    |
## Magnitude of residues in plants

### Summary of residues data from the supervised residue trials

| Commodity   | Region/Indoor\(^{(a)}\)             | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) |
|-------------|------------------------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------|------------------------|----------------------|------------------------|
| Sugar beet  | USA: indoor (post-harvest treatment) | 0.73; 1.1; 1.3; 1.4; 2.0; 2.4                                  | Residue trials on sugar beet compliant with GAP (Austria, 2020). MRL\(_{OECD}\) = 4.5 | 5                      | 2.4                  | 1.35                   |

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

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

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

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

The GAP under assessment is a post-harvest treatment for imported commodities, thus investigations of residues in rotational crops are not required.

B.1.2.3. Processing factors

| Processed commodity          | Number of valid studies(a) | Processing Factor (PF) | Comment/Source                                      |
|------------------------------|-----------------------------|------------------------|-----------------------------------------------------|
| Sugar beet, refined sugar    | 1                           | 0.017                  | Median PF 0.017(a) Indicative processing factor supported by one trial (Austria, 2020). |
| Sugar beet, dried pulp       | 1                           | 0.47                   | Median PF 0.47(a) Indicative processing factor supported by one trial (Austria, 2020). |
| Sugar beet, ensiled pulp     | 1                           | 0.12                   | Median PF 0.12(a) Indicative processing factor supported by one trial (Austria, 2020). |
| Sugar beet, molasses         | 1                           | 0.20                   | Median PF 0.20(a) Indicative processing factor supported by one trial (Austria, 2020). |

(a): Indicative PF derived based on a limited data set.

B.2. Residues in livestock

Dietary burden calculation according to OECD, 2013.

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(b) | Trigger exceeded (Y/N) | Previous assessment (EFSA, 2020) mg/kg bw per day |
|-----------------------------|---------------------------------------------|---------------------------|------------------------|--------------------------------------------------|
|                             | Median Maximum | Median Maximum | Dairy cattle | Citrus, dried pulp | Y | 0.59 |
| Cattle (all)                | 0.46 0.59      | 12.0 15.4     | Dairy cattle | Citrus, dried pulp | Y | 0.59 |
| Cattle (dairy only)         | 0.46 0.59      | 12.0 15.4     | Dairy cattle | Citrus, dried pulp | Y | 0.59 |
| Sheep (all)                 | 0.10 0.23      | 2.85 5.79     | Lamb        | Rye, straw         | Y | 0.23 |
| Sheep (ewe only)            | 0.10 0.19      | 2.85 5.79     | Ram/Ewe    | Rye, straw         | Y | 0.19 |
| Swine (all)                 | 0.20 0.25      | 8.76 10.6     | Swine (breeding) | Citrus, dried pulp | Y | 0.25 |
| Poultry (all)               | 0.05 0.10      | 0.66 1.42     | Poultry layer | Wheat, straw       | Y | 0.10 |
| Poultry (layer only)        | 0.05 0.10      | 0.66 1.42     | Poultry layer | Wheat, straw       | Y | 0.10 |
| Fish                        | n.a. n.a.      | n.a. n.a.     | n.a.        | n.a.                | n.a. n.a. |

bw: body weight; DM: dry matter; n.a.: not applicable.
(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.
B.2.1. Nature of residues and methods of analysis in livestock

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

| Livestock (available studies) | Animal | Dose (mg/kg bw per d) | Duration (days) | Comment/Source |
|-------------------------------|--------|-----------------------|-----------------|----------------|
| Laying hen (available studies) | 11     | 10                    | Studies using $^{14}$C-pyrimidinyl $^{14}$C-cyanophenyl and $^{14}$C-phenylacrylate radiolabelled azoxystrobin (EFSA, 2010). |
|                               | 12.5   | 10                    | Study performed on goat using $^{14}$C-pyrimidinyl $^{14}$C-cyanophenyl and $^{14}$C-phenylacrylate radiolabelled azoxystrobin (EFSA, 2010). |
| Lactating ruminants           | 23.2 – 32.7 | 7                  | Study performed on goat using $^{14}$C-cyanophenyl radiolabelled azoxystrobin (EFSA, 2010). |

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

- Milk: not relevant
- TRR in milk range between 0.004 and 0.01 mg eq/L
- Eggs: 6–8
- Observed in egg yolk (United Kingdom, 2009)
- Metabolism in rat and ruminant similar

- Yes
- The general metabolic pathways in rodents and ruminants were found to be comparable.

Can a general residue definition be proposed for animals?

- Yes
- –

Animal residue definition for monitoring (RD-Mo)

- Azoxystrobin

Animal residue definition for risk assessment (RD-RA)

- Azoxystrobin (tentative, EFSA, 2010, 2013)
- Genotoxicity of metabolites L1, L4 and L9 can be ruled out, but general toxicity of these metabolites was not addressed (EFSA, 2020).

Fat soluble residues

- No
- Log P_o/w < 3

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

- GC-NPD (EFSA, 2010):
  - Milk: LOQ 0.001 mg/kg.
  - Eggs, muscle, fat, liver/kidney: 0.01 mg/kg
  - ILV available but confirmatory method missing.

- HPLC–MS/MS (validated method in FAO, 2008):
  - LOQ: 0.01 mg/kg in all tissues, milk and eggs

bw: body weight; P_o/w: partition coefficient between n-octanol and water; LOQ: limit of quantification; GC-NPD: gas chromatography with nitrogen/phosphorous detector; ILV: independent laboratory validation; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry.
### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal    | Commodity | T (°C) | Stability period | Compounds covered | Comment/ Source |
|-------------------------------------|-----------|-----------|--------|-----------------|-------------------|----------------|
|                                     | Ruminant  | Muscle    | -18    | 10 Months       | Azoxystrobin      | EFSA (2010)     |
|                                     | Ruminant  | Fat       | -18    | 10 Months       | Azoxystrobin      | EFSA (2010)     |
|                                     | Ruminant  | Liver     | -18    | 10 Months       | Azoxystrobin      | EFSA (2010)     |
|                                     | Ruminant  | Kidney    | -18    | 10 Months       | Azoxystrobin      | EFSA (2010)     |
|                                     | Ruminant  | Milk      | -18    | 10 Months       | Azoxystrobin      | EFSA (2010)     |
|                                     | Poultry   | Eggs      | -18    | 10 Months       | Azoxystrobin      | EFSA (2010)     |

### B.2.2. Magnitude of residues in livestock

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

MRL calculations based on the EU MRL dietary burdens calculated for azoxystrobin in the current assessment (refer to the table above).

Calculations performed with Animal model 2017.7

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | Calculated MRL (mg/kg) |
|------------------|-----------------------------------------------|-----------------------|------------------------|
|                  | Mean/ Highest                                | STMR<sup>(a)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) |
| Cattle (all) – Closest feeding level (0.91 mg/kg bw; 1.5 N rate)<sup>(c)</sup> | | | |
| Muscle           | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01* |
| Fat              | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01* |
| Liver            | 0.01/ 0.01                                  | < 0.01                | < 0.01                 | 0.01*<sup>(f)</sup> |
| Kidney           | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01*<sup>(f)</sup> |
| Cattle (dairy only) – Closest feeding level (0.91 mg/kg bw; 1.5 N rate)<sup>(c)</sup> | | | |
| Milk<sup>(d)</sup> | < 0.01/ n.a.                               | < 0.01                | < 0.01                 | 0.01* |
| Sheep (all)<sup>(e)</sup> – Closest feeding level (0.18 mg/kg bw; 0.8 N rate)<sup>(c)</sup> | | | |
| Muscle           | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01* |
| Fat              | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01* |
| Liver            | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01*<sup>(f)</sup> |
| Kidney           | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01*<sup>(f)</sup> |
| Sheep (ewe only)<sup>(e)</sup> – Closest feeding level (0.18 mg/kg bw; 0.9 N rate)<sup>(c)</sup> | | | |
| Milk<sup>(d)</sup> | < 0.01/ n.a.                               | < 0.01                | < 0.01                 | 0.01* |
| Swine (all)<sup>(e)</sup> – Closest feeding level (0.18 mg/kg bw; 0.7 N rate)<sup>(c)</sup> | | | |
| Muscle           | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01* |
| Fat              | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01* |
| Liver            | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01*<sup>(f)</sup> |
| Kidney           | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01*<sup>(f)</sup> |
| Poultry (all) – Closest feeding level (0.39 mg/kg bw; 4 N rate)<sup>(c)</sup> | | | |
| Muscle           | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01* |
| Fat              | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01* |
| Liver            | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01* |
| Poultry (layer only) – Closest feeding level (0.39 mg/kg bw; 4 N rate)<sup>(c)</sup> | | | |
| Eggs             | < 0.01/ < 0.01                               | < 0.01                | < 0.01                 | 0.01* |

MRL: maximum residue level; bw: body weight; n.a.: not applicable.
*: Indicates that the MRL is proposed at the limit of quantification.

7 https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en
(a): Median residues recalculated at the 1N rate for the median dietary burden.
(b): Highest residues recalculated at the 1N rate for the maximum dietary burden.
(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): For milk, mean was derived from samplings performed from day 1 to day 30 (daily mean of 4 cows).
(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
(f): Noting that the general toxicity of metabolites L1, L4 and L9 (found in liver and kidney) was not addressed.

B.3. Consumer risk assessment

Short-term (acute) risk assessment: not relevant since no ARfD has been considered necessary (European Commission, 2015).

| ADI | 0.2 mg/kg bw per day (European Commission, 2015) |
|-----|------------------------------------------------|
| Highest IEDI, according to EFSA PRIMo (rev.3.1) | 22% ADI (NL toddler) |
| Contribution of crops assessed: |
| Sugar beet roots: 5.7% of ADI (NL child diet) |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities. |
| For the intended important tolerance (sugar beet roots), the calculation is based on the median residue level derived for raw sugar beet roots (no consideration of the indicative processing factor for refined sugar, which is based on one trial only). |
| Contributions of all commodities assessed in the framework of the MRL review and its confirmatory data assessment (EFSA, 2013, 2020) were considered. |
| The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. |
| The calculation was performed using PRIMo rev.3.1. |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level.

B.4. Recommended MRLs

| Code(s) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 0900010 | Sugar beet roots | 0.2 | 5 | The submitted data are sufficient to derive an import tolerance MRL proposal on the basis of the US authorised use. No consumer health risk was identified. The MRL proposal is derived for raw sugar beet roots. However, the imported commodities are expected to be refined sugar and molasses (processed commodities). A robust processing factor (PF) for these commodities could not be derived. Therefore, enforcement of azoxystrobin residues in the imported processed commodities is uncertain. Risk managers may require additional data on the effect of processing on the magnitude of residues in refined sugar and its by-products (e.g. molasses, dried pulp, ensiled pulp) in order to derive a robust PF for inclusion in Annex VI in view of monitoring of residues in imported commodities. |

MRL: maximum residue level.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
## Appendix C – Pesticide Residue Intake Model (PRiMo)

### Azoxystrobin

**LOQs (mg/kg) range from:**
- 0.01
- 0.01

**ADI (mg/kg bw per day):** 0.2

**ARfD (mg/kg bw):** not necessary

**Source of ADI:** EFSA

**Source of ARfD:** EFSA

**EFSA PRiMo revision 3.1; 2019/03/19**

**Year of evaluation:** 2010

### Normal mode

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

| Commodity/group of commodities | No of diets exceeding the ADI | Exposure resulting from | MRLs set at the LOQ (in % of ADI) |
|---------------------------------|-----------------------------|------------------------|----------------------------------|

#### Supplementary results – chronic risk assessment

| Commodity/group of commodities | No of diets exceeding the ADI | Exposure resulting from | MRLs set at the LOQ (in % of ADI) |

#### Supplementary results – acute risk assessment/children

| Commodity/group of commodities | No of diets exceeding the ADI | Exposure resulting from | MRLs set at the LOQ (in % of ADI) |

#### Supplementary results – acute risk assessment/adults

| Commodity/group of commodities | No of diets exceeding the ADI | Exposure resulting from | MRLs set at the LOQ (in % of ADI) |

### Details – chronic risk assessment

The estimated long-term dietary intake (TMG/TMDI/IEDI) was below the ADI. The long-term intake of residues of azoxystrobin is unlikely to present a public health concern.

### Details – acute risk assessment

### Details – acute risk assessment

### Input values

- Normal mode
- Supplementary results – chronic risk assessment
- Supplementary results – acute risk assessment/children
- Supplementary results – acute risk assessment/adults

### Settings of import tolerance for azoxystrobin in sugar beet roots

[www.efsa.europa.eu/efsajournal 21 EFSA Journal 2021;19(2):6401]
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Show results for all crops

| Unprocessed commodities | Processed commodities |
|-------------------------|-----------------------|
| **Results for children** | **Results for adults** |
| No of commodities for which ARfD/ADI is exceeded (IESTI): — | No of commodities for which ARfD/ADI is exceeded (IESTI): — |
| **INTERNATIONAL** | **INTERNATIONAL** |
| Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
| Commodities | — | — | Commodities | — | — |

Expand/collapse list

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

### Conclusion:

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

Results for adults

No of processed commodities for which ARfD/ADI is exceeded (IESTI): —

| **INTERNATIONAL** | **INTERNATIONAL** |
|-------------------|-------------------|
| Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
| Processed commodities | — | — | Processed commodities | — | — |

Expand/collapse list

Conclusion:
## Appendix D – Input values for the exposure calculations

### D.1. Livestock dietary burden calculations

| Feed commodity                        | Median dietary burden | Maximum dietary burden |
|---------------------------------------|-----------------------|------------------------|
|                                       | Input value (mg/kg)   | Comment                |
|                                       |                       |                        |
| Risk assessment residue definition:  | azoxystrobin          |                        |
| Barley straw                          | 2.3 STMR (EFSA, 2013) | 5.5 HR (EFSA, 2013)   |
| Beet, sugar tops                      | 0.21 STMR (EFSA, 2013)| 0.38 HR (EFSA, 2013)  |
| Cabbage, heads leaves                 | 0.03 STMR (EFSA, 2013)| 0.17 HR (EFSA, 2013)  |
| Kale leaves (forage)                  | 1.04 STMR (EFSA, 2013)| 3.5 HR (EFSA, 2013)   |
| Oat straw                             | 2.3 STMR (EFSA, 2013) | 5.5 HR (EFSA, 2013)   |
| Rye straw                             | 3.85 STMR (EFSA, 2013)| 10.1 HR (EFSA, 2013)  |
| Triticale straw                       | 3.85 STMR (EFSA, 2013)| 10.1 HR (EFSA, 2013)  |
| Wheat straw                           | 3.85 STMR (EFSA, 2013)| 10.1 HR (EFSA, 2013)  |
| Carrot culls                          | 0.06 STMR (EFSA, 2013)| 0.11 HR (EFSA, 2013)  |
| Potato culls                          | 0.02 STMR (EFSA, 2013)| 0.03 HR (EFSA, 2013)  |
| Swede roots                           | 0.05 STMR (EFSA, 2013)| 0.1 HR (EFSA, 2013)   |
| Turnip roots                          | 0.06 STMR (EFSA, 2013)| 0.11 HR (EFSA, 2013)  |
| Barley grain                          | 0.1 STMR (EFSA, 2013) | 0.1 STMR (EFSA, 2013) |
| Bean seed (dry)                       | 0.01 STMR (EFSA, 2013)| 0.01 STMR (EFSA, 2013) |
| Corn, field (Maize) grain             | 0.01 STMR (EFSA, 2013)| 0.01 STMR (EFSA, 2013) |
| Corn, pop grain                       | 0.01 STMR (EFSA, 2013)| 0.01 STMR (EFSA, 2013) |
| Cowpea seed                           | 0.01 STMR (EFSA, 2013)| 0.01 STMR (EFSA, 2013) |
| Lupin seed                            | 0.01 STMR (EFSA, 2013)| 0.01 STMR (EFSA, 2013) |
| Oat grain                             | 0.1 STMR (EFSA, 2013) | 0.1 STMR (EFSA, 2013) |
| Pea (Field pea) seed (dry)            | 0.01 STMR (EFSA, 2013)| 0.01 STMR (EFSA, 2013) |
| Rye grain                             | 0.08 STMR (EFSA, 2013)| 0.08 STMR (EFSA, 2013) |
| Soyabean seed                         | 0.05 STMR (EFSA, 2013)| 0.05 STMR (EFSA, 2013) |
| Triticale grain                       | 0.08 STMR (EFSA, 2013)| 0.08 STMR (EFSA, 2013) |
| Wheat grain                           | 0.08 STMR (EFSA, 2013)| 0.08 STMR (EFSA, 2013) |
| Beet, sugar dried pulp                | 1.35 STMR (see Appendix B.1.2.1(a)) | 1.35 STMR (see Appendix B.1.2.1(a)) |
| Beet, sugar ensiled pulp              | 1.35 STMR (see Appendix B.1.2.1(a)) | 1.35 STMR (see Appendix B.1.2.1(a)) |
| Beet, sugar molasses                  | 1.35 STMR (see Appendix B.1.2.1(a)) | 1.35 STMR (see Appendix B.1.2.1(a)) |
| Brewer’s grain dried                  | 0.33 STMR (EFSA, 2013) × default PF (3.3) | 0.33 STMR (EFSA, 2013) × default PF (3.3) |
| Canola (Rape seed) meal               | 0.11 STMR (EFSA, 2013) × default PF (2) | 0.11 STMR (EFSA, 2013) × default PF (2) |
| Citrus dried pulp                     | 47.5 STMR (EFSA, 2013) × default PF (10) | 47.5 STMR (EFSA, 2013) × default PF (10) |
| Corn, field milled by-products        | 0.01 STMR (EFSA, 2013)(b) | 0.01 STMR (EFSA, 2013)(b) |
| Corn, field hominy meal               | 0.01 STMR (EFSA, 2013)(b) | 0.01 STMR (EFSA, 2013)(b) |
| Corn, field gluten feed               | 0.01 STMR (EFSA, 2013)(b) | 0.01 STMR (EFSA, 2013)(b) |
| Corn, field gluten, meal              | 0.01 STMR (EFSA, 2013)(b) | 0.01 STMR (EFSA, 2013)(b) |
| Distiller’s grain dried               | 0.25 STMR (EFSA, 2013) × default PF (3.3) | 0.25 STMR (EFSA, 2013) × default PF (3.3) |
| Flaxseed/Linseed meal                 | 0.04 STMR (EFSA, 2016b) × default PF (2) | 0.04 STMR (EFSA, 2016b) × default PF (2) |

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### Feed commodity

| Feed commodity               | Median dietary burden | Maximum dietary burden |
|-----------------------------|-----------------------|------------------------|
|                             | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment |
| Lupin seed meal             | 0.01                  | STMR (EFSA, 2013) x default PF (1.1) | 0.01 | STMR (EFSA, 2013) x default PF (1.1) |
| Potato process waste        | 0.3                   | STMR (EFSA, 2013) x default PF (20) | 0.3 | STMR (EFSA, 2013) x default PF (20) |
| Potato dried pulp           | 0.57                  | STMR (EFSA, 2013) x default PF (38) | 0.57 | STMR (EFSA, 2013) x default PF (38) |
| Rape meal                   | 0.11                  | STMR (EFSA, 2013) x default PF (2)  | 0.11 | STMR (EFSA, 2013) x default PF (2)  |
| Rice bran/pollard           | 0.61                  | STMR (EFSA, 2013) x PF (1.2) | 0.61 | STMR (EFSA, 2013) x PF (1.2) |
| Safflower meal              | 0.04                  | STMR (EFSA, 2016b) x default PF (2) | 0.04 | STMR (EFSA, 2016b) x default PF (2) |
| Soyabean meal               | 0.07                  | STMR (EFSA, 2013) x default PF (1.3) | 0.07 | STMR (EFSA, 2013) x default PF (1.3) |
| Soyabean hulls              | 0.65                  | STMR (EFSA, 2013) x default PF (13) | 0.65 | STMR (EFSA, 2013) x default PF (13) |
| Sunflower meal              | 0.02                  | STMR (EFSA, 2013) x default PF (2) | 0.02 | STMR (EFSA, 2013) x default PF (2) |
| Wheat gluten meal           | 0.14                  | STMR (EFSA, 2013) x default PF (1.8) | 0.14 | STMR (EFSA, 2013) x default PF (1.8) |
| Wheat milled by-products    | 0.13                  | STMR x PF (1.7) (EFSA, 2013) | 0.13 | STMR x PF (1.7) (EFSA, 2013) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

(a): For sugar beet roots by-products, no default processing factor was applied because tentative PF calculated in Section B.1.2.3 indicate that that concentration of residues in these commodities is not expected.

(b): For maize/corn by-products no default processing factor was applied because residues are expected to be below the LOQ (EFSA, 2013). Concentration of residues in these commodities is therefore not expected.

### Consumer risk assessment

### Commodity

| Commodity       | Input value (mg/kg) | Comment                  |
|-----------------|---------------------|--------------------------|
| Grapefruits     | 4.9                 | STMR (EFSA, 2013)        |
| Oranges         | 4.75                | STMR (EFSA, 2013)        |
| Lemons          | 4.9                 | STMR (EFSA, 2013)        |
| Limes           | 4.9                 | STMR (EFSA, 2013)        |
| Mandarin        | 4.9                 | STMR (EFSA, 2013)        |
| Almonds         | 0.01                | STMR (EFSA, 2013)        |
| Brazil nuts     | 0.01                | STMR (EFSA, 2013)        |
| Cashew nuts     | 0.01                | STMR (EFSA, 2013)        |
| Chestnuts       | 0.01                | STMR (EFSA, 2013)        |
| Coconuts        | 0.01                | STMR (EFSA, 2013)        |
| Hazelnuts/cobnuts | 0.01               | STMR (EFSA, 2013)        |
| Macadamia       | 0.01                | STMR (EFSA, 2013)        |
| Pecans          | 0.01                | STMR (EFSA, 2013)        |
| Pine nut kernels | 0.01               | STMR (EFSA, 2013)        |
| Pistachios      | 0.44                | STMR (EFSA, 2013)        |
| Walnuts         | 0.01                | STMR (EFSA, 2013)        |
| Apricots        | 0.74                | STMR (EFSA, 2013)        |
| Cherries (sweet)| 0.74                | STMR (EFSA, 2013)        |
| Commodity                              | Input value (mg/kg) | Comment                      |
|----------------------------------------|---------------------|------------------------------|
| Peaches                                | 0.74                | STMR (EFSA, 2013)            |
| Plums                                  | 0.74                | STMR (EFSA, 2013)            |
| Table grapes                           | 0.72                | STMR (EFSA, 2016a)           |
| Wine grapes                            | 0.72                | STMR (EFSA, 2016a)           |
| Strawberries                           | 1.3                 | STMR (EFSA, 2013)            |
| Blackberries                           | 1.03                | STMR (EFSA, 2013)            |
| Dewberries                             | 1.03                | STMR (EFSA, 2013)            |
| Raspberries (red and yellow)           | 1.03                | STMR (EFSA, 2013)            |
| Blueberries                            | 1.03                | STMR (EFSA, 2013)            |
| Cranberries                            | 0.23                | STMR (EFSA, 2013)            |
| Currants (red, black and white)        | 1.03                | STMR (EFSA, 2013)            |
| Gooseberries (green, red and yellow)   | 1.03                | STMR (EFSA, 2013)            |
| Rose hips                              | 1.03                | STMR (EFSA, 2013)            |
| Mulberries (black and white)           | 1.03                | STMR (EFSA, 2013)            |
| Azarole/Mediterranean medlar           | 1.03                | STMR (EFSA, 2013)            |
| Elderberries                           | 1.03                | STMR (EFSA, 2013)            |
| Carambolas                              | 0.023               | STMR (EFSA, 2013)            |
| Passion fruits/amaracuas                | 1.1                 | STMR (EFSA, 2013)            |
| Prickly pears/cactus fruits            | 0.041               | STMR (FAO, 2017)             |
| Bananas                                | 0.0326              | STMR*PeF (EFSA, 2013)        |
| Mangoes                                | 0.28                | STMR (EFSA, 2013)            |
| Papayas                                | 0.1                 | STMR (EFSA, 2013)            |
| Potatoes                               | 2.3                 | STMR (FAO, 2013)             |
| Cassava roots/manioc                    | 0.23                | STMR (EFSA, 2013)            |
| Sweet potatoes                         | 0.23                | STMR (EFSA, 2013)            |
| Yams                                   | 0.23                | STMR (EFSA, 2013)            |
| Arrowroots                             | 0.23                | STMR (EFSA, 2013)            |
| Beetroots                              | 0.23                | STMR (EFSA, 2013)            |
| Carrots                                | 0.23                | STMR (EFSA, 2013)            |
| Celeriacs/turnip-rooted celeriacs      | 0.23                | STMR (EFSA, 2013)            |
| Horseradishes                          | 0.23                | STMR (EFSA, 2013)            |
| Jerusalem artichokes                   | 0.23                | STMR (EFSA, 2013)            |
| Parsnips                               | 0.23                | STMR (EFSA, 2013)            |
| Parsley roots/Hamburg roots parsley    | 0.23                | STMR (EFSA, 2013)            |
| Radishes                               | 0.295               | STMR (EFSA, 2013)            |
| Salsiflies                              | 0.23                | STMR (EFSA, 2013)            |
| Swedes/rutabagas                       | 0.23                | STMR (EFSA, 2013)            |
| Turnips                                | 0.23                | STMR (EFSA, 2013)            |
| Garlic                                 | 2.2                 | STMR (EFSA, 2013)            |
| Onions                                 | 2.2                 | STMR (EFSA, 2013)            |
| Shallots                               | 2.2                 | STMR (EFSA, 2013)            |
| Spring onions/green onions and Welsh onions | 2.2 | STMR (EFSA, 2013) |
| Tomatoes                               | 0.35                | STMR (EFSA, 2013)            |
| Sweet peppers/bell peppers             | 0.71                | STMR (EFSA, 2013)            |
| Aubergines/egg plants                  | 0.35                | STMR (EFSA, 2013)            |
| Okra/lady's fingers                    | 0.35                | STMR (EFSA, 2013)            |
| Cucumbers                              | 0.17                | STMR (EFSA, 2013)            |
| Gherkins                               | 0.17                | STMR (EFSA, 2013)            |
| Commodity                        | Input value (mg/kg) | Comment            |
|---------------------------------|---------------------|--------------------|
| Courgettes                     | 0.17                | STMR (EFSA, 2013)  |
| Melons                          | 0.17                | STMR (EFSA, 2013)  |
| Pumpkins                        | 0.17                | STMR (EFSA, 2013)  |
| Watermelons                     | 1                   | MRL (EFSA, 2013)   |
| Broccoli                        | 1.2                 | STMR (EFSA, 2013)  |
| Cauliflower                     | 1.2                 | STMR (EFSA, 2013)  |
| Brussels sprouts                | 1.2                 | STMR (EFSA, 2013)  |
| Head cabbages                   | 1.2                 | STMR (EFSA, 2013)  |
| Chinese cabbages/pe-tsai        | 1.04                | STMR (EFSA, 2013)  |
| Kales                           | 1.04                | STMR (EFSA, 2013)  |
| Kohlrabies                      | 1.2                 | STMR (EFSA, 2013)  |
| Lamb’s lettuce/corn salads      | 3.4                 | STMR (EFSA, 2020)  |
| Lettuces                        | 3.4                 | STMR (EFSA, 2020)  |
| Escaroles/broad-leaved endives  | 3.4                 | STMR (EFSA, 2020)  |
| Cress and other sprouts and shoots | 3.4             | STMR (EFSA, 2020)  |
| Land cress                      | 3.4                 | STMR (EFSA, 2020)  |
| Roman rocket/rucola             | 3.4                 | STMR (EFSA, 2020)  |
| Red mustards                    | 3.4                 | STMR (EFSA, 2020)  |
| Baby leaf crops (including brassica species) | 3.4             | STMR (EFSA, 2020)  |
| Spinaches                       | 3.9                 | STMR (EFSA, 2013)  |
| Purslanes                       | 3.9                 | STMR (EFSA, 2013)  |
| Chards/beet leaves              | 3.9                 | STMR (EFSA, 2013)  |
| Witloofs/Belgian endives        | 0.05                | STMR (EFSA, 2013)  |
| Chervil                         | 23                  | STMR (EFSA, 2013)  |
| Chives                          | 23                  | STMR (EFSA, 2013)  |
| Celery leaves                   | 23                  | STMR (EFSA, 2013)  |
| Parsley                         | 23                  | STMR (EFSA, 2013)  |
| Sage                            | 23                  | STMR (EFSA, 2013)  |
| Rosemary                        | 23                  | STMR (EFSA, 2013)  |
| Thyme                           | 23                  | STMR (EFSA, 2013)  |
| Basil and edible flowers        | 23                  | STMR (EFSA, 2013)  |
| Laurel/bay leaves               | 23                  | STMR (EFSA, 2013)  |
| Tarragon                        | 23                  | STMR (EFSA, 2013)  |
| Beans (with pods)               | 1.04                | STMR (EFSA, 2013)  |
| Beans (without pods)            | 1.04                | STMR (EFSA, 2013)  |
| Peas (with pods)                | 1.04                | STMR (EFSA, 2013)  |
| Peas (without pods)             | 1.04                | STMR (EFSA, 2013)  |
| Lentils (fresh)                 | 1.04                | STMR (EFSA, 2013)  |
| Asparagus                       | 0.01                | STMR (EFSA, 2013)  |
| Cardoons                        | 1.98                | STMR (EFSA, 2013)  |
| Celeries                        | 1.98                | STMR (EFSA, 2013)  |
| Florence fennels                | 2.2                 | STMR (EFSA, 2013)  |
| Globe artichokes                | 1.8                 | STMR (EFSA, 2013)  |
| Leeks                           | 2.2                 | STMR (EFSA, 2013)  |
| Rhubarbs                        | 0.1                 | STMR (EFSA, 2013)  |
| Beans                            | 0.01                | STMR (EFSA, 2013)  |
| Lentils                          | 0.01                | STMR (EFSA, 2013)  |
| Peas                             | 0.01                | STMR (EFSA, 2013)  |
| Commodity                              | Input value (mg/kg) | Comment                     |
|----------------------------------------|---------------------|-----------------------------|
| Lupins/lupini beans                    | 0.01                | STMR (EFSA, 2013)           |
| Linseeds                               | 0.02                | STMR (EFSA, 2016b)          |
| Peanuts/groundnuts                     | 0.01                | STMR (EFSA, 2013)           |
| Poppy seeds                            | 0.06                | STMR (EFSA, 2013)           |
| Sunflower seeds                        | 0.04                | STMR (EFSA, 2013)           |
| Rapeseeds/canola seeds                 | 0.06                | STMR (EFSA, 2013)           |
| Soyabeans                              | 0.05                | STMR (EFSA, 2013)           |
| Mustard seeds                          | 0.06                | STMR (EFSA, 2013)           |
| Cotton seeds                           | 0.01                | STMR (EFSA, 2013)           |
| Safflower seeds                        | 0.02                | STMR (EFSA, 2016b)          |
| Borage seeds                           | 0.02                | STMR (EFSA, 2016b)          |
| Gold of pleasure seeds                 | 0.06                | STMR (EFSA, 2013)           |
| Barley                                 | 0.05                | STMR (FAO, 2013)            |
| Maize/corn                             | 0.01                | STMR (EFSA, 2013)           |
| Oat                                    | 0.05                | STMR (FAO, 2013)            |
| Rice                                   | 0.52                | STMR (EFSA, 2013)           |
| Rye                                    | 0.08                | STMR (EFSA, 2013)           |
| Sorghum                                | 1.85                | STMR (FAO, 2013)            |
| Wheat                                  | 0.08                | STMR (EFSA, 2013)           |
| Coffee beans                           | 0.01                | STMR (FAO, 2013)            |
| Hops (dried)                           | 3.93                | STMR (EFSA, 2013)           |
| **Sugar beet roots**                   | **1.35**            | STMR (see Appendix B.1.2.1) |
| Sugar canes                            | 0.02                | STMR (FAO, 2017)            |
| Chicory roots                          | 0.03                | STMR (EFSA, 2013)           |
| Swine: Muscle/meat                     | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Swine: Fat tissue                      | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Swine: Liver                           | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Swine: Kidney                          | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Bovine: Muscle/meat                    | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Bovine: Fat tissue                     | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Bovine: Kidney                         | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Sheep: Muscle/meat                     | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Sheep: Fat tissue                      | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Sheep: Liver                           | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Sheep: Kidney                          | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Goat: Muscle/meat                      | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Goat: Fat tissue                       | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Goat: Liver                            | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Goat: Kidney                           | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Poultry: Muscle/meat                   | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Poultry: Fat tissue                    | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Poultry: Liver                         | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Milk: Cattle                           | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Milk: Sheep                            | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Milk: Goat                            | 0.01                | STMR (EFSA, 2013 based on CXL) |
| Eggs: Chicken                          | 0.01                | STMR (EFSA, 2013 based on CXL) |

STMR: supervised trials median residue; PeF: Peeling factor; CXL: Codex maximum residue limit.
### Appendix E – Used compound codes

| Code/Trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-------------------------------------------------|----------------------------------|
| **Azoxystrobin**                | methyl (2E)-2-[(6-(2-cyanophenoxy)pyrimidin-4-yl)oxy]phenyl]-3-methoxyacrylate <br> O=C(OC)(C=OC)c1cccc1 Oc1cc(Oc2ccccc2C#N)ncn1 <br> WFDXOXNFRHQEC-GHRJWEEISA-N | ![Structural formula for Azoxystrobin](image) |
| **L1**                          | methyl (2E)-2-[(6-(2-cyanophenoxy)pyrimidin-4-yl)oxy]-x-hydroxyphenyl]-3-methoxyprop-2-enoate <br> O=C(OC)(C=OC)c1cc(O)c10c1cc(Oc2ccccc2C#N)ncn1 <br> YGORCRAVOJDUML-SFQUDFHCSA-N | ![Structural formula for L1](image) |
| **L4**                          | S-(2-cyano-x-hydroxyphenyl)cysteine <br> O=C(O)(N)Sc1ccc(O)c1c1C#N <br> HHJSURCWSNDRKW-UHFFFAOYSA-N | ![Structural formula for L4](image) |
| **L9**                          | 2-[(6-(2-cyanophenoxy)pyrimidin-4-yl)oxy]-x-hydroxybenzoic acid <br> O=C(O)c1ccc(O)c10c1cc(Oc2ccccc2C#N)ncn1 <br> KBPYPVCAGBHCJS-UHFFFAOYSA-N | ![Structural formula for L9](image) |
| Code/Trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-----------------------------------------------|--------------------------------|
| K1                            | 4-[[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy]-3-[[1E]-1,3-dimethoxy-3-oxoprop-1-en-2-yl]phenyl glucopyranuronic acid | ![Structural formula](image) |
|                               | Refers to a non-determined mixture of isomers with glucopyranuronic acid moiety in one of the alternative positions. Name and codes of one of the compounds is given for illustrative purposes. |
|                               | 3-[[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy]-4-[[1E]-1,3-dimethoxy-3-oxoprop-1-en-2-yl]phenyl L-glucopyranosiduronic acid |
|                               | N#Cc1ccccc1Oc1cc(ncn1)Oc1cc(O[C@H]2OC (((C@H)[O(C)(O)C2O)(C(-O))O)ccc1C(-C\(\))C(-O)OC |
|                               | BPMGKBSEQEJFIY-SFQUDFHCSA-N |

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(c): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).