REASONED OPINION

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Evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for azoxystrobin

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Abstract

The applicant Syngenta submitted a request to the competent national authority in the United Kingdom to evaluate the confirmatory data that were identified for azoxystrobin in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 as not available, and to consider new good agricultural practices (GAPs) for lettuces and other salad plants. To address the data gaps, new residue trials performed on open leaf varieties of lettuce supporting adjusted indoor, northern and southern GAPs, an assessment of the genotoxicity of the livestock metabolites L1, L4 and L9 and an assessment of the human dietary exposure to the livestock metabolites L1, L4 and L9 were submitted. The data gaps were considered partially addressed. The new information provided may require a revision (lowering) of the existing MRLs for lettuce and other salad plants and further risk management consideration for MRLs in animal commodities.

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Summary

In 2013, when the European Food Safety Authority (EFSA) reviewed the existing Maximum Residue Levels (MRLs) for azoxystrobin according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) further information about the open leaf varieties used in the northern residue trials;
2) three additional residue trials supporting the southern outdoor GAP and four additional trials supporting the indoor GAP on lettuce other salad plants;
3) additional information on the toxicological relevance of metabolites L1, L4 and L9, which were identified in products of animal origin.

Tentative MRL proposals for Lamb's lettuces/corn salads, Escaroles/broad-leaved endives, Cresses and other sprouts and shoots, Land cresses, Roman rocket/rucola, Red mustards, Baby leaf crops (including brassica species) and commodities of animal origin have been implemented in the MRL legislation by Commission Regulation (EU) No 2015/1040, including footnotes related to data gaps 1, 2 and 3, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 1 July 2017.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, Syngenta submitted an application to the competent national authority in the United Kingdom (rapporteur Member State, RMS) to evaluate the confirmatory data addressing the data gaps identified during the MRL review. The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to the EFSA on 16 September 2019.

Together with the confirmatory data, the applicant submitted in accordance with Article 6 of Regulation (EC) No 396/2005, a request to confirm the existing MRL for the active substance azoxystrobin at the level of 15 mg/kg in lettuces and other salad plants. Following the assessment of the confirmatory data, the RMS proposed to lower the existing MRL from 15 mg/kg to 10 mg/kg in lettuces and other salad plants and to confirm the tentative residue definition for risk assessment and MRL in animal commodities. The RMS produced a single evaluation report, which was submitted to the European Commission and forwarded to the EFSA on 16 September 2019.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
Enforcement residue definition: Azoxystrobin				
0251010 0251030 0251040 0251050 0251060 0251070 0251080	Lamb's lettuces/corn salads Escaroles/broad-leaved endives Cresses and other sprouts and shoots Land cresses Roman rocket/rucola Red mustards Baby leaf crops (including brassica spp.)	15 (ft 1)	10	The data gap identified by EFSA has been addressed. The MRL may be lowered to 10 mg/kg in support of adjusted and authorised critical indoor GAPs. The previous consumer risk assessment remains valid
0251020	Lettuce	15	10	There were no data gaps identified for this commodity. However, the new data submitted in support of adjusted GAPs indicate that the current MRL can be lowered to the value of 10 mg/kg

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
1011010 1012010 1013010 1014010	Swine muscle Bovine muscle Sheep muscle Goat muscle	0.01* (ft 2)	0.01*	The data gap identified by EFSA is partially addressed as full characterisation of the toxicological profile of metabolites L1, L4 and L9 is not available. However, these metabolites were not found in muscle. Therefore, the existing MRLs are not affected by this data gap and can be confirmed
1011020 1012020 1013020 1014020	Swine fat Bovine fat Sheep fat Goat fat	0.05 (ft 2)	Further risk management considerations required	The data gap identified by EFSA is partially addressed as a full characterisation of the toxicological profile of metabolites L1, L4 and L9 is not available. However, these metabolites were not found in fat. Therefore, the existing MRLs are not affected by this data gap. However, these MRLs are based on CXLs, derived by the JMPR for a more critical EU livestock dietary burden. The EU dietary burden calculated under this assessment is lower, indicating that an MRL of 0.01* mg/kg would be sufficient
1011030 1011040 1011050 1012030 1012040 1012050 1013030 1013040 1013050 1014030 1014040 1014050	Swine liver Swine kidney Swine (edible offals) Bovine liver Bovine kidney Bovine (edible offals) Sheep liver Sheep kidney Sheep (edible offals) Goat liver Goat kidney Goat (edible offals)	0.07 (ft 2)	Further risk management considerations required	The data gap identified by EFSA is partially addressed as the genotoxic potential of metabolites L1, L4 and L9 (found exclusively in ruminant liver and kidney) can be ruled out, but a full characterisation of the toxicological profile of these metabolites has not been provided The indicative human exposure resulting to the occurrence of metabolites L1, L4 and L9 in liver and kidney (estimated for the EU livestock dietary burden) was estimated and the RMS concluded that the low exposure does not trigger further investigation for these compounds. The RMS proposed to confirm the risk assessment residue definition in animal commodities as azoxystrobin alone Further risk management considerations should be given to decide whether the argument of the low exposure is acceptable to waive the need to submit data on the general toxicity of L1, L4 and L9. Nevertheless, EFSA noted that this argument does not support the existing EU MRLs (based on CXLs and more critical (5N) livestock dietary burden). Therefore, in the case where risk managers would accept the rationale of the RMS to address the data gap, MRLs for liver, kidney and other edible offals should be set at the LOQ (0.01* mg/kg), in line with the EU dietary burden calculated under the present assessment

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
1016010 1016020 1016030 1016040 1016050	Poultry muscle Poultry fat Poultry liver Poultry kidney Poultry (edible offals)	0.01* (ft 2)	0.01*	The data gap identified by EFSA is partially addressed as full characterisation of the toxicological profile of metabolites L1, L4 and L9 is not available However, as these compounds were not found in the metabolism studies performed on poultry, the existing MRLs are not affected by this data gap and can be confirmed
1020010 1020020 1020030 1020040	Cattle milk Sheep milk Goat milk Horse milk	0.01* (ft 2)	0.01*	The data gap identified by EFSA is partially addressed as full characterisation of the toxicological profile of metabolites L1, L4 and L9 is not available However, as these compounds were not found in milk, the existing MRLs are not affected by this data gap and can be confirmed
1030000	Birds eggs	0.01* (ft 2)	0.01*	The data gap identified by EFSA is partially addressed as full characterisation of the toxicological profile of metabolites L1, L4 and L9 is not available However, as these compounds were not found in eggs, the existing MRL is not affected by this data gap and can be confirmed

*: Indicates that the MRL is proposed at the limit of quantification.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2017, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1 and No 2).
ft 2: The European Food Safety Authority identified some information on toxicity of metabolites as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2017, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 3).

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Assessment

The review of existing maximum residue levels (MRLs) for the active substance azoxystrobin according to Article 12 of Regulation (EC) No 396/2005[1] (MRL review) has been performed in 2013 (EFSA, 2013). European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The list of GAPs assessed in the framework of the MRL review that were not fully supported by data and for which confirmatory data were requested are listed in Appendix A.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2015/1040[2], including footnote(s) for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 1 July 2017.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2020), the applicant, Syngenta, submitted an application to the competent national authority in the United Kingdom (designated rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review. The following data gaps were identified by EFSA:

1) further information about the open leaf varieties used in the northern residue trials;
2) three additional residue trials supporting the southern outdoor GAP and four additional trials supporting the indoor GAP on lettuce other salad plants;
3) additional information on the toxicological relevance of metabolites L1, L4 and L9, which were identified in products of animal origin.

Tentative MRL proposals for lamb's lettuces/corn salads, escaroles/broad-leaved endives, cresses and other sprouts and shoots, land cresses, Roman rocket/rucola, red mustards, baby leaf crops (including brassica species) and commodities of animal origin have been implemented in the MRL legislation by Commission Regulation (EU) No 2015/1040, including footnotes related to data gaps 1, 2 and 3, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 1 July 2017.

To address the data gaps identified by EFSA, the applicant provided new residue trials performed on open leaf varieties of lettuce supporting indoor, northern and southern GAPs, an assessment of the genotoxicity of the livestock metabolites L1, L4 and L9 and further detailed assessment of the residue levels of livestock metabolites L1, L4 and L9 and their expected intake in the human diet.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 16 September 2019 (United Kingdom, 2019). EFSA assessed the application as requested by the European Commission in accordance with Article 9 of Regulation (EC) No 396/2005.

In addition, under the same application and in accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta also submitted an application to modify the existing MRLs for azoxystrobin in lettuces and other salad plants. The RMS produced a single evaluation report, which was submitted to the European Commission and forwarded to the EFSA on 16 September 2019.

EFSA based its assessment on the evaluation report submitted by the RMS (United Kingdom, 2019), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 and additional assessments on azoxystrobin performed after the MRL review (EFSA, 2016a,b).

For this application, the data requirements established in Regulation (EU) No 544/2011[3] and the relevant guidance documents applicable at the date of implementation of the confirmatory data requirements by Regulation (EU) No 2015/1040 and the guidance documents applicable at the date of submission of the application to the RMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal

[1] 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, 16.03.2005, p. 1–16.

[2] Commission Regulation (EU) 2015/1040 of 30 June 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products OJ L 167, 1.7.2015, p. 10–56.

[3] 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.

provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[4].

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B.

The evaluation report submitted by the RMS (United Kingdom, 2019) 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. Mammalian toxicology

In the goat metabolism study assessed under the EU pesticides peer review, the metabolites L1, L4 and L9 were identified. The toxicological profile of these metabolites could not be assessed and therefore a data gap was set for the toxicological profile of these metabolites (EFSA, 2010). New studies to address the toxicity of metabolites L1, L4 and L9 were not provided for the MRL review either (EFSA, 2013) and consequently the data gap on toxicological relevance of these metabolites, affecting the MRL proposals for animal commodities, was implemented in Regulation (EU) 2015/1040 (data gap number 3[5]). In order to address this data gap, an additional evaluation of these metabolites was provided in the context of the present MRL application (United Kingdom, 2019).

The genotoxicity potential of metabolites L1, L4 and L9 was assessed by using a range of (Q)SAR predication models and supported by structurally similarity to parent. Overall, it is concluded that for these metabolites, genotoxicity is unlikely based on (Q)SAR predictions which do not indicate any particular concern with respect to the parent.

Regarding general toxicity, further toxicological data were not submitted to assess whether these metabolites are of qualitatively or/and quantitatively similar toxicity in comparison with the parent compound azoxystrobin.

EFSA concludes that the data gap is only partially addressed. Considerations of the RMS and applicant on the relevance of these metabolites in the consumer exposure and justification of why the general toxicological profile of these metabolites was not assessed, are reported in Sections 3 (residue levels) and 4 (consumer dietary exposure) and discussed in Section 5.

2. Residues in plants

2.1. Nature of residues and methods of analysis in plants

Not relevant for the current assessment.

The previously derived residue definitions are still applicable (see Appendix B.2.1.1).

2.2. Magnitude of residues in plants

Lettuces and other salad plants: lamb's lettuce, lettuce, escarole, cress, land cresses, rocket/rucola, red mustard and leaves and sprouts of Brassica spp.

After the MRL review carried under article 12 of Regulation 396/2005, an MRL of 15 mg/kg was set on lamb's lettuce, lettuce, escarole, cress, land cresses, rocket/rucola, red mustard and leaves and sprouts of Brassica spp., on the basis of authorised indoor use. For all these commodities except lettuce, the MRL was set on a tentative basis because residue trials performed on open leaf varieties of lettuce were found to be missing in the northern outdoor,[6] southern outdoor[7] and indoor[14] zones (EFSA, 2013).

In order to address the data gaps number 1 and 2, the applicant submitted adjusted GAPs on lamb's lettuce, lettuce, escarole, cress, land cresses, rocket/rucola, red mustard and leaves and sprouts of Brassica spp., and supporting trials for the indoor zone, the northern outdoor zone and the southern outdoor zone. The adjusted indoor GAP is like the authorised GAP assessed in the MRL

[4] 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.

[5] Data gap number 3: additional information on the toxicological relevance of metabolites L1, L4 and L9, which were identified in products of animal origin.

[6] Data gap number 1: further information about the open leaf varieties used in the northern residue trials.

[7] Data gap number 2: three additional residue trials supporting the southern outdoor GAP and four additional trials supporting the indoor GAP on lettuce other salad plants.

review except that the interval between applications is now 7 days (instead of 14 days in the MRL review). The adjusted GAPs for northern and southern outdoor zones are less critical than the authorised GAPs assessed in the MRL review due to a lower number of applications. The data sets reported in the present opinion are combinations of old trials (submitted in previous MRL assessments) and new trials. An overview of all trials is available in Appendix B.2.2.1.

Authorised indoor GAP (MRL review, EFSA, 2013): 2 × 250 g a.s./ha; PHI 14 d (14 days interval)

Adjusted indoor GAP: 2 × 250 g a.s./ha; PHI 14 days (7 days interval)

In order to address the data gap number 2, 12 trials performed with two applications at 250 g a.s./ha and a PHI 14 days were reported in the evaluation report (United Kingdom, 2019). Eight of these trials have been previously assessed in EFSA outputs (EFSA, 2012, 2013). It should be noted that four of these trials (2.2; 4.7; 4.3 and 6.2 mg/kg) which were previously considered as performed on closed leaf lettuce varieties (i.e. `cos` lettuce) (EFSA, 2012, 2013) are now considered to belong to open leaf lettuce varieties according to the extrapolation guidance document SANCO 7525/VI/95 Rev. 10.3 (Table 4) (European Commission, 2017). Therefore, these eight trials can be considered representative of open leaf varieties of lettuce. Two of these trials were performed with an interval between application of 7 days, whereas the remaining six trials had an interval of 14 days. In addition, the applicant submitted four new trials on lettuce, which were performed on open leaf varieties of lettuce (namely *Charles*, *Batavia* and *Kinshasa*) and are fully compliant with the adjusted GAP. Consequently, a total of six trials fully compliant with the adjusted GAP (7 days interval) and six trials compliant with the authorised GAP (14 days interval), all conducted on open leaf lettuce varieties, are available. Based on the residue decline studies, a significant decrease of residue concentrations is generally observed 21 days after application. Therefore, the interval between applications (7 or 14 days) is not expected to have an impact on the final residue concentration when the harvest is done 14 days after the last application. This is confirmed by a comparison of the six results obtained with the interval 7 days vs. interval 14 days. A statistical comparison performed with the U-test (Mann–Whitney) does not indicate significant difference between the two data sets. Consequently, it is concluded that the 12 indoor trials can be merged to derive an MRL based on the adjusted indoor GAPs. Further residues trials supporting the indoor GAP are not required.

Authorised NEU GAP (MRL review, EFSA, 2013): 4 × 250 g a.s./ha; PHI 14 days (7 days interval)

Adjusted Northern outdoor GAP: 2 × 250 g a.s./ha; PHI 14 days (7 days interval)

In order to address the data gap number 1, no new information/data were submitted in support of the authorised GAP. Instead, the applicant reported nine trials on lettuce compliant with the adjusted GAP. Eight of these trials are the same as the ones previously assessed in the EFSA opinion on MRL setting: six trials performed on open leaf varieties and two trials performed on close leaf varieties (EFSA, 2012). In addition, one new northern trial was submitted in the present dossier. This trial was performed on open leaf varieties of lettuce (namely *Frisee*).

Consequently, a total of nine trials compliant with the adjusted GAP, seven of them conducted on open leaf varieties and two on close leaf varieties, are available.

Authorised SEU GAP (MRL review, EFSA, 2013): 3 × 250 g a.s./ha; PHI 7 d (7 d interval)

Adjusted Southern outdoor GAP: 2 × 250 g a.s./ha; PHI 7 days (7 days interval)

In order to address the data gap number 2, no new data were submitted in support of the authorised GAP. Instead, 11 trials compliant with the adjusted GAP were reported in the evaluation report. Eight of these trials have been previously assessed in the EFSA opinion on MRL setting: four trials performed on open leaf varieties and four trials performed on close leaf varieties (EFSA, 2012). In addition, three new southern trials were submitted in the framework of the current assessment. These trials were performed on open leaf varieties of lettuce (namely *Canasta and Cervantes*).

Consequently, a total of 11 trials compliant with the adjusted GAP, seven of them conducted on open leaf varieties and four on close leaf varieties, is available.

Discussion and conclusion:

Based on the adjusted indoor GAP and its supporting data set (12 trials on open leaf varieties), a robust MRL of 10 mg/kg can be derived for lettuce (see details in Appendix B.2.2.1). According to the extrapolation guidance document SANCO 7525/VI/95 Rev. 10.3 (Table 4) (European Commission, 2017), these results can be extrapolated to lamb's lettuce, escarole, cress, land cresses, rocket/rucola, red mustard and leaves and sprouts of Brassica spp. in support of the adjusted indoor GAPs on these crops.

Based on the northern data set (nine trials) and southern data set (11 trials), MRLs of 1 mg/kg and 5 mg/kg, respectively, would be derived for lettuce (see details in Appendix B.2.2.1). For these GAPs, a minor deficiency is to be noted: only seven trials were performed on open leaf varieties while the guidance document on extrapolation requires eight trials on open leaf varieties to allow extrapolation from lettuce trials to all crops belonging to the group of lettuce and other salad plants (crop group code 251000). However, considering that the northern outdoor GAPs and the southern outdoor GAPs result in significantly lower MRLs compared to the indoor GAP, one additional trial on open leaf varieties in NEU and one additional trial on open leaf varieties in SEU are not required.

EFSA notes that the MRL proposal of 10 mg/kg as derived in support of the adjusted indoor GAP for lamb's lettuce, lettuce, escarole, cress, land cresses, rocket/rucola, red mustard and leaves and sprouts of Brassica spp. is lower than the existing EU MRL of 15 mg/kg. A risk management decision is required for the lowering of MRL for azoxystrobin in lettuces and other salad plants. It is concluded that the data gaps number 1 and 2 identified in the framework of the MRL review are addressed.

3. Residues in livestock

In the framework of the MRL review, EFSA identified data gaps related to the toxicological relevance of metabolites L1, L4 and L9, which were identified in ruminant liver and kidney (data gap number 3[5]). In order to address this data gap, the applicant provided, in the framework of the current assessment, information that allowed to conclude that the genotoxic potential of these three compounds can be ruled out (see Section 1). However, the applicant did not provide data on the general toxicity of these metabolites. Instead, calculations were provided to demonstrate that the expected dietary exposure of consumers to these metabolites (from the intake of liver and kidney) is low and would therefore not be of toxicological concern.

EFSA assessed whether the newly submitted information may change the conclusion of the previous assessment (EFSA, 2013) as regards the toxicological relevance of metabolites L1, L4 and L9 and the tentative risk assessment residue definition in animal commodities. First, EFSA recalculated the livestock exposure according to the OECD methodology (OECD, 2013), considering all crops on which the use of azoxystrobin is authorised, including also those commodities on which the uses of azoxystrobin were assessed since the MRL review, namely linseed and safflower (EFSA, 2016b). The input values used to perform this calculation are reported in Annex D.1. and the outcome of the calculations is reported in Appendix B.3. Secondly, EFSA assessed the calculations of the RMS regarding the respective residue levels of metabolites L1, L4 and L9 in animal tissues (see Section 3.3.2). Finally, EFSA assessed the calculations of the RMS regarding the human dietary exposure to metabolites L1, L4 and L9 (see Section 4.2).

As lettuces and other salad plants are not used as a livestock feed, the new data provided on the magnitude of azoxystrobin residues in lettuce and other salad plants did not impact this assessment.

3.1. Nature of residues

No new data.

The previously derived residue definition for monitoring is still applicable (see Appendix B.2.1).

The RMS proposed to confirm the residue definition for risk assessment in animal commodities which was tentatively set as azoxystrobin, pending information on the toxicological profile of metabolites L1, L4 and L9. This is discussed in Section 5.

3.2. Methods of analysis in livestock

No new data.

3.3. Magnitude of residues in livestock

3.3.1. Azoxystrobin

As lettuces and other salad plants are not used as a livestock feed, the new data provided on the magnitude of azoxystrobin residues in lettuce and other salad plants did not impact on the azoxystrobin levels in livestock commodities.

EFSA reminds that the EU livestock dietary burden calculated in the MRL review resulted in the MRL values at the limit of quantification (LOQ) in all animal matrices (EFSA, 2013). However, the MRL review also assessed existing CXLs for animal commodities, which were set at higher levels (also based

on the EU dietary burden (FAO, 2008, 2011)). Consequently, the MRL review proposed to take these CXLs over in the EU legislation, noting the general data gap on the toxicological relevance of livestock metabolites L1, L4 and L9.

The EU MRLs which are derived from CXLs (e.g. mammalian liver, kidney, edible offal (0.07 mg/kg) and fat (0.05 mg/kg)) reflect a significantly higher livestock dietary burden (72 mg/kg DM) compared to the EU livestock dietary burden calculated in the current assessment. EFSA is not in position to reassess these calculations of the JMPR but notes that considering the EU livestock dietary burden calculated in the current assessment (see Appendix B.3), lower MRLs would be sufficient to accommodate the existing EU uses of azoxystrobin (see Appendix B.3.2).

3.3.2. Metabolites L1, L4 and L9

The data from livestock metabolism studies were used by the RMS to assess the magnitude of metabolites L1, L4 and L9 in livestock matrices at the EU dietary burdens (i.e. calculated for the existing EU uses of azoxystrobin). The concentrations of metabolites L1, L4 and L9 observed in liver and kidney from the goat metabolism study (25 mg/kg diet) and scaled to the 1N dose (considering updated EU dietary burden in respective animal categories) are reported in Table 1. Metabolite K1 is the glucuronide conjugate of L1 and it is therefore also considered in this assessment.

Table 1: Estimated TRR levels (mg eq/kg) of metabolites L1, L4, L9 and K1 in livestock kidney and liver at the calculated maximum EU dietary burdens

	Highest TRR observed	**Expected TRR in 1N, based on MAX dietary burden (DB) (mg eq/kg)**						
	Metabolism study performed on goat at 25 mg/kg diet	**Cattle MAX DB: 15.35 mg/kg DM**		**Sheep MAX DB: 5.79 mg/kg DM**		**Swine MAX DB: 10.60 mg/kg DM**		
Metabolite	Liver	Kidney	Liver	Kidney	Liver	Kidney	Liver	Kidney
L1	0.03	0.009	0.018	0.006	0.007	0.002	0.013	0.004
L4	0.35	ND	0.215	–	0.081	–	0.148	–
L9	0.01	ND	0.006	–	0.002	–	0.004	–
K1	0.01	0.03	0.006	0.018	0.002	0.007	0.004	0.013

ND: not detected.

The maximum calculated residue levels for metabolites L1, L4, L9 and K1 in animal tissues are 0.018 mg eq/kg (cattle liver), 0.215 mg eq/kg (cattle liver) and 0.006 mg eq/kg (cattle liver) and 0.018 mg eq/kg (cattle kidney), respectively. These levels are associated with the maximum EU dietary burden of cattle calculated in the present opinion (15.35 mg/kg DM).

The current EU MRLs for livestock commodities come from the CXLs which were derived on the basis of a significantly higher dietary burden for cattle (i.e. 72 mg/kg DM for dairy cattle; FAO, 2008, 2011). For the dietary burden of 72 mg/kg DM, the calculated levels for metabolites L1, L4, L9 and K1 in cattle liver and kidney would be multiplied by a factor of 5 (indicative ratio based on the dietary burdens[8]).

4. Consumer risk assessment

4.1. Consumer risk assessment for azoxystrobin

Although the additional data submitted in the present application are not expected to have a major impact on the dietary exposure of consumers, an updated consumer risk assessment was performed by EFSA considering:

- As residue definition for risk assessment for plant and animal products: azoxystrobin.
- All input values previously considered for the consumer risk assessment of azoxystrobin (last update in EFSA, 2016b).
- The risk assessment values for lettuce and other salad plants calculated in this opinion.

[8] JMPR dietary burden (72 mg/kg DM)/EU dietary burden (15 mg/kg DM) = 4.8.

- The CXLs and associated risk assessment values for prickly pears/cactus fruits and sugar cane (FAO, 2017), recently implemented in the EU legislation by Regulation (EU) No 2019/552.
- The last version of PRIMo (Rev3.1).

The toxicological profile of azoxystrobin was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive a toxicological reference value for acceptable daily intake (ADI) of 0.2 mg/kg per day. The derivation of an acute reference dose (ARfD) was considered not necessary (EFSA, 2010).

The input values used to perform this calculation are reported in Annex D.2. The estimated chronic exposures were compared with the ADI of azoxystrobin. The outcome of the calculations is reported in Appendix B.4.

The highest calculated chronic intake accounted for 19% of the ADI (DE child diet). The short-term (acute) exposure is not relevant since no ARfD has been considered necessary for azoxystrobin. The confirmatory data assessed in this opinion do not increase the current consumer exposure to azoxystrobin, which is unlikely to pose a concern for public health.

4.2. Indicative exposure to metabolites L1, L4, L9 and K1 (conjugate of L1) (as a sum)

The general toxicity of the metabolites identified in livestock metabolism studies (i.e. L1, L4, L9 and K1 (conjugate of L1)) has not been assessed (see Section 1). However, the RMS performed a dietary exposure assessment for these compounds. The exposure was expressed as μg/kg body weight (bw) day for long-term exposure and μg/kg bw for short-term exposure. These metabolites were only found in ruminant liver and kidney; thus, the RMS calculated the exposure based on the occurrence of these compounds in liver and kidney of each animal category. The input values considered by the RMS for the consumer exposure calculation were expressed as the sum of metabolites L1, L4, L9 and K1. The levels were as calculated at 1N rate of the EU dietary burden and corrected using the respective molecular weights of these compounds. The RMS performed the exposure calculations using PRIMo rev.2. The maximum chronic exposure calculated by the RMS was 0.053 μg/kg bw per day; the maximum acute intake of 1.86 μg/kg bw (bovine liver) (United Kingdom, 2019).

EFSA performed a similar calculation considering the residue concentrations of L1, L4, L9 and K1 at the updated EU dietary burden (see Section 3.3.2) and using PRIMo rev.3.1. The input values for the exposure calculation are presented in Appendix D.3. This resulted in a maximum chronic intake of 0.042 μg/kg bw per day and maximum acute intake of 1.3 μg/kg bw (bovine liver). The intake calculated by EFSA is slightly lower but in the same order of magnitude as the one calculated by the RMS.

The RMS compared the exposure calculated for metabolites L1, L4, L9 and K1 (conjugate of L1)) to the toxicological threshold of concern (TTC) for Cramer Class III (United Kingdom, 2019). However, the TTC approach as proposed in the EFSA PPR Guidance on the Residue Definition for risk assessment (EFSA PPR Panel, 2016) has not been endorsed by the Commission and the Member States. Therefore, the TTC approach cannot be applied in this context. Consequently, lacking toxicological information required to derive an ADI/ARfD, a definitive conclusion on the risk for consumers exposed to L1, L4 and L9 via intake of animal products cannot be derived by EFSA.

Furthermore, the exposure calculations proposed by the RMS (and updated by EFSA) are affected by a non-standard uncertainty because occurrence data in livestock tissues are based on the goat metabolism study (only one study result) instead of feeding studies. The consumer exposure calculations reflect the intake of metabolites as estimated in liver and kidney for the maximum EU dietary burden as calculated in the current assessment (i.e. max 15 mg/kg DM). This dietary burden, as noted before, would lead to azoxystrobin MRLs at the LOQ in all livestock commodities (see Appendix B.3.2).

The existing EU MRLs for azoxystrobin in mammalian liver and kidney are set at the levels above the LOQ and are based on the Codex MRLs (CXLs), for which the maximum dietary burden in cattle was much higher (72 mg/kg DM) than the one calculated in the present opinion (15 mg/kg DM). Therefore, the above calculations do not reflect the consumer exposure to metabolites L1, L4 and L9 if mammalian kidney and liver contain residues of azoxystrobin at the levels of existing EU MRLs (CXLs).

EFSA considers that the results of the above scenario (based on EU dietary burden) are underestimated by a factor of 5 compared to a scenario associated with residues resulting from the existing EU MRLs. Consequently, the argument of the applicant and the RMS to consider low consumer exposure as a reason for waiving the assessment of general toxicity of metabolites L1, L4 and L9 is not fully valid if consumers are exposed to azoxystrobin residues in animal commodities at the levels of existing EU MRLs.

5. Conclusion and Recommendations

To address data gaps identified in the framework of the MRL review (EFSA, 2013), the applicant has submitted the following data/information:

- Residue trials performed on open leaf varieties of lettuce supporting indoor, northern and southern adjusted GAPs.
- An assessment of the genotoxicity of the livestock metabolites L1, L4 and L9.
- New calculations on the occurrence of livestock metabolites L1, L4 and L9 in livestock tissues and argumentation on their relevance in the consumer dietary exposure.

Regarding the magnitude of residues in lettuce and other salad plants, the data gaps identified in the framework of the MRL review were addressed. The applicant reported adjusted indoor, NEU and SEU GAPs and supporting residue trials on lettuce. The new data allow to derive a lower MRL of 10 mg/kg for lamb's lettuce, lettuce, escarole, cress, land cresses, rocket/rucola, red mustard and leaves and sprouts of Brassica spp. in support of the adjusted critical indoor GAP. A risk management decision is needed for the lowering of MRL for azoxystrobin in lettuces and other salad plants.

Regarding the toxicological assessment of livestock metabolites L1, L4 and L9, the submitted data allowed to conclude that the genotoxic potential of these three compounds can be ruled out. However, data addressing the general toxicity of these compounds were not provided. Based on calculations to demonstrate that the expected dietary exposure of consumers to these metabolites was lower than the TTC, the RMS concluded that further data addressing the general toxicity of these compounds were not needed and thus proposed to confirm the residue definition for risk assessment in animal commodities as azoxystrobin alone. EFSA highlighted that the TTC approach cannot be applied in this context. EFSA concludes that the data gap identified in the framework of the MRL review was only partially addressed. Further risk management considerations should be given to decide whether the argument of the low exposure calculated for metabolites L1, L4, L9 and K1 (conjugate of L1) is acceptable to waive the need to submit data on the general toxicity of L1, L4 and L9. Meanwhile, the residue definition for risk assessment in animal commodities is still deemed tentative.

Furthermore, EFSA highlighted the following points for risk managers considerations:

- The current MRLs in mammalian liver, kidney, edible offal and fat are based on CXLs, which were derived from higher livestock dietary burden compared to the EU scenario assessed in the present opinion (e.g. five times higher for the cattle dietary burden). Therefore, the low exposures calculated by the RMS for metabolites L1, L4, L9 and K1, which account only for EU dietary burden calculated under current assessment, do not cover the existing EU MRLs for livestock commodities.
- The calculations on the occurrence of metabolites L1, L4, L9 and K1 (conjugate of L1) in animal products were based on the EU dietary burden assessed in this opinion. Therefore, the low exposure calculated by the RMS should be associated with azoxystrobin MRLs at the LOQs for all animal commodities. Consequently, if risk managers consider the exposure calculated by the RMS as a relevant argument to address the data gap on general toxicity for those metabolites, MRLs for animal commodities would need to be updated accordingly (i.e. lowered to LOQ).

The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix B.5.

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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
CAS	Chemical Abstract Service

CF	conversion factor for enforcement to risk assessment residue definition
CIRCA	(EU) Communication & Information Resource Centre Administrator
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DS	powder for dry seed treatment
EC	emulsifiable concentrate
EDI	estimated daily intake
Eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GC-NPD	gas chromatography with nitrogen/phosphorous detector
GS	growth stage
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
NPD	nitrogen/phosphorous detector
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TAR	total applied radioactivity
TRR	total radioactive residue
TTC	toxicological threshold of concern
UV	ultraviolet (detector)
WHO	World Health Organization

Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

Crop and/or situation	NEU, SEU, MS or country	F, G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Authorised indoor GAP (MRL review, EFSA, 2013)															
Lettuces and salad plants	FR	I	Fungal diseases	SC	250 g/L	Foliar treatment – spraying	Max 49	2	14	–	–	250	g a.i./ha	14	All crops belonging to code Number: 0251000
Adjusted indoor GAPs (United Kingdom, 2019)															
Lamb's lettuce/ corn salads	BE	I	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	This GAP is also valid for Ireland, Luxemburg, Slovenia, United Kingdom and France
Lettuces	BE	I	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Escaroles/ broad-leaved endives	BE	I	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Cress and other sprouts and shoots	BE	I	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Land cress	BE	I	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark

Crop and/or situation	NEU, SEU, MS or country	F, G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Roman rocket/ rucola	BE	I	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Red mustards	BE	I	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Baby leaf crops (including brassica species)	BE	I	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Authorised NEU GAP (MRL review, EFSA, 2013)															
Lamb's lettuce/ corn salads	NEU	F	Fungal diseases	UK, SE	250 g/L	Foliar treatment – spraying		4				250	g a.i./ha	14	
Lettuces	NEU	F	Fungal diseases	UK, SE, BE, NL	250 g/L	Foliar treatment – spraying		4				250	g a.i./ha	14	
Escaroles/ broad-leaved endives	NEU	F	Fungal diseases	UK, SE	250 g/L	Foliar treatment – spraying		4				250	g a.i./ha	14	
Cress and other sprouts and shoots	NEU	F	Fungal diseases	UK, SE	250 g/L	Foliar treatment – spraying		4				250	g a.i./ha	14	
Land cress	NEU	F	Fungal diseases	FR	250 g/L	Foliar treatment – spraying	Max 49	2	7			250	g a.i./ha	14	
Roman rocket/ rucola	NEU	F	Fungal diseases	UK, SE	250 g/L	Foliar treatment – spraying		4				250	g a.i./ha	14	

Crop and/or situation	NEU, SEU, MS or country	F, G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Red mustards	NEU	F	Fungal diseases	UK, SE	250 g/L	Foliar treatment – spraying		4				250	g a.i./ha	14	
Baby leaf crops (including brassica species)	NEU	F	Fungal diseases	UK, SE	250 g/L	Foliar treatment – spraying		4				250	g a.i./ha	14	
Adjusted NEU GAPs (United Kingdom, 2019)															
Lamb's lettuce/ corn salads	NEU	F	Bremia lactucae, Rhizoctonia solani	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	This GAP is valid for Denmark, Finland, Sweden, Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxemburg, Netherlands, Poland and United Kingdom.
Lettuces	NEU	F	Bremia lactucae, Rhizoctonia solani	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Escaroles/ broad-leaved endives	NEU	F	Bremia lactucae, Rhizoctonia solani	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Cress and other sprouts and shoots	NEU	F	Bremia lactucae, Rhizoctonia solani	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Land cress	NEU	F	Bremia lactucae, Rhizoctonia solani	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark

Crop and/or situation	NEU, SEU, MS or country	F, G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Roman rocket/ rucola	NEU	F	Bremia lactucae, Rhizoctonia solani	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Red mustards	NEU	F	Bremia lactucae, Rhizoctonia solani	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Baby leaf crops (including brassica species)	NEU	F	Bremia lactucae, Rhizoctonia solani	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	14	Same remark
Authorised SEU GAP (MRL review, EFSA, 2013)															
Lamb's lettuce/ corn salads	SEU	F	Fungal diseases	FR, IT	250 g/L	Foliar treatment – spraying	Max 49	3	7			250	g a.i./ha	7	
Lettuces	SEU	F	Fungal diseases	PT, IT	250 g/L	Foliar treatment – spraying	Max 49	3	7			250	g a.i./ha	7	
Escaroles/ broad-leaved endives	SEU	F	Fungal diseases	IT	250 g/L	Foliar treatment – spraying	Max 49	3	7			250	g a.i./ha	7	
Cress and other sprouts and shoots	SEU	F	Fungal diseases	PT, IT	250 g/L	Foliar treatment – spraying	Max 49	3	7			250	g a.i./ha	7	
Land cress	SEU	F	Fungal diseases	FR, IT	250 g/L	Foliar treatment – spraying	Max 49	3	7			250	g a.i./ha	7	
Roman rocket/ rucola	SEU	F	Fungal diseases	FR, IT	250 g/L	Foliar treatment – spraying	Max 49	3	7			250	g a.i./ha	7	

Crop and/or situation	NEU, SEU, MS or country	F, G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Red mustards	SEU	F	Fungal diseases	FR, IT	250 g/L	Foliar treatment – spraying	Max 49	3	7			250	g a.i./ha	7	
Baby leaf crops (including brassica species)	SEU	F	Fungal diseases	IT	250 g/L	Foliar treatment – spraying	Max 49	3	7			250	g a.i./ha	7	
Adjusted SEU GAPs (United Kingdom, 2019)															
Lamb's lettuce/ corn salads	SEU	F	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	7	This GAP is valid for Greece, Spain, France, Italy and Portugal
Lettuces	SEU	F	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14-49	2	7	–	300–1,200	250	g a.i./ha	7	This GAP is valid for Greece, Spain, France, Italy and Portugal
Escaroles/ broad-leaved endives	SEU	F	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	7	This GAP is valid for Greece, Spain, France, Italy and Portugal
Cress and other sprouts and shoots	SEU	F	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	7	This GAP is valid for Greece, Spain, France, Italy and Portugal
Land cress	SEU	F	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	7	This GAP is valid for Greece, Spain, France, Italy and Portugal

Crop and/or situation	NEU, SEU, MS or country	F, G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Roman rocket/ rucola	SEU	F	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	7	This GAP is valid for Greece, Spain, France, Italy and Portugal
Red mustards	SEU	F	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	7	This GAP is valid for Greece, Spain, France, Italy and Portugal
Baby leaf crops (including brassica species	SEU	F	Bremia lactucae, Rhizoctonia solani, Erysiphe cichoracearum, Cercospora sp.	SC	250 g/L	Foliar treatment – broadcast spraying	14–49	2	7	–	300–1,200	250	g a.i./ha	7	This GAP is valid for Greece, Spain, France, Italy and Portugal

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. Mammalian toxicology

Other toxicological studies

Supplementary studies on the active substance	–
Endocrine disrupting properties	–
Studies performed on metabolites or impurities	Metabolites L1, L4 and L9, identified in goat metabolism studies, are unlikely genotoxic based on (Q)SAR predictions which do not indicate any particular concern with respect to the parent

B.2. Residues in plants

B.2.1. Nature of residues and methods of analysis in plants

B.2.1.1. 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	^{14}C-pyrimidinyl ^{14}C-cyanophenyl ^{14}C-phenylacrylate
	Cereals/grass	Wheat	Foliar: 2 × 500 g/ha; BBCH 30–31 and 59–61	Forage: 13 Grain and straw: 61–62	^{14}C-pyrimidinyl ^{14}C-cyanophenyl ^{14}C-phenylacrylate
			Foliar: 1× unknown; BBCH 71	28	14C-pyrimidinyl
	Pulses/oilseeds	Peanut	Foliar: 850 + 850 + 300 g/ha	10	^{14}C-pyrimidinyl ^{14}C-cyanophenyl ^{14}C-phenylacrylate
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	^{14}C-pyrimidinyl ^{14}C-cyanophenyl ^{14}C-phenylacrylate
	Leafy crops	Lettuce	Bare soil: 2.2 kg/ha	30, 200, 365	^{14}C-pyrimidinyl ^{14}C-cyanophenyl ^{14}C-phenylacrylate
	Cereal (small grain)	Wheat	Bare soil: 2.2 kg/ha	30, 200, 365	^{14}C-pyrimidinyl ^{14}C-cyanophenyl ^{14}C-phenylacrylate

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	EFSA (2010)
	Sterilisation (20 min, 120°C, pH 6)	Yes	EFSA (2010)

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
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)

DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.

B.2.1.2. 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	United Kingdom (2009)
		Peach	–18	24	Months	Azoxystrobin	United Kingdom (2009)
		Tomato	–18	24	Months	Azoxystrobin	United Kingdom (2009)
		Cucumber	–18	24	Months	Azoxystrobin	United Kingdom (2009)
		Lettuce	–18	24	Months	Azoxystrobin	United Kingdom (2009)
		Carrot	–18	24	Months	Azoxystrobin	United Kingdom (2009)
	High oil content	Oilseed rape	–18	24	Months	Azoxystrobin	United Kingdom (2009)
		Pecans	–18	24	Months	Azoxystrobin	United Kingdom (2009)
		Peanut	–18	24	Months	Azoxystrobin	United Kingdom (2009)
	Dry/High starch	Cereal grain	–18	24	Months	Azoxystrobin	United Kingdom (2009)
	High acid content	Grape	–18	24	Months	Azoxystrobin	United Kingdom (2009)
		Apple	–18	24	Months	Azoxystrobin	United Kingdom (2009)
		Orange	–18	24	Months	Azoxystrobin	United Kingdom (2009)
	Others	Straw	–18	24	Months	Azoxystrobin	United Kingdom (2009)

B.2.2. Magnitude of residues in plants

B.2.2.1. Summary of residues data from the supervised residue trials

Commodity	Region/ Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)
Lamb's lettuce, lettuce, escarole, cress, Land Cresses, rocket/rucola, red mustard and leaves and sprouts of Brassica spp.	NEU	< 0.01[d]; < 0.01[d]; 0.03; 0.13; 0.17; 0.22; 0.24; 0.46; 0.49	Residue trials on lettuce compliant with adjusted GAP. Extrapolation to other salad plants (crop group code 251000) is possible MRL_{OECD}: 0.92	1	0.49	0.17
	SEU	0.07[d]; 0.09; 0.20; 0.29; 0.31[d]; 0.43; 1.1; 1.4[d]; 1.9[d]; 2.1; 2.1	Residue trials on lettuce compliant with adjusted GAP. Extrapolation to other salad plants (crop group code 251000) is possible MRL_{OECD}: 4.24	5	2.1	0.43
	Indoor	Trials fully compliant with the adjusted GAP: 0.45; 0.59; 2.6; 2.9; 3.2; 4.8 Trials compliant with adjusted GAP (except interval between applications of 14 days instead of 7 days): 2.2; 3.5; 4.3; 4.4; 4.7; 6.2	Residue trials on lettuce all performed on open leaf varieties. Extrapolation to other salad plants (crop group code 251000) is possible MRL_{OECD}: 10.16	10	6.2	3.4

MRL: maximum residue level; GAP: Good Agricultural Practice.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Residue trial performed on head forming varieties of lettuce. The other trials were performed on open leaf varieties.

B.2.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	The residues declined significantly at longer plant back intervals (EFSA, 2013)
Residues in rotational and succeeding crops expected based on field rotational crop study?	No	Several rotational crop field trials were evaluated in the framework of the peer review (United Kingdom, 2009). At harvest, azoxystrobin residues were expected to be below the LOQ (0.01 mg/kg) in all mature plant parts except in wheat forage and wheat straw where the highest residues were expected to be 0.05 mg/kg and 0.04 mg/kg, respectively. However, no impact on the residue level in products of animal origin is expected (EFSA, 2013)

LOQ: limit of quantification.

B.2.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.3. Residues in livestock

EU Dietary burden assessed according to OECD GD (2013), using EFSA Animal Model.

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all)	0.46	0.59	12.0	15.4	Dairy cattle	Citrus, dried pulp	Y
Cattle (dairy only)	0.46	0.59	12.0	15.4	Dairy cattle	Citrus, dried pulp	Y
Sheep (all)	0.10	0.23	2.85	5.79	Lamb	Rye, straw	Y
Sheep (ewe only)	0.10	0.19	2.85	5.79	Ram/Ewe	Rye, straw	Y
Swine (all)	0.20	0.25	8.76	10.6	Swine (breeding)	Citrus, dried pulp	Y
Poultry (all)	0.05	0.10	0.66	1.42	Poultry layer	Wheat, straw	Y
Poultry (layer only)	0.05	0.10	0.66	1.42	Poultry layer	Wheat, straw	Y
Fish	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.3.1. Nature of residues and methods of analysis in livestock

B.3.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	**Animal**	**Dose (mg/kg diet)**	**Duration (days)**	**Comment/Source**
	Laying hen	11	10	Studies performed on goat using ^{14}C-pyrimidinyl ^{14}C-cyanophenyl and ^{14}C-phenylacrylate radiolabels
		12.5	10	
	Lactating ruminants	23.2–32.7	7	Study performed on goat using ^{14}C-pyrimidinyl ^{14}C-cyanophenyl and ^{14}C-phenylacrylate radiolabels
		25	7	Study performed on goat using ^{14}C-cyanophenyl radiolabel

Time needed to in milk and eggs (days)	Milk: not relevant	TRR in milk is ranging between 0.004–0.01 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]	
Fat soluble residues	No	Log $P_{o/w}$ < 3
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	GC-NPD (United Kingdom, 2009): 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	

TRR: total radioactive residue; $P_{o/w}$: partition coefficient between n-octanol and water; GC-NPD: gas chromatography with nitrogen phosphorous detector; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.3.1.2. Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability period		Compounds covered	Comment/Source
				Value	Unit		
	Ruminant	Muscle	–18	10	months	Azoxystrobin	United Kingdom (2009)
	Ruminant	Fat	–18	10	months	Azoxystrobin	United Kingdom (2009)
	Ruminant	Liver	–18	10	Months	Azoxystrobin	United Kingdom (2009)
	Ruminant	Kidney	–18	10	Months	Azoxystrobin	United Kingdom (2009)
	Ruminant	Milk	–18	10	Months	Azoxystrobin	United Kingdom (2009)
	Poultry	Eggs	–18	10	Months	Azoxystrobin	United Kingdom (2009)

B.3.2. Magnitude of residues in livestock

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

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

n.a.: not applicable.
*: Indicates that the MRL is proposed at the limit of quantification.
(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 four 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.4. Consumer risk assessment

B.4.1. Azoxystrobin

Short-term (acute) risk assessment: Not relevant since no ARfD has been considered necessary (EFSA, 2010).

ADI	0.2 mg/kg bw per day (EFSA, 2010)
Highest IEDI, according to EFSA PRIMo (rev. 3.1)	19% ADI (DE child) Contribution of crops assessed: <0.25% of ADI (for the sum of all lettuce and other salad plants)
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities. Contributions of all commodities assessed in the framework of the MRL review (EFSA, 2013), plus MRL applications (EFSA, 2016a,b) and CXLs implemented after the MRL review (FAO, 2013, 2017) were considered. The calculation was performed using PRIMo rev.3.1

ARfD: acute reference dose; bw: body weight; ADI: acceptable daily intake; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; CXL: Codex maximum residue limit.

B.4.2. Indicative exposure to metabolites L1, L4 and L9 and K1 (conjugate of L1) (as a sum)

ADI	Not available because general toxicity of L1, L4 and L9 was not addressed
Highest chronic intake, according to EFSA PRIMo (rev. 3.1)	0.042 µg/kg bw per day
Assumptions made for the calculations	The calculation is performed considering residues in swine, ruminant and equine liver and kidney. The input values considered for this exposure calculation is the sum of metabolites L1, L4, L9 and K1, observed in the goat metabolism study, estimated levels at 1N (based on the EU dietary burdens calculated in the present opinion) and corrected using the respective molecular weights of these compounds. These exposure calculations do not represent the situation if azoxystrobin residues in ruminant and swine kidney and liver are present at the levels of existing EU MRLs, which were derived from the CXLs for 5 times higher livestock dietary burden. The calculation was performed using PRIMo rev.3.1
ARfD	Not available because general toxicity of L1, L4 and L9 was not addressed
Highest acute intake, according to EFSA PRIMo (rev. 3.1)	1.3 µg/kg bw (bovine liver)
Assumptions made for the calculations	The calculation is performed considering residues in swine, ruminant and equine liver and kidney. The input values considered for this exposure calculation is the sum of metabolites L1, L4, L9 and K1, observed in the goat metabolism study, estimated levels at 1N (based on the EU dietary burdens calculated in the present opinion) and corrected using the respective molecular weights of these compounds. These exposure calculations do not represent the situation if azoxystrobin residues in ruminant and swine kidney and liver are present at the levels of existing EU MRLs, which were derived from the CXLs for 5 times higher livestock dietary burden. The calculation was performed using PRIMo rev.3.1

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; CXL: Codex maximum residue limit.

B.5. Recommended MRLs

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
Enforcement residue definition: Azoxystrobin				
0251010 0251030 0251040 0251050 0251060 0251070 0251080	Lamb's lettuces/corn salads Escaroles/broad-leaved endives Cresses and other sprouts and shoots Land cresses Roman rocket/rucola Red mustards Baby leaf crops (including brassica spp.)	15 (ft 1)	10	The data gap identified by EFSA has been addressed. The MRL may be lowered to 10 mg/kg in support of adjusted and authorised critical indoor GAPs. The previous consumer risk assessment remains valid
0251020	Lettuce	15	10	There were no data gaps identified for this commodity. However, the new data submitted in support of adjusted GAPs indicate that the current MRL can be lowered to the value of 10 mg/kg
1011010 1012010 1013010 1014010	Swine muscle Bovine muscle Sheep muscle Goat muscle	0.01* (ft 2)	0.01*	The data gap identified by EFSA is partially addressed as full characterisation of the toxicological profile of metabolites L1, L4 and L9 is not available. However, these metabolites were not found in muscle. Therefore, the existing MRLs are not affected by this data gap and can be confirmed
1011020 1012020 1013020 1014020	Swine fat Bovine fat Sheep fat Goat fat	0.05 (ft 2)	Further risk management considerations required	The data gap identified by EFSA is partially addressed as a full characterisation of the toxicological profile of metabolites L1, L4 and L9 is not available. However, these metabolites were not found in fat. Therefore, the existing MRLs are not affected by this data gap. However, these MRLs are based on CXLs, derived by the JMPR for a more critical EU livestock dietary burden. The EU dietary burden calculated under this assessment is lower, indicating that an MRL of 0.01* mg/kg would be sufficient

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
1011030 1011040 1011050 1012030 1012040 1012050 1013030 1013040 1013050 1014030 1014040 1014050	Swine liver Swine kidney Swine (edible offals) Bovine liver Bovine kidney Bovine (edible offals) Sheep liver Sheep kidney Sheep (edible offals) Goat liver Goat kidney Goat (edible offals)	0.07 (ft 2)	Further risk management considerations required	The data gap identified by EFSA is partially addressed as the genotoxic potential of metabolites L1, L4 and L9 (found exclusively in ruminant liver and kidney) can be ruled out, but a full characterisation of the toxicological profile of these metabolites has not been provided The indicative human exposure resulting to the occurrence of metabolites L1, L4 and L9 in liver and kidney (estimated for the EU livestock dietary burden) was estimated and the RMS concluded that the low exposure does not trigger further investigation for these compounds. The RMS proposed to confirm the risk assessment residue definition in animal commodities as azoxystrobin alone Further risk management considerations should be given to decide whether the argument of the low exposure is acceptable to waive the need to submit data on the general toxicity of L1, L4 an L9. Nevertheless, EFSA noted that this argument does not support the existing EU MRLs (based on CXLs and more critical (5N) livestock dietary burden). Therefore, in the case where risk managers would accept the rationale of the RMS to address the data gap, MRLs for liver, kidney and other edible offals should be set at the LOQ (0.01* mg/kg), in line with the EU dietary burden calculated under the present assessment
1016010 1016020 1016030 1016040 1016050	Poultry muscle Poultry fat Poultry liver Poultry kidney Poultry (edible offals)	0.01* (ft 2)	0.01*	The data gap identified by EFSA is partially addressed as full characterisation of the toxicological profile of metabolites L1, L4 and L9 is not available However, as these compounds were not found in the metabolism studies performed on poultry, the existing MRLs are not affected by this data gap and can be confirmed
1020010 1020020 1020030 1020040	Cattle milk Sheep milk Goat milk Horse milk	0.01* (ft 2)	0.01*	The data gap identified by EFSA is partially addressed as full characterisation of the toxicological profile of metabolites L1, L4 and L9 is not available However, as these compounds were not found in milk, the existing MRLs are not affected by this data gap and can be confirmed
1030000	Birds eggs	0.01* (ft 2)	0.01*	The data gap identified by EFSA is partially addressed as full characterisation of the toxicological profile of metabolites L1, L4 and L9 is not available However, as these compounds were not found in eggs, the existing MRL is not affected by this data gap and can be confirmed

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

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
ft 3: The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2017, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1 and No 2).
ft 4: The European Food Safety Authority identified some information on toxicity of metabolites as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2017, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 3).

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Azoxystrobin

LOQs (mg/kg) range from: 0.01 to: 0.01

Toxicological reference values

ADI (mg/kg bw per day):	0.2	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
19%	DE child	38.93	10%	Oranges	3%	Potatoes	1%	Mandarins		19%
18%	NL toddler	36.30	5%	Oranges	5%	Potatoes	1%	Spinaches		18%
13%	FR child 3 15 yr	26.30	8%	Oranges	2%	Potatoes	0.4%	Mandarins		13%
13%	NL child	25.97	4%	Potatoes	3%	Oranges	2%	Mandarins		13%
13%	IE adult	25.32	3%	Potatoes	2%	Oranges	2%	Grapefruits		13%
13%	GEMS/Food G07	25.24	4%	Potatoes	3%	Oranges	0.5%	Wine grapes		13%
12%	GEMS/Food G11	23.69	4%	Potatoes	2%	Oranges	0.9%	Lemons		12%
12%	SE general	23.46	5%	Potatoes	2%	Oranges	1%	Mandarins		12%
12%	GEMS/Food G10	23.35	3%	Potatoes	3%	Oranges	0.6%	Onions		12%
11%	GEMS/Food G06	22.93	2%	Oranges	2%	Potatoes	0.8%	Onions		11%
11%	UK toddler	22.69	5%	Oranges	4%	Potatoes	0.7%	Mandarins		11%
11%	GEMS/Food G08	22.20	4%	Potatoes	1%	Oranges	0.6%	Lemons		11%
11%	PT general	21.63	6%	Potatoes	1%	Oranges	0.9%	Wine grapes		11%
11%	GEMS/Food G15	21.15	4%	Potatoes	2%	Oranges	0.6%	Onions		11%
10%	FR toddler 2 3 yr	20.88	3%	Oranges	2%	Potatoes	2%	Mandarins		10%
10%	ES child	20.36	5%	Oranges	2%	Potatoes	0.7%	Lettuces		10%
9%	RO general	18.57	4%	Potatoes	0.9%	Head cabbages	0.8%	Onions		9%
9%	DE women 14-50 yr	18.22	5%	Oranges	1%	Potatoes	0.5%	Lemons		9%
9%	FI 3 yr	17.89	5%	Potatoes	1.0%	Mandarins	0.4%	Onions		9%
9%	UK infant	17.80	4%	Potatoes	3%	Oranges	0.3%	Peas (without pods)		9%
8%	NL general	16.54	3%	Potatoes	2%	Oranges	0.4%	Mandarins		8%
8%	DE general	16.41	4%	Oranges	1%	Potatoes	0.5%	Lemons		8%
7%	FI 6 yr	14.79	4%	Potatoes	0.8%	Mandarins	0.4%	Oranges		7%
7%	ES adult	14.19	3%	Oranges	1%	Potatoes	0.9%	Lettuces		7%
6%	UK vegetarian	11.78	2%	Oranges	2%	Potatoes	0.3%	Wine grapes		6%
6%	PL general	11.41	4%	Potatoes	0.4%	Onions	0.2%	Head cabbages		6%
6%	DK child	11.20	3%	Potatoes	0.4%	Oranges	0.3%	Onions		6%
6%	FR infant	11.10	2%	Potatoes	0.6%	Oranges	0.5%	Spinaches		6%
5%	IT toddler	10.20	1%	Oranges	1%	Potatoes	0.5%	Mandarins		5%
5%	FR adult	9.67	1%	Oranges	0.8%	Potatoes	0.8%	Wine grapes		5%
5%	UK adult	9.54	2%	Potatoes	1%	Oranges	0.4%	Wine grapes		5%
5%	LT adult	9.40	4%	Potatoes	0.2%	Head cabbages	0.2%	Oranges		5%
5%	IT adult	9.09	0.9%	Oranges	0.7%	Potatoes	0.6%	Lettuces		5%
4%	FI adult	7.78	1%	Potatoes	1.0%	Oranges	0.3%	Mandarins		4%
4%	DK adult	7.16	1%	Potatoes	0.3%	Wine grapes	0.3%	Oranges		4%
1%	IE child	2.86	0.7%	Potatoes	0.2%	Oranges	0.1%	Rice		1%

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

Acute risk assessment/children	Acute risk assessment/adults/general population
Details - acute risk assessment/children	Details - acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
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	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)
Soybean 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	0.18	STMR (EFSA, 2013) × default PF (18)	0.18	STMR (EFSA, 2013) × default PF (18)
Beet, sugar ensiled pulp	0.03	STMR (EFSA, 2013) × default PF (3)	0.03	STMR (EFSA, 2013) × default PF (3)
Beet, sugar molasses	0.28	STMR (EFSA, 2013) × default PF (28)	0.28	STMR (EFSA, 2013) × default PF (28)
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)[(a)]	0.01	STMR (EFSA, 2013)[(a)]
Corn, field hominy meal	0.01	STMR (EFSA, 2013)[(a)]	0.01	STMR (EFSA, 2013)[(a)]

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

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

D.2. Consumer risk assessment for azoxystrobin

Commodity	Chronic risk assessment	
	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)
Mandarins	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)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
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)
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/maracujas	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 celeries	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)
Salsifies	0.23	STMR (EFSA, 2013)
Swedes/rutabagas	0.23	STMR (EFSA, 2013)
Turnips	0.23	STMR (EFSA, 2013)
Garlic	2.2	STMR (EFSA, 2013)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
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)
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)
Cauliflowers	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 (updated in the current opinion; see Appendix B.2.2.1)
Lettuces	3.4	STMR (updated in the current opinion; see Appendix B.2.2.1)
Escaroles/broad-leaved endives	3.4	STMR (updated in the current opinion; see Appendix B.2.2.1)
Cress and other sprouts and shoots	3.4	STMR (updated in the current opinion; see Appendix B.2.2.1)
Land cress	3.4	STMR (updated in the current opinion; see Appendix B.2.2.1)
Roman rocket/rucola	3.4	STMR (updated in the current opinion; see Appendix B.2.2.1)
Red mustards	3.4	STMR (updated in the current opinion; see Appendix B.2.2.1)
Baby leaf crops (including brassica species)	3.4	STMR (updated in the current opinion; see Appendix B.2.2.1)
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)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
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)
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	0.01	STMR (EFSA, 2013)
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: Liver	0.01	STMR (EFSA, 2013 based on CXL)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
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; CXL: Codex maximum residue limit.

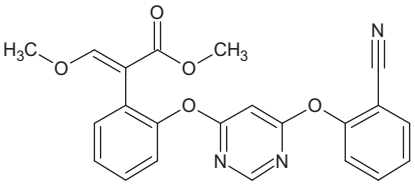
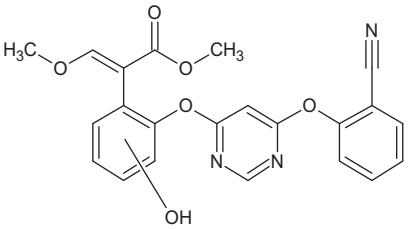
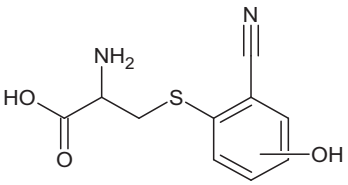
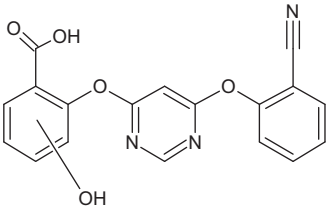
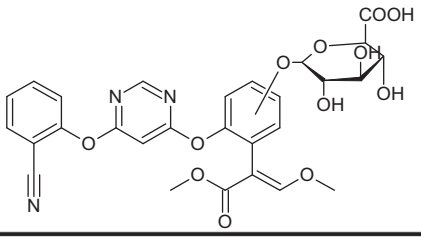
D.3. Exposure calculations for metabolites L1, L4, L9 and K1 (conjugate to L1)

Commodity	Chronic exposure		Acute exposure	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine: Liver	0.111	Sum of metabolites L1, L4, L9 and K1 (conjugate of L1), as calculated in Section 3.3.2 (Swine DB), and corrected according to their respective molecular weights[(a)]	0.111	Sum of metabolites L1, L4, L9 and K1 (conjugate of L1), as calculated in Section 3.3.2, and corrected according to their respective molecular weight[(a)]
Swine: Kidney	0.023	Same comment	0.023	Same comment
Swine: edible offals (other than liver and kidney)	0.111	Same comment	0.111	Same comment
Swine: other products	0.111	Same comment	0.111	Same comment
Bovine: Liver	0.160	Same comment (based on Cattle DB)	0.160	Same comment (based on Cattle DB)
Bovine: Kidney	0.033	Same comment	0.033	Same comment
Bovine: edible offals (other than liver and kidney)	0.160	Same comment	0.160	Same comment
Bovine: other products	0.160	Same comment	0.160	Same comment
Sheep: Liver	0.061	Same comment (based on sheep DB)	0.061	Same comment (based on sheep DB)
Sheep: Kidney	0.012	Same comment	0.012	Same comment (based on Cattle DB)

Commodity	Chronic exposure		Acute exposure	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sheep: edible offals (other than liver and kidney)	0.061	Same comment	0.061	Same comment
Sheep: other products	0.061	Same comment	0.061	Same comment
Goat: Liver	0.061	Extrapolated from Sheep	0.061	Extrapolated from Sheep
Goat: Kidney	0.012	Extrapolated from Sheep	0.012	Extrapolated from Sheep
Goat: edible offals (other than liver and kidney)	0.061	Extrapolated from Sheep	0.061	Extrapolated from Sheep
Goat: other products	0.061	Extrapolated from Sheep	0.061	Extrapolated from Sheep
Equine: Liver	0.161	Extrapolated from Bovine	0.160	Extrapolated from Bovine
Equine: Kidney	0.033	Extrapolated from Bovine	0.033	Extrapolated from Bovine
Equine: edible offals (other than liver and kidney)	0.160	Extrapolated from Bovine	0.160	Extrapolated from Bovine
Equine: other products	0.160	Extrapolated from Bovine	0.160	Extrapolated from Bovine

(a): molecular weight of metabolites L1 (419.4 $kg.mol^{-1}$), L4 (238.3 $kg.mol^{-1}$), L9 (349.3 $kg.mol^{-1}$), K1 (595.5 $kg.mol^{-1}$).

Appendix E – Used compound codes

Code/Trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Azoxystrobin	methyl (2*E*)-2-(2-{[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}phenyl)-3-methoxyacrylate O=C(OC)\C(=C\OC)c1ccccc1Oc1cc(Oc2ccccc2C#N)ncn1 WFDXOXNFNRHQEC-GHRIWEEISA-N	
L1	methyl (2E)-2-(2-{[6-(2- cyanophenoxy)pyrimidin-4-yl]oxy}-xhydroxyphenyl)-3-methoxyprop-2-enoate	
L4	S-(2-cyano-x-hydroxyphenyl)cysteine	
L9	2-{[6-(2-cyanophenoxy)pyrimidin-4- yl]oxy}-x-hydroxybenzoic acid	
K1	4-{[6-(2-cyanophenoxy)pyrimidin-4- yl]oxy}-3-[(1E)-1,3-dimethoxy-3-oxoprop1-en-2-yl]phenyl glucopyranuronic acid	

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).