REASONED OPINION

efsa JOURNAL

ADOPTED: 28 July 2023

doi: 10.2903/j.efsa.2023.8124

Modification of the existing maximum residue level for azoxystrobin in hops

European Food Safety Authority (EFSA),
Giulia Bellisai, Giovanni Bernasconi, Luis Carrasco Cabrera, Irene Castellan, Monica del Aguila, Lucien Ferreira, German Giner Santonja, Luna Greco, Samira Jarrah, Renata Leuschner, Javier Martinez Perez, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Manuela Tiramani and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Crop Protection AG submitted a request to the competent national authority in Germany to modify the existing maximum residue level (MRL) for the active substance azoxystrobin in hops. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for hops. Adequate analytical methods for enforcement are available to control the residues of azoxystrobin on the commodity under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, noting that an acute risk assessment was not deemed necessary for azoxystrobin, EFSA concluded that the long-term intake of residues resulting from the use of azoxystrobin according to the reported agricultural practice is unlikely to present a risk to consumer health.

Keywords: azoxystrobin, hops, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2022-00582

Correspondence: pesticides.mrl@efsa.europa.eu

Acknowledgements: EFSA wishes to thank: Stathis Anagnos, Andrea Mioč, Marta Szot, for the support provided to this scientific output.

Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

Suggested citation: EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Carrasco Cabrera, L., Castellan, I., del Aguila, M., Ferreira, L., Santonja, G. G., Greco, L., Jarrah, S., Leuschner, R., Perez, J. M., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. 2023. Modification of the existing maximum residue level for azoxystrobin in hops. *EFSA Journal*, *21*(8), 1–25. https://doi.org/10.2903/j.efsa.2023.8124

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance azoxystrobin in hops.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the European Food Safety Authority (EFSA) Central Submission System on 4 July 2022. The appointed EMS, Germany, assessed the dossier and declared its admissibility on 20 September 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 24 March 2023 to 14 April 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 3 May 2023. To accommodate for the intended use of azoxystrobin, the EMS proposed to raise the existing MRL from 30 to 40 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS. The additional information was duly considered by the EMS who submitted a revised evaluation report to EFSA on 14 June 2023, which replaced the previously submitted evaluation report.

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

The metabolism of azoxystrobin following foliar applications was investigated in crops belonging to the groups of fruit crops (grapes), cereals/grass (wheat) and pulses/oilseeds (peanuts). The metabolism pattern was similar in all plant groups with the parent azoxystrobin being the major compound.

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

As the proposed use of azoxystrobin is on a permanent crop, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies and on the results of the hydrolysis studies, the residue definitions for enforcement and risk assessment in all plant commodities following foliar application were proposed as 'azoxystrobin' for primary crops and processed products.

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

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

The available residue trials are sufficient to derive an MRL proposal of 40 mg/kg for hops.

A processing factor (PF) for the crop under assessment was derived in the current application based on studies provided and assessed in the MRL review. For beer, a median PF is derived from three processing studies and can be recommended to be included in Annex VI of Regulation (EC) No 396/2005:

- Hops/beer: 0.003

Residues of azoxystrobin in commodities of animal origin were not assessed because the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of azoxystrobin was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.2 mg/kg body weight (bw) per day, whereby an acute reference dose (ARfD) deemed unnecessary.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The highest estimated long-term dietary intake accounted for 22% of the ADI (Dutch toddler diet). The contribution of residues expected in hops assessed in this application to the overall long-term exposure is 0.02% of the ADI (UK, adult diet). An acute exposure calculation was not required since an ARfD was considered unnecessary for azoxystrobin.

EFSA concluded that the proposed use of azoxystrobin on hops will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health. The chronic consumer risk assessment shall be regarded as indicative considering the data gap for general toxicity identified by EFSA for the metabolites L1, its conjugate K1, L4 and L9, which were identified in products of animal origin.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Azoxystrobin				
0700000	Hops	30	40	The submitted data are sufficient to derive an MRL proposal for the NEU outdoor use. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe.

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

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for azoxystrobin in hops. The detailed description of the intended use of azoxystrobin, which is the basis for the current MRL application, is reported in Appendix A.

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

Azoxystrobin was evaluated in the framework of Directive 91/414/EEC[1] with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on cereals and brassica vegetables. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2010). Azoxystrobin was approved[2] for the use as fungicide on 1 January 2012 and the approval is restricted to uses as fungicide only.

The EU MRLs for azoxystrobin are established in Annex II of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2013) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for azoxystrobin, including the evaluation of the MRL review confirmatory data (EFSA, 2016a,b, 2020, 2021a,b, 2022). The proposals from these reasoned opinions have been considered in recent MRL regulations.[4] Also, certain Codex maximum residue limits (CXLs) have been assessed (EFSA, 2014, 2018b, 2021c) and taken over in the EU MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[5], the applicant Syngenta Crop Protection AG submitted on 4 July 2022 an application to the competent national authority in Germany, alongside the dossier containing the supporting data using the IUCLID format.

The appointed EMS, Germany, assessed the dossier and declared its admissibility on 20 September 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 24 March 2023 to 14 April 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 3 May 2023. To accommodate for the intended use of azoxystrobin, the EMS proposed to raise the existing MRL from 30 to 40 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2023), the draft assessment report (DAR) and its addendum (United Kingdom, 2009a,b) prepared under Council Directive 91/414/EEC, the Commission review report on azoxystrobin (European Commission, 2015), the conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin (EFSA, 2010), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2013), the Article 12 confirmatory data assessment (EFSA, 2020), as well as the conclusions from previous EFSA opinions on azoxystrobin (EFSA, 2016a,b, 2021a,b, 2022).

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

[2] Commission Implementing Regulation (EU) No 703/2011 of 20 July 2011 approving the active substance azoxystrobin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 190, 21.7.2011, p. 33–37.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[4] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/mrls

[5] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the IUCLID application are applicable (European Commission, 1997a,b,c,d,e,f,g, 2010, 2017, 2018, 2020, 2021; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[7].

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, is presented in Appendix B.

The evaluation report submitted by the EMS (Germany, 2023) 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.[8]

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of azoxystrobin in primary crops belonging to the group of fruit crops (grapes), cereals/grass (wheat) and pulses/oilseeds (peanuts) has been investigated in the framework of the EU pesticides peer review (EFSA, 2010). All metabolism studies assessed in this framework were performed with foliar applications.

The metabolism pattern was similar in all plant groups with the parent azoxystrobin being the major compound, accounting for 17–43% total radioactive residue (TRR) in cereal grain and straw, 35–65% TRR in grapes and 14–48% TRR in peanut hulls and hay. Azoxystrobin was not detected in peanut nuts, where radioactivity was found to be mainly incorporated in fatty acids (up to 49% TRR) and no individual metabolite was present in peanut kernel at a level greater than 1% TRR (EFSA, 2010, 2013).

For the intended use (foliar use on hops which belongs to the metabolism group of leafy crops), the metabolic behaviour in primary crops is considered as sufficiently addressed based on the body of knowledge derived from three metabolic groups.

1.1.2. Nature of residues in rotational crops

As the proposed use of azoxystrobin is on a permanent crop, investigations on the nature of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

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

1.1.4. Analytical methods for enforcement purposes in plant commodities

Analytical methods for the determination of azoxystrobin residues were assessed during the EU pesticides peer review and the MRL review (EFSA, 2010, 2013).

The HPLC-MS/MS method RAM 305/03 and the multi-residue DFG S19 methods are sufficiently validated for the quantification of residues of azoxystrobin at or above the limit of quantification (LOQ) of 0.01 mg/kg in crops belonging to the high water, high oil, high-acid content and dry commodities. The first method (RAM 305/03) is also sufficiently validated for the quantification of residues of

[6] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

[7] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

[8] Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link:https://open.efsa.europa.eu/study-inventory/EFSA-Q-2023-00582

azoxystrobin at or above the LOQ of 0.01 mg/kg in hops (EFSA, 2013). In addition, the multi-residue Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) (QuEChERS) method in combination with HPLC-MS/MS and gas chromatography with mass spectrometry (GC–MS), is also available to analyse parent azoxystrobin (EFSA, 2013).

In a previous application a comprehensive cross-validation study was provided to assess extraction efficiency for representatives from each major crop group and a difficult matrix (hops) by using the solvent systems of the QuEChERS method, the DFG S19 and RAM 305/03 methods in comparison with the solvent system used in the metabolism studies. Extraction efficiency when using the solvents of all four methods, ranged between 90% to 103% for the major crop groups including hops whereby the specific percentage of the TRR of parent azoxystrobin in the solvents of all analytical the methods was not reported. It was therefore concluded that extraction efficiency was partially demonstrated (EFSA, 2021b, 2022).

Based on the previous assessments, it can be concluded that the extraction efficiency of the enforcement methods for hops is partially demonstrated. EFSA, therefore, recommends considering extraction efficiency further in the framework of the peer review for the renewal of approval of the active substance.

1.1.5. Storage stability of residues in plants

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

It was demonstrated that, in commodities belonging to the high-oil content group to which hops was assigned meanwhile (OECD, 2007), residues of azoxystrobin are stable for at least 24 months when stored at −18°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies and the results of hydrolysis studies, the following residue definitions were proposed in all plant commodities following foliar application:

- residue definition for risk assessment: 'azoxystrobin' (EFSA, 2010, 2013).
- residue definition for enforcement: 'azoxystrobin' (EFSA, 2010, 2013).

The same residue definition is applicable to rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

EFSA concluded that based on the information provided for this application, these residue definitions are appropriate, and no modification is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Hops

NEU outdoor GAP (foliar treatment): 2 × 400 g a.s./ha, 8–14 days-interval, BBCH 31–89, PHI 28 days (Germany, 2023)

In support of the intended NEU outdoor foliar Good Agricultural Practice (GAP) on hops (two foliar applications (interval between applications: 8–14 days) × 400 g a.s./ha, PHI 28 days), eight new trials were submitted and performed on hops during the 2008 (two trials) and during the 2009 (six trials) growing seasons (Germany, 2023). Four (two times 2) trials were considered as not independent and were treated as duplicates (trials S09-01444-01 and S09-01444-02 in United Kingdom and trials S09-01444-04 and S09-01444-05 in Germany). The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The EMS proposed to consider in addition to the six independent newly provided residue trials, eight trials on hops which were already assessed during the MRL review in support of a notified authorised GAP (two foliar applications (interval between applications: 14–28 days) × 400 g a.s./ha, PHI 28 days (EFSA, 2013; Germany, 2023). This GAP differs only in length of the interval between the applications to the intended GAP under assessment (see Appendix B.1.2.1).

The analytical method RAM 305/03 used to analyse the new residue trials based on HPLC-MS/MS is sufficiently validated for the quantification of residues of azoxystrobin at or above the LOQ of 0.01 mg/kg in hops (EFSA, 2013; Germany, 2023). Extraction efficiency of the solvent system used in the analytical method RAM 305/03 (acetonitrile:water) was assessed via cross-validation and considered as partially demonstrated (see also Section 1.1.4). Information on the percent TRR of parent azoxystrobin in the solvent is still required to conclude on the extraction efficiency of the RAM 305/03 method.

EFSA concludes that the available trials are sufficient to derive an MRL proposal of 40 mg/kg on hops for the intended NEU use combining the six new and eight previously assessed residue trials, as proposed by the EMS. The same MRL value of 40 mg/kg is also derived when considering only the newly provided, fully complaint six trials.

1.2.2. Magnitude of residues in rotational crops

As the use under assessment is on a permanent crop (hops), investigations on the magnitude of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Residues of azoxystrobin in hops are exceeding 0.1 mg/kg and processing studies are required, however it is to be noted that the chronic exposure does not exceed 10% of the ADI in hops (see Section 3 and Appendix B.4) and investigations on the effect of industrial processing are in principle not required (European Commission, 1997d).

Nevertheless, three processing studies in hops on beer processing were resubmitted and have been assessed during the MRL review (EFSA, 2013). The studies demonstrated that hops processing to beer leads to a significance reduction of residues by around two orders of magnitude.

For beer, a median PF is derived from three processing studies and can be recommended to be included in Annex VI of Regulation (EC) No 396/2005 (see Appendix B.1.2.3).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for the commodity under evaluation, (see Appendix B.1.2.1). In Section 3 EFSA assessed whether residues on hops resulting from the intended use are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as hops are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference value for acceptable daily intake (ADI) of 0.2 mg/kg body weight (bw) per day assessed in the framework of the EU pesticides peer review is applicable. The derivation of an ArfD was considered unnecessary (European Commission, 2015).

A short-term (acute) risk assessment was not required since an ArfD has been considered unnecessary for azoxystrobin.

The previous long-term (chronic) consumer risk assessment performed in the context of an MRL application on rapeseeds and linseeds (EFSA, 2022) is now revised considering the risk assessment values derived from the residue trials submitted in support of this MRL application for hops. The input values used to perform the consumer risk assessment are reported in Appendix D.1.

The estimated chronic exposures were compared with the ADI of azoxystrobin. The estimated long-term dietary intake was up to 22% of the ADI (Dutch toddler). The contribution of residues expected in hops to the overall long-term exposure does not exceed 0.02% of the ADI (UK, adult). More details of the contribution of the residues is included in Appendix B.4.

EFSA concluded that the consumer intake of residues of azoxystrobin resulting from the existing, intended uses and the import of commodities resulting from the authorised uses previously assessed by EFSA are unlikely to present a risk to consumer health. The chronic consumer risk assessment shall

be regarded as indicative due to the information (data gap) on the metabolites L1, its conjugate K1, L4 and L9, which were identified in products of animal origin. Genotoxicity was ruled out, but general toxicity for these metabolites is not addressed[9] (EFSA, 2020).

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for hops. EFSA concluded that the proposed use of azoxystrobin on hops will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health. The chronic consumer risk assessment shall be regarded as indicative considering the data gap for general toxicity identified by EFSA for the metabolites L1, its conjugate K1, L4 and L9, which were identified in products of animal origin. The MRL recommendations are summarised in Appendix B.5.

References

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin. EFSA Journal 2010;8(4):1542, 110 pp. https://doi.org/10.2903/j.efsa.2010.1542

EFSA (European Food Safety Authority), 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for azoxystrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(12):3497, 97 pp. https://doi.org/10.2903/j.efsa.2013.3497

EFSA (European Food Safety Authority), 2014. Scientific support for preparing an EU position in the 46th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2014;12(7):3737, 182 pp. https:/doi.org/10.2903/j.efsa.2014.3737

EFSA (European Food Safety Authority), 2016a. Reasoned opinion on the modification of the existing maximum residue levels for azoxystrobin in grapes. EFSA Journal 2016;14(2):4415, 17 pp. https://doi.org/10.2903/j.efsa.2016.4415

EFSA (European Food Safety Authority), 2016b. Reasoned opinion on the modification of the existing maximum residue levels for azoxystrobin in various crops. EFSA Journal 2016;14(5):4459, 17 pp. https://doi.org/10.2903/j.efsa.2016.4459

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), 2018. Scientific Report of EFSA on scientific support for preparing an EU position in the 50th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2018;16(7):5306, 229 pp. https://doi.org/10.2903/j.efsa.2018.5306

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A, Verani A, 2019. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). EFSA supporting publication 2019;EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1605

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for azoxystrobin. EFSA Journal 2020;18(8):6231, 42 pp. https://doi.org/10.2903/j.efsa.2020.6231

EFSA (European Food Safety Authority) Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021a. Reasoned Opinion on the setting of import tolerance for azoxystrobin in sugar beet roots. EFSA Journal 2021;19(2):6401, 29 pp. https://doi.org/10.2903/j.efsa.2021.6401

[9] Tentative MRLs for commodities of animal origin were implemented in the MRL legislation by Commission Regulation (EU) 2022/1363, including a footnote for confirmatory data related to this data gap.

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021b. Reasoned Opinion on the setting of import tolerances for azoxystrobin in mangoes and oil palm fruits. EFSA Journal 2021;19(8):6821, 30 pp. https://doi.org/10.2903/j.efsa.2021.6821

EFSA (European Food Safety Authority), 2021. Scientific support for preparing an EU position for the 52nd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2021;19(8):6766, 342 pp. https://doi.org/10.2903/j.efsa.2021.6766

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Cabrera LC, Ferreira L, Giner G, Greco L, Jarrah S, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2022. Reasoned Opinion on the modification of the existing maximum residue levels for azoxystrobin in rapeseeds and linseeds. EFSA Journal 2022;20(1):7051, 34 pp. https://doi.org/10.2903/j.efsa.2022.7051

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/VI/95-rev.3, 22 July 1997.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2015. Review report for the active substance azoxystrobin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 17 June 2011 in view of the approval of azoxystrobin as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/11027/2011-Rev. 3, 20 March 2015.

European Commission, 2017. Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods. SANTE 2017/10632, Rev. 4, 23 February 2022.

European Commission, 2018. Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey. SANTE/2016/11956, Rev. 9, 14 September 2018.

European Commission, 2020. Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation on residue data on products from plant and animal origin. SANTE/2019/12752, 23 November 2020.

European Commission, 2021. Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1 24 February 2021.

FAO (Food and Agriculture Organization of the United Nations), 2014. In: Azoxystrobin (ed). Pesticide residues in food – 2013. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 219.

FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd edn. FAO Plant Production and Protection Paper 225, 298 pp.

FAO (Food and Agriculture Organization of the United Nations), 2017. In: Azoxystrobin (ed). Pesticide residues in food – 2017. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 232.

FAO (Food and Agriculture Organization of the United Nations), 2020. Azoxystrobin. Pesticide residues in food – 2019. Report of the Extra Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection. https://doi.org/10.4060/cb6975en

Germany, 2023. Evaluation report on the modification of the existing maximum residue level for azoxystrobin in hops. April 2023, revised in June 2023. 27 pp. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 2007. Test No 506: Stability of Pesticide Residues in Stored Commodities, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing, Paris. Available online: https://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In : Pesticide Publications/Publications on Pesticide Residues. Available online: https://www.oecd.org/

United Kingdom, 2009a. Draft assessment report on the active substance azoxystrobin prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, May, 2009. Available online: www.efsa.europa.eu

United Kingdom, 2009b. Final addendum to the assessment report on the active substance azoxystrobin prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, compiled by EFSA, December, 2009. Available online: www.efsa.europa.eu

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organisation of the United Nations
GAP	Good Agricultural Practice
GC	gas chromatography
GC–MS	gas chromatography with mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MW	molecular weight
NEU	northern Europe
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
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RMS	rapporteur Member State
SEU	southern Europe
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type (b)	Conc. a.s. (g/L)	Method kind	Range of growth stages & season[(c)]	Number min-max	Interval between application (days) min-max	L a.s./ hL min–max	Water (L/ha) min-max	Rate min-max	Unit		
Hops	NEU	F	*Pseudo-peronospora humuli* (PSPEHU)	SC	250	Foliar spraying	BBCH 31–89	1–2	8–14	0.0357–0.075	1,000–4,200	187.5–400	g a.s./ ha	28	Crop destination: grown for human consumption. Application rate product: ≥ 0.75 – ≤ 1.6 L/ha. Maximum annual rate a.s.: 800 g/ha.

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 pre-harvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and analytical methods for enforcement purposes in plant commodities

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Grapes	Foliar: 250 + 1,000 + 1,000 + 250 g/ha	21	Radiolabelled azoxystrobin: ^{14}C-pyrimidinyl ^{14}C-cyanophenyl ^{14}C-phenylacrylate (EFSA, 2010)
	Cereals/grass	Wheat	Foliar: 2 × 500 g/ha; BBCH 30–31 and 59–61	Forage: 13 Grain and Straw: 61–62	Radiolabelled azoxystrobin: ^{14}C-pyrimidinyl ^{14}C-cyanophenyl ^{14}C-phenylacrylate (EFSA, 2010)
			Foliar: 1 × 284 g/ha; BBCH 71	28	Radiolabelled azoxystrobin: ^{14}C-pyrimidinyl (EFSA, 2010)
	Pulses/ oilseeds	Peanuts	Foliar: 850 + 850 + 300 g/ha	10	Radiolabelled azoxystrobin: ^{14}C-pyrimidinyl ^{14}C-cyanophenyl ^{14}C-phenylacrylate (EFSA, 2010)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radishes	Bare soil: 2.2 kg/ha	30, 200, 365	Radiolabelled azoxystrobin: ^{14}C-pyrimidinyl ^{14}C-cyanophenyl ^{14}C-phenylacrylate (EFSA, 2010)
	Leafy crops	Lettuces			
	Cereal (small grain)	Wheat			
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		EFSA (2010)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		EFSA (2010)
	Sterilisation (20 min, 120°C, pH 6)		Yes		EFSA (2010)
	Other processing conditions		–		–

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2010)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2010)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2010)
Plant residue definition for monitoring (RD-Mo)	Azoxystrobin (EFSA, 2010, 2013)	
Plant residue definition for risk assessment (RD-RA)	Azoxystrobin (EFSA, 2010, 2013)	
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 (RAM 305) with a LOQ of 0.01 mg/kg. As HPLC–MS/MS using two mass transitions is a highly specific detection technique, a confirmatory method is not required. ILV available (EFSA, 2010, 2013). Extraction efficiency partially demonstrated (2021b). Matrices with high water content, high oil content, high acid content and dry matrices: HPLC–MS/MS (DFG S19) with a LOQ of 0.01 mg/kg. ILV available (EFSA, 2010, 2013). Extraction efficiency partially demonstrated (2021b). HPLC–MS/MS and GC–MS (QuEChERS) with an LOQ of 0.01 mg/kg (EFSA, 2013). Extraction efficiency for HPLC method partially demonstrated (EFSA, 2021b)	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; GC–MS: gas chromatography with mass spectrometry; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	High-water content	Bananas	−18	24	Months	Azoxystrobin	EFSA (2010)
		Peaches	−18	24	Months	Azoxystrobin	EFSA (2010)
		Tomatoes	−18	24	Months	Azoxystrobin	EFSA (2010)
		Cucumbers	−18	24	Months	Azoxystrobin	EFSA (2010)
		Lettuces	−18	24	Months	Azoxystrobin	EFSA (2010)
		Carrots	−18	24	Months	Azoxystrobin	EFSA (2010)
	High-oil content	Rapeseeds	−18	24	Months	Azoxystrobin	EFSA (2010)
		Pecan	−18	24	Months	Azoxystrobin	EFSA (2010)
		Peanuts	−18	24	Months	Azoxystrobin	EFSA (2010)
	Dry/High starch	Cereal grain	−18	24	Months	Azoxystrobin	EFSA (2010)
	High-acid content	Grapes	−18	24	Months	Azoxystrobin	EFSA (2010)
		Apples	−18	24	Months	Azoxystrobin	EFSA (2010)
		Oranges	−18	24	Months	Azoxystrobin	EFSA (2010)
	Others	Cereal straw	−18	24	Months	Azoxystrobin	EFSA (2010)

B.1.2. Magnitude of residues in plants

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

Commodity	Region[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Hops	NEU	Germany, 2023: 1.13; 5.6; 7.03; 8.37; 17.3; 20.8	New GAP compliant trials on hops (GAP of 2 × 0.4 kg as/ha, interval 8–14 days, PHI 28 days) (Germany, 2023). Underlined trials represent replicate trials where mean values [5.6 mg/kg (replicates: 5.3; 5.9 mg/kg) and 20.8 mg/kg (replicates: 12.4; 29.2 mg/kg)] were derived.	40.0	20.80	7.70	1.0
Hops	NEU	EFSA, 2013: 0.83; 1.1; 1.3; 2.15; 5.7; 10.5; 11; 12	Already assessed trials and used in the MRL review to support the GAP of 2 × 0.4 kg as/ha, interval 14–28 days, PHI 28 days (EFSA, 2013)	30.00	12.00	3.93	1.0
Hops	NEU	0.83; 1.1; 2 × 1.13; 2.15; 5.6; 5.7; 7.03; 8.37; 10.5; 11; 12; 17.3; 20.8	Combined data set (EFSA, 2013; Germany, 2023)	**40.0**	**20.80**	**6.37**	1.0

MRL: maximum residue level; GAP: Good Agricultural Practice.
(a): NEU: Outdoor trials conducted in northern Europe.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	Hops is a permanent crop.
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	-

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[(a)]	Processing Factor (PF)		CF_P[(b)]	Comment/Source
		Individual values	Median PF		
Hops, beer	3	0.0022, 0.0027, 0.0044	0.0027	1	EFSA (2013)

PF: processing factor.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

B.2. Residues in livestock

Not relevant. Hops are not used as a livestock or fish feeding stuff.

B.3. Residues in honey

Not relevant. Hops (code 700000) are not melliferous crops (European Commission, 2018).

B.4. Consumer risk assessment

ARfD not relevant since it has not been considered necessary (European Commission, 2015).

ADI	0.2 mg/kg bw per day (European Commission, 2015)
Highest IEDI, according to EFSA PRIMo	22% of ADI (NL toddler diet) Contribution of crop assessed: Hops: 0.02% of ADI (UK adult diet)
Assumptions made for the calculations	The calculation is based on the median residue levels (STMR value) derived for raw agricultural commodities according to the risk assessment residue definition. For hops, the STMR value was derived from the data collected from the residue trials submitted. For the remaining commodities covered by the MRL regulation, the STMR values derived in the MRL review, its confirmatory data assessment, previous MRL applications and, where relevant, in the evaluations by the JMPR were selected as input values (EFSA, 2013, 2016a,b, 2020, 2021a,b; 2022; FAO, 2014, 2017, 2020). Peeling factors were used for bananas and mangos. The crops on which no uses have been reported in the MRL review or in the subsequent EFSA outputs, were not included in the exposure calculation. Uncertainty in the consumer risk assessment related to the consumer exposure to metabolites L1, L4 and L9 and K1 (conjugate of L1) for products of animal origin highlighted in the framework of the MRL review of the confirmatory data is still valid (EFSA, 2020). Calculations performed with PRIMo revision 3.1

ARfD: acute reference dose; bw: body weight; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

B.5. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Azoxystrobin				
0700000	Hops	30	40	The submitted data are sufficient to derive an MRL proposal for the NEU outdoor use. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

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:	EC	Source of ARfD:	EC
Year of evaluation:	2015	Year of evaluation:	2015

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	22%	NL toddler	43.42	5%	Oranges	5%	Potatoes	4%	Sugar beet roots		22%
	19%	DE child	38.93	10%	Oranges	3%	Potatoes	1%	Mandarins		19%
	19%	NL child	37.33	6%	Sugar beet roots	4%	Potatoes	3%	Oranges		19%
	16%	FR child 3 15 yr	31.21	8%	Oranges	2%	Sugar beet roots	2%	Potatoes		16%
	13%	UK toddler	26.98	5%	Oranges	4%	Potatoes	2%	Sugar beet roots		13%
	13%	GEMS/Food G07	25.30	4%	Potatoes	3%	Oranges	0.5%	Wine grapes		13%
	13%	IE adult	25.26	3%	Potatoes	2%	Oranges	2%	Grapefruits		13%
	12%	GEMS/Food G06	24.90	2%	Oranges	2%	Potatoes	1%	Sugar beet roots		12%
	12%	FR toddler 2 3 yr	24.68	3%	Oranges	2%	Potatoes	2%	Sugar beet roots		12%
	12%	DE women 14-50 yr	24.36	5%	Oranges	3%	Sugar beet roots	1%	Potatoes		12%
	12%	GEMS/Food G11	23.68	4%	Potatoes	2%	Oranges	0.9%	Lemons		12%
	12%	SE general	23.46	5%	Potatoes	2%	Oranges	1%	Mandarins		12%
	12%	GEMS/Food G10	23.38	3%	Potatoes	3%	Oranges	0.6%	Onions		12%
	11%	GEMS/Food G08	22.24	4%	Potatoes	1%	Oranges	0.6%	Lemons		11%
	11%	DE general	22.07	4%	Oranges	3%	Sugar beet roots	1%	Potatoes		11%
	11%	PT general	21.63	6%	Potatoes	1%	Oranges	0.9%	Wine grapes		11%
	11%	GEMS/Food G15	21.18	4%	Potatoes	2%	Oranges	0.6%	Onions		11%
	10%	ES child	20.60	5%	Oranges	2%	Potatoes	0.7%	Lettuces		10%
	10%	NL general	20.42	3%	Potatoes	2%	Oranges	2%	Sugar beet roots		10%
	10%	RO general	20.34	4%	Potatoes	0.9%	Sugar beet roots	0.9%	Head cabbages		10%
	10%	UK infant	19.69	4%	Potatoes	3%	Oranges	1.0%	Sugar beet roots		10%
	9%	FI 3 yr	17.90	5%	Potatoes	1.0%	Mandarins	0.4%	Onions		9%
	7%	FI 6 yr	14.80	4%	Potatoes	0.8%	Mandarins	0.4%	Oranges		7%
	7%	ES adult	14.37	3%	Oranges	1%	Potatoes	0.9%	Lettuces		7%
	6%	FR infant	12.91	2%	Potatoes	0.9%	Sugar beet roots	0.6%	Oranges		6%
	6%	UK vegetarian	12.49	2%	Oranges	2%	Potatoes	0.4%	Sugar beet roots		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%
	5%	FR adult	10.75	1%	Oranges	0.8%	Potatoes	0.8%	Wine grapes		5%
	5%	UK adult	10.30	2%	Potatoes	1%	Oranges	0.4%	Wine grapes		5%
	5%	IT toddler	10.20	1%	Oranges	1%	Potatoes	0.5%	Mandarins		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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment	
			Input value (mg/kg)	Comment
Risk assessment residue definition: azoxystrobin				
HOPS (dried)	40	MRL proposal	6.37	STMR-RAC
Grapefruits	15	EFSA (2013)	4.9	STMR-RAC
Oranges	15	EFSA (2013)	4.75	STMR-RAC
Lemons	15	EFSA (2013)	4.9	STMR-RAC
Limes	15	EFSA (2013)	4.9	STMR-RAC
Mandarins	15	EFSA (2013)	4.9	STMR-RAC
Other citrus fruit	15	EFSA (2013)	4.9	STMR-RAC
Almonds	0.01	EFSA (2013)	0.01	STMR-RAC
Brazil nuts	0.01	EFSA (2013)	0.01	STMR-RAC
Cashew nuts	0.01	EFSA (2013)	0.01	STMR-RAC
Chestnuts	0.01	EFSA (2013)	0.01	STMR-RAC
Coconuts	0.01	EFSA (2013)	0.01	STMR-RAC
Hazelnuts/cobnuts	0.01	EFSA (2013)	0.01	STMR-RAC
Macadamias	0.01	EFSA (2013)	0.01	STMR-RAC
Pecans	0.01	EFSA (2013)	0.01	STMR-RAC
Pine nut kernels	0.01	EFSA (2013)	0.01	STMR-RAC
Pistachios	1	EFSA (2013)	0.44	STMR-RAC
Walnuts	0.01	EFSA (2013)	0.01	STMR-RAC
Other tree nuts	0.01	EFSA (2013)	0.01	STMR-RAC
Stone fruits	2	EFSA (2013)	0.74	STMR-RAC
Table grapes	3	EFSA (2016a)	0.72	STMR-RAC
Wine grapes	3	EFSA (2016a)	0.72	STMR-RAC
Strawberries	10	EFSA (2013)	1.3	STMR-RAC
Cane fruits	5	EFSA (2013)	1.03	STMR-RAC
Blueberries	5	EFSA (2013)	1.03	STMR-RAC
Cranberries	0.5	EFSA (2013)	0.23	STMR-RAC
Currants (red, black and white)	5	EFSA (2013)	1.03	STMR-RAC
Gooseberries (green, red and yellow)	5	EFSA (2013)	1.03	STMR-RAC
Rose hips	5	EFSA (2013)	1.03	STMR-RAC
Mulberries (black and white)	5	EFSA (2013)	1.03	STMR-RAC
Azarole/Mediterranean medlar	5	EFSA (2013)	1.03	STMR-RAC
Elderberries	5	EFSA (2013)	1.03	STMR-RAC
Other small fruit & berries	5	EFSA (2013)	1.03	STMR-RAC
Carambolas	0.1	EFSA (2013)	0.02	STMR-RAC
Passion fruits/maracujas	4	EFSA (2013)	1.1	STMR-RAC
Prickly pears/cactus fruits	0.3	FAO (2017)	0.04	STMR-RAC
Bananas	2	EFSA (2013)	0.03	STMR-RAC (0.82) × PeF (0.04)
Mangoes	4	EFSA (2021b)	0.04	STMR-RAC (2.24) × PeF (0.02)
Papayas	0.3	EFSA (2013)	0.1	STMR-RAC
Guavas	0.2	FAO (2020)	0.055	STMR-RAC

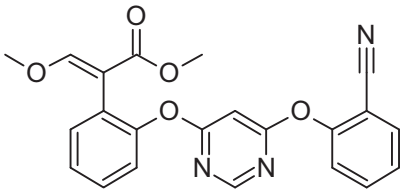
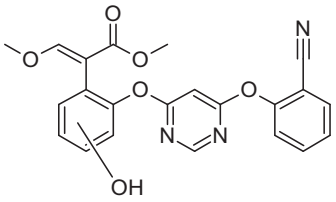
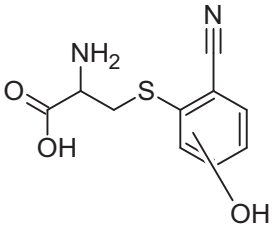
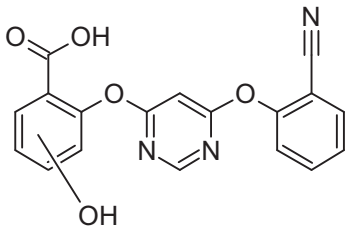
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment	
			Input value (mg/kg)	Comment
Potatoes	7	FAO (2014)	2.3	STMR-RAC
Tropical root and tuber vegetables	1	EFSA (2013)	0.23	STMR-RAC
Beetroots	1	EFSA (2013)	0.23	STMR-RAC
Carrots	1	EFSA (2013)	0.23	STMR-RAC
Celeriacs/turnip rooted celeries	1	EFSA (2013)	0.23	STMR-RAC
Horseradishes	1	EFSA (2013)	0.23	STMR-RAC
Jerusalem artichokes	1	EFSA (2013)	0.23	STMR-RAC
Parsnips	1	EFSA (2013)	0.23	STMR-RAC
Parsley roots/Hamburg roots parsley	1	EFSA (2013)	0.23	STMR-RAC
Radishes	1.5	EFSA (2013)	0.30	STMR-RAC
Salsifies	1	EFSA (2013)	0.23	STMR-RAC
Swedes/rutabagas	1	EFSA (2013)	0.23	STMR-RAC
Turnips	1	EFSA (2013)	0.23	STMR-RAC
Other root and tuber vegetables	1	EFSA (2013)	0.23	STMR-RAC
Bulb vegetables	10	EFSA (2013)	2.2	STMR-RAC
Tomatoes	3	EFSA (2013)	0.35	STMR-RAC
Sweet peppers/bell peppers	3	EFSA (2013)	0.71	STMR-RAC
Aubergines/egg plants	3	EFSA (2013)	0.35	STMR-RAC
Okra/lady's fingers	3	EFSA (2013)	0.35	STMR-RAC
Other Solanaceae	3	EFSA (2013)	0.35	STMR-RAC
Cucurbits with edible peel	1	EFSA (2013)	0.17	STMR-RAC
Cucurbits with inedible peel	1	EFSA (2013)	0.17	STMR-RAC
Flowering brassica	5	EFSA (2013)	1.2	STMR-RAC
Head brassica	5	EFSA (2013)	1.2	STMR-RAC
Leafy brassica	6	EFSA (2013)	1.04	STMR-RAC
Kohlrabies	5	EFSA (2013)	1.2	STMR-RAC
Lettuce and other salad plants	10	EFSA (2013)	3.4	STMR-RAC
Spinach and similar (leaves)	15	EFSA (2013)	3.9	STMR-RAC
Witloofs/Belgian endives	0.3	EFSA (2013)	0.05	STMR-RAC
Herbs and edible flowers	70	EFSA (2013)	23	STMR-RAC
Legume vegetables (fresh)	3	EFSA (2013)	1.04	STMR-RAC
Asparagus	0.01	EFSA (2013)	0.01	STMR-RAC
Cardoons	15	EFSA (2013)	1.98	STMR-RAC
Celeries	15	EFSA (2013)	1.98	STMR-RAC
Florence fennels	10	EFSA (2013)	2.2	STMR-RAC
Globe artichokes	5	EFSA (2013)	1.8	STMR-RAC
Leeks	10	EFSA (2013)	2.2	STMR-RAC
Rhubarbs	0.6	EFSA (2013)	0.1	STMR-RAC
Pulses (dry)	0.15	EFSA (2013)	0.01	STMR-RAC
Linseeds	0.4	EFSA (2016b)	0.02	STMR-RAC
Peanuts/groundnuts	0.2	EFSA (2013)	0.01	STMR-RAC
Poppy seeds	0.5	EFSA (2013)	0.06	STMR-RAC

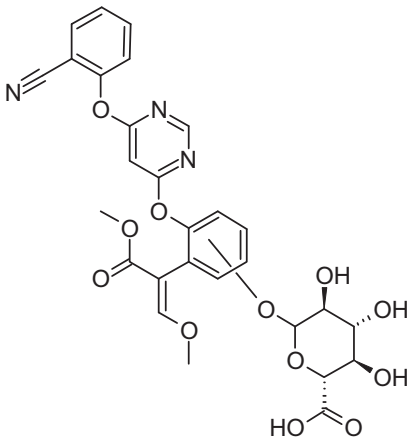
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment	
			Input value (mg/kg)	Comment
Sunflower seeds	0.5	EFSA (2013)	0.04	STMR-RAC
Rapeseeds/canola seeds	0.7	EFSA (2022)	0.18	STMR-RAC
Soyabeans	0.5	EFSA (2013)	0.05	STMR-RAC
Mustard seeds	0.5	EFSA (2013)	0.06	STMR-RAC
Cotton seeds	0.7	EFSA (2013)	0.01	STMR-RAC
Safflower seeds	0.4	EFSA (2016b)	0.02	STMR-RAC
Borage seeds	0.4	EFSA (2016b)	0.02	STMR-RAC
Gold of pleasure seeds	0.5	EFSA (2013)	0.06	STMR-RAC
Oil palm fruits	0.03	EFSA (2021b)	0.01	STMR-RAC
Barley	1.5	FAO (2014)	0.05	STMR-RAC
Maize/corn	0.02	EFSA (2013)	0.01	STMR-RAC
Oat	1.5	FAO (2014)	0.05	STMR-RAC
Rice	5	EFSA (2013)	0.52	STMR-RAC
Rye	0.5	EFSA (2013)	0.08	STMR-RAC
Sorghum	10	FAO (2014)	1.85	STMR-RAC
Wheat	0.5	EFSA (2013)	0.08	STMR-RAC
Coffee beans	0.03	FAO (2014)	0.01	STMR-RAC
Herbal infusions (dried flowers)	60	EFSA (2013)	10.2	STMR-RAC
Herbal infusions (dried leaves)	60	EFSA (2013)	10.2	STMR-RAC
Herbal infusions (dried roots)	0.3	EFSA (2013)	0.07	STMR-RAC
Spices (seeds)	0.3	EFSA (2013)	0.05	STMR-RAC
Spices (fruits)	0.3	EFSA (2013)	0.05	STMR-RAC
Sugar beet roots	5	EFSA (2021a)	1.35	STMR-RAC
Sugar canes	0.05	FAO (2017)	0.02	STMR-RAC
Chicory roots	0.09	EFSA (2013)	0.03	STMR-RAC
Swine: Muscle/meat	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Swine: Fat tissue	0.05(a)	EFSA (2013)	0.01	STMR-RAC
Swine: Liver	0.07(a)	EFSA (2013)	0.01	STMR-RAC
Swine: Kidney	0.07(a)	EFSA (2013)	0.01	STMR-RAC
Swine: Edible offal (other than liver and kidney)	0.07(a)	EFSA (2013)	0.01	STMR-RAC
Swine: Other products	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Bovine: Muscle/meat	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Bovine: Fat tissue	0.05(a)	EFSA (2013)	0.01	STMR-RAC
Bovine: Liver	0.07(a)	EFSA (2013)	0.01	STMR-RAC
Bovine: Kidney	0.07(a)	EFSA (2013)	0.01	STMR-RAC
Bovine: Edible offals (other than liver and kidney)	0.07(a)	EFSA (2013)	0.01	STMR-RAC
Bovine: Other products	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Sheep: Muscle/meat	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Sheep: Fat tissue	0.05(a)	EFSA (2013)	0.01	STMR-RAC
Sheep: Liver	0.07(a)	EFSA (2013)	0.01	STMR-RAC
Sheep: Kidney	0.07(a)	EFSA (2013)	0.01	STMR-RAC
Sheep: Edible offals (other than liver and kidney)	0.07(a)	EFSA (2013)	0.01	STMR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment	
			Input value (mg/kg)	Comment
Sheep: other products	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Goat: Muscle/meat	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Goat: Fat tissue	0.05(a)	EFSA (2013)	0.01	STMR-RAC
Goat: Liver	0.07(a)	EFSA (2013)	0.01	STMR-RAC
Goat: Kidney	0.07(a)	EFSA (2013)	0.01	STMR-RAC
Goat: Edible offal (other than liver and kidney)	0.07(a)	EFSA (2013)	0.01	STMR-RAC
Goat: other products	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Equine: Muscle/meat	0.01*	EFSA (2013)	0.01	STMR-RAC
Equine: Fat tissue	0.05	EFSA (2013)	0.01	STMR-RAC
Equine: Liver	0.07	EFSA (2013)	0.01	STMR-RAC
Equine: Kidney	0.07	EFSA (2013)	0.01	STMR-RAC
Equine: Edible offals (other than liver and kidney)	0.07	EFSA (2013)	0.01	STMR-RAC
Equine: Other products	0.01*	EFSA (2013)	0.01	STMR-RAC
Poultry: Muscle/meat	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Poultry: Fat tissue	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Poultry: Liver	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Poultry: Kidney	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Poultry: Edible offals (other than liver and kidney)	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Poultry: Other products	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Other farmed animals: Muscle/meat	0.01*	EFSA (2013)	0.01	STMR-RAC
Other farmed animals: Fat tissue	0.05	EFSA (2013)	0.01	STMR-RAC
Other farmed animals: Liver	0.07	EFSA (2013)	0.01	STMR-RAC
Other farmed animals: Kidney	0.07	EFSA (2013)	0.01	STMR-RAC
Other farmed animals: Edible offals (other than liver and kidney)	0.07	EFSA (2013)	0.01	STMR-RAC
Other farmed animals: Other products	0.01*	EFSA (2013)	0.01	STMR-RAC
Milk: cattle, sheep, goat, horse, others	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC
Eggs: chicken, duck, goose, quail, others	0.01*,(a)	EFSA (2013)	0.01	STMR-RAC

STMR-RAC: supervised trials median residue in raw agricultural commodity; PeF: Peeling factor.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Tentative MRLs implemented in the MRL legislation by Commission Regulation (EU) 2022/1363, including a footnote for confirmatory data. The residue definition for risk assessment in commodities of animal origin is tentatively set as parent compound (EFSA, 2010, 2013, 2020).

Appendix E – Used compound codes

Code/Trivial name	IUPAC name/SMILES notation/InChiKey[a]	Structural formula[b]
Azoxystrobin	methyl (2*E*)-2-(2-{[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}phenyl)-3-methoxyprop-2-enoate 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 Refers to a non determined mixture of isomers with hydroxyl group in one of the alternative positions. Name and codes of one of the compounds is given for illustrative purposes. methyl (2E)-2-(2-{[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}-4-hydroxyphenyl)-3-methoxyprop-2-enoate O=C(OC)\C(=C\OC)c1ccc(O)cc1Oc1cc(Oc2ccccc2C#N)ncn1 YGORCRAVOJDUML-SFQUDFHCSA-N	
L4	S-(2-cyano-x-hydroxyphenyl)cysteine Refers to a non-determined mixture of isomers with hydroxyl group in one of the alternative positions. Name and codes of one of the compounds is given for illustrative purposes. S-(2-cyano-4-hydroxyphenyl)cysteine O=C(O)C(N)CSc1ccc(O)cc1C#N HHJSURCWSNDRKW-UHFFFAOYSA-N	
L9	2-{[6-(2-cyanophenoxy)pyrimidin-4- yl]oxy}-x-hydroxybenzoic acid Refers to a non-determined mixture of isomers with hydroxyl group in one of the alternative positions. Name and codes of one of the compounds is given for illustrative purposes. 2-{[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}-4-hydroxybenzoic acid O=C(O)c1ccc(O)cc1Oc1cc(Oc2ccccc2C#N)ncn1 KBPYPCVAGBHCJS-UHFFFAOYSA-N	

Code/Trivial name	IUPAC name/SMILES notation/InChiKey[a]	Structural formula[b]
K1	4-{[6-(2-cyanophenoxy)pyrimidin-4- yl]oxy}-3-[(1E)-1,3-dimethoxy-3-oxoprop1-en-2-yl]phenyl glucopyranuronic acid Refers to a non-determined mixture of isomers with glucopyranuronic acid moiety in one of the alternative positions. Name and codes of one of the compounds is given for illustrative purposes. 3-{[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}-4-[(1E)-1,3-dimethoxy-3-oxoprop-1-en-2-yl]phenyl L-glucopyranosiduronic acid N#Cc1ccccc1Oc1cc(ncn1)Oc1cc(O[C@H]2OC([C@H](O)C(O)C2O)C(=O)O)ccc1C(=C\OC)/C(=O)OC BPMGKBSQEJFZIY-SFQUDFHCSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).
(b): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).