Modification of the existing maximum residue levels for azoxystrobin in rapeseeds and linseeds

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Industrias Afrasa SA – Albaugh TKI d.o.o. – Lainco S.A. submitted a request to the competent national authority in Greece to modify the existing maximum residue levels (MRLs) for the active substance azoxystrobin in rapeseeds and linseeds. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for rapeseeds. No modification of the existing EU MRL was proposed for linseeds. Adequate analytical methods for enforcement are available to control the residues of azoxystrobin in the commodities 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 practices is unlikely to present a risk to consumer health.

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In accordance with Article 6 of Regulation (EC) No 396/2005, Industrias Afrasa SA - Albaugh TKI d.o.o. - Lainco S.A. submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance azoxystrobin in rapeseeds and linseeds. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 13 January 2021. To accommodate for the intended uses of azoxystrobin, the EMS proposed to raise the existing MRLs for rapeseeds from 0.5 to 0.7 mg/kg and for linseeds from 0.4 to 0.9 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested from the EMS. On 14 September 2021, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

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

In rotational crops, the major residue identified was also the parent compound.

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

Based on the metabolic pattern identified in metabolism studies and on the results of hydrolysis studies, the residue definitions for plant products were proposed as 'azoxystrobin' both for enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in this application, the metabolism of azoxystrobin in primary and in rotational 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 method (HPLC-MS/MS) and the multiresidue DFG S19 method using HPLC-MS/MS are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above the limit of quantification (LOQ) of 0.01 mg/kg in the crops assessed. In addition, the multiresidue Quick, Easy, Cheap, Effective, Rugged and Safe (QuEChERS) methods in combination with HPLC-MS/MS and GC/MS, as described by the European Committee for Standardization (CEN), are also available to analyse parent azoxystrobin.

The available residue trials are sufficient to derive an MRL proposal of 0.7 mg/kg for rapeseeds. For linseeds, no modification of the existing EU MRL was proposed, as the critical GAP (SEU) was not supported by GAP-compliant residue data, according to EFSA, and the residue data compliant with the NEU GAP lead to lower residue levels (< LOQ) compared to the existing MRL (0.4 mg/kg).

The occurrence of azoxystrobin residues in rotational crops was investigated in the framework of the EU pesticides peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed Good Agricultural Practice (GAP).

Processing factors (PFs) for the crops under assessment were derived in the current application and a previous one. For oilseed rape/meal (press cake), the PF is only supported by two processing studies. However, as supporting information are available to corroborate the value derived, the following PF can be recommended to be included in Annex VI of Regulation (EC) No 396/2005:

- Oilseed rape/meal: 0.175.

The other PFs derived in the current application (e.g. crude oil) are on tentative basis because these are supported by one trial only. However, further specific studies investigating the magnitude of azoxystrobin residues in other processed commodities are not required, considering the low individual contribution of residues in the commodities under assessment to the total chronic consumer exposure.
As the crops under consideration and their by-products are used as feed products, the potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal groups. However, the contribution of azoxystrobin residues in the crops under consideration in this MRL application to the total livestock exposure was not significant, and therefore, a modification of the existing MRLs for commodities of animal origin, which are set on the basis of the Codex maximum residue limits (CXL), was not considered necessary.

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

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The highest estimated long-term dietary intake accounted for 22% of the ADI (NL toddler diet). The contributions of residues expected in the commodities assessed in this application to the overall long-term exposure are 0.09% of the ADI (NL toddler diet) for rapeseeds and below 0.01% of the ADI (all EU diets) for linseeds. An acute exposure calculation was not required since ARfD was considered not necessary for azoxystrobin.

EFSA concluded that the proposed uses of azoxystrobin on rapeseeds and linseeds will not result in a consumer exposure exceeding the toxicological reference value and are therefore unlikely to pose a risk to consumers’ health.

It is noted that the uncertainty in the consumer risk assessment related to the calculated consumer exposure to livestock metabolites L1, L4, L9 and K1 (conjugate of L1) highlighted in the framework of the MRL review of the confirmatory data is still valid.

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

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

| Code(a) | Commodity               | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                 |
|---------|-------------------------|-------------------------|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| 0401010 | Linseeds                | 0.4                     | No change               | The submitted data indicate that the NEU use does not lead to residue above the enforcement LOQ (0.01 mg/kg). EFSA concluded that the SEU use was not supported by GAP compliant data. The submitted data do not provide evidence that the existing MRL has to be modified. |
| 0401060 | Rapeseeds/canola seeds  | 0.5                     | 0.7                     | The submitted data indicate that the NEU use does not lead to residue above the enforcement LOQ (0.01 mg/kg). The SEU use is fully supported by GAP compliant data, which are sufficient to derive an MRL proposal of 0.7 mg/kg. Risk for consumer unlikely. |

MRL: maximum residue level; NEU: northern Europe; LOQ: limit of quantification; SEU: southern Europe; GAP: Good Agricultural Practice.
(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 levels (MRLs) for azoxystrobin in rapeseeds and linseeds. The detailed description of the intended uses of azoxystrobin in rapeseed and linseed, which are the basis for the current MRL application, is reported in Appendix A.

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

Azoxystrobin was evaluated in the framework of Directive 91/414/EEC⁴ with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on cereals and brassica vegetables. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2010). The decision on the renewal of azoxystrobin entered into force on 1 January 2012. The approval is restricted to uses as fungicide² only.

The EU MRLs for azoxystrobin are established in Annex II of Regulation (EC) No 396/2005³. 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 (EFSA, 2016a,b, 2021a,b). The proposals from these reasoned opinions have been considered in recent MRL regulations. Also, certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.⁴

In accordance with Article 6 of Regulation (EC) No 396/2005, Industrias Afrasa SA - Albaugh TKI d.o.o. - Lainco S.A. submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance azoxystrobin in rapeseeds and linseeds. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 13 January 2021. To accommodate for the intended uses of azoxystrobin, the EMS proposed to raise the existing MRLs for rapeseeds from 0.5 to 0.7 mg/kg and for linseeds from 0.4 to 0.9 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested from the EMS. On 14 September 2021, the EMS submitted a revised evaluation report (Greece, 2020), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Greece, 2020), the renewal assessment report (RAR) (and its addendum) (United Kingdom, 2009a,b) prepared under 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).

For this application, the data requirements established in Regulation (EU) No 544/2011⁵ the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1996, 1997a-g, 2000, 2010a,b, 2017a,b; OECD, 2011, 2013). The assessment

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¹ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, 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, 16.03.2005, 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/active-substances/event-search.as
⁵ Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
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. 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 (Greece, 2020) and the exposure calculations using
the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this
reasoned opinion and, thus, are made publicly available as background documents to this reasoned
opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

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

The metabolism pattern was similar in all plant groups 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.

For the intended uses (foliar uses on oilseed crops), the metabolic behaviour in primary crops is
sufficiently addressed.

1.1.2. Nature of residues in rotational crops

As the proposed uses of azoxystrobin is on crops that can be grown in rotation with other crops,
the investigation of residues in succeeding crops is required.

According to the soil degradation studies evaluated in the framework of the peer review, the DT50
value of azoxystrobin is 262 days (EFSA, 2010). DT90 value is expected to be higher than the trigger
value of 100 days (EFSA, 2010), and therefore, studies investigating the nature of residues in
rotational crops are required.

The nature of azoxystrobin residues in rotational crops was evaluated in the framework of the EU
pesticide peer review (EFSA, 2010). On the basis of confined studies conducted in lettuce, radish and
wheat at a maximum dose rate of 2.2 kg a.s./ha, it was concluded that the metabolism of
azoxystrobin is similar to that of the primary crops (EFSA, 2010).

For the proposed uses assessed in this application, no further information is 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. Methods of analysis in plants

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

The method RAM 305 using high-performance liquid chromatography with tandem mass
spectrometry detection (HPLC-MS/MS) and the multiresidue DFG S19 method using HPLC-MS/MS 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) is also sufficiently validated for the quantification
of residues of azoxystrobin at or above the LOQ of 0.01 mg/kg in hops (EFSA, 2013).

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6 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European
Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L
155, 11.6.2011, p. 127–175.
In addition, the multiresidue QuEChERS method in combination with HPLC-MS/MS and GC-MS, as described by the European Committee for Standardization (CEN, 2008), is also available to analyse parent azoxystrobin (EFSA, 2013).

The crops under consideration in the present MRL application belong to the high oil content commodity group. Therefore, sufficiently validated methods for the enforcement of azoxystrobin residues in rapeseeds and linseeds are available.

EFSA notes that the extraction efficiency for the first two analytical methods proposed for enforcement (RAM 305 and DFG S19) is not proven as indicated according to the requirements of the extraction efficiency Technical Guideline (European Commission, 2017b). Further investigation on this matter would in principle be required. EFSA would therefore recommend reconsidering this point in the framework of the peer review for the renewal of approval of the active substance.

It is acknowledged that a comprehensive cross-validation study was provided in the context of the recent MRL application on azoxystrobin in mangoes and oil palm fruits to assess extraction efficiency of the QuEChERS method (EFSA, 2021b). It was demonstrated that the extraction efficiency of the solvents used in the QuEChERS methods for enforcement and in the radiolabelled metabolism studies were comparable (amounts of extracted residues in the two systems differ by no more than 30%) for all commodity categories. However, the specific % TRR of the parent azoxystrobin in the various solvents was not reported. It was therefore concluded that extraction efficiency was partially demonstrated (EFSA, 2021b).

Based on the previous assessment (EFSA, 2021b), it can be concluded that the extraction efficiency of the enforcement methods for rapeseeds and linseeds is partially demonstrated. EFSA, therefore, recommends reconsidering this 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 pesticides peer review (EFSA, 2010).

It was demonstrated that, in commodities belonging to the high oil content group, residues of azoxystrobin are stable for at least 24 months when stored at \(-18^\circ C\).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies and the capabilities of enforcement analytical methods, the residue definition for enforcement and risk assessment in all plant commodities following foliar application was proposed as ‘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 these residue definitions are appropriate for the crops under assessment.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the present MRL application on rapeseeds and linseeds, the applicant submitted residue trials performed on rapeseeds in northern and southern Europe.

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated and were analysed for the parent compound, according to the residue definitions for enforcement and risk assessment. The method used in the analysis of samples in the context of the residue trials is based on liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). According to the assessment of the EMS, the method used was sufficiently validated and fit for purpose (Greece, 2020).

It is noted that the solvent system used in the analytical methods for risk assessment (acetonitrile:water) is the same as the one used in the QuEChERS method for enforcement (acetonitrile:water 50:50). However, since no sufficient evidence is available to demonstrate that the extraction conditions of these methods are comparable and considering that the extraction efficiency of the QuEChERS method is only partially demonstrated (see Section 1.1.4), EFSA concludes that the extraction efficiency of the solvent system used in the analytical method for risk assessment is also partially
demonstrated according to the Technical Guideline for extraction efficiency (European Commission, 2017b).

**Rapeseeds**

*NEU outdoor GAP (foliar treatment):* 2 × 250 g a.s./ha, 10 day-interval, BBCH 60–67, PHI 70 days

*SEU outdoor GAP (foliar treatment):* 2 × 250 g a.s./ha, 10 day-interval, BBCH 60–67, PHI 21 days

A total of four NEU field residue trials were conducted in Germany and the United Kingdom in 2015. The trials are considered sufficiently independent and are in line with the NEU GAP for rapeseeds. No decline studies were submitted (only sampling at preharvest interval (PHI) 69–84 days), however, considering that the measured residue levels were all below the LOQ of 0.01 mg/kg, the lack of decline studies was considered a minor deviation and is not expected to have an impact on the outcome of the assessment.

A total of eight independent SEU residue trials were conducted in Greece, Italy, Southern France and Spain during the growing seasons of 2018 and 2019. They were performed with two foliar spray applications at a nominal rate of 250 g a.s./ha, with an interval between applications of 9–11 days and a PHI of 20–25 days. Four of these trials were designed as decline studies. In these trials, the growth stages at second application (as reported by the study investigators) ranged between BBCH 71 and 83 (instead of BBCH 60–67). However, based on the time between last application and harvest (PHI), the available trials were performed in compliance with the GAP. Therefore, the trials were considered sufficient and suitable to support the SEU GAP for rapeseeds.

EFSA concludes that an MRL proposal of 0.7 mg/kg can be derived for rapeseeds based on the southern GAP. The residue data from the supervised residue trials in primary crops are summarised in Appendix B.1.2.1.

**Linseeds**

*NEU/SEU outdoor GAP:* 2 × 250 g a.s./ha, 10-day interval, BBCH 65–70, PHI not defined

In support of the intended NEU/SEU GAP for linseeds, the EMS proposed to extrapolate residue data from the NEU/SEU trials on rapeseeds (described above) to linseeds. In accordance with the EU technical guidelines on extrapolation (European Commission, 2017a), such an extrapolation is possible. However, in the absence of a defined PHI, the growth stage at last application is the critical parameter to be considered to assess the compliance of the trials to the GAP, according to the intended application timing.

For the NEU zone, the extrapolation was considered acceptable as the NEU trials on rapeseeds (growth stage at application: BBCH 67) were performed in compliance with the NEU GAP on linseeds. Based on the available trials, the intended uses of azoxystrobin on linseeds in NEU lead to residue levels below the LOQ.

For the SEU zone however, the available trials were performed with applications at more advanced growth stages than the intended ones: second applications (as reported by the study investigators) were performed between BBCH 71 and 83 instead of BBCH 65–70. Therefore, these trials are not applicable to support the SEU GAP on linseeds.

It is noted that the above conclusion regarding the SEU GAP on linseeds does not reflect the view of the EMS. The EMS clarified that different PHIIs are expected in the southern and northern zones but, despite an EFSA’s request for clarifications, no PHI was defined by Applicant/EMS for the SEU GAP on linseeds. The EMS supported the proposal of the Applicant to define the application timing by the growth stages at application rather than by the PHI (Greece, 2020). The EMS selected four SEU residue trials which first application was performed at the end of the flowering stage (BBCH 69) and second application after formation of the edible part of the crop (BBCH 71–83). Based on these trials, an MRL of 0.9 mg/kg would be derived for linseeds. It is acknowledged that the accuracy of the reporting of the growth stage ranges (using BBCH scale) may vary between the field study investigators. It is also notoriously recognised that not all plants reach the same growth stage (e.g. end of flowering) at the same time. However, considering the BBCH ranges (as reported in the trials) and the absence of defined PHI in the intended GAP, the application timings of the trials (based on growth stage) appear to be more critical than the ones indicated in the GAP for linseed. The EMS approach may therefore lead to an overestimation of the residue levels in the harvested product and to a higher MRL than necessary for the intended GAP on linseeds.
EFSA concludes that the SEU GAP on linseeds is not supported by GAP compliant trials. Overall, considering that the NEU use is not expected to lead to residue above the enforcement LOQ (0.01 mg/kg) and that the SEU use was not supported by GAP compliant data, a new MRL recommendation could not be derived for linseeds.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of azoxystrobin residues to crops that are grown in crop rotation has been assessed in the EU pesticides peer review and the MRL review (EFSA, 2010, 2013). In the context of the MRL review, it was concluded that no residues above the LOQ (0.01 mg/kg) are expected in crop parts intended for human consumption and that residues are very low in commodities intended for feed purposes (0.05 mg/kg in wheat forage and 0.04 mg/kg in wheat straw) (EFSA, 2013).

Since the maximum annual application rate for the crops under consideration (i.e. 0.5 kg a.s./ha) is lower than the maximum seasonal application rate assessed during the MRL review (i.e. 1 kg a.s./ha), the previous conclusion remains valid, provided that the active substance is applied according to the proposed GAP.

1.2.3. Magnitude of residues in processed commodities

Two processing studies on rapeseeds were submitted in the framework of the present MRL application (Greece, 2020).

Rapeseeds were processed into oil, press cake and meal. In one trial, residues in the raw commodity were below the LOQ of 0.01 mg/kg, and therefore, the effect of processing on the magnitude of residues could not be estimated. The second trial indicates a concentration of residues in crude oil (processing factor \( PF = 3.1 \)) and mixed oil (\( PF = 1.8 \)) and a reduction of residues in press cake (\( PF = 0.17 \)), solvent-extracted meal (\( PF = 0.07 \)) and extract oil (\( PF = 0.47 \)). These data are in line with data evaluated by EFSA in the context of a previous MRL application on poppy seeds, mustard seeds and gold of pleasure seeds (oilseeds) (EFSA, 2011), where PFs of 1.18 and 0.18 were derived from one trial on processed rapeseeds for refined oil and press cake, respectively.

Furthermore, an additional study from the literature (Jiang et al., 2013) was mentioned in the Evaluation Report (Greece, 2020) in support of the processing study submitted in the context of the current application. In the mentioned study, processing factors for crude oil and rapeseed meal were derived based on two trials performed in Nanjing (China) (0.64 and 0.70 for crude oil; 0.16 and 0.19 for rapeseed meal/press cake). It is noted that the processing procedures for rapeseed oil production (Jiang et al., 2013) are not comparable to the ones performed in the trial submitted in the context of the current application; therefore, the PFs derived (Jiang et al., 2013) were not considered to derive the overall median PFs for oil and press cake. However, it is remarkable that PFs derived for rapeseed meal/press cake in the supporting study from the literature (Jiang et al., 2013) are comparable with the ones reported in the processing study provided in the current and a previous MRL application (EFSA, 2011; Greece, 2020), and, therefore, corroborate the submitted data. In addition, it is noted that the study is conducted according to the OECD Guidelines (OECD, 2008a) and that the analytical method is described in detail and complies with the applicable Guidance Document on Analytical methods (European Commission, 2010b).

It is acknowledged that, according to the applicable data requirements, three processing studies per commodity and procedure would in principle be required to derive a robust PF. Therefore, it was not possible to derive robust processing factors for rapeseed and linseed oil. EFSA does not propose inclusion of the derived processing factors in Annex VI of Regulation (EC) No 396/2005. If risk managers wish to derive robust processing factors, which allow enforcement of azoxystrobin residues in rapeseed and linseed oil, further processing trials would be required in these commodities. However, as supporting data corroborate the PFs derived for rapeseed meal/press cake in the studies submitted in the current and a previous MRL application (EFSA, 2011; Greece, 2020), EFSA concludes that the derived PF of 0.175 is sufficiently reliable and proposes its inclusion in Annex VI of Regulation (EC) No 396/2005 (see Appendix B.1.2.3). The above-mentioned PF has been considered for dietary burden calculation (see Section 2).

No conversion factor was deemed necessary, as residue definitions for monitoring and risk assessment are the same in processed commodities.

Further processing studies on rapeseeds and linseeds are not required, since, considering the low individual contribution of residues in the commodities under assessment to the total chronic consumer exposure (< 0.1% of the acceptable daily intake (ADI)), such results would not be expected to affect the outcome of the risk assessment (see Section 3).
1.2.4. Proposed MRLs

The available data are considered sufficient to derive a proposal for MRL and risk assessment values for rapeseeds (see Appendix B.1.2.1).

For linseeds however, no modification of the existing EU MRL could be proposed as the critical GAP (SEU) was not supported by GAP-compliant residue data, according to EFSA, and the residue data compliant with the NEU GAP lead to lower residue levels (< LOQ) compared to the existing MRL (0.4 mg/kg).

In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

By-products of rapeseeds and linseeds may be used for feed purposes. Hence, it was necessary to update the previous dietary burden calculation for livestock (EFSA, 2021b), including rapeseed and linseed by-products, to estimate whether the intended use of azoxystrobin would have an impact on the residues expected in food of animal origin and would trigger a modification of the MRLs.

EFSA updated the calculations performed in the previous assessment (EFSA, 2021b), adding the input values for rapeseed and linseed meals. As the PFs derived for these processed commodities indicate a reduction of azoxystrobin concentrations in rapeseed and linseed meals, the default processing factor for these by-products (2) was replaced by the PF calculated in the context of the current MRL application (0.175).

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

The calculated dietary burden resulted to be the same as in the assessment of the MRL review confirmatory data and two previous import tolerance applications on sugar beets, mangoes and oil palm fruits (EFSA, 2020, 2021a,b). Consequently, a modification of the existing MRLs in products of animal origin is not necessary and the conclusion of the article 12 confirmatory data assessment remains valid (EFSA, 2020).

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

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). This exposure assessment model contains food consumption data for different subgroups 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 (TRV) for azoxystrobin used in the risk assessment (i.e. ADI of 0.2 mg/kg bw per day) was derived in the framework of the EU pesticides peer review (European Commission, 2015). The derivation of an acute reference dose (ARfD) was considered not necessary (European Commission, 2015).

Short-term (acute) dietary risk assessment

Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required.

Long-term (chronic) dietary risk assessment

EFSA updated the calculations performed in the previous assessment (EFSA, 2021b), including the STMR value derived for rapeseeds. For linseeds, no modification of the MRL is proposed (see Section 1.2.4). Therefore, the STMR value derived in a previous application was selected as input value (EFSA, 2016b).
The input values used in the exposure calculations are summarised in Appendix D.2. The highest estimated long-term dietary intake accounted for 22% of the ADI (NL toddler diet). The contributions of residues expected in the commodities assessed in this application to the overall long-term exposure are 0.09% of the ADI (NL toddler diet) for rapeseeds and below 0.01% of the ADI (all EU diets) for linseeds (see Appendix B.3).

EFSA concluded that the long-term intake of residues of azoxystrobin resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

It is noted that the uncertainty in the consumer risk assessment related to the calculated consumer exposure to livestock metabolites L1, L4, L9 and K1 (conjugate of L1) highlighted in the framework of the MRL review of the confirmatory data is still valid (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 rapeseeds.

For linseeds however, no modification of the existing EU MRL could be proposed as, the critical GAP (SEU) was not supported by GAP compliant trials, according to EFSA, and as the NEU GAP lead to lower residue levels (< LOQ) compared to the existing MRL (0.4 mg/kg).

EFSA concluded that the proposed use of azoxystrobin on rapeseed will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers’ health.

It is noted that the uncertainty in the consumer risk assessment related to the calculated consumer exposure to livestock metabolites L1, L4, L9 and K1 (conjugate of L1) highlighted in the framework of the MRL review of the confirmatory data is still valid (EFSA, 2020).

The MRL recommendations are summarised in Appendix B.4.

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**Abbreviations**

| Abbreviation | Definition |
|--------------|------------|
| a.s. | active substance |
| ADI | acceptable daily intake |
| AR | applied radioactivity |
| ARF | acute reference dose |
| BBCH | growth stages of mono- and dicotyledonous plants |
| bw | body weight |
| CAS | Chemical Abstract Service |
| CEN | European Committee for Standardisation (Comité Européen de Normalisation) |
| CF | conversion factor for enforcement to risk assessment residue definition |
| CXL | Codex maximum residue limit |
| DM | dry matter |
| DT$_{90}$ | period required for 90% dissipation (define method of estimation) |
| EC | emulsifiable concentrate |
| ECD | electron capture detector |
| EMS | evaluating Member State |
| eq | residue expressed as a.s. equivalent |
| EURL | EU Reference Laboratory (former Community Reference Laboratory (CRL)) |
| FAO | Food and Agriculture Organization of the United Nations |
| GAP | Good Agricultural Practice |
| GC | gas chromatography |
| GC-MS | gas chromatography with 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 |
| 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 |
| OECD | Organisation for Economic Co-operation and Development |
| PBI | plant back interval |
| PF | processing factor |
| PHI | preharvest interval |
| $P_{ow}$ | partition coefficient between n-octanol and water |
| PRIMo | (EFSA) Pesticide Residues Intake Model |
| QuEChERS | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA | risk assessment |
| Acronym | Description |
|---------|-------------|
| RAC     | raw agricultural commodity |
| RD      | residue definition |
| RMS     | rapporteur Member State |
| RPF     | relative potency factor |
| SANCO   | Directorate-General for Health and Consumers |
| SC      | suspension concentrate |
| SCPAFF  | Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH) |
| SEU     | southern Europe |
| SG      | water-soluble granule |
| SL      | soluble concentrate |
| SP      | water-soluble powder |
| STMR    | supervised trials median residue |
| TRR     | total radioactive residue |
| UV      | ultraviolet (detector) |
| WHO     | World Health Organization |
| WP      | wettable powder |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F/G/I (a) | Pests or group of pests controlled | Preparation | Conc. a.s. | Method Kind | Range of growth stages and season (c) | Number min–max | Interval between application (days) min–max | Water (L/ha) min–max | Rate max Unit | PHI (days)(d) | Remarks |
|-----------------------|------------------------|----------|-----------------------------------|-------------|------------|------------|-------------------------------|----------------|--------------------------------|-------------------|-------------|-------------|---------|
| Rapeseeds/canola seeds | SEU NEU | F | **Sclerotinia sclerotiorum** (Principal disease) **Leptosphaeria, Alternaria brassicae, Botrytis** | SC | 250 g/L | Foliar treatment – broadcast spraying | BBCH 60–67 | 1–2 | 10–14 | – | 200–400 | 0.25 kg a.s./ha | 21 | 70 |
| Linseeds | NEU and SEU (France)(e) | F | **Sclerotinia sclerotiorum, Alternaria brassicae** | SC | 250 g/L | Foliar treatment – spray application | BBCH 65–70 | 2 | 10–14 | – | 200–400 | 0.25 kg a.s./ha | n.a. | PHI is covered by time elapsed from last application to commercial harvest |

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; n.a.: not applicable.

(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.

(e): One single GAP (intended in France) has been reported for linseeds. As indicated in the Evaluation Report (Greece, 2020), different growth developments of linseed seeds and PHIs are expected in Northern and Southern France as a result of differences in temperature conditions in the two zones. However, as the uses are intended in a single country, a single GAP was reported and different PHIs were not defined.
## Appendix B – List of end points

### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       |             |         |                |                |                |
|                                   | Fruit crops | Grapes  | Foliar: 250 + 1,000 + 1,000 + 250 g/ha | 21 | Radiolabelled azoxystrobin: 14C-pyrimidinyl 14C-cyanophenyl 14C-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: 14C-pyrimidinyl 14C-cyanophenyl 14C-phenylacrylate (EFSA, 2010) |
|                                   |             |         | Foliar: 1 × unknown; BBCH 71 | 28 | Radiolabelled azoxystrobin: 14C-pyrimidinyl (EFSA, 2010) |
| Pulses/oilseeds                  |             | Peanuts | Foliar: 850 + 850 + 300 g/ha | 10 | Radiolabelled azoxystrobin: 14C-pyrimidinyl 14C-cyanophenyl 14C-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: 14C-pyrimidinyl 14C-cyanophenyl 14C-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) |
### B.1.1.2. Storage stability of residues in plants

| Plant products (available studies) | Category                 | Commodity   | T (°C) | Stability period | Compounds covered | Comment/Source |
|------------------------------------|--------------------------|-------------|--------|------------------|-------------------|----------------|
|                                     | 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         | Oilseed rape| –18    | 24 Months        | Azoxystrobin      | EFSA (2010)    |
|                                     |                          | Pecan       | –18    | 24 Months        | Azoxystrobin      | EFSA (2010)    |
|                                     |                          | Peanuts     | –18    | 24 Months        | Azoxystrobin      | EFSA (2010)    |
|                                     | Dry/high starch commodities | 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)    |

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

Can a general residue definition be proposed for primary crops? Yes EFSA (2010)
Rotational crop and primary crop metabolism similar? Yes EFSA (2010)
Residue pattern in processed commodities similar to residue pattern in raw commodities? Yes EFSA (2010)
Plant residue definition for monitoring (RD-Mo) Azoxystrobin
Plant residue definition for risk assessment (RD-RA) Azoxystrobin
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

Matrices with high water content, high oil content, high acid content, dry matrices and hops: HPLC–MS/MS 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).

Matrices with high water content, high oil content, high acid content and dry matrices: multi-residue DFG S19 method using HPLC-MS/MS with a LOQ of 0.01 mg/kg. ILV available (EFSA, 2010, 2013).

Multi-residue QuEChERS methods in combination with HPLC-MS/MS and GC–MS, as described by CEN (CEN, 2008), are also available to analyse parent azoxystrobin (EFSA, 2013).
## 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) |
|-----------|-----------|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|---------------|
| Rapeseeds | NEU       | $4 \times < 0.01$                                               | Residue trials on rapeseeds compliant with NEU-GAP on rapeseeds. The trials are sufficient to conclude that the intended NEU use of azoxystrobin on rapeseeds does not lead to residues above the enforcement LOQ (0.01 mg/kg). The submitted data do not provide evidence that the existing MRL has to be modified. | 0.01*                  | < 0.01       | < 0.01        |
|           | SEU       | $< 0.01; 0.03; 0.07; 0.14; 0.22; 2 \times 0.27; 0.37$          | Residue trials on rapeseeds performed at higher BBCH stages than indicated in the GAP. However, as the last applications were performed in compliance with the intended PHI, the trials can be considered compliant with the SEU-GAP on rapeseeds. The trials are sufficient to derive an MRL on rapeseeds. | 0.7                    | 0.37         | 0.18          |
| Linseeds  | NEU       | $4 \times < 0.01$                                               | Residue trials on rapeseeds compliant with NEU-GAP on linseeds. Extrapolation to linseeds possible. The trials are sufficient to conclude that the intended NEU use of azoxystrobin on linseeds does not lead to residues above the enforcement LOQ (0.01 mg/kg). The submitted data do not provide evidence that the existing MRL has to be modified. | 0.01*                  | < 0.01       | < 0.01        |
|           | SEU       | –                                                               | No GAP compliant trials available. The residue trials performed on rapeseeds could not be extrapolated to linseeds as the trials were conducted at a more critical GAP than the SEU-GAP for linseeds, i.e.: more advanced growth stage (second application at BBCH 71–83 instead of BBCH 60–67). As a PHI was not defined for the SEU-GAP for linseeds, it was not possible to consider the application timings of the trials to be GAP-compliant based on the PHI. MRL and risk assessment values cannot be derived. | –                      | –            | –             |

MRL: maximum residue level; GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants.

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

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

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

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

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Yes | Three confined rotational crop studies on lettuces, radishes and wheat were assessed in the framework of the EU pesticide peer review (EFSA, 2010). The residues declined significantly at longer plant back intervals (EFSA, 2013, 2020). |
| 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 (EFSA, 2010). 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, 2020). |

**LOQ:** limit of quantification.

### B.1.2.3. Processing factors

| Processed commodity | Number of valid studies$^{(a)}$ | Processing Factor (PF) | $C_{PF}^{(b)}$ | Comment/Source |
|--------------------|-------------------------------|------------------------|---------------|----------------|
| Oilseed rape/crude oil | 1 | 3.1 | – | 1 | Indicative processing factor supported by one trial (Greece, 2020). |
| Oilseed rape/press cake | 2 | 0.17; 0.18 | 0.175 | 1 | Processing factor supported by two trials (Greece, 2020; EFSA, 2011, respectively). In addition, a study (Jiang et al., 2013) was proposed for consideration by EMS (Greece, 2020). In this study, two trials were performed in Nanjing (China) and PFs of 0.16 and 0.19 could be derived. It is noted that these values are in line with the ones derived in the current and a previous MRL application (EFSA, 2011; Greece, 2020); the study can be used as supporting material. Based on the available data, EFSA concludes that the derived PF of 0.175 is sufficiently reliable and proposes its inclusion in Annex VI of Regulation (EC) No 396/2005. |
| Oilseed rape/solvent-extracted meal | 1 | 0.07 | – | 1 | Indicative processing factor supported by one trial (Greece, 2020). |
| Oilseed rape/extract oil | 1 | 0.47 | – | 1 | Indicative processing factor supported by one trial (Greece, 2020). |
| Oilseed rape/mixed oil | 1 | 1.8 | – | 1 | Indicative processing factor supported by one trial (Greece, 2020). |
| Oilseed rape/refined oil | 1 | 1.18 | – | 1 | Indicative processing factor supported by one trial (EFSA, 2011). |
PF: processing factor; MS: Evaluating Member State; MRL: maximum residue level.

(a): Studies with residues in the raw agricultural commodities (RACs) at or close to the LOQ were disregarded. Residue data from one trial were < LOQ in all cases; therefore, this trial could not be used to derive processing factors.

(b): Conversion factor for risk assessment in the processed commodity. Considering that the residue definition for risk assessment is the same as the residue definition for enforcement, a conversion factor of 1 was derived.

### B.2. Residues in livestock

Dietary burden calculation according to OECD (2013).

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup (a) | Most critical commodity (b) | Trigger exceeded (Y/N) | Previous assessment (EFSA, 2020) |
|----------------------------|-----------------------------|-----------------------------|-----------------------------|------------------------|----------------------------------|
|                            | mg/kg bw per day            | mg/kg DM                    |                             |                        | mg/kg DM Maximum                |
|                            | Median                      | Maximum                     | Median                      | Maximum                |
| Cattle (all)               | 0.46                        | 0.59                        | 11.97                       | 15.35                  |                                 |
| (dairy only)               | 0.46                        | 0.59                        | 11.97                       | 15.35                  |                                 |
| Sheep (all)                | 0.10                        | 0.23                        | 2.85                        | 5.79                   |                                 |
| (ewe only)                 | 0.10                        | 0.19                        | 2.85                        | 5.79                   |                                 |
| Swine (all)                | 0.20                        | 0.25                        | 8.76                        | 10.60                  |                                 |
| Poultry (all)              | 0.05                        | 0.10                        | 0.66                        | 1.42                   |                                 |
| (layer only)               | 0.05                        | 0.10                        | 0.66                        | 1.42                   |                                 |
| Fish                       | n.a.                        | n.a.                        | n.a.                        | n.a.                   | n.a.                            |

bw: body weight; DM: dry matter; n.a.: not applicable.

(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.
B.2.1. Nature of residues and methods of analysis in livestock

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

| Livestock (available studies) | Animal          | Dose (mg/kg bw/d) | Duration (days) | Comment/Source                                                                 |
|-------------------------------|-----------------|-------------------|-----------------|--------------------------------------------------------------------------------|
|                               | Laying hen      | 11                | 10              | Studies using $^{14}$C-pyrimidinyl, $^{14}$C-cyanophenyl and $^{14}$C-phenylacrylate radiolabelled azoxystrobin (EFSA, 2010) |
|                               |                 | 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 radiolabelled azoxystrobin (EFSA, 2010) |
|                               |                 | 25                | 7               | Study performed on goat using $^{14}$C-cyanophenyl radiolabelled azoxystrobin (EFSA, 2010) |

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

| Milk: not relevant | TRR in milk range between 0.004 and 0.01 mg eq/L (EFSA, 2020) |
|--------------------|----------------------------------------------------------------|
| Eggs: 6–8          | Observed in egg yolk (EFSA, 2020) |

Metabolism in rat and ruminant similar

| Yes               | The general metabolic pathways in rodents and ruminants were found to be comparable. (EFSA, 2010) |

Can a general residue definition be proposed for animals?

| Yes               | – |

Animal residue definition for monitoring (RD-Mo)

| Azoxystrobin |

Animal residue definition for risk assessment (RD-RA)

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

Fat soluble residues

| No | Log $P_{ow}$ < 3 (EFSA, 2010) |

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

| GC-NPD (EFSA, 2010): | Milk: LOQ 0.001 mg/kg for azoxystrobin. Eggs, muscle, fat, liver/kidney: 0.01 mg/kg for azoxystrobin. ILV available but confirmatory method missing (EFSA, 2010, 2013). |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| HPLC–MS/MS (validated method in FAO, 2008): | LOQ 0.01 mg/kg in all animal tissues, milk and eggs for azoxystrobin. ILV available; HPLC–MS/MS is a highly specific detection technique and a confirmatory method is not required (EFSA, 2013). |

Bw: body weight; TRR: total radioactive residue; GC-NPD: gas chromatography with nitrogen/phosphorous detector; LOQ: limit of quantification; ILV: independent laboratory validation; HPLC–MS/MS: high performance liquid chromatography with tandem mass spectrometry.
B.2.1.2. Storage stability of residues in livestock

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

B.2.2. Magnitude of residues in livestock

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

Not needed. The calculated dietary burden is the same as in the assessment of the MRL review confirmatory data and two previous import tolerance applications (EFSA, 2020, 2021a,b). Consequently, a modification of the existing MRLs in products of animal origin is not necessary and the conclusion of the article 12 confirmatory data assessment remains valid (EFSA, 2020).
B.3. Consumer risk assessment

Acute consumer risk assessment not relevant since no ARfD has been considered necessary (European Commission, 2015).

| ADI | 0.2 mg/kg bw per day (European Commission, 2015) |
| --- | --- |
| Highest IEDI, according to EFSA PRiMo | 22% of ADI (NL toddler diet) |

Contribution of crops assessed:
- Linseeds: < 0.01% of ADI (all EU diets)
- Rapeseeds: 0.09% of ADI (NL toddler diet)

Assumptions made for the calculations

Calculations performed with PRiMo revision 3.1.

The calculation is based on the median residue levels (STMR values) derived for raw agricultural commodities according to the risk assessment residue definition. For rapeseeds, the STMR value was derived from the data collected from the residue trials; for linseeds, no modification of the MRL is proposed. Therefore, the STMR value derived in a previous application was selected as input value (EFSA, 2016b).

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; FAO, 2014, 2017).

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 calculated 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).

B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
| --- | --- | --- | --- | --- |
| 0401010 | Linseeds | 0.4 | No change | The submitted data indicate that the NEU use does not lead to residues above the enforcement LOQ (0.01 mg/kg). EFSA concluded that the SEU use was not supported by GAP compliant data. The submitted data do not provide evidence that the existing MRL has to be modified. |
| 0401060 | Rapeseeds/ canola seeds | 0.5 | 0.7 | The submitted data indicate that the NEU use does not lead to residues above the enforcement LOQ (0.01* mg/kg). The SEU use is fully supported by GAP compliant data, which are sufficient to derive an MRL proposal of 0.7 mg/kg. Risk for consumer unlikely. |

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

**Enforcement residue definition:** azoxystrobin

MRL: maximum residue level; NEU: northern Europe; LOQ: limit of quantification; SEU: southern Europe; GAP: Good Agricultural Practice.

<sup>(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.</sup>
## Appendix C – Pesticide Residue Intake Model (PRImo)

### Azoxystron

| LOQs (mg/kg) range from: | 0.01 to: 0.05 |
|--------------------------|----------------|
| Source of ADI:           | EC              |
| Source of ARfD:          | not necessary   |
| Year of evaluation:      | 2015            |
| No of diets exceeding the ADI: | --- |

| Calculated exposure | 2nd contributor to MS diet | Commodity/ group of commodities |
|---------------------|---------------------------|--------------------------------|
| % of ADI             | % in % of ADI              |                                |
| 22% NL toddler       | 5% Sugar beet roots        | 1% Potatoes                     |
| 20% DE child         | 3% Potatoes                | 2% Sugar beet roots            |
| 19% NL child         | 4% Potatoes                | 3% Oranges                     |
| 16% FR child 3-15 yr | 3% Sugar beet roots        | 2% Potatoes                     |
| 13% UK toddler       | 4% Potatoes                | 2% Sugar beet roots            |
| 13% It child         | 3% Oranges                 | 2% Sugar beet roots            |
| 13% GEMS/Food G17    | 3% Oranges                 | 1% Sugar beet roots            |
| 12% FR toddler 2-3 yr| 2% Potatoes                | 1% Potatoes                     |
| 12% DE women 14-50 yr| 2% Oranges                 | 1% Oranges                     |
| 12% GEMS/Food G30    | 3% Oranges                 | 1% Oranges                     |
| 12% GEMS/Food G11    | 2% Oranges                 | 1% Oranges                     |
| 12% SE general       | 3% Oranges                 | 1% Oranges                     |
| 12% GEMS/Food G10    | 3% Oranges                 | 1% Oranges                     |
| 11% DE general       | 1% Oranges                 | 1% Oranges                     |
| 11% GEMS/Food G08    | 1% Oranges                 | 1% Oranges                     |
| 11% PT general       | 1% Oranges                 | 1% Oranges                     |
| 10% GEMS/Food G15    | 4% Oranges                 | 1% Oranges                     |
| 10% NL general       | 4% Oranges                 | 1% Oranges                     |
| 10% RD general       | 4% Oranges                 | 1% Oranges                     |
| 10% UK infant        | 4% Oranges                 | 1% Oranges                     |
| 9% FI 3-yr           | 3% Oranges                 | 1% Oranges                     |
| 7% FI 6-yr           | 1% Oranges                 | 1% Oranges                     |
| 7% ES adult          | 1% Oranges                 | 1% Oranges                     |
| 6% FR infant         | 2% Oranges                 | 1% Oranges                     |
| 5% UK vegetation     | 2% Oranges                 | 1% Oranges                     |
| 5% PL general        | 4% Oranges                 | 1% Oranges                     |
| 6% FR adult          | 1% Oranges                 | 1% Oranges                     |
| 6% DK child          | 3% Oranges                 | 1% Oranges                     |
| 6% IT toddler        | 0.4% Oranges               | 1% Oranges                     |
| 5% UK adult          | 0.1% Oranges               | 1% Oranges                     |
| 5% IT adult          | 0.7% Oranges               | 1% Oranges                     |
| 5% LT adult          | 0.2% Oranges               | 1% Oranges                     |
| 4% FI adult          | 1% Oranges                 | 1% Oranges                     |
| 4% DK adult          | 0.3% Oranges               | 1% Oranges                     |
| 1% EC child          | 0.2% Oranges               | 1% Oranges                     |

### Comments:

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

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**Details – acute risk assessment**

| Commodity/ group of commodities | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
|---------------------------------|-----------------------------------|-----------------------------------------------|
| Sugar beet roots                | 22%                               | 1%                                            |
| Mandarins                       | 20%                               | 1%                                            |
| Oranges                         | 19%                               | 1%                                            |
| Potatoes                        | 16%                               | 1%                                            |
| Sugar beet roots                | 13%                               | 1%                                            |
| Grapefruits                     | 13%                               | 1%                                            |
| Wine grapes                     | 13%                               | 1%                                            |
| Potatoes                        | 12%                               | 1%                                            |
| Sugar beet roots                | 12%                               | 1%                                            |
| Lemons                          | 12%                               | 1%                                            |
| Onions                          | 12%                               | 1%                                            |
| Lemons                          | 11%                               | 1%                                            |
| Wine grapes                     | 11%                               | 1%                                            |
| Oranges                         | 11%                               | 1%                                            |
| Oranges                         | 10%                               | 1%                                            |
| Lettuces                        | 10%                               | 1%                                            |
| Sugar beet roots                | 9%                                | 1%                                            |
| Oranges                         | 7%                                | 1%                                            |
| Oranges                         | 6%                                | 1%                                            |
| Sugar beet roots                | 5%                                | 1%                                            |
| Oranges                         | 4%                                | 1%                                            |
| Oranges                         | 1%                                | 1%                                            |

**Conclusion:**

- The estimated long-term dietary intake (TMDI/IEDI) was below the ADI.
- The long-term intake of residues of Azoxystron 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.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Show results for all crops

#### Unprocessed commodities

| % of ARD/ADI | Commodities | MRL Input for RA (mg/kg) | Exposure (µg/kg bw) | % of ARD/ADI | Commodities | MRL Input for RA (mg/kg) | Exposure (µg/kg bw) |
|--------------|-------------|--------------------------|---------------------|--------------|-------------|--------------------------|---------------------|

#### Processed commodities

| % of ARD/ADI | Processed commodities | MRL Input for RA (mg/kg) | Exposure (µg/kg bw) | % of ARD/ADI | Processed commodities | MRL Input for RA (mg/kg) | Exposure (µg/kg bw) |
|--------------|-----------------------|--------------------------|---------------------|--------------|-----------------------|--------------------------|---------------------|

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

#### Conclusion:

Total number of commodities exceeding the ARD/ADI in children and adult diets (IESTI calculation)
## 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)      | 0.10                 | HR (EFSA, 2013) |
| Turnip roots                    | 0.06                  | STMR (EFSA, 2013)      | 0.11                 | HR (EFSA, 2013) |
| Barley grain                    | 0.10                  | STMR (EFSA, 2013)      | 0.10                 | STMR (EFSA, 2013) |
| Bean seed (dry)                 | 0.01                  | STMR (EFSA, 2013)      | 0.01                 | STMR (EFSA, 2013) |
| Corn, field grain (Maize)       | 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                       | 0.10                  | STMR (EFSA, 2013)      | 0.10                 | 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          | 1.35                  | STMR (EFSA, 2021a)(a)  | 1.35                 | STMR (EFSA, 2021a)(a) |
| Beet, sugar ensiled pulp        | 1.35                  | STMR (EFSA, 2021a)(a)  | 1.35                 | STMR (EFSA, 2021a)(a) |
| Beet, sugar molasses            | 1.35                  | STMR (EFSA, 2021a)(a)  | 1.35                 | STMR (EFSA, 2021a)(a) |
| Brewer’s grain dried            | 0.33                  | STMR (0.1) × default PF (3.3) (EFSA, 2013)(b) | 0.33 | STMR (0.1) × default PF (3.3) (EFSA, 2013)(b) |
| **Canola (Rape seed) meal**     | 0.03                  | STMR (0.18) × PF (0.18) | 0.03 | STMR (0.18) × PF (0.18) |
| Citrus dried pulp               | 47.5                  | STMR (4.75) × default PF (10) (EFSA, 2013)(b) | 47.5 | STMR (4.75) × default PF (10) (EFSA, 2013)(b) |
| Corn, field milled by-pdts      | 0.01                  | STMR (EFSA, 2013)(c)   | 0.01                 | STMR (EFSA, 2013)(c) |
| Corn, field hominy meal         | 0.01                  | STMR (EFSA, 2013)(c)   | 0.01                 | STMR (EFSA, 2013)(c) |
| Corn, field gluten feed         | 0.01                  | STMR (EFSA, 2013)(c)   | 0.01                 | STMR (EFSA, 2013)(c) |
| Corn, field gluten meal         | 0.01                  | STMR (EFSA, 2013)(c)   | 0.01                 | STMR (EFSA, 2013)(c) |
| Distiller’s grain dried         | 0.25                  | STMR (0.075) × default PF (3.3) (EFSA, 2013)(b) | 0.25 | STMR (0.075) × default PF (3.3) (EFSA, 2013)(b) |
| **Flaxseed/Linseed meal**       | 0.004                 | STMR (0.02) (EFSA, 2016b) × PF (0.18)(d) | 0.004 | STMR (0.02) (EFSA, 2016b) × PF (0.18)(d) |

**Note:**
- EFSA, EFSA Journal 2022;20(1):7051
- www.efsa.europa.eu/efsajournal
| Feed commodity              | Median dietary burden | Maximum dietary burden |
|-----------------------------|-----------------------|------------------------|
|                             | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment                |
| Lupin seed meal             | 0.01                  | STMR (0.01) × default PF (1.1) (EFSA, 2013) (b) | 0.01 | STMR (0.01) × default PF (1.1) (EFSA, 2013) (b) |
| Palm, kernel meal           | 0.003                 | STMR (0.01) × tentative PF (0.3) (EFSA, 2021b) | 0.003 | STMR × tentative PF (0.3) (EFSA, 2021b) |
| Potato process waste        | 0.3                   | STMR (0.015) × default PF (20) (EFSA, 2013) (b) | 0.3 | STMR (0.015) × default PF (20) (EFSA, 2013) (b) |
| Potato dried pulp           | 0.57                  | STMR (0.015) × default PF (38) (EFSA, 2013) (b) | 0.57 | STMR (0.015) × default PF (38) (EFSA, 2013) (b) |
| Rapeseed meal               | 0.03                  | STMR (0.18) × PF (0.18) | 0.03 | STMR (0.18) × PF (0.18) |
| Rice bran/pollard           | 0.61                  | STMR (0.52) × PF (1.2) (EFSA, 2013) | 0.61 | STMR (0.52) × PF (1.2) (EFSA, 2013) |
| Safflower meal              | 0.04                  | STMR (0.02) × default PF (2) (EFSA, 2016b) (b) | 0.04 | STMR (0.02) × default PF (2) (EFSA, 2016b) (b) |
| Soybean meal                | 0.07                  | STMR (0.05) × default PF (1.3) (EFSA, 2013) (b) | 0.07 | STMR (0.05) × default PF (1.3) (EFSA, 2013) (b) |
| Soybean hulls               | 0.65                  | STMR (0.05) × default PF (13) (EFSA, 2013) (b) | 0.65 | STMR (0.05) × default PF (13) (EFSA, 2013) (b) |
| Sunflower meal              | 0.02                  | STMR (0.01) × default PF (2) (EFSA, 2013) (b) | 0.02 | STMR (0.01) × default PF (2) (EFSA, 2013) (b) |
| Wheat gluten meal           | 0.14                  | STMR (0.075) × default PF (1.8) (EFSA, 2013) (b) | 0.14 | STMR (0.075) × default PF (1.8) (EFSA, 2013) (b) |
| Wheat milled by-pdts        | 0.13                  | STMR (0.075) × PF (1.7) (EFSA, 2013) | 0.13 | STMR (0.075) × PF (1.7) (EFSA, 2013) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): For sugar beet roots by-products, no default processing factor was applied because tentative PFs indicate that that concentration of residues in these commodities is not expected (EFSA, 2021a).
(b): In the absence of processing factors supported by data, default processing factors (in bracket) were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.
(c): For maize/corn by-products, no default processing factor was applied because azoxystrobin residues are expected to be below the LOQ (EFSA, 2013). Concentration of residues in these commodities is therefore not expected.
(d): For linseeds, no new STMR value could be derived as the critical GAP (SEU) was not supported by data and the NEU GAP lead to a lower STMR value (< 0.01) than the one derived in EFSA, 2016b. The latter was therefore used as input value for the livestock dietary burden calculations.
D.2. Consumer risk assessment

| Commodity                          | Existing/proposed MRL (mg/kg) | Source                      | Input value (mg/kg) | Comment       |
|------------------------------------|-------------------------------|-----------------------------|---------------------|---------------|
| Rapeseeds/canola seeds             | 0.7 MRL proposal              | EFSA (2016b)                | 0.18                | STMR-RAC      |
| Linseeds                           | 0.4 EFSA (2016b)              | 0.02                        | 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            |
| Potatoes                           | 7 FAO (2014)                  | 2.3                         | STMR-RAC            |

Risk assessment residue definition: azoxystrobin
| Commodity                        | Existing/proposed MRL (mg/kg) | Source                        | Chronic risk assessment        | Input value (mg/kg) | Comment     |
|---------------------------------|-----------------------------|--------------------------------|--------------------------------|---------------------|-------------|
| 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    |
| Cucubits with edible peel       | 1                           | EFSA (2013)                   |                                | 0.17                | STMR-RAC    |
| Cucubits 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    |
| Kohlrabes                       | 5                           | EFSA (2013)                   |                                | 1.2                 | STMR-RAC    |
| Lettuce and other salad plants  | 15                          | 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    |
| Peanuts/groundnuts              | 0.2                         | EFSA (2013)                   |                                | 0.01                | STMR-RAC    |
| Poppy seeds                     | 0.5                         | EFSA (2013)                   |                                | 0.06                | STMR-RAC    |
| Sunflower seeds                 | 0.5                         | EFSA (2013)                   |                                | 0.04                | STMR-RAC    |
| Soybeans                        | 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    |
| Commodity                          | Existing/proposed MRL (mg/kg) | Source            | Chronic risk assessment | Input value (mg/kg) | Comment    |
|-----------------------------------|-------------------------------|-------------------|-------------------------|---------------------|------------|
| Gold of pleasure seeds           | 0.5                           | EFSA (2013)       |                         | 0.06                | STMR-RAC   |
| Oil palm fruits                  | 0.03                          | EFSA (2021b)(b)   |                         | 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   |
| HOPS (dried)                     | 30                            | EFSA (2013)       |                         | 3.93                | 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                          | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Swine: Fat tissue                | 0.05(c)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Swine: Liver                     | 0.07(d)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Swine: Kidney                    | 0.07(d)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Swine: Edible offals (other than liver and kidney) | 0.07(d) | EFSA (2013) |                         | 0.01                | STMR-RAC   |
| Swine: Other products            | 0.01                          | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Bovine: Muscle/meat              | 0.01                          | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Bovine: Fat tissue               | 0.05(c)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Bovine: Liver                    | 0.07(d)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Bovine: Kidney                   | 0.07(d)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Bovine: Edible offals (other than liver and kidney) | 0.07(d) | EFSA (2013) |                         | 0.01                | STMR-RAC   |
| Bovine: Other products           | 0.01                          | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Sheep: Muscle/meat               | 0.01                          | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Sheep: Fat tissue                | 0.05(c)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Sheep: Liver                     | 0.07(d)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Sheep: Kidney                    | 0.07(d)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Sheep: Edible offals (other than liver and kidney) | 0.07(d) | EFSA (2013) |                         | 0.01                | STMR-RAC   |
| Sheep: other products            | 0.01                          | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Goat: Muscle/meat                | 0.01                          | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Goat: Fat tissue                 | 0.05(c)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Goat: Liver                      | 0.07(d)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Goat: Kidney                     | 0.07(d)                       | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Goat: Edible offals (other than liver and kidney) | 0.07(d) | EFSA (2013) |                         | 0.01                | STMR-RAC   |
| Goat: other products             | 0.01                          | EFSA (2013)       |                         | 0.01                | STMR-RAC   |
| Commodity                                                                 | Existing/proposed MRL (mg/kg) | Source                  | Chronic risk assessment | Input value (mg/kg) | Comment  |
|--------------------------------------------------------------------------|-------------------------------|-------------------------|-------------------------|---------------------|----------|
| Equine: Muscle/meat                                                      | 0.01                          | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Equine: Fat tissue                                                       | 0.05<sup>(c)</sup>            | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Equine: Liver                                                            | 0.07<sup>(d)</sup>            | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Equine: Kidney                                                           | 0.07<sup>(d)</sup>            | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Equine: Edible offals (other than liver and kidney)                     | 0.07<sup>(d)</sup>            | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Equine: Other products                                                   | 0.01                          | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Poultry: Muscle/meat                                                     | 0.01                          | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Poultry: Fat tissue                                                      | 0.01                          | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Poultry: Liver                                                           | 0.01                          | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Poultry: Kidney                                                          | 0.01                          | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Poultry: Edible offals (other than liver and kidney)                    | 0.01                          | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Poultry: Other products                                                  | 0.01                          | 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<sup>(c)</sup>            | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Other farmed animals: Liver                                              | 0.07<sup>(d)</sup>            | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Other farmed animals: Kidney                                             | 0.07<sup>(d)</sup>            | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Other farmed animals: Edible offals (other than liver and kidney)       | 0.07<sup>(d)</sup>            | 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                          | EFSA (2013)             |                         | 0.01                | STMR-RAC |
| Eggs: chicken, duck, goose, quail, others                                 | 0.01                          | EFSA (2013)             |                         | 0.01                | STMR-RAC |

STMR-RAC: supervised trials median residue in raw agricultural commodity; PeF: Peeling factor.

(a): For linseed, no modification of the existing EU MRL was proposed, as the critical GAP (SEU) was not supported by data and the NEU GAP lead to lower residue levels (< LOQ) compared to the existing MRL (0.4 mg/kg).

(b): MRL proposals for mango and oil palm fruit not yet implemented in the MRL legislation.

(c): The existing MRL is based on Codex maximum residue limits (CXLs), derived by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) for a more critical EU livestock dietary burden. The EU dietary burden calculated under the assessment of the article 12 confirmatory data, indicates that an MRL of 0.01* mg/kg would be sufficient (EFSA, 2020).

(d): The existing MRL is based on CXLs, derived by the JMPR for a more critical EU livestock dietary burden. Further risk management considerations on the data gap identified by EFSA on the toxicological profile of metabolites L1, L4 and L9 are required. In the case where risk managers would consider the data gap to be addressed, MRLs for liver, kidney and other edible offals should be set at the LOQ of 0.01* mg/kg (EFSA, 2020).
## Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|---------------------|--------------------------------------|-----------------------|
| Azoxyastrobin      | methyl (2E)-2-(2-{[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}phenyl)-3-methoxyacrylate O = C(OC)\(\text{C(=C(OC)c1ccc1Oc1cc(Oc2cccc2C#N)ncc1)}\) WFDXOXNFRHQC-GHRIWEEISA-N | ![Structural formula](attachment:struct1.png) |
| L1                  | methyl (2E)-2-(2-{[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}-x-hydroxyphenyl)-3-methoxyprop-2-enolate 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-enolate O = C(OC)\(\text{C(-C(OC)c1ccc1Oc1cc(Oc2cccc2C#N)ncc1)}\) YGORCRAVOJDUML-SFQUDFHCSA-N | ![Structural formula](attachment:struct2.png) |
| 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 HHJSURCWSNRKU-UHFFFAOYSA-N | ![Structural formula](attachment:struct3.png) |
| 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)c1cc(Oc2cccc2C#N)ncc1 KBPYPVCVAGBHCJS-UHFFFAOYSA-N | ![Structural formula](attachment:struct4.png) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---|---|---|
| K1 | 4-{[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}-3-[(1E)-1,3-dimethoxy-3-oxoprop-1-en-2-yl]phenyl glucopyranuronic acid | ![Structural formula](image) |
|  | Refers to a non-determined mixture of isomers with glucopyranuronic acid moiety in one of the alternative positions. Name and codes of one of the compounds is given for illustrative purposes. | |
|  | 3-{[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}-4-[(1E)-1,3-dimethoxy-3-oxoprop-1-en-2-yl]phenyl L-glucopyranosiduronic acid | |
|  | N#Cc1ccccc1Oc1cc(ncn1)Oc1cc(O[C@H]2OC([C@H] (O)C(O)C2O)C(=O)0)ccc1C(=C(OC)C(=O)OC | |
|  | BPMGKBSQEFZIY-SFQUDFHCSA-N | |

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

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.
<sup>(b)</sup> ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
<sup>(c)</sup> ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C2SH41, Build 121153, 22 March 2021).