REASONED OPINION

APPROVED: 7 April 2016

doi: 10.2903/j.efsa.2016.4459

Modification of the existing maximum residue levels for azoxystrobin in various crops

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), Greece, received an application from the company Syngenta Switzerland to modify the existing maximum residue level (MRL) for the active substance azoxystrobin in chervil, rhubarb, linseed, safflower and borage seeds. Greece 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 EFSA. According to EFSA, the data are sufficient to derive an MRL proposal of 0.4 mg/kg for linseed, safflower and borage seeds supporting uses in northern and southern Europe. No change of the MRL was proposed for chervil as the submitted residue dataset results in a lower MRL proposal than the value currently in force in the EU legislation. An MRL is not proposed for rhubarb, as the submitted trials were not conducted according to the intended agricultural practices (GAP). Based on the risk assessment results, EFSA concludes that the proposed use of azoxystrobin in chervil, linseed, safflower and borage seeds will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

Keywords: azoxystrobin, chervil, rhubarb, linseed, safflower seeds, borage seeds, MRL application, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2015-00812

Correspondence: pesticides.mrl@efsa.europa.eu

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

ISSN: 1831-4732

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

Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Greece received an application from Syngenta Switzerland to modify the existing maximum residue levels (MRL) for the active substance azoxystrobin in chervil, rhubarb, linseed, safflower and borage seeds. Greece 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 26 November 2015.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) prepared under Directive 91/414/EEC, the conclusions on the peer review of the pesticide risk assessment as well as previous reasoned opinions on the review of existing MRLs according to Article 12 (hereafter Article 12 MRL review) or according to Article 10 of Regulation (EC) No 396/2005.

The toxicological profile of azoxystrobin was assessed in the framework of the 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. No acute reference dose (ARfD) was deemed necessary.

The metabolism of azoxystrobin in primary crops was investigated in the fruit, cereal/grass and pulses/oilseeds crop groups following foliar applications and the residue definition for enforcement and risk assessment were established as azoxystrobin. For the crops under consideration, EFSA concludes that the metabolism of azoxystrobin has been sufficiently addressed and that the residue definitions derived are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.4 mg/kg on linseed, safflower and borage. For chervil, the submitted trials indicate no need to modify the existing MRL, while for rhubarb, the submitted residue trials do not support the intended good agricultural practice (GAP). Adequate analytical enforcement methods are available to monitor the residues of azoxystrobin in crops under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg.

Studies investigating the magnitude of azoxystrobin residues in processed commodities were not submitted and are not required, as the contribution of the residues in crops under consideration to the total theoretical maximum daily intake (TMDI) is below 10% of the ADI.

The occurrence of azoxystrobin residues in rotational crops was investigated in the framework of the peer review. On the basis of the available information, it was concluded that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on the crops under consideration according to the proposed GAP.

The contribution of azoxystrobin residues in linseed, safflower and borage to the overall dietary livestock burden is insignificant. Thus, EFSA concludes that an amendment to the MRLs for the products of animal origin is unnecessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). No long-term or acute consumer intake concerns were identified. For azoxystrobin, the highest estimated chronic intake accounted for 21% of the ADI (NL child). The contribution of residues in the crops under consideration to the total consumer exposure is insignificant (lower than 0.1% of the ADI).

EFSA concludes that the intended use of azoxystrobin on chervil, linseed, safflower and borage will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a concern for public health. EFSA proposes to amend the existing MRLs as reported in the following summary table

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: azoxystrobin				
0256010	Chervil	70	No change	The submitted data result in a lower MRL proposal of 10 mg/kg
0270070	Rhubarb	0.6	No proposal	No data were submitted to support the intended GAP on rhubarb
0401010	Linseeds	0.01*	0.4	Extrapolation from SEU and NEU residue trials on rapeseeds
0401110	Safflower seeds			
0401120	Borage seeds			

MRL: maximum residue level; GAP: good agricultural practice; SEU: southern Europe; NEU: northern Europe.
*: Limit of quantification.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Background

Regulation (EC) No 396/2005[1] establishes the rules governing the setting of pesticide maximum residue levels (MRL) at European Union (EU) level. Article 6 of the Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC,[2] repealed by Regulation (EC) No 1107/2009[3], shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of the Regulation.

Greece, hereafter referred to as the evaluating Member State (EMS), received an application from the company Syngenta Switzerland[4] to modify the existing MRLs for the active substance azoxystrobin in chervil, linseed, rhubarb, safflower and borage seeds. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission and to EFSA on 26 November 2015. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00812 and the following subject:

Azoxystrobin: application to modify existing MRLs in various crops

Greece proposed to raise the existing MRLs of azoxystrobin in chervil from 3 to 10 mg/kg and from 0.05 to 0.5 mg/kg in linseed, safflower and borage seeds. No MRL was proposed for rhubarb by the EMS.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the EMS, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of the Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months (which may be extended to 6 months if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The active substance and its use pattern

Azoxystrobin is the ISO common name for (2*E*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate (IUPAC). The chemical structure of the active substance is reported in Appendix C.

Azoxystrobin was evaluated in the framework of Directive 91/414/EEC with Germany being the designated rapporteur Member State (RMS). The representative use supported for the peer review process included outdoor foliar treatments on wheat, barley, rye, triticale and vines. Following the peer review, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Directive 1998/47/EC,[5] which entered into force on 1 July 1998. Azoxystrobin was then re-evaluated for the renewal of the Annex I inclusion with the United Kingdom and Czech Republic being the designated RMS and co-RMS, respectively. The representative uses submitted for the Annex I renewal process were foliar applications on leafy crops and cereals. Following the peer review, which was carried out by EFSA (EFSA, 2010), a decision on approval of the active substance under Regulation (EC) No 1107/2009 (replacing Directive 91/414/EEC) was published by means of Regulation (EU) No 703/2011[6] which entered into force on 1 January 2012. This approval is restricted to uses as fungicide only.

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

[2] 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.

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[4] Syngenta Switzerland, Schwarzwaldallee 215, WRO-1008.P.32, Basel 4002, Switzerland.

[5] Commission Directive 98/47/EC of 25 June 1998 including an active substance (azoxystrobin) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ L 191, 7.07.1998, p. 50–52.

[6] 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, 21.07.2011, p. 33–37.

The EU MRLs for azoxystrobin are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued several reasoned opinions on the modification of MRLs for azoxystrobin that have been considered in the EU legislation. The review of the existing MRLs for azoxystrobin according to Article 12 of Regulation (EC) No 396/2005 (hereafter Article 12 MRL review) was also finalised and the proposals have been implemented by Regulation (EU) 2015/1040[7]. All the MRL changes after the implementation of the Article 12 MRL review are reported in Table 1.

Table 1: Overview of the MRL changes after Article 12 of Regulation (EC) No 396/2005

Procedure[(a)]	Considered by Regulation	Remarks
Art. 12 (EFSA, 2013)	(EU) No 2015/1040	Review of the existing MRLs (including chervil)
Art 10 (EFSA, 2016)	Not yet implemented	Table and wine grapes

MRL: maximum residue level.
(a): Art. 10: Assessment of MRL application according to Article 6 to 10 of Regulation (EC) No 396/2005.
Art. 12: Review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005.

Codex Alimentarius has established maximum residue limits (CXL) for a wide range of commodities, including chervil for which a CXL of 70 mg/kg is set.

The details of the intended good agricultural practices (GAPs) for azoxystrobin on crops under consideration are given in Appendix A.

Assessment

EFSA bases its assessment on the updated evaluation report submitted by the EMS (Greece, 2016), the draft assessment report (DAR) prepared under Directive 91/414/EEC (United Kingdom, 2009), the conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin (EFSA, 2010) as well as the conclusions from the Article 12 MRL review (EFSA, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[8] and the currently applicable guidance documents relevant to the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2015; OECD, 2011).

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of azoxystrobin residues in plant commodities were assessed during the peer review for the renewal of the authorisation of azoxystrobin under Directive 91/414/EEC and under the Article 12 MRL review (EFSA, 2010, 2013).

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

The crops under consideration belong to the high water and high oil content commodity groups and therefore EFSA concludes that sufficiently validated analytical methods are available to control azoxystrobin residues in chervil, linseed, safflower and borage seeds.

1.2. Methods for enforcement of residues in food of animal origin

During the peer review under Directive 91/414/EEC, an analytical method using Gas Chromatography Nitrogen-Phosphorus detector (GC-NPD) and its independent laboratory validation (ILV) were evaluated and validated for determination of parent azoxystrobin with an LOQ of

[7] Commission Regulation (EU) No 2015/1040 of 30 June 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products. OJ L 167, 1.07.2015, p. 10–56.

[8] 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, 11.06.2011, p. 127–175.

0.001 mg/kg in milk and 0.01 mg/kg in eggs, liver, fat and muscle, but no confirmatory method was available (EFSA, 2013).

2. Mammalian toxicology

The toxicological profile of the active substance azoxystrobin was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2010). The data were sufficient to derive toxicological reference values compiled in Table 2.

Table 2: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Azoxystrobin					
ADI	EFSA	2010	0.2 mg/kg bw per day	Rat, 2 year	100
ARfD	EFSA	2010	Not necessary		

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of azoxystrobin in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC on the cereal/grass (wheat), fruit (grape) and pulses/oilseeds (peanuts) crop groups, using foliar applications (EFSA, 2010). An overview of the available metabolism studies is presented in Table 3.

Table 3: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling[(a)] (day, DAT)	Comments
Fruit	Grape	Foliar: 250 + 1,000 + 1,000 + 250 g/ha	21 DAT_4	–
Cereal/grass	Wheat	Foliar: 2 × 500 g/ha; BBCH 30–31 and 59–61	13 and 61–62 DAT_2	–
		Foliar: 1 × unknown; BBCH 71	28 DAT	–
Pulses/oilseeds	Peanut	Foliar: 850 + 850 + 300 g/ha	28 DAT_3	–

BBCH: growth stages of mono- and dicotyledonous plants.
(a): DAT*x*, days after treatment *x*.

On the basis of these metabolism studies, the residue definition for monitoring and risk assessment in all plant commodities was proposed as parent azoxystrobin in the conclusion of the peer review (EFSA, 2010). The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

For the uses on the crops under consideration, EFSA concludes that the metabolism of azoxystrobin is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the peer review and confirmed under the Article 12 MRL review are applicable.

3.1.1.2. Magnitude of residues

Chervil cGAP: southern Europe (SEU) 2 × 250 g/ha, pre-harvest interval (PHI) 7 days
Northern Europe (NEU) and indoor 2 × 250 g/ha, PHI 14 days

The applicant submitted a total of 31 residue trials conducted on lettuces, matching the intended GAPs (12 indoor, 8 NEU and 11 SEU trials) and conducted in Germany, France, Italy, Spain and the United Kingdom during the growing seasons 2000, 2001, 2009 and 2012. All trials were claimed to be conducted on lettuce 'open leaf varieties'. However, two SEU trials were disregarded as they were performed on 'iceberg lettuce' which is a head forming variety. In some locations, two different formulations (A12705B and A13703G) were experimented and the highest residue level per location was taken into account for MRL calculation.

As significant higher residue levels were observed in the trials conducted under indoor conditions (H-Test, 5%), an MRL proposal of 10 mg/kg was derived from this dataset and extrapolated to chervil.

However, during the Article 12 MRL review, an MRL of 70 mg/kg was recommended for chervil and recently implemented in EU legislation by Regulation (EU) 1040/2015. Therefore, no change is recommended for chervil.

Rhubarb SEU and NEU GAP: 2 × 200 g/ha, PHI 21 days

The applicant proposed the extrapolation to rhubarb from residue trials (4 NEU and 4 SEU) conducted on celery. No MRL is proposed, as the trials on celery were not performed in compliance with the GAP supported for rhubarb. Trials were conducted with three applications instead of two and residue data were provided up to 14 days PHI and no information was available for 21 days after application. Although an extrapolation from celery to rhubarb would be possible according to European Commission (2015), no MRL is proposed as residue trials conducted according to the intended GAP were not submitted.

Linseed, safflower and borage seeds SEU and NEU GAP: 2 × 250 g/ha, PHI 21 days

In support of the intended GAP, the applicant submitted eight NEU and four SEU GAP-compliant residue trials on rapeseed conducted in France and the United Kingdom during the growing seasons 1996 and 1997. The applicant proposes to extrapolate the residue data from rapeseed to linseed, safflower and borage seeds as suggested by the EU guideline 7525/VI/95 (European Commission, 2015). In some locations, two different formulations (YF9247 and YF10136) were experimented and the highest residue level per location was taken into account for the MRL calculation.

As the residue trials from NEU and SEU were in the same range (U-test 5%), both datasets were merged together to derive the MRL proposal of 0.4 mg/kg and to extrapolate to linseed, safflower and borage seeds.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 4.

Table 4: Overview of the available residue trial data

Crop (GAPs)	Region/ indoor[a]	Residue levels observed in the supervised residue trials[b] (mg/kg)	Recommendations/ comments[c]	MRL proposal (mg/kg)	HR[d] (mg/kg)	STMR[e] (mg/kg)
Lettuce (2 × 250 g/ha, PHI 14 days)	Indoor	0.45, 0.59, 2.20, 2.60, 2.90, 3.20; 3.50, 4.30, 4.40, 4.70, 4.75, 6.20	Residue levels in the indoor dataset significantly higher than in NEU or SEU datasets (H-Test, 5%). MRL, STMR HR derived from indoor trials; All trials on open leaf varieties MRL_{OECD}: 10.1/10 **Extrapolation to chervil**	10	6.20	3.35
	NEU	< 0.01, 0.03; 0.17; 0.22; 0.24; 0.46; 0.49				
(2 × 250 g/ha, PHI 7 days)	SEU	0.07; 0.09, 0.20, 0.29, 0.31, 0.43, 1.10; 2 × 2.10				
Celery (2 × 200 g/ha, PHI 21 days)	NEU	GAP-compliant trials not available		No proposal	–	–
	SEU	GAP-compliant trials not available				
Rapeseed (2 × 250 g/ha, PHI 21 days)	NEU	2 × 0.01, 0.03, 0.04, 0.07, 0.10, 0.22, 0.24	NEU and SEU datasets similar (U-Test 5%) MRL is derived from merged data MRL_{OECD}: 0.39/0.4 **Extrapolation to linseed, safflower and borage**	0.4	0.25	0.02
	SEU	2 × 0.01, 0.02, 0.05				

GAP: good agricultural practice; PHI: pre-harvest interval; MRL: maximum residue level.
(a): NEU: outdoor trials conducted in northern Europe; SEU: outdoor trials conducted in southern Europe; Indoor: indoor EU trials or country code: if non-EU trials.
(b): Individual residue levels considered for MRL calculation are reported in ascending order.
(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values).
(d): HR: highest residue level according to the residue definition for risk assessment.
(e): STMR: median residue level according to residue definition for risk assessment.

In the framework of the peer review, storage stability of azoxystrobin was demonstrated for a period of 24 months at −18°C in high water- (apple, peach, tomato, cucumber, lettuce, banana), high starch- (carrot), high acid- (grape, orange), high oil- (soybean meal, oilseed rape, pecans, peanut), dry/starch (cereal grain) content commodities and in cereal straw (EFSA, 2013). As the lettuce and rapeseed samples were stored for a period of 10 and 12 months, respectively, under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability (Greece, 2016).

According to the EMS, the analytical methods used to analyse the residue trial samples have been sufficiently validated and were proved to be fit for purpose (Greece, 2016).

EFSA concludes that the data are sufficient to derive an MRL proposal of 0.4 mg/kg for linseed, safflower and borage seeds (NEU and SEU) (extrapolation from rapeseed). No change is proposed for chervil as the submitted residue dataset results in a lower proposal than the MRL value of 70 mg/kg currently set in the EU legislation. No MRL is proposed for rhubarb as GAP-compliant trials supporting the intended GAP have not been submitted.

3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the nature of azoxystrobin residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the peer review and it was concluded that the compound is hydrolytically stable (EFSA, 2010). Thus, for processed commodities, the same residue definition as for raw agricultural commodities is applicable.

Studies to assess the magnitude of azoxystrobin residues during processing have been assessed in the framework of the peer review and the Article 12 MRL review and processing factors were derived for several crops (EFSA, 2010, 2013). Additional processing studies were not provided for the crops under consideration and are not necessary, as the theoretical maximum daily intake (TMDI) was calculated to be less than 10% of the ADI.

3.1.2. Rotational crops

As the proposed use of azoxystrobin is on crops that may be grown in rotation, the investigation of residues in succeeding crops is required.

The nature and magnitude of azoxystrobin residues in rotational crops were investigated during the peer review. On the basis of studies conducted in lettuce, radish and wheat at a maximum dose rate of 2,200 g/ha, it was concluded that the metabolism of azoxystrobin is similar to that of the primary crops and that residues above 0.05 mg/kg are not expected in the rotational crops (EFSA, 2013).

Considering that the uses of azoxystrobin on chervil, linseed, safflower and borage seeds are limited to an application rate of 500 g/ha (2 × 250 g/ha), EFSA concludes that residues of azoxystrobin are unlikely to occur in rotational crops provided that the active substance is applied according to the proposed GAPs.

3.2. Nature and magnitude of residues in livestock

Linseed and safflower by-products can be fed to livestock and therefore the nature and magnitude of azoxystrobin residue were assessed in the framework of this application (European Commission, 2015).

3.2.1. Dietary burden of livestock

The median and maximum dietary burdens for livestock were calculated under the Article 12 MRL review using the animal feedstuff table listed in the EU guideline 7031/VI/95 (European Commission, 1996) and considering livestock intake of all feed products containing residues resulting from all authorised uses of azoxystrobin in Europe (EFSA, 2013). After the Article 12 MRL review, no additional EFSA reasoned opinions which have an impact on livestock dietary burdens were issued.

EFSA now updated the dietary burden calculations considering the residues resulting from the additional uses of azoxystrobin on linseed and safflower, the feedstuff table reported in the OECD guidance 64 Series on Pesticides 32 (OECD, 2009) and the animal model calculator developed by EFSA. As processing studies were not submitted, a default processing factor of 2 was considered to estimate the residue levels in linseed and safflower meal. The input values for the dietary burden calculation are summarised in Table 5.

Table 5: Input values for dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Linseed meal	0.04	STMR (Table 4) × 2	0.04	STMR (Table 4) × 2
Safflower meal	0.04	STMR (Table 4) × 2	0.04	STMR (Table 4) × 2
Other feed commodities	See Table 3-5 in EFSA reasoned opinion on Article 12 MRL review (EFSA, 2013). (Note: As consumption in the OECD feedstuff table is given for dry pomace, a value of 47.5 mg/kg was used to estimate the residues in citrus pomace, taking into account an STMR of 4.75 mg/kg and a default processing factor of 10).			

STMR: supervised trials median residue; OECD: Organisation for Economic Co-operation and Development.

The estimated animal dietary intakes taking into account the feed commodities listed in Table 5 and including the crops under consideration in this MRL application are summarised in Table 6. The maximum animal intakes estimated in the previous EFSA opinion (EFSA, 2013) are reported in the column 'Previous assessment'.

Table 6: Results of the dietary burden calculations

Animal	Maximum burden[(a)] (mg/kg DM)	Above 0.1 mg/kg DM	Highest contributing commodities	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	Previous assessment (mg/kg bw)
Beef cattle	7.7	Yes	Citrus pulp	0.10	0.185	0.925
Dairy cattle	15.2	Yes	Citrus pulp	0.46	0.586	0.416
Ram/ewe	4.9	Yes	Rye straw	0.06	0.164	Ovine not considered in the previous assessment
Lamb	4.9	Yes	Rye straw	0.08	0.209	
Pig (breeding)	10.5	Yes	Citrus pulp	0.20	0.243	0.178
Pig (finishing)	0.5	Yes	Swede roots	0.01	0.014	
Poultry broiler	0.2	Yes	Swede roots	0.01	0.013	0.098
Poultry layer	1.3	Yes	Wheat straw	0.04	0.092	
Turkey	0.2	Yes	Swede roots	0.01	0.013	

DM: dry matter; bw: body weight.
(a): Considering the maximum dietary animal burden.

For all animal species, estimated intakes were calculated to be above 0.1 mg/kg dry matter (DM) feed and therefore, the setting of MRLs for products of animal origin should be considered.

No significant increase compared to the animal intakes previously estimated in the framework of the Article 12 MRL review is observed, as the highest contributors to animal burden remain citrus pulp, rye straw and swede roots. In contrast, the new OECD feedstuff table results in a significant decrease in the maximum intake calculated for beef cattle, from 0.925 to 0.185 mg/kg bw.

Taking into account that residues in all animal matrices were below the LOQ of 0.01 mg/kg in the cow and poultry feeding studies conducted at the feeding levels of 0.91 and 0.39 mg/kg bw, respectively (1.6N study for dairy cattle and 4N study for poultry layer), it is concluded that azoxystrobin residues above 0.01 mg/kg are not expected in animal matrices. Therefore, considering all feed products containing residues resulting from all authorised uses of azoxystrobin in Europe, the setting of MRLs above the LOQ of 0.01 mg/kg is not necessary for animal products.

However, it is noted that CXLs were derived by the Joint Meeting on Pesticides Residues (JMPR) (FAO, 2008, 2011) for mammalian matrices (liver, kidney, offal: 0.07 mg/kg and fat: 0.05 mg/kg) and these CXLs were implemented in the EU legislation by Regulation (EU) No 459/2010[9]. However and considering the conclusion of the Article 12 MRL review, these MRLs were reported as 'tentative' in the last Regulation (EU) No 2015/1040, pending the submission of additional data to

[9] Commission Regulation (EU) No 459/2010 of 27 May 2010 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products OJ L 129, 28.5.2010, p. 3–49.

address the toxicity of metabolites and to conclude on the risk assessment residue definition for animal products.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population[10] (EFSA, 2007).

In the framework of the Article 12 MRL review, a comprehensive long-term exposure assessment was performed for azoxystrobin, taking into account the existing uses at the EU level and the acceptable CXLs (EFSA, 2013). The food commodities, for which no uses were reported in the framework of the Article 12 MRL review, were excluded from the exposure calculation, assuming that there are no uses of azoxystrobin on these crops. EFSA now updated the consumer risk assessment performed under the Article 12 MRL review with the median residue levels (STMR) derived for linseed, safflower and borage seeds from the residue trials conducted on rapeseed (see Table 4) and considering the STMRs listed in a previous Article 10 reasoned opinion (EFSA, 2016).

An acute consumer exposure assessment was not performed, as the setting of an ARfD was concluded to be unnecessary for azoxystrobin.

The input values used for the dietary exposure calculation are summarised in Table 7.

Table 7: Input values for consumer dietary exposure assessment

Commodity	Chronic exposure assessment	
	Input (mg/kg)	Comment
Risk assessment residue definition: azoxystrobin		
Linseeds	0.02	STMR (Table 4)
Safflower seeds	0.02	STMR (Table 4)
Borage seeds	0.02	STMR (Table 4)
Other plant and animal commodities	STMR	See Table 4-5 in reasoned opinion on Article 12 MRL review (EFSA, 2013) and Table 5 in reasoned opinion under Article 10 (EFSA, 2016)

STMR: supervised trials median residue; MRL: maximum residue level.

The estimated exposure was then compared with the toxicological reference value derived for azoxystrobin (see Table 2). The results of the intake calculation are presented in Appendix B of this reasoned opinion.

The highest calculated chronic intake accounted for 21% of the ADI (NL child). The contribution of residues in the crops under consideration to the total consumer exposure accounted is insignificant (lower than 0.1% of the ADI).

EFSA concludes that the intended use of azoxystrobin on chervil, linseed, safflower and borage seeds will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a concern for public health.

Conclusions and recommendations

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: azoxystrobin				
0256010	Chervil	70	No change	The submitted data results in a lower MRL proposal of 10 mg/kg
0270070	Rhubarb	0.6	No proposal	No data were submitted to support the intended GAP on rhubarb

[10] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative of 22 national diets collected from MS surveys plus one regional and four cluster diets from the WHO GEMS Food database; for the acute exposure assessment, the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0401010	Linseeds	0.01*	0.4	Extrapolation from SEU and NEU trials on rapeseeds
0401110	Safflower seeds			
0401120	Borage seeds			

MRL: maximum residue level; GAP: good agricultural practice; SEU: southern Europe; NEU: northern Europe.
*: Limit of quantification.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CXL	Codex maximum residue limit (Codex MRL)
DAR	draft assessment report
DE	Germany
DM	dry matter
EMS	evaluating Member State
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry detector
NEU	northern Europe
NL	Netherlands
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RD	residue definition
RMS	rapporteur Member State
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
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WHO	World Health Organization

Appendix A – Good agricultural practice (GAP)

Crop and/or situation[a]	MS or NEU/SEU or country	F, G or I[b]	Pest or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (days)	Remarks[k]
				Type[d,e]	Conc. a.s.[h]	Method kind[f,g]	Growth stage and season[i]	Number min–max[j]	Interval min–max	g/hL min–max	Water L/ha min–max	g/ha min–max		
Chervil	NEU and Indoor	F	Fungal diseases	SC	250 g/L	Foliar spray	BBCH 14-49	2			300–1,200	250	14	
Chervil	SEU	F	Fungal diseases	SC	250 g/L	Foliar spray	BBCH 14-49	2			300–1,200	250	7	
Rhubarb	NEU and SEU	F	Fungal diseases	SC	250 g/L	Foliar spray	BBCH 40	2			200–1,000	200	21	
Linseed, safflower and borage	NEU and SEU	F	Fungal diseases	SC	250 g/L	Foliar spray	BBCH 60-69	2			200–500	250	21	

MS: Member State; NEU: northern Europe; SEU: southern Europe; SC: suspension concentrate; a.s.: active substance; BBCH: growth stages of mono- and dicotyledonous plants; PHI: pre-harvest interval.
(a): For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage situation should be described (e.g. fumigation of a structure).
(b): Outdoor or field use (F), glasshouse application (G) or indoor application (I).
(c): For example, biting and sucking insects, soil-borne insects, foliar fungi, weeds.
(d): For example, wettable powder (WP), water-soluble granule (WG).
(e): GCPF Codes – GIFAP Technical Monograph No 2, 1989.
(f): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
(g): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants. Type of equipment used must be indicated.
(h): g/kg or µg/L.
(i): Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Edition, Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 2001), including where relevant, information on season at time of application.
(j): The minimum and maximum number of application possible under practical conditions of use must be provided.
(k): Remarks may include: extent of use/economic importance/restrictions.

Appendix B – Pesticide Residue Intake Model (PRIMo)

Azoxystrobin

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.2**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum–maximum
4–21

No. diets exceeding ADI:

Highest calculated TMDI values in % of ADI	MS diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
21	NL child	7.4	Oranges	6.8	Potatoes	1.8	Mandarins	0.2
18	DE child	9.0	Oranges	2.9	Potatoes	1.0	Mandarins	0.1
17	FR toddler	5.8	Potatoes	4.8	Oranges	1.4	Spinach	0.2
14	IE adult	2.6	Potatoes	2.5	Oranges	1.7	Grapefruit	0.0
14	WHO cluster diet B	3.1	Potatoes	2.0	Oranges	0.9	Onions	0.1
11	UK toddler	4.7	Oranges	4.0	Potatoes	0.7	Mandarins	0.2
11	SE general population 90th percentile	4.8	Potatoes	1.8	Oranges	1.1	Mandarins	0.1
11	PT general population	6.1	Potatoes	1.5	Oranges	0.9	Wine grapes	0.0
11	FR infant	4.8	Potatoes	2.2	Oranges	0.9	Spinach	0.1
10	WHO cluster diet E	4.4	Potatoes	1.1	Oranges	0.6	Wine grapes	0.0
10	NL general	3.5	Oranges	3.1	Potatoes	0.5	Mandarins	0.0
10	ES child	5.1	Oranges	2.1	Potatoes	0.8	Lettuce	0.1
10	WHO regional European diet	4.6	Potatoes	1.2	Oranges	0.7	Lettuce	0.0
9	WHO cluster diet D	4.7	Potatoes	0.8	Herbs	0.6	Oranges	0.0
9	WHO cluster diet F	3.9	Potatoes	2.1	Oranges	0.6	Lettuce	0.0
9	UK infant	3.7	Potatoes	3.1	Oranges	0.3	Peas (without pods)	0.3
7	ES adult	3.1	Oranges	1.1	Potatoes	1.0	Lettuce	0.0
6	FR all population	1.5	Wine grapes	1.3	Potatoes	0.7	Oranges	0.0
6	UK vegetarian	2.1	Oranges	1.6	Potatoes	0.3	Wine grapes	0.0
6	PL general population	4.0	Potatoes	0.4	Onions	0.2	Head cabbage	0.0
6	IT kids/toddler	1.1	Oranges	1.0	Potatoes	0.6	Lettuce	0.0
5	DK child	2.8	Potatoes	0.4	Oranges	0.3	Onions	0.1
5	IT adult	0.9	Oranges	0.7	Lettuce	0.7	Potatoes	0.0
5	FI adult	2.3	Oranges	1.4	Potatoes	0.3	Mandarins	0.0
5	UK adult	1.6	Potatoes	1.3	Oranges	0.4	Wine grapes	0.0
5	LT adult	3.7	Potatoes	0.2	Head cabbage	0.2	Oranges	0.0
4	DK adult	1.7	Potatoes	0.5	Wine grapes	0.3	Oranges	0.0

Conclusion:

The estimated theoretical maximum daily intakes (TMDI), based on pTMRLs were below the acceptable daily intake (ADI).

A long-term intake of residues of azoxystrobin is unlikely to present a public health concern.

LOQ: limit of quantification; bw: body weight; ARfD: acute reference dose; MS: Member State; NL: Netherlands; DE: Germany; FR: France; IE: Ireland; WHO: World Health Organization; UK: United Kingdom; SE: Sweden; PT: Portugal; ES: Spain; PL: Poland; IT: Italy; DK: Denmark; FI: Finland; LT: Lithuania.

Appendix C – Used compound codes

Code/trivial name	Chemical name	Structural formula
Azoxystrobin	Methyl (2*E*)-2-{2-[6-(2-cyanophenoxy) pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate