

Evaluation of confirmatory data following the Article 12 MRL review for ametoctradin

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The declarations of interest of all scientific experts active in EFSA's work are available at <https://open.efsa.europa.eu/experts>.

Abstract

The applicant BASF SE submitted a request to the competent national authority in Germany to evaluate the confirmatory data for ametoctradin, which had been identified as unavailable in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005. To address the data gaps, additional information was submitted for analytical methods, residue trials on primary and rotational crops, storage stability and a feeding study in ruminants. The data gaps were considered satisfactorily addressed. The new information provided confirmed existing MRLs for spring onions, barley, oat, rye, wheat and hops and required an increase of MRLs for certain products of animal origin. A revision of the consumer risk assessment for ametoctradin was also performed, including the contribution of residues in rotational crops, and indicated no consumer health concerns. However, the chronic consumer risk assessment for products of animal origin shall be regarded as indicative, pending toxicological information on the metabolites M650F01 and M650F06.

KEYWORDS

ametoctradin, confirmatory data, MRL review, pesticide, risk assessment

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SUMMARY

In 2020, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1. Additional validation data to confirm the suitability of the method for enforcement for hops;
2. Representative storage stability studies for animal commodities (all animal tissues, milk and eggs);
3. A representative feeding study in cattle. Considering that according to the metabolism study at the calculated dietary burden, residues in livestock are expected to remain below the LOQ in all commodities, except for cattle liver, risk managers may contemplate not to require a livestock feeding study in view of animal welfare implications.

In addition, the following data gaps were identified without an impact on the validity of the MRLs derived but which might have an impact on national authorisations:

4. One additional residue trial supporting the import tolerance GAP on spring onions/green onions and Welsh onions;
5. Representative field rotational crop studies reporting soil characteristics to allow a conclusion as to whether the plateaus for soil metabolites M650F03 and M650F04 are covered and including additional crop groups such as fruits and fruiting vegetables.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2021/1110, including footnotes indicating the type of confirmatory data that should be provided fully reflecting the data gaps noted in the MRL review, reported above. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 7 July 2023.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, BASF SE submitted an application to the competent national authority in Germany (rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 3 July 2023. The appointed RMS, Germany, assessed the dossier and declared its admissibility on 1 February 2024. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 15 February 2024 to 7 March 2024. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the RMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and EFSA on 19 February 2025.

On 14 March 2025, the European Commission sent a mandate to EFSA to assess the application and the evaluation report as required by Article 10 of the MRL regulation. When assessing the evaluation report, EFSA identified data gaps which needed further clarifications. On 24 June 2025, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the RMS who submitted a revised evaluation report to EFSA on 8th of September, which replaced the previously submitted evaluation report.

EFSA reviewed additional data submitted to address data gaps identified in the MRL review, which were found to be sufficient. Based on revised dietary burden, higher EU MRLs for ametoctradin in certain animal commodities are proposed. Consumer exposure was updated to include residues from rotational crops and animal products. EFSA concluded that the existing uses of ametoctradin are unlikely to present a risk to consumer health. However, the chronic consumer risk assessment for products of animal origin shall be regarded as indicative, pending toxicological information on the metabolites M650F01 and M650F06.

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

Code ^a	Commodity	Existing MRL ^b	Proposed MRL	Conclusion/recommendation
Enforcement residue definition: Ametoctradin				
0220040	Spring onions/green onions and Welsh onions	20	15 or 20	The data gap identified by EFSA has been addressed. Based on the combined set of new and old residue trials, EFSA derived a lower MRL of 15 mg/kg for the import tolerance use assessed in the MRL review. A Codex MRL of 20 mg/kg was proposed in 2012 based on the same GAP and original 3 trials, but it was not implemented in the EU legislation at that time (EU reservation). The new trials address the data gap identified by EFSA for the CXL as well.

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Code ^a	Commodity	Existing MRL ^b	Proposed MRL	Conclusion/recommendation
		(ft 3)	(risk management decision)	A risk management decision is requested to determine whether the MRL value should be confirmed at 20 mg/kg or lowered to 15 mg/kg. Risk for consumers is unlikely.
0500010	Barley	0.01*	0.01*	The data gap identified by EFSA has been addressed. The MRL should be maintained at the LOQ.
0500050	Oat	(ft 1)		Risk for consumers is unlikely.
0500070	Rye			
0500090	Wheat			
0700000	HOPS	90	90	The data gap identified by EFSA has been addressed. The MRL is confirmed.
		(ft 2)		Risk for consumers is unlikely.
Enforcement residue definition: Sum of ametoctradin, M650F01 and M650F06, expressed as ametoctradin (F)				
1012010	Bovine muscle	0.03*	0.03*	The data gaps identified by EFSA have been addressed.
1012020	Bovine fat	0.03*	0.03*	Based on the revised animal dietary burden and the new feeding study, the MRLs should be increased for bovine liver and kidney (extrapolated to equine) while they should be maintained for bovine muscle and fat (extrapolated to equine).
1015010	Equine muscle	0.03*	0.03*	Risk for consumers is unlikely.
1015020	Equine fat	0.03* (ft 4)	0.03*	
1012030	Bovine liver	0.04	0.09	
1012040	Bovine kidney	0.03*	0.04	
1015030	Equine liver	0.04	0.09	
1015040	Equine kidney	0.03* (ft 4)	0.04	
1011010	Swine muscle	0.03*	0.03*	The data gap identified by EFSA has been addressed.
1011020	Swine fat	0.03*	0.03*	Based on the revised animal dietary burden and the new feeding study, the MRLs should be increased for swine, sheep, goat liver and kidney while they should be maintained all other animal commodities.
1011030	Swine liver	0.03*	0.04	Risk for consumers is unlikely.
1011040	Swine kidney	0.03*	0.03	
1013010	Sheep muscle	0.03*	0.03*	
1013020	Sheep fat	0.03*	0.03*	
1013030	Sheep liver	0.03*	0.05	
1013040	Sheep kidney	0.03*	0.04	
1014010	Goat muscle	0.03*	0.03*	
1014020	Goat fat	0.03*	0.03*	
1014030	Goat liver	0.03*	0.05	
1014040	Goat kidney	0.03*	0.04	
1016010	Poultry muscle	0.03*	0.03*	
1016020	Poultry fat	0.03*	0.03*	
1016030	Poultry liver	0.03*	0.03*	
1016040	Poultry kidney	0.03*	0.03*	
1020010	Milk cattle	0.03*	0.03*	
1020020	Milk sheep	0.03*	0.03*	
1020030	Milk goat	0.03*	0.03*	
1020040	Milk horse	0.03*	0.03*	
1030010	Chicken eggs	0.03*	0.03*	
1030020	Duck eggs	0.03*	0.03*	
1030030	Geese eggs	0.03*	0.03*	
1030040	Quail eggs	0.03* (ft 5)	0.03*	

(Continued)

Abbreviations: GAP, Good agricultural practice; MRL, maximum residue level.

* Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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

^b Existing EU MRL and corresponding footnote on confirmatory data.

^{ft1} The European Food Safety Authority identified some information on residues in rotational crops as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

^{ft2} The European Food Safety Authority identified some information on analytical methods as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

^{ft3} The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

^{ft4} The European Food Safety Authority identified some information on storage stability and feeding studies as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

^{ft5} The European Food Safety Authority identified some information on storage stability as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

^F Fat soluble.

ASSESSMENT

The review of existing MRLs for the active substance according to Article 12 of Regulation (EC) No 396/2005¹ (MRL review) has been performed in 2020 (EFSA, 2020). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The list of GAPs assessed in the framework of the MRL review that were not fully supported by data and for which confirmatory data were requested are listed in [Appendix A](#).

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2021/1110,² including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 7 July 2023.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2023c) and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381,³ the applicant BASF SE, on 3 July 2023 submitted an application to the competent national authority in Germany (designated rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review alongside the dossier containing the supporting data using the IUCLID format.

To address the data gaps identified by EFSA, the applicant provided a new livestock feeding study, and additional information for analytical methods, residue trials on primary and rotational crops and storage stability studies for residues in animal commodities.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 19 February 2025 (Germany, 2025). EFSA assessed the application as requested by the European Commission in accordance with Article 10 of Regulation (EC) No 396/2005. During the detailed assessment, EFSA identified data gaps which needed further clarifications. On 24 June 2025, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the EMS who submitted a revised evaluation report to EFSA on 8 September 2025 (Germany, 2025), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the RMS (Germany, 2025), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 and additional assessment of performed after the MRL review (EFSA, 2020, 2021).

For this application, the data requirements established in Regulation (EU) No 544/2011⁴ and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 2021/1110 are applicable. 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 546/2011.⁵

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

The peer review of the renewal of approval of ametoctradin in accordance with Regulation (EC) No 1107/2009 is not yet initiated in EFSA but a dossier and review assessment report have been submitted. Therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

The evaluation report submitted by the RMS (Germany, 2025) is made publicly available as a background document to this reasoned opinion.⁶

1 | RESIDUES IN PLANTS

1.1 | Nature of residues and methods of analysis in plants

1.1.1 | Nature of residues in primary crops

Not relevant for the current assessment.

¹Regulation (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.

²Commission Regulation (EU) 2021/1110 of 6 July 2021 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, bixafen, fenazaquin, spinetoram, tefluthrin and thien carbazon-methyl in or on certain products. C/2021/4855. OJ L 239, 7.7.2021, p. 4–21.

³Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

⁴Commission 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.

⁵Commission 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.

⁶Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: <https://open.efsa.europa.eu/study-inventory/EFSA-Q-2023-00796>.

1.1.2 | Nature of residues in rotational crops

According to the soil degradation studies assessed in the framework of the EU pesticides peer review, the DT_{90} value of parent ametoctradin is below the trigger value of 100 days (EFSA, 2012b). However, ametoctradin soil metabolites M650F03 and M650F04 are highly persistent in the soil, with the worst-case $DT_{90 \text{ field}}$ values above 365 days (M650F03 for 420 days⁷ and M650F04 for > 720 days⁸) (EFSA, 2012b). Therefore, long-term residue soil accumulation also needs to be considered when estimating the concentration of residues in the soil that are available for the uptake by rotational crops.

For the assessment of the present MRL review confirmatory data application, the applicant and the EMS propose to consider new DT_{90} and DT_{50} values for metabolite M650F03 and M650F04 which have been derived from the previously available soil degradation studies (considered by EFSA for the approval of ametoctradin and summarised in the next paragraph) but using a new kinetics analysis, that is applicable according to the FOCUS (2006), revised in 2014) kinetics guidance. Using the single first-order (SFO) model, the DT_{50} of 87.5 days and DT_{90} of 290.5 days are derived for metabolite M650F03. For metabolite M650F04, using the SFO model, the DT_{50} was derived at 668.5 days and DT_{90} at 2219.42 days (Germany, 2025). EFSA agrees with the RMS to use the updated soil degradation endpoints for the present assessment, but notes that these values have not been peer reviewed. Considering that the same calculations for soil degradation endpoints studies are expected to be submitted for the renewal of the approval of ametoctradin, the conclusions derived under the present assessment shall be considered provisional and might be revised depending on the outcome of the renewal of approval process.

The metabolism of ametoctradin in rotational crops was investigated in the framework of the EU pesticides peer review in radish, lettuce and wheat, following the soil treatment with ametoctradin at an application rate of 1.44 kg/ha (EFSA, 2012b). Crops were planted 30, 120 and 365 days after soil treatment. On the basis of study results, the EU pesticides peer review (2012) concluded that, in rotational crops, metabolites M650F03 and M650F04 are relevant residues to be additionally included in the residue definition for the risk assessment. The parent ametoctradin was concluded to be a sufficient marker for the enforcement of residues in rotational crops.

1.1.3 | Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4 | Analytical methods for enforcement purposes in plant commodities

In order to address the confirmatory data requirements, set by Commission Regulation (EU) No 2021/1110 concerning information on analytical methods⁹ relevant for hops, the applicant provided a new analytical method (L0117/03) for the determination of ametoctradin in dried hops which was assessed by the RMS (Germany, 2025). Details on the analytical method are described below and presented in Appendix B.1.1.1.

This new analytical method is based on liquid chromatography with tandem mass spectrometry (LC-MS/MS) and it allows the quantification of residues of ametoctradin in dried hops with a limit of quantification (LOQ) of 0.01 mg/kg. The new method has been validated according to the EU guidance document SANTE/2020/12830 (European Commission, 2023a). Two fortification levels (at the LOQ and 10 times of LOQ) were analysed for two different mass transitions (m/z 276→176 and m/z 276→149) with five samples per fortification level. All guideline criteria related to specificity, linearity, accuracy and repeatability were met and this analytical method was sufficiently validated by an independent test facility demonstrating the suitability of the method. No separate confirmatory method is needed for this analytical technique since it is performed simultaneously providing results for two mass transitions.

The method can, therefore, be proposed as enforcement method for the determination of ametoctradin residues in dried hops at the validated LOQ of 0.01 mg/kg. EFSA concluded that the data gap identified in the framework of the MRL review has been addressed and the tentative MRL of 90 mg/kg in hops can be confirmed.

1.1.5 | Stability of residues in plants

Not relevant for the current assessment.

⁷Worst-case DT_{90} value for silt loam (Italy). The corresponding DT_{50} value is 16.6 days. Method of calculation: DFOP (EFSA, 2012b). However, for PEC soil calculation field study end points derived from trial in Denmark, with a DT_{50}/DT_{90} of 19.8 days/65.8 days, calculated with SFO, was demonstrated to represent the worst case. Therefore, significant accumulation of this metabolites after repeated seasonal application is not expected.

⁸Worst-case value for silt loam (Italy), recalculated from the corresponding DT_{50} value of 186.5 days. Method of calculation: DFOP (EFSA, 2012b). DT_{90} exceeding two times study duration of 360 days, and therefore, the reliability of the precise value is questionable. However, potential for accumulation after repeated seasonal application can be confirmed.

⁹Confirmatory Data set by Commission Regulation (EU) No 2021/1110: The European Food Safety Authority identified some information on analytical methods as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

and including additional crop groups such as fruits and fruiting vegetables'. According to the Regulation (EU) 2021/1110, this data gap was implemented only for barley, oat, rye and wheat grain. The existing EU MRL for parent ametoctradin in the grains of these cereals is tentatively set at the LOQ of 0.01 mg/kg because of the above data gap and is reflecting the potential contribution of residues uptake in rotated small grains (EFSA, 2020).

In order to address this MRL review confirmatory data, the applicant

1. updated the soil degradation endpoints (DT_{90} and DT_{50} values) for metabolites M650F03 and M650F04 on the basis of new kinetics analysis (see Section 1.1.2)
2. submitted new rotational crop field studies where the magnitude of residues of parent ametoctradin and soil metabolites M650F03 and M650F04 was investigated in fruits and fruiting vegetables (strawberry, tomato), stem vegetables (leek) and oilseeds (rape) grown in soil previously treated with ametoctradin at an application rate of 960 g/ha.

Additionally, the RMS is of the opinion that the decision on the soil residue uptake by rotational crops shall not be based on a single use on potatoes (authorised in the Netherlands) with five applications of 240 g ametoctradin/ha while, for remaining primary crops, the authorised ametoctradin uses are limited to a maximum of three applications at 240 g/ha, according to data reported for the MRL review. The RMS proposes that measures to mitigate soil residue uptake from the uses on potatoes (referring to 5 applications) shall be taken at national level. Indeed, according to the MRL review, only the NEU use of ametoctradin and only on potatoes refer to five applications at 240 g/ha, while the remaining EU uses on annual crops (bulb vegetables, fruiting vegetables, cucurbits, lettuces and other salad plants) refer to two to three applications of ametoctradin at 240 g/ha. EFSA views that describing the situation of ametoctradin soil residues in all Europe from the NEU uses of potatoes with five applications would not be fully proportionate and result in an overestimation of residue situation. Moreover, according to the peer review, when granting ametoctradin authorisations, the MS shall pay particular attention to the leakage of metabolite M650F04 that may exceed 10 µg/L in ground water under vulnerable conditions (the assessment of ground water exposure assumes application of ametoctradin on potatoes only once every 3 years) (European Commission, 2013). Therefore, the MSs shall already have measures in place to mitigate leakage of metabolite M650F04 into groundwater. Currently, MSs are encouraged to implement risk mitigation measures also to avoid accumulation of metabolite M650F04 in the soil. Four new rotational crop field studies (2 NEU and 2 SEU) were submitted and assessed in the evaluation report (Germany, 2025). Crops were planted/sown 30 and 120 days following the soil treatment with ametoctradin and sampled at maturity. By submitting the rotational crop studies, the applicant has also addressed the part of the MRL review data gap related to additional crop groups (such as fruits and fruiting vegetables) investigated in rotational crop studies (EFSA, 2020).

Parent ametoctradin was not identified above the LOQ of 0.01 mg/kg in any of the crop samples, confirming its fast degradation in soil.

In strawberry fruits, metabolite M650F03 ranged from <0.01 to 0.028 mg/kg (30-day PBI) and <0.01 to 0.02 mg/kg (120-day PBI). Metabolite M650F04 was below the LOQ of 0.01 mg/kg at 30-day PBI and increased at PBI of 120 days, ranging from <0.01 to 0.042 mg/kg.

In tomato fruit, metabolite M650F03 ranged from <0.01 to 0.014 mg/kg at 30-day PBI and was below 0.01 mg/kg at 120-day PBI. Metabolite M650F04 was below 0.01 mg/kg at both investigated PBIs.

In leek (whole plant), metabolite M650F03 ranged from <0.01 to 0.02 mg/kg (30-day PBI) and decreased to <0.01–0.01 mg/kg (120-day PBI). Metabolite M650F04 was below 0.01 mg/kg at 30-day PBI and slightly increased, ranging from <0.01 to 0.023 mg/kg, at 120-day PBI.

In oilseed rape, metabolites M650F03 and M650F04 were below the LOQ in all seed samples from both investigated PBIs. In mature forage, from 120-day PBI, residues of metabolite M650F03 were above the LOQ in all samples and ranged from 0.014 to 0.064 mg/kg; metabolite M650F04 was quantified above the LOQ in two out of four samples at 0.021 mg/kg and 0.013 mg/kg.

An overview of total residues identified in rotational crops is provided in Table 1.2.2.1.

In the submitted studies, also soil samples (dry soil) were analysed for residues. In bare soil specimens taken at seeding/planting 29/30 days after soil treatment, residues of parent ametoctradin were between <0.01 and 0.37 mg/kg, of metabolite M650F03 at <0.01–0.075 mg/kg and of metabolite M650F04 at <0.01–0.021 mg/kg. In bare soil specimens taken at seeding/planting 117/120 days after soil treatment, residues of parent ametoctradin declined to <0.01–0.014 mg/kg, remained at nearly the same levels for metabolite M650F03 (<0.01–0.07 mg/kg) and increased for metabolite M650F04 to <0.01–0.10 mg/kg. No information, however, was provided on the soil sampling depth.

Up to now, all available rotational crop field studies have been performed with ametoctradin applied to bare soil at 960 g/ha. To address the part of MRL review data gap on whether the expected soil plateau concentrations of metabolites M650F03 and M650F04 are covered for the critical primary crop uses, the applicant calculated soil plateau concentrations for metabolites on the basis of the revised DT_{90}/DT_{50} values (see Section 1.1.2) for the use on potatoes referring to three applications at 240 g/ha (5-day retreatment interval and 7-day PHI, application every year). According to soil degradation studies, parent ametoctradin in soil forms 57% of metabolite M650F03 and 54.9% of metabolite M650F04 (EFSA, 2012b). Furthermore, to express ametoctradin as metabolite equivalents, the molecular weight conversion factor of 0.802 for M650F03 and of 0.752 for M650F04 was applied.¹⁴

¹⁴Molecular weight (MW) M650F003/ametoctradin, 221.2/275.4 g/mol = 0.803; MW M650F004/ametoctradin, 207.2/275.4 g/mol = 0.752 (Germany, 2025).

The RMS and applicant concluded that an application rate of 929.41 g/ha of ametoctradin on primary crops (considering the 60% interception) would be sufficient to cover the soil plateau levels of relevant metabolites M650F03 and M650F04 for the ametoctradin uses referring to three applications at 240 g/ha.

EFSA verified the calculations and derived a different result. The applicant's and RMS's calculation of soil plateau concentration for metabolite M650F04 at 0.087 mg/kg was limited to 10 years of accumulation whereas EFSA did not limit the accumulation to a certain period of time and the modelling indicated that metabolite M650F04 could reach maximum soil plateau concentrations of 0.125 mg/kg. Moreover, EFSA is of the opinion that combination of data on metabolites M650F03 and M650F04 is not necessary and that only the accumulation of metabolite M650F04 should be considered, because if this metabolite is covered by the application rate of the parent, then metabolite M650F03 will also be covered, as it is a precursor of metabolite M650F04 with a shorter half-life and therefore accumulates less.

Based on these arguments, EFSA concludes that, in order to reach soil plateau concentrations of metabolite M650F04, the application rate of ametoctradin on bare soil in rotational crop residue trials would need to be 1201.2 g/ha (if applied every year) or 711.8 g/ha, if applied every third year.

Input values for the calculations of application rate corresponding to soil plateau concentrations of ametoctradin metabolites are summarised in the table below.

	M650F03	M650F04	M650F04
	Germany (2025)	Germany (2025)	EFSA
PEC initial, 5 cm (mg/kg)	0.169	0.158	0.158
Total seasonal application rate on potatoes reaching soil (A_0), g/ha, calculated from PEC initial	126.7	118.9	118.9
PEC plateau, 20 cm (mg/kg)	0.003 (10 year)	0.087 (10 year)	0.125 (> 10 years)
Application rate (A_{plateau}) g/ha, calculated from PEC plateau	9	261	495
PEC accu (PEC initial (5 cm) + PEC plateau (20 cm)), mg/kg	0.172	0.245	0.284
A_{plateau} (expressed as metabolite and calculated from PEC accu), g/ha	135.75	379.5	495.9
A_{plateau} (expressed as ametoctradin and calculated from PEC accu), g/ha	238.16	691.26	1201 (every year) 711 (every 3 years)

Considering that the theoretically estimated soil application rate of 1201.2 g/ha is within the 25% deviation from the actual application rate of 960 g/ha, EFSA concludes that the available residue trials on rotational crops are considered acceptable to cover the expected soil residue plateau concentrations of metabolites M650F03 and M650F04 from the critical primary crop uses authorised in Europe referring to two to three applications of ametoctradin at 240 g/ha.

For the uses involving more than three applications of ametoctradin, the Member States shall implement necessary risk mitigation measures to avoid accumulation of metabolite MF650F004 in soil and leakage into the groundwater. It is noted that if five applications of ametoctradin at 240 g/ha would be considered for the estimation of soil plateau level of metabolites M650F04, the corresponding total application rate would be 2003 g/ha and the available field studies would be considered underdosed (0.4N) with respect to the soil plateau concentrations of M650F04. In this case, the proportionality principle could still be applicable, meaning that available rotational crop trial field data would have to be scaled up by a factor of 2.1, on the basis of NEU use on potatoes. According to EFSA, this would lead to an unnecessary overestimation of the livestock and consumer exposure, which, however, still would not result in the risk to consumers, given the large margin of the safety (0.22% of the acceptable daily intake (ADI) calculated in the present assessment).

Thus, EFSA concludes that the MRL review confirmatory data, implemented as a footnote¹² for oat, rye and wheat according to Commission Regulation (EU) No 2021/1110 and referring to the data gap of the MRL review for 'representative field rotational crop studies reporting soil characteristics to allow a conclusion as to whether the plateaus for soil metabolites M650F03 and M650F04 are covered and including additional crop groups such as fruits and fruiting vegetables', is sufficiently addressed. Additional rotational crop trials are currently not required. This conclusion is considered as provisional, since the soil degradation data, which will be submitted for the renewal of approval of ametoctradin have not been peer reviewed and might be revised depending on the outcome of the renewal of approval process.

On the basis of rotational crop trials available from the MRL review and from the rotational crop trials submitted within the present assessment, EFSA derived the risk assessment values representing the worst-case situation in rotational crops that are further used to calculate the consumer and livestock exposure to residue intake from rotational crops. The overview table is reported in [Table 1.2.2.1](#).

2 | RESIDUES IN LIVESTOCK

Ametoctradin is authorised for uses on potatoes, cassava, kale and head cabbage, which might be fed to livestock. Moreover, ametoctradin, M650F03 and M650F04 residues were also identified in cereal and oilseed forage, cereal grain and straw according to the rotational crop field studies after bare soil application of ametoctradin.

Hence, in the framework of the MRL review (EFSA, 2020), livestock dietary burden calculations were performed for the different groups of livestock. The dietary burdens calculated for all groups of livestock exceeded the trigger value of 0.1 mg/kg dry matter. Therefore, the nature and magnitude of residues were assessed in commodities of animal origin.

As a result of this the assessment, the MRL review (EFSA, 2020) set data gaps for (i) representative storage stability studies for animal commodities (all animal tissues, milk and eggs (data gap number 2) and (ii) a representative feeding study in cattle (data gap number 3). These data gaps were included as footnotes in the MRL Regulation (EU) No 2021/1110. It is also noted that new data now available on the magnitude of residues in rotational crops (see Section 1.2.2) shall be taken into consideration when assessing the livestock dietary burden. The livestock dietary burden as calculated by the MRL review was then updated considering the contribution of residues in rotational crops. The calculation is performed using the Animal Model 2017 developed by EFSA according to the OECD guidelines (OECD, 2013).

The approach on how to consider rotational crop residue contribution in livestock exposure and the selection of input values followed the recommendations of EFSA Guidance on the assessment of pesticide residues in rotational crops (EFSA, 2023). The input values for rotational crops were derived from the rotational crop data reported in Table 1.2.2.1 and, in order to cover all potential feed items in Europe, were extrapolated to a corresponding crop according to recommendations of the above-mentioned EFSA guidance and OECD Guidance on rotational crops (EFSA, 2023; OECD, 2018).

Three cases can be distinguished for the choice of input values:

- a. Crops which are treated with ametoctradin as primary crops in EU and can also be grown in a crop rotation: Risk assessment values from primary crop uses are combined with residues measured in a respective rotational crop from the rotational crop field trials. Such crops according to the MRL review are potatoes, cassava and tapioca.
- b. Crops which are imported in EU (no EU uses are authorised) and can eventually enter the livestock feed chain: Risk assessment values as derived from primary crop uses are used as input values. Such crops are head cabbage, kales, cassava and potatoes. EFSA took a decision to exclude kale from the calculation of the livestock dietary burden, despite the fact that it is considered as a livestock feed item. EFSA assumed that import of kale in EU is mainly directed to food market and that the share of kale that might potentially enter the feed chain will be low. Therefore, to avoid overestimation of livestock exposure, this crop was excluded from the dietary burden calculation.
- c. Crops which are not treated as primary crops but can be grown in soils previously treated with ametoctradin and can be fed to livestock: Risk assessment values derived from rotational crop field trials. Such crops are all crops which can be grown in crop rotation in EU, potentially accumulate soil residues and be fed to livestock, such as cereals, grass, legumes, alfalfa, clover, trefoil, oilseeds, roots and tubers, etc.

The risk assessment values for primary crops were reported as in the MRL review and the risk assessment values for rotational crops are as compiled in Table 1.2.2.1. For food by-products used as feed items, the relevant default processing factors were applied.

EFSA notes that the livestock dietary burden might be overestimated since it is assumed that all potential feed items in Europe contain residues of ametoctradin and its relevant metabolites at levels observed in rotational crops planted under conditions simulating crop failure (30-day PBI). The summary of input values used in the dietary burden calculation is provided in Appendix D.1.

2.1 | Nature of residues in livestock

Nature of residues in livestock was previously investigated in lactating goats and laying hens in the framework of a previous MRL application on various commodities and in the MRL review (EFSA, 2012a; EFSA, 2020). A livestock residue definition for monitoring and risk assessment was proposed by the MRL review as '*ametoctradin, M650F01 and M650F06 metabolites, expressed as ametoctradin*'. However, a confirmatory data requirement was set in MRL review for the storage stability of ametoctradin, M650F01 and M650F06 residues in metabolism study samples for animal commodities (all animal tissues, milk and eggs). The MRL review also highlighted that a detailed toxicological assessment confirming whether the toxicological reference value of ametoctradin applies to M650F01 and M650F06 was not available (EFSA, 2020).

EFSA noted that the animals in the metabolism studies were dosed with parent ametoctradin, while rotational crop residues in the form of metabolites M650F03 and M650F04 may represent a significant source of livestock exposure. It was concluded that, due to the structural similarity of these metabolites with the parent and the major animal metabolites M650F01 and M650F06, the behaviour of M650F03 and M650F04 could be addressed by the available animal metabolism data and no new metabolism studies with M650F03 and M650F04 were deemed necessary (EFSA, 2012b; EFSA, 2020).

Since the storage time of ametoctradin, M650F01 and M650F06 in metabolism studies was not provided, the MRL review proposed tentative MRLs in animal commodities based on the results of the metabolism studies and set a data gap for representative storage stability studies. In order to address data gap number 2¹⁵ of the MRL review, the RMS referred to the dossier submitted in the framework of the upcoming renewal of approval of ametoctradin where it is clarified that '*available poultry and ruminant metabolism data demonstrated stability of samples under frozen conditions ($\leq -18^{\circ}\text{C}$) in the relevant matrices*'. All

¹⁵Data Gap Number 2: Representative storage stability studies for animal commodities (all animal tissues, milk and eggs).

samples were stored at -18°C or below from time of sacrifice until analysis. When necessary, extracts were reanalysed. No significant changes in the basic profile of radiolabelled residues were observed (Germany, 2025). Therefore, this indicates that samples used in the previous metabolism studies remained stable for the duration of storage.

EFSA concluded that the data gap number 2 identified in the framework of the MRL review is addressed.

2.2 | Magnitude of residues and methods of analysis in livestock

In order to address the confirmatory data implemented by Commission Regulation (EU) No 2021/1110 concerning a representative feeding study in cattle,¹⁶ the applicant provided a GLP feeding study in cow which was performed in 2010. The study, which had already been assessed by the JMPR (FAO/WHO, 2013), was then evaluated by the RMS (Germany, 2025).

In this feeding study, lactating dairy cows were administered ametoctradin by oral gavage for 28 days. Three dose levels (1 \times , 3 \times and 10 \times , i.e. 0.086 mg/kg bw, 0.218 mg/kg bw and 0.862 mg/kg bw) plus one control group were established. Control, low- and middle-dose level groups consisted of three cows each while the high-dose level group consisted of five cows, as two more cows were used for this group for a 'deuration study' to measure decline.

Milk was collected twice daily and pooled on a daily basis. One day after the final dose, the cows were sacrificed and milk plus the following tissues analysed: liver, kidney, muscle and fat. The analytical method employed for the analysis of ametoctradin, M650F01 and M650F06 metabolites (BASF method L0104) was validated for all animal tissues and milk with a combined LOQ of 0.03 mg/kg. Samples were stored at -20°C for a maximum of 19 days for all tissues and 34 days for milk. As the storage period was less than 30 days for all tissues analysed, no further information on storage stability of ametoctradin, M650F01 and M650F06 metabolites in animal tissues was needed. However, for milk, since the storage period exceeded 30 days, a study on the storage stability of ametoctradin, M650F01 and M650F06 metabolites was provided. The study demonstrated stability of ametoctradin and these metabolites for 41 days, a time sufficient to prove the stability of the milk samples stored before the analysis.

No residues above the combined LOQ of 0.03 mg/kg were found in milk, muscle and fat at any dose level. Residues above the combined LOQ of 0.03 mg/kg were only detected in liver at the middle- and high-dose level groups and in kidney at the high-dose level group.

Based on the updated dietary burden, the result of this feeding study leads to increase of MRLs for bovine liver and kidney (extrapolated to equine), sheep liver and kidney (extrapolated to goat) and swine liver and kidney (extrapolated from goat), as reported in Appendix B.2.2.1.

The extrapolation of residues data from ruminants to swine is possible if the metabolisms in rats and ruminants are similar. EU pesticide peer review and MRL review concluded that metabolisms in rats and ruminants are not similar. The JMPR assessing the same livestock metabolism studies in 2012, concluded the opposite, i.e. that metabolisms in rats and ruminants are similar. EFSA suggests to provisionally accept the extrapolation from ruminants to swine assuming a similar metabolism. If, in the framework of the renewal of approval of ametoctradin, metabolisms in rats and ruminants would be considered different, the extrapolation from ruminants to swine will not be supported and a feeding study with swine would be needed.

EFSA concluded that the data gap number 3 identified in the framework of the MRL review is addressed.

3 | CONSUMER RISK ASSESSMENT

The consumer exposure was calculated separately for the residue intake from primary crops and animal origin commodities (scenario 1) and for the residue intake from rotational crops (scenario 2). It was then verified whether the overall sum of the two contributions exceeds the toxicological reference value.

The consumer exposure was calculated using the 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 for ametoctradin used in the risk assessment (i.e. ADI value of 10 mg/kg bw per day) was derived in the framework of the EU pesticides peer review (European Commission, 2013) while no acute reference dose (ARfD) is established for ametoctradin. Therefore, only the long-term consumer exposure to ametoctradin residues was calculated.

Scenario 1 – Primary crops and animal origin commodities. In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing ametoctradin uses at EU level and the acceptable CXLs (EFSA, 2020). Under the present assessment, EFSA updated this risk assessment, considering the new input values from an EFSA opinion published after the MRL review (EFSA, 2021) and the new data submitted under this application. This updated long-term exposure assessment includes the confirmed MRLs (and input values) which were subject to Article 12 confirmatory data and the increased MRLs (and input values) proposed for certain products of animal origin due to the updated dietary burden and new feeding study in ruminants. It is noted that the risk assessment residue definition for

¹⁶Confirmatory data set by Commission Regulation (EU) No 2021/1110: The European Food Safety Authority identified some information on storage stability and feeding studies as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

animal commodities also contains metabolites M650F01 and M650F06, which are covered by the toxicological reference values (TRVs) of the parent compound (EFSA, 2012b) and residues are fat soluble. The input values used in the exposure calculations are summarised in Appendix D.2.

The estimated long-term dietary intake from primary plant commodities and animal commodities is very low, reaching a maximum of 0.2% of ADI for the NL toddler diet. EFSA concluded that the long-term intake of residues of ametoctradin resulting from the existing uses is unlikely to present a risk to consumer health. However, the chronic consumer risk assessment for products of animal origin shall be regarded as indicative pending toxicological information on the metabolites M650F01 and M650F06. EFSA performed the consumer risk assessment assuming that they are unlikely to be genotoxic and their toxicity is covered by the toxicity of the parent compound.

Scenario 2 – Rotational crops. The consumer exposure to ametoctradin and its soil metabolites M650F03 and M650F04 was calculated for all annual crops that can be grown in a crop rotation and potentially contain ametoctradin residues (metabolites M650F03 and M650F04) from the soil uptake. The calculated exposure was compared to the TRVs of parent ametoctradin since metabolites M650F03 and M650F04 are covered by the toxicity of ametoctradin (EFSA, 2012b).

The input values were as derived from the rotational crop field trials (reported in Table 1.2.2.1) and extrapolated to related commodities according to principles of OECD guidance on rotational crops (OECD, 2018). The calculation was performed only for annual plant commodities as the livestock exposure to soil metabolites is covered with primary crop exposure calculation scenario 1.

Rotational crop residue data were not available for sweet corn, legumes and pulses as there are no rotational crop studies available to derive input data for these commodities. This is not expected to have an impact on the calculated dietary exposure, which is very low, i.e. 0.02% of the ADI (NL toddler diet). EFSA also notes that the calculated exposure reflects the worst-case situation, assuming that all crops contain residues at levels of 30-day PBI (simulating crop failure).

Combined exposure: The combined dietary exposure (scenario 1 + scenario 2) represents the 0.22% of the ADI (NL toddler diet). Although affected by non-standard uncertainty, this indicative exposure calculation did not indicate a risk to consumer's health. The summary of input values used in the dietary burden calculation is provided in Appendix D.2.

4 | CONCLUSION AND RECOMMENDATIONS

To address data gaps identified in the framework of the MRL review (EFSA, 2020), a new livestock feeding study and additional information on analytical methods, residue trials on primary and rotational crops and details on the storage of the samples in the livestock metabolism studies were submitted by the applicant. EFSA concludes that all data gaps were sufficiently addressed. On the basis of the submitted livestock feeding study and revised livestock dietary burden, which considered contribution of potential residues in primary and rotational crop feed items, a need to raise existing EU MRLs for ametoctradin in certain animal commodities was identified. A risk management decision is requested to determine whether the MRL value for spring/green/Welsh onions should be confirmed at 20 mg/kg or lowered to 15 mg/kg.

Consumer exposure was updated by adding the contribution of residues in rotational crops and proposed higher residues in several animal commodities.

EFSA concluded that the existing uses of ametoctradin are unlikely to present a risk to consumer health. However, the chronic consumer risk assessment for products of animal origin shall be regarded as indicative, pending toxicological information on the metabolites M650F01 and M650F06. EFSA performed an indicative consumer risk assessment assuming that they are unlikely to be genotoxic and their toxicity is covered by the toxicity of the parent compound.

The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix B.4.

ABBREVIATIONS

ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
CIRCA	(EU) Communication & Information Resource Centre Administrator
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report

DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
DT ₉₀	period required for 90% dissipation (define method of estimation)
Dw	dry weight
EC	emulsifiable concentrate
EDI	estimated daily intake
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
FID	flame ionisation detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GC-NPD	gas chromatography with nitrogen/phosphorous detector
GLP	Good Laboratory Practice
GR	granule
GS	growth stage
HPLC	high-performance liquid chromatography
HPLC-MS	high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HPLC-UVD	high-performance liquid chromatography with ultra-violet detector
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
K _{oc}	organic carbon adsorption coefficient
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	mass spectrometry detector
MS	Member States
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
NPD	nitrogen/phosphorous detector
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
P _{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
SEU	southern Europe
SG	water-soluble granule
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TAR	total applied radioactivity
UV	ultraviolet (detector)
WHO	World Health Organization
WP	wettable powder

REQUESTOR

European Commission

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APPENDIX A

Summary of GAPs assessed in the evaluation of confirmatory data

Crop and/or situation	NEU, SEU, MS or country	F, G or I ^a	Pests or group of pests Controlled	Preparation		Application				Application rate per treatment				PHI (days) ^d	Remarks
				Type ^b	Conc.a.s.	Method kind	Range of growth stages and season ^c	Number Min–max	Interval between application (min)	g a.s./hL Min–max	Water L/ha Min–max	Rate	Unit		
MRL review GAPs (confirmatory data, import tolerance)															
Spring onions, green onions and Welsh onions	US/CA	F	Downy mildew	SC	200 g/L	Foliar treatment – spraying	BBCH 14–49	3	5	–	–	300	g a.i./ha	0	

Abbreviations: MS, Member State; NEU, northern European Union; SEU, southern European Union.

^a Outdoor or field use (F), greenhouse application (G) or indoor application (I).

^b CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.

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

^d PHI: minimum preharvest interval.

APPENDIX B

List of end points

B.1 | RESIDUES IN PLANTS

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

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

Primary crops (available studies)					
Crop groups	Crops	Applications	Sampling	Comment/source	
Fruit crops	Tomatoes	Foliar (post-emergence): 3 × 300 g a.i./ha	1 DALA	Radiolabelled mixture of 2,7- ¹⁴ C ametoctradin and 2,5,7- ¹³ C-ametoctradin Post-emergence; 3 foliar treatments of tomato plants 47, 54 and 61 days after planting (EFSA, 2020)	
	Tomatoes	30 µg/L	8 DAT	Radiolabelled 5- ¹⁴ C-M650F03 or 5- ¹⁴ C-M650F04 in nutrient solution; tomato plants transferred to flask with nutrient solution and test item placed in greenhouse (EFSA, 2020) Supporting information only.	
Root crops	Potatoes	Foliar (post-emergence): 3 × 441 g a.i./ha	7 after 2nd appl., 14 DALA	Radiolabelled mixture of 2,7- ¹⁴ C ametoctradin and 2,5,7- ¹³ C-ametoctradin; Post-emergence; 3 foliar treatments of potato plants 35, 21 and 7 days prior to harvest (EFSA, 2020)	
Leafy crops	Lettuces	Foliar (post-emergence): 3 × 223 g a.i./ha	7 DALA	Radiolabelled mixture of 2,7- ¹⁴ C ametoctradin and 2,5,7- ¹³ C-ametoctradin; Post-emergence; 3 foliar treatments of lettuce plants 21, 31 and 39 days after planting (EFSA, 2020)	
Rotational crops (available studies)					
Crop groups	Crops	Application	PBI (DAT)	Comment/Source	
Root/tuber crops	White radishes	Bare soil: 1 × 1.44 kg a.i./ha	30, 120, 365	Radiolabelled mixture of non-radiolabelled, 2,7- ¹⁴ C-ametoctradin and 2,5,7- ¹³ C-ametoctradin; soil treatment; harvested 89–91 days after planting and separated into edible parts (root) and remaining green parts (top) (EFSA, 2012b)	
Leafy crops	Lettuces	Bare soil: 1 × 1.44 kg a.i./ha	30, 120, 365	Radiolabelled mixture of non-radiolabelled, 2,7- ¹⁴ C-ametoctradin and 2,5,7- ¹³ C ametoctradin; soil treatment; harvested 28–35 and 56–63 days after planting (EFSA, 2012b)	
Cereal (small grain)	Wheat	Bare soil: 1 × 1.44 kg a.i./ha	30, 120, 365	Radiolabelled mixture of non-radiolabelled, 2,7- ¹⁴ C-ametoctradin and 2,5,7- ¹³ C-ametoctradin; soil treatment; immature green plants (wheat forage) were harvested 48–56 days after planting for PBIs of 120 and 365 days only; mature wheat was harvested 110–125 days after planting (EFSA, 2012b)	

(Continues)

(Continued)

Processed commodities (hydrolysis study)	Conditions	Stable?	Comment/Source
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Radiolabelled ametoctradin, label not specified (EFSA, 2020)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	Radiolabelled ametoctradin, label not specified (EFSA, 2020)
	Sterilisation (20 min, 120°C, pH 6)	Yes	Radiolabelled ametoctradin, label not specified (EFSA, 2020)

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2020)
Rotational crop and primary crop metabolism similar?	No	In primary crops, ametoctradin is the main residue, whereas in rotational crops, soil metabolites M650F03 and M650F04 are the main residues, with occasional to low occurrence of the parent compound (EFSA, 2020)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	Ametoctradin is stable under standard hydrolysis conditions (EFSA, 2020).
Plant residue definition for monitoring (RD-Mo)	Ametoctradin	
Plant residue definition for risk assessment (RD-RA)	Primary crops and processed commodities: ametoctradin (EFSA, 2012b; EFSA, 2020) Rotational crops: sum of ametoctradin, M650F03 and M650F04, expressed as ametoctradin (EFSA, 2012b; EFSA, 2020)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	<p>Ametoctradin</p> <p>Matrices with high water content, high oil content, high acid content and dry matrices:</p> <ul style="list-style-type: none"> HPLC-MS/MS, LOQ 0.01 mg/kg; Confirmatory method and ILV available (EFSA, 2012b). Method is also able to determine residues of M650F03 and M650F04 at the individual LOQ of 0.01 mg/kg. <p>Matrices with high water and acid content:</p> <ul style="list-style-type: none"> LC-MS/MS (QuEChERS-method EN 15662:2008), LOQ 0.005 mg/kg; (EFSA, 2020) <p>Dry matrices:</p> <ul style="list-style-type: none"> LC-QqQ-MS/MS (QuEChERS-method EN 15662:2008), LOQ 0.005 mg/kg (EFSA, 2020); <p>Matrices with high oil content:</p> <p>LC-MS/MS (QuEChERS-method EN 15662:2008), LOQ 0.005 mg/kg (EFSA, 2020)</p> <p>Hops:</p> <ul style="list-style-type: none"> HPLC-MS/MS, LOQ 0.01 mg/kg Confirmation by monitoring 1 additional fragment ion, ILV available (Germany, 2025) <p>Method is also able to determine residues of M650F03 and M650F04 at the individual LOQ of 0.01 mg/kg.</p>	

Abbreviations: a.s., active substance; DAT, days after treatment; HPLC-MS/MS, high performance liquid chromatography with tandem mass spectrometry; ILV, independent laboratory validation; LC-MS/MS, liquid chromatography with tandem mass spectrometry; LC-QqQ-MS/MS, Liquid Chromatography with Triple Quadrupole Tandem Mass Spectrometry; LOQ, limit of quantification; PBI, plant-back interval; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe.

B.1.1.2 | Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/Source
				Value	Unit		
Plant products (available studies)	High water content	Tomato fruit	-20	24	Months	Ametoctradin	Metabolism studies (EFSA, 2020)
		Tomato	-20	36	Months	Ametoctradin	Stability study EFSA, 2020
			-20	24	Months	M650F03	Rotational crop study (EFSA, 2020)
	Wheat forage	-20	24	Months	M650F04	Rotational crop study (EFSA, 2020)	
		-20	24	Months	Ametoctradin	Stability study (EFSA, 2020)	
		-20	24	Months	M650F03	Rotational crop study (EFSA, 2020)	
	Lettuce	-20	24	Months	M650F04	Rotational crop study (EFSA, 2020)	
		-20	36	Months	Ametoctradin	Metabolism studies (EFSA, 2020)	
		-20	24	Months	Ametoctradin	Stability study (EFSA, 2020)	
	Potato	-20	24	Months	M650F03	Rotational crop study (EFSA, 2020)	
		-20	24	Months	M650F04	Rotational crop study (EFSA, 2020)	
		-20	24	Months	Ametoctradin	Stability study (EFSA, 2020)	
	High protein content)	Pea (dry) ¹	-20	24	Months	Ametoctradin,	Stability study (EFSA, 2020)
			-20	24	Months	M650F03	Rotational crop study (EFSA, 2020)
			-20	24	Months	M650F04	Rotational crop study (EFSA, 2020)
	High starch content	Wheat grain ¹	-20	24	Months	Ametoctradin	Stability study (EFSA, 2020)
			-20	24	Months	M650F03	Rotational crop study (EFSA, 2020)
			-20	24	Months	M650F04	Rotational crop study (EFSA, 2020)
High acid content	Grape	-20	16	Months	Ametoctradin	Stability study (EFSA, 2020)	
		-20	24	Months	M650F03	Rotational crop study (EFSA, 2020)	
		-20	24	Months	M650F04	Rotational crop study (EFSA, 2020)	
Others	Wheat straw ¹	-20	24	Months	Ametoctradin	Stability study (EFSA, 2020)	
		-20	24	Months	M650F03	Rotational crop study (EFSA, 2020)	
		-20	24	Months	M650F04	Rotational crop study (EFSA, 2020)	
Products of animal origin (available studies)	Honey	-18	6	Months	Ametoctradin	EFSA (2021)	
		-	-	-	M650F03	EFSA (2021)	
		-	-	-	M650F04	EFSA (2021)	

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)
Spring onions	U.S./CA	MRL review: 3.4, <u>4.3</u> , 9.1 Germany (2025): 2×2.3, <u>3.5</u>	Residue trials on spring onions compliant with GAP already assessed (EFSA, 2012a, 2020) and new trials (Germany, 2025). Higher results at longer PHI of 1 day are underlined.	15	9.1	3.5

Abbreviations: GAP, Good agricultural practice; MRL, maximum residue level.

^aNon-EU trials. US, United States of America; CA, Canada.

^bHighest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

^cSupervised 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	Metabolism of ametoctradin investigated in a confined rotational crop study on root crops (white radishes), leafy crops (lettuces) and cereals (spring wheat) at plant-back intervals (PBIs) of 30, 120 and 365 days (EFSA, 2012b, 2020). Significant residues of soil metabolites M650F03 and M650F04 are identified in the confined rotational crop study in small grain cereals after 1 year (EFSA, 2020).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Yes	<p>Field rotational crop studies conducted with ametoctradin applied to bare soil at 960 g/ha investigating the uptake in rotational wheat (only at PBI 120 d) and wheat, carrot, lettuce, cauliflower (PBI 30, 120 and 360 d) (EFSA, 2012b, 2020). The only residues observed in significant concentrations in mature crops were metabolites M650F03 and M650F04. The data indicate that at PBIs of 120 days or beyond, crop parts for the human consumption are not expected to contain residues above the LOQ with an exception of cereal grains. In grains, total residue of M650F03 and M650F04 up to 0.33 mg/kg at 0.8N the rate of the authorised NEU GAP on potatoes (assessed in the MRL Review. In all studies, significant residue levels were also found in potential animal feed items (EFSA, 2012b, 2020).</p> <p>New field rotational crop studies conducted with ametoctradin applied to bare soil at 960 g/ha investigating residue uptake in rotational crops strawberries, oilseed rape, leek and tomato. The studies were limited to 30 and 120 d PBIs (Germany, 2025).</p> <p>In strawberry fruits, metabolite M650F03 < 0.01-0.028 mg/kg (30 d PBI) and < 0.01-0.02 mg/kg (120 d PBI). Metabolite M650F04 was < 0.01 mg/kg (30 d PBI) and < 0.01-0.042 mg/kg (120 d PBI).</p> <p>In tomato fruit, metabolite M650F03 < 0.01-0.014 mg/kg (30 d PBI) and was < 0.01 mg/kg (120 d PBI). Metabolite M650F04 was < 0.01 mg/kg (both 30 and 120 d PBIs).</p> <p>In leek (whole plant), metabolite M650F03 < 0.01-0.02 mg/kg (30 d PBI) and < 0.01-0.01 mg/kg (120 d PBI). Metabolite M650F04 was < 0.01 mg/kg (30 d PBI) and < 0.01-0.023 mg/kg (120 d PBI).</p> <p>In oilseed rape, metabolites M650F03 and M650F04 were < 0.01 mg/kg in all seed samples from both 30 and 120 d PBIs. In mature forage, metabolite M650F03 was 0.014-0.064 mg/kg (120 d PBI); metabolite M650F04 was quantified above the LOQ in two out of four samples: 0.021 mg/kg and 0.013 mg/kg.</p>

TABLE 1.2.2.1. An overview of available rotational crop residue trials.

The data in the table below from previously available studies are limited to information about residues in samples from crops planted at PBI 30 days and full information on the magnitude of residues in rotational trials is available with the EFSA output on MRL review (EFSA, 2020). The data in the table from the new submitted studies are compiled from 30- and 120-days PBIs (Germany, 2025).

Crop	Matrix	PBI	Residues ^a (mg/kg)	STMR (mg/kg)	HR (mg/kg)
Residue definition risk assessment rotational crops: Sum of ametoctradin, M650F03 and M650F04, expressed as ametoctradin					
Root crops					
Carrot	Whole Plant	30	0.13; 0.14; 0.15; 0.19	0.145	0.19
	Tops	30	0.11; 0.13; 0.14; 0.14	0.135	0.14
	Roots	30	0.042; 0.052; 0.054; 0.058	0.053	0.058
Pulses and oilseeds					
Oilseed rape	Whole plan (no roots)	29	2 × < 0.035; 0.064; 0.071	0.0495	0.071
	Seeds	29	4 × < 0.035	< 0.035	< 0.035
	Rest of plant no roots	29	0.044; 0.33; 0.14; 0.064	0.102	0.33
	Rest of plant no roots	29	0.044; 0.064; 0.14; 0.33	0.102	0.33
	Whole plan (no roots)	120	4 × < 0.035	< 0.035	< 0.035
	Seeds	120	4 × < 0.035	< 0.035	< 0.035
Cereals					
Wheat	Whole plant	30	0.24; 0.36; 0.71; 1.192	0.535	1.192
	Grain	30	0.031; 0.039; 0.13; 0.18	0.0845	0.18
	Straw	30	0.11; 0.27; 1.1; 1.3251	0.685	1.3251
Leafy crops					
Lettuce	Heads	30	< 0.03; 0.031; 0.035; 0.051	0.033	0.051
Lettuce	Heads	120	4 × < 0.03	< 0.03	< 0.03
Leek	Whole plan (no roots)	30	5 × < 0.035; 0.036; 0.037; 0.048;	< 0.035	0.048
Leek	Whole plan (no roots)	120	6 × < 0.035; 0.046; 0.053	< 0.035	0.053
<i>Leek and lettuce combined</i>		30	<i>See above data for leek and cabbage</i>	< 0.035	0.051
<i>Leek and lettuce combined</i>		120	<i>See above data for leek and cabbage</i>	< 0.035	0.053
Fruit crops					
Strawberry	Fruit	30	< 0.035; 0.035; 0.042; 0.057	0.0385	0.057
Strawberry	Fruit	120	2 × 0.035; 0.044; 0.088	0.0395	0.088
Tomato	Fruit	30	2 × 0.035; 0.039; 0.04	0.037	0.04
Tomato	Fruit	120	4 × < 0.035	< 0.035	< 0.035
Brassica vegetables					
Cauliflower	Whole plant	30	2 × < 0.03; 0.051; 0.11	0.041	0.11
	Inflorescence	30	2 × < 0.03; 0.04; 0.06	0.035	0.06

^aResidues expressed as parent ametoctradin equivalents by molecular weight (MW) conversion factor of 1.245 for M650F03 (MW ametoctradin/MW M650F03 = 275.4/221.2 g/mol) and 1.3292 for M650F04 (MW ametoctradin/MW M650F04 = 275.4/207.2 g/mol).

B.1.2.3 | Processing factors

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

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) 0.1 mg/kg DM
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all)	0.231	0.514	7.13	14.51	Beef cattle	Cabbage head/leaves	Y
Cattle (dairy only)	0.231	0.514	6.00	13.38	Dairy cattle	Cabbage head/leaves	Y

(Continued)

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup ^a	Most critical commodity ^b	Trigger exceeded (Y/N) 0.1 mg/kg DM
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Sheep (all)	0.191	0.314	5.74	9.43	Lamb	Cabbage head/leaves	Y
Sheep (ewe only)	0.191	0.314	5.74	9.43	Ram/Ewe	Cabbage head/leaves	Y
Swine (all)	0.085	0.171	3.70	7.40	Swine (breeding)	Cabbage head/leaves	Y
Poultry (all)	0.083	0.209	1.21	3.05	Poultry layer	Cabbage head/leaves	Y
Poultry (layer only)	0.083	0.209	1.21	3.05	Poultry layer	Cabbage head/leaves	Y
Fish	N/A						

Abbreviations: bw, body weight; DM, dry matter; N/A, not applicable.

^aWhen 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'.

^bThe most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.2.1 | Nature of residues and methods of analysis in livestock

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

Livestock (available studies)	Animal	Dose (mg/kg bw per day)	Duration (days)	Comment/Source
	Laying hen	0.81	10	Radiolabelled 2,7- ¹⁴ C-ametoctradin and 2,5,7- ¹³ C ametoctradin and non-labelled ametoctradin (EFSA, 2012a, 2020)
	Lactating goats	0.49–0.51	10	Radiolabelled 2,7- ¹⁴ C-ametoctradin and 2,5,7- ¹³ C ametoctradin and non-labelled ametoctradin (EFSA, 2012a, 2020)

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 5-8 days	(EFSA, 2020)
	Eggs: 7 days	(EFSA, 2020)
Metabolism in rat and ruminant similar	Open	EFSA recommends concluding on this point in the framework of the upcoming renewal of approval.
Can a general residue definition be proposed for animals?	Yes	Based on metabolism studies on laying hen and lactating goats
Animal residue definition for monitoring (RD-Mo)	Ametoctradin, metabolite 4-(7-amino-5-ethyl [1,2,4]triazolo, [1,5-a]pyrimidin-6-yl) butanoic acid (M650F01) and metabolite 6-(7-amino-5-ethyl [1,2,4]triazolo [1,5-a]pyrimidin-6-yl) hexanoic acid (M650F06), expressed as ametoctradin (Regulation (EC) No 396/2005)	
	Sum of ametoctradin, M650F01 and M650F06, expressed as ametoctradin (still pending the clarification on the toxicological profile of the metabolites M650F01 and M650F06, EFSA, 2012a,b)	
Animal residue definition for risk assessment (RD-RA)	Sum of ametoctradin, M650F01 and M650F06, expressed as ametoctradin, provisional pending a detailed toxicological assessment confirming whether the toxicological reference value of ametoctradin applies to M650F01 and M650F06 (EFSA, 2012a, 2012b)	
Fat soluble residues	Yes	Ametoctradin detected in eggs and hen fat; log P _{ow} = 4.4 (at pH 7.1), indicating fat solubility (log P _{ow} >3)
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	<p>Ametoctradin, M650F01 and M650F06</p> <p>Matrix fat, liver, kidney, muscle, milk, cream and eggs</p> <ul style="list-style-type: none"> HPLC-MS/MS, combined LOQ 0.03 mg/kg <p>Confirmatory methods and ILV available (EFSA, 2012 a,b).</p> <p>Ametoctradin</p> <ul style="list-style-type: none"> LC-MS-Q-ToF (QuEChERS method), screening detection limit (SDL) of 0.0025 mg/kg in muscle and of 0.01 mg/kg in milk (EFSA, 2020). <p>M650F01, M650F06</p> <ul style="list-style-type: none"> LC-MS/MS (QuEChERS method), LOQ of 0.01 mg/kg for each analyte in muscle, liver, eggs (EFSA, 2020). <p>Ametoctradin, Honey:</p> <p>LC-MS-Q-ToF (QuEChERS method), screening detection limit (SDL) of 0.0025 mg/kg</p>	

Abbreviations: bw, body weight; GC-MS, gas chromatography with mass spectrometry; ILV, independent laboratory validation; LC-MS/MS, liquid chromatography with tandem mass spectrometry; LOQ, limit of quantification.

B.2.1.2 | Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability period			Comment/Source
				Value	Unit	Compounds covered	
	Bovine	Milk	-18	41	Days	Ametoctradin	Germany (2025)
-18			41	Days	M650F01	Germany (2025)	
-18			41	Days	M650F06	Germany (2025)	

B.2.2 | Magnitude of residues in livestock

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

Calculations performed with Animal model 2017.¹⁷

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)	CF ^c
	Mean	Highest	STMR ^a (mg/kg)	HR ^b (mg/kg)		
Cattle (all)						
Closest feeding level: 0.218 mg/kg bw; 0.4 N dairy cattle (highest diet) ^c						
Muscle	0.03	0.03	0.030	0.03	0.03*	n.c.
Fat	0.03	0.03	0.030	0.03	0.03*	n.c.
Liver	0.03	0.04	0.036	0.08	0.09	n.c.
Kidney	0.03	0.03	0.031	0.04	0.04	n.c.
Cattle (dairy only)						
Closest feeding level: 0.218 mg/kg bw; 0.4 N dairy cattle ^c						
Milk ^d	0.03	0.03	0.03	0.03	0.03*	n.c.
Sheep (all)^e						
Closest feeding level: 0.218 mg/kg bw; 0.7 N ram/ewe (highest diet) ^c						
Muscle	0.03	0.03	0.030	0.03	0.03*	n.c.
Fat	0.03	0.03	0.030	0.03	0.03*	n.c.
Liver	0.03	0.04	0.033	0.05	0.05	n.c.
Kidney	0.03	0.03	0.031	0.04	0.04	n.c.
Sheep (ewe only)^e						
Closest feeding level: 0.218 mg/kg bw; 0.7 N ewe ^c						
Milk ^d	0.03	0.03	0.03	0.03	0.03*	n.c.
Swine (all)^e						
Closest feeding level: 0.218 mg/kg bw; 1.3 N breeding (highest diet) ^c						
Muscle	0.03	0.03	0.030	0.03	0.03*	n.c.
Fat	0.03	0.03	0.030	0.03	0.03*	n.c.
Liver	0.03	0.04	0.030	0.04	0.04	n.c.
Kidney	0.03	0.03	0.030	0.03	0.03	n.c.
Poultry (all)						
Closest feeding level: 0.81 mg/kg bw; 3.9 N layer (highest diet) ^c						
Muscle	0.03	0.03	0.03	0.03	0.03*	n.c.
Fat	0.03	0.03	0.03	0.03	0.03*	n.c.
Liver	0.03	0.03	0.03	0.03	0.03*	n.c.
Poultry (layer only)						
Closest feeding level: 0.81 mg/kg bw; 3.9 N layer ^c						
Eggs	0.03	0.03	0.03	0.03	0.03*	n.c.

Abbreviations: bw, body weight; HR, highest residue; n.a., not applicable; n.c., not calculated; STMR, supervised trials median residue.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

^aThe mean residue level for milk and the mean residue levels for eggs and tissues were recalculated at the 1N rate for the median dietary burden.

^bThe mean residue level in milk and the highest residue levels in eggs and tissues were recalculated at the 1N rate for the maximum dietary burden.

^cClosest feeding level and N dose rate related to the maximum dietary burden. n.c. not calculated.

^dHighest residue level from day 1 to day 28 (daily mean of 3 cows).

^eSince extrapolation from cattle to other ruminants and swine is provisionally accepted, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

¹⁷https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en.

B.3 | Consumer risk assessment

ADI	10 mg/kg bw per day (European Commission, 2013)
Highest IEDI, according to EFSA PRIMO	<p>Scenario 1 - Exposure from primary crops and animal origin commodities: 0.2% ADI (NL toddler diet)</p> <p>Scenario 2 - Exposure from rotational crop intake: 0.02% ADI (NL toddler)</p> <p>Combined (scenario 1 + scenario 2): 0.22% of the ADI (NL toddler diet)</p>
Assumptions made for the calculations	<p>Scenario 1. Exposure from residues in primary crops and animal origin commodities.</p> <p>In the framework of the MRL review a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2020). EFSA updated this risk assessment, considering the new input values for honey from an EFSA opinion published after the MRL review (EFSA, 2021) and the new data submitted under this application. This updated long-term exposure assessment includes the confirmation of the tentative MRLs (and input values) which were subject to article 12 confirmatory data and the increased MRLs (and input values) proposed in this output for certain products of animal origin due to the updated dietary burden and new feeding study.</p> <p>The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.</p> <p>Scenario 2. Exposure from rotational crops.</p> <p>The input values used in the calculation were derived from the rotational crop field trials (Table 1.2.2.1) and extrapolated to related commodities according to principles of OECD guidance on rotational crops (OECD, 2018).</p> <p>Rotational crop residue data were not available for sweet corn, legumes and pulses as there are no rotational crop studies available to derive input data for these commodities. This is not expected to have an impact on the calculated dietary exposure which is very low.</p> <p>The calculated exposure reflects the worst-case situation, assuming that all crops contain residues at levels measured at 30 d PBI (simulating crop failure).</p> <p>However, the chronic consumer risk assessment for products of animal origin shall be regarded as indicative, pending toxicological information on the metabolites M650F01 and M650F06.</p>

B.4 | RECOMMENDED MRLS

Code ^a	Commodity	Existing MRL ^b	Proposed MRL	Conclusion/recommendation
Enforcement residue definition: Ametoctradin				
0220040	Spring onions/green onions and Welsh onions	20	15 or 20	The data gap identified by EFSA has been addressed. Based on the combined set of new and old residue trials, EFSA derived a lower MRL of 15 mg/kg for the import tolerance use assessed in the MRL review. A Codex MRL of 20 mg/kg was proposed in 2012 based on the same GAP and original 3 trials, but it was not implemented in the EU legislation at that time (EU reservation). The new trials address the data gap identified by EFSA for the CXL as well.

(Continued)

Code ^a	Commodity	Existing MRL ^b	Proposed MRL	Conclusion/recommendation
		(ft 3)	(risk management decision)	A risk management decision is requested to determine whether the MRL value should be confirmed at 20 mg/kg or lowered to 15 mg/kg. Risk for consumers is unlikely.
0500010	Barley	0.01*	0.01*	The data gap identified by EFSA has been addressed. The MRL should be maintained at the LOQ.
0500050	Oat	(ft 1)		Risk for consumers is unlikely.
0500070	Rye			
0500090	Wheat			
0700000	HOPS	90	90	The data gap identified by EFSA has been addressed. The MRL is confirmed.
		(ft 2)		Risk for consumers is unlikely.
Enforcement residue definition: Sum of ametoctradin, M650F01 and M650F06, expressed as ametoctradin (F)				
1012010	Bovine muscle	0.03*	0.03*	The data gaps identified by EFSA have been addressed.
1012020	Bovine fat	0.03*	0.03*	Based on the revised animal dietary burden and the new feeding study, the MRLs should be increased for bovine liver and kidney (extrapolated to equine) while they should be maintained for bovine muscle and fat (extrapolated to equine).
1015010	Equine muscle	0.03*	0.03*	Risk for consumers is unlikely.
1015020	Equine fat	0.03* (ft 4)	0.03*	
1012030	Bovine liver	0.04	0.09	
1012040	Bovine kidney	0.03*	0.04	
1015030	Equine liver	0.04	0.09	
1015040	Equine kidney	0.03* (ft 4)	0.04	
1011010	Swine muscle	0.03*	0.03*	The data gap identified by EFSA has been addressed.
1011020	Swine fat	0.03*	0.03*	Based on the revised animal dietary burden and the new feeding study, the MRLs should be increased for swine, sheep, goat liver and kidney while they should be maintained all other animal commodities.
1011030	Swine liver	0.03*	0.04	Risk for consumers is unlikely.
1011040	Swine kidney	0.03*	0.03	
1013010	Sheep muscle	0.03*	0.03*	
1013020	Sheep fat	0.03*	0.03*	
1013030	Sheep liver	0.03*	0.05	
1013040	Sheep kidney	0.03*	0.04	
1014010	Goat muscle	0.03*	0.03*	
1014020	Goat fat	0.03*	0.03*	
1014030	Goat liver	0.03*	0.05	
1014040	Goat kidney	0.03*	0.04	
1016010	Poultry muscle	0.03*	0.03*	
1016020	Poultry fat	0.03*	0.03*	
1016030	Poultry liver	0.03*	0.03*	
1016040	Poultry kidney	0.03*	0.03*	
1020010	Milk cattle	0.03*	0.03*	
1020020	Milk sheep	0.03*	0.03*	
1020030	Milk goat	0.03*	0.03*	
1020040	Milk horse	0.03*	0.03*	
1030010	Chicken eggs	0.03*	0.03*	
1030020	Duck eggs	0.03*	0.03*	
1030030	Geese eggs	0.03*	0.03*	
1030040	Quail eggs	0.03* (ft 5)	0.03*	

(Continues)

(Continued)

Abbreviations: GAP, Good agricultural practice; MRL, maximum residue level.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

^aCommodity code number according to Annex I of Regulation (EC) No 396/2005.

^bExisting EU MRL and corresponding footnote on confirmatory data.

^{ft1}The European Food Safety Authority identified some information on residues in rotational crops as unavailable. When reviewing the MRL, the commission will take into account the information referred to in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

^{ft2}The European Food Safety Authority identified some information on analytical methods as unavailable. When reviewing the MRL, the commission will take into account the information referred to in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

^{ft3}The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the commission will take into account the information referred to in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

^{ft4}The European Food Safety Authority identified some information on storage stability and feeding studies as unavailable. When reviewing the MRL, the commission will take into account the information referred in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

^{ft5}The European Food Safety Authority identified some information on storage stability as unavailable. When reviewing the MRL, the commission will take into account the information referred in the first sentence, if it is submitted by 7 July 2023, or, if that information is not submitted by that date, the lack of it.

^fFat soluble.

APPENDIX C

Pesticide Residue Intake Model (PRIMO)

Scenario 1

EFSa-Q-2023-00796_ametoctradin_PRIMO_Scenario 1ev3.1.xlsm



EFSA PRIMO revision 3.1; 2021/01/06

Ametoctradin (F)			
LOQs (mg/kg) range from:		0.01	to: 0.05
Toxicological reference values			
ADI (mg/kg bw/day):	10	ARID (mg/kg bw):	Not necessary
Source of ADI:	EC, 2013	Source of ARID:	EC, 2013
Year of evaluation:		Year of evaluation:	

Input values

- Details - chronic risk assessment
- Supplementary results - chronic risk assessment
- Details - acute risk assessment/children
- Details - acute risk assessment/adults

Comments:										
Refined calculation mode										
Chronic risk assessment: JMPR methodology (IEDI/TMDI)										
No of diets exceeding the ADI : ---										
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS Diet (in % of ADI)		2nd contributor to MS diet (in % of ADI)	3rd contributor to MS diet (in % of ADI)		Exposure resulting from MRLs set at the LOQ (in % of ADI)		commodities not under assessment (in % of ADI)
			Commodity / group of commodities	Commodity / group of commodities		Commodity / group of commodities	Commodity / group of commodities			
0.2%	NL toddler	20.08	0.1%	Spinaches	0.0%	0.0%	0.0%	Milk: Cattle	0.2%	
0.1%	SE general	13.70	0.1%	Lettuces	0.0%	0.0%	0.0%	Head cabbages	0.1%	
0.1%	GEMS/Food G10	12.19	0.0%	Lettuces	0.0%	0.0%	0.0%	Cress and other sprouts and shoots	0.1%	
0.1%	ES adult	10.54	0.1%	Lettuces	0.0%	0.0%	0.0%	Spinaches	0.1%	
0.1%	IT adult	9.98	0.0%	Lettuces	0.0%	0.0%	0.0%	Other spinach and similar	0.1%	
0.1%	GEMS/Food G08	9.68	0.0%	Lettuces	0.0%	0.0%	0.0%	Wine grapes	0.1%	
0.1%	DE child	9.64	0.0%	Spinaches	0.0%	0.0%	0.0%	Lettuces	0.1%	
0.1%	NL child	9.59	0.0%	Spinaches	0.0%	0.0%	0.0%	Lettuces	0.1%	
0.1%	GEMS/Food G11	9.27	0.0%	Lamb's lettuce/corn salads	0.0%	0.0%	0.0%	Spinaches	0.1%	
0.1%	GEMS/Food G06	9.20	0.0%	Lettuces	0.0%	0.0%	0.0%	Tomatoes	0.1%	
0.1%	ES child	9.12	0.1%	Lettuces	0.0%	0.0%	0.0%	Chards/beet leaves	0.1%	
0.1%	GEMS/Food G07	8.66	0.0%	Lettuces	0.0%	0.0%	0.0%	Celeries	0.1%	
0.1%	IE adult	8.19	0.0%	Spinaches	0.0%	0.0%	0.0%	Lettuces	0.1%	
0.1%	NL general	8.10	0.0%	Spinaches	0.0%	0.0%	0.0%	Lettuces	0.1%	
0.1%	IT toddler	7.90	0.0%	Lettuces	0.0%	0.0%	0.0%	Spinaches	0.1%	
0.1%	GEMS/Food G15	7.15	0.0%	Head cabbages	0.0%	0.0%	0.0%	Wine grapes	0.1%	
0.1%	PT general	6.91	0.0%	Kales	0.0%	0.0%	0.0%	Lettuces	0.1%	
0.1%	RO general	6.40	0.0%	Head cabbages	0.0%	0.0%	0.0%	Tomatoes	0.1%	
0.1%	FR infant	6.37	0.0%	Spinaches	0.0%	0.0%	0.0%	Cauliflowers	0.1%	
0.1%	DE women 14-50 yr	5.69	0.0%	Lettuces	0.0%	0.0%	0.0%	Spinaches	0.1%	
0.1%	DE general	5.48	0.0%	Lettuces	0.0%	0.0%	0.0%	Spinaches	0.1%	
0.1%	FR toddler 2-3 yr	5.31	0.0%	Spinaches	0.0%	0.0%	0.0%	Cauliflowers	0.1%	
0.0%	FR child 3-15 yr	5.00	0.0%	Spinaches	0.0%	0.0%	0.0%	Cauliflowers	0.0%	
0.0%	FR adult	4.80	0.0%	Wine grapes	0.0%	0.0%	0.0%	Lamb's lettuce/corn salads	0.0%	
0.0%	UK vegetarian	4.75	0.0%	Lettuces	0.0%	0.0%	0.0%	Spinaches	0.0%	
0.0%	UK adult	3.97	0.0%	Lettuces	0.0%	0.0%	0.0%	Spinaches	0.0%	
0.0%	DK child	3.96	0.0%	Lettuces	0.0%	0.0%	0.0%	Cucumbers	0.0%	
0.0%	DK adult	3.44	0.0%	Lettuces	0.0%	0.0%	0.0%	Head cabbages	0.0%	
0.0%	FI 6 yr	3.34	0.0%	Lettuces	0.0%	0.0%	0.0%	Chinese cabbages/pe-tsai	0.0%	
0.0%	FI adult	3.30	0.0%	Lettuces	0.0%	0.0%	0.0%	Wine grapes	0.0%	
0.0%	FI 3 yr	3.02	0.0%	Spinaches	0.0%	0.0%	0.0%	Chinese cabbages/pe-tsai	0.0%	
0.0%	UK infant	2.82	0.0%	Milk: Cattle	0.0%	0.0%	0.0%	Brussels sprouts	0.0%	
0.0%	UK toddler	2.76	0.0%	Milk: Cattle	0.0%	0.0%	0.0%	Lettuces	0.0%	
0.0%	PL general	2.35	0.0%	Head cabbages	0.0%	0.0%	0.0%	Table grapes	0.0%	
0.0%	LT adult	2.12	0.0%	Lettuces	0.0%	0.0%	0.0%	Tomatoes	0.0%	
0.0%	IE child	0.65	0.0%	Milk: Cattle	0.0%	0.0%	0.0%	Lettuces	0.0%	

Conclusion:
 The estimated long-term dietary intake (TMDI/IEDI) was below the ADI.
 The long-term intake of residues of Ametoctradin (F) 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.

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

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

Show results for all crops

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

Processed commodities	Results for children						Results for adults					
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):						No of processed commodities for which ARfD/ADI is exceeded (IESTI):					
	---						---					
	IESTI						IESTI					
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)			
Expand/collapse list												

Conclusion:

Scenario 2

EFSA-Q-2023-00796_ametoctradin_PRIMo_rev3.1_Scenario2.xlsm



EFSA PRIMo revision 3.1; 2021/01/06

Ametoctradin (F)			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	10	ARID (mg/kg bw):	Not necessary
Source of ADI:	EC, 2013	Source of ARID:	EC, 2013
Year of evaluation:		Year of evaluation:	

Input values

- Details - chronic risk assessment
- Supplementary results - chronic risk assessment
- Details - acute risk assessment/children
- Details - acute risk assessment/adults

Comments:										
Refined calculation mode										
Chronic risk assessment: JMPR methodology (IEDI/TMDI)										
No of diets exceeding the ADI : ---										
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from	
									MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.02%	NL toddler	1.85	0.0%	Maize/corn	0.0%	Wheat	0.0%	Sugar beet roots	0.0%
	0.01%	GEMS/Food G06	1.46	0.0%	Wheat	0.0%	Tomatoes	0.0%	Rice	0.0%
	0.01%	DK child	1.23	0.0%	Rye	0.0%	Wheat	0.0%	Potatoes	0.0%
	0.01%	NL child	1.20	0.0%	Sugar beet roots	0.0%	Wheat	0.0%	Potatoes	0.0%
	0.01%	GEMS/Food G10	1.08	0.0%	Wheat	0.0%	Potatoes	0.0%	Soyabeans	0.0%
	0.01%	GEMS/Food G15	1.06	0.0%	Wheat	0.0%	Potatoes	0.0%	Barley	0.0%
	0.01%	GEMS/Food G08	1.06	0.0%	Wheat	0.0%	Potatoes	0.0%	Barley	0.0%
	0.01%	RO general	1.06	0.0%	Wheat	0.0%	Potatoes	0.0%	Maize/corn	0.0%
	0.01%	GEMS/Food G11	0.97	0.0%	Wheat	0.0%	Potatoes	0.0%	Soyabeans	0.0%
	0.01%	GEMS/Food G07	0.95	0.0%	Wheat	0.0%	Potatoes	0.0%	Soyabeans	0.0%
	0.01%	FR child 3 15 yr	0.90	0.0%	Wheat	0.0%	Sugar beet roots	0.0%	Potatoes	0.0%
	0.01%	PT general	0.87	0.0%	Wheat	0.0%	Potatoes	0.0%	Rice	0.0%
	0.01%	UK toddler	0.83	0.0%	Wheat	0.0%	Potatoes	0.0%	Sugar beet roots	0.0%
	0.01%	DE child	0.83	0.0%	Wheat	0.0%	Potatoes	0.0%	Rye	0.0%
	0.01%	IE adult	0.82	0.0%	Wheat	0.0%	Sweet potatoes	0.0%	Potatoes	0.0%
	0.01%	SE general	0.77	0.0%	Wheat	0.0%	Potatoes	0.0%	Carrots	0.0%
	0.01%	UK infant	0.76	0.0%	Wheat	0.0%	Potatoes	0.0%	Maize/corn	0.0%
	0.01%	IT toddler	0.75	0.0%	Wheat	0.0%	Tomatoes	0.0%	Potatoes	0.0%
	0.01%	FR toddler 2 3 yr	0.70	0.0%	Wheat	0.0%	Sugar beet roots	0.0%	Potatoes	0.0%
	0.01%	FI 3 yr	0.68	0.0%	Potatoes	0.0%	Wheat	0.0%	Rye	0.0%
	0.01%	DE women 14-50 yr	0.66	0.0%	Sugar beet roots	0.0%	Wheat	0.0%	Potatoes	0.0%
	0.01%	ES child	0.65	0.0%	Wheat	0.0%	Potatoes	0.0%	Rice	0.0%
	0.01%	DE general	0.65	0.0%	Sugar beet roots	0.0%	Wheat	0.0%	Potatoes	0.0%
	0.01%	NL general	0.62	0.0%	Wheat	0.0%	Sugar beet roots	0.0%	Potatoes	0.0%
	0.01%	FI 6 yr	0.54	0.0%	Potatoes	0.0%	Wheat	0.0%	Rye	0.0%
	0.01%	IT adult	0.52	0.0%	Wheat	0.0%	Tomatoes	0.0%	Potatoes	0.0%
	0.00%	LT adult	0.47	0.0%	Potatoes	0.0%	Rye	0.0%	Wheat	0.0%
	0.00%	ES adult	0.43	0.0%	Wheat	0.0%	Potatoes	0.0%	Barley	0.0%
	0.00%	UK vegetarian	0.40	0.0%	Wheat	0.0%	Potatoes	0.0%	Rice	0.0%
	0.00%	FR infant	0.39	0.0%	Potatoes	0.0%	Sugar beet roots	0.0%	Wheat	0.0%
	0.00%	FR adult	0.38	0.0%	Wheat	0.0%	Sugar beet roots	0.0%	Potatoes	0.0%
	0.00%	UK adult	0.34	0.0%	Wheat	0.0%	Potatoes	0.0%	Rice	0.0%
	0.00%	DK adult	0.30	0.0%	Wheat	0.0%	Potatoes	0.0%	Rye	0.0%
	0.00%	PL general	0.29	0.0%	Potatoes	0.0%	Tomatoes	0.0%	Carrots	0.0%
	0.00%	FI adult	0.26	0.0%	Potatoes	0.0%	Rye	0.0%	Wheat	0.0%
0.00%	IE child	0.18	0.0%	Wheat	0.0%	Potatoes	0.0%	Rice	0.0%	
Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Ametoctradin (F) 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.										

Acute risk assessment /children		Acute risk assessment / adults / general population					
Details - acute risk assessment /children		Details - acute risk assessment/adults					
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.							
Show results for all crops							
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):		Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):				
	---		---				
	IESTI		IESTI				
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							
Processed commodities	Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):		Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI):				
	---		---				
	IESTI		IESTI				
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)
Expand/collapse list							
Conclusion:							

APPENDIX D

Input values for the exposure calculations

D.1 | LIVESTOCK DIETARY BURDEN CALCULATIONS

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment
Risk assessment residue definition: Ametoctradin				
Cabbage heads, leaves	2.04	STMR (EFSA, 2021, FAO/ WHO, 2013)	7.56	HR (EFSA, 2021, FAO/WHO, 2013)
Risk assessment residue definition: Sum of ametoctradin, MF650F003 and MF650F004				
Forages				
Forage of alfalfa, clover, cowpea, lespedeza, rape, soybean, trefoil, vetch, pea and bean vines	0.05	STMR _{RC} (rape forage) (Table 1.2.2.1.)	0.07	HR _{RC} (rape forage) (Table 1.2.2.1.)
Alfalfa hay, meal	0.12	STMR _{RC} (rape forage) (Table 1.2.2.1.) × PF (2.5) ^c	0.18	HR _{RC} (rape forage) (Table 1.2.2.1.) × PF (2.5) ^c
Alfalfa silage	0.05	STMR _{RC} (rape forage) (Table 1.2.2.1.) × PF (1.1) ^c	0.08	HR _{RC} (rape forage) (Table 1.2.2.1.) × PF (1.1) ^c
Cowpea hay	0.14	STMR _{RC} (rape forage) (Table 1.2.2.1.) × PF (2.9) ^c	0.20	HR _{RC} (rape forage) (Table 1.2.2.1.) × PF (2.9) ^c
Clover hay	0.15	STMR _{RC} (rape forage) (Table 1.2.2.1.) × PF (3) ^c	0.21	HR _{RC} (rape forage) (Table 1.2.2.1.) × PF (3) ^c
Clover silage	0.05	STMR _{RC} (rape forage) (Table 1.2.2.1.) × PF (1) ^c	0.07	HR _{RC} (rape forage) (Table 1.2.2.1.) × PF (1) ^c
Lespedeza hay	0.20	STMR _{RC} (rape forage) (Table 1.2.2.1.) × PF (4) ^c	0.28	HR _{RC} (rape forage) (Table 1.2.2.1.) × PF (4) ^c
Pea hay	0.17	STMR _{RC} (rape forage) (Table 1.2.2.1.) × PF (3.5) ^c	0.25	HR _{RC} (rape forage) (Table 1.2.2.1.) × PF (3.5) ^c
Pea silage	0.08	STMR _{RC} (rape forage) (Table 1.2.2.1.) × PF (1.6) ^c	0.11	HR _{RC} (rape forage) (Table 1.2.2.1.) × PF (1.6) ^c
Soybean hay	0.07	STMR _{RC} (rape forage) (Table 1.2.2.1.) × PF (1.5) ^c	0.11	HR _{RC} (rape forage) (Table 1.2.2.1.) × PF (1.5) ^c
Soybean silage	0.02	STMR _{RC} (rape forage) (Table 1.2.2.1.) × PF (0.5) ^c	0.04	HR _{RC} (rape forage) (Table 1.2.2.1.) × PF (0.5) ^c
Trefoil hay, vetch hay	0.14	STMR _{RC} (rape forage) (Table 1.2.2.1.) × PF (2.8) ^c	0.20	HR _{RC} (rape forage) (Table 1.2.2.1.) × PF (2.8) ^c
Barley, corn, millet, oat, rye, sorghum, triticale, wheat forage	0.54	STMR _{RC} (wheat forage) (Table 1.2.2.1.)	1.19	HR _{RC} (wheat forage) (Table 1.2.2.1.)
Barley, millet, oat, rye, triticale, wheat straw	0.69	STMR _{RC} (wheat straw) (Table 1.2.2.1.)	1.33	HR _{RC} (wheat straw) (Table 1.2.2.1.)
Barley silage	0.70	STMR _{RC} (wheat forage) (Table 1.2.2.1.) × PF (1.3) ^c	1.55	HR _{RC} (wheat forage) (Table 1.2.2.1.) × PF (1.3) ^c
Oat hay	1.62	STMR _{RC} (wheat forage) (Table 1.2.2.1.) × PF (3) ^c	3.57	HR _{RC} (wheat forage) (Table 1.2.2.1.) × PF (3) ^c
Sorghum silage	0.32	STMR _{RC} (wheat forage) (Table 1.2.2.1.) × PF (0.6) ^c	0.71	HR _{RC} (wheat forage) (Table 1.2.2.1.) × PF (0.6) ^c
Triticale hay	1.57	STMR _{RC} (wheat forage) (Table 1.2.2.1.) × PF (2.9) ^c	3.45	HR _{RC} (wheat forage) (Table 1.2.2.1.) × PF (2.9) ^c
Wheat hay	1.89	STMR _{RC} (wheat forage) (Table 1.2.2.1.) × PF (3.5) ^c	4.17	HR _{RC} (wheat forage) (Table 1.2.2.1.) × PF (3.5) ^c
Turnip leaves, beet/mangel fodder, sugar beet tops	0.14	STMR _{RC} (carrot tops)	0.14	HR _{RC} (carrot tops)

(Continues)

(Continued)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment
Roots and tubers				
Potato culls	0.063	STMR _{PC} (0.01 mg/kg EU uses) (EFSA, 2020) + STMR _{RC} (carrot root)	0.068	HR _{PC} (0.01 mg/kg EU uses) (EFSA, 2020) + STMR _{RC} (carrot root)
Cassava/tapioca, roots	0.063	STMR _{PC} (0.01 mg/kg EU uses) (EFSA, 2020) + STMR _{RC} (carrot root)	0.068	HR _{PC} (0.01 mg/kg EU uses) (EFSA, 2020) + STMR _{RC} (carrot root)
Carrot culls, swede roots, turnip roots	0.053	STMR _{RC} (carrot roots) (Table 1.2.2.1.)	0.058	HR _{RC} carrot roots (Table 1.2.2.1.)
Cereal grain/Crop seeds				
Grain of barley, corn, millet, oat, rye, sorghum, triticale, wheat	0.0845	STMR _{RC} (wheat grain) (Table 1.2.2.1.)	0.0845	STMR _{RC} (wheat grain) (Table 1.2.2.1.)
Seed of bean, cowpea, lupin, pea, soybean	0.035	STMR _{RC} (rapeseed) (Table 1.2.2.1.)	0.035	STMR _{RC} (rapeseed) (Table 1.2.2.1.)
By-products				
Sugar beet dried pulp	0.95	STMR _{RC} carrot roots (Table 1.2.2.1.) × PF (18) ^c	0.95	STMR _{RC} carrot roots (Table 1.2.2.1.) × PF (18) ^c
Sugar beet, ensiled pulp	0.16	STMR _{RC} carrot roots (Table 1.2.2.1.) × PF (3) ^c	0.16	STMR _{RC} carrot roots (Table 1.2.2.1.) × PF (3) ^c
Sugar beet, molasses	1.48	STMR _{RC} carrot roots (Table 1.2.2.1.) × PF (28) ^c	1.48	STMR _{RC} carrot roots (Table 1.2.2.1.) × PF (28) ^c
Brewer's grain, dried	0.28	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (3.3) ^c	0.28	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (3.3) ^c
Rapeseed, linseed, safflower, sunflower, lupin seed and soybean meal; soybean hulls	0.035	STMR _{RC} (rapeseed) (Table 1.2.2.1.) × PF (1) ^b	0.035	STMR _{RC} (rapeseed) (Table 1.2.2.1.) × PF (1) ^b
Corn, milled by-products	0.0845	STMR _{RC} (wheat grain) (Table 1.2.2.1.)	0.0845	STMR _{RC} (wheat grain) (Table 1.2.2.1.)
Corn, hominy meal	0.51	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF(6) ^b	0.51	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF(6) ^c
Corn, gluten feed	0.21	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (2.5) ^c	0.21	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (2.5) ^c
Corn, gluten meal	0.0845	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (1) ^c	0.0845	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (1) ^c
Distiller's grain, dried	0.28	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (3.3) ^c	0.28	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (3.3) ^c
Potato, process waste	1.26	STMR potatoes × CF (20) ^c	1.26	STMR potatoes × CF (20) ^c
Potato, dried pulp	2.39	STMR potatoes × CF (38) ^c	2.39	STMR potatoes × CF (38) ^c
Wheat gluten meal	0.15	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (1.8) ^c	0.15	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (1.8) ^c
Wheat milled by-products	0.59	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (7) ^c	0.59	STMR _{RC} (wheat grain) (Table 1.2.2.1.) × PF (7) ^c

Abbreviations: HR, highest residue; PF, processing factor; PR, primary crop; RC, rotational crop; STMR, supervised trials median residue.

^a Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

^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 oilseed meals, no default processing factor was applied because total ametoctradin residues in rotational crop are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

D.2 | CONSUMER RISK ASSESSMENT

(a) Primary plant commodities:

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment ^b
Residue definition for the risk assessment: Ametoctradin						
Table grapes	6	EFSA (2020)	0.91	STMR-RAC		
Wine grapes	6	EFSA (2020)	0.91	STMR-RAC		
Potatoes	0.05	EFSA (2020)	0.01	STMR-RAC		
Cassava roots/manioc	0.05	EFSA (2020)	0.01	STMR-RAC		
Sweet potatoes	0.05	EFSA (2020)	0.01	STMR-RAC		
Yams	0.05	EFSA (2020)	0.01	STMR-RAC		
Arrowroots	0.05	EFSA (2020)	0.01	STMR-RAC		
Other tropical root and tuber vegetables	0.05	EFSA (2020)	0.01	STMR-RAC		
Garlic	1.5	EFSA (2020)	0.22	STMR-RAC		
Onions	1.5	EFSA (2020)	0.22	STMR-RAC		
Shallots	1.5	EFSA (2020)	0.22	STMR-RAC		
Spring onions/green onions and Welsh onions	20	EFSA (2020)	4.3	STMR-RAC		
Tomatoes	2	EFSA (2020)	0.255	STMR-RAC		
Sweet peppers/bell peppers	1.5	EFSA (2020)	0.31	STMR-RAC		
Aubergines/egg plants	2	EFSA (2020)	0.255	STMR-RAC		
Okra/lady's fingers	1.5	EFSA (2020)	0.155	STMR-RAC		
Other solanaceae	1.5	EFSA (2020)	0.155	STMR-RAC		
Cucumbers	2	EFSA (2020)	0.16	STMR-RAC		
Gherkins	3	EFSA (2020)	0.54	STMR-RAC		
Courgettes	3	EFSA (2020)	0.54	STMR-RAC		
Other cucurbits – edible peel	3	EFSA (2020)	0.54	STMR-RAC		
Melons	3	EFSA (2020)	0.66	STMR-RAC		
Pumpkins	3	EFSA (2020)	0.34	STMR-RAC		
Watermelons	3	EFSA (2020)	0.66	STMR-RAC		
Other cucurbits – inedible peel	3	EFSA (2020)	0.66	STMR-RAC		
Broccoli	9	EFSA (2020)	1.75	STMR-RAC		
Cauliflowers	9	EFSA (2020)	1.75	STMR-RAC		
Other flowering brassica	9	EFSA (2020)	1.75	STMR-RAC		
Brussels sprouts	9	EFSA (2020)	1.75	STMR-RAC		
Head cabbages	15	EFSA (2020)	2	STMR-RAC		
Chinese cabbages/pe-tsai	60	EFSA (2020)	16	STMR-RAC		
Kales	50	EFSA (2020)	13	STMR-RAC		
Kohlrabies	9	EFSA (2020)	1.75	STMR-RAC		
Lamb's lettuce/corn salads	70	EFSA (2020)	20	STMR-RAC		
Lettuces	50	EFSA (2020)	13	STMR-RAC		
Escaroles/broad-leaved endives	50	EFSA (2020)	13	STMR-RAC		
Cress and other sprouts and shoots	50	EFSA (2020)	13	STMR-RAC		
Land cress	50	EFSA (2020)	13	STMR-RAC		
Roman rocket/rucola	50	EFSA (2020)	13	STMR-RAC		
Red mustards	50	EFSA (2020)	13	STMR-RAC		
Baby leaf crops (including brassica species)	50	EFSA (2020)	13	STMR-RAC		
Spinaches	60	EFSA (2020)	13	STMR-RAC		
Purslanes	60	EFSA (2020)	13	STMR-RAC		
Chards/beet leaves	60	EFSA (2020)	13	STMR-RAC		

(Continues)

(Continued)

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment ^b
Other spinach and similar	60	EFSA (2020)	13	STMR-RAC		
Grape leaves and similar species	50	EFSA (2020)	13	STMR-RAC		
Watercress	50	EFSA (2020)	13	STMR-RAC		
Chervil	50	EFSA (2020)	13	STMR-RAC		
Chives	40	EFSA (2020)	8.5	STMR-RAC		
Celery leaves	40	EFSA (2020)	8.5	STMR-RAC		
Parsley	40	EFSA (2020)	8.5	STMR-RAC		
Sage	40	EFSA (2020)	8.5	STMR-RAC		
Rosemary	40	EFSA (2020)	8.5	STMR-RAC		
Thyme	40	EFSA (2020)	8.5	STMR-RAC		
Basil and edible flowers	40	EFSA (2020)	8.5	STMR-RAC		
Laurel/bay leaves	40	EFSA (2020)	8.5	STMR-RAC		
Tarragon	40	EFSA (2020)	8.5	STMR-RAC		
Other herbs	40	EFSA (2020)	8.5	STMR-RAC		
Celeries	20	EFSA (2020)	5.5	STMR-RAC		
Florence fennels	20	EFSA (2020)	5.5	STMR-RAC		
Leeks	5	EFSA (2020)	1.055	STMR-RAC		
Barley	0.01	EFSA (2020)	0.053	STMR-RAC		
Oat	0.01	EFSA (2020)	0.053	STMR-RAC		
Rye	0.01	EFSA (2020)	0.053	STMR-RAC		
Wheat	0.01	EFSA (2020)	0.053	STMR-RAC		
HOPS (dried)	90	EFSA (2020)	28	STMR-RAC		
Honey and other apiculture products	5	EFSA (2021)	0.7	STMR-RAC		
Residue definition for the risk assessment: Sum of ametoctradin, M650F01 and M650F06, expressed as ametoctradin						
Swine: Muscle/meat ^c	0.03*	EFSA (2020)	0.030	STMR-RAC		
Swine: Fat tissue	0.03*	EFSA (2020)	0.030	STMR-RAC		
Swine: Liver	0.04	Proposed	0.030	STMR-RAC		
Swine: Kidney	0.03	Proposed	0.030	STMR-RAC		
Swine: Edible offal (other than liver and kidney)	0.03*	EFSA (2020)	0.030	STMR-RAC		
Swine: Other products	0.03*	EFSA (2020)	0.030	STMR-RAC		
Bovine: Muscle/meat ^c	0.03*	EFSA (2020)	0.030	STMR-RAC		
Bovine: Fat tissue	0.03*	EFSA (2020)	0.030	STMR-RAC		
Bovine: Liver	0.09	Proposed	0.036	STMR-RAC		
Bovine: Kidney	0.04	Proposed	0.031	STMR-RAC		
Bovine: Edible offal (other than liver and kidney)	0.03*	EFSA (2020)	0.030	STMR-RAC		
Bovine: Other products	0.03*	EFSA (2020)	0.030	STMR-RAC		
Sheep: Muscle/meat ^c	0.03*	EFSA (2020)	0.030	STMR-RAC		
Sheep: Fat tissue	0.03*	EFSA (2020)	0.030	STMR-RAC		
Sheep: Liver	0.05	Proposed	0.033	STMR-RAC		
Sheep: Kidney	0.04	Proposed	0.031	STMR-RAC		
Sheep: Edible offal (other than liver and kidney)	0.03*	EFSA (2020)	0.030	STMR-RAC		
Sheep: other products	0.03*	EFSA (2020)	0.030	STMR-RAC		
Goat: Muscle/meat ^c	0.03*	EFSA (2020)	0.030	STMR-RAC		
Goat: Fat tissue	0.03*	EFSA (2020)	0.030	STMR-RAC		
Goat: Liver	0.05	Proposed	0.033	STMR-RAC		
Goat: Kidney	0.04	Proposed	0.031	STMR-RAC		

(Continued)

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment ^b
Goat: Edible offal (other than liver and kidney)	0.03*	EFSA (2020)	0.030	STMR-RAC		
Goat: other products	0.03*	EFSA (2020)	0.030	STMR-RAC		
Equine: Muscle/meat ^c	0.03*	EFSA (2020)	0.030	STMR-RAC		
Equine: Fat tissue	0.03*	EFSA (2020)	0.030	STMR-RAC		
Equine: Liver	0.09	Proposed	0.036	STMR-RAC		
Equine: Kidney	0.04	Proposed	0.031	STMR-RAC		
Equine: Edible offal (other than liver and kidney)	0.03*	EFSA (2020)	0.030	STMR-RAC		
Equine: Other products	0.03*	EFSA (2020)	0.030	STMR-RAC		
Poultry: Muscle/meat ^c	0.03*	EFSA (2020)	0.030	STMR-RAC		
Poultry: Fat tissue	0.03*	EFSA (2020)	0.030	STMR-RAC		
Poultry: Liver	0.03*	EFSA (2020)	0.030	STMR-RAC		
Poultry: Kidney	0.03*	EFSA (2020)	0.030	STMR-RAC		
Poultry: Edible offal (other than liver and kidney)	0.03*	EFSA (2020)	0.030	STMR-RAC		
Poultry: Other products	0.03*	EFSA (2020)	0.030	STMR-RAC		
Milk: Cattle	0.03*	EFSA (2020)	0.030	STMR-RAC		
Milk: Sheep	0.03*	EFSA (2020)	0.030	STMR-RAC		
Milk: Goat	0.03*	EFSA (2020)	0.030	STMR-RAC		
Milk: Horse	0.03*	EFSA (2020)	0.030	STMR-RAC		
Milk: Others	0.03*	EFSA (2020)	0.030	STMR-RAC		
Eggs: Chicken	0.03*	EFSA (2020)	0.030	STMR-RAC		
Honey and other apiculture products	5	EFSA (2021)	0.7	STMR-RAC		

Note: The MRL proposal used for risk assessment is underlined in bold.

Abbreviations: HR-RAC, highest residue in raw agricultural commodity; STMR-RAC, supervised trials median residue in raw agricultural commodity.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

^aFigures in the table are rounded to two or three digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

^bInput values for the acute risk assessment are not reported since an ARfD was deemed unnecessary (European Commission, 2013).

^cConsumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticides, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat, respectively (FAO, 2016).

(b) Rotational crops:

Code	Commodity	Chronic risk assessment	
		Input value (mg/kg) ^a	Source of input value (Table 1.2.2.1.)
Residue definition for the risk assessment: Sum of ametoctradin, M650F03 and M650F04, expressed as ametoctradin			
152000	Strawberries	0.039	STMR-RC strawberries
211000	Potatoes	0.053	STMR RC carrot roots
212020	Sweet potatoes	0.053	STMR RC carrot roots
213000	Other root and tuber vegetables except sugar beet	0.053	STMR RC carrot roots
220000	Bulb vegetables	0.035	STMR-RC leek
230000, except 234000	Fruiting vegetables, except sweet corn	0.037	STMR-RC tomato
240000	Brassica vegetables	0.035	STMR-RC cauliflower
250000	Leaf vegetables, herbs and edible flowers	0.033	STMR-RC lettuce
270000	Stem vegetables	0.035	STMR-RC leek
401000	Oilseeds	0.035	STMR-RC rapeseed
500000	Cereals	0.085	STMR-RC wheat grain
631010	Chamomile	0.033	STMR-RC lettuce

(Continues)

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Code	Commodity	Chronic risk assessment	
		Input value (mg/kg) ^a	Source of input value (Table 1.2.2.1.)
900010	Sugar beet roots	0.053	STMR RC carrot roots
900030	Chicory roots	0.053	STMR RC carrot roots

Abbreviation: STMR-RC, supervised trials median residue in rotational crop.

^aFigures in the table are rounded to three digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

APPENDIX E

Used compound codes

Code/trivial name ^a	IUPAC name/SMILES notation/InChiKey ^b	Structural formula ^c
Ametoctradin (BAS 650 F)	5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine <chem>Nc1c(CCCCCCC)c(nc2ncn1)CC</chem> GGKQIOFASHYUJZ-UHFFFAOYSA-N	
M650F03	(7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidin-6-yl)acetic acid <chem>O=C(O)Cc1c(N)n2ncnc2nc1CC</chem> FLMGQFFLZHIWOW-UHFFFAOYSA-N	
M650F04	7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidine-6-carboxylic acid <chem>O=C(O)c1c(N)n2ncnc2nc1CC</chem> IAKVACUHWXCBHI-UHFFFAOYSA-N	
M650F01	4-(7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidin-6-yl)butanoic acid <chem>O=C(O)CCCc1c(N)n2ncnc2nc1CC</chem> SBOXHLTXNTZTBN-UHFFFAOYSA-N	
M650F06	6-(7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidin-6-yl)hexanoic acid <chem>O=C(O)CCCCc1c(N)n2ncnc2nc1CC</chem> XWEXJCLUDJVJQP-UHFFFAOYSA-N	

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

^aThe metabolite name in bold is the name used in the conclusion.

^bACD/Name 2023.2.4 ACD/Labs 2023.2.4 (File Version N25E41, Build 137185, 31 January 2024).

^cACD/ChemSketch 2023.2.4 ACD/Labs 2024.2.4 (File Version C45H41, Build 137017, 18 January 2024).