Modification of the existing maximum residue levels for ametoctradin in herbs and edible flowers

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Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), Belgium, compiled an application to modify the existing maximum residue level (MRL) for the active substance ametoctradin in the group of herbs and edible flowers, except sage and basil. The data submitted in support of the request were found to be sufficient to derive a MRL proposal for these herbs. An adequate analytical method for enforcement is available to control the residues of ametoctradin on the commodities under consideration. Based on the risk assessment results, EFSA concluded that the intake of residues resulting from the use of ametoctradin according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Keywords: ametoctradin, fresh herbs, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Belgium, compiled an application to modify the existing maximum residue level (MRL) for the active substance ametoctradin in the group of herbs and edible flowers, except sage and basil. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 2 August 2016. To accommodate for the intended uses of ametoctradin, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) to 20 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) and its addendum prepared under Directive 91/414/EEC, the Commission review report on ametoctradin, the conclusion on the peer review of the pesticide risk assessment of the active substance ametoctradin, the Joint Meeting on Pesticide Residues (JMPR) evaluation report as well as the conclusions from previous EFSA opinions and scientific report on ametoctradin.

The metabolism of ametoctradin following foliar applications was investigated in crops belonging to the groups of fruits, root and leafy vegetables. Studies investigating the effect of processing on the nature of ametoctradin (hydrolysis studies) demonstrated that the active substance is stable. In rotational crops, the major residues identified were the soil metabolites M650F03 and M650F04.

Based on the metabolic pattern identified in primary and rotational crops, the nature of the residues in processed commodities and the toxicological profile of the identified relevant metabolites, the residue definition for enforcement was proposed as ametoctradin for all plant groups. For risk assessment, the residue definition was set as ametoctradin for primary crops and processed commodities while for rotational crops the residue definition for risk assessment was proposed as the sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin. EFSA concluded that for the crops assessed in this application, the metabolism of ametoctradin in primary and rotational crops and the nature of residues in processed products have been sufficiently addressed.

A sufficiently validated analytical method is available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The method enables quantification of ametoctradin residues at or above 0.01 mg/kg (LOQ). The available residue trials are sufficient to derive a MRL proposal of 20 mg/kg for the group of herbs and edible flowers, except sage and basil, by extrapolation from residue data on open leaf lettuces. The residue trials submitted are supported by acceptable storage stability data.

Specific studies investigating the magnitude of ametoctradin residues in processed commodities are not required as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI).

Based on the available information, EFSA could not exclude that the use of ametoctradin according to the proposed good agricultural practice (GAP) will not result in significant residues of the soil metabolites M650F03 and M650F04 in rotational crops. Therefore, Member States should consider specific risk mitigation measures to avoid the presence of residues in rotational crops.

Residues of ametoctradin in commodities of animal origin were not assessed in the framework of this application, since herbs are normally not fed to livestock.

The toxicological profile of ametoctradin was assessed in the framework of the European Union (EU) pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 10 mg/kg body weight (bw) per day. No acute reference dose (ARfD) was deemed necessary; therefore, a short-term consumer risk assessment was not performed.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). A long-term consumer intake concern was not identified. The total estimate intake accounted for 0.14% of the ADI (FR toddler). Based on the risk assessment results, EFSA concluded that the proposed use of ametoctradin on the herbs and edible flowers under assessment will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumer health.

EFSA proposes to amend the existing MRLs as reported in the summary table below.
| Code<sup>(a)</sup> | Commodity              | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|------------------------|------------------------|------------------------|-----------------------|
| 0256010           | Chervil                | 0.01*                  | 20                     | Indoor use supported by extrapolation from residue data on open leaf lettuces. Unlikely to pose consumer health risk |
| 0256020           | Chives                 | 0.01*                  | 20                     |                       |
| 0256030           | Celery leaves          | 0.01*                  | 20                     |                       |
| 0256040           | Parsley                | 0.01*                  | 20                     |                       |
| 0256060           | Rosemary               | 0.01*                  | 20                     |                       |
| 0256070           | Thyme                  | 0.01*                  | 20                     |                       |
| 0256090           | Laurel/bay leave       | 0.01*                  | 20                     |                       |
| 0256100           | Tarragon               | 0.01*                  | 20                     |                       |
| 0256990           | Others herbs and edible flowers | 0.01* | 20 |                       |

Enforcement residue definition: Ametoctradin

MRL: maximum residue level.

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

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

Regulation (EC) No 396/20051 (hereinafter referred to as ‘the MRL regulation’) establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the MRL regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC,2 repealed by Regulation (EC) No 1107/20093, shall submit an application to a Member State to modify a MRL in accordance with the provisions of Article 7 of the MRL regulation.

The competent authority in Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for ametoctradin in the group of herbs and edible flowers (except sage and basil). This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in an evaluation report which was submitted to the European Commission and forwarded to EFSA on 2 August 2016. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00504 and the following subject:

Ametoctradin: Application to modify MRL(s) in fresh herbs

Belgium proposed to set MRLs of ametoctradin in herbs and edible flowers at 20 mg/kg. Since the existing MRLs for sage and basil have been already set at 20 mg/kg following EFSA recommendation (EFSA, 2015), it is not necessary to amend the MRLs on these two herbs.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated limit of quantification (LOQ) for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within three months from the date of receipt of the application.

The evaluation report submitted by the EMS (Belgium, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

The active substance and its use pattern

The detailed description of the intended use of ametoctradin in herbs and edible flowers, which is the basis for the current MRL application, is reported in Appendix A.

Ametoctradin is the ISO common name for 5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine (IUPAC).

The chemical structures of the active substance and its main metabolites are reported in Appendix E.

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1 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
3 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
Ametoctradin was evaluated in the framework of Directive 91/414/EEC with the Netherlands, designated as rapporteur Member State (RMS), for the representative uses as foliar spray applications on potatoes and tomatoes. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2012b). Ametoctradin was approved4 for the use as a fungicide on 1 August 2013.

The EU MRLs for ametoctradin are established in Annex III A of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed. EFSA has issued several reasoned opinions on the modification of MRLs for ametoctradin. The proposals from these reasoned opinions have been considered in several regulations up to the most recent5 for EU MRL legislation.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Belgium, 2016), the DAR and its final addendum prepared under Directive 91/414/EEC (Netherlands, 2010, 2012), the European Commission review report on ametoctradin (European Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance ametoctradin (EFSA, 2012b), the JMPR Evaluation reports (FAO, 2012) as well as the conclusions from previous EFSA opinions and scientific report on ametoctradin (EFSA, 2009, 2012a, 2013, 2014, 2015, 2016).

For this application, the data requirements established in Regulation (EU) No 544/20116 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2016; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/20117.

A selected list of end points of the studies assessed by EFSA in the framework of the peer review, including the end points of residue studies submitted in support of the current MRL application, are presented in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of ametoctradin in primary crops belonging to the groups of fruit crops (tomatoes), root crops (potatoes) and leafy crops (lettuce), has been investigated in the framework of the EU pesticides peer review (Netherlands, 2010; EFSA, 2012b). Ametoctradin was the predominant compound of residue in tomatoes and lettuces, representing up to 99% of the total radioactive residues (TRR). In potato tubers at harvest, low residues were found (up to 0.04 mg eq/kg), with ametoctradin accounting only for 4% TRR (0.001 mg/kg) whilst two major metabolites were identified (M650F03, 40% TRR; 0.016 mg eq/kg; M650F04, 27% TRR; 0.011 mg eq/kg (Netherlands, 2010)). In potato leaves, ametoctradin was found to be the pertinent compound (85% TRR). It can therefore be concluded that the metabolism of ametoctradin in root crops is mainly driven by the uptake of the major soil metabolites M650F03 and M650F04.

For the intended use, the metabolic behaviour in primary crops is sufficiently addressed.

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4 Commission Implementing Regulation (EU) No 200/2013 of 8 March 2013 approving the active substance ametoctradin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, OJ L 67, 9.3.2013, p. 1–5.
5 Commission Regulation (EU) 2016/1902 of 27 October 2016 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 acetamiprid, ametoctradin, azoxystrobin, cyfluthrin, difluoroacetic acid, dimethomorph, fenpyrazamine, flonicamid, fluzinam, fluoxadifen, flupyradifurone, flutriafol, flupyradocox, metconazole, proquinazid, prothioconazole, pyriproxyfen, spirodiclofen and trifloxystrobin in or on certain products. OJ L 298, 4.11.2016, p. 1–60.
6 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances, OJ L 155, 11.6.2011, p. 1–66.
7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
1.1.2. Nature of residues in rotational crops

Ametoctradin is proposed to be used on crops that may be grown in rotation with other crops. The soil degradation studies assessed during the EU peer review demonstrated the low persistence of ametoctradin while the major soil metabolites M650F03 and M650F04 showed a moderate to high persistence with a DT_{90} above the trigger value of 100 days. Thus, further studies investigating the nature of residues in rotational crops are required (European Commission, 1997c).

The metabolism of ametoctradin was investigated in a confined rotational crop study on root crops (radishes), leafy crops (lettuces) and cereals (wheat) at plant back intervals (PBIs) of 30, 120 and 365 days in the framework of the EU pesticides peer review (Netherlands, 2010; EFSA, 2012b). The total radioactive residues in all the edible parts of the rotational crops decreased significantly along with the PBI. In the harvested crops, parent compound was detected only in lettuces (< 0.01 mg/kg) at PBI 30 DAT, in wheat forage (< 0.01 mg/kg) at PBI 120 DAT, and straw at PBI 30 and 120 DAT (0.044 mg/kg and 0.029 mg/kg, respectively). M650F03 was by far the major component of residues in all crops at all PBIs (10% TRR in wheat grain to 96% TRR in radish roots) with metabolite M650F04 that occurred also at significant proportions in all plant parts (22.5% TRR in radish roots to 80% TRR in wheat grain).

For the intended use, the metabolic behaviour in rotational crops is sufficiently addressed.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of ametoctradin was investigated in the framework of the EU pesticides peer review (Netherlands, 2010; EFSA, 2012b). These studies showed that ametoctradin is hydrolytically stable under standard processing conditions.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of ametoctradin residues in plants were assessed during the EU pesticides peer review (EFSA, 2012b). A high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) method with methanol/water (1/1 v/v) extraction and sodium hydroxide, dichloromethane partitioning was concluded to be sufficiently validated in plants at or above the LOQ of 0.01 mg/kg.

For the intended use, a sufficiently validated analytical method for enforcement is available.

1.1.5. Stability of residues in plants

The storage stability of ametoctradin in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2012b). EFSA concluded that residues of ametoctradin, M650F03 and M650F04 were stable in high water content commodities to which the herb crop group belongs for at least 36 months when stored at –20°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in primary and rotational crops, the results of hydrolysis studies, the toxicological significance of metabolites, the capabilities of enforcement analytical method, the following residue definitions were proposed in the framework of the EU peer review:

- residue for risk assessment: ametoctradin (primary crops, processed products) sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin (rotational crops);
- residue definition for enforcement: ametoctradin (primary crops, processed products).

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical.

For the intended use, the above cited residue definitions are appropriate and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant proposed to extrapolate the results from four indoor residue trials performed in open leaf lettuces according to the intended good agricultural practice (GAP) for herbs and edible flowers. These trials were already assessed by EFSA and used to
set, by extrapolation, the current MRL of 20 mg/kg for sage and basil (EFSA, 2015). These studies were considered as valid with regards to storage stability and analytical method applied.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of ametoctradin residues to crops that are grown in rotation has been assessed in EU pesticides peer review (EFSA, 2012b). The only residues observed in significant concentrations in the mature crops were the metabolites M650F03 and M650F04. The data indicated that at PBI of 120 days or beyond crop parts for human consumption are not expected to contain residues above the LOQ with the exception of cereal grains. In grains, the sum of ametoctradin, M650F03 and M650F04 for up to 0.33 mg/kg was found after treatment of the bare soil at the dose of 960 g/ha (about 1.3N the intended rate on herbs and edible flowers). Significant residue levels were also found in potential animal feed items (up to 1.25 mg eq/kg in cereal straw).

Based on the available rotational crop field trials, there is clear evidence that residues of metabolites M650F03 and M650F04 are expected to be present at a level above 0.01 mg/kg in all the edible parts of the crops grown in rotation to the primary crops treated in compliance with the intended GAP. Therefore, EFSA confirms the previous recommendation (EFSA, 2015) that Member States should consider specific risk mitigation measures when granting an authorisation at national level to avoid the presence of residues in rotational crops.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crops under assessment were not provided and are not required since the total theoretical maximum daily intake (TMDI) is expected to be below the trigger value of 10% of the ADI (European Commission, 1997d).

1.2.4. Proposed MRLs

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

2. Residues in livestock

Not relevant as herbs and edible flowers are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). 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 as ARfD unnecessary) was derived in the framework of the EU pesticides peer review (European Commission, 2013). The same reference values as for ametoctradin are applied for metabolites M650F03 and M650F04 (EFSA, 2012b).

The potential consumer exposure with regard to residues of the soil metabolites M650F03 and M650F04 in groundwater used as drinking water was assessed during the EU peer review. Based on the predicted environmental concentration (PEC) groundwater (gw) levels calculated for the representative uses on potato and tomato, the additional intake through drinking water of M650F03 and M650F04 was estimated to be < 0.04% of the ADI for all consumer groups considered (EFSA, 2012b). Since the intended GAP on herbs and edible flowers is less critical compared to the representative uses, the PECgw values and the intake calculation through drinking water remain unchanged.

The long-term exposure assessment was performed, taking into account the STMR values derived for the herbs and edible flowers assessed in this application and in previous MRL applications (EFSA, 2009, 2012a, 2014, 2015, 2016); for the remaining commodities, the existing EU MRLs were selected as input values. The complete list of input values is presented in Appendix D.2.
The estimated long-term dietary intake was in the range of 0–0.14% of the ADI. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix B.3.

EFSA concluded that the long-term intake of residues of ametoctradin resulting from the existing and the intended uses on ametoctradin is unlikely to present a risk to consumer health. It was not necessary to assess short-term consumer risk for ametoctradin.

Conclusions and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive a MRL proposal for the herbs and edible flowers under consideration.

An adequate analytical method for enforcement is available to control the residues of ametoctradin in the commodities under consideration.

Based on the risk assessment results, EFSA concluded that the intake of residues resulting from the use of ametoctradin according to the reported agricultural practice is unlikely to present a risk to consumer health.

The MRL recommendations are summarised in Appendix B.4.

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**Abbreviations**

- **a.s.** active substance
- **ADI** acceptable daily intake
- **ARfd** acute reference dose
- **BBCH** growth stages of mono- and dicotyledonous plants
- **bw** body weight
- **CCPR** Codex Committee on Pesticide Residues
- **CF** conversion factor for enforcement to risk assessment residue definition
- **DALA** days after last application
- **DAR** draft assessment report
- **DAT** days after treatment
- **DT90** period required for 90% dissipation (define method of estimation)
- **EMS** evaluating Member State
- **eq** residue expressed as a.s. equivalent
- **FAO** Food and Agriculture Organization of the United Nations
- **GAP** Good Agricultural Practice
- **HPLC–MS/MS** high-performance liquid chromatography with tandem mass spectrometry
- **HR** highest residue
- **IEEDI** international estimated daily intake
- **IESTI** international estimated short-term intake
- **ISO** International Organisation for Standardisation
- **IUPAC** International Union of Pure and Applied Chemistry
- **JMPR** Joint FAO/WHO Meeting on Pesticide Residues
- **LOQ** limit of quantification
- **MRL** maximum residue level
- **NEU** northern Europe
- **OECD** Organisation for Economic Co-operation and Development
- **PBI** plant back interval
- **PEC** predicted environmental concentration
- **PECgw** predicted environmental concentration in groundwater
- **PHI** preharvest interval
- **PRIMo** (EFSA) Pesticide Residues Intake Model
| Acronym | Definition |
|---------|------------|
| RA      | risk assessment |
| RD      | residue definition |
| RMS     | rapporteur Member State |
| SANCO   | Directorate-General for Health and Consumers |
| SC      | suspension concentrate |
| SEU     | southern Europe |
| SMILES  | simplified molecular-input line-entry system |
| STMR    | supervised trials median residue |
| TMDI    | theoretical maximum daily intake |
| TRR     | total radioactive residue |
| WHO     | World Health Organization |
| Crop and/or situation | NEU, SEU, MS or country | F G or T \(^{(a)}\) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI \(^{(d)}\) | Remarks |
|-----------------------|-------------------------|-------------------|-----------------------------------|-------------|-----------------|------------------------|----------|---------|
| Herbs and edible flowers | BE | I | Downey mildew | SC | 300 g/L | Foliar spraying | 1-3 | 7 days | 240 | 7 |

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; MRL: maximum residue level; a.s.: active substance; SC: suspension concentrate.

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

\(^{(b)}\): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

\(^{(c)}\): 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 selected end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crops       | Applications                  | Sampling |
|----------------------------------|-------------|-------------|-------------------------------|----------|
| Fruit crops                      | Tomato      | Foliar, 3 × 300 g/ha | 1 DALA                      |
| Root crops                       | Potato      | Foliar, 3 × 440 g/ha  | 14 prior DAT, 7 DALA        |
| Leafy crops                      | Lettuce     | Foliar, 3 × 220 g/ha  | 7 DALA                      |

Radiolabelled active substance: mixture of [2,7-14C] and [2,5,7-13C] ametoctradin (Netherlands, 2010)

| Rotational crops (available studies) | Crop groups | Crops         | Application                  | PBI (DAT) |
|-------------------------------------|-------------|---------------|------------------------------|-----------|
| Root/tuber crops                    | Radish      | To bare soil at 1,440 g/ha | 30, 120, 365 |
| Leafy crops                         | Lettuce     |               |                              |
| Cereals                             | Wheat       | To bare soil at 1,440 g/ha | 30, 120, 365 |
| Other                               | –           |               |                              |

Radiolabelled active substance: mixture of non- and radio-labelled (2,7-14C and 2,5,7-13C) ametoctradin (Netherlands, 2010)

| Processed commodities (hydrolysis study) | Conditions                               | Investigated? |
|------------------------------------------|------------------------------------------|----------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4)      | Yes            |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes            |
|                                          | Sterilisation (20 min, 120°C, pH 6)      | Yes            |

Comment: Ametoctradin showed to be stable (EFSA, 2012b)

DALA: days after last application; DAT: days after treatment; PBI: plant back interval.
Can a general residue definition be proposed for primary crops?  

| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes |
|---|---|

Rotational crop and primary crop metabolism similar?  

| Plant residue definition for monitoring (RD-Mo) | Ametoctradin |
| Plant residue definition for risk assessment (RD-RA) | Primary crops, processed commodities: Ametoctradin, Rotational crops: sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin |

Conversion factor (monitoring to risk assessment)  

| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | HPLC–MS/MS (BASF method L0117/01), LOQ 0.01 mg/kg (EFSA, 2012b) |

### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability (Months/years) |
|---|---|---|---|---|
| High water content | Tomato | –20 | 3 years |
| Dry/high starch | Potato | –20 | 2 years |
| No group | Cereal grain | –20 | 2 years |
| | Cereal straw | –20 | 2 years |

Comment: storage stability of metabolites M650F03 and M650F04 same as the parent compound (EFSA, 2012b)
### Magnitude of residues in plants

#### Summary of residues data from the supervised residue trials

| Crop (supervised trials) | Region/indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments (OECD calculations) | MRL proposals (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|--------------------------|--------------------------|---------------------------------------------------------------|-----------------------------|----------------------|----------------|----------------|-------------|
| Lettuces                 | NEU                      | 1.2; 6.3; 7.5\(^{(e)}\); 9.2\(^{(e)}\) | Open leaf varieties        |                      | 20             | 9.2            | 6.9          | 1.0         |

MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development.

- \(^{(a)}\): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
- \(^{(b)}\): Highest residue according to the residue definition for monitoring.
- \(^{(c)}\): Supervised trials median residue according to the residue definition for monitoring.
- \(^{(d)}\): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
- \(^{(e)}\): Higher residue measured at a longer PHI (13/14 days) than the PHI of the intended GAP (7 days).
B.1.2.2. Conversion factors for risk assessment in plant products

Not applicable.

B.1.2.3. Residues in succeeding crops

| Confined rotational crop study (quantitative aspect) | Significant residues of soil metabolites (> 0.01 mg/kg per metabolite) in lettuces planted 30 DAT, in forage, straw and grain of wheat planted 30, 120, and 365 DAT, in radish tops planted 30, 120 and 365 DAT, and radish roots planted 30 and 120 DAT (EFSA, 2012b) |
| --- | --- |
| Field rotational crop study | Field trial with carrots, cauliflowers, lettuces, and wheat planted to bare soil treated at 960 g/ha. No residues of parent > 0.01 mg/kg, except for cauliflowers (max 0.02 mg/kg) and wheat straw (max 0.04 mg/kg) at plant back interval of 30 DAT. Low to significant residues of M650F03 and M650F04 at 30, 120 and 365 DAT. Maximum residues in rotational crops as sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin: 0.058 mg/kg in carrots, 0.060 mg/kg in cauliflowers, 0.037 mg/kg in lettuces, 0.326 mg/kg and 1.25 mg/kg in wheat grain and straw, respectively (EFSA, 2012b). |

B.1.2.4. Processing factors

Not relevant.

B.2. Residues in livestock

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

Not relevant.

B.2.1.2. Stability of residues in livestock

Not relevant.

B.2.2. Magnitude of residues in livestock

Not relevant.

B.3. Consumer risk assessment

| ARfD | Not necessary (European Commission, 2013) |
| ADI | 10 mg/kg bw per day (European Commission, 2013) |
| Highest IEDI, according to EFSA PRIMo | 0.14% ADI (French toddler diet) |
| Contribution of crops assessed: Parsley: 0.003% of ADI Celery leaves: 0.002% of ADI Remaining crops 0.001% of ADI or less |
| Assumptions made for the calculations | The calculation is based on the median residue levels available for raw agricultural commodities and existing |
**B.4. Recommended MRLs**

| Code<sup>(a)</sup> | Commodity               | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                      |
|-------------------|-------------------------|-------------------------|-------------------------|-----------------------------------------------------------|
| 0256010           | Chervil                 | 0.01*                   | 20                      | Indoor use supported by extrapolation from data on open leaf lettuces. Unlikely to pose consumer health risk |
| 0256020           | Chives                  | 0.01*                   | 20                      |                                                           |
| 0256030           | Celery leaves           | 0.01*                   | 20                      |                                                           |
| 0256040           | Parsley                 | 0.01*                   | 20                      |                                                           |
| 0256060           | Rosemary                | 0.01*                   | 20                      |                                                           |
| 0256070           | Thyme                   | 0.01*                   | 20                      |                                                           |
| 0256090           | Laurel/bay leave        | 0.01*                   | 20                      |                                                           |
| 0256100           | Tarragon                | 0.01*                   | 20                      |                                                           |
| 0256990           | Others herbs and edible flowers | 0.01*   | 20                      |                                                           |

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.

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MRLs
Additional potential contribution through drinking water (M650F03 and M650F04) < 0.04% of ADI
## Appendix C – Pesticide Residue Intake Model (PRIMo)

### Ametoctradin

| Status of the active substance | Approved | Code no. | LOQ (mg/kg bw) | Proposed LOQ |
|--------------------------------|----------|----------|----------------|--------------|
| ADI (mg/kg bw/day)             | 10       | COM      | 2013           | n.n.         |
| Source of ADI:                 | COM      | Source of ARfD: | COM          |
| Year of evaluation:            | 2013     | Year of evaluation: | 2013  |

#### Toxicological end points

| No of diets exceeding ADI: | Highest calculated TMDI values in % of ADI | Highest contributor to MS diet | Commodity/group of commodities | 2nd contributor to MS diet | Commodity/group of commodities | 3rd contributor to MS diet | Commodity/group of commodities | pTMRls at LOQ in % of ADI |
|----------------------------|--------------------------------------------|--------------------------------|--------------------------------|---------------------------|--------------------------------|---------------------------|--------------------------------|----------------------------|
|                            | TMDI (range) in % of ADI                   |                                |                               |                           |                               |                           |                                |                            |
| 0.14                       | 0.08 Spinach                              | 0.01 Milk and cream            | 0.01 Lettuce                  | 0.01                   | Leek                         | 0.01 Milk and cream            | 0.01 Milk and cream            | 0.01 Milk and cream            |
| 0.12                       | 0.05 Spinach                              | 0.02 Spinach                   | 0.02 Spinach                  | 0.02                   | Spinach                      | 0.02 Spinach                   | 0.02 Spinach                   | 0.02 Spinach                   |
| 0.08                       | 0.06 Spinach                              | 0.01 Table grapes              | 0.01 Table grapes             | 0.01                   | Table grapes                 | 0.01 Table grapes             | 0.01 Table grapes             | 0.01 Table grapes             |
| 0.07                       | 0.03 Spinach                              | 0.01 Head cabbage              | 0.01 Head cabbage             | 0.01                   | Head cabbage                 | 0.01 Head cabbage             | 0.01 Head cabbage             | 0.01 Head cabbage             |
| 0.07                       | 0.02 Spinach                              | 0.01 Wine grapes               | 0.01 Wine grapes              | 0.01                   | Wine grapes                  | 0.01 Wine grapes              | 0.01 Wine grapes              | 0.01 Wine grapes              |
| 0.07                       | 0.02 Spinach                              | 0.01 Spinach                   | 0.01 Spinach                  | 0.01                   | Spinach                      | 0.01 Spinach                   | 0.01 Spinach                   | 0.01 Spinach                   |
| 0.06                       | 0.03 Chinese cabbage                      | 0.01 Head cabbage              | 0.01 Head cabbage             | 0.01                   | Head cabbage                 | 0.01 Head cabbage             | 0.01 Head cabbage             | 0.01 Head cabbage             |
| 0.06                       | 0.02 Spinach                              | 0.01 Chinese cabbage           | 0.01 Chinese cabbage          | 0.01                   | Chinese cabbage              | 0.01 Chinese cabbage          | 0.01 Chinese cabbage          | 0.01 Chinese cabbage          |
| 0.06                       | 0.02 Spinach                              | 0.01 Sprouts                   | 0.01 Sprouts                  | 0.01                   | Sprouts                      | 0.01 Sprouts                  | 0.01 Sprouts                  | 0.01 Sprouts                  |
| 0.05                       | 0.04 Spinach                              | 0.00 Lettuce                   | 0.00 Lettuce                  | 0.00                   | Lettuce                      | 0.00 Lettuce                   | 0.00 Lettuce                   | 0.00 Lettuce                   |
| 0.06                       | 0.02 Wine grapes                          | 0.00 Table grapes              | 0.00 Table grapes             | 0.00                   | Table grapes                 | 0.00 Table grapes             | 0.00 Table grapes             | 0.00 Table grapes             |
| 0.05                       | 0.02 Lettuce                              | 0.00 Milk and cream            | 0.00 Milk and cream           | 0.00                   | Milk and cream               | 0.00 Milk and cream           | 0.00 Milk and cream           | 0.00 Milk and cream           |
| 0.03                       | 0.01 Wine grapes                          | 0.00 Spinach                   | 0.00 Spinach                  | 0.00                   | Spinach                      | 0.00 Spinach                   | 0.00 Spinach                   | 0.00 Spinach                   |
| 0.03                       | 0.01 Milk and cream                       | 0.00 Table grapes              | 0.00 Table grapes             | 0.00                   | Table grapes                 | 0.00 Table grapes             | 0.00 Table grapes             | 0.00 Table grapes             |
| 0.02                       | 0.01 Wine grapes                          | 0.00 Chinese cabbage           | 0.00 Chinese cabbage          | 0.00                   | Chinese cabbage              | 0.00 Chinese cabbage          | 0.00 Chinese cabbage          | 0.00 Chinese cabbage          |
| 0.02                       | 0.01 Head cabbage                         | 0.00 Chinese cabbage           | 0.00 Chinese cabbage          | 0.00                   | Chinese cabbage              | 0.00 Chinese cabbage          | 0.00 Chinese cabbage          | 0.00 Chinese cabbage          |
| 0.02                       | 0.01 Lettuce                              | 0.00 Lettuce                   | 0.00 Lettuce                  | 0.00                   | Lettuce                      | 0.00 Lettuce                   | 0.00 Lettuce                   | 0.00 Lettuce                   |
| 0.02                       | 0.01 Head cabbage                         | 0.00 Lettuce                   | 0.00 Lettuce                  | 0.00                   | Lettuce                      | 0.00 Lettuce                   | 0.00 Lettuce                   | 0.00 Lettuce                   |

### Chronic risk assessment – refined calculations

**Conclusion:**
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRls were below the ADI. A long-term intake of residues of Ametoctradin is unlikely to present a public health concern.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Not relevant.

D.2. Consumer risk assessment

| Commodity                              | Chronic risk assessment | Acute risk assessment |
|----------------------------------------|-------------------------|-----------------------|
|                                        | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Herbs and edible flowers\(^{(a)}\)     | 6.90                    | STMR (lettuce)        | Acute risk assessment not performed as setting of ARfD considered unnecessary |
| Grapes (table, wine)                   | 0.96                    | STMR (EFSA, 2009)     |                       |
| Potatoes                               | 0.01                    | STMR (EFSA, 2012a)    |                       |
| Tropical root and tuber vegetables    | 0.01                    | STMR (EFSA, 2012a)    |                       |
| Garlic, onions, shallots               | 0.22                    | STMR (EFSA, 2012a)    |                       |
| Spring onions                          | 1.60                    | STMR (EFSA, 2016)     |                       |
| Tomatoes                               | 0.26                    | STMR (EFSA, 2009)     |                       |
| Sweet peppers/bell peppers            | 0.36                    | STMR (EFSA, 2009)     |                       |
| Aubergines/eggplants                   | 0.17                    | STMR (EFSA, 2012a)    |                       |
| Okra/lady’s fingers)                   | 0.16                    | STMR (EFSA, 2012a)    |                       |
| Cucumber, edible peel                  | 0.16                    | STMR (EFSA, 2012a)    |                       |
| Melons, watermelons                    | 0.66                    | STMR (EFSA, 2012a)    |                       |
| Pumpkins                               | 0.34                    | STMR (EFSA, 2012a)    |                       |
| Broccoli                               | 1.70                    | STMR (EFSA, 2012a)    |                       |
| Head cabbages                          | 2.00                    | STMR (EFSA, 2012a)    |                       |
| Chinese cabbages                       | 16.0                    | STMR (EFSA, 2012a)    |                       |
| Lamb’s lettuces/corn salads            | 20.0                    | STMR (EFSA, 2009)     |                       |
| Lettuces                               | 5.20                    | STMR (EFSA, 2012a)    |                       |
| Lettuces and salad plants, except lamb’s lettuces and lettuces | 8.50 | STMR (EFSA, 2012a) |                       |
| Spinaches and similar leaves           | 13.0                    | STMR (EFSA, 2012a)    |                       |
| Celeries, Florence fennels             | 5.50                    | STMR (EFSA, 2012a)    |                       |
| Leeks                                  | 1.06                    | STMR (EFSA, 2012a)    |                       |
| Hops                                   | 35.4                    | STMR (EFSA, 2014)     |                       |
| All other commodities of plant and animal origin | MRL | Regulation (EU) No 2016/1902 |                       |

STMR: supervised trials median residue; MRL: maximum residue level; ARfD: acute reference dose.

\(^{(a)}\): For sage and basil, the STMR of 6.90 mg/kg was derived based on the same dataset in a previous EFSA reasoned opinion (EFSA, 2015).
**Appendix E – Used compound codes**

| Code/trivial name       | Chemical name/SMILES notation<sup>(a)</sup>                                                                 | Structural formula<sup>(a)</sup> |
|------------------------|-------------------------------------------------------------------------------------------------------------|---------------------------------|
| Ametoctradin (BAS560F) | 5-Ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine Nc1(cCCCCCCCC)c(nc2ncnn12)CC                          | ![Structural formula](image1.png) |
| M650F03                | (7-Amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidin-6-yl)acetic acid O=C(O)c1c(N)n2ncnc2nc1CC                       | ![Structural formula](image2.png) |
| M650F04                | 7-Amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidine-6-carboxylic acid O=C(O)c1c(N)n2ncnc2nc1CC                      | ![Structural formula](image3.png) |

SMILES: simplified molecular-input line-entry system.

<sup>(a)</sup>: (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).