The evaluation of a new MRL for ametoctradin in honey

UK Competent Authority Evaluation Report and Reasoned Opinion

- Prepared under Article 8 of Assimilated Regulation 396/2005 and Data Requirements of Assimilated Regulation 544/2011
- Application Reference Number: COP 2023/01969

January 2026

Contents

Summary

In accordance with Article 6 of Assimilated Regulation 396/2005,[1] HSE received an application from BASF plc on 25 June 2021 to amend the existing MRLs for the ametoctradin in honey. This was to accommodate an authorisation in GB.

The applicant submitted a dossier in accordance with the data requirements outlined in Assimilated Regulation 544/2011.

In accordance with Article 8 of Assimilated Regulation 396/2005, HSE evaluated the dossier in accordance with the uniform principles as outlined in Article 29(6) of Assimilated Regulation 1107/2009.[2]

Based on the assessment HSE prepared an Evaluation Report that included its Reasoned Opinion on the risk to consumers associated with amending the MRLs. HSE also took into account the data assessed for the approval of the active substance and previous Reasoned Opinions.

Sufficiently validated analytical methods for the determination of ametoctradin in honey, in line with the enforcement residue definition for honey, are available to support the MRL under consideration in the MRL application.

Toxicological reference values were established for the approval of the active substance: an ADI of 10 mg/kg bw/day and no ARfD allocated or required.

According to SANTE/11956/2016 rev. 9, in the absence of honey metabolism studies, the risk assessment residue definition for honey can be derived by taking into account the nature of residues in plants and the stability of the residues during pasteurisation.

Consideration of primary and rotational crop metabolism has been made in order to derive appropriate definitions for honey. The metabolism of ametoctradin in primary crops was investigated in root, leafy and fruit crop groups following foliar applications for the approval of the active substance (EFSA Conclusion, 2012).

The residue definition for risk assessment (RD-RA) in primary crops has been agreed as:

- Ametoctradin

[1] Assimilated Regulation No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin

[2] Assimilated Regulation No 1107/2009 concerning the placing of plant protection products on the market

The residue definition for enforcement (RD-Enf) in primary crops has been agreed as:

- Ametoctradin

Hydrolysis of ametoctradin under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrate that ametoctradin is stable under standard conditions, therefore specific residue definitions for processed commodities are not required.

Residues in rotational crops were considered for the approval of the active substance. The metabolism studies demonstrated that specific residue definitions for rotational crops are required.

The RD-RA in rotational crops has been agreed as:

- Sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin.

The RD-Enf in rotational crops has been agreed as:

- Ametoctradin

Considering the metabolism and hydrolysis data, the residue definition for risk assessment (RD-RA) in honey has been agreed as:

- Sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin.

The residue definition for enforcement (RD-Enf) in honey has been agreed as:

- Ametoctradin

Four tunnel trials on honey conducted in Italy, Austria and Spain were submitted to support an MRL for honey. The trials are supported by validated analytical methods and storage stability data.

There is no consumption data in the UK models for honey. Nonetheless, a chronic risk assessment for the current GB MRLs has been performed in the UK model. The highest UK NEDI was <1% of the ADI (toddler). The risk assessment for the proposed honey MRL is covered by PRIMo which has consumption data for honey. The highest PRIMo IEDI was 0.5% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of honey from melliferous crops treated with ametoctradin.

Consideration of acute exposure was not required as the active substance is not acutely toxic and an ARfD has not been allocated.

HSE concludes that sufficient data have been provided to support the setting of a new MRL for ametoctradin in honey. These will not result in consumer exposures exceeding

the toxicological reference values at the proposed GAPs and therefore harmful effects on human health are not expected. HSE recommends that the MRL outlined in Table 0.1 is amended in the GB MRL Statutory Register.

Table 0.1 MRL recommended by HSE

Product code	**Product**	**Existing GB MRL (mg/kg)**	**New or amended GB MRL (mg/kg)**	**Comments**
Enforcement	**residue**	**definition**	**for honey:**	**Ametoctradin**
1040000	Honey and other apiculture products†	0.05*	5	The MRL is sufficiently supported by data. No health effects are expected.

* Indicates that the MRL is set at the limit of quantification/determination

† In Part 1 of the GB MRL Statutory Register the following footnote is relevant to MRLs for honey: 'No MRLs are applicable to other apiculture products until individual products have been identified and listed within this group.' Therefore, the MRL applies to honey only at

Background

Assimilated Regulation 396/2005 outlines the rules for setting MRLs in GB. Article 6 covers the submission of applications for MRLs, including the parties which can submit an application. Article 7 outlines that a dossier in accordance with the data requirements of Assimilated Regulation 1107/2009 must be provided.

On 25 June 2021, HSE accepted an application from BASF plc to set a new MRL for ametoctradin in honey.

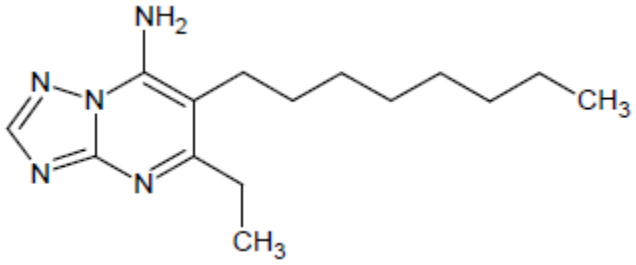
HSE evaluated the information submitted to uniform principles, as defined by Article 8 of Assimilated Regulation 396/2005 and prepared an Evaluation Report. HSE also took into account EFSA Reasoned Opinions and Conclusions on the peer review relating to decisions implemented in GB.

The Evaluation Report is the basis of HSE's Reasoned Opinion.

The active substance and its use pattern

Information on the active substance ametoctradin is outlined in Table 0.2.

Table 0.2 Information on the active substance

Common name (ISO)	Ametoctradin
Chemical name (IUPAC)	5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine
CAS number	865318-97-4
Structural formula	
Molecular formula	$C_{15}H_{25}N_5$
Molecular mass	275.4 g/mol

Ametoctradin is an approved active substance in GB. An EFSA Conclusion is available (EFSA, 2012). MRLs are established for ametoctradin in Part 3 of the GB MRL Statutory Register.

Appendix A outlines the GAPs (Good Agricultural Practices) supported in this application.

There are no CXLs available for ametoctradin in honey.

Assessment

1 Methods of Analysis

1.1 Methods for enforcement and monitoring of residues in food of plant origin

Not required as the MRL application does not require the setting or amendment of MRLs in food of plant origin.

1.2 Methods for enforcement and monitoring of residues in food of animal origin

A new HPLC-MS/MS method (method R0072/01) has been validated in this assessment for the determination of ametoctradin and its metabolites M650F03 and M650F04 in honey with an LOQ of 0.01 mg/kg per analyte. Full details and validation data for this method can be found in Appendix C.1.2. This method is sufficient to determine residues of ametoctradin in line with the residue definition for enforcement.

Evaluation of extraction efficiency is not necessary for honey.

The commodity under consideration in the MRL application (honey) is covered by the analytical methods available.

Analytical methods for other products of animal origin are not required as the MRL application does not require the setting or amendment of MRLs in these products.

2 Mammalian toxicology

The toxicological end points established for the approval of the active substance are summarised in Table 2.1.

Table 2.1 Overview of the toxicological reference values for ametoctradin

TRVs	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA	2012	10 mg/kg bw/d	overall NOAEL of 1000 mg/kg bw per day	100
ARfD	EFSA	2012	Not allocated	No ARfD necessary	Not applicable

3 Residues in Plants

3.1 Primary crops

Metabolism in primary crops was investigated following foliar spray treatment in leafy crops (lettuce) root crops (potato) and fruit (tomato) for the approval of ametoctradin (EFSA, 2012).

The following summary is presented by EFSA (EFSA, 2012):

"The metabolism of ametoctradin was investigated in primary crops (lettuce, potato and tomato) and rotational crops (wheat, lettuce and radish). Based on the findings of these studies the residue definition for monitoring for plant commodities was proposed as ametoctradin. For risk assessment, ametoctradin was defined as the relevant residue for primary crops."

Table 3.1-1 Summary of the primary plant metabolism studies

Crop group	Crop(s)	Applications	DAT [(a)] (days)
Fruit	Tomato	Foliar, 3 x 300 g a.s/ha, 47, 54 and 61 days after planting	1
Root crops	Potato	Foliar, 3 x 441 g a.s./ha, 35, 21 and 7 days prior to harvest	7 & 14
Leafy crops	Lettuce	Foliar, 3 x 223 g a.s/ha, 21, 31 and 39 days after planting	7

(a) DAT where identification/characterisation of the residues has been investigated

As a consistent metabolic pathway was observed across crops from three crop groups, the available data are sufficient to support all crop groups.

A proposed cGAP on grapes is notified in Appendix A, which represents the use of ametoctradin on a melliferous crop. The application type in the primary crop metabolism studies is foliar spray, which is the same as the application type for the representative use.

The residue definition for risk assessment (RD-RA) in plants has been agreed as:

- Ametoctradin †

The residue definition for enforcement (RD- Enf) in plants has been agreed as:

- Ametoctradin

† A separate RD-RA applies to rotational crops (see Section 3.5)

3.2 Magnitude of residues in primary crops

Consideration of the magnitude of residues in primary crops is not required as this MRL application is for honey only. A study on the residues in honey following application on buckwheat as a representative primary crop has been evaluated in Section 5.

3.3 Conversion factors for risk assessment for products of plant origin

As the residue definitions for enforcement (RD-Enf) and risk assessment (RD-RA) are equivalent, conversion factors (CFs) for enforcement to risk assessment are not required.

3.4 Effect of industrial processing and/or household preparation

3.4.1 Nature of the residues in processed commodities

Hydrolysis of ametoctradin under representative conditions of pasteurisation, baking, brewing, boiling and sterilization was evaluated for the approval of active (EFSA, 2012).

Table 3.4.1 Overview of the available hydrolysis studies

Conditions	Ametoctradin (% applied radioactivity recovered)
30 min, 90°C, pH 4	109.3%
60 min, 100°C, pH 5	95.9%
20 min, 120°C, pH 6	97.2%

The hydrolysis data demonstrates that ametoctradin is stable across the standard conditions, therefore specific residue definitions for processed commodities have not been set.

Hydrolysis studies for the metabolites M650F03 and M650F04 found in rotational crops and included in the residue definition for risk assessment in rotational crops, are not available. Considering the overall low intake of ametoctradin and its metabolites compared to the ADI (<1%), the lack of studies investigating the hydrolytic stability of M650F03 and M650F04 is desirable but can be considered a minor deficiency and it is not expected to have an impact on the outcome of the risk assessment.

3.4.2 Magnitude of the residues in processed commodities

As this MRL application only concerns honey, and the contribution to the TMDI is low (<10% ADI), no consideration of the magnitude of residues in processed commodities is required.

3.5 Rotational crops

Rotational crop metabolism has been considered to confirm the nature of residues in honey and set appropriate residue definitions in honey.

3.5.1 Nature of residues (Confined metabolism study on rotational crops)

Metabolism in rotational crops was investigated following bare soil treatment in wheat (cereals), lettuce (leafy vegetables) and radish (root and tuber vegetables) for the approval of ametoctradin (EFSA, 2012).

Table 3.5-1 Summary of the available rotational crop metabolism studies

Crop groups	Crop(s)	PBI (days)	Comments
Root and tuber vegetables	Radish	30, 120, 365	Trials conducted with an application at 1440 g a.s./ha on bare soil.
Leafy vegetables	Lettuce	30, 120, 365	
Cereals	Wheat	30, 120, 365	

The following summary is presented by EFSA (EFSA, 2017):

"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)."

Metabolism in rotational crops was found to be via a different pathway to primary crops, therefore specific residue definitions for rotational crops are required.

The residue definition for risk assessment (RD-RA) in rotational crops has been agreed as:

- Sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin (necessary for combined exposure/risk assessment since metabolites may also occur in drinking water)

The residue definition for enforcement (RD- Enf) in rotational crops has been agreed as:

- Ametoctradin

As the RD-RA and RD-Enf are different the following molecular weight conversion factor has been calculated to express M650F03 and M650F04 residues as ametoctradin equivalents:

- Molecular weight conversion factor for calculation of M650F03 to parent ametoctradin is 1.245

The molecular weight of ametoctradin is 275.4 g/mol and the molecular weight of M650F03 is 221.2 g/mol. Therefore, to express M650F03 residues as ametoctradin, a molecular weight conversion factor of 1.245 is applied (275.4/221.2 = 1.245).

- Molecular weight conversion factor for calculation of M650F04 to parent ametoctradin is 1.329

The molecular weight of ametoctradin is 275.4 g/mol and the molecular weight of M650F04 is 207.2 g/mol. Therefore, to express M650F04 residues as ametoctradin, a molecular weight conversion factor of 1.329 is applied (275.4/207.2 = 1.329).

Due to the specific residue definition for rotational crops, additional consideration is required for the nature of the residues in honey following the foraging of rotational crops by bees (see Section 5).

3.5.2 Magnitude of residues (Rotational crop field trials)

Consideration of the magnitude of residues in rotational crops is required as residues of metabolites M650F03 and M650F04 cannot be excluded in succeeding crops.

Residues in rotational crops were investigated following bare soil treatment in carrots (root crops), cauliflower and lettuce (leafy crops) and wheat (cereals/grass crops) for the approval of ametoctradin (EFSA Conclusion, 2012). A further study on wheat with a PBI of 120 days was investigated during the peer review (EFSA Article 12 RO, 2012).

Table 3.5.2 Summary of the field rotational crop studies

Crop group	Crop	Crop part	App.		Residue levels (mg/kg)	
			PBI (day)	g a.s./ha	Ametoctradin	Sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin[(a)]
Root crops	Carrot	Roots	30	960	<0.01	0.042 – 0.058
			120		<0.01	<0.03
			360		<0.01	<0.03 – 0.03
		Tops	30		<0.01	0.106 – 0.138
			120		<0.01	<0.03 – 0.03

			360		<0.01	<0.03 – 0.058
Leafy crops	Lettuce	Head	30	960	<0.01	<0.03 – 0.037
			120		<0.01	<0.03
			360		<0.01	<0.03
		Whole plant	30		<0.01	<0.03 – 0.051
			120		<0.01	<0.03
			360		<0.01	<0.03
	Cauliflower	Inflorescence	30	960	<0.01	<0.03 – 0.060
			120		<0.01	<0.03
			360		<0.01	0.03 – 0.036
		Whole plant	30		<0.01	<0.03 – 0.114
			120		<0.01 – 0.020	<0.03
			360		<0.01	<0.03 – 0.03
Cereals/Grass crops	Wheat	Grain	30	960	<0.01	0.031 - 0.181
			120		<0.01	<0.03 – 0.326
			360		<0.01	<0.03 – 0.03
		Straw	30		<0.01 – 0.038	0.111 - 1.251
			120		<0.01	0.03 – 1.155
			360		<0.01	0.033 – 0.049
		Forage	30		<0.01	0.134 – 0.427
			120		<0.01	0.041 – 0.356
			360		<0.01	<0.03 – 0.047

[a] In line with RD-RA applicable to rotational crops. A molecular weight conversion factor of 1.245 is applicable for converting M650F03 into parent equivalents. A molecular weight conversion factor of 1.329 is applicable for converting M650F04 into parent equivalents.

The following summary is presented by EFSA (EFSA, 2017):

"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."

The rotational crop residues trials demonstrate residues are expected to be >0.01 mg/kg for the sum of ametoctradin, M650F03 and M650F04 residues expressed as ametoctradin,

in all crop groups across a range of PBIs. The rotational crop field study confirms the presence of metabolites M650F03 and M650F04 in rotational crops at significant levels and therefore supports the need for these residues to be included in the residue risk assessment definition for honey to cover the potential for bees to forage on succeeding crops.

In relation to honey, residues of M650F03 and M650F04 were analysed for in residue trials on honey arising from use of ametoctradin on buckwheat as the representative melliferous crop. For the purpose of this application, further information on the possible transfer of the metabolites M650F03 and M650F04 from the soil to the flowers and floral nectar of rotational crops would be desirable but is not required in accordance with SANTE/11956/2016 rev.9.

The transfer of residues from rotational crops to honey does not require further consideration. Residues of ametoctradin, M650F03 and M650F04 have been analysed for in trials on honey supporting this application (see Section 5).

4 Residues in livestock

No consideration of residues in products of animal origin is required as the commodity under consideration is not used as an animal feedstuff.

5 Residues in honey

5.1 Nature of residues (residue definitions)

According to SANTE/11956/2016 rev. 9, in the absence of honey metabolism studies, the risk assessment definition for honey can be derived by taking into account the nature of residues in primary crops, the degradation during pasteurisation and studies investigating the nature of residues in rotational crops.

The residue definitions for primary and rotational crops are different. The rotational crop residue definition is relevant to honey due to the likelihood of significant residues in aerial parts of rotational crops during the bee foraging period.

Ametoctradin was shown to be stable during pasteurisation so the production of honey by bees is considered unlikely to alter the nature of the residue. As such, the conclusions of the studies investigating the nature of residues in primary and rotational crops are used to derive the residue definitions for honey.

The residue definition for risk assessment (RD-RA) in honey can be agreed as:

- Sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin

The residue definition for enforcement (RD-Enf) in honey can be agreed as:

- Ametoctradin

As the RD-RA and RD-Enf are different the following molecular weight conversion factor has been calculated to express M650F03 and M650F04 residues as ametoctradin equivalents:

- Molecular weight conversion factor for calculation of M650F03 to parent ametoctradin is 1.245

The molecular weight of ametoctradin is 275.4 g/mol and the molecular weight of M650F03 is 221.2 g/mol. Therefore, to express M650F03 residues as ametoctradin, a molecular weight conversion factor of 1.245 is applied (275.4/221.2 = 1.245).

- Molecular weight conversion factor for calculation of M650F04 to parent ametoctradin is 1.329

The molecular weight of ametoctradin is 275.4 g/mol and the molecular weight of M650F04 is 207.2 g/mol. Therefore, to express M650F04 residues as ametoctradin, a molecular weight conversion factor of 1.329 is applied (275.4/207.2 = 1.329).

5.2 Magnitude of residues (field study)

Residue trials

1040000 Honey and other apiculture products

The proposed cGAP for ametoctradin on a crop with melliferous capacity is on grapes: 2 x 0.39 kg a.s./ha with an RTI of 10 days and a PHI of 35 days, BBCH 53 - 83. The cGAP allows for applications to take place prior to and during the flowering period (BBCH 60 - 69).

A full analysis of the newly submitted honey residue trials can be found in Appendix C.3.5. Data has been evaluated in accordance with SANTE/11956/2016 rev.9.

Four tunnel trials on buckwheat were conducted in Germany using an SC formulation, containing 75 g/L ametoctradin, in the 2020 growing season. The application rate in the trials was 3 x 0.39 kg ametoctradin/ha at BBCH 55 - 65 with a PHI of 7-14 days. Applications were performed during inflorescence at BBCH 55-59, at beginning of flowering at BBCH 61 - 63 and full flowering at BBCH 65. The application intervals were between 6 – 15 days. This is within the application growth stages of the proposed GAP for grapes (BBCH 53 - 83). Ametoctradin is not a systemic substance therefore the GAP in the honey trials allowed for two applications during the flowering period (BBCH 60 – 69).

Samples of honey were taken at maturity (water content < 20%, 7 - 14 days after the last application). Only 20 g of honey was taken per sample rather than the 100 g recommended. Nonetheless, the samples are still considered representative, as it is often difficult for larger quantities of honey to be produced within the short time frame, and the deviation is not expected to affect the outcome of the assessment.

The total application rate used in the trials is overdosed (1.5N) compared to the proposed cGAP on grape. It is noted that the individual application rates in the trials compared to the GAP are identical and it is the number of applications that varies; three applications in the trials vs two applications in the GAP. Ametoctradin is non-systemic and is non-persistent in the environment (the field DT_{90} reported in the soil degradation studies evaluated for the approval was 13.3 days). The residue decline data evaluated to support the use on grapes and considered for the approval indicates that ametoctradin would be expected to decline between applications over 10 days. Residue trials, conducted at 2 x 0.39 kg as/ha, for grapes (HSE internal reference COP 2023/01596, W002116137, RR B7 UK), demonstrate that residues in the leaves were significantly less at 0 DBLA (days before last application) compared to the residue 0 days after the last application. In the grapes, the residue at 0

DBLA was < 0.01 mg/kg, with residues at a PHI of 35 days ranging from 0.25 mg/kg – 0.96 mg/kg. Additionally, as ametoctradin is non-systemic, it can be considered unlikely that in the trials for honey that the first application of ametoctradin made at inflorescence would translocate in the plant to the nectar. Based on the evidence available, ametoctradin is expected to decline between applications; although there is uncertainty around the rate of decline between applications, and hence there is uncertainty on the overall contribution of each individual application to the total residue and it is not possible to conclude that the final application will definitely drive the residue. However, in the specific context of residues in honey, it is reasonable to use these trials for MRL setting.

A summary of the residue data arising from the trials on honey is presented in Table 5.2.

At a PHI of 7 – 14 days, metabolites M650F03 and M650F04 were determined as <LOQ in all trials except one where a residue of M650F04 was determined at 0.078 mg/kg. This represented 6.5% percent of parent residue for this trial. It is notable however that substantive residues of M650F03 and M650F04 were determined in the aerial parts of the crop (inflorescences) at shorter PHI, from spray application of parent only. These residues represented a maximum of 0.33% percent of parent residues. The trials were not designed to account for residues of soil metabolites (M650F03 and M650F04) taken up by succeeding crops planted on soil previously treated with ametoctradin. Therefore, the residue levels of the metabolites M650F03 and M650F04 may be underestimated, compared to the level in honey produced under real field conditions, where bees can forage on crops grown on soil containing residues of M650F03 and M650F04 from previous treatments. Further information on the potential transfer of residues of the metabolites M650F03 and M650F04 from rotational crops to honey via soil uptake would therefore be desirable. However, considering the overall low intake of ametoctradin and its metabolites compared to the ADI (<1%), the lack of further information on the transfer of residues of the metabolites M650F03 and M650F04 from rotational crops to honey via soil uptake, can be considered a minor deficiency and it is not expected to have an impact on the outcome of the risk assessment.

Future consideration of potential rotational crop metabolite residues in honey may be needed for other uses where there is the potential for significant honey residues arising from rotated crops.

Storage stability

Sufficient storage stability in honey is available in the new stability study (Appendix C.3.6.3) to support the maximum storage period of 142 days in the trials on honey.

Analytical methods

Analysis was performed using HPLC-MS/MS method included in Study Report No. 886594, (method R0072/01). Full details and validation data for this method can be found in Appendix C.1.2.

Analytical method R0072/01 is satisfactorily validated according to SANTE/2020/12830 rev.1 for ametoctradin, M650F03 and M650F04 with an LOQ of 0.01 mg/kg for each analyte in honey and pollen. Acceptable mean procedural recovery data in the range 72.1 – 102% for each analyte using an appropriate number of samples were presented. The method was not validated for inflorescences, however acceptable procedural recoveries were provided. As residue values in inflorescences are not relied upon for the setting of the honey MRL, the lack of validation data is deemed acceptable. Extraction efficiency was not investigated in the report however this does not need addressing for honey methods.

Table 5.2 Overview of the available residue trials data

Commodity	Region/ Indoor (a)	Residue levels (mg/kg) observed in the trials representative for the intended GAPs (b)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
RD-RA: **RD-Enf:**	**Sum of** **Ametoctradin**	**ametoctradin, M650F03 and**	**M650F04 expressed as**	**ametoctradin**		
Honey produced from buckwheat (3 x 390 g/ha, BBCH 63-65, PHI 7-14 d)	NEU / Tunnel	RD-RA: 2 x 0.10, 1.29, 1.83 RD-Enf: 0.077, 0.079, 1.20, 1.80	MRL_{OECD}: 4.22 / 5 mg/kg	**5**	1.83	0.695

(a) GB or the country for an import tolerance and whether the GAP is for an outdoor use or an indoor/protected/glasshouse use.

(b) Residue levels in trials conducted according to GAPs reported in ascending order. When residue definitions for enforcement and risk assessment differ, **Enf/RA** differentiate data expressed according to the residue definition for **Enf**orcement and **R**isk **A**ssessment.

(c) **HR**: Highest Residue according to the residue definition for risk assessment (within brackets when expressed according to the residue definition for enforcement: HR_{Enf}).

(d) **STMR**: Supervised Trials Median Residue according to the residue definition for risk assessment (within brackets when expressed according to the residue definition for enforcement: $STMR_{Enf}$).

6 MRLs for products not covered in Sections 3 and 4

This section is to cover MRLs that can be extrapolated to other products included in Part 1 of the GB MRL Statutory Register but are not covered in Sections 3 and 4 of this ER/RO. Examples include MRLs for edible offals (other than liver and kidney) or MRLs to cover products derived from other species such as goat or equine.

No MRL extrapolations are recommended on the basis of this assessment.

7 Consumer risk assessment

7.1 Dietary Exposure

Consumer intake calculations have been performed using the UK chronic dietary exposure model and the EFSA PRIMo model.

The chronic risk assessments have been calculated based on the uses of ametoctradin considered in this application, the uses considered in previous assessments supporting existing GB MRLs (EFSA, 2017), and, for the remaining commodities, the existing MRLs established in the GB MRL Statutory Register.

Consideration of acute exposure is not required as the active substance is not acutely toxic and an ARfD has not been allocated.

UK NEDIs
There is no consumption data in the UK models for honey. As there is no suitable surrogate commodity to cover the lack of consumption data then the dietary exposures estimated using EFSA PRIMo are likely to cover UK consumers. In addition, the EFSA PRIMo includes the WHO/GEMS food consumption data and includes European consumption data that are in the same WHO/GEMS food clusters as the UK.

The UK NEDIs for the active substance and commodities listed in Table 7.1-1 have been calculated for ten consumer groups using the UK chronic model (version 1.1) as detailed in Regulatory Update 21/2005. The following assumptions have been made:

- For the NEDIs, the 'Rees-Day' approach is taken which sums the two highest 97.5th percentile intakes and the mean intakes for all remaining commodities.
- All produce eaten which may have been treated has been treated and contains residues at the levels given in Table 7.1-1.
- There is no loss of residue during transport, storage or processing of foods prior to consumption.

The input values for the UK consumer risk assessment are given in Table 7.1-1.

Table 7.1-1 Input values for the UK consumer risk assessment

Commodity	**Chronic risk assessment**	
	Input (mg/kg)	**Comment**
RD-RA in plants:	**Ametoctradin**	
Table grapes	0.96	STMR (EFSA, 2009)
Wine grapes	0.96	STMR (EFSA, 2009)
Yams	0.01*	STMR (EFSA, 2012)
Garlic	0.22	STMR (EFSA, 2012)
Onions	0.22	STMR (EFSA, 2012)
Spring onions	1.6	STMR (EFSA, 2016)
Tomatoes	0.26	STMR (EFSA, 2014)
Peppers	0.16	STMR (EFSA, 2017)
Aubergines	0.17	STMR (EFSA, 2017)
Cucumbers	0.12	STMR (EFSA, 2012)
Gourd	0.66	STMR (EFSA, 2017)
Courgettes, marrow	0.16	STMR (EFSA, 2012)
Gherkins	0.16	STMR (EFSA, 2012)
Melon	0.66	STMR (EFSA, 2012)
Broccoli	1.7	STMR (EFSA, 2012)
Head cabbage	2.0	STMR (EFSA, 2012)
Chinese cabbage	16	STMR (EFSA, 2012)
Cress	8.5	STMR (EFSA, 2012)
Lettuce	5.2	STMR (EFSA, 2012)
Spinach	13	STMR (EFSA, 2012)
Chicory, parsley	6.9	STMR (EFSA, 2017)
Celery	5.5	STMR (EFSA, 2012)
Fennel	5.5	STMR (EFSA, 2012)
Leeks	1.06	STMR (EFSA, 2012)
Potatoes	0.01*	STMR (EFSA, 2012)
Hops	35.4	STMR (EFSA, 2014)
All other commodities	MRL	GB MRL Statutory Register (Regulation (EU) 2018/70)

* indicates residue at LOQ

Model outputs for the UK chronic model (version 1.1) is presented in Appendix B.

PRIMo

The PRIMo IEDIs for the active substance and commodities listed in Table 7.2 have been calculated using PRIMo revision 3.1 – Pesticide Residues Intake Model.

The following assumptions have been made:

- All produce eaten which may have been treated, has been treated and contains residues at the levels as given in Table 7.1-2.
- There is no loss of residue during transport or storage, or processing of foods prior to consumption.

The input values for the PRIMo risk assessment are given in Table 7.2.

Table 7.1-2 Input values for the PRIMo consumer risk assessment

Commodity	**Chronic risk assessment**	
	Input (mg/kg)	**Comment**
RD-RA for honey: Sum of ametoctradin	**ametoctradin, M650F03**	**and M650F04 expressed as**
Honey	**0.695**	**$STMR_{RA}$ (current assessment)**
RD:RA for plants:	**Ametoctradin**	
Table grapes	0.96	STMR (EFSA, 2009)
Wine grapes	0.96	STMR (EFSA, 2009)
Potatoes	0.01*	STMR (EFSA, 2012)
Tropical root and tuber vegetables	0.01*	STMR (EFSA, 2012)
Garlic	0.22	STMR (EFSA, 2012)
Onions	0.22	STMR (EFSA, 2012)
Shallots	0.22	STMR (EFSA, 2012)
Spring onions/green onions and Welsh onions	1.60	STMR (EFSA, 2016)
Tomatoes	0.26	STMR (EFSA, 2014)
Sweet peppers/bell peppers	0.16	STMR (EFSA, 2017)

Commodity	Chronic risk assessment	
	Input (mg/kg)	Comment
Aubergines	0.17	STMR (EFSA, 2017)
Okra/lady's fingers	0.16	STMR (EFSA, 2017)
Other Solanaceae	0.16	STMR (EFSA, 2017)
Cucumbers	0.12	STMR (EFSA, 2012)
Gherkins	0.16	STMR (EFSA, 2012)
Courgettes	0.16	STMR (EFSA, 2012)
Other cucurbits - edible peel	0.16	STMR (EFSA, 2017)
Melons	0.66	STMR (EFSA, 2012)
Pumpkins	0.34	STMR (EFSA, 2012)
Watermelons	0.66	STMR (EFSA, 2012)
Other cucurbits - inedible peel	0.66	STMR (EFSA, 2017)
Broccoli	1.7	STMR (EFSA, 2012)
Head cabbage	2.0	STMR (EFSA, 2012)
Chinese cabbage	16	STMR (EFSA, 2012)
Lamb's lettuces/corn salads	20.0	STMR (EFSA, 2012)
Lettuce	5.20	STMR (EFSA, 2012)
Lettuces and salad plants, except lamb's lettuces and lettuces (cress and other sprouts and shoots, land cress, roman rocket/rucola, red mustards, baby leaf crops, other lettuce and salad plants)	8.5	STMR (EFSA, 2012)
Spinach and similar (leaves)	13.0	STMR (EFSA, 2012)
Herbs and edible flowers	6.9	STMR (EFSA, 2017)
Celeries	5.5	STMR (EFSA, 2012)
Fennel	5.5	STMR (EFSA, 2012)
Leek	1.06	STMR (EFSA, 2012)

Commodity	Chronic risk assessment	
	Input (mg/kg)	Comment
Hops	35.4	STMR (EFSA, 2014)
All other plant commodities	MRL	GB MRL Statutory Register (Regulation (EU) 2018/70)

* indicates residue at LOQ

In bold uses proposed as part of the current assessment.

Model outputs for EFSA PRIMo revision 3.1 are presented in Appendix B.

Conclusions

The highest UK NEDI was <1% of the ADI (toddler).

The highest PRIMo IEDI is 0.5% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of honey from melliferous crops treated with ametoctradin.

Consideration of acute exposure was not required as the active substance is not acutely toxic and an ARfD has not been allocated.

7.2 Other routes of exposure

The metabolites M650F03 and M650F04 are in the rotational crop and honey residue definition for risk assessment (sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin).

M650F03 and M650F04 exceed the TTC of 0.75 µg/L (equivalent to 0.02 µg/kg bw/day) in drinking water. Therefore, a drinking water consumer assessment is required to assess the risk of the overall dietary exposure.

M650F03

The estimated worst case PECgw from other authorised UK GAPs for ametoctradin indicate that M650F03 is present above the trigger value of 0.1 µg/L in groundwater.

In relation to the drinking water contribution, the highest intake is expected for an infant (< 4 months). EFSA Guidance on pesticides in foods for infants and young children estimates the water consumption of bottle-fed infants as 1.135 L/d (EFSA Journal 2018; 16(6) 5286, 75 pp.).

For M650F03, based on the PECgw for the use on grapes (5.71 µg/L), the intake of M650F03 from drinking water for the critical consumer group infants is expected to be ≤ 0.00130 mg/kg bw/day. This is <0.1 % of the ADI (10 mg/kg bw/day).

The estimated intake from food (plant and animal commodities) of ametoctradin, M650F03 and M650F04 is up to 1% of the ADI for the critical consumer group from the UK chronic model (toddler) and 0.5% for the PRIMo model (NL toddler). For reference, the values for infants are <1% in the UK Chronic model and 0.2% in the PRIMo model (based on FR infant).

The combined intake from food and drinking water is <1.1% ADI when estimating the NEDI (critical consumer: toddler) and <0.6% of the ADI when estimating the IEDI (critical consumer: NL toddler).

As the contribution from groundwater is significantly below the ADI, no health effects are expected.

M650F04

The estimated worst case PECgw from other authorised UK GAPs for ametoctradin indicate that M650F04 is present above the trigger value of 0.1 µg/L in groundwater.

In relation to the drinking water contribution, the highest intake is expected for an infant (< 4 months). EFSA Guidance on pesticides in foods for infants and young children estimates the water consumption of bottle-fed infants as 1.135 L/d (EFSA Journal 2018; 16(6) 5286, 75 pp.).

Based on the PECgw for the use on grapes (9.66 µg/L), the intake of M650F04 from drinking water for the critical consumer group infants is expected to be ≤ 0.00219 mg/kg bw/day. This is <0.1 % of the ADI (10 mg/kg bw/day).

The estimated intake from food (plant and animal commodities) of ametoctradin, M650F03 and M650F04 is up to 1% of the ADI for the critical consumer group from the UK chronic model (toddler) and 0.5% for the PRIMo model (NL toddler). For reference, the values for infants are <1% in the UK Chronic model and 0.2% in the PRIMo model (based on FR infant).

The combined intake from food and drinking water is <1.1% ADI when estimating the NEDI (critical consumer: toddler) and <0.6% of the ADI when estimating the IEDI (critical consumer: NL toddler).

As the contribution from groundwater is significantly below the ADI, no health effects are expected.

8 The conclusion of the competent authority

Sufficiently validated analytical methods for the determination of ametoctradin in honey, in line with the enforcement residue definition for honey, are available to support the MRL under consideration in the MRL application.

Toxicological reference values were established for the approval of the active substance: an ADI of 10 mg/kg bw/day and no ARfD allocated or required.

According to SANTE/11956/2016 rev. 9, in the absence of honey metabolism studies, the risk assessment residue definition for honey can be derived by taking into account the nature of residues in plants and the stability of the residues during pasteurisation.

Consideration of primary and rotational crop metabolism has been made in order to derive appropriate definitions for honey. The metabolism of ametoctradin in primary crops was investigated in root, leafy and fruit crop groups following foliar applications for the approval of the active substance (EFSA Conclusion, 2012).

The residue definition for risk assessment (RD-RA) in primary crops has been agreed as:

- Ametoctradin

The residue definition for enforcement (RD-Enf) in primary crops has been agreed as:

- Ametoctradin

Hydrolysis of ametoctradin under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrate that ametoctradin is stable under standard conditions, therefore specific residue definitions for processed commodities are not required.

Residues in rotational crops were considered for the approval of the active substance. The metabolism studies demonstrated that specific residue definitions for rotational crops are required.

The RD-RA in rotational crops has been agreed as:

- Sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin.

The RD-Enf in rotational crops has been agreed as:

- Ametoctradin

Considering the metabolism and hydrolysis data, the residue definition for risk assessment (RD-RA) in honey has been agreed as:

- Sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin.

The residue definition for enforcement (RD-Enf) in honey has been agreed as:

- Ametoctradin

Four tunnel trials on honey conducted in Italy, Austria and Spain were submitted to support an MRL for honey. The trials are supported by validated analytical methods and storage stability data.

There is no consumption data in the UK models for honey. Nonetheless, a chronic risk assessment for the current GB MRLs has been performed in the UK model. The highest UK NEDI was <1% of the ADI (toddler). The risk assessment for the proposed honey MRL is covered by PRIMo which has consumption data for honey. The highest PRIMo IEDI was 0.5% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of honey from melliferous crops treated with ametoctradin.

Consideration of acute exposure was not required as the active substance is not acutely toxic and an ARfD has not been allocated.

HSE concludes that sufficient data have been provided to support the setting of a new MRL for ametoctradin on honey. These will not result in consumer exposures exceeding the toxicological reference values at the proposed GAPs and therefore harmful effects on human health are not expected. HSE recommends that the MRL outlined in Table 8.1 is amended in the GB MRL Statutory Register.

Table 8.1 MRL recommended by HSE

Product code	**Product**	**Existing GB MRL (mg/kg)**	**New or amended GB MRL (mg/kg)**	**Comments**
Enforcement	**residue**	**definition**	**for honey:**	**Ametoctradin**
1040000	Honey and other apiculture products†	0.05*	5	The MRL is sufficiently supported by data. No health effects are expected.

* Indicates that the MRL is set at the limit of quantification/determination

† In Part 1 of the GB MRL Statutory Register the following footnote is relevant to MRLs for honey: ‘No MRLs are applicable to other apiculture products until individual products have been identified and listed within this group.’ Therefore, the MRL applies to honey only at this time.

References

The Netherlands, 2009. Draft Assessment Report (DAR) on the active substance ametoctradin, prepared by the rapporteur Member State The Netherlands in the framework of framework of Regulation (EC) No 1107/2009, September 2009

EFSA (European Food Safety Authority), 2009. Setting of new MRLs for BAS 650 F in table and wine grapes, potatoes, tomatoes, peppers, cucumbers, courgettes, melons and lettuce. EFSA Journal 2009; 7(10):1367.

EFSA, 2012. Reasoned opinion on the modification of the existing MRLs for ametoctradin in various commodities. EFSA Journal 2012;10(6):2771.

EFSA, 2014. Reasoned opinion on the modification of the existing MRL for ametoctradin in hops, EFSA Journal 2014;12(10):3879.

EFSA, 2015. Reasoned opinion on the modification of the existing MRLs for ametoctradin in sage and basil. EFSA Journal 2015;13(6):4153.

EFSA, 2016. Modification of the existing maximum residue level for ametoctradin in spring onions, EFSA Journal 2016;14(4):4448.

EFSA, 2017. Modification of the existing maximum residue levels for ametoctradin in herbs and edible flowers. EFSA Journal 2017;15(6):4869.

Appendix A – GAPs notified in the MRL application

Crop and/or situation (a)	**GB or Country For Import Tolerance**	**Product name**	**F or G Or I** (b)	**Pests or Group of pests controlled** (c)	**Preparation**		**Application**				**Application rate per treatment**			**PHI (days)** (m)
					Type (d-f)	**Conc. a.s.** (i)	**method kind** (f-h)	**range of growth stages & season** (j)	**number min-max** (k)	**Interval between application (min)**	**kg a.s /hL min-max** (l)	**Water (L/ha) min-max**	**kg a.s./ha min-max** (l)	
Grapes	GB	Privest	F	*Plasmopara viticola*	SC	75 g/L	Foliar spray	BBCH 53-83	1 - 2	10 days	0.03 - 0.08	500-1200	0.39	35

(a) For crops, the GB and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) State if the use is outdoor, field use (F) or glass house (G) or indoor use (I).
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) 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
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Appendix B – UK models and Pesticide Residues Intake Model (PRIMo)

Table B.1 Chronic risk assessment undertaken using UK Chronic model 1.1

Active substance: Ametoctradin **ADI:** 10 mg/kg bw/day **Source:** EFSA, 2012

			TOTAL INTAKE based on 97.5th percentile									
			ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
	mg/kg bw/day		0.01936	0.01840	0.02694	0.01668	0.01651	0.01116	0.00921	0.02036	0.01509	0.00819
	% of ADI		<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%
Commodity	STMR (mg/kg)	P	COMMODITY INTAKES (mg/kg bw/day)									
Grapefruit	0.01		0.00002	0.00002	0.00006	0.00005	0.00012	0.00002	0.00001	0.00002	0.00002	0.00002
Lemons	0.01		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Limes	0.01		0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001
Mandarins	0.01		0.00001	L/C	0.00006	0.00004	0.00003	0.00002	0.00002	0.00001	0.00002	0.00001
Oranges	0.01		0.00004	0.00011	0.00016	0.00011	0.00008	0.00008	0.00007	0.00005	0.00004	0.00003
Almonds	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Brazil nuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Cashew nuts	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Chestnuts	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	L/C
Coconuts	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000

Hazelnuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Pistachios	0.01		0.00000	L/C	0.00000	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Peanuts	0.01		0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000
Apples	0.01		0.00003	0.00008	0.00015	0.00009	0.00008	0.00004	0.00004	0.00003	0.00002	0.00001
Pears	0.01		0.00001	0.00003	0.00007	0.00004	0.00002	0.00002	0.00001	0.00002	0.00002	0.00001
Apricots	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Peaches	0.01		0.00001	0.00001	0.00003	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000
Plums	0.01		0.00001	0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Cherries	0.01		0.00000	0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000
Table grapes	0.96		0.00126	0.00159	0.00451	0.00207	0.00248	0.00106	0.00060	0.00196	0.00127	0.00044
Wine grapes	0.96		0.00945	0.00117	0.00085	0.00087	0.00030	0.00097	0.00339	0.00933	0.00638	0.00140
Strawberries	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Blackberries	0.01		0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Loganberries	0.01		0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Raspberries	0.01		0.00000	L/C	0.00002	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Gooseberries	0.01		0.00000	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00001	0.00000
Blackcurrants	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00000	0.00001	0.00000
Red currants	0.01		0.00000	L/C	0.00001	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
White currants	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.01		0.00001	L/C	0.00001	L/C	L/C	L/C	0.00000	0.00001	0.00001	L/C
Bananas	0.01		0.00002	0.00007	0.00007	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002
Dates	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00001	0.00000
Figs	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Kiwi fruit	0.01		0.00001	L/C	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000

Lychees	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Mangoes	0.01		0.00001	L/C	0.00002	0.00001	0.00002	0.00001	0.00004	0.00001	0.00000	L/C
Olives	0.01		0.00000	L/C	0.00001	0.00001	L/C	0.00000	L/C	0.00000	0.00000	L/C
Passion fruit	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Pineapples	0.01		0.00001	0.00005	0.00005	0.00007	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Pomegranates	0.01		0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000	0.00001	0.00001	0.00001
Beetroot	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Carrots	0.01		0.00001	0.00004	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Celeriac	0.01		0.00000	L/C	L/C	0.00000	0.00000	L/C	L/C	L/C	L/C	L/C
Horseradish	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C
Jerusalem artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Parsnips	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Radishes	0.01		0.00000	L/C	0.00001	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Salsify	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Swedes	0.01		0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Yam	0.01		0.00003	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.22		0.00001	L/C	0.00001	0.00002	0.00003	0.00002	0.00003	0.00003	0.00003	L/C
Onions	0.22		0.00012	0.00025	0.00025	0.00020	0.00017	0.00016	0.00011	0.00016	0.00012	0.00007
Spring onions	1.6		0.00040	L/C	0.00025	0.00105	0.00029	0.00014	0.00017	0.00040	0.00041	0.00014
Tomatoes	0.26		0.00036	0.00048	0.00068	0.00050	0.00048	0.00028	0.00035	0.00046	0.00038	0.00035
Peppers	0.16		0.00006	L/C	0.00013	0.00007	0.00011	0.00005	0.00005	0.00010	0.00009	0.00003
Aubergines	0.17		0.00005	L/C	0.00024	0.00012	0.00004	0.00008	0.00006	0.00010	0.00006	L/C
Marrows	0.16		0.00008	L/C	0.00025	0.00006	0.00010	0.00010	0.00004	0.00008	0.00022	0.00010
Cucumbers	0.12		0.00005	0.00003	0.00029	0.00018	0.00013	0.00006	0.00006	0.00007	0.00006	0.00002
Gourd	0.66		0.00036	L/C	L/C	L/C	L/C	0.00018	L/C	0.00013	L/C	L/C

Courgettes	0.16		0.00007	0.00024	0.00038	0.00021	0.00013	0.00007	0.00006	0.00009	0.00008	0.00007
Melons	0.66		0.00163	0.00201	0.00346	0.00233	0.00201	0.00142	0.00182	0.00168	0.00197	0.00065
Sweet corn	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	1.7		0.00110	0.00195	0.00291	0.00207	0.00178	0.00122	0.00107	0.00116	0.00163	0.00059
Cauliflower	0.01		0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Brussels sprouts	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Head cabbage	2		0.00109	0.00352	0.00341	0.00253	0.00150	0.00143	0.00106	0.00151	0.00232	0.00147
Chinese cabbage	16		0.00796	L/C	L/C	L/C	L/C	L/C	L/C	0.00801	0.00558	L/C
Kohl Rabi	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Cress	8.5		0.00032	L/C	0.00041	0.00058	0.00019	0.00035	0.00025	0.00065	0.00082	0.00034
Lettuce	5.2		0.00322	0.00185	0.00445	0.00358	0.00377	0.00210	0.00230	0.00366	0.00278	0.00143
Spinach	13		0.00683	0.01300	0.02035	0.01116	0.01140	0.00813	0.00452	0.00887	0.00729	0.00458
Watercress	0.01		0.00000	L/C	L/C	0.00000	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Chicory	6.9		0.00052	L/C	L/C	L/C	L/C	L/C	L/C	0.00050	L/C	L/C
Parsley	6.9		0.00117	L/C	0.00076	L/C	0.00109	0.00029	0.00010	0.00118	0.00124	0.00253
Beans with pods	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000
Runner Beans	0.01		0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01		0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Beansprouts	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	5.5		0.00179	0.00234	0.00231	0.00158	0.00087	0.00139	0.00100	0.00252	0.00266	0.00062
Fennel	5.5		0.00211	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Globe artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C

Leeks	1.06		0.00052	L/C	0.00068	0.00039	0.00032	0.00038	0.00024	0.00051	0.00061	0.00038
Rhubarb	0.01		0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Cultivated mushrooms	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.01		0.00002	0.00006	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00001	0.00001
Lentils	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Oils	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Oilseeds	0.01		0.00003	0.00006	0.00007	0.00007	0.00006	0.00004	0.00004	0.00005	0.00003	0.00004
Potatoes	0.01		0.00003	0.00011	0.00009	0.00008	0.00007	0.00005	0.00005	0.00004	0.00003	0.00003
Hops (dried 0.25% of beer)	35.4		0.00219	L/C	L/C	L/C	L/C	0.00022	0.00194	0.00186	0.00220	0.00167
Oats	0.01		0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01		0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Millet	0.01		L/C	L/C	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Buckwheat	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Maize	0.01		0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.01		0.00004	0.00003	0.00008	0.00009	0.00007	0.00005	0.00004	0.00004	0.00003	0.00003
Rice	0.01		0.00002	0.00003	0.00005	0.00004	0.00005	0.00004	0.00003	0.00002	0.00001	0.00000
Rye	0.01		0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0.03		0.00005	0.00005	0.00009	0.00008	0.00005	0.00005	0.00005	0.00005	0.00005	0.00002
Meat fat	0.03		0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00000	0.00001	0.00000
Meat excl. poultry & offal	0.03		0.00006	0.00012	0.00012	0.00010	0.00009	0.00006	0.00006	0.00001	0.00005	0.00005
All types of kidney	0.03		0.00001	0.00001	0.00004	0.00001	0.00001	0.00001	0.00001	L/C	0.00001	0.00001
All types of Liver	0.03		0.00001	0.00007	0.00007	0.00001	0.00001	0.00002	0.00001	L/C	0.00002	0.00001
Other types of offal	0.03		0.00002	0.00005	0.00007	0.00003	0.00003	0.00003	0.00001	0.00000	0.00002	0.00002
Eggs	0.03		0.00003	0.00014	0.00010	0.00007	0.00005	0.00004	0.00003	0.00003	0.00003	0.00004
Milk	0.03		0.00025	0.00293	0.00167	0.00088	0.00055	0.00035	0.00028	0.00029	0.00026	0.00035

Sugar beet	0.01		0.00014	0.00033	0.00056	0.00034	0.00031	0.00020	0.00019	0.00012	0.00011	0.00015

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001
L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Table B.2 Chronic risk assessment undertaken using PRIMo revision 3.1

Chronic risk assessment: JMPR methodology (IEDI/TMDI)												
				No of diets exceeding the ADI :	- - -						Exposure resulting from	
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)	
TMDI/NEDI/IEDI calculation (based on average food	0.5%	NL toddler	52.49	0.4%	Spinaches	0.0%	Escaroles/broad-leaved endives	0.0%	Milk: Cattle			
	0.2%	DE child	20.81	0.1%	Spinaches	0.0%	Tomatoes	0.0%	Table grapes			
	0.2%	NL child	20.46	0.2%	Spinaches	0.0%	Table grapes	0.0%	Tomatoes			
	0.2%	IT adult	20.34	0.1%	Spinaches	0.0%	Other spinach and similar	0.0%	Chards/beet leaves			
	0.2%	FR infant	19.84	0.2%	Spinaches	0.0%	Chards/beet leaves	0.0%	Milk: Cattle			
	0.2%	GEMS/Food G06	16.85	0.1%	Tomatoes	0.0%	Spinaches	0.0%	Roman rocket/rucola			
	0.2%	GEMS/Food G11	16.80	0.1%	Spinaches	0.0%	Lamb's lettuce/corn salads	0.0%	Celeries			
	0.2%	IT toddler	16.52	0.0%	Chards/beet leaves	0.0%	Spinaches	0.0%	Other spinach and similar			
	0.2%	ES child	15.25	0.0%	Spinaches	0.0%	Chards/beet leaves	0.0%	Lettuces			
	0.2%	ES adult	15.24	0.0%	Chards/beet leaves	0.0%	Spinaches	0.0%	Lettuces			
	0.1%	SE general	14.53	0.0%	Spinaches	0.0%	Chinese cabbages/pe-tsai	0.0%	Lettuces			
	0.1%	GEMS/Food G10	14.20	0.0%	Spinaches	0.0%	Chinese cabbages/pe-tsai	0.0%	Tomatoes			
	0.1%	NL general	13.78	0.1%	Spinaches	0.0%	Escaroles/broad-leaved endives	0.0%	Tomatoes			
	0.1%	FR toddler 2 3 yr	13.70	0.1%	Spinaches	0.0%	Milk: Cattle	0.0%	Tomatoes			

	0.1%	IE adult	13.52	0.1%	Spinaches	0.0%	Wine grapes	0.0%	Celeries		
	0.1%	GEMS/Food G08	12.47	0.0%	Lamb's lettuce/corn salads	0.0%	Spinaches	0.0%	Tomatoes		
	0.1%	FR child 3 15 yr	11.96	0.1%	Spinaches	0.0%	Tomatoes	0.0%	Other lettuce and other salad plants		
	0.1%	GEMS/Food G07	10.62	0.0%	Spinaches	0.0%	Tomatoes	0.0%	Wine grapes		
	0.1%	FR adult	9.92	0.0%	Spinaches	0.0%	Wine grapes	0.0%	Other lettuce and other salad plants		
	0.1%	RO general	9.69	0.0%	Tomatoes	0.0%	Head cabbages	0.0%	Wine grapes		
	0.1%	GEMS/Food G15	9.00	0.0%	Tomatoes	0.0%	Head cabbages	0.0%	Wine grapes		
	0.1%	DE women 14-50 yr	8.59	0.0%	Spinaches	0.0%	Tomatoes	0.0%	Lamb's lettuce/corn salads		
	0.1%	DE general	8.15	0.0%	Spinaches	0.0%	Tomatoes	0.0%	Lamb's lettuce/corn salads		
	0.1%	FI 3 yr	6.52	0.0%	Spinaches	0.0%	Tomatoes	0.0%	Chinese cabbages/pe-tsai		
	0.1%	FI 6 yr	5.95	0.0%	Spinaches	0.0%	Tomatoes	0.0%	Chinese cabbages/pe-tsai		
	0.1%	UK vegetarian	5.88	0.0%	Spinaches	0.0%	Tomatoes	0.0%	Wine grapes		
	0.1%	PT general	5.17	0.0%	Wine grapes	0.0%	Tomatoes	0.0%	Lettuces		
	0.0%	UK toddler	4.50	0.0%	Spinaches	0.0%	Tomatoes	0.0%	Milk: Cattle		
	0.0%	UK adult	4.46	0.0%	Spinaches	0.0%	Wine grapes	0.0%	Tomatoes		
	0.0%	DK adult	3.96	0.0%	Wine grapes	0.0%	Tomatoes	0.0%	Spinaches		
	0.0%	DK child	3.75	0.0%	Tomatoes	0.0%	Lettuces	0.0%	Milk: Cattle		
	0.0%	PL general	3.73	0.0%	Tomatoes	0.0%	Head cabbages	0.0%	Chinese cabbages/pe-tsai		
	0.0%	FI adult	3.63	0.0%	Spinaches	0.0%	Tomatoes	0.0%	Lettuces		
	0.0%	UK infant	3.16	0.0%	Milk: Cattle	0.0%	Spinaches	0.0%	Tomatoes		
	0.0%	LT adult	2.46	0.0%	Tomatoes	0.0%	Head cabbages	0.0%	Lettuces		
	0.0%	IE child	0.82	0.0%	Spinaches	0.0%	Milk: Cattle	0.0%	Broccoli		
	Conclusion:										

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

Appendix C - Detailed evaluation of the additional studies relied on

C.1 Methods of analysis

C.1.1 Methods for enforcement and monitoring of residues in food and feed of plant origin

No additional studies submitted.

C.1.2 Methods for enforcement and monitoring of residues in food and feed of animal origin

C.1.2.1 Validation of Method R0072/01

Reference:	Validation of Method R0072/01: Method for the determination of BAS 181 S (Reg.No. 4117133), BAS 650 F (Reg.No. 4993353), M650F003 (Reg.No. 5178870, and M650F004 (Reg.No. 5211623) in pollen and honey by LC-MS/MS, [redacted] 2020; report No 886594; BASF DocID 2020/2032164
GLP:	Yes
Acceptability of the method:	Acceptable

Test materials

The test materials used in this method validation study were untreated control pollen and honey samples obtained from commercial sources, through an on-line retailer. Further details on the characteristics of the honey (e.g. its origin, its pH and whether it's a multi flower honey) were not provided. However, this deficiency has no impact on the validity of this method and as the study was completed in December 2020, further details are not required.

Principle of the method

Samples were homogenised prior to analysis. For honey 1 g of sample was weighed and residues of phosphonic acid were extracted by adding 20 mL of methanol:water (50:50, v/v) and centrifuged. For pollen samples, 1 g of sample was added to 10 mL methanol:water (50:50, v/v) and underwent sequential extraction by methanol.

Residues in a separate 1 mL aliquot of the extract (or combined pollen extract) were cleaned up on a Waters Oasis® MAX SPE column eluted with methanol buffered with ammonium formate, evaporated to dryness, and then re-dissolved. 0.5 mL of the extract was further diluted in 0.5 mL methanol/water/formic acid (50:50:0.1, v/v/v). If necessary, further dilution into the linear range using methanol/water/formic acid (50/50/0.1, v/v/v) was doneThe final determination of ametoctradin, M650F03 and M650F04 is performed by the following LC-MS/MS conditions:

Table 1.2.1-1: Analytical conditions of method R0072/01

HPLC-MS/MS System	Sciex Triple Quad 6500^{+} with SelexION
Column	XSelect HSS T3, 3 x 150 mm, 2.5 µm (P/N 186006740)
Column temperature	45 °C
Injection volume	10 µL
Mobile phase	A: Water/ formic acid (1000:1, v/v) B: 5 mM Ammonium acetate in methanol/formic acid (1000:5, v/v)
Flow rate	600 µL/min
Ions monitored	Ametoctradin: 276 m/z → 176 m/z (primary quantitation ion) 276 m/z → 149 (confirmatory ion) M650F03: 222 m/z → 176 m/z (primary quantitation ion) 222 m/z → 121 m/z (confirmatory ion) M650F04: 208 m/z → 123 m/z (primary quantitation ion) 208 m/z → 95 m/z (confirmatory ion)

Results and discussion

External standards were used and matrix effects were accounted for. Due to the high specificity of LC-MS/MS using two mass transitions a confirmatory method is not necessary. Sample extracts were analysed within 1 day of extraction.

Table C.1.2.1-2 Recovery Results in honey and pollen

Analyte	Ion transition	Fortification level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)
Honey						
Ametoctradin	276 m/z → 176 m/z	0.01	5	81.9, 82.1, 84.0, 84.5, 85.4	83.6	1.8
	Quantification	0.1	5	79.9, 80.6, 80.6, 80.9, 82.4,	80.9	1.1
	276 m/z → 149 m/z	0.01	5	80.7, 82.8, 83.3, 83.5, 84.5	83.0	1.7
	Qualification	0.1	5	79.1, 80.2, 80.8, 81.0, 81.4	80.5	1.1
M650F03	222 m/z → 176 m/z	0.1	5	73.9, 74.9, 77.4, 76.1, 76.9	75.8	1.9
	Quantification	1.0	5	79.9, 80.8, 81.2, 82.6, 83.8	81.6	1.9

Analyte	Ion transition	Fortification level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)
	222 m/z → 121 m/z	0.1	5	70.2, 75.2, 82.0, 84.4, 85.3	79.4	8.2
	Qualification	1.0	5	78.8, 79.6, 79.9, 83.4, 83.7	81.1	2.8
M650F04	208 m/z → 123 m/z	0.01	5	70.0, 72.4, 74.3, 74.4, 75.9	73.4	3.1
	Quantification	0.1	5	73.5, 73.6, 73.6, 75.1, 76.4	74.4	1.7
	208 m/z → 95 m/z	0.01	5	75.8, 76.0, 79.8, 80.7, 84.1	79.3	4.4
	Qualification	0.1	5	72.5, 74.2, 77.1, 78.8, 84.3	77.4	5.9
Pollen						
Ametoctradin	276 m/z → 176 m/z	0.01	5	86.3, 88.4, 88.6, 89.2, 96.1	89.7	4.2
	Quantification	0.1	5	87.3, 88.2, 89.6, 91.3, 92.0	89.7	2.2

Analyte	Ion transition	Fortification level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)
	276 m/z → 149 m/z	0.01	5	86.9, 87.9, 89.0, 89.7, 93.4	89.4	2.8
	Qualification	0.1	5	86.2, 87.8, 88.9, 91.0, 92.5	89.3	2.8
M650F03	222 m/z → 176 m/z	0.1	5	85.8, 86.9, 87.9, 90, 96.6	89.4	4.8
	Quantification	1.0	5	83.7, 92.3, 92.6, 93.2, 93.4,	91.0	4.5
	222 m/z → 121 m/z	0.1	5	71.7, 75.8, 76.6, 84, 85	78.6	7.2
	Qualification	1.0	5	85.6, 85.9, 87.3, 89.0, 92.3	88.0	3.1
M650F04	208 m/z → 123 m/z	0.01	5	77.7, 80.2, 81.5, 82.9, 83.1	81.1	2.7
	Quantification	0.1	5	83.2, 84.1, 85.6, 86.7, 88.8	85.7	2.6
	208 m/z → 95 m/z	0.01	5	67.0, 75.7, 75.9, 76.4, 84.3	75.9	8.1

Analyte	Ion transition	Fortification level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)
	Qualification	0.1	5	83.9, 85.1, 86.9, 87.3, 88.0	86.2	2.0

The spike concentrations of the recovery samples were in the range 0.01 – 0.1 mg/kg. Five samples were prepared at each fortification level. Mean recovery levels were in the range 73.4 – 91.0% and are deemed acceptable. The %RSD at each level was ≤8.2%.

Table 1.2.1-3 Characteristics of the analytical method for the quantitation of ametoctradin and its metabolites M650F03 and M650F04 residues in honey and pollen

Ametoctradin, M650F03 and M650F04 in honey and pollen	
Chromatographic method	LC-MS/MS
Specificity demonstrated (yes/no, by…)	Yes by two mass transitions – highly specific therefore no confirmatory technique required.
Linearity demonstrated (yes/no)	Yes
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	Honey and pollen: 0.025 to 2.0 ng/mL (0.005 – 0.4 mg/kg), r ≥0.9962
Calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes – 7 single points
Matrix effects	Yes, matrix matched calibration standard solutions used (significant matrix effects identified)
Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)	Yes
Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ratio? (yes/no)	Yes

Ametoctradin, M650F03 and M650F04 in honey and pollen	
LOQ (mg/kg)	0.01

Conclusion

The method R0072/01 for analysis of ametoctradin and its metabolites M650F03 and M650F04 in honey and pollen matrices using LC-MS/MS for final determination, fulfils the requirements with regard to linearity, specificity, repeatability, and recoveries with a limit of quantification of 0.01 mg/kg for each analyte in honey and pollen, respectively. Therefore, analytical method (R0072/01) was satisfactorily validated in accordance with SANTE/2020/12830 rev.1.

C.1.2.2 Independent laboratory validation

Reference: Independent Lab Validation of BASF Analytical Method R0072/01: "Method for the determination of BAS 181 S (Reg. No. 4117133), BAS 650 F (Reg. No.4993353), M650F003 (Reg. No. 5178870), and M650F004 (Reg. No. 5211623) in Pollen and Honey by LC-MS/MS", [redacted] 2020, BASF Registration Document Number: 2020/2032165, CRO Study Identification Number: 137G2694, BASF Study Number: 886595

GLP: Yes

Acceptability of the method: Acceptable

Material and methods

The test materials used in this method validation study were untreated honey samples. Further details on the characteristics of the honey (e.g. its origin, its pH and whether it's a multi flower honey) were not provided.

The same method outlined in Appendix C.1.2.1 was used, except different fortifications levels were used. The higher fortification levels would have no impact on the study and further support adequate method performance.

Results and discussion

Table 1.2.2-1 Recovery results from ILV for method R0072/01

Matrix	Fortification level (mg/kg)	Recoveries (%)	Mean recovery (%)	RSD (%)
Honey (276 m/z → 176 m/z)	0.01	96.1, 97.8, 98.0, 98.0, 100	98.0	1.52
	1.0	92.4, 93.9, 100, 102, 103	98.3	4.99
Honey (276 m/z → 149 m/z)	0.01	97.9, 99.2, 99.3, 99.4, 102	99.6	1.62
	1.0	93.0, 95.3, 102, 103, 104,	99.4	5.03

According to the method R0072/01, honey matrix samples were fortified with a solution containing ametoctradin to obtain concentrations of 0.010 mg/kg (LOQ) and 1.0 mg/kg (100x LOQ). The mean recovery values at a fortification level of 0.01 mg/kg were within the acceptable range of 98.0 – 99.6% with an RSD of < 2%. The mean recovery values at a fortification level of 0.1 mg/kg were within the acceptable range of 98.3 – 99.4% with an RSD of < 6%.

Table 1.2.2-2 Characteristics of the ILV for method R0072/01

Ametoctradin in honey (ILV)	
Chromatographic method	LC-MS/MS
Specificity demonstrated (yes/no, by…)	Yes by two mass transitions – highly specific therefore no confirmatory technique required.
Linearity demonstrated (yes/no)	Yes
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.020 to 0.500 ng/mL (0.004– 0.1 mg/kg), r > 0.98
Calibration consists of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes – 10 single points
Matrix effects	Yes, matrix matched calibration standard solutions used

Ametoctradin in honey (ILV)	
Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)	Yes
Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ratio? (yes/no)	Yes
LOQ (mg/kg)	0.01

Conclusion

No deviation to the original method described in C.1.2.1 is shown. The analytical method (R0072/01) is satisfactorily validated in accordance with SANTE/2020/12830 rev.1 for monitoring of ametoctradin in honey with an LOQ of 0.01 mg/kg, in line with the residue definition for enforcement.

C.1.3 Methods for risk assessment for residues in food and feed of plant origin

No additional studies submitted.

C.1.4 Methods for risk assessment for residues in food and feed of animal origin

See Appendix C.1.2

C.1.5 Methods for risk assessment for toxicological studies

No additional studies submitted.

C.2 Mammalian toxicology

No additional studies submitted.

C.3 Residue data

C.3.1 Nature and magnitude of residues in primary crops

No additional studies submitted.

C.3.2 Nature and magnitude of residues in processed commodities

No additional studies submitted.

C.3.3 Nature and magnitude of residues in rotational crops

No additional studies submitted.

C.3.4 Nature and magnitude of residues in livestock

No additional studies submitted.

C.3.5 Residues in honey

Reference:	Determination of residues of BAS 650 F (Ametoctradin) and BAS 181 S (Phosphonic Acid) in buckwheat and buckwheat honey after three applications of BAS 657 00 F under semi-field conditions in Germany, 2020, [redacted] 2021, report No 886593, BASF DocID 2020/2031155
Guideline(s):	Yes OECD – Guideline for the Testing of Chemicals, Test Guideline 509; Crop field trial, 07/09/2009 SANCO 7029/VI/95 rev.5 - General recommendations for the design, preparation and realization of residue trials, 22/07/1997 SANTE/11956/2016 rev. 9 - Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey, 14/09/2018
Deviations:	No
GLP:	Yes
Validity of the study:	Acceptable

Materials and methods

Four trials were conducted in Germany (Northern Europe) in order to determine the magnitude of residues of phosphonic acid in honey, pollen and inflorescence of buckwheat under semi-field conditions after application of 'BAS 657 00 F'. Semi field trials were conducted with the use of a tunnel to allow sun light, cloud cover and humidity to be the same as the surrounding areas. Tunnel size was above the minimum required size.

It was confirmed that a visual assessment was performed on the colony and the presence of the healthy queen was recorded before start of the trial and after the collection of honey.

The trials consisted of one control plot and one treated plot. The test item 'BAS 657 00 F' (75.0 g/L ametoctradin), a suspension concentrate (SC), was applied as foliar application three times on buckwheat under semi-field conditions during inflorescence at BBCH 55-59, at beginning of flowering at BBCH 61-63 and full flowering at BBCH 65. The application rate used was 3 x 0.39 kg ametoctradin/ha. The water volume used was within ≤ 10 % of variation of 200 L/ha.

At last application, the inflorescences were sampled randomly by hand across the entire plot, within boundaries to excluded 0.5 m at each end and 0.5 m at each side. The pollen specimens were sampled by using pollen traps installed in front of the beehives. Honey specimens were collected from combs, which were installed empty shortly before the

exposure phase. Pollen was taken 4-12 days after last treatment and honey was taken 7-14 days after last treatment.

A minimum of 20 g of honey, pollen and inflorescences were taken per sample, except for pollen specimen L2003320002 where 12.1 g was sampled. As this was a control sample and as all other samples were at least 20 g it can be considered a minor deviation. Although it is recommended that 100 g of honey and pollen be collected for each sample (SANTE/11956/2016 rev. 9), the 20 g collected is considered acceptable as tunnel trials make it difficult for large quantities to be gathered. It was confirmed that the tunnels were larger than the minimum size required for a reasonable chance of sufficient honey production.

Samples were stored for a maximum of 142 days (approx. 5 months) and supported by a new storage stability study (see Appendix C 3.6 for full analysis) which confirmed stability of ametoctradin and its metabolites M650F03 and M650F04 for a minimum of 6 months in honey and pollen. Acceptable storage stability data for high water matrices is available to support the storage interval for ametoctradin and its metabolites M650F03 and M650F04 in inflorescences (EFSA, 2012).

Specimens of honey, pollen and inflorescences were analysed for residues of ametoctradin and its metabolites M650F03 and M650F04 using BASF method R0072/01. This method was sufficiently validated against SANTE/2020/12830 rev.1 (see further details in Appendix C 1.2). The limit of quantification (LOQ) of 0.01 mg/kg for each analyte in the respective matrices. The method was not validated for inflorescences, however acceptable procedural recoveries were provided. As residue values in inflorescences are not relied up on for enforcement or risk assessment the lack of validation data is considered acceptable.

The amount of buckwheat pollen in the pollen spectrum of honey was investigated. The content of buckwheat pollen in the honey varied greatly from 3 to 93.7%. Buckwheat pollen is generally underrepresented in honey as relatively low levels of pollen fall in the nectar during nectar collection. Steps were taken to improve the pollen content (empty combs were placed inside hives to reduce impact of over representative pollens from other plants). Therefore, as steps were taken to improve buckwheat pollen content and as bees only had access to buckwheat flowers, this variability is considered acceptable.

Water content was <20% in all honey samples, therefore honey had reached commercial maturity.

Results and discussions

Procedural recoveries were conducted using an appropriate number of samples and were all acceptable for honey, pollen and inflorescences.

Table C.3.5-1 Recoveries of ametoctradin, M650F03 and M650F04 in honey, pollen, and buckwheat inflorescences

Analyte	Matrix	Fortification level (mg/kg)	Individual recoveries (%)	Mean recoveries (%)	RSD (%)
Ametoctradin	Honey	0.01	89.0, 91.5, 94.0, 95.2, 96.3	93.2	3.2
		0.10	93.2, 93.7, 93.8, 98.0, 98.4,	95.4	2.7
		5.0	97.7	-	-
	Pollen	0.01	75.4, 77.2, 78.3, 79.2, 84.2	79.0	4.2
		0.10	69.9, 73.0, 76.2, 78.3, 81.3	75.5	5.9
		50.0	102	-	-
	Inflorescences	0.01	71.0, 75.0, 77.4, 80.8, 87.0	78.2	7.7
		0.10	62.5, 68.1, 74.9, 76.6, 78.3,	72.1	9.2
		50.0	106	-	-
M650F03	Honey	0.01	87.8, 88.7, 92.6, 93.9, 96.3	91.9	3.9
		0.10	89.7, 90.2, 91.2, 91.7, 93.3	91.2	1.5
	Pollen	0.01	83.4, 86.1, 87.5, 87.6, 88.7	86.7	2.3
		0.10	77.7, 77.9, 78.5, 80.9, 85.8	80.1	4.2
	Inflorescences	0.01	77.1, 78.7, 80.2, 81.6, 82.5	80.0	2.7
		0.10	74.7, 75.2, 75.4, 76.7, 82.6	76.9	4.2
M650F04	Honey	0.01	61.9, 66.3, 81.4, 83.9, 90.5	76.8	16
		0.10	86.0, 87.8, 109, 112, 113	102	13
	Pollen	0.01	85.5, 86.2, 87.6, 88.1, 88.5	87.2	1.4

		0.10	83.0, 89.1, 91.0, 91.1, 92.2	89.3	4.1
	Inflorescences	0.01	76.3, 79.8, 82.5, 84.2, 84.6	81.5	4.2
		0.10	73.3, 76.2, 76.7, 77.2, 80.4	76.7	3.3

No residues of ametoctradin, M650F03 or M650F04 were found in the control samples above the LOQ.

In treated specimens of buckwheat inflorescences, taken at 0 DALA (BBCH 63-65), the residues of ametoctradin ranged from 26 - 43 mg/kg, for pollen specimens collected at 4-12 DALA (BBCH 65 - 69) from 1.3 - 31 mg/kg and for honey specimens taken at 7-14 DALA (BBCH 65 - 69) from 0.077 - 1.8 mg/kg.

In treated specimens of buckwheat inflorescences, taken at 0 DALA (BBCH 63 - 65), the residues of M650F03 expressed as parent equivalent ranged from <0.012 to 0.014 mg/kg. For pollen specimens collected at 4-12 DALA (BBCH 65 - 69) and for honey specimens taken at 7-14 DALA (BBCH 65 - 69) the residues of M650F03 expressed as parent equivalent were <0.012 mg/kg.

In treated specimens of buckwheat inflorescences, taken at 0 DALA (BBCH 63 - 65), the residues of M650F04 expressed as parent equivalent ranged from <0.013 - 0.086 mg/kg. For pollen specimens collected at 4-12 DALA (BBCH 65 - 69) from <0.013 - 0.083 mg/kg for honey specimens taken at 7-14 DALA (BBCH 65 - 69) the residues of M650F04 expressed as parent equivalent ranged from < 0.013 - 0.078 mg/kg.

Table C.1.5-2: Residue trials on honey

Reference:	Determination of residues of BAS 650 F (Ametoctradin) and BAS 181 S (Phosphonic Acid) in buckwheat and buckwheat honey after three applications of BAS 657 00 F under semi-field conditions in Northern Europe, 2020, [redacted] 2021, report No. 856593, BASF DocID 2020/2031155		
GLP:	Yes	Sample storage conditions:	max. 142 days at ≤ -18°C
Crop/crop group:	Buckwheat	Analytical method:	R0072/01
Indoor/Outdoor:	Outdoor	Limit of Quantification (mg/kg):	0.01 mg/kg
Formulation:	SC	Residues calculated as:	Ametoctradin, M650F03 (expressed as parent equivalent M650F04 (expressed as parent equivalent)
Content of active substance (g/kg or g/l):	75 g/L ametoctradin		

Trial No./ Location/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or number and last date	Interval between applications (days)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)				PHI (days)
			kg a.s./ha	Water (L/ha)	kg a.s./hL					Ametoctradin	M650F03 (1)	M650F04 (2)	Sum (3)	
L200329/ 04827 Machern, Germany / 2020	Buckwheat GC 0641 Lileia	1. 08.05.2020 2. 05.06.2020 – 06.07.2020 3. 24.06.2020	0.39	200	0.195	27/05/2020 11/06/2020 17/06/2020	15 6	BBCH 65	Inflorescence Pollen Honey	33.0 2.70 1.80	<0.012 <0.012 <0.012	0.018 0.035 <0.013	33.0 2.75 1.83	0 12 7

Trial No./ Location/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or number and last date	Interval between applications (days)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)				PHI (days)
			kg a.s./ha	Water (L/ha)	kg a.s./hL					Ametoctradin	M650F03 (1)	M650F04 (2)	Sum (3)	
L200330/ 04668 Grimma, Germany / 2020	Buckwheat GC 0641 Lileia	1. 06.05.2020 2. 10.06.2020 – 12.07.2020 3. 02.07.2020	0.39	200	0.195	09/06/2020 17/06/2020 24/06/2020	8 7	BBCH 65	Inflorescence Pollen Honey	26.0 31.0 1.20	0.014 <0.012 <0.012	0.086 0.080 0.078	26.10 31.09 1.29	0 5 8
L200331/ 47652 Weeze, Germany / 2020	Buckwheat GC 0641 Panda	1. 18.05.2020 2. 25.06.2020 – 14.07.2020 3. 14.07.2020	0.39	200	0.195	17/06/2020 25/06/2020 02/07/2020	8 15	BBCH 63-65	Inflorescence Pollen Honey	34.0 3.20 0.079	<0.012 <0.012 <0.012	0.030 0.083 <0.013	34.04 3.30 0.10	0 6/12 12
L200332/ 46342 Velen-Ramsdorf, Germany / 2020	Buckwheat GC 0641 Panda	1. 26.05.2020 2. 05.07.2020 – 02.08.2020 3. 31.07.2020	0.39	200	0.195	28/06/2020 11/07/2020 17/07/2020	13 6	BBCH 65	Inflorescence Pollen Honey	43.0 1.30 0.077	<0.012 <0.012 <0.012	<0.013 <0.013 <0.013	43.03 1.33 0.10	0 4/10 14

1) Expressed as parent equivalent; molecular weight conversion factor for calculation of M650F03 to parent ametoctradin is 1.245, the LOQ for M650F03 expressed as parent equivalent is then 0.012 mg/kg.

(2) Expressed as parent equivalent; molecular weight conversion factor for calculation of M650F04 to parent ametoctradin is 1.329, the LOQ for M650F04 expressed as parent equivalent is then 0.013 mg/kg.

(3) Sum of ametoctradin, M650F03 and M650F04, expressed as ametoctradin.

C.3.6 Storage stability

C.3.6.1 Storage stability of residues in plant products

No additional studies submitted.

C.3.6.2 Storage stability of residues in animal products

No additional studies submitted.

C.3.6.3 Storage stability in honey

Reference: Freezer Storage Stability of BAS 181 S (Reg. No. 4117133), BAS 650 F (Reg.No. 4993353), M650F003 (Reg. No. 5178870) and M650F004 (Reg. No. 5211623) in Honey and Pollen for 24 Months, [redacted] 2021. BASF Study Number 886596, BASF Registration Document Number: 2020/2032167.

Guideline(s): EU Test Guidelines: OECD Guideline 506, Stability of Pesticide Residues in Stored Commodities; SANCO7032/VI/95 rev. 5 (22/07/1997)

Deviations: No

GLP: Yes

Validity of the study: Acceptable

Materials and methods

The purpose of the study was to determine the freezer storage stability of ametoctradin, M650F03 and M650F04 residues in honey and pollen for 24 months. A report which only gives the storage results for up to 6 months has been provided. Samples of honey and pollen fortified with standard solutions of ametoctradin, M650F03 and M650F04 each separately at a level of 0.1 mg/kg (10 x LOQ), were stored frozen (approximately -18°C) for durations of 0, 58 - 59, 107 - 113, and 183 - 185 days of frozen storage (approximately 0, 2, 4, 6 months).

On the day of analysis, for each time interval, a minimum of two replicates of each treated bee matrix sample were analysed along with one untreated control sample and two procedural fortification samples. Thus, each sample set consisted of one control, two untreated control samples freshly fortified with each analyte, and two stored samples fortified separately with phosphonic acid (except for 0-day in which case five fortified samples were analysed).

The honey and pollen samples were analysed for ametoctradin, M650F03 and M650F04 using BASF Analytical Method No. R0072/01. This method is validated satisfactorily according to SANTE/2020/12830 rev.1 (see Appendix C.1.2). The validated LOQ is 0.01 mg/kg in honey and pollen, for each analyte.

Results and discussions

Acceptable concurrent recovery data for each analyte were obtained for each tested matrix during the storage stability study. Recovery rates of fortified samples stored up to six months are shown in Table C.3.6.1. Concurrent recoveries range from 73% to 92.5%. Mean storage recoveries were between 72.9% to 94.3% and are considered acceptable.

The data indicate that ametoctradin, M650F03 and M650F04 are stable (>70% of fortified recovered) when stored frozen in honey and pollen for 183-185 days (~6 months), the longest sampling interval tested in the subject study to date.

Table C.3.6.1 Stability of ametoctradin, M650F03 and M650F04 residues following storage at -18°C

Matrix	Spike level (mg/kg)	Storage Interval (days)	% Fresh procedural recoveries (mean)	Storage recoveries		
				Individual values (mg/kg)	Mean (mg/kg)	Recovery (% of nominal fortification level)
Ametoctradin						
Honey	0.1	0	77, 86, 86, 90, 92 (86)	0.0770, 0.0855, 0.0855, 0.0895, 0.0920	0.086	85.9
		58	89.5, 90.5 (90)	0.0905, 0.0945	0.093	92.5
		107	83.5, 85.5 (85)	0.0845, 0.0945	0.090	89.5
		183	76.0, 86.5 (81)	0.0825, 0.0875	0.085	85.0
Pollen	0.1	0	80, 82, 84, 85, 88 (84)	0.0800, 0.0820, 0.0840, 0.0855, 0.0875	0.084	83.8
		59	86.0, 90.0(88)	0.0850, 0.0870	0.086	86.0
		113	81.5, 85.5 (84)	0.0805, 0.0850	0.083	82.8
		185	83.5, 85.5 (85)	0.0880, 0.0900	0.089	89.0
M650F03						
Honey	0.1	0	75, 77, 84, 86, 89 (82)	0.0750, 0.0770, 0.0840, 0.0855, 0.0890	0.082	82.1

Matrix	Spike level (mg/kg)	Storage Interval (days)	% Fresh procedural recoveries (mean)	Storage recoveries		
				Individual values (mg/kg)	Mean (mg/kg)	Recovery (% of nominal fortification level)
		58	80.0, 81.0 (81)	0.0750, 0.0815	0.078	78.3
		107	81.0, 81.0 (81)	0.0750, 0.0850	0.080	80.0
		183	76.0, 85.0 (81)	0.0825, 0.0885	0.085	85.5
Pollen	0.1	0	86, 86, 92, 94, 94 (90)	0.0860, 0.0855, 0.0920, 0.0940, 0.0940	0.090	90.3
		59	86.5, 92.5 (90)	0.0900, 0.0985	0.094	94.3
		113	88.5, 90.0 (89)	0.0900, 0.0925	0.091	91.3
		185	86.0, 88.5 (86)	0.0810, 0.0835	0.082	82.3
M650F04						
Honey	0.1	0	65, 72, 72, 76, 79 (73)	0.0650, 0.0725, 0.0730, 0.0755, 0.0785	0.073	72.9
		58	75.5, 81.5 (79)	0.0780, 0.0825	0.080	80.3
		107	77.5, 82.0 (80)	0.0710, 0.0930	0.082	82.0
		183	73.0, 84.5 (79)	0.0790, 0.0815	0.080	80.3
Pollen	0.1	0	74, 76, 77, 83, 94, (79)	0.0740, 0.0755, 0.0770, 0.0825, 0.0835	0.079	78.5
		59	82.0, 82.5 (82)	0.0760, 0.0795	0.078	77.8
		113	78.5, 83.0 (81)	0.0805, 0.0865	0.083	83.5
		185	79.5, 81.5 (81)	0.0745, 0.0750	0.075	74.8

Conclusion

The results obtained in this study demonstrate that ametoctradin and its metabolites M650F03 and M650F04 are stable in honey and pollen for a storage period of at least 6 months at -18°C.

Appendix D – List of endpoints

The endpoints outlined in Table D.1 and D.2 have been derived as a result of this assessment. All other endpoints remained unchanged. The full list of endpoints is outlined in EFSA Conclusion, 2012.

Table D.1 Stability of residues in products of animal origin

Analytes	Commodity	Temperature (°C)	Stability (months)	Comment/source
Ametoctradin, M650F03 and M650F04	Honey	-18	6	[redacted]
	Pollen	-18	6	

Table D.2 Residue definitions and methods for monitoring/enforcement in honey

Honey residue definition for enforcement (RD-Enf) (For compliance with MRLs)	Ametoctradin
Honey residue definition for risk assessment (RD-RA) (For estimation of dietary exposure)	Sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin
Conversion factors (risk assessment to enforcement)	Molecular weight conversion factor for calculation of M650F03 to parent ametoctradin is 1.245 Molecular weight conversion factor for calculation of M650F04 to parent ametoctradin is 1.329
Methods of analysis for monitoring/enforcement of residues (analytical technique, crop groups, LOQs)	LC-MS/MS LOQ of 0.01 mg/kg

Appendix E – Import Tolerances

Not applicable.

Appendix F – Compound codes

No new metabolism studies were evaluated during this assessment and hence this section has not been completed.

Appendix G – Abbreviations

ADI	Acceptable daily intake
ADME	Absorption, distribution, metabolism and excretion
Animal model 2017	EFSA model used to calculate the dietary burden of livestock using the OECD feeding tables
ARfD	Acute reference dose
a.s.	Active substance
BBCH	Growth stages of mono- and dicotyledonous plants
bw	Body weight
CF	Conversion factor
cGAP	Critical GAP
CXL	Codex maximum residue limit
DAR	Draft assessment report
DAT	Days after treatment
DT_{90}	Period required for 90% dissipation (define method of estimation)
DT_{50}	Period required for 50% dissipation (define method of estimation)
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GB	Great Britain
GC-MS	Gas chromatography with mass spectrometry

GLP	Good laboratory practice
HPLC-MS/MS (LC-MS/MS)	High-performance liquid chromatography with tandem mass spectrometry
HR	Highest residue
HSE	Health and Safety Executive
IEDI	International estimate of daily intake
IESTI	International estimate of short-term intake
ILV	Independent laboratory validation
ISO	International Organisation for Standardization
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC_{50}	Lethal concentration, median
LD_{50}	Lethal dose, median
LOAEL	Lowest observed adverse effect level
LOD	Limit of detection or limit of determination (should be defined)
LoEP	List of endpoints
LOQ	Limit of quantification **NB** the limit of quantification and limit of determination are the same. Assimilated Regulation 396/2005 refers to the limit of determination Assimilated Regulation 1107/2009 refers to the limit of quantification MRLs marked with an asterisk (e.g. 0.01* mg/kg) are MRLs set at the limit of determination/quantification
MRL	Maximum residue level
NEDI	National estimate of dietary intake
NESTI	National estimate of short-term intake

NOAEL	No observed adverse effect level
NRL	National reference laboratory
OECD	Organisation for Economic Co-operation and Development
PBI	Plant-back interval
PES	Post-extraction solids
Pf	Processing factor
PHI	Preharvest interval
PRIMo	(EFSA) Pesticide Residue Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	Risk assessment
RD	Residue definition
RD-Enf	Residue definition for enforcement (also referred to as RD-Mo i.e. residue definition for monitoring)
RD-RA	Residue definition for risk assessment
RTI	Re-treatment interval
STMR	Supervised trials median residue
TRR	Total radioactive residue
TTC	Threshold of toxicological concern
WG	Water dispersible granule
WHO	World Health Organization

Additional studies relied upon

Author(s)	Year	Title/Testing Facility/Report No./GLP or GEP Status/Published or not	Submitter
[redacted]	2020	Freezer Storage Stability of BAS 181 S (Reg. No. 4117133), BAS 650 F (Reg.No. 4993353), M650F003 (Reg. No. 5178870) and M650F004 (Reg. No. 5211623) in Honey and Pollen for 24 Months Report No 886596, 2020/2032167 GLP Unpublished	BASF plc
	2020	Determination of residues of BAS 650 F (Ametoctradin) and BAS 181 S (Phosphonic Acid) in buckwheat and buckwheat honey after three applications of BAS 657 00 F under semi-field conditions in Northern Europe Report No 886593 BASF DocID 2020/2031155 GLP Unpublished	BASF plc
	2020	Validation of Method L0275/02: Method for the Determination of Phosphorous Acid (BAS 181 S, Reg. No. 4117133) in Plant Matrices by LC-MS/MS report No 833617 BASF DocID 2018/1203034 GLP Unpublished	BASF plc
	2020	Independent Lab Validation of BASF Analytical Method R0072/01: "Method for the determination of BAS 181 S (Reg. No. 4117133), BAS 650 F (Reg. No. 4993353), M650F003 (Reg. No. 5178870), and M650F004 (Reg. No. 5211623) in Pollen and Honey by LC-MS/MS" BASF Registration Document Number: 2020/2032165 BASF Study Number: 886595 CRO Study Identification Number: 137G2694 GLP Unpublished	BASF plc