The evaluation of a new MRL for flonicamid in or on beans (without pods)

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 2022/00443

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Contents

Summary

In accordance with Article 6 of Assimilated Regulation 396/2005,[1] HSE received an application on 5 April 2023 to amend the existing MRL for the active substance flonicamid in or on beans (without pods). The application was to support an extension of authorisation for minor use.

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 MRL. 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 flonicamid in products of plant origin, in line with the residue definition for enforcement, are available to support the use under consideration in the MRL application.

Toxicological reference values were established for the approval of the active substance: an ADI of 0.025 mg/kg bw/day and an ARfD of 0.025 mg/kg bw.

The metabolism of flonicamid in primary crops was investigated in fruit crops (peach, pepper), root crops (potato), and cereals and grasses (wheat) following foliar application for the approval of flonicamid (EFSA Conclusion, 2010 and EFSA Reasoned Opinion, 2014). As a consistent metabolic pathway was observed across crops from three crop groups, the available data are sufficient to support all crop groups. This includes pulses and oilseeds which the crop included in this MRL application belongs to.

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

- Sum of flonicamid, TFNA and TFNG expressed as flonicamid

[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 plants has been agreed as:

- Sum of flonicamid, TFNA and TFNG expressed as flonicamid

Nine outdoor trials on peas, conducted in Northern France and Belgium, were submitted to support an MRL for beans (without pods). Samples of peas (without pods) were analysed for residues of flonicamid and its metabolites TFNG and TFNA. These trials were extrapolated to support beans (without pods), in accordance with SANCO 7525/VI/95 rev. 10.3. These trials are supported by validated analytical methods and storage stability data.

Hydrolysis of flonicamid and its metabolites TFNG and TFNA was investigated and determined to be hydrolytically stable under the representative conditions of pasteurisation, baking, brewing, boiling and sterilisation. The hydrolysis data demonstrate that flonicamid and its metabolites TFNG and TFNA are stable under standard conditions, therefore specific residue definitions for processed commodities are not required.

Since the DT_{90} values for flonicamid and its metabolites in soil are all below the trigger value of 100 days, no further consideration of residues in rotational crops is required.

No consideration of the dietary burden of livestock is required as the crop considered in this assessment is not used as an animal feedstuff.

The highest UK NEDI was 32% of the ADI (infant). The highest PRIMo IEDI was 32% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with flonicamid.

The highest UK NESTI was 12.7% of the ARfD (7–10 year old child/beans without pods). The highest PRIMo IESTI was 14% of the ARfD (children/beans without pods). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with flonicamid.

HSE concludes that sufficient data have been provided to support the setting of a new MRL for the proposed use of flonicamid on beans (without pods). This use will not result in consumer exposures exceeding the toxicological reference values 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 0.1 MRLs recommended by HSE

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
Enforcement residue definition for products of plant origin: Sum of flonicamid, TFNA and TFNG expressed as flonicamid				
0260020	Beans without pods	0.03*	0.7	The MRL is derived by extrapolation of residue trials on peas without pods. No health effects are expected.

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

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 5 April 2023 HSE accepted an application to set a new MRL for flonicamid in or on beans (without pods).

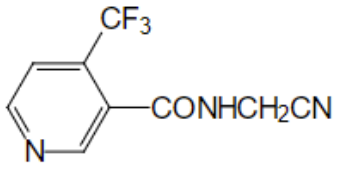
HSE evaluated the information submitted to uniform principles, as defined by Article 8 of Assimilated Regulation 396/2005, and prepared an Evaluation Report. HSE also took into account EFSA Reasoned Opinions and Conclusions on the peer review relating to decisions implemented in GB.

The Evaluation Report is the basis of HSE's Reasoned Opinion; HSE recommends that the MRL for beans (without pods) is amended from 0.03* mg/kg to 0.7 mg/kg.

The active substance and its use pattern

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

Table 0.2 Information on the active substance

Common name (ISO)	Flonicamid
Chemical name (IUPAC)	N-cyanomethyl-4-(trifluoromethyl)nicotinamide
CAS number	158062-67-0
Structural formula	
Molecular formula	$C_9H_6F_3N_3O$
Molecular mass	229.16 g/mol

Flonicamid is an approved active substance in GB. An EFSA conclusion is available (EFSA Conclusion, 2010). The MRLs for flonicamid were reviewed under Article 12 of Assimilated Regulation 396/2005 (EFSA Article 12 RO, 2014). MRLs are established for flonicamid in Part 2 of the GB MRL Statutory Register.

Flonicamid is an insecticide/aphicide. It exhibits systemic and translaminar activity and inhibits feeding. Foliar application is used to control aphids in various crops.

Appendix A outlines the GAPs (Good Agricultural Practices) supported in this application. In GB, the terminology used for PPP authorisations is outlined in the crop definitions list.[3] The authorisation in GB will be for broad beans and the applicable MRLs are on beans (with pods) and beans (without pods). Only the MRL for beans (without pods) has been considered in this assessment. The applicable MRL is used to refer to the crop commodity throughout this assessment.

It is noted that a CXL of 0.3 mg/kg is available for flonicamid in or on succulent beans without pods (subgroup) (except for soya beans (succulent seeds)). This CXL is relevant to this MRL assessment. However, this CXL was not previously adopted by the EU since it was based on the residue definition endorsed by the JMPR, which contained flonicamid only. The trials evaluated by the JMPR did not provide data on the metabolites TFNA and TFNG, and it is not possible to estimate the residue levels for the metabolites since suitable metabolism data is not available to determine a conversion factor (CF). The trials

[3] HSE Crop Definitions List

data submitted for this MRL assessment also cannot be used to estimate a CF for the metabolites since this data was generated based on a different GAP. Furthermore, the trials data submitted for this MRL assessment indicates that the metabolites are major components of the total residue, which supports the GB residue definition. On this basis, the CXL in or on succulent beans without pods (subgroup) cannot be adopted.

Assessment

1 Methods of analysis

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

Analytical methods for the determination of residues of flonicamid and its metabolites TFNA and TFNG in products of plant origin (wheat grain and straw, potato), in line with the residue definition for enforcement, were assessed for the approval of the active substance (EFSA Conclusion, 2010). Additional methods were assessed as part of the Article 12 MRL Review (EFSA, 2014) determining residues in other plant commodities (potato, oilseed rape, wheat grain, plum and lemon).

The HPLC-MS/MS method is validated for the high water, high fat, high acid and dry commodity groups with an LOQ of 0.01 mg/kg for each analyte in crops (combined LOQ of 0.03 mg/kg). Acceptable ILV data were provided.

The enforcement method uses a mixture of acetonitrile/water/acetic acid (60/40/0.1, v/v/v) for the extraction of residues from the plum fruit. The radiolabelled metabolism studies in the DAR used acetonitrile: water in various ratios, sometimes in the presence of an acid, as the extraction solvent. Since the solvent in the metabolism studies is the same as the solvent in the analytical method, extraction efficiency is considered to be sufficiently demonstrated.

The crop under consideration in this application (beans without pods) is a high water content commodity. This crop matrix is covered by the available enforcement methods.

Hence, it is concluded that the sum of flonicamid and its metabolites TFNA and TFNG, expressed as flonicamid, can be enforced with a combined LOQ of 0.03 mg/kg in high water content commodities.

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

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

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 flonicamid

TRVs	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA	2010	0.025 mg/kg bw/d	Rabbit developmental	100
ARfD	EFSA	2010	0.025 mg/kg bw	Rabbit developmental	100

3 Residues in plants

3.1 Nature of residues in primary crops

Metabolism in primary crops was investigated following foliar spray treatment in cereals and grasses (wheat), root crops (potatoes) and fruit crops (peach and pepper) for the approval of flonicamid (DAR, FR, 2005).

The following summary is presented by EFSA (EFSA RO, 2018):

"The metabolism of flonicamid in primary crops belonging to the group of fruit crops (peach, pepper), root crops (potato) and cereals/grass (wheat) has been investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2010, 2014). When primary crops were treated with 3-^{14}C-phenyl flonicamid, parent compound and the two metabolites 4-trifluoromethylnicotinic acid (TFNA) and N-(4-trifluoromethylnicotinoyl)glycine (TFNG) were found to be the main residues."

A summary of the available primary crop metabolism data is presented in Table 3.1-1 below:

Table 3.1-1 Summary of the primary plant metabolism studies

Crop groups	Crop(s)	Applications	DAT [(a)] (days)
Fruit	Peach	Foliar, 2 x 100 g a.s./ha and 2 x 500 g a.s./ha	21
	Pepper	Foliar, 1 x 100 g a.s./ha	7, 14
Root crops	Potato	Foliar, 2 x 100 g a.s./ha and 2 x 500 g a.s./ha	14
Cereals/grass crops	Wheat	Foliar, 2 x 100 g a.s./ha and 2 x 500 g a.s./ha	21

(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. The application type in the studies is foliar spray, which is the same as the application type for the proposed use. On this basis the proposed crop assessed within this evaluation is supported by the available metabolism data.

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

- Sum of flonicamid, TFNA and TFNG expressed as flonicamid

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

- Sum of flonicamid, TFNA and TFNG expressed as flonicamid

3.2 Magnitude of residues in primary crops

The uses notified in the MRL application are outlined in Appendix A.

Residue trials

0260020 Beans (without pods)

The proposed critical GAP on outdoor broad beans (fresh) is 1 x 70 g a.s./ha with a PHI of 14 days. Application is at BBCH 16 – 88.

Fresh broad beans can be harvested and marketed with or without the pod. The GB MRL currently in force for beans with pods covers the proposed GAP and hence no further consideration is made in this ER/RO. The MRL for beans without pods is considered in this ER/RO.

It is noted that the trials submitted and summarised below were evaluated for the purposes of setting an MRL in peas (without pods) (EFSA, 2015) – these trials form the basis of the current GB MRL on peas (without pods). The trials have been summarised below and reported in the appendix for completeness.

Nine trials were conducted on outdoor peas across three separate studies. These trials are summarised below:

- Two outdoor trials were conducted in Belgium and were performed within 25% of the cGAP (1 x 69 g a.s./ha) with a PHI of 14 days. Application was at BBCH 69. Both trials determined residues at harvest (14 days after treatment).

- Three outdoor trials were conducted in Northern France and were performed within 25% of the cGAP (1 x 71 g a.s./ha) with a PHI of 13 days. Application was at BBCH 76. One trial had a PHI of 22 days due to poor weather; the overall residues trials data available from the DAR and previous assessments indicates that flonicamid is not likely to be persistent, and residues will tend to decline over time. The metabolites could potentially be at similar levels over the period 7 – 14 days after treatment. As the measured residue levels 22 days after application were similar to those found in the other trials 13 days after application, then this trial has been included as supporting the GAP. Two of the trials determined residues at harvest (13 days after treatment), while one trial determined residues 22 days after treatment.

- Four outdoor trials were conducted in Northern France and were performed within 25% of the cGAP (1 x 71 – 73 g a.s./ha) with a PHI of 14 days. Application was at BBCH 75. All four trials determined residues at harvest (14 days after treatment).

All trials were conducted using ‘Teppeki’, a WG formulation containing 500 g/kg flonicamid. The individual studies submitted in the framework of the MRL application are reported and assessed in detail in Appendix C.3.1.2.

Samples of peas (whole pods) were collected and manually processed to separate seeds from pods. Only residues determined in seeds (peas without pods) have been considered in this MRL assessment.

As set out in SANCO 7525/VI/95 rev. 10.3, beans (without pods) is a minor crop, therefore four trials are required to support the proposed use on broad beans. SANCO 7525/VI/95 rev. 10.3 also stipulates that residue trials on peas (without pods) (0260040) may be extrapolated to support beans (without pods) (0260020).

As the application to beans without pods will occur when the edible portion of the crop is present, then half the trials should be decline trials. All the trials supporting the GAP were harvest trials. In this specific case further data are not required for the following reasons:

- Beans with pods are a minor crop and as such only 4 trials are required, 9 trials are available.
- The trials cover 3 different growing seasons
- The trials are spread over a reasonable geographical region
- Residues are not expected to increase further at longer intervals after application

Based on all 4 factors it is considered that there is sufficient variation within the data available to cover the likely residues that will arise and to use the data to set an MRL that covers the GAP. A lack of decline data may not be acceptable in other cases. Nine trials on peas (without pods) are available across the three studies. The trials in all three studies are all considered representative of the cGAP.

Residue trials data are summarised in Table 3.2. The residue trials demonstrate residues above the current MRL (0.03* mg/kg) and support an MRL of 0.7 mg/kg.

Storage stability

Peas (without pods) are considered high water content commodities. The stability of residues of flonicamid and its metabolites TFNG and TFNA during storage of samples was considered in a number of crop matrices for the approval of the active substance (DAR, FR, 2005, 2009). This included a study on apples and potatoes (both high water content commodities), which demonstrated stability for all analytes for a period of 18 months at –18 °C. This study supports the maximum storage period of 9 months in the trials.

Analytical methods

Analysis for residues of flonicamid, TFNA and TFNG was conducted using an LC-MS/MS method. Residues of TFNA and TFNG are expressed as flonicamid equivalents using the following molecular weight conversions:

$MWC_{TFNA} = MW_{flonicamid} / MW_{TFNA} = 229.16/191.11 = 1.199$

$MWC_{TFNG} = MW_{flonicamid} / MW_{TFNG} = 229.16/248.16 = 0.923$

The analytical method was considered satisfactorily validated in accordance with SANTE/2020/12830 rev.1 in peas (without pods). Analytes were extracted from the crop matrix by agitation with acetonitrile and water with 0.2% acetic acid. The radiolabelled metabolism studies in the DAR used acetonitrile: water in various ratios, sometimes in the presence of an acid, as the extraction solvent. Since the solvent in the metabolism studies is the same as the solvent in the analytical method, extraction efficiency is considered to be sufficiently demonstrated. See section C.1.3 for full details.

The LOQ of this method was determined to be 0.01 mg/kg for all analytes. Acceptable linearity, specificity, accuracy, and precision data have been reported. See section C.1.3 for full details.

Table 3.2 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 flonicamid, TFNA and TFNG expressed as flonicamid						
Peas (without pods) → beans (without pods) Intended GAP: 1 x 70 g a.s./ha, BBCH 16 – 88, 14 day PHI Trials GAP: (1 x 69 – 74 g/ha, BBCH 69 – 77, 13 – 22 day PHI)	GB/outdoor	0.104, 0.11, 0.13†, 0.17, 0.18, 0.214, 0.28, 0.37, 0.43	MRL_{OECD}: 0.686/0.7	0.7	0.43	0.18

† Result excluded in EFSA 2015 due to late PHI (22 days); however, it has been included in the current assessment as the result is comparable to the remaining trials which were considered.

(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 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 risk assessment (within brackets when expressed according to the residue definition for enforcement: $STMR_{Enf}$)

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

Studies on the hydrolysis of flonicamid under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation were evaluated as part of the EFSA Article 12 MRL Review (EFSA, 2014). These studies were re-reviewed in an evaluation report produced by HSE (HSE reference: COP 2017/01329). The re-review of these data supports the conclusion that residues of parent flonicamid are hydrolytically stable.

A study on the effect of processing on the nature of residues of the metabolites TFNG and TFNA under standard hydrolysis conditions was also evaluated as part of the evaluation report produced by HSE. It was concluded that both TFNG and TFNA are hydrolytically stable. No degradation products were observed for either TFNG or TFNA.

The hydrolysis data demonstrates that flonicamid, TFNG and TFNA are stable across the standard conditions, therefore specific residue definitions for processed commodities are not required.

3.4.2 Magnitude of the residues in processed commodities

The residue trials indicate that residues in the RACs are expected to be >0.1 mg/kg when the crops are treated in line with the cGAP.

The cooking of beans (without pods) is relevant to the intended crop (broad beans). According to the Annex of OECD Guidance No. 96, the cooking of beans (without pods) is an example of procedure VI (cooking vegetables, pulses and grains in water (including steaming)). This procedure is listed as Category 2 within OECD 508 and therefore this is not regarded as a major industrial procedure. Data for these processing procedures are more relevant when the consumer risk assessment needs to be refined. A refinement of the consumer risk assessment is not required at this time.

No further consideration of processing for beans (without pods) is required.

3.5 Rotational crops

According to the EFSA Conclusion on the peer review of flonicamid (EFSA Journal 2010; 8(5):1445):

"A study on residues in succeeding crops is not required, since it is not expected that significant residues remain in soil and may be taken up by succeeding crops. The degradation of flonicamid is extremely rapid in soil with a geometric mean DT_{50} of 1 day. Similarly, the degradation of all soil metabolites is very rapid. DT_{50} values ranged between 0.3 and 2.6 days for the metabolites TFNA, TFNA-OH, TFNG, TFNG-AM and TFNA-AM."

Since the DT_{90} values for flonicamid and its metabolites in soil are all below the trigger value of 100 days, no further consideration of residues in rotational crops is required.

4 Residues in livestock

No consideration of residues in products of animal origin is required as the crop under consideration is not used as an animal feedstuff and significant residues are not expected in rotational crops.

5 Residues in honey

No consideration of residues in honey is required, as the application is being assessed to the data requirements set out under Assimilated Regulation 544/2011.

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 and acute dietary exposure models and the EFSA PRIMo model.

The chronic risk assessments have been estimated based on the use of flonicamid considered in this application, the uses considered in previous assessments supporting existing GB MRLs (GB MRL 2022/015) and, for the remaining commodities, the existing MRLs established in the GB MRL Statutory Register.

The acute risk assessments have only been estimated for the use of flonicamid considered in this application.

UK NEDIs and NESTIs

The UK NEDIs and NESTIs for the active substance and commodities listed in Table 7.1-1 have been calculated for ten consumer groups using the UK chronic and acute models (versions 1.1 and 1.2 respectively) as detailed in Regulatory Update 21/2005. The following assumptions have been made:

- For the NESTIs, upper range of normal (97.5th percentile) consumption of each individual crop which may have been treated.
- 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**		**Acute risk assessment**	
	Input (mg/kg)	**Comment**	**Input (mg/kg)**	**Comment**
Risk assessment residue definition for plants: Sum of flonicamid, TFNA and TFNG expressed as flonicamid **Risk assessment residue definition for products of animal origin:** Sum of flonicamid and TFNA-AM, expressed as flonicamid				
Beans (without pods)	**0.18**	**STMR (current assessment, extrapolated from trials on peas without pods)**	**0.43**	**HR (current assessment)**
Grapefruit	0.04	STMR (EFSA, 2014)	Acute risk assessment undertaken only for the uses proposed as part of the current assessment	
Lemons	0.04			
Limes	0.04			
Mandarins	0.04			
Oranges	0.04			
Almonds	0.06*	MRL (GB MRL 2022/015)		
Brazil nuts	0.06*			
Cashew nuts	0.06*			
Chestnuts	0.06*			
Coconuts	0.06*			
Hazelnuts	0.06*			
Pecan nuts	0.06*			
Pistachios	0.06*			
Walnuts	0.06*			
Peanuts	0.06*			
Apples	0.06*	STMR (EFSA, 2014)		
Pears	0.06*			
Apricots	0.099	STMR (EFSA, 2017)		
Peaches	0.08	STMR (EFSA, 2014)		
Plums	0.09			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Cherries	0.13			
Table grapes	0.03*	MRL (GB MRL 2022/015)		
Wine grapes	0.03*			
Strawberries	0.03*			
Blackberries	0.421	STMR (HSE, 2022)		
Loganberries	0.36			
Raspberries	0.421			
Gooseberries	0.421			
Blackcurrants	0.421			
Red currants	0.421			
White currants	0.421			
Avocadoes	0.03*	MRL (GB MRL 2022/015)		
Bananas	0.03*			
Dates	0.03*			
Figs	0.03*			
Kiwi fruit	0.03*			
Lychees	0.03*			
Mangoes	0.03*			
Olives	0.03*			
Passion fruit	0.03*			
Pineapples	0.03*			
Pomegranates	0.03*			
Beetroot	0.05	STMR (EFSA, 2018)		
Carrots	0.05			
Celeriac	0.05			
Horseradish	0.05			
Jerusalem artichokes	0.05			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Parsnips	0.05			
Radishes	0.05			
Salsify	0.05			
Swedes	0.05			
Turnips	0.05			
Yam	0.03*	MRL (GB MRL 2022/015)		
Garlic	0.03*			
Onions	0.03*			
Spring onions	0.03*			
Tomatoes	0.14	STMR (EFSA, 2014)		
Peppers	0.06			
Aubergines	0.14			
Marrows	0.15			
Cucumbers	0.15			
Gourd	0.06			
Courgettes	0.15			
Melons	0.06			
Sweet corn	0.03*	MRL (GB MRL 2022/015)		
Broccoli	0.03*			
Cauliflower	0.03*			
Brussels sprouts	0.07	STMR (EFSA, 2015)		
Head cabbage	0.14	STMR (EFSA, 2017)		
Chinese cabbage	0.03*	MRL (GB MRL 2022/015)		
Kohl rabi	0.03*			
Cress	0.03*			
Lettuce	0.03*			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Spinach	0.03*			
Watercress	0.03*			
Chicory	0.03*			
Parsley	0.71	STMR (EFSA, 2016)		
Beans with pods	0.34	STMR (EFSA, 2017)		
Runner beans	0.34			
Peas with pods	0.34			
Peas without pods	0.2			
Beansprouts	0.03*	MRL (GB MRL 2022/015)		
Asparagus	0.03*			
Bamboo shoots	0.03*			
Celery	0.03*			
Fennel	0.03*			
Globe artichokes	0.03*			
Leeks	0.03*			
Rhubarb	0.03*			
Cultivates mushrooms	0.03*			
Beans	0.03*			
Lentils	0.03*			
Dried peas	0.03*			
Oilseeds	0.04	STMR (EFSA, 2016)		
Potatoes	0.03	STMR (EFSA, 2014)		
Hops (dried)	0.61			
Oats	0.17	STMR (EFSA, 2015)		
Barley	0.17			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Millet	0.03*	MRL (GB MRL 2022/015)		
Buckwheat	0.03*			
Maize	0.03*			
Wheat	0.35	STMR (EFSA, 2014)		
Rice	0.03*	MRL (GB MRL 2022/015)		
Rye	0.35	STMR (EFSA, 2014)		
Poultry	0.04	STMR (FAO, 2016)		
Meat fat	0.02			
Meat excl. poultry & offal[(a)]	0.06	STMR (FAO, 2016) – not fat soluble		
All types of kidney	0.1	STMR (FAO, 2016)		
All types of liver	0.1			
Other types of offal	0.1			
Eggs	0.084	STMR (EFSA, 2017)		
Milk	0.05	STMR (FAO, 2016)		
Sugar beet	0.03	STMR (EFSA, 2017)		

* indicates residues at the LOQ

[(a)] Consumption figures are expressed as meat. The EFSA RO reports residues in muscle. It is noted that the active is not fat soluble.

In bold uses proposed as part of the current assessment.

Model outputs for the UK chronic and acute models (versions 1.1 and 1.2 respectively) are presented in Appendix B.

PRIMo

The PRIMo IEDIs and IESTIs for the active substance and commodities listed in Table 7.1-2 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 given in Table 7.2-1.
- There is no loss of residue during transport, storage or processing of foods prior to consumption.

The input values for the PRIMo risk assessment are given in Table 7.1-2.

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

Commodity	**Chronic risk assessment**		**Acute risk assessment**	
	Input (mg/kg)	**Comment**	**Input (mg/kg)**	**Comment**
Risk assessment residue definition for plants: Sum of flonicamid, TFNA and TFNG expressed as flonicamid **Risk assessment residue definition for products of animal origin:** Sum of flonicamid and TFNA-AM, expressed as flonicamid				
Beans (without pods)	**0.18**	**STMR (current assessment)**	**0.43**	**HR (current assessment)**
Citrus fruit	0.04	STMR (EFSA, 2014)	Acute risk assessment undertaken only for the uses proposed as part of the current assessment	
Pome fruit	0.06*			
Apricots	0.099	STMR (EFSA, 2017)		
Peaches	0.08	STMR (EFSA, 2014)		
Plums	0.09			
Cherries	0.13			
Blackberries	0.421	STMR (HSE, 2022)		
Dewberries	0.36			
Raspberries	0.421			
Other small fruits and berries	0.421			
Potatoes	0.03	STMR (EFSA, 2014)		
Beetroot	0.05	STMR (EFSA, 2018)		
Carrots	0.05			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Celeriac	0.05			
Horseradish	0.05			
Jerusalem artichokes	0.05			
Parsnips	0.05			
Parsley root	0.05			
Radishes	0.05			
Salsify	0.05			
Swedes	0.05			
Turnips	0.05			
Tomatoes	0.14	STMR (EFSA, 2014)		
Peppers	0.06			
Aubergines	0.14			
Cucumbers	0.15			
Gherkins	0.15			
Courgettes	0.15			
Cucurbits – inedible peel (melons, pumpkins, watermelons, others)	0.06			
Brussels sprouts	0.07	STMR (EFSA, 2015)		
Head cabbage	0.14	STMR (EFSA, 2017)		
Herbs and edible flowers	0.71	STMR (EFSA, 2016)		
Beans with pods	0.34	STMR (EFSA, 2017)		
Peas with pods	0.34			
Peas without pods	0.2			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Cotton seed	0.04	STMR (EFSA, 2016)		
Hops	0.61			
Oats	0.17	STMR (EFSA, 2015)		
Barley	0.17			
Wheat	0.35	STMR (EFSA, 2014)		
Rye	0.35			
Sugar beet	0.03	STMR (EFSA, 2017)		
Swine, bovine, sheep, goat, horse: meat	0.06	STMR (FAO, 2016)		
Swine, bovine, sheep, goat, horse: fat free of lean meat	0.02			
Swine, bovine, sheep, goat, horse: liver	0.10			
Swine, bovine, sheep, goat, horse: kidney	0.10			
Swine, bovine, sheep, goat, horse: edible offal	0.10			
Poultry: meat	0.04			
Poultry: fat	0.04			
Poultry liver	0.037	STMR (EFSA, 2017)		
Milk and cream	0.05	STMR (FAO, 2016)		
Bird’s eggs	0.084	STMR (EFSA, 2017)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Other plant and animal commodities	MRL	MRL (GB MRL 2022/015)		

* indicates residues at the 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 32% of the ADI (infant). The highest PRIMo IEDI was 32% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with flonicamid.

The highest UK NESTI was 12.7% of the ARfD (7–10 year old child/beans without pods). The highest PRIMo IESTI was 14% of the ARfD (children/beans without pods). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with flonicamid.

The use will not result in consumer exposures exceeding the toxicological reference values and therefore the use is unlikely to have harmful effects on human health.

7.2 Other routes of exposure

Not applicable.

8 The conclusion of the competent authority

Sufficiently validated analytical methods for the determination of flonicamid in products of plant origin, in line with the residue definition for enforcement, are available to support the use under consideration in the MRL application.

Toxicological reference values were established for the approval of the active substance: an ADI of 0.025 mg/kg bw/day and an ARfD of 0.025 mg/kg bw.

The metabolism of flonicamid in primary crops was investigated in fruit crops (peach, pepper), root crops (potato), and cereals and grasses (wheat) following foliar application for the approval of flonicamid (EFSA Conclusion, 2010 and EFSA Reasoned Opinion, 2014). As a consistent metabolic pathway was observed across crops from three crop groups, the available data are sufficient to support all crop groups. This includes pulses and oilseeds which the crop included in this MRL application belongs to.

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

- Sum of flonicamid, TFNA and TFNG expressed as flonicamid

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

- Sum of flonicamid, TFNA and TFNG expressed as flonicamid

Nine outdoor trials on peas, conducted in Northern France and Belgium, were submitted to support an MRL for beans (without pods). Samples of peas without pods were analysed for residues of flonicamid and its metabolites TFNG and TFNA. These trials were extrapolated to support beans (without pods), in accordance with SANCO 7525/VI/95 rev. 10.3. These trials are supported by validated analytical methods and storage stability data.

Hydrolysis of flonicamid and its metabolites TFNG and TFNA was investigated and determined to be hydrolytically stable under the representative conditions of pasteurisation, baking, brewing, boiling and sterilisation. The hydrolysis data demonstrate that flonicamid and its metabolites TFNG and TFNA are stable under standard conditions, therefore specific residue definitions for processed commodities are not required.

Since the DT_{90} values for flonicamid and its metabolites in soil are all below the trigger value of 100 days, no further consideration of residues in rotational crops is required.

No consideration of the dietary burden of livestock is required as the crop considered in this assessment is not used as an animal feedstuff and significant residues are not expected in rotational crops.

The highest UK NEDI was 32% of the ADI (infant). The highest PRIMo IEDI was 32% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with flonicamid.

The highest UK NESTI was 12.7% of the ARfD (7–10 year old child/beans without pods). The highest PRIMo IESTI was 14% of the ARfD (children/beans without pods). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with flonicamid.

HSE concludes that sufficient data have been provided to support the setting of a new MRL for the proposed use of flonicamid on beans (without pods). This use will not result in consumer exposures exceeding the toxicological reference values 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 MRLs recommended by HSE

Product code	**Product**	**Existing GB MRL (mg/kg)**	**New or amended GB MRL (mg/kg)**	**Comments**
Enforcement residue definition for products of plant origin: Sum of flonicamid, TFNA and TFNG expressed as flonicamid				
0260020	Beans without pods	0.03*	0.7	The MRL is derived by extrapolation of residue trials on peas without pods. No health effects are expected.

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

References

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France, 2005. Draft Assessment Report (DAR) on the active substance flonicamid prepared by the rapporteur member state France in the framework of Directive 91/414/EEC, February 2005.

France, 2009. Final Addendum to Draft Assessment Report on flonicamid, compiled by EFSA, November 2009.

HSE, 2022. The evaluation of new MRLs for flonicamid in or on various berries and small fruits. September 2022.

The Netherlands, 2016. Evaluation Report Prepared under Article 8 of Regulation (EC) No 396/2005. MRL application on the setting of MRLs for flonicamid in several commodities (Pulses, lettuce and other salad plants, strawberries, other small fruits & berries, cane fruits). 03 November 2016.

Appendix A – GAPs notified in the MRL application

Crop and/or situation (a)	GB or Country For Import Tolerance	Product name	F,G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					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)	g a.s /hL min-max (l)	Water (L/ha) min-max	g a.s./ha min-max (l)		
Broad bean (fresh)	GB	Teppeki	F	Peach potato aphid (*Myzus persicae*), black bean aphid (*Aphis fabae*), pea aphid (*Acyrthosiphon pisum*)	WG	500 g/kg	Horizontal boom sprayer	BBCH 16 – 88	1	N/A	17.5 – 35	200 – 400	70	14 days	Fresh broad beans are harvested and marketed either with or without the pod. The current MRL for beans with pods supports the GAP. Only the MRL for beans without pods has been considered in the application.

(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 glasshouse (G) or indoor use (I).
(c) *e.g.* biting and sucking insects, soil borne 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. fluroxypyr). 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 model version 1.1

Active substance: Flonicamid **ADI:** 0.025 mg/kg bw/day **Source:** EFSA, 2010

			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		0.00233	0.00788	0.00755	0.00623	0.00451	0.00314	0.00265	0.00285	0.00210	0.00244
	% of ADI		9%	32%	30%	25%	18%	13%	11%	11%	8%	10%
	STMR	**P**	**COMMODITY INTAKES**									
Commodity	**(mg/kg)**		**(mg/kg bw/day)**									
Grapefruit	0.04		0.00008	0.00006	0.00023	0.00021	0.00046	0.00008	0.00006	0.00009	0.00010	0.00008
Lemons	0.04		0.00001	0.00003	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00000
Limes	0.04		0.00001	L/C	0.00007	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00002
Mandarins	0.04		0.00006	L/C	0.00026	0.00014	0.00012	0.00006	0.00007	0.00005	0.00006	0.00003
Oranges	0.04		0.00015	0.00043	0.00066	0.00045	0.00033	0.00032	0.00026	0.00018	0.00014	0.00011
Almonds	0.06		0.00001	0.00003	0.00001	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Brazil nuts	0.06		0.00001	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	L/C
Cashew nuts	0.06		0.00001	L/C	0.00003	0.00001	0.00000	0.00000	0.00000	0.00001	0.00001	0.00000
Chestnuts	0.06		0.00001	L/C	L/C	L/C	L/C	L/C	0.00000	0.00002	0.00001	L/C

Coconuts	0.06		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00002	0.00001	0.00001
Hazelnuts	0.06		0.00001	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.06		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00002	0.00001	L/C
Pistachios	0.06		0.00002	L/C	0.00002	L/C	0.00001	L/C	L/C	0.00001	L/C	L/C
Walnuts	0.06		0.00001	L/C	0.00002	0.00000	0.00000	0.00000	0.00001	0.00001	0.00001	0.00000
Peanuts	0.06		0.00002	0.00004	0.00006	0.00005	0.00003	0.00004	0.00002	0.00003	0.00002	0.00000
Apples	0.06		0.00016	0.00051	0.00089	0.00057	0.00045	0.00025	0.00021	0.00020	0.00013	0.00006
Pears	0.06		0.00008	0.00015	0.00039	0.00022	0.00013	0.00011	0.00009	0.00011	0.00014	0.00007
Apricots	0.099		0.00004	0.00013	0.00010	0.00006	0.00004	0.00004	0.00002	0.00007	0.00004	0.00004
Peaches	0.08		0.00011	0.00011	0.00025	0.00013	0.00009	0.00006	0.00004	0.00007	0.00007	0.00003
Plums	0.09		0.00008	0.00004	0.00019	0.00012	0.00007	0.00003	0.00002	0.00006	0.00006	0.00002
Cherries	0.13		0.00006	0.00019	0.00014	0.00020	0.00007	0.00009	0.00008	0.00007	0.00005	0.00001
Table grapes	0.03		0.00004	0.00005	0.00014	0.00006	0.00008	0.00003	0.00002	0.00006	0.00004	0.00001
Wine grapes	0.03		0.00030	0.00004	0.00003	0.00003	0.00001	0.00003	0.00011	0.00029	0.00020	0.00004
Strawberries	0.03		0.00002	0.00006	0.00006	0.00004	0.00003	0.00002	0.00002	0.00003	0.00003	0.00002
Blackberries	0.421		0.00005	L/C	0.00082	0.00003	0.00014	0.00011	0.00004	0.00013	0.00011	0.00002
Loganberries	0.36		0.00003	0.00022	0.00041	0.00006	0.00018	0.00009	0.00006	0.00008	0.00006	0.00004
Raspberries	0.421		0.00017	L/C	0.00100	0.00028	0.00042	0.00011	0.00003	0.00017	0.00035	0.00016
Gooseberries	0.421		0.00010	0.00022	0.00028	0.00010	0.00010	0.00010	0.00008	0.00030	0.00035	0.00010
Blackcurrants	0.421		0.00024	0.00050	0.00075	0.00076	0.00058	0.00043	0.00047	0.00015	0.00023	0.00012
Red currants	0.421		0.00003	L/C	0.00033	L/C	0.00002	0.00005	0.00002	0.00002	0.00014	L/C
White currants	0.421		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.03		0.00002	L/C	0.00004	L/C	L/C	L/C	0.00001	0.00002	0.00002	L/C
Bananas	0.03		0.00006	0.00021	0.00020	0.00013	0.00010	0.00006	0.00004	0.00006	0.00005	0.00005
Dates	0.03		0.00001	L/C	0.00001	0.00001	0.00000	0.00000	L/C	0.00001	0.00002	0.00001
Figs	0.03		0.00001	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00002	0.00001	0.00000

Kiwi fruit	0.03		0.00002	L/C	0.00007	0.00006	0.00004	0.00003	0.00007	0.00004	0.00002	0.00000
Lychees	0.03		0.00001	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Mangoes	0.03		0.00002	L/C	0.00005	0.00004	0.00005	0.00002	0.00011	0.00002	0.00001	L/C
Olives	0.03		0.00001	L/C	0.00002	0.00002	L/C	0.00000	L/C	0.00001	0.00001	L/C
Passion fruit	0.03		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	L/C	L/C
Pineapples	0.03		0.00003	0.00016	0.00014	0.00020	0.00007	0.00004	0.00003	0.00003	0.00002	0.00002
Pomegranates	0.03		0.00004	0.00002	0.00002	0.00001	0.00001	0.00002	0.00000	0.00002	0.00002	0.00003
Beetroot	0.05		0.00002	L/C	0.00007	0.00002	0.00002	0.00002	0.00001	0.00002	0.00002	0.00001
Carrots	0.05		0.00004	0.00018	0.00012	0.00010	0.00006	0.00004	0.00005	0.00004	0.00005	0.00004
Celeriac	0.05		0.00002	L/C	L/C	0.00000	0.00000	L/C	L/C	L/C	L/C	L/C
Horseradish	0.05		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C
Jerusalem artichokes	0.05		0.00001	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Parsnips	0.05		0.00002	0.00005	0.00006	0.00004	0.00002	0.00002	0.00001	0.00002	0.00003	0.00001
Radishes	0.05		0.00002	L/C	0.00005	L/C	0.00001	0.00001	0.00001	0.00002	0.00001	0.00000
Salsify	0.05		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Swedes	0.05		0.00002	0.00014	0.00009	0.00003	0.00004	0.00003	0.00002	0.00002	0.00003	0.00002
Turnips	0.05		0.00002	L/C	0.00005	0.00004	0.00003	0.00003	0.00002	0.00001	0.00003	0.00002
Yam	0.03		0.00009	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.03		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.03		0.00002	0.00003	0.00003	0.00003	0.00002	0.00002	0.00002	0.00002	0.00002	0.00001
Spring onions	0.03		0.00001	L/C	0.00000	0.00002	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Tomatoes	0.14		0.00019	0.00026	0.00037	0.00027	0.00026	0.00015	0.00019	0.00025	0.00020	0.00019
Peppers	0.06		0.00002	L/C	0.00005	0.00002	0.00004	0.00002	0.00002	0.00004	0.00003	0.00001
Aubergines	0.14		0.00004	L/C	0.00021	0.00011	0.00004	0.00007	0.00005	0.00009	0.00006	L/C
Marrows	0.15		0.00008	L/C	0.00023	0.00006	0.00009	0.00010	0.00004	0.00008	0.00021	0.00010
Cucumbers	0.15		0.00006	0.00003	0.00036	0.00023	0.00016	0.00008	0.00007	0.00008	0.00007	0.00003

Gourd	0.06		0.00003	L/C	L/C	L/C	L/C	0.00002	L/C	0.00001	L/C	L/C
Courgettes	0.15		0.00006	0.00022	0.00036	0.00019	0.00012	0.00006	0.00006	0.00008	0.00008	0.00007
Melons	0.06		0.00015	0.00018	0.00031	0.00021	0.00018	0.00013	0.00017	0.00015	0.00018	0.00006
Sweet corn	0.03		0.00002	0.00003	0.00007	0.00003	0.00004	0.00001	0.00002	0.00002	0.00003	0.00001
Broccoli	0.03		0.00002	0.00003	0.00005	0.00004	0.00003	0.00002	0.00002	0.00002	0.00003	0.00001
Cauliflower	0.03		0.00003	0.00009	0.00007	0.00005	0.00003	0.00002	0.00003	0.00004	0.00003	0.00002
Brussels sprouts	0.07		0.00004	0.00016	0.00013	0.00010	0.00005	0.00006	0.00004	0.00006	0.00007	0.00003
Head cabbage	0.14		0.00008	0.00025	0.00024	0.00018	0.00010	0.00010	0.00007	0.00011	0.00016	0.00010
Chinese cabbage	0.03		0.00001	L/C	L/C	L/C	L/C	L/C	L/C	0.00002	0.00001	L/C
Kohl Rabi	0.03		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Cress	0.03		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Lettuce	0.03		0.00002	0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00002	0.00002	0.00001
Spinach	0.03		0.00002	0.00003	0.00005	0.00003	0.00003	0.00002	0.00001	0.00002	0.00002	0.00001
Watercress	0.03		0.00000	L/C	L/C	0.00000	0.00000	0.00001	L/C	0.00001	0.00001	L/C
Chicory	0.03		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Parsley	0.71		0.00012	L/C	0.00008	L/C	0.00011	0.00003	0.00001	0.00012	0.00013	0.00026
Beans with pods	0.34		0.00018	0.00041	0.00065	0.00045	0.00023	0.00012	0.00024	0.00014	0.00025	0.00011
Runner Beans	0.34		0.00021	L/C	0.00050	0.00017	0.00025	0.00020	0.00017	0.00051	0.00033	0.00019
Beans without pods	0.18		0.00008	0.00011	0.00043	0.00007	0.00019	0.00007	0.00008	0.00011	0.00014	0.00009
Peas with pods	0.34		0.00010	L/C	0.00016	0.00043	0.00008	0.00010	0.00006	0.00009	0.00017	L/C
Peas without pods	0.2		0.00015	0.00048	0.00041	0.00028	0.00021	0.00015	0.00018	0.00017	0.00020	0.00015
Beansprouts	0.03		0.00001	L/C	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00002	0.00001
Asparagus	0.03		0.00001	L/C	L/C	L/C	L/C	L/C	0.00001	0.00002	0.00001	L/C
Bamboo shoots	0.03		0.00000	L/C	0.00001	L/C	0.00000	0.00001	0.00000	0.00001	0.00000	L/C
Celery	0.03		0.00001	0.00001	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00001	0.00000
Fennel	0.03		0.00001	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C

Globe artichokes	0.03		0.00001	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	L/C	L/C
Leeks	0.03		0.00001	L/C	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00002	0.00001
Rhubarb	0.03		0.00001	0.00002	0.00003	0.00001	0.00002	0.00000	0.00000	0.00001	0.00002	0.00001
Cultivated mushrooms	0.03		0.00001	0.00001	0.00003	0.00001	0.00001	0.00001	0.00001	0.00002	0.00001	0.00001
Beans	0.03		0.00005	0.00018	0.00014	0.00010	0.00009	0.00006	0.00006	0.00005	0.00004	0.00003
Lentils	0.03		0.00002	0.00004	0.00006	0.00006	0.00002	0.00004	0.00002	0.00002	0.00002	0.00001
dried Peas	0.03		0.00002	L/C	0.00005	0.00001	0.00002	0.00004	0.00002	0.00002	0.00003	0.00002
Oilseeds	0.04		0.00013	0.00025	0.00029	0.00029	0.00022	0.00016	0.00014	0.00019	0.00013	0.00015
Potatoes	0.03		0.00010	0.00033	0.00028	0.00025	0.00021	0.00016	0.00014	0.00011	0.00010	0.00010
Hops (dried 0.25% of beer)	0.61		0.00004	L/C	L/C	L/C	L/C	0.00000	0.00003	0.00003	0.00004	0.00003
Oats	0.17		0.00006	0.00037	0.00021	0.00013	0.00008	0.00006	0.00011	0.00011	0.00009	0.00010
Barley	0.17		0.00004	L/C	0.00006	0.00006	0.00014	0.00003	0.00004	0.00004	0.00004	0.00003
Millet	0.03		L/C	L/C	0.00001	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Buckwheat	0.03		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Maize	0.03		0.00000	0.00014	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000
Wheat	0.35		0.00126	0.00098	0.00297	0.00311	0.00236	0.00175	0.00141	0.00149	0.00114	0.00121
Rice	0.03		0.00007	0.00008	0.00014	0.00011	0.00015	0.00012	0.00008	0.00006	0.00004	0.00001
Rye	0.35		0.00018	0.00048	0.00013	0.00016	0.00017	0.00009	0.00004	0.00021	0.00016	0.00005
Poultry	0.04		0.00006	0.00007	0.00012	0.00011	0.00007	0.00006	0.00006	0.00007	0.00007	0.00003
Meat fat	0.02		0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000
Meat excl. poultry & offal	0.06		0.00011	0.00024	0.00025	0.00021	0.00018	0.00012	0.00013	0.00002	0.00011	0.00010
All types of kidney	0.1		0.00003	0.00004	0.00014	0.00004	0.00002	0.00002	0.00003	L/C	0.00005	0.00003
All types of Liver	0.1		0.00005	0.00022	0.00024	0.00003	0.00004	0.00006	0.00003	L/C	0.00007	0.00005
Other types of offal	0.1		0.00007	0.00016	0.00022	0.00011	0.00009	0.00010	0.00005	0.00002	0.00008	0.00007
Eggs	0.084		0.00008	0.00040	0.00029	0.00020	0.00013	0.00012	0.00008	0.00009	0.00008	0.00012
Milk	0.05		0.00041	0.00488	0.00279	0.00147	0.00091	0.00059	0.00046	0.00048	0.00043	0.00059

Sugar beet	0.03		0.00042	0.00100	0.00167	0.00101	0.00094	0.00060	0.00058	0.00036	0.00032	0.00046

* 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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Flonicamid

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.025	ARfD (mg/kg bw):	0.025
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	32%	NL toddler	7.90	12%	Milk: Cattle	6%	Wheat	3%	Apples		
	21%	DK child	5.30	8%	Rye	6%	Wheat	3%	Milk: Cattle		
	20%	DE child	5.00	6%	Wheat	4%	Milk: Cattle	3%	Apples		
	19%	NL child	4.77	6%	Wheat	5%	Milk: Cattle	1%	Apples		
	18%	GEMS/Food G06	4.43	10%	Wheat	2%	Tomatoes	0.5%	Milk: Cattle		
	17%	FR child 3 15 yr	4.27	6%	Wheat	5%	Milk: Cattle	0.6%	Beans (with pods)		
	16%	UK infant	3.93	8%	Milk: Cattle	4%	Wheat	0.5%	Peas (without pods)		
	16%	FR toddler 2 3 yr	3.91	6%	Milk: Cattle	4%	Wheat	1%	Beans (with pods)		
	15%	RO general	3.68	7%	Wheat	2%	Milk: Cattle	1%	Tomatoes		
	14%	GEMS/Food G15	3.60	6%	Wheat	1%	Milk: Cattle	0.7%	Tomatoes		
	14%	GEMS/Food G08	3.51	6%	Wheat	1%	Milk: Cattle	0.8%	Rye		
	14%	UK toddler	3.47	5%	Wheat	4%	Milk: Cattle	0.4%	Potatoes		
	14%	GEMS/Food G07	3.38	6%	Wheat	1%	Milk: Cattle	0.6%	Tomatoes		
	13%	ES child	3.27	6%	Wheat	2%	Milk: Cattle	0.5%	Tomatoes		
	13%	GEMS/Food G10	3.25	5%	Wheat	1%	Milk: Cattle	0.8%	Soyabeans		
	13%	GEMS/Food G11	3.21	5%	Wheat	2%	Milk: Cattle	0.9%	Soyabeans		
	13%	SE general	3.14	4%	Wheat	2%	Milk: Cattle	1%	Bovine: Muscle/meat		
	12%	IT toddler	2.97	9%	Wheat	0.8%	Tomatoes	0.2%	Apples		
	11%	DE women 14-50 yr	2.65	3%	Wheat	2%	Milk: Cattle	0.7%	Rye		
	10%	DE general	2.59	3%	Wheat	2%	Milk: Cattle	0.8%	Rye		
	10%	IE adult	2.55	3%	Wheat	0.9%	Milk: Cattle	0.4%	Sweet potatoes		
	9%	PT general	2.23	5%	Wheat	0.6%	Potatoes	0.5%	Tomatoes		
	9%	NL general	2.17	3%	Wheat	2%	Milk: Cattle	0.3%	Apples		
	8%	IT adult	2.02	6%	Wheat	0.7%	Tomatoes	0.2%	Beans (with pods)		
	8%	ES adult	1.91	3%	Wheat	1.0%	Milk: Cattle	0.4%	Tomatoes		
	7%	FR infant	1.84	3%	Milk: Cattle	1%	Wheat	0.7%	Beans (with pods)		
	7%	FR adult	1.75	3%	Wheat	0.9%	Milk: Cattle	0.3%	Beans (with pods)		
	6%	FI 3 yr	1.62	2%	Wheat	0.9%	Rye	0.6%	Cucumbers		
	6%	LT adult	1.59	2%	Rye	1%	Wheat	0.8%	Milk: Cattle		
	6%	UK vegetarian	1.40	3%	Wheat	0.7%	Milk: Cattle	0.3%	Tomatoes		
	6%	DK adult	1.39	2%	Wheat	1%	Milk: Cattle	0.7%	Rye		
	5%	FI adult	1.32	2%	Coffee beans	1.0%	Rye	0.4%	Wheat		
	5%	FI 6 yr	1.27	1%	Wheat	0.9%	Rye	0.5%	Potatoes		
	5%	UK adult	1.20	2%	Wheat	0.6%	Milk: Cattle	0.2%	Tomatoes		
	3%	IE child	0.76	2%	Wheat	0.7%	Milk: Cattle	0.1%	Apples		
	2%	PL general	0.59	0.5%	Tomatoes	0.5%	Apples	0.4%	Potatoes		

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

Table B.3 Acute risk assessment undertaken using UK model version 1.2

Acute Intakes (97.5th percentiles)

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Beans without pods	0.43		0.00083	3.3	0.00171	6.8	0.00299	12.0	0.00114	4.6	0.00317	12.7

			11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Beans without pods	0.43		0.00062	2.5	0.00119	4.8	0.00169	6.8	0.00108	4.3	0.00084	3.4

Table B.4 Acute risk assessment undertaken using PRIMo revision 3.1

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

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
14%	Beans (without pods)	0 / 0.43	3.4	7%	Beans (without pods)	0 / 0.43	1.7
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

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

Not required.

C.1.1.2 Independent laboratory validation

Not required.

C.1.1.3 Confirmatory method (if necessary)

Not required.

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

Not required.

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

The same analytical method was used to determine residues in/on beans without pods in all three studies containing the residue trials. Validation data was available in all three study reports:

Reference:	Determination of residues of flonicamid and its 3 metabolites (TFNG, TFNA and TFNA-AM) in fresh peas after treatment with IBE 3894 – Final report, [redacted] 2011, Report No. 22323.
GLP:	Yes
Acceptability of the method:	Acceptable
Reference:	Residue of flonicamid after 1 application of Teppeki in peas in support of the registration – Final report, [redacted] 2009, Report No. RLPS05307.
GLP:	Yes
Acceptability of the method:	Acceptable
Reference:	Residue of flonicamid after 1 application of Teppeki in peas in support of the registration – Final report, [redacted] 2011, Report No. RLPS07908.
GLP:	Yes
Acceptability of the method:	Acceptable

The following UHPLC-MS/MS method has been used to determine residues of flonicamid and its metabolites in the submitted residue trials. These residue trials are covered in three separate study reports: Study No. 22323, Study No. RLPS05307, and Study No. RLPS07908. The method was previously validated in potato, lemon, oilseed rape, wheat grain, plum, and prune (Study No. ISK/IKI/06001). Additional validation data for the method of analysis have been submitted in each of the three reports to demonstrate the suitability of the method for peas (seeds without pods).

It is noted that there are minor differences between the extraction steps and chromatographic conditions outlined in each study report. However, these differences are not considered to be significant.

Principle of the method and sample preparation:

10 g of homogenised sample material were weighed into a 100 mL extraction flask. 50 mL of acetonitrile / water (60/40, v/v) solution with 0.2% acetic acid was added, followed by 5 g of celite. The extraction mixture was placed on an Ultra Turrax blender at high speed for 1 minute, after which the extract was filtered by suction and the filtrate was collected in a 250 mL volumetric flask. The Ultra Turrax blender was rinsed, along with the extraction flask and filter cake, with the acetonitrile / water (60/40, v/v) solution with 0.2% acetic acid. Washings were added to the 250 mL volumetric flask, which was subsequently made up to volume with further acetonitrile / water (60/40, v/v) solution with 0.2% acetic acid.

A 100 mL aliquot of the extraction mixture was transferred to a 100 mL conical flask. For study no. RLPS05307 and RLPS07908), an additional separation step was performed using hexane. The extract was then partially evaporated using a vacuum rotary evaporator at 40 °C and < 70 mbar. The pH of the extract was adjusted to pH 3 with 1 M HCl solution (study no. 22323) and with 85% phosphoric acid (study no. RLPS05307 and RLPS07908), after which 10 mL of saturated salt (NaCl) deionised water was added. The solution was homogenised. The aqueous extract was then cleaned by Solid Supported Liquid / Liquid Extraction (SSLLE); the extract was applied onto a diatomaceous earth cartridge and allowed to penetrate into the cartridge for 5 minutes. Subsequently, the analytes were eluted from the cartridge into a 200 mL conical flask using 4 x 40 mL ethyl acetate, and the ethyl acetate eluate was evaporated to dryness using a vacuum rotary evaporator at 40 °C.

The sample extract was reconstituted in 2 mL of methanol using an ultrasonic bath. The final extract (containing 0.02 µg of sample material/mL) was filtered through a 0.2 µm nylon membrane filter into a UPLC injection vial, before being analysed by UHPLC-MS/MS.

Results and discussion

Report No. 22323: Validation data

Table C.1.3.1-1 Recovery results in peas (seeds without pods)

Matrix matched standards were used.

Analyte	Level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)	Comments
Flonicamid	0.0094	3	83 – 117	97	18.6	Reduced validation dataset acceptable. See overall
	0.0984	3	75 – 92	81	11.6	
TFNG	0.009	3	67 – 75	71	6.3	
	0.934	3	73 – 78	75	3.3	

Analyte	Level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)	Comments
TFNA	0.0093	3	69 – 79	74	6.8	conclusion below.
	0.0968	3	77 – 85	81	5.1	

Table C.1.3.1-2 Characteristics of the analytical method for the quantitation of flonicamid and metabolite residues in peas (seeds without pods)

	Flonicamid	TFNG	TFNA
Chromatographic method	UHPLC-MS/MS	UHPLC-MS/MS	UHPLC-MS/MS
Specificity demonstrated (yes/no, by…)	Yes. Representative chromatograms were provided for peas (seeds without pods) fortified at 0.01 mg/kg (LOQ) and 0.1 mg/kg (10 x LOQ), untreated crop samples, and treated crop samples from the residue trials. No significant interference at the retention time of interest.	Yes. Representative chromatograms were provided for peas (seeds without pods) fortified at 0.01 mg/kg (LOQ) and 0.1 mg/kg (10 x LOQ), untreated crop samples, and treated crop samples from the residue trials. No significant interference at the retention time of interest.	Yes. Representative chromatograms were provided for peas (seeds without pods) fortified at 0.01 mg/kg (LOQ) and 0.1 mg/kg (10 x LOQ), untreated crop samples, and treated crop samples from the residue trials. No significant interference at the retention time of interest.
Linearity demonstrated (yes/no)	Yes	Yes	Yes
Calibration			

	Flonicamid	**TFNG**	**TFNA**
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.0125 – 1 µg/mL, equivalent to 0.00625 – 0.5 mg/kg	0.0125 – 1 µg/mL, equivalent to 0.00625 – 0.5 mg/kg	0.0125 – 1 µg/mL, equivalent to 0.00625 – 0.5 mg/kg
Calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/no)	Yes (7 levels with 4 injections each)	Yes (7 levels with 4 injections each)	Yes (7 levels with 4 injections each)
Matrix effects	Yes, suppression observed so matrix matched calibration standards were used.	Yes, suppression observed so matrix matched calibration standards were used.	Yes, suppression observed so matrix matched calibration standards were used.
Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)	Yes	Yes	Yes
Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ration? (yes/no)	Yes	Yes	Yes
LOQ (mg/kg)	0.01	0.01	0.01

Report No. RLPS05307: Validation data

Table C.1.3.1-3 Recovery results in peas (seeds without pods)

Matrix matched standards were used.

Analyte	Level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)	Comments
Flonicamid	0.01	1	73	-	-	Reduced validation dataset acceptable. See overall conclusion below.
	1.00	1	73	-	-	
TFNG	0.01	1	83	-	-	
	1.00	1	93	-	-	
TFNA	0.01	1	85	-	-	
	1.00	1	91	-	-	

Table C.1.3.1-4 Characteristics of the analytical method for the quantitation of flonicamid and metabolite residues in peas (seeds without pods)

	Flonicamid	TFNG	TFNA
Chromatographic method	UHPLC-MS/MS	UHPLC-MS/MS	UHPLC-MS/MS
Specificity demonstrated (yes/no, by…)	Yes. Representative chromatograms were provided for peas (seeds without pods) fortified at 0.01 mg/kg (LOQ), untreated crop samples, and treated crop samples from the residue trials. No significant interference at the retention time of interest.	Yes. Representative chromatograms were provided for peas (seeds without pods) fortified at 0.01 mg/kg (LOQ), untreated crop samples, and treated crop samples from the residue trials. No significant interference at the retention time of interest.	Yes. Representative chromatograms were provided for peas (seeds without pods) fortified at 0.01 mg/kg (LOQ), untreated crop samples, and treated crop samples from the residue trials. No significant interference at the retention time of interest.
Linearity demonstrated (yes/no)	Yes	Yes	Yes
Calibration			

	Flonicamid	**TFNG**	**TFNA**
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.0125 – 0.5 µg/mL, equivalent to 0.00625 – 0.5 mg/kg	0.0125 – 0.25 µg/mL, equivalent to 0.00625 – 0.25 mg/kg	0.0125 – 0.25 µg/mL, equivalent to 0.00625 – 0.25 mg/kg
Calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/no)	Yes (5 levels with single points)	Yes (5 levels with single points)	Yes (5 levels with single points)
Matrix effects	Not investigated but matrix matched calibration standards were used.	Not investigated but matrix matched calibration standards were used.	Not investigated but matrix matched calibration standards were used.
Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)	Yes	Yes	Yes
Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ration? (yes/no)	Yes	Yes	Yes
LOQ (mg/kg)	0.01	0.01	0.01

Report No. RLPS07908: Validation data

Table C.1.3.1-5 Recovery results in peas (seeds without pods)

Matrix matched standards were used.

Analyte	**Level (mg/kg)**	**No samples per level**	**Range of recoveries (%)**	**Mean recovery**	**RSD (%)**	**Comments**
Flonicamid	0.01	1	77	-	-	

Analyte	Level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)	Comments
	1.00	1	99	-	-	Reduced validation dataset acceptable. See overall conclusion below.
TFNG	0.01	1	88	-	-	
	1.00	1	97	-	-	
TFNA	0.01	1	88	-	-	
	1.00	1	101	-	-	

Table C.1.3.1-6 Characteristics of the analytical method for the quantitation of flonicamid and metabolite residues in peas (seeds without pods)

	Flonicamid	TFNG	TFNA
Chromatographic method	UHPLC-MS/MS	UHPLC-MS/MS	UHPLC-MS/MS
Specificity demonstrated (yes/no, by…)	Yes. Representative chromatograms were provided for peas (seeds without pods) fortified at 0.01 mg/kg (LOQ), untreated crop samples, and treated crop samples from the residue trials. No significant interference at the retention time of interest.	Yes. Representative chromatograms were provided for peas (seeds without pods) fortified at 0.01 mg/kg (LOQ), untreated crop samples, and treated crop samples from the residue trials. No significant interference at the retention time of interest.	Yes. Representative chromatograms were provided for peas (seeds without pods) fortified at 0.01 mg/kg (LOQ), untreated crop samples, and treated crop samples from the residue trials. No significant interference at the retention time of interest.
Linearity demonstrated (yes/no)	Yes	Yes	Yes
Calibration			

	Flonicamid	**TFNG**	**TFNA**
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.0125 – 0.5 µg/mL, equivalent to 0.00625 – 0.5 mg/kg	0.0125 – 0.5 µg/mL, equivalent to 0.00625 – 0.5 mg/kg	0.0125 – 0.5 µg/mL, equivalent to 0.00625 – 0.5 mg/kg
Calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/no)	Yes (6 levels with single points)	Yes (6 levels with single points)	Yes (6 levels with single points)
Matrix effects	Not investigated but matrix matched calibration standards were used.	Not investigated but matrix matched calibration standards were used.	Not investigated but matrix matched calibration standards were used.
Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)	Yes	Yes	Yes
Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ration? (yes/no)	Yes	Yes	Yes
LOQ (mg/kg)	0.01	0.01	0.01

Overall conclusion

The method was previously validated in a range of crop matrices, including in plum, a high water content commodity (Study No. ISK/IKI/06001). In accordance with SANTE/2020/12830 rev. 1, additional commodities belonging to the same matrix group do not require a separate validation. Instead, the applicability of the method to a different commodity should be determined by concurrent recoveries (minimum of 3 recoveries at LOQ and 3 recoveries at a higher level).

In Study No. 22323, acceptable linearity, specificity, accuracy and precision data have been reported. The available data demonstrate the applicability of the method to peas (seeds without pods). In addition, one procedural recovery determination (which was the mean of four replicate injections) was also reported for each fortification level. Therefore, the reduced dataset is acceptable.

It is noted that only one recovery determination at each fortification level was presented in Study No. RLPS05307 and Study No. RLPS07908. While this does not comply with the requirements of SANTE/2020/12830 rev. 1, it is considered that sufficient data are available across the three studies to demonstrate the acceptability of the method in peas (seeds without pods). All of the recovery determinations across the three studies are of an acceptable level and the residues measured in all trials are comparable, therefore the acceptability of the method on the day of analysis has been demonstrated.

Considering all of the available validation data, the method is considered to be sufficiently validated in accordance with SANTE/2020/12830 rev. 1 for the determination of residues of flonicamid and its metabolites in peas (seeds without pods), with an LOQ of 0.01 mg/kg for each analyte.

Extraction efficiency: In the method outlined above, analytes were extracted from the crop matrix by agitation with acetonitrile and water with 0.2% acetic acid. The radiolabelled metabolism studies in the DAR generally used a combination of acetonitrile and water as the extraction solvent. Since the solvent in the metabolism study is the same as the solvent in the analytical method, extraction efficiency is considered to be sufficiently demonstrated. Therefore, no further data are required at this time.

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

Not required.

C.1.5 Methods for risk assessment for toxicological studies

Not required.

C.2 Mammalian toxicology

No additional studies submitted.

C.3 Residue data

C.3.1 Nature and magnitude of residues in primary crops

C.3.1.1 Nature of residues

Not required for this application.

C.3.1.2 Magnitude of residues

C.3.1.2.1 Peas (seeds without pods) (study 1)

Reference:	Determination of residues of flonicamid and its 3 metabolites (TFNG, TFNA and TFNA-AM) in fresh peas after treatment with IBE 3894 – Final report, [redacted] 2011, Report No. 22323.
Guideline(s):	Directive 96/46/EC, Directive 96/68/EC, Directive 91/414/EEC, SANCO 3029/99; SANCO 825/00, SANCO/10684/2009, Regulation (EC) No. 396/2005
Deviations:	No
GLP:	Yes
Validity of the study:	Acceptable

Materials and methods

Two outdoor trials on peas were conducted in Belgium using 'Teppeki' ('IBE 3894'), a WG formulation containing 500 g/kg flonicamid, in the 2010 growing season.

'Teppeki' was applied as a foliar spray at a rate of 69 g a.s./ha in 390 L/ha of water. The application was at BBCH 69 – 71 and the PHI was 14 days. The application was within 25% of the proposed critical GAP (1 x 70 g a.s./ha, BBCH 16 – 88, 14 day PHI).

Both trials were harvest trials, with samples of whole pods taken 14 days after application. Samples containing at least 2 kg were collected from both treated and control plots. These specimens were subsequently manually processed to separate seeds from pods. Samples were frozen within 24 hours and stored at ≤–18 °C until analysis. The maximum storage interval between harvest and analysis was 9 months. The stability of flonicamid and the metabolites TFNG and TFNA has been demonstrated for this period of time in high water crops when stored at ≤–18 °C.

Results and discussions

Only samples of peas (seeds without pods) were analysed in the study.

Residues of flonicamid and the metabolites TFNG and TFNA were analysed using UHPLC-MS/MS (LOQ of 0.01 mg/kg for each analyte, combined LOQ of 0.03 mg/kg). Full details and validation data for this method can be found in Section C.1.3. This method is considered sufficiently validated for the purposes of the regulatory process. While an appropriate number of procedural recovery samples was not presented, the method was

demonstrated to be applicable to the matrix and was shown to be working at the time of use.

Samples were also analysed for the metabolite TFNA-AM, however this metabolite is not included in the residue definition for risk assessment or enforcement. Therefore, these residues are not relevant to the MRL assessment and have not been considered further.

Residues of TFNG and TFNA are expressed as flonicamid equivalents using the following molecular weight conversions:

$MWC_{TFNA} = MW_{flonicamid} / MW_{TFNA} = 229.16/191.11 = 1.199$

$MWC_{TFNG} = MW_{flonicamid} / MW_{TFNG} = 229.16/248.16 = 0.923$

A summary of the trials is given in Table C.3.1.2-1 below.

Two independent trials on peas were conducted outdoors in Belgium, and the trials were within 25% of the proposed critical GAP.

No residues were detected in control samples for both trials. Residues of the sum of flonicamid and its metabolites TFNG and TFNA, expressed as flonicamid, were 0.104 and 0.214 mg/kg in peas (seeds without pods), 14 days after last application (the proposed timing in the GAP).

Table C.3.1.2.1-1 Residue trials on peas (seeds without pods)

Reference:	Determination of residues of flonicamid and its 3 metabolites (TFNG, TFNA and TFNA-AM) in fresh peas after treatment with IBE 3894 – Final report, [redacted] 2011, Report No. 22323.		
GLP:	Yes	Sample storage conditions:	Up to 9 months at –18 °C
Crop/crop group:	Peas (seeds without pods)	Analytical method:	UPHLC-MS/MS, validated
Indoor/outdoor:	Outdoor	Limit of Quantification (mg/kg):	0.01 mg/kg for each analyte
Formulation:	WG	Residues calculated as:	Flonicamid, TFNG, TFNA expressed as flonicamid
Content of active substance:	500 g/kg		

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)**	**Remarks**
			g a.s./ ha	Water (L/ha)	g a.s./ hL					Flonicamid	TFNG (a)	TFNA (a)	Sum (b)		
22323/1, Gesves, Belgium (2010)	Peas / Arnesa	1. 05.06.2010 2. Not stated 3. 20.08.2010	69	390	18	06.08.2010 (1 application)	-	BBCH 69 – 71	Seeds without pods	<0.01	<0.01	0.084	0.104	14	-

22323/2, Nivelles, Begium (2010)	Peas / Spring	1. 20.07.2010 2. Not stated 3. 17.09.2010	69	390	18	03.09.2010 (1 application)	-	BBCH 69 – 71	Seeds without pods	0.050	0.039	0.125	0.214	14	-

(a) TFNG and TFNA are expressed as parent equivalents

(b) Sum of flonicamid, TFNG and TFNA (expressed as parent equivalents)

C.3.1.2.2 Peas (seeds without pods) (study 2)

Reference:	Residue of flonicamid after 1 application of Teppeki in peas in support of the registration – Final report, [redacted] 2009, Report No. RLPS05307.
Guideline(s):	OECD ENV/JM/MONO(2002)9; Annex 2 of Directive 91/414/EEC; 7029/VI/95 rev. 5.
Deviations:	No
GLP:	Yes
Validity of the study:	Acceptable

Materials and methods

Four outdoor trials on peas were conducted in France using 'Teppeki', a WG formulation containing 500 g/kg flonicamid, in the 2007 growing season. Three of these trials were conducted in Northern France and reflect the agronomic and climatic conditions in the UK. The final trial (no. RE07046) was conducted in Southern France and therefore is not considered representative of the UK. On this basis, residues from this trial have not been considered further in this MRL assessment.

'Teppeki' was applied as a foliar spray at a rate of 71 – 74 g a.s./ha in 295 – 513 L/ha of water. The application was at BBCH 76 – 77. In two of the Northern France trials, the PHI was 13 days. In the trial no. RE07037, the PHI was 22 days due to poor climatic conditions. The application was within 25% of the proposed critical GAP (1 x 70 g a.s./ha, BBCH 16 – 88, 14 day PHI). The PHI of 22 days is notably longer than the PHI outlined in the GAP and is therefore expected to be less critical. However, the longer PHI did not appear to have an impact on the results of the trial as the measured residues were similar to those determined in the other Northern France trials.

All three Northern France trials were harvest trials and samples of whole pods were taken 13 days after application, except for in trial no. RE07037 when samples were collected 22 days after application. Samples containing at least 0.665 kg of seeds and 0.665 kg of pods were collected from both treated and control plots. In two of the trials, seeds were separated from pods manually. In trial no. RE07039, some of the samples were separated manually, while the rest of the crop was threshed mechanically. As part of this process, the seeds were washed, drained, blanched, cooled, and then dried. These seeds were then packed and canned, or frozen. Residues from these processed seeds have not been considered as part of this MRL assessment.

Samples were frozen and stored at ≤–20 °C until analysis. The maximum storage interval between harvest and analysis was 5 months. The stability of flonicamid and the

metabolites TFNG and TFNA has been demonstrated for this period of time in high water crops when stored at ≤–18 °C.

Results and discussions

Seeds and pods were analysed separately in the study. Since this MRL assessment is for beans (without pods), only residues in pea seeds have been considered.

Residues of flonicamid and the metabolites TFNG and TFNA were analysed using UHPLC-MS/MS (LOQ of 0.01 mg/kg for each analyte, combined LOQ of 0.03 mg/kg). Full details and validation data for this method can be found in Section C.1.3. This method is considered sufficiently validated for the purposes of the regulatory process. While an appropriate number of procedural recovery samples was not presented, the method was demonstrated to be applicable to the matrix and was shown to be working at the time of use.

Samples were also analysed for the metabolite TFNA-AM, however this metabolite is not included in the residue definition for risk assessment or enforcement. Therefore, these residues are not relevant to the MRL assessment and have not been considered further.

Residues of TFNG and TFNA are expressed as flonicamid equivalents using the following molecular weight conversions:

$MWC_{TFNA} = MW_{flonicamid} / MW_{TFNA} = 229.16/191.11 = 1.199$

$MWC_{TFNG} = MW_{flonicamid} / MW_{TFNG} = 229.16/248.16 = 0.923$

A summary of the trials is given in Table C.3.1.2-2 below.

Three independent trials on peas were conducted outdoors in Northern France, and the trials were within 25% of the proposed critical GAP. A fourth trial (no. RE07046) was conducted in Southern France which does not reflect the agronomic and climatic conditions in the UK. Therefore, residues from this trial have not been considered further as part of this MRL assessment.

No residues were detected in control samples for all trials. Residues of the sum of flonicamid and its metabolites TFNG and TFNA, expressed as flonicamid, were 0.11 – 0.18 mg/kg in peas (seeds without pods), 13 days (or 22 days) after last application (the proposed timing in the GAP).

Table C.3.1.2.2-1 Residue trials on peas (seeds without pods)

Reference:	Residue of flonicamid after 1 application of Teppeki in peas in support of the registration – Final report, [redacted] 2009, Report No. RLPS05307.		
GLP:	Yes	Sample storage conditions:	Up to 5 months at –20 °C
Crop/crop group:	Peas (seeds without pods)	Analytical method:	UPHLC-MS/MS, validated
Indoor/outdoor:	Outdoor	Limit of Quantification (mg/kg):	0.01 mg/kg for each analyte
Formulation:	WG	Residues calculated as:	Flonicamid, TFNG, TFNA expressed as flonicamid
Content of active substance:	500 g/kg		

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)**	**Remarks**
			g a.s./ ha	Water (L/ha)	g a.s./ hL					Flonicamid	TFNG (a)	TFNA (a)	Sum (b)		
RE07037, 45130 Épieds-en-Beauce, France (2007)	Peas / Geneva	1. 16.04.2007 2. Not stated 3. 05.07.2007	71	295	24	13.06.2007 (1 application)	-	Not stated	Seeds without pods	<0.01	<0.01	0.11	0.13	22	-

RE07038, 29380 Saint-Thurien, France (2007)	Peas / Bomba	1. 27.03.2007 2. Not stated 3. 18.06.2007	74	513.3	14.4	05.06.2007 (1 application)	-	BBCH 76	Seeds without pods	0.02	<0.01	0.08	0.11	13	-
RE07039, 29350 Moëlan-sur-Mer, France (2007)	Peas / Bomba	1. 17.03.2007 2. Not stated 3. 18.06.2007	71	493.3	14.4	05.06.2007 (1 application)	-	BBCH 77	Seeds without pods	0.03	0.02	0.13	0.18	13	-
RE07046, 40210 Solférino, France (2007)	Peas / Garden peas	1. 12.04.2007 2. Not stated 3. 25.06.2007	74	410	18	11.06.2007 (1 application)	-	2 stages of pods	Seeds without pods	0.02	0.01	0.31	0.34	14	Does not reflect agronomic and climatic conditions in the UK

(a) TFNG and TFNA are expressed as parent equivalents

(b) Sum of flonicamid, TFNG and TFNA (expressed as parent equivalents)

C.3.1.2.3 Peas (seeds without pods) (study 3)

Reference:	Residue of flonicamid after 1 application of Teppeki in peas in support of the registration – Final report, [redacted] 2011, Report No. RLPS07908.
Guideline(s):	OECD ENV/JM/MONO(2002)9; Annex 2 of Directive 91/414/EEC; 7029/VI/95 rev. 5.
Deviations:	No
GLP:	Yes
Validity of the study:	Acceptable

Materials and methods

Four outdoor trials on peas were conducted in Northern France using 'Teppeki', a WG formulation containing 500 g/kg flonicamid, in the 2008 growing season.

'Teppeki' was applied as a foliar spray at a rate of 71 – 73 g a.s./ha in 493 – 510 L/ha of water. The application was at BBCH 75 and the PHI was 14 days. The application was within 25% of the proposed critical GAP (1 x 70 g a.s./ha, BBCH 16 – 88, 14 day PHI).

All four trials were harvest trials and samples of whole pods were taken 14 days after application. Samples containing at least 0.645 kg of seeds and 0.685 kg of pods were collected from both treated and control plots. These specimens were subsequently manually processed to separate seeds from pods. Samples were frozen and stored at ≤–20 °C until analysis. The maximum storage interval between harvest and analysis was 2 months. The stability of flonicamid and the metabolites TFNG and TFNA has been demonstrated for this period of time in high water crops when stored at ≤–18 °C.

Results and discussions

Seeds and pods were analysed separately in the study. Since this MRL assessment is for beans (without pods), only residues in pea seeds have been considered.

Residues of flonicamid and the metabolites TFNG and TFNA were analysed using UHPLC-MS/MS (LOQ of 0.01 mg/kg for each analyte, combined LOQ of 0.03 mg/kg). Full details and validation data for this method can be found in Section C.1.3. This method is considered sufficiently validated for the purposes of the regulatory process. While an appropriate number of procedural recovery samples was not presented, the method was demonstrated to be applicable to the matrix and was shown to be working at the time of use.

Samples were also analysed for the metabolite TFNA-AM, however this metabolite is not included in the residue definition for risk assessment or enforcement. Therefore, these residues are not relevant to the MRL assessment and have not been considered further.

Residues of TFNG and TFNA are expressed as flonicamid equivalents using the following molecular weight conversions:

$MWC_{TFNA} = MW_{flonicamid} / MW_{TFNA} = 229.16/191.11 = 1.199$

$MWC_{TFNG} = MW_{flonicamid} / MW_{TFNG} = 229.16/248.16 = 0.923$

A summary of the trials is given in Table C.3.1.2-2 below.

Four independent trials on peas were conducted outdoors in France, and the trials were within 25% of the proposed critical GAP.

No residues were detected in control samples for all trials. Residues of the sum of flonicamid and its metabolites TFNG and TFNA, expressed as flonicamid, were 0.17 – 0.43 mg/kg in peas (seeds without pods), 14 days after last application (the proposed timing in the GAP).

Table C.3.1.2.3-1 Residue trials on peas (seeds without pods)

Reference:	Residue of flonicamid after 1 application of Teppeki in peas in support of the registration – Final report, [redacted] 2011, Report No. RLPS07908.		
GLP:	Yes	Sample storage conditions:	Up to 2 months at –20 °C
Crop/crop group:	Peas (seeds without pods)	Analytical method:	UPHLC-MS/MS, validated
Indoor/outdoor:	Outdoor	Limit of Quantification (mg/kg):	0.01 mg/kg for each analyte
Formulation:	WG	Residues calculated as:	Flonicamid, TFNG, TFNA expressed as flonicamid
Content of active substance:	500 g/kg		

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)**	**Remarks**
			g a.s./ ha	Water (L/ha)	g a.s./ hL					Flonicamid	TFNG (a)	TFNA (a)	Sum (b)		
RE08072, 56240 Lanvaudan, France (2008)	Peas / Valette	1. 03.04.2008 2. Not stated 3. 24.06.2008	73	506.7	14.4	10.06.2008 (1 application)	-	BBCH 75	Seeds without pods	0.03	0.03	0.31	0.37	14	

RE08073, 56240 Calan, France (2008)	Peas / Valette	1. 03.04.2008 2. Not stated 3. 30.06.2008	73	510	14.3	16.06.2008 (1 application)	-	BBCH 75	Seeds without pods	0.01	0.02	0.14	0.17	14	
RE08074, 56240 Plouay, France (2008)	Peas / Bonette	1. 02.04.2008 2. Not stated 3. 30.06.2008	73	506.7	14.4	16.06.2008 (1 application)	-	BBCH 75	Seeds without pods	0.02	0.05	0.36	0.43	14	
RE08075, 29360 Clohars-Carnoët, France (2008)	Peas / Columbia	1. 08.04.2008 2. Not stated 3. 24.06.2008	71	493.3	14.4	10.06.2008 (1 application)	-	BBCH 75	Seeds without pods	0.02	0.03	0.23	0.28	14	

(a) TFNG and TFNA are expressed as parent equivalents

(b) Sum of flonicamid, TFNG and TFNA (expressed as parent equivalents)

C.3.2 Nature and magnitude of residues in processed commodities

C.3.2.1 Nature of residues (Standard hydrolysis study)

Not required.

C.3.2.2 Magnitude of residues (Processing studies)

Not required.

C.3.3 Nature and magnitude of residues in rotational crops

C.3.3.1 Nature of residue

Not required.

C.3.3.2 Magnitude of residues (field rotational crop studies)

Not required.

C.3.4 Nature and magnitude of residues in livestock

C.3.4.1 Nature of residues

Not required.

C.3.4.2 Magnitude of residues (feeding studies)

Not required.

C.3.5 Residues in honey

Not required.

C.3.6 Storage stability

C.3.6.1 Storage stability of residues in plant products

Not required.

C.3.6.2 Storage stability of residues in animal products

Not required.

C.3.6.3 Storage stability in honey

Not required.

Appendix D – List of endpoints

The endpoints have not changed as a result of this assessment. The full list of endpoints is outlined in EFSA Conclusion, 2010.

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
[redacted]	2011	Determination of residues of flonicamid and its 3 metabolites (TFNG, TFNA and TFNA-AM) in fresh peas after treatment with IBE 3894 – Final report Report No.: 22323. ISK Biosciences Europe S.A. GLP Unpublished
	2009	Residue of flonicamid after 1 application of Teppeki in peas in support of the registration – Final report Report No.: RLPS05307 ISK Biosciences Europe S.A. GLP Unpublished
	2011	Residue of flonicamid after 1 application of Teppeki in peas in support of the registration – Final report Report No.: RLPS07908 ISK Biosciences Europe S.A. GLP Unpublished