

The evaluation of new MRLs for flonicamid in or on lettuce and endives

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 2026/00107

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Summary

In accordance with Article 6 of Assimilated Regulation 396/2005,¹ HSE received an application on 23 January 2026 to amend the existing MRLs for the active substance flonicamid in or on lettuce and endives. 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 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 0.075 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 leafy crops which the crops 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

Eight outdoor and four protected trials, conducted in Germany, the UK, the Netherlands and Northern France, were submitted to support MRLs for lettuce and escarole / broad leaved endives. Samples of lettuce were analysed for residues of flonicamid and its metabolites TFNG and TFNA. These trials were supported by validated analytical methods and storage stability data.

In addition, two CXLs are available which are applicable to lettuces. The CXL for leaf lettuce (8 mg/kg) leads to acute intake concerns and cannot be adopted as a GB MRL. The CXL for head lettuce (1.5 mg/kg) is acceptable and is recommended for adoption as a GB MRL. It is noted that the JMPR residue definitions are less extensive than the GB definitions; however, the JMPR evaluation contains the relevant metabolite information, and the values have been re-calculated based on the GB residue definition – the CXL in terms of the GB residue definition is 2 mg/kg and is recommended for adoption in GB.

Processing data was not required as the commodities are not normally consumed processed beyond simple physical processing such as washing.

Since the DT₉₀ 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 (4-6 year old child). 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 16% of the ARfD (infant/lettuce). The highest PRIMo IESTI was 34% of the ARfD (lettuce/NL child). 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 new MRLs for the proposed uses of flonicamid on lettuce and these 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 MRLs outlined in Table 0.1 are amended in the GB MRL Statutory Register.

Table 0.1 MRLs recommended by HSE

Enforcement residue definition for products of plant origin: Sum of flonicamid, TFNA and TFNG expressed as flonicamid

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
0251020	Lettuce	0.03*	2.0	The MRL is based on the CXL for lettuce (head). No health effects are expected.
0251030	Escarole / broad leaved	0.03*	0.6	The MRL is derived from an extrapolation of residue trials on protected lettuce. No health effects are expected.

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

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 23 January 2026 HSE accepted an application to set new MRLs for flonicamid in or on lettuce and endives.

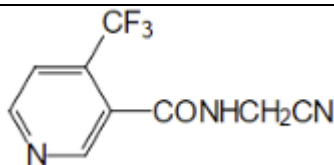
HSE evaluated the information submitted to uniform principles, as defined by Article 8 of Assimilated Regulation 396/2005, and prepared an Evaluation Report. HSE also took into account EFSA Reasoned Opinions and Conclusions on the peer review relating to decisions implemented in GB.

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

The active substance and its use pattern

Information on the active substance 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 ₉ H ₆ F ₃ N ₃ O
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.

The following CXLs are available for the proposed uses (Codex Pesticide Residues in food online database).

Table 0.3 CXLs relevant to the proposed uses

Commodity	CXL (mg/kg)	Comments	Year of adoption
Lettuce (head)	1.5 (2)†	The CXL is higher than the current GB MRL (0.03* mg/kg). As the dietary exposures are below the toxicological reference value, HSE recommends the adoption of the CXL for lettuce (head).	2016
Lettuce (leaf)	8.0	The CXL is higher than the current GB MRL (0.03* mg/kg). As the dietary exposures exceed the acute toxicological reference value, this CXL	2016

		cannot be recommended for adoption. See tables B.5 and B.6.	
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†The CXL has been re-calculated using the data available in the JMPR report, and is expressed in terms of the GB RD-Enf

As outlined in Table 0.4, the residue definitions for risk assessment are not comparable between the JMPR and GB. The GB residue definition for enforcement and risk assessment include the metabolites TFNA and TFNG and is expressed as flonicamid.

Table 0.4 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable?
Plants	Enforcement	Flonicamid	Sum of flonicamid, TFNA and TFNG expressed as flonicamid	No
	Risk assessment	Flonicamid	Sum of flonicamid, TFNA and TFNG expressed as flonicamid	No

The trials used by the JMPR to recommend the CXL contain information on both metabolites, and therefore it is straightforward to re-calculate the CXL in terms of the GB residue definitions. The JMPR data and re-calculated information is outlined in the table below.

Table 0.5 JMPR trials (JMPR, 2015)

Trial no.	Flonicamid (mg/kg)	TFNA as flonicamid (mg/kg)	TFNG as flonicamid (mg/kg)	Sum, as flonicamid (mg/kg)
Germansvi lle PA, 2002 (Sun Devil)	0.493	0.025	0.024	0.542
Belle Glade FL, 2002 (Iceberg 35x110)	0.617	0.026	0.023	0.666
Lagurta AZ, 2002 (Desert Spring)	0.518	0.022	0.021	0.561
Visalia CA, 2002 (Great Lakes 659)	0.584	0.028	0.026	0.637
Bard CA, 2002 (Green Lightning)	0.431	0.026	0.024	0.481
Greenfield CA, 2002 (Big Ben)	0.394	0.032	0.030	0.456

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 crops under consideration in this application (lettuce and endives) are high water commodities. 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 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 a tabular form as proposed below.

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	HSE	2024	0.075 mg/kg bw	Rabbit developmental	100

The ARfD has been updated in July 2024 following an assessment in accordance with Article 7 of Assimilated Regulation 1107/2009. The published evaluation can be found on the HSE website.³

³ [Active substance amendments - HSE](#)

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 (potato) and fruit crops (peach and pepper) for the approval of flonicamid (DAR, 2005):

The following summary is presented by EFSA (EFSA, 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 3-14C-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 drench, which is comparable to the application type for the proposed use.

The residue definition for risk assessment (RD-RA) and 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

0251020 Lettuce

0251030 Escaroles / broad leaved endives

The proposed critical GAP on lettuce and escaroles / broad leaved endives, are 1 x dip / drench application pre-transplant at an application rate of 1 mg a.s./plant, BBCH 11-16, 49 day PHI. **An equivalent outdoor GAP was also notified but has not been authorised in GB, therefore, reference to outdoor trials is for information only.**

It is noted that there is a CXL available for lettuce (head) of 1.5 mg/kg, which will be considered as part of this assessment. The CXL is 2.0 mg/kg when expressed according to the residue definition for GB.

However, the CXL does not apply to escaroles / broad leaved endives, therefore the trials on lettuce have been considered in order to support an MRL for escaroles/broad leaved endives.

Eight outdoor and four protected trials were conducted across two studies, these trials are summarised below:

- Eight outdoor trials were conducted in Northern Europe (Germany, the UK, the Netherlands and Northern France) on lettuce and were performed within 25% of the cGAP (1 x 1 mg a.s./plant), application was between BBCH 12-16, 49 day PHI. The study contained four decline and four at harvest trials.
- Four protected trials were conducted in Northern Europe (Germany, the UK, the Netherlands and Northern France) on lettuce and were performed within 25% of the cGAP (1 x 1 mg a.s./plant), application was between BBCH 12-16, 49 day PHI. The study contained two decline and two at harvest trials.

All trials were conducted using IBE 4131, 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. In Trial S19-02137-02, control samples of lettuce recorded positive residues of TFNA (0.03 mg/kg) and TFNG (0.01 mg/kg) 49 days after application. This result is higher than that recorded in the treated sample for the same PHI, which found residues <0.01 mg/kg in parent flonicamid, TFNG and TFNA. As a result, this trial was discarded, therefore only seven GAP compliant trials are available.

As set out in GB extrapolations guidance 2024, lettuce is a major crop, therefore eight trials are required to support the use. It also stipulates that four trials on open leaf varieties

of lettuce are required to extrapolate to escarole / broad leaved endives. There only are seven outdoor trials available on open leaf varieties, which is insufficient to support the use and increased MRL in lettuce.

Seven outdoor and four protected trials on open leaf varieties of lettuce are available to support the uses and are appropriate for MRL setting on escarole / broad leaved endives. Escaroles/broad leaved endives are a minor crop and four trials are required to support the use.

The residue trials demonstrate residues greater than the current GB MRL for escarole / broad leaved endives (0.03* mg/kg) and support an MRL of 0.6 mg/kg (indoor use). The MRL calculated based on the outdoor trials is lower than the indoor use.

Storage stability

Lettuce and escarole / broad leaved endives are considered high water 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 commodities, which demonstrated stability for all analytes for a period of 18 months at $\leq -18^{\circ}\text{C}$. This study supports the maximum storage period of 14 months in the trials.

Analytical methods

Analysis for floncaimid, 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:

$$\text{MWC}_{\text{TFNA}} = \text{MW}_{\text{flonicamid}} / \text{MW}_{\text{TFNA}} = 229.16/191.11 = 1.199$$

$$\text{MWC}_{\text{TFNG}} = \text{MW}_{\text{flonicamid}} / \text{MW}_{\text{TFNG}} = 229.16/248.16 = 0.923$$

The analytical method was considered satisfactorily validated in accordance with SANTE/2020/12830 rev.1 in lettuce

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**RD-RA & RD-Enf:** Sum of flonicamid, TFNA and TFNG, expressed as flonicamid

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)
Lettuce (head) 3 x 100 g a.s./ha, 7 ± 1 d RTI, 0 d PHI	CXL, 2016 (VL 0482)	0.46, 0.48, 0.54, 0.56, 0.64, 0.67	JMPR trials included analysis of TFNA and TFNG and have been recalculated according to the GB RD-Enf	2.0[†]	0.67	0.55
Lettuce → escarole / broad leaved endives 1 x 1 mg a.s./plant, BBCH 16, 49 d PHI	GB / outdoor	<0.03, 0.044, 2 x 0.056, 0.08, 0.12, 0.20	Trial in line with the cGAP. Extrapolation from lettuce to escarole / broad leaved endives is acceptable. MRL _{OECD} : 0.309/0.3 NOTE: outdoor use not authorised in GB	0.4	0.20	0.056
Lettuce → escarole / broad leaved endives	GB / protected	0.108, 0.15, 0.16, 0.33	Trial in line with the cGAP.	0.6	0.33	0.155

1 x 1 mg a.s./plant, BBCH 16, 49 d PHI			Extrapolation from lettuce to escarole / broad leaved endives is acceptable. MRL _{OECD} : 0.579/0.6			
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- (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 **Enforcement** and **Risk Assessment**.
- (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})

† Residues from the JMPR have been expressed as the GB residue definition

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

The commodities are considered to be consumed raw, therefore this section is not relevant for these commodities.

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 crops are not used as animal feedstuffs.

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 2024/018) 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 estimated 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.

There are no consumption data available for escarole / broad leaved endives in the UK model. The input for lettuce is expected to cover any consumption of escarole/broad leaved endives. In addition, the STMR and HR available for lettuce is greater than escarole.

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

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Lettuce	0.55	STMR (FAO, 2016) current assessment	0.67	HR (FAO, 2016) current assessment
Citrus fruits	0.04	STMR (EFSA, 2014)	Acute risk assessment undertaken only for the uses proposed as part of the current assessment	
Pome fruit	0.06*	STMR (EFSA, 2014)		
Apricots	0.099	STMR (EFSA, 2017)		
Peaches	0.08	STMR (EFSA, 2014)		
Plums	0.09	STMR (EFSA, 2014)		
Cherries	0.13	STMR (EFSA, 2014)		
Blackberries	0.421	STMR (HSE, 2022)		
Dewberries	0.36	STMR (HSE, 2022)		
Raspberries	0.421	STMR (HSE, 2022)		
Gooseberries	0.421	STMR (HSE, 2022)		
Other small fruits and berries	0.421	STMR (HSE, 2022)		
Beetroots	0.05	STMR (EFSA, 2018)		
Carrots	0.05	STMR (EFSA, 2018)		
Celeriac	0.05	STMR (EFSA, 2018)		
Horseradish	0.05	STMR (EFSA, 2018)		
Jerusalem artichoke	0.05	STMR (EFSA, 2018)		
Parsnips	0.05	STMR (EFSA, 2018)		
Radishes	0.05	STMR (EFSA, 2018)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Salsify	0.05	STMR (EFSA, 2018)		
Swedes	0.05	STMR (EFSA, 2018)		
Turnips	0.05	STMR (EFSA, 2018)		
Tomatoes	0.14	STMR (EFSA, 2014)		
Peppers	0.06	STMR (EFSA, 2014)		
Aubergines	0.14	STMR (EFSA, 2014)		
Marrows	0.15	STMR (EFSA, 2014)		
Cucumbers	0.15	STMR (EFSA, 2014)		
Gourds	0.06	STMR (EFSA, 2014)		
Courgettes	0.15	STMR (EFSA, 2014)		
Melons	0.06	STMR (EFSA, 2014)		
Brussels sprouts	0.07	STMR (EFSA, 2015)		
Head cabbage	0.14	STMR (EFSA, 2017)		
Parsley	0.71	STMR (EFSA, 2016)		
Beans with pods	0.34	STMR (EFSA, 2017)		
Runner beans	0.34	STMR (EFSA, 2017)		
Beans without pods	0.18	STMR (GB MRL 2024/012)		
Peas with pods	0.34	STMR (EFSA, 2017)		
Peas without pods	0.2	STMR (EFSA, 2015)		
Celery	0.03	STMR (GB MRL 2024/018)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Oilseeds	0.04	STMR (EFSA, 2016)		
Potatoes	0.061	STMR (HSE, 2026)		
Hops (dried)	0.61	STMR (EFSA, 2014)		
Oats	0.17	STMR (EFSA, 2015)		
Barley	0.17	STMR (EFSA, 2015)		
Wheat	0.35	STMR (EFSA, 2014)		
Rye	0.35	STMR (EFSA, 2014)		
Poultry	0.04	STMR (FAO, 2016)		
Meat fat	0.02	STMR (FAO, 2016)		
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	STMR (FAO, 2016)		
Other types of offal	0.1	STMR (FAO, 2016)		
Eggs	0.084	STMR (EFSA, 2017)		
Milk	0.05	STMR (FAO, 2016)		
Sugar beet	0.03	STMR (EFSA, 2017)		
Other plant and animal commodities		GB MRL [†]		

* 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.

[†]GB MRL Statutory Register (GB MRL decision number: 2024/018)

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 estimated 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, 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

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Lettuce	0.55	STMR (FAO, 2016) current assessment	0.67	HR (FAO, 2016) current assessment
Escarole / broad leaved endives	0.155	STMR (protected), current assessment	0.33	HR (protected) 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 fruits	0.06	STMR (EFSA, 2014)		
Apricots	0.099	STMR (EFSA, 2017)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Peaches	0.08	STMR (EFSA, 2014)		
Plums	0.09	STMR (EFSA, 2014)		
Cherries	0.13	STMR (EFSA, 2014)		
Blackberries	0.421	STMR (HSE, 2022)		
Dewberries	0.36	STMR (HSE, 2022)		
Raspberries	0.421	STMR (HSE, 2022)		
Other small fruits and berries	0.421	STMR (HSE, 2022)		
Potatoes	0.061	STMR (HSE, 2026)		
Beetroot	0.05	STMR (EFSA, 2018)		
Carrots	0.05	STMR (EFSA, 2018)		
Celeriac	0.05	STMR (EFSA, 2018)		
Horseradish	0.05	STMR (EFSA, 2018)		
Jerusalem artichokes	0.05	STMR (EFSA, 2018)		
Parsnips	0.05	STMR (EFSA, 2018)		
Parsley root	0.05	STMR (EFSA, 2018)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Radishes	0.05	STMR (EFSA, 2018)		
Salsify	0.05	STMR (EFSA, 2018)		
Swedes	0.05	STMR (EFSA, 2018)		
Turnips	0.05	STMR (EFSA, 2018)		
Tomatoes	0.14	STMR (EFSA, 2014)		
Peppers	0.06	STMR (EFSA, 2014)		
Aubergines	0.14	STMR (EFSA, 2014)		
Cucumbers	0.15	STMR (EFSA, 2014)		
Gherkins	0.15	STMR (EFSA, 2014)		
Courgettes	0.15	STMR (EFSA, 2014)		
Cucurbits – inedible peel (melons, pumpkins, watermelons, others)	0.06	STMR (EFSA, 2014)		
Brussels sprouts	0.07	STMR (EFSA, 2015)		
Head cabbage	0.14	STMR (EFSA, 2017)		
Herbs and edible flowers	0.71	STMR (EFSA, 2016)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Beans with pods	0.34	STMR (EFSA, 2017)		
Beans without pods	0.18	STMR (GB MRL 2024/012)		
Peas with pods	0.34	STMR (EFSA, 2017)		
Peas without pods	0.2	STMR (EFSA, 2015)		
Celeries	0.03	STMR (GB MRL 2024/018)		
Cotton seed	0.04	STMR (EFSA, 2016)		
Hops	0.61	STMR (EFSA, 2014)		
Oats	0.17	STMR (EFSA, 2015)		
Barley	0.17	STMR (EFSA, 2015)		
Wheat	0.35	STMR (EFSA, 2014)		
Rye	0.35	STMR (EFSA, 2014)		
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	STMR (FAO, 2016)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Swine, bovine, sheep, goat, horse: liver	0.10	STM [*] R (FAO, 2016)		
Swine, bovine, sheep, goat, horse: kidney	0.10	STM [*] R (FAO, 2016)		
Swine, bovine, sheep, goat, horse: edible offal	0.10	STM [*] R (FAO, 2016)		
Poultry: meat	0.04	STM [*] R (FAO, 2016)		
Poultry: fat	0.04	STM [*] R (FAO, 2016)		
Poultry liver	0.037	STM [*] R (FAO, 2016)		
Milk and cream	0.05	STM [*] R (FAO, 2016)		
Bird's eggs	0.084	STM [*] R (FAO, 2016)		
Other plant commodities and animal		GB MRL [†]		

* indicates residues at the LOQ

†GB MRL Statutory Register (GB MRL decision number: 2024/018)

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 (4-6 year old child). 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 16% of the ARfD (infant/lettuce). The highest PRIMo IESTI was 34% of the ARfD (lettuce/NL child). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with flonicamid.

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 0.075 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 leafy crops which the crops 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

Eight outdoor and four protected trials, conducted in Germany, the UK, the Netherlands and Northern France, were submitted to support MRLs for lettuce and escarole / broad leaved endives. Samples of lettuce were analysed for residues of flonicamid and its metabolites TFNG and TFNA. These trials were supported by validated analytical methods and storage stability data.

In addition, two CXLs are available which are applicable to lettuces. The CXL for leaf lettuce (8 mg/kg) leads to acute intake concerns and cannot be adopted as a GB MRL. The CXL for head lettuce (1.5 mg/kg) is acceptable, and is recommended for adoption as a GB MRL. It is noted that the JMPR residue definitions are less extensive than the GB definitions; however, the JMPR evaluation contains the relevant metabolite information, and the values have been re-calculated based on the GB residue definition – the CXL in terms of the GB residue definition is 2 mg/kg and is recommended for adoption in GB.

Processing data was not required as the commodities are not normally consumed processed beyond simple physical processing such as washing.

Since the DT₉₀ 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 (4-6 year old child). 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 16% of the ARfD (infant/lettuce). The highest PRIMo IESTI was 34% of the ARfD (lettuce/NL child). 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 new MRLs for the proposed uses of flonicamid on lettuce and these 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 MRLs outlined in Table 8.1 are amended in the GB MRL Statutory Register.

Table 8.1 MRLs recommended by HSE

Enforcement residue definition for products of plant origin: Sum of flonicamid, TFNA and TFNG expressed as flonicamid

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
0251020	Lettuce	0.03*	2.0	The MRL is based on the CXL for lettuce (head). No health effects are expected.
0251030	Escarole / broad leaved	0.03*	0.6	The MRL is derived from an extrapolation of residue trials on protected lettuce. No health effects are expected.

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

References

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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)	kg a.s /hL min-max (l)	Water (L/ha) min-max	kg a.s./ha min-max (l)		
Lettuce	GB	<i>Teppeki</i>	F	Aphids	WG	500 g/L	Drench	BBCH 11-16 (pre-transplant)	1	-	-	-	1 mg a.s./plant	49	Pre-transplant, minimum 1 day before the planned transplant date. Note: Outdoor uses not authorised in GB.
Escarole / broad leaved endives	GB	<i>Teppeki</i>	F	Aphids	WG	500 g/L	Drench	BBCH 11-16 (pre-transplant)	1	-	-	-	1 mg a.s./plant	49	Pre-transplant, minimum 1 day before the planned transplant date. Note: Outdoor uses not authorised in GB.

The evaluation of new MRLs for flonicamid in or on lettuce and escarole / broad leaved endives

Lettuce	GB	<i>Teppeki</i>	G	Aphids	WG	500 g/L	Drench	BBCH 11-16 (pre-transplant)	1	-	-	-	1 mg a.s./plant	49	Pre-transplant, minimum 1 day before the planned transplant date.
Escarole / broad leaved endives	GB	<i>Teppeki</i>	G	Aphids	WG	500 g/L	Drench	BBCH 11-16 (pre-transplant)	1	-	-	-	1 mg a.s./plant	49	Pre-transplant, minimum 1 day before the planned transplant date.

(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. benthialvalicarb-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
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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	0.00244	0.00798	0.00767	0.00637	0.00464	0.00324	0.00275	0.00296	0.00218	0.00249
% of ADI	10%	32%	31%	25%	19%	13%	11%	12%	9%	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

The evaluation of new MRLs for flonicamid in or on lettuce and escarole / broad leaved endives

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

The evaluation of new MRLs for flonicamid in or on lettuce and escarole / broad leaved endives

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

The evaluation of new MRLs for flonicamid in or on lettuce and escarole / broad leaved endives

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	0.55		0.00034	0.00020	0.00047	0.00038	0.00040	0.00022	0.00024	0.00039	0.00029	0.00015
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		0.00009	0.00012	0.00048	0.00008	0.00021	0.00008	0.00008	0.00013	0.00016	0.00011
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

The evaluation of new MRLs for flonicamid in or on lettuce and escarole / broad leaved endives

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	0.061		0.00020	0.00068	0.00056	0.00050	0.00043	0.00033	0.00028	0.00022	0.00020	0.00019
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
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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
	Calculate 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 consumption)	32.29%	NL toddler	8.07	11.95%	Milk: Cattle	5.5%	Wheat	2.6%	Apples		0.2%
	21.78%	DK child	5.44	7.71%	Rye	6.2%	Wheat	2.5%	Milk: Cattle		0.3%
	20.49%	DE child	5.12	5.88%	Wheat	4.0%	Milk: Cattle	3.0%	Apples		0.2%
	19.72%	NL child	4.93	5.76%	Wheat	4.9%	Milk: Cattle	1.4%	Apples		0.2%
	18.19%	GEMS/Food G06	4.55	10.13%	Wheat	2.0%	Tomatoes	0.5%	Milk: Cattle		0.2%
	17.27%	FR child 3 15 yr	4.32	6.43%	Wheat	4.6%	Milk: Cattle	0.6%	Beans (with pods)		0.0%
	16.13%	UK infant	4.03	7.74%	Milk: Cattle	3.7%	Wheat	0.8%	Potatoes		
	15.88%	FR toddler 2 3 yr	3.97	5.86%	Milk: Cattle	4.3%	Wheat	1.1%	Beans (with pods)		0.0%
	15.20%	RO general	3.80	7.09%	Wheat	2.3%	Milk: Cattle	1.1%	Tomatoes		
	15.10%	GEMS/Food G15	3.77	6.36%	Wheat	1.4%	Milk: Cattle	0.9%	Potatoes		0.2%
	14.93%	GEMS/Food G08	3.73	5.71%	Wheat	1.1%	Milk: Cattle	1.0%	Potatoes		0.4%
	14.48%	GEMS/Food G07	3.62	5.91%	Wheat	1.3%	Milk: Cattle	0.9%	Potatoes		0.5%
	14.34%	UK toddler	3.59	5.48%	Wheat	4.1%	Milk: Cattle	0.9%	Potatoes		0.0%
	14.16%	ES child	3.54	6.21%	Wheat	2.5%	Milk: Cattle	0.9%	Lettuces		0.9%

The evaluation of new MRLs for flonicamid in or on lettuce and escarole / broad leaved endives

14.05%	GEMS/Food G10	3.51	5.49%	Wheat	1.1%	Milk:	0.8%	Soyabeans	0.7%
13.93%	SE general	3.48	4.48%	Wheat	2.5%	Cattle			
13.51%	GEMS/Food G11	3.38	5.05%	Wheat	1.6%	Milk:	1.1%	Bovine:	0.9%
12.61%	IT toddler	3.15	9.31%	Wheat	0.8%	Cattle		Muscle/meat	
10.97%	DE women 14-50 yr	2.74	3.00%	Wheat	2.5%	Milk:	1.0%	Potatoes	0.2%
10.7%	DE general	2.68	2.6%	Wheat	2.5%	Cattle			
10.7%	IE adult	2.66	3.2%	Wheat	0.9%	Milk:	0.6%	Lettuces	0.6%
9.8%	PT general	2.45	5.5%	Wheat	1.3%	Cattle	0.7%	Rye	0.3%
9.2%	NL general	2.30	2.7%	Wheat	1.7%	Milk:	0.8%	Rye	0.2%
9.0%	IT adult	2.24	5.8%	Wheat	0.8%	Cattle		Potatoes	0.2%
8.9%	ES adult	2.22	3.3%	Wheat	1.2%	Potatoes	0.5%	Tomatoes	0.2%
7.6%	FR infant	1.89	3.4%	Milk: Cattle	1.1%	Milk:	0.6%	Potatoes	0.3%
7.1%	FI 3 yr	1.79	1.7%	Wheat	1.2%	Cattle			
7.1%	FR adult	1.78	3.1%	Wheat	0.9%	Lettuces	0.7%	Tomatoes	0.8%
6.9%	LT adult	1.72	1.5%	Rye	1.5%	Lettuces	1.0%	Milk: Cattle	1.2%
6.1%	UK vegetarian	1.51	2.9%	Wheat	0.7%	Wheat	0.7%	Beans (with pods)	
5.9%	DK adult	1.47	1.6%	Wheat	1.1%	Potatoes	0.9%	Rye	0.1%
5.7%	FI 6 yr	1.43	1.4%	Wheat	0.9%	Milk:	0.3%	Beans (with pods)	0.0%
5.7%	FI adult	1.43	2.2%	Coffee beans	1.0%	Cattle			
5.2%	UK adult	1.30	2.3%	Wheat	0.6%	Wheat	0.8%	Milk: Cattle	0.1%
3.1%	IE child	0.79	1.6%	Wheat	0.7%	Milk:	0.3%	Tomatoes	0.3%
2.8%	PL general	0.71	0.8%	Potatoes	0.5%	Cattle			
						Potatoes	0.7%	Rye	0.2%
						Tomatoes	0.9%	Rye	0.2%
							0.4%	Wheat	0.3%
							0.3%	Potatoes	0.3%
							0.1%	Potatoes	0.0%
							0.5%	Apples	0.0%

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
Lettuce	0.67		0.00661	8.8	0.00847	11.3	0.00809	10.8	0.01193	15.9	0.00901	12.0

			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
Lettuce	0.67		0.00558	7.4	0.00538	7.2	0.00736	9.8	0.00472	6.3	0.00264	3.5

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

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)
	34.01%	Lettuces	0 / 0.67	25.51				
	17.67%	Escaroles/broad-leaved endives	0 / 0.33	13.26				
	Expand/collapse list							

Table B.5 Acute risk assessment undertaken using UK model version 1.2 – CXL for leaf lettuce
HR - 3.17 mg/kg in terms of GB RD-RA

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
Lettuce	3.17		0.03128	41.7	0.04008	53.4	0.03826	51.0	0.05644	75.3	0.04263	56.8

			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
Lettuce	3.17		0.02642	35.2	0.02544	33.9	0.03484	46.4	0.02234	29.8	0.01251	16.7

Table B.6 Acute risk assessment undertaken using PRIMo revision 3.1 – CXL for leaf lettuce

HR – 3.17 mg/kg in terms of GB RD-RA

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	1				---			
	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)
	160.91%	Lettuces	0 / 3.17	120.68	51.32%	Lettuces	0 / 3.17	38.49
	Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								
1								

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

Appendix C - Detailed evaluation of the additional studies relied on

C.1 Methods of analysis

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

C.3.1.1 Nature of residues

No additional studies submitted

C.3.1.2 Magnitude of residues

C.3.1.2.1 Lettuce (outdoor)

Reference: Study to generate samples of outdoor lettuce after a single pre transplant dip application of IBE 4131 for subsequent residue analysis of flonicamid and its metabolites TFNA, TFNG and TFNA-AM, 8 trials in Northern Europe (4 x MOR and 4 x DEC) during 2019, [REDACTED] 2022, Report No. S19-02137

Guideline(s): Yes
OECD TG 509 – Crop Field Trial
SANCO 7525/VI/95, rev. 10.3
SANCO/3029/99 rev. 4
SANCO/825/00 rev. 8.1

Deviations: Yes – Sampling to placing samples in the freezer was 8 hours, 16 minutes instead of planned 8 hours

Lettuce samples were less than the minimum 0.5 kg in some cases. Sample size was sufficient to be considered representative

No impact on study

GLP: Yes

Validity of the study: Acceptable

Materials and methods

Eight independent, outdoor trials on open leaf varieties of lettuce were conducted in Northern Europe (Germany, The United Kingdom, The Netherlands, Poland and Northern France) during the 2019 growing season. Each trial consisted of two plots, one untreated and one treated plot.

One pre transplant dip application of IBE 4131, a WG formulation containing 500 g/kg flonicamid, was applied at nominal rate of 1 mg a.s./plant, diluted with water immediately prior to application. Dip application occurred prior to transplanting, the time taken between the start of application and transplanting were not recorded.

For the four decline trials, samples of whole lettuce were taken 0, 14, 35, 42 and 49 days after application. Samples from the four at harvest trials were taken 49 days after application. Samples containing at least 0.5 kg or sufficient number of samples to be considered representative (see deviations) were collected from treated and untreated plots. Samples were frozen within 9 hours of sampling and stored at $\leq -18^{\circ}\text{C}$ for a maximum of 390 days until analysis. The stability of parent flonicamid and metabolites TFNG and TFNA has been demonstrated for this period in high water commodities when stored at $\leq -18^{\circ}\text{C}$.

Results and discussion

Residues of flonicamid and metabolites TFNG and TFNA were analysed using a QuEChERS HPLC-MS/MS validated during SGS Study BPL19-0032 ((LOQ of 0.01 mg/kg for each analyte, combined LOQ of 0.03 mg/kg). This method was previously validated by HSE ('Teppeki', COP 2021/00982, HSE int. ref.: W002006844) This method is sufficiently validated according in accordance with SANCO/3029/99 rev. 4.

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:

$$\text{MWC}_{\text{TFNA}} = \text{MW}_{\text{flonicamid}} / \text{MW}_{\text{TFNA}} = 229.16/191.11 = 1.199$$

$$\text{MWC}_{\text{TFNG}} = \text{MW}_{\text{flonicamid}} / \text{MW}_{\text{TFNG}} = 229.16/248.16 = 0.923$$

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

Eight independent trials on lettuce were conducted outdoors in Northern Europe (Germany, The United Kingdom, The Netherlands, Poland and Northern France) and the trials were within 25% of the proposed critical GAP.

Control samples did not have positive residues for seven of the eight trials. Residues of TFNA and TFNG were found in the control samples of Trial S19-02137-02, ranging between 0.02-0.03 mg/kg and at 0.01 mg/kg for TFNA and TFNG, respectively. The residues were found in control samples that were harvested 49 days after application to the treated plots, with no residues recorded in the 0 DAA application. In the treated samples, all residues were <LOQ 49 DAA.

Residues of the sum of flonicamid and its metabolites TFNG and TFNA, expressed as flonicamid, were <0.03-0.20 mg/kg 49 days after last application, the cGAP harvest interval.

Table C.3.1.2.1-1 Residue trials on lettuce (outdoors)

Reference:	Study to generate samples of outdoor lettuce after a single pre transplant dip application of IBE 4131 for subsequent residue analysis of flonicamid and its metabolites TFNA, TFNG and TFNA-AM, 8 trials in Northern Europe (4 x MOR and 4 x DEC) during 2019, [REDACTED] 2022, Report No. S19-02137			
GLP:	Yes	Sample storage conditions:	≤-18°C for 390 days	
Crop/crop group:	Lettuce	Analytical method:	QuEChERS HPLC-MS/MS, Study BPL19-0032, validated	
Indoor/outdoor:	Outdoor	Limit of Quantification (mg/kg):	0.01 for each analyte	
Formulation:	WG	Residues as:	calculated	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	Growth stage at last treatment	Portion analysed	Residues (mg/kg)				PHI (days)	Remarks
			g a.s./ha	mg a.s./plant	g a.s./hL				Flonicamid	TFNG ¹	TFNA ¹	Sum ²		

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	Growth stage at last treatment	Portion analysed	Residues (mg/kg)				PHI (days)	Remarks
S19-02137-01 German y 2019	Lettuce / Lungarilla	1. 17/05/2019 2. n/a 3. 04/07/2019	50	1.0	n/a	16/05/201	BBCH 13	Whole plant	0.96, 1.08 (1.02 ³)	<0.01, <0.01 (<0.01 ³)	<0.01, 0.012 (0.011 ³)	1.041	0	Open leaf variety
									1.30	0.38	0.50	2.18	14	
									<0.01	<0.01	0.036	0.056	35	
									<0.01	<0.01	0.024	0.044	42	
									<0.01	<0.01	0.024	<u>0.044</u>	49	
S19-02137-02 UK 2019	Lettuce / Sideral	1. 18/06/2019 2. n/a 3. 06/08/2019	90	1.0	n/a	18/06/2019	BBCH 12-14	Whole plant	7.45	<0.01	<0.01	7.47	0	Open leaf variety
									1.99	0.42	0.26	2.67	14	
									0.09	0.055	0.06	0.205	35	
									0.02	0.018	0.036	0.074	42	
									<0.01, <0.01 (<0.01 ³)	<0.01, <0.01 (<0.01 ³)	<0.01, <0.01 (<0.01 ³)	<0.03	49	Control samples contained positive residues for TFNA and TFNG

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	Growth stage at last treatment	Portion analysed	Residues (mg/kg)				PHI (days)	Remarks
S19-02137-03 The Netherlands 2019	Lettuce / Bionda Onyx (lollo bionda)	1. 18/07/2019 2. n/a 3. 05/09/2019	n/a	1.0	n/a	18/07/2019	BBCH 14	Whole plant	3.39 0.26 <0.01 <0.01 <0.01	<0.01 0.16 <0.01 <0.01 <0.01	<0.01 0.35 0.036 <0.01 <0.01	3.41 0.77 0.056 <0.03 <u><0.03</u>	0 14 35 42 49	Open leaf variety
S19-02137-04 Northern France 2019	Lettuce / Lollo rossa	1. 14/05/2019 2. n/a 3. 02/07/2019	111	1.0	n/a	14/05/2019	BBCH 16	Whole plant	4.05 1.47 0.01 <0.01 <0.01	<0.01 0.22 0.018 <0.01 <0.01	<0.01 0.46 0.10 0.06 0.06	4.07 2.15 0.13 0.08 <u>0.08</u>	0 14 35 42 49	Open leaf variety
S19-02137-05 Germany 2019	Lettuce / Lollo Rot	1. 22/05/2019 2. n/a 3. 10/07/2019	111	1.0	n/a	22/05/2019	BBCH 13	Whole plant	0.03	<0.01	0.084	<u>0.12</u>	49	Open leaf variety

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	Growth stage at last treatment	Portion analysed	Residues (mg/kg)				PHI (days)	Remarks
S19-02137-06 UK 2019	Lettuce / Jabeque	1. 22/05/2019 2. n/a 3. 10/07/2019	n/a	1.0	n/a	30/05/2019	BBCH 14-16	Whole plant	<0.01	<0.01	0.036	<u>0.056</u>	49	Open leaf variety
S19-02137-07 The Netherlands 2019	Lettuce / Lollo Rosso Antonet	1. 19/07/2019 2. n/a 3. 05/09/2019	n/a	1.0	n/a	18/07/2019	BBCH 14	Whole plant	0.01	<0.01	0.036	<u>0.056</u>	49	Open leaf variety
S19-02137-04 Northern France 2019	Lettuce / Lollo Bionda	1. 29/05/2019 2. n/a 3. 17/07/2019	n/a	1.0	n/a	29/05/2019	n/a	Whole plant	0.01	0.018	0.17	<u>0.20</u>	49	Open leaf variety

- (1) TFNG and TFNA are expressed as parent equivalents
- (2) Sum of flonicamid, TFNG and TFNA (expressed as parent equivalents)
- (3) Retained samples analysed; mean of two determinations are given in parenthesis

C.3.1.2.2 Lettuce (protected)

Reference:	Study to generate samples of protected lettuce after a single pre transplant dip application of IBE 4131 for subsequent residue analysis of flonicamid and its metabolites TFNA, TFNG and TFNA-AM, 4 trials in Northern Europe (2 x MOR and 2 x DEC) during 2019, [REDACTED] 2022, Report No. S19-01979
Guideline(s):	Yes OECD TG 509 – Crop Field Trial SANCO 7525/VI/95, rev. 10.3 SANCO/3029/99 rev. 4 SANCO/825/00 rev. 8.1
Deviations:	Yes – Lettuce samples were less than the minimum 0.5 kg in some cases. Sample size was sufficient to be considered representative No impact on study
GLP:	Yes
Validity of the study:	Acceptable

Materials and methods

Four independent, protected (greenhouse) trials on open leaf varieties of lettuce were conducted in Northern Europe (Germany, The United Kingdom, The Netherlands, Poland and Northern France) during the 2019 growing season. Each trial consisted of two plots, an untreated and treated plots.

One pre-transplant dip application of IBE 4131, a WG formulation containing 500g/kg flonicamid, was applied at a nominal rate of 1 mg a.s./plant, diluted with water immediately prior to application. Dip application occurred prior to planting, the time taken between the start of application and transplanting were not recorded.

For the two decline trials, samples of whole lettuce were taken 0, 14, 35, 42 and 49 days after application. Samples containing at least 0.5 kg or sufficient number of samples to be considered representative (see deviations) were collected from treated and untreated plots. Samples were frozen within 3 hours of sampling and stored at $\leq -18^{\circ}\text{C}$ for a maximum of 418 days until analysis. The stability of parent flonicamid and metabolites TFNG and TFNA has been demonstrated for this period in high water commodities when stored at $\leq -18^{\circ}\text{C}$.

Results and discussion

Residues of flonicamid and metabolites TFNG and TFNA were analysed using a QuEChERS HPLC-MS/MS validated during SGS Study BPL19-0032 ((LOQ of 0.01 mg/kg for each analyte, combined LOQ of 0.03 mg/kg). This method was previously validated by HSE ('Teppeki', COP 2021/00982, HSE int. ref.: W002006844) This method is sufficiently validated according in accordance with SANCO/3029/99 rev. 4.

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 lettuce were conducted under protected conditions (greenhouse) in Northern Europe (Germany, the UK, the Netherlands and Northern France) and the trials were within 25% of the proposed critical GAP.

No residues were detected in the control samples for all trials. Residues of the sum of flonicamid and its metabolites TFNG and TFNA, expressed as flonicamid, were 0.108-0.33 mg/kg 49 days after last application, the cGAP harvest interval.

Table C.3.1.2.1-1 Residue trials on lettuce (protected)

Reference:	Study to generate samples of protected lettuce after a single pre transplant dip application of IBE 4131 for subsequent residue analysis of flonicamid and its metabolites TFNA, TFNG and TFNA-AM, 4 trials in Northern Europe (2 x MOR and 2 x DEC) during 2019, [REDACTED] 2022, Report No. S19-01979			
GLP:	Yes	Sample storage conditions:	≤-18°C for 418 days	
Crop/crop group:	Lettuce	Analytical method:	QuEChERS HPLC-MS/MS, Study BPL19-0032, validated	
Indoor/outdoor:	Protected	Limit of Quantification (mg/kg):	0.01 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	Growth stage at last treatment	Portion analysed	Residues (mg/kg)				PHI (days)	Remarks
			g a.s./ha	mg a.s./plant	g a.s./hL				Flonicamid	TFNG ¹	TFNA ¹	Sum ²		
S19-01979 01 Germany 2019	Lettuce / Romana	1. 18/04/2019 2. n/a 3. 05/06/2019	70	1.0	n/a	17/04/2019	BBCH 13	Whole plant	2.19, 1.95 (2.07 ³) 4.31 0.36 0.11 0.06	<0.01, <0.01 (<0.01 ³) 0.73 0.22 0.09 0.037	<0.01, <0.01 (<0.01 ³) 0.52 0.29 0.12 0.12	2.09 5.56 0.87 0.32 <u>0.16</u>	0 14 35 42 49	Open leaf variety

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	Growth stage at last treatment	Portion analysed	Residues (mg/kg)				PHI (days)	Remarks
S19-01979 02 Northern France 2019	Lettuce / Bacchus (lollo rosso)	1. 07/06/2019 2. n/a 3. 25/07/2019	111	1.0	n/a	06/06/2019	BBCH 15	Whole plant	0.41, 0.43 (0.42 ³) 2.78 0.09 0.03 0.03, 0.03 (0.03 ³)	<0.01, <0.01 (<0.01 ³) 0.41 1.80 0.26 0.13 0.11, 0.028 (0.023 ³)	<0.01, <0.01 (<0.01) 1.80 0.26 0.13 0.11, 0.096 (0.10 ³)	0.44 4.99 0.33 0.18 <u>0.15</u>	0 14 35 42 49	Open leaf variety
S19-01979 03 UK 2019	Lettuce / Cos	1. 07/08/2019 2. n/a 3. 25/07/2019	n/a	1.0	n/a	19/08/2019	BBCH 13-15	Whole plant	0.02	0.028	0.06	<u>0.108</u>	49	Open leaf variety
S19-01979 04 The Netherlands 2019	Lettuce / Corentine (lollo rosso)	1. 07/08/2019 2. n/a 3. 25/07/2019	n/a	1.0	n/a	26/09/2019	BBCH 14	Whole plant	0.13, 0.13 (0.13 ³)	0.065, 0.074 (0.070 ³)	0.13, 0.13 (0.13 ³)	<u>0.33</u>	4	Open leaf variety

- (1) TFNG and TFNA are expressed as parent equivalents
- (2) Sum of flonicamid, TFNG and TFNA (expressed as parent equivalents)
- (3) Retained samples analysed; mean of two determinations are given in parenthesis

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

No additional studies submitted

C.3.6 Storage stability

No additional studies submitted

Appendix D – List of endpoints

The endpoints have not changed as a result of this assessment. The full list of endpoints is outlined in HSE, Conclusion of the Assessing Competent Authority on the Amendment of the Approval of the Active Substance flonicamid. HSE 2024.

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
	2022	Study to generate samples of outdoor lettuce after a single pre transplant dip application of IBE 4131 for subsequent residue analysis of flonicamid and its metabolites TFNA, TFNG and TFNA-AM, 8 trials in Northern Europe (4 x MOR and 4 x DEC) during 2019 Report No.: S19-02137 Eurofins Agrosience Services Ltd, Melbourne, Derbyshire GLP Unpublished
	2022	Study to generate samples of protected lettuce after a single pre transplant dip application of IBE 4131 for subsequent residue analysis of flonicamid and its metabolites TFNA, TFNG and TFNA-AM, 4 trials in Northern Europe (2 x MOR and 2 x DEC) during 2019 Report No. S19-1979 Eurofins Agrosience Services Ltd, Melbourne, Derbyshire GLP Unpublished

