The evaluation of a new MRL for flonicamid in or on potatoes

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 2021/00982

July 2026

Contents

Summary

In accordance with Article 6 of Assimilated Regulation 396/2005,[1] HSE received an application on 21 May 2021 to amend the existing MRL for the active substance flonicamid in or on potatoes. The application was to support an amendment to the current authorised use in GB. The amendment to the MRL was progressed following the amendment of the ARfD from 0.025 mg/kg bw to 0.075 mg/kg bw (HSE, 2024).

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

An ADI of 0.025 mg/kg bw/day was established for the approval of the active substance. An ARfD of 0.075 mg/kg bw was established by HSE in 2024 following an assessment of the amendment to the approval of flonicamid to adopt a new ARfD.

The metabolism of flonicamid in primary crops was investigated in fruit crops (peach, pepper), root crops (potato) and cereals and grasses (wheat) following foliar applications for the approval of flonicamid. The crop included in this MRL application is potato and is therefore covered by the available metabolism studies.

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

Sixteen outdoor trials on potatoes conducted in Austria, Germany, France, and the UK were submitted to support an MRL for potatoes. The trials are supported by validated analytical methods and storage stability data. Fifteen of these trials were considered acceptable to support the GAP, as explained in Section 3.2.

Trials were conducted that investigated the effect of an adjuvant (tank mix of a mineral oil-based adjuvant). The tank mix led to more critical residues, and indicate a higher MRL is required. For the current product authorisation, the label currently restricts the use of oil based adjuvants. Additionally, as no authorised use of mineral oil based adjuvants is available for use with Teppeki at the full rate used in the trials, these trials have not been considered further. Only trials conducted without the adjuvant tank mix have been used to estimate the MRL and undertake the consumer risk assessment. The label restriction will remain in place.

Hydrolysis of flonicamid and its metabolites TFNG and TFNA were investigated and determined to be hydrolytically stable under the representative conditions of pasteurisation, baking, brewing, boiling and sterilisation. Specific residue definitions for processed commodities are not required. Data to address the magnitude of residues in potatoes on processing is not required to support this assessment and the amendment to the GB MRL.

There is no potential for accumulation of flonicamid or its metabolites in soil. Therefore, no further consideration of residues in rotational crops is required.

The maximum livestock dietary burden exceeded the trigger value for further assessment (0.1 mg/kg DM and AR) for all livestock species. Metabolism of flonicamid in livestock was considered for the approval of the active substance. The approval assessment concluded that metabolic pathways in rodents and ruminants are comparable; the findings in ruminants can therefore be extrapolated to pigs. Based on the results of the livestock metabolisms studies, feeding studies and the calculated dietary burdens, residues of flonicamid and its metabolite TFNA-AM are not expected to exceed current MRLs in any products of animal origin (POAO).

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

- Sum of flonicamid and TFNA-AM expressed as flonicamid

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

- Sum of flonicamid and TFNA-AM expressed as flonicamid

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 22.6% of the ARfD (infant/potatoes). The highest PRIMo IESTI was 23% of the ARfD (children/potatoes). 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 potatoes. This will not result in consumer exposures exceeding the toxicological reference values and therefore is unlikely to have harmful effects on human health. HSE recommends that the MRL outlined in Table 0.1 is 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
0211000	Potatoes	0.09	0.2	The MRL is sufficiently supported by data No health effects are expected.

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 21 May 2021 HSE accepted an application from ISK Biosciences Europe N.V to set a new MRL for flonicamid in or on potatoes. This assessment was progressed following the conclusion on the amendment to the approval of flonicamid in which the ARfD was changed from 0.025 mg/kg bw to 0.075 mg/kg bw (HSE, 2024).

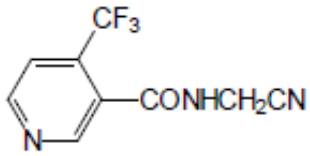
HSE evaluated the information submitted to uniform principles, as defined by Article 8 of Assimilated Regulation 396/2005 and prepared an Evaluation Report. HSE also took into account EFSA Reasoned Opinions and Conclusions on the peer review relating to decisions implemented in GB.

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	$C_9H_6F_3N_3O$
Molecular mass	229.16 g/mol

Flonicamid is an approved active substance in GB. An EFSA conclusion is available (EFSA, 2010). The MRLs for flonicamid were reviewed under Article 12 of Regulation (EC) No 396/2005 (EFSA, 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).

Whilst no MRLs for products of animal origin (POAO) are proposed to be raised within this evaluation, the dietary burden has been updated and is more critical, therefore the CXLs for POAO have been included in the table below for completeness. The CXLs are equivalent to or lower than the current GB MRLs. The CXLs are set on the basis of the same RD-Enf that applies in GB.

Table 0.3 CXLs relevant to the proposed uses

Commodity	CXL (mg/kg)	Comments	Year of adoption
Potato	0.01*	The CXL is lower than the current GB MRL and the proposed MRL in this assessment and therefore no further consideration is required.	2017
Edible offal (mammalian)	0.2	The CXL is the basis of the current GB MRL	2017
Eggs	0.15	The CXL is the basis of the current GB MRL	2017
Mammalian fats (except milk)	0.05	The CXL is the basis of the current GB MRL	2017
Meat (from mammals other than marine mammals)	0.15	The CXL is the basis of the current GB MRL	2017
Milks	0.15	The CXL is the basis of the current GB MRL	2017
Poultry fats	0.05	The CXL is the basis of the current GB MRL	2017
Poultry meat	0.1	The CXL is the basis of the current GB MRL	2017
Poultry, edible offal of	0.1	The CXL is the basis of the current GB MRL	2017

The CXL database is available at the following link:

http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/

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 plant commodities (wheat grain and straw, potato) in line with the enforcement residue definition for products of plant origin, were assessed for the approval of the active substance (EFSA, 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 commodity under consideration in the MRL application: potato (high water commodity for analytical methods) is covered by the analytical methods available.

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

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 (potatoes) and fruit crops (peach and pepper) for the approval of flonicamid (FR, 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 3.1.1-1 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 use on potatoes 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

Residue trials

0211000 Potatoes

The proposed critical outdoor GAP in GB is 2 x 0.08 kg a.s./ha with a RTI of 21 days and a latest time of application up to BBCH 55.

The following considerations demonstrate how the available trials support the cGAP under this MRL application:

- Translocation and metabolism of flonicamid in potatoes
- Potato varieties
- Previous consideration of potato trials/GAP, supporting the current authorisation and MRL of 0.09 mg/kg.

Translocation and metabolism of flonicamid in potatoes

Flonicamid is a systemic active substance and foliar application can result in translocation to the tubers over time. Therefore, longer PHIs may result in higher residues in the edible part (tubers) of the plant.

Additionally, the metabolism of flonicamid in plants results in the production of two major metabolites: TFNA and TFNG. Longer PHIs provide more time for this metabolism to occur, and as evidenced by the residue trials presented: the majority of the total residue in potato tubers is comprised of these metabolites rather than parent flonicamid. Longer PHIs would be expected to produce more critical residues due to higher residues of TFNA and TFNG.

In contrast, the latest time of application (BBCH 55) is during inflorescence emergence, this indicates that the final application will be made when tubers are only just beginning to develop, as tuber development, BBCH 40 – 49, occurs alongside BBCH 51 – BBCH 96 for the above ground part of the crop. Therefore residues may be subject to dilution as the tubers grow. Information on the growth stage of the tubers is not available from the studies, and only the growth stage for the visible portion of the crop is stated.

The residues demonstrated in study 1 are consistently higher in potatoes harvested at shorter PHIs (40-60 days). However, in these plots, the crop was treated at a much later BBCH stage (from BBCH 69), and varying crop cover/inflorescence could significantly impact the residues in the tubers. Residues are low at very short PHIs (<15 days), as there is limited time for translocation into the tubers and for metabolism to take place. The trials also demonstrate that at much longer PHIs (>60 days) residues decline as degradation and growth dilution in the tubers takes place. While PHI plays a role, the growth stage at

final application has a more significant effect on residues and is further supported by the information presented in study 2.

Study 2 used multiple plots to demonstrate the effect of earlier application timings and longer PHIs. This study design is more useful in establishing the residue profile of flonicamid and its metabolites over time, and demonstrates that the application timing appears to have a stronger effect than PHI on the residues. Discounting crops treated after BBCH 55 (as these are not representative of the GAP), an earlier application timing (prior to BBCH 36) and a longer PHI did not appear to give rise to higher residues, and in most trials the most critical residues were from plots treated close to BBCH 55. It is noted that for treatments after BBCH 55, the residues in tubers followed a similar pattern that seen in study 1, where residues at intermediate PHIs are most critical, and low residues in plots with very short PHIs.

While not fully elucidated, the lower residues arising from treatment at much earlier growth stages (prior to BBCH 36) may be due to lower crop coverage (which is closer to 100% coverage after BBCH 39), resulting in less foliage being covered by the active substance on treatment, and hence less active substance being available to be translocated to the tubers. Given the long PHIs, it is unlikely to be due to less time for translocation and metabolism. This is supported by the two trials with higher residues resulting from application between BBCH 36 and 39, when foliar coverage is high. The PHI in these plots was slightly longer than the BBCH 55 trial (between 3 and 10 days) and show a slight increase in residues.

Potato varieties

Due to the large number of potato varieties grown in GB, care must be taken where possible to ensure that a wide range of PHIs are considered when establishing whether trials are supportive of the GAP. Potatoes known as first or second earlies (also known as new potatoes in some cases) are harvested much earlier than maincrop potatoes, and as a result could contain higher residues than those varieties with longer PHIs. For the reasons outlined above, it is not considered that potatoes treated with flonicamid will necessarily have higher residues if harvested earlier. Additionally, early potatoes are often treated earlier than BBCH 55, and as demonstrated by the data from study 2, early treatment does not necessarily translate to higher residues, as would be expected for a systemic active substance. The effect of longer PHIs does not appear to significantly impact residue levels when the application was outside BBCH 36-55.

Previous consideration of potato trials/GAP

Trials were conducted on potatoes for the approval of the active substance at 2 x 0.08 kg a.s./ha with a PHI of 14 days. The current authorisation does not specify a growth stage for the latest time of application. The EFSA Conclusion (2010a) states the latest time of application as BBCH 81-95, referring to the visible part of the plant above the soil. The

MRL review (EFSA, 2014) re-evaluated these trials and listed the latest time of application as BBCH 49. As potato growth is measured for tubers separately, these GAPs are equivalent, and the MRL review presented the tuber growth stage rather than the visible part.

For this reason, the GAP proposed within this MRL evaluation (2 x 0.08 kg a.s./ha, RTI 21 days, up to BBCH 55) is considered to be more critical than currently authorised (2 x 0.08 kg a.s./ha, PHI 14 days). Additionally, the stipulation of a PHI is not considered necessary. The timing between application and harvest can be covered by the growth stage of application of BBCH 55:

- BBCH 55 is during inflorescence emergence, when the potato tubers are still at an early stage of development
- The trials available cover the range of PHIs possible and show residues are most critical at intermediate PHI rather than shorter or much longer PHIs
- Short PHIs will not result in higher residues owing to limited time for translocation and the metabolism for formation of the two metabolites

This GAP and trials data are considered to cover both maincrop potatoes, and early potatoes. In the case of early potatoes, an application earlier than BBCH 55 would be expected and a subsequent earlier harvest is not indicated to result in higher residues.

Newly submitted residue trials

Sixteen trials were submitted that were conducted in Austria, Germany, France, the UK, The Netherlands and Poland. The trials were submitted within two study reports conducted over two growing seasons, however, they were performed in a similar manner, with multiple trial plots running concurrently in each trial to simulate expected decline of residues. Trials undertaken in accordance with this approach are referred to as reverse decline trials.

In both studies, duplicate trials were conducted that investigated the effect of an adjuvant (tank mix of a mineral oil-based adjuvant). The tank mix led to more critical residues, and indicate a higher MRL is required. For the current product authorisation, a label restriction is currently in force to restrict the use of oil based adjuvants. Additionally, as no authorised use of mineral oil based adjuvants is available for Teppeki at the full rate used in the trials, these trials have not been considered further. Only trials conducted without the adjuvant tank mix have been relied upon. The label restriction will remain in place.

<u>Study 1</u>

Eight residue trials were undertaken without an adjuvant. Each trial was divided into multiple plots. The application rate to each plot in each trial reflected the GAP (2 x 0.08 kg

a.s./ha, with a RTI of approx. 21 days). In some of the plots of each trial, there was a shorter RTI. Based on the overall data available (multiple treated plots from 8 trials, different DALA and growth stages of treatment) this is not regarded to significantly impact the residue trials.

In each plot potato tubers were sampled at different time intervals. Potato tubers were sampled 0, 13 – 16, 41 – 44, 54 – 57, 69 – 71 and 71 - 87 days after the last application. The growth stage at the last application varied from BBCH 51 – BBCH 97, however the proposed growth stage at final application is BBCH 55. Trials reflecting this last application timing were selected.

All eight trials support the GAP.

Study 2

Eight residue trials were conducted without an adjuvant. The experimental design was similar to study 1, with multiple harvest timings occurring in each trial, but with differing application timings in plots within the trial. Potatoes were treated at earlier growth stages than in study 1, with the final application between BBCH 19 – 70. Plots with final application at BBCH 55 have been selected, however, higher residues obtained for applications at earlier BBCH growth stages have been selected if appropriate.

Trial NL06 deviated significantly from the study plan as most applications were performed at double the planned application rate: 0.160 kg a.s./ha rather than 0.08 kg a.s./ha. As a sufficient number of other trials are available to derive a robust MRL, this trial has been excluded from the set; as scaling residues performed at a higher rate is considered to have additional uncertainties compared to trials performed at the GAP. If the residue values were scaled, they would be within the expected range seen in other trials.

The nominal RTI was 21 days, however, some plots had shorter RTIs of around 8 -14 days. As the BBCH growth stage at final application is the main driver of the residue and considering the long PHIs in these trials, the shorter RTI is unlikely to impact residue levels significantly.

As set out in the 2024 GB extrapolations guidance, eight trials are required to support a use on potato as it is a major crop. As 15 acceptable trials have been provided, this is sufficient to support the MRL.

Storage stability

Stability of residues during storage was considered for the approval of the active substance (FR, 2005) for a number of commodities, including potatoes and wheat (forage) which are high water commodities. Flonicamid and its metabolites TFNG and TFNA were found to be stable in matrices with high water content for at least 18 months at ≤-18 °C. As stability of flonicamid has been determined for potatoes, this is sufficient to cover the

maximum storage of 153 days in the residue trials on potatoes that supports this application.

Analytical methods

Analysis for residues of flonicamid, TFNA and TFNG was conducted using LC-MS/MS method BPL19-0032, with one minor variation for study 2 (RDE-21-50691). The variation consisted of an additional water addition step, and does not significantly impact the performance of the method, as evidenced by additional validation data provided within the study. Acceptable procedural recovery data is available. Residues of TFNG and TFNA are expressed as flonicamid equivalents using the following molecular weight conversions:

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

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

The analytical method BPL19-0032 was considered satisfactorily validated in accordance with SANCO/3029/99 rev. 4. However, the extraction efficiency of the method has not been fully addressed. In principle, further data to support the extraction efficiency of the method is required. However, the lack of data for extraction efficiency is unlikely to impact the calculated MRL or the outcome of the dietary exposure assessment. Therefore, no further data are required at this time. See section C.1.3 for full details. The LOQ of this method was determined to be 0.01 mg/kg for all analytes. The summed LOQ for the RD-RA and RD-Enf is 0.03 mg/kg. Acceptable linearity, specificity, accuracy, and precision data have been reported for method BPL19-0032, as well as a reduced data set in the potato matrix. See section C.1.3 for full details.

Table 3.2-2 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)
Potatoes: 2 x 0.08 kg/ha, 21 day interval, (BBCH 55).	GB/Outdoor	0.03, 2 x 0.04, 0.042, 0.05, 0.055, 0.058, 0.061, 0.066, 0.079, 0.09, 0.097, 0.10, 0.11, 0.12	MRL_{OECD}: 0.208 (unrounded)	0.2	0.12	0.061

(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 considered as part of the EU Article 12 MRL Review (EFSA, 2014). Due to the unclear origin of the previous evaluation, these studies were re-reviewed in an evaluation report produced by HSE (UK, 2018) and found to be acceptable. 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 TFNA and TFNG under standard hydrolysis conditions was also evaluated as part of the evaluation report produced by HSE (UK, 2018). 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 residues in the RAC exceed the threshold of 0.1 mg/kg and the TMDIs for potatoes are > 10 % of the ADI. Therefore, a further consideration of the magnitude of residues in potatoes after processing is required. In principle, as the data requirements outlined in Assimilated Regulation 544/2011 apply, the relevant processing guidance is SANCO 7035/VI/95 rev.5. However, the OECD guideline 508 and guidance No 96 gives additional useful information including on whether a specific processing procedure is regarded major (category 1) or not (category 2); this information is summarised below.

As outlined below, the category 1 processes are all used in order to refine the dietary burden, for which default processing factors are available in the 2017 animal model. In addition, the data on the nature of the residue on processing shows that all three components of the RD-RA are stable on high temperature hydrolysis. Therefore, as no MRLs are being set in products of animal origin, no further data on the magnitude of residues are required at this time.

Table 3.4.2 Summary of required processing data

Processed fraction (Type)	Comments
Peeled potatoes (VI)	Category 2 process. Information not required at this time.
Wet peel (VI)	
Boiled potatoes (VI)	
Microwaved/boiled potatoes (unpeeled) (IX/XVIII)	
Baked potatoes (IX)	
Fried potatoes (IX)	
Crisps (IX)	
Chips (IX)	
Granules/flakes (IX)	
Process waste (IX)	
Ensiled (XIV)	Category 1 process. As the data is used to refine the dietary burden, the default processing factor can be used at this time.
Starch (XI)	Category 1 process. As the data is used to refine the dietary burden, the default processing factor can be used at this time.
Dried pulp (XVI)	Category 2 process. Information not required at this time.
Potato protein (XI)	Category 1 process. As the data is used to refine the dietary burden, the default processing factor can be used at this time.

3.5 Rotational crops

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

No consideration of residues in rotational crops is required, as the active substance (and soil metabolites) are not persistent in soil.

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 DT50 of 1 day. Similarly, the degradation of all soil metabolites is very rapid. DT50 values ranged between 0.3 and 2.6 days for the metabolites TFNA, TFNA-OH, TFNG, TFNG-AM and TFNA-AM.

3.5.2 Magnitude of residues (Rotational crop field trials)

No consideration required. See Section 3.5.1 above.

4 Residues in livestock

4.1 Dietary burden

The proposed use within this assessment (potatoes) can be fed to livestock, and therefore consideration of residues in products of animal origin is made.

The dietary burden calculation has been undertaken using the OECD feeding tables (OECD guidance document on overview of residue chemistry studies Series 64/32) and the EFSA Animal Model 2017.

The following assumptions have been made:

- The highest likely inclusion rate of all crops which may have been treated has been used with the proviso that the aggregate does not exceed 100% diet.
- All produce eaten which may have been treated, has been treated and contains residues at the STMR/HR found in the trials considered to support the GAP.
- There is no loss of residue during transport, storage, preparation of feed prior to consumption.
- Default processing factors as set out in the EFSA Animal Model 2017 have been used unless other specific processing factors are available or residues <LOQ are expected.

Input values are summarised in Table 4.1-1 and the estimated animal intakes are summarised in Table 4.1-2.

Table 4.1-1 Input values for the dietary burden calculation
RD-RA: Sum of flonicamid, TFNA and TFNG, expressed as flonicamid

Feed commodity	Median dietary burden input (mg/kg)	Comment	Maximum dietary burden input (mg/kg)	Comment
Barley (straw)	0.05	STMR (EFSA, 2015)	0.07	HR (EFSA, 2015)
Beet, sugar (tops)	0.09	STMR (EFSA, 2017)	0.20	HR (EFSA, 2017)
Cabbage, heads (leaves)	0.14	STMR (EFSA, 2017)	0.23	HR (EFSA, 2017)

Feed commodity	**Median dietary burden input (mg/kg)**	**Comment**	**Maximum dietary burden input (mg/kg)**	**Comment**
Oat (straw)	0.05	STMR (EFSA, 2015)	0.07	HR (EFSA, 2015)
Rye (straw)	0.18	STMR (EFSA, 2014)	0.48	HR (EFSA, 2014)
Triticale (straw)	0.18	STMR (EFSA, 2014)	0.48	HR EFSA, 2014)
Turnip tops (leaves)	0.07	STMR (EFSA, 2018b)	0.29	HR (EFSA, 2018b)
Wheat (straw)	0.18	STMR (EFSA, 2014)	0.48	HR (EFSA, 2014)
Carrot (culls)	0.05	STMR (EFSA, 2018b)	0.15	HR (EFSA, 2018b)
Potato (culls)	**0.061**	**STMR (this assessment)**	**0.12**	**HR (this assessment)**
Swede (roots)	0.05	STMR (EFSA, 2018b)	0.15	HR (EFSA, 2018b)
Turnip (roots)	0.05	STMR (EFSA, 2018b)	0.15	HR (EFSA, 2018b)
Barley (grain)	0.14	STMR (EFSA, 2015)	0.14	STMR (EFSA, 2015)
Bean (seed, dry)	0.16	STMR (EFSA, 2018)	0.16	STMR (EFSA, 2018)
Cotton (undelinted seed)	0.04	STMR (EFSA, 2015)	0.04	STMR (EFSA 2015)
Lupin (seed)	0.16	STMR (EFSA, 2018)	0.16	STMR (EFSA, 2018)

Feed commodity	Median dietary burden input (mg/kg)	Comment	Maximum dietary burden input (mg/kg)	Comment
Oat (grain)	0.14	STMR (EFSA, 2015)	0.14	STMR (EFSA, 2015)
Pea (seed, dry)	0.16	STMR (EFSA, 2018)	0.16	STMR (EFSA, 2018)
Rye (grain)	0.35	STMR (EFSA, 2014)	0.35	STMR (EFSA, 2014)
Triticale (grain)	0.35	STMR (EFSA, 2014)	0.35	STMR (EFSA, 2014)
Wheat (grain)	0.35	STMR (EFSA, 2014)	0.35	STMR (EFSA, 2014)
Apple (pomace, wet)	0.30	STMR (0.06) x default PF (5) (EFSA, 2014)	0.30	STMR (0.06) x default PF (5) (EFSA, 2014)
Beet, sugar (dried pulp)	1.62	STMR (0.09) x default PF (18) (EFSA, 2017)	1.62	STMR (0.09) x default PF (18) (EFSA, 2017)
Beet, sugar (ensiled pulp)	0.27	STMR (0.09) x default PF (3) (EFSA, 2017)	0.27	STMR (0.09) x default PF (3) (EFSA, 2017)
Beet, sugar (molasses)	2.52	STMR (0.09) x default PF (28) (EFSA, 2017)	2.52	STMR (0.09) x default PF (28) (EFSA, 2017)

Feed commodity	**Median dietary burden input (mg/kg)**	**Comment**	**Maximum dietary burden input (mg/kg)**	**Comment**
Brewer's grain	0.46	STMR (0.14) x default PF (3.3) (EFSA, 2014)	0.46	STMR (0.14) x default PF (3.3) (EFSA, 2014)
Citrus (dried pulp)	0.40	STMR (0.04) x default PF (10) (EFSA, 2014)	0.40	STMR (0.04) x default PF (10) (EFSA, 2014)
Cotton (meal)	0.05	STMR (0.04) x default PF (1.3) (EFSA, 2016)	0.05	STMR (0.04) x default PF (1.3) (EFSA, 2016)
Distiller's grain (dried)	1.16	STMR (0.35) x default PF (3.3) (EFSA, 2014)	1.16	STMR (0.35) x default PF (3.3) (EFSA, 2014)
Lupin seed (meal)	0.18	STMR (0.16) x default PF (1.1) (EFSA, 2018)	0.18	STMR (0.16) x default PF (1.1) (EFSA, 2018)
Potato (process waste)	**1.22**	**STMR (0.061) x default PF (20)**	**1.22**	**STMR (0.061) x default PF (20)**
Potato (dried pulp)	**2.32**	**STMR (0.061) x default PF (38)**	**2.32**	**STMR (0.061) x default PF (38)**
Wheat gluten (meal)	0.63	STMR (0.35) x default PF (1.8) (EFSA, 2014)	0.63	STMR (0.35) x default PF (1.8) (EFSA, 2014)

Feed commodity	**Median dietary burden input (mg/kg)**	**Comment**	**Maximum dietary burden input (mg/kg)**	**Comment**
Wheat (milled by-products)	2.45	STMR (0.35) x default PF (7) (EFSA, 2014)	2.45	STMR (0.35) x default PF (7) (EFSA, 2014)

Table 4.1-2 Estimated animal intakes

Animal	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	>0.1 mg /kg DM (Y/N)	Maximum burden (mg/kg DM)	Highest contributing commodity[(a)]	Previous assessment (EFSA, 2018) (Max. burden) (mg/kg DM)
Cattle (all diets)	0.133	0.145	Y	4.97	Potato process waste	2.91
Cattle (dairy only)	0.133	0.145	Y	3.78	Potato process waste	2.23
Sheep (all diets)	0.146	0.160	Y	4.81	Potato process waste	2.74
Sheep (ewe only)	0.146	0.160	Y	4.81	Potato process waste	2.74
Swine (all diets)	0.056	0.067	Y	2.91	Potato process waste	2.15
Poultry (all diets)	0.062	0.071	Y	1.04	Wheat milled by-products	1.04

Animal	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	>0.1 mg /kg DM (Y/N)	Maximum burden (mg/kg DM)	Highest contributing commodity[(a)]	Previous assessment (EFSA, 2018) (Max. burden) (mg/kg DM)
Poultry (layer only)	0.062	0.071	Y	1.04	Wheat milled by-products	1.04

(a) Considering the maximum dietary animal burden

Based on the dietary burden calculations consideration of the likely residues in food of animal origin is required as the trigger of 0.1 mg/kg DM or AR is exceeded for all animal groups. On this basis, further consideration of POAO is required.

For poultry, as the dietary burden from the use under consideration does not exceed that previously calculated (EFSA, 2018) residues in poultry matrices do not need to be considered further.

For ruminants, further consideration has been made in Section 4.3 below.

4.2 Nature of residues (Animal metabolism studies)

Metabolism in livestock was investigated in lactating goats (ruminants) and laying hens (poultry) for the approval of flonicamid (DAR, FR, 2005).

The studies are summarised in Table 4.2-1.

Table 4.2-1 Summary of the available animal metabolism studies

Animal	Dosing rate (mg/kg bw/day)	Duration	Comment
Laying hen	0.78	5	*ca.* 5.9 N
Lactating goat	1.69	5	*ca.* 4.4N (sheep)
Pig	Not required	-	Rat and ruminant metabolism similar

As acceptable livestock metabolism data is presented for poultry and ruminants, and as the dose rate in the metabolism studies is greater than the calculated dietary burden in each case (5.9N for poultry and 11N for ruminants), it is considered that the results of these studies are applicable to this application.

Residue definitions

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

- Sum of flonicamid and TFNA-AM, expressed as flonicamid

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

- Sum of flonicamid and TFNA-AM, expressed as flonicamid

The residue is non-fat soluble.

4.3 Magnitude of residues

Livestock feeding studies were undertaken in lactating cows (ruminants) and laying hens (poultry) for the approval of flonicamid (DAR, FR, 2005).

Lactating cows were dosed with flonicamid/TFNG, at a rate of 2.50, 6.89 and 23.69 mg/kg DM (which equates to of 0.086, 0.252 and 0.839 mg/kg bw/day). The study duration was 28 days. Residues of flonicamid, TFNA, TFNG, OH-TFNA-AM, and TFNA-AM were analysed for in milk and tissues.

It is noted that the animals were dosed with a flonicamid/TFNG mixture, when according to the residue trials, it is TFNA and TFNG that make up the vast majority of the residues in the potato RAC. As mentioned in the EFSA Conclusion (2010) TFNG is an intermediate metabolite and is considered to be covered by the metabolism of parent. TFNA is a final metabolite, however the studies on rat metabolism demonstrated this metabolite is rapidly excreted and therefore accumulation is not expected in ruminant matrices. In poultry, this evidence was less clear, however as residues are low even with a more critical dietary burden, and no MRLs in POAO need to be raised, it is concluded that the livestock metabolism studies are sufficient at this time and is acceptable to support this application.

It is noted that the data presented in the DAR does not give the results for the residue levels determined in the individual cows (n=3) at each dose level. However, the data are sufficient to demonstrate that the residues determined will be below the current GB MRLs which are the CXLs.

The highest feed rates are 4.97 mg/kg (DM) and 3.78 mg/kg (DM) for beef and dairy cattle respectively. At a feeding rate of 6.89 mg/kg (DM) residues of flonicamid in milk were < 0.01 mg/kg. At this feeding rate, residues of TFNA-AM were reported to be 0.0215 mg/kg over the plateau period; therefore at a feeding rate of 3.78 mg/kg (DM) residues of TFNA-AM will be 0.012 mg/kg. The current MRL of 0.15 mg/kg does not need to be amended.

In muscle at the 6.89 mg/kg DM feeding rate, residues of flonicamid were <0.01 mg/kg. Residues of TFNA-AM were 0.0271 mg/kg therefore at a feeding rate of 4.97 mg/kg DM, residues of TFNA-AM will be 0.019 mg/kg. The current MRL in muscle of 0.15 mg/kg does not need to be amended.

In fat, residues of flonicamid were <0.01 mg/kg at all dose rates. Residues of TFNA-AM were <0.01 mg/kg at the 6.89 mg/kg DM dose rate and therefore residues will be <0.01 mg/kg at a feeding rate of 4.97 mg/kg DM. The MRL in fat of 0.05* mg/kg does not need to be amended.

In liver at the 6.89 mg/kg DM feeding rate, residues of flonicamid were <0.01 mg/kg. Residues of TFNA-AM were 0.0387 mg/kg therefore at a feeding rate of 4.97 mg/kg DM, residues of TFNA-AM will be 0.028 mg/kg. The current MRL in liver of 0.2 mg/kg does not need to be amended.

In kidney at the 6.89 mg/kg DM feeding rate, residues of flonicamid were <0.01 mg/kg. Residues of TFNA-AM were 0.0312 mg/kg therefore at a feeding rate of 4.97 mg/kg DM,

residues of TFNA-AM will be 0.022 mg/kg. The current MRL in kidney of 0.2 mg/kg does not need to be amended.

Residues in the milk and tissues of other ruminants will all be lower than those considered for cattle, and hence the current MRLs in force do not need to be amended.

No amendments to the MRLs for products of animal origin are required.

4.4 Conversion factor for risk assessment for products of animal 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.

5 Residues in honey

No consideration of residues in honey is required as the application is to ‘old’ 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

Dietary exposures have been estimated using the UK chronic and acute models and the EFSA PRIMo.

Chronic dietary exposures have been estimated based on the uses 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.

Acute dietary exposures have only been estimated for the uses 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.

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**
Potatoes	**0.061**	**STMR (current assessment)**	**0.12**	**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			
Cherries	0.13			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
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			

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			
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)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
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*			
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			
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)		
Beansprouts	0.03*	MRL (GB MRL 2022/015)		
Asparagus	0.03*			
Bamboo shoots	0.03*			
Celery	0.03	STMR (GB MRL 2024/018)		
Fennel	0.03*	MRL (GB MRL 2022/015)		
Globe artichokes	0.03*			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
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)		
Hops (dried)	0.61	STMR (EFSA, 2014)		
Oats	0.17	STMR (EFSA, 2015)		
Barley	0.17			
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)	0.076	HR (FAO, 2016)
Meat fat	0.02		0.03	
Meat excl. poultry & offal[(a)]	0.06	STMR (FAO, 2016) – not fat soluble	0.102	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
All types of kidney	0.1	STMR (FAO, 2016)	0.17	
All types of liver	0.1		0.17	
Other types of offal	0.1		0.17	
Eggs	0.084	STMR (EFSA, 2017)	0.1	STMR (EFSA, 2017)
Milk	0.05	STMR (FAO, 2016)	0.05	STMR (FAO, 2016)
Sugar beet	0.03	STMR (EFSA, 2017)	Acute risk assessment undertaken only for the uses proposed as part of the current assessment	

* indicates residues at the LOQ

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
RD-RA: **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**
Potatoes	**0.061**	**STMR (current assessment)**	**0.12**	**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			
Beetroot	0.05	STMR (EFSA, 2018)		
Carrots	0.05			
Celeriac	0.05			
Horseradish	0.05			
Jerusalem artichokes	0.05			
Parsnips	0.05			
Parsley root	0.05			
Radishes	0.05			
Salsify	0.05			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
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)		
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)		

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	STMR (EFSA, 2014)		
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)	0.102	HR (FAO,2016)
Swine, bovine, sheep, goat, horse: fat free of lean meat	0.02		0.03	
Swine, bovine, sheep, goat, horse: liver	0.10		0.17	
Swine, bovine, sheep, goat, horse: kidney	0.10		0.17	
Swine, bovine, sheep, goat, horse: edible offal	0.10		0.17	
Poultry: meat	0.04		0.076	
Poultry: fat	0.04		0.04	
Poultry liver	0.037	STMR (EFSA, 2017)	0.09	
Poultry kidney	0.04	STMR (FAO, 2016)	0.09	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Milk and cream	0.05		0.05	
Bird's eggs	0.084	STMR (EFSA, 2017)	0.10	HR (EFSA, 2017)
Other plant and animal commodities	MRL	MRL (GB MRL 2024/018)	Not required for this assessment	

* 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 24.6% of the ARfD (infant/potatoes). The highest PRIMo IESTI was 25% of the ARfD (children/potatoes). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with flonicamid.

7.2 Other routes of exposure

As part of the fate and behaviour assessment for this application, the levels of parent active substance were predicted to be < 0.001 µg/L in groundwater. The EFSA Conclusion (2010) states that PECgw values for flonicamid metabolites are not expected to exceed those of the active substance itself, and therefore modelling was performed on active substance only.

Given the levels of flonicamid and metabolites expected in ground water, then a further consideration of dietary exposure is not required.

8 The conclusion of the competent authority

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

An ADI of 0.025 mg/kg bw/day was established for the approval of the active substance. An ARfD of 0.075 mg/kg bw was established by HSE in 2024 following an assessment of the amendment to the approval of flonicamid to adopt a new ARfD.

The metabolism of flonicamid in primary crops was investigated in fruit crops (peach, pepper), root crops (potato) and cereals and grasses (wheat) following foliar applications for the approval of flonicamid. The crop included in this MRL application is potato and is therefore covered by the available metabolism studies.

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

Sixteen outdoor trials on potatoes conducted in Austria, Germany, France, and the UK were submitted to support an MRL for potatoes. The trials are supported by validated analytical methods and storage stability data. Fifteen of these trials were considered acceptable to support the GAP, as explained in Section 3.2.

Trials were conducted that investigated the effect of an adjuvant (tank mix of a mineral oil-based adjuvant). The tank mix led to more critical residues, and indicate a higher MRL is required. For the current product authorisation, the label currently restricts the use of oil based adjuvants. Additionally, as no authorised use of mineral oil based adjuvants is available for use with Teppeki at the full rate used in the trials, these trials have not been considered further. Only trials conducted without the adjuvant tank mix have been used to estimate the MRL and undertake the consumer risk assessment. The label restriction will remain in place.

Hydrolysis of flonicamid and its metabolites TFNG and TFNA were investigated and determined to be hydrolytically stable under the representative conditions of pasteurisation, baking, brewing, boiling and sterilisation. Specific residue definitions for

processed commodities are not required. Data to address the magnitude of residues in potatoes on processing is not required to support this assessment and the amendment to the GB MRL.

There is no potential for accumulation of flonicamid or its metabolites in soil. Therefore, no further consideration of residues in rotational crops is required.

The maximum livestock dietary burden exceeded the trigger value for further assessment (0.1 mg/kg DM and AR) for all livestock species. Metabolism of flonicamid in livestock was considered for the approval of the active substance. The approval assessment concluded that metabolic pathways in rodents and ruminants are comparable; the findings in ruminants can therefore be extrapolated to pigs. Based on the results of the livestock metabolisms studies, feeding studies and the calculated dietary burdens, residues of flonicamid and its metabolite TFNA-AM are not expected to exceed current MRLs in any products of animal origin (POAO).

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

- Sum of flonicamid and TFNA-AM expressed as flonicamid

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

- Sum of flonicamid and TFNA-AM expressed as flonicamid

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 22.6% of the ARfD (infant/potatoes). The highest PRIMo IESTI was 23% of the ARfD (children/potatoes). 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 potatoes. This will not result in consumer exposures exceeding the toxicological reference values and therefore is unlikely to have harmful effects on human health. 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

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
0211000	Potatoes	0.09	0.2	The MRL is sufficiently supported by data No health effects are expected.

References

France, 2005 Draft Assessment Report (DAR) on the active substance Flonicamid.

EFSA (European Food Safety Authority) Conclusion on the peer review of the pesticide risk assessment of the active substance flonicamid, 2010. EFSA Journal 2010; 8(5):1445.

EFSA (European Food Safety Authority) Reasoned opinion on the review of the existing maximum residue levels (MRLs) for flonicamid according to Article 12 of Regulation (EC) No 396/20051, 2014. EFSA Journal 2014;12(6):3740

EFSA (European Food Safety Authority) Modification of existing maximum residue levels for flonicamid in various commodities, 2017. EFSA Journal 2017;15(3):4748

EFSA (European Food Safety Authority) Modification of existing maximum residue levels for flonicamid in various root crops, 2018. EFSA Journal 2018;16(9):5414

UK, Evaluation Report, MRL application on the setting of MRLs in carrots and other root and tuber vegetables, except sugar beet, UK, 2018.

HSE, GB MRL Evaluation Report, The evaluation of new MRLs for flonicamid in or on various berries and small fruits. HSE 2022.

HSE, Conclusion of the Assessing Competent Authority on the Amendment of the Approval of the Active Substance flonicamid. HSE 2024.

HSE, Decision on the amendment of the approval of the active substance flonicamid. HSE, 2024.

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)		
Industrial, ware potatoes and seed potatoes (*Solanum tuberosum*; SOLTU) [0211000]	GB	IKI-220 50 % WG	F	*Aphids species; Aphis nasturtii* (APHINA), *Myzus persicae* (MYZUPE), *Macrosiphum euphorbiae* (MACSEU),	WG	500 g/kg	Hydraulic tractor-applied foliar spray	BBCH 10-11† until latest BBCH 55 (Spring: March/April-July)	2	21	0.08	200-500	0.016-0.040	**1 day**	Aphid control; † ware potato use - only at aphid arrival/warnings; † Seed potato use - obligatory starting of treatments for virus vector control

(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)	(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).
(b) State if the use is outdoor, field use (F) or glasshouse (G) or indoor use (I).	(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
(c) *e.g.* biting and sucking insects, soil borne insects, foliar fungi, weeds	(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(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	(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: **ADI:** 0.025 mg/kg bw/day **Source:**

			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		0.00238	0.00798	0.00766	0.00635	0.00461	0.00322	0.00271	0.00289	0.00214	0.00248
	% of ADI		10%	32%	31%	25%	18%	13%	11%	12%	9%	10%
Commodity	STMR (mg/kg)	P	COMMODITY INTAKES (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	0.061		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

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

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

Chronic risk assessment: JMPR methodology (IEDI/TMDI)										
			No of diets exceeding the ADI :	-- -					Exposure resulting from	
Calculated exposure (% of ADI)	MS Diet	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
32.1%	NL toddler	8.03	11.9%	Milk: Cattle	5.5%	Wheat	2.6%	Apples		13.8%
21.5%	DK child	5.38	7.7%	Rye	6.2%	Wheat	2.5%	Milk: Cattle		4.5%
20.3%	DE child	5.09	5.9%	Wheat	4.0%	Milk: Cattle	3.0%	Apples		5.4%
19.5%	NL child	4.88	5.8%	Wheat	4.9%	Milk: Cattle	1.4%	Apples		6.6%
18.0%	GEMS/Food G06	4.50	10.1%	Wheat	2.0%	Tomatoes	0.5%	Milk: Cattle		1.4%
17.3%	FR child 3 15 yr	4.33	6.4%	Wheat	4.6%	Milk: Cattle	0.6%	Beans (with pods)		6.3%
16.2%	UK infant	4.04	7.7%	Milk: Cattle	3.7%	Wheat	0.8%	Potatoes		9.5%
15.9%	FR toddler 2 3 yr	3.98	5.9%	Milk: Cattle	4.3%	Wheat	1.1%	Beans (with pods)		7.4%
15.3%	RO general	3.82	7.1%	Wheat	2.3%	Milk: Cattle	1.1%	Tomatoes		4.0%
14.9%	GEMS/Food G15	3.73	6.4%	Wheat	1.4%	Milk: Cattle	0.9%	Potatoes		3.1%
14.6%	GEMS/Food G08	3.64	5.7%	Wheat	1.1%	Milk: Cattle	1.0%	Potatoes		2.9%
14.3%	UK toddler	3.58	5.5%	Wheat	4.1%	Milk: Cattle	0.9%	Potatoes		5.7%

14.1%	GEMS/Food G07	3.52	5.9%	Wheat	1.3%	Milk: Cattle	0.9%	Potatoes		3.2%	
13.5%	GEMS/Food G10	3.37	5.5%	Wheat	1.1%	Milk: Cattle	0.8%	Soyabeans		2.7%	
13.4%	ES child	3.35	6.2%	Wheat	2.5%	Milk: Cattle	0.5%	Tomatoes		4.2%	
13.4%	GEMS/Food G11	3.34	5.0%	Wheat	1.6%	Milk: Cattle	1.0%	Potatoes		3.3%	
13.1%	SE general	3.27	4.5%	Wheat	2.5%	Milk: Cattle	1.1%	Bovine: Muscle/meat		4.8%	
12.0%	IT toddler	3.00	9.3%	Wheat	0.8%	Tomatoes	0.2%	Potatoes		0.2%	
10.7%	DE women 14-50 yr	2.68	3.0%	Wheat	2.5%	Milk: Cattle	0.7%	Rye		3.3%	
10.5%	DE general	2.63	2.6%	Wheat	2.5%	Milk: Cattle	0.8%	Rye		3.3%	
10.4%	IE adult	2.61	3.2%	Wheat	0.9%	Milk: Cattle	0.6%	Potatoes		2.0%	
9.6%	PT general	2.39	5.5%	Wheat	1.3%	Potatoes	0.5%	Tomatoes		1.3%	
9.0%	NL general	2.25	2.7%	Wheat	1.7%	Milk: Cattle	0.6%	Potatoes		2.9%	
8.2%	IT adult	2.04	5.8%	Wheat	0.7%	Tomatoes	0.2%	Beans (with pods)		0.1%	
7.8%	ES adult	1.95	3.3%	Wheat	1.0%	Milk: Cattle	0.4%	Tomatoes		1.9%	
7.6%	FR infant	1.90	3.4%	Milk: Cattle	1.1%	Wheat	0.7%	Beans (with pods)		4.1%	
7.1%	FR adult	1.78	3.1%	Wheat	0.9%	Milk: Cattle	0.3%	Beans (with pods)		1.7%	
7.0%	FI 3 yr	1.76	1.7%	Wheat	1.2%	Potatoes	0.9%	Rye		1.2%	
6.8%	LT adult	1.69	1.5%	Rye	1.5%	Wheat	0.8%	Milk: Cattle		2.1%	
5.8%	UK vegetarian	1.44	2.9%	Wheat	0.7%	Milk: Cattle	0.3%	Tomatoes		1.1%	
5.7%	DK adult	1.43	1.6%	Wheat	1.1%	Milk: Cattle	0.7%	Rye		1.9%	
5.5%	FI 6 yr	1.38	1.4%	Wheat	0.9%	Potatoes	0.9%	Rye		0.9%	
5.4%	FI adult	1.35	2.2%	Coffee beans	1.0%	Rye	0.4%	Wheat		0.3%	
5.0%	UK adult	1.25	2.3%	Wheat	0.6%	Milk: Cattle	0.3%	Potatoes		1.3%	
3.1%	IE child	0.78	1.6%	Wheat	0.7%	Milk: Cattle	0.1%	Potatoes		1.0%	

2.8%	PL general	0.70	0.8%	Potatoes	0.5%	Tomatoes	0.5%	Apples		0.8%

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
Potatoes	0.12		0.00288	3.8	0.01845	24.6	0.01276	17.0	0.00961	12.8	0.00661	8.8
Poultry	0.08		0.00042	0.6	0.00052	0.7	0.00066	0.9	0.00072	1.0	0.00054	0.7
Meat fat	0.03		0.00002	0.0	0.00006	0.1	0.00006	0.1	0.00006	0.1	0.00004	0.1
Meat excl.poultry & offal	0.10		0.00050	0.7	0.00120	1.6	0.00104	1.4	0.00093	1.2	0.00079	1.1
All types of kidney	0.17		0.00029	0.4	0.00041	0.5	0.00064	0.9	0.00042	0.6	0.00028	0.4
All types of liver	0.17		0.00046	0.6	0.00137	1.8	0.00114	1.5	0.00031	0.4	0.00043	0.6
Other types of offal	0.17		0.00050	0.7	0.00124	1.6	0.00121	1.6	0.00098	1.3	0.00093	1.2
Eggs	0.10		0.00028	0.4	0.00124	1.7	0.00078	1.0	0.00067	0.9	0.00049	0.7
Milk	0.05		0.00065	0.9	0.00621	8.3	0.00367	4.9	0.00233	3.1	0.00149	2.0

			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
Potatoes	0.12		0.00467	6.2	0.00349	4.7	0.00358	4.8	0.00285	3.8	0.00312	4.2
Poultry	0.08		0.00045	0.6	0.00041	0.5	0.00089	1.2	0.00035	0.5	0.00019	0.3
Meat fat	0.03		0.00003	0.0	0.00003	0.0	0.00001	0.0	0.00001	0.0	0.00001	0.0
Meat excl.poultry & offal	0.10		0.00058	0.8	0.00058	0.8	0.00027	0.4	0.00038	0.5	0.00032	0.4
All types of kidney	0.17		0.00023	0.3	0.00036	0.5	0.00000	0.0	0.00029	0.4	0.00022	0.3
All types of liver	0.17		0.00071	0.9	0.00034	0.4	0.00000	0.0	0.00039	0.5	0.00033	0.4
Other types of offal	0.17		0.00078	1.0	0.00038	0.5	0.00016	0.2	0.00042	0.6	0.00042	0.6
Eggs	0.10		0.00038	0.5	0.00030	0.4	0.00038	0.5	0.00021	0.3	0.00023	0.3
Milk	0.05		0.00103	1.4	0.00088	1.2	0.00074	1.0	0.00055	0.7	0.00071	1.0

Pesticide		
ARfD	0.075	mg/Kg bw/day
Source		

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001

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

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
24.60%	Potatoes	0 / 0.12	18.45	4.77%	Potatoes	0 / 0.12	3.58
8.28%	Milk: Cattle	0 / 0.05	6.21	2.57%	Milk: Cattle	0 / 0.05	1.93
1.83%	Bovine: Liver	0 / 0.17	1.37	1.23%	Milk: Goat	0 / 0.05	0.92
1.72%	Poultry: Muscle/meat	0 / 0.08	1.29	1.19%	Poultry: Muscle	0 / 0.08	0.89
1.66%	Eggs: Chicken	0 / 0.1	1.24	1.01%	Milk: Sheep	0 / 0.05	0.76
1.65%	Bovine: Edible offals (other than liver and kidney)	0 / 0.17	1.24	0.91%	Bovine: Liver	0 / 0.17	0.68
1.65%	Swine: Muscle/meat	0 / 0.1	1.24	0.78%	Bovine: Muscle	0 / 0.1	0.58
1.61%	Milk: Goat	0 / 0.05	1.21	0.76%	Other farmed animals: Muscle/meat	0 / 0.1	0.57
0.98%	Bovine: Muscle/meat	0 / 0.1	0.74	0.75%	Bovine: Edible offals (other than liver and kidney)	0 / 0.17	0.56
0.94%	Other farmed animals: Muscle/meat	0 / 0.1	0.70	0.66%	Swine: Muscle/meat	0 / 0.1	0.49
0.85%	Bovine: Kidney	0 / 0.17	0.64	0.65%	Equine: Muscle/meat	0 / 0.1	0.49
0.82%	Equine: Muscle/meat	0 / 0.1	0.61	0.64%	Sheep: Muscle/meat	0 / 0.1	0.48
0.74%	Sheep: Muscle/meat	0 / 0.1	0.55	0.63%	Sheep: Liver	0 / 0.17	0.48

	0.68%	Swine: Edible offals (other than liver and kidney)	0 / 0.17	0.51	0.59%	Swine: Edible offals (other than liver and kidney)	0 / 0.17	0.44
	0.29%	Swine: Kidney	0 / 0.17	0.22	0.57%	Eggs: Chicken	0 / 0.1	0.43
	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

No additional studies submitted.

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

No additional studies submitted.

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

Method BPL19-0032 has been used to determine residues of flonicamid and its metabolites in both study RDE-20-44808 and RDE-21-50691. The method was initially validated in wheat grain, wheat straw, sugar beet root, oil seed rape seed, orange whole fruit and lettuce within study BPL19-0032, and has been evaluated below. As this validation data set did not include validation in the potato matrix additional data has been presented, taken from procedural recovery data in both residue trial studies. It is noted that for study RDE-21-50691, a water addition step is included which is a slight variation to the additional BPL19-0032 method. Validation data has been presented to demonstrate this method remains acceptable.

Method BPL19-0032

Reference:	Validation Of Residue Analytical Method for Determination of Flonicamid (IKI-220) And Its Metabolites TFNA, TFNA-AM And TFNG in Wheat Grain and Straw, Sugar Beet Root, Oil Seed Rape Seed, Orange Whole Fruit And Lettuce [redacted] 2020, Report No. BPL19-0032
Method ID:	BPL19-0032
GLP:	Yes

Acceptability of the method:	Acceptable
Reference:	Magnitude of the residues of flonicamid and its metabolites TFNA, TFNG and TFNA-AM in potato (RAC tubers) following two foliar applications of IBE 3894 (IKI-220 50% WG) with or without oil-based adjuvant in Northern Europe –2020, [redacted] 2021, RDE-44808
Method ID:	BPL19-0032
GLP:	Yes
Acceptability of the method:	Acceptable

Principle of the method and sample preparation

Samples of wheat grain and straw, sugar beet root, oil seed rape seed, orange whole fruit and lettuce (2.5 g) are weighed into centrifuge tubes (50 mL) and water is added (12 mL for wheat straw, 8 mL for orange whole fruit and lettuce, 10 mL for wheat grain, sugar beet root and oil seed rape seed). 10mL of 1% formic acid in acetonitrile is added and the samples are shaken vigorously for 1 minute. The contents of a QuEChERS Extraction kit (containing magnesium sulfate (4 g) and sodium chloride (1 g)) are added, the samples shaken vigorously by hand for 1 minute and the samples are centrifuged at 4500 rpm for 5 minutes. Aliquots of the supernatant (200 µL) are transferred to autosampler vials containing 0.1% formic acid in water (800 µL) and vortex mixed.

Table C.1.3.1-1 Recovery results in wheat grain and straw, sugar beet root, oil seed rape seed, orange whole fruit and lettuce.

Analyte (m/z ratio transition)	level (mg/kg)	No samples per level	Recovery range (%)	Mean recovery (%)	RSD (%)	Comments
Wheat grain						
Flonicamid quantification (230 >203)	0.01	5	89 – 91	90	1.3	-
	0.1	5	92 – 103	96	4.8	
Flonicamid confirmation (230 >174)	0.01	5	86 – 92	88	3.1	-
	0.1	5	88 – 104	94	7.7	

Analyte (m/z ratio transition)	level (mg/kg)	No samples per level	Recovery range (%)	Mean recovery (%)	RSD (%)	Comments
TFNA Quantification (189.9 > 69.1)	0.01	5	83 – 90	86	3.4	-
	0.1	5	85 – 97	90	5.3	
TFNA Confirmation (189.9 > 69.1)	0.01	5	79 – 86	82	3.0	-
	0.1	5	83 – 86	85	1.1	
TFNG Quantification (246.9 >163)	0.01	5	74 – 83	79	4.5	-
	0.1	5	80 – 95	89	7.7	
TFNG Confirmation (246.9 > 183)	0.01	5	77 – 83	80	2.8	-
	0.1	5	81 – 91	88	4.3	
Wheat straw						
Flonicamid quantification (230 >203)	0.01	5	97 – 108	104	4.4	-
	0.1	5	93 – 106 (	102	5.3	
Flonicamid confirmation (230 >174)	0.01	5	95 – 103	99	2.8	
	0.1	5	96 – 108	105	5.3	
TFNA Quantification (189.9 > 69.1)	0.01	5	80 – 106	88	14.2	-
	0.1	5	78 – 82	79	1.9	
TFNA Confirmation (189.9 > 69.1)	0.01	5	87 – 91	88	2.3	
	0.1	5	84 – 86	85	0.9	
TFNG Quantification (246.9 >163)	0.01	5	67 – 72	70	3.0	-
	0.1	5	75 – 86	79	5.4	
TFNG Confirmation (246.9 > 183)	0.01	5	62 – 77	70	9.5	
	0.1	5	70 – 81	76	5.9	
Sugar beet root						
	0.01	5	96 – 103	101	3.0	-

Analyte (m/z ratio transition)	level (mg/kg)	No samples per level	Recovery range (%)	Mean recovery (%)	RSD (%)	Comments
Flonicamid quantification (230 >203)	0.1	5	91 – 103	99	5.5	
Flonicamid confirmation (230 >174)	0.01	5	92 – 100	96	3.7	
	0.1	5	92 – 102	98	4.9	
TFNA Quantification (189.9 > 69.1)	0.01	5	90 – 99	93	3.8	-
	0.1	5	75 – 84	80	4.5	
TFNA Confirmation (189.9 > 69.1)	0.01	5	78 – 92	84	6.4	
	0.1	5	75 – 83	80	5.0	
TFNG Quantification (246.9 >163)	0.01	5	79 – 9	84	4.7	-
	0.1	5	82 – 96	89	6.6	
TFNG Confirmation (246.9 > 183)	0.01	5	74 – 91	83	7.4	
	0.1	5	88 – 102	93	6.1	
Oil seed rape seed						
Flonicamid quantification (230 >203)	0.01	5	88 – 104	97	6.3	-
	0.1	5	102 – 105	103	1.1	
Flonicamid confirmation (230 >174)	0.01	5	84 – 99	93	6.1	
	0.1	5	98 – 108	103	3.7	
TFNA Quantification (189.9 > 69.1)	0.01	5	72 – 98	83	11.3	-
	0.1	5	72 – 76	73	2.2	
TFNA Confirmation (189.9 > 69.1)	0.01	5	81 – 86	83	2.2	
	0.1	5	76 – 80	78	1.9	
TFNG Quantification (246.9 >163)	0.01	5	83 – 98	90	6.6	-
	0.1	5	75 – 80	77	2.5	

Analyte (m/z ratio transition)	level (mg/kg)	No samples per level	Recovery range (%)	Mean recovery (%)	RSD (%)	Comments
TFNG Confirmation (246.9 > 183)	0.01	5	86 – 94	91	3.6	
	0.1	5	92 – 99	95	2.8	
Orange whole fruit						
Flonicamid quantification (230 >203)	0.01	5	81 – 94	86	6.2	-
	0.1	5	77 – 98	86	12.3	
Flonicamid confirmation (230 >174)	0.01	5	87 – 99	93	4.9	
	0.1	5	91 – 96	94	2.4	
TFNA Quantification (189.9 > 69.1)	0.01	5	73 – 85	77	6.2	-
	0.1	5	77 – 85	80	5.1	
TFNA Confirmation (189.9 > 69.1)	0.01	5	70 – 87	80	9.1	
	0.1	5	73 – 84	79	6.1	
TFNG Quantification (246.9 >163)	0.01	5	76 – 103	84	13.8	-
	0.1	5	75 – 87	79	6.5	
TFNG Confirmation (246.9 > 183)	0.01	5	73 – 95	82	9.8	
	0.1	5	75 – 85	79	5.0	
Lettuce						
Flonicamid quantification (230 >203)	0.01	5	82 – 93	88	4.8	-
	0.1	5	90 – 102	94	5.4	
Flonicamid confirmation (230 >174)	0.01	5	76 – 85	82	4.3	
	0.1	5	87 – 101	93	6.1	
TFNA Quantification (189.9 > 69.1)	0.01	5	84 – 99	90	6.7	-
	0.1	5	86 – 96	92	4.5	
TFNA	0.01	5	95 – 99	97	1.6	

Analyte (m/z ratio transition)	level (mg/kg)	No samples per level	Recovery range (%)	Mean recovery (%)	RSD (%)	Comments
Confirmation (189.9 > 69.1)	0.1	5	93 – 100	96	2.9	
TFNG Quantification (246.9 >163)	0.01	5	74 – 87	80	6.5	-
	0.1	5	75 – 86	80	5.9	
TFNG Confirmation (246.9 > 183)	0.01	5	70 – 89	79	9.9	
	0.1	5	77 – 84	79	3.8	

Table C.1.3.1-2 Characteristics of the analytical method for the quantitation of flonicamid and metabolite residues in wheat grain and straw, sugar beet root, oil seed rape seed, orange whole fruit, lettuce, and potato

	Flonicamid	TFNG	TFNA
Chromatographic method	LC-MS/MS	LC-MS/MS	LC-MS/MS
Specificity demonstrated (yes/no, by…)	Yes. Representative chromatograms were provided for all crop matrices fortified at 0.01 mg/kg (LOQ) and 0.1mg/kg (10 x LOQ), matrix matched standards, and untreated crop samples. No significant interference was noted at the retention time of interest.	Yes. Representative chromatograms were provided for all crop matrices fortified at 0.01 mg/kg (LOQ) and 0.1mg/kg (10 x LOQ), and untreated crop samples. No significant interference was noted at the retention time of interest.	Yes. Representative chromatograms were provided for all crop matrices fortified at 0.01 mg/kg (LOQ) and 0.1mg/kg (10 x LOQ), and untreated crop samples. No significant interference was noted 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)	0.125 – 7.5 ng/mL, equivalent to 0.0025-0.15 mg/kg	0.125 – 7.5 ng/mL, equivalent to 0.0025-0.15 mg/kg	0.125 – 7.5 ng/mL, equivalent to 0.0025-0.15 mg/kg
Calibration consists of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes (5 in duplicate)	Yes (5 in duplicate)	Yes (5 in duplicate)
Matrix effects	Significant matrix effects were noted for all analytes and matrices (except sugar beet root) and therefore matrix-matched standards were used for quantification (except sugar beet root where standards in solvent were used).	Significant matrix effects were noted for all analytes and matrices (except sugar beet root) and therefore matrix-matched standards were used for quantification (except sugar beet root where standards in solvent were used).	Significant matrix effects were noted for all analytes and matrices (except sugar beet root) and therefore matrix-matched standards were used for quantification (except sugar beet root where standards in solvent 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

Conclusion

The analytical procedure has been successfully validated with regards to specificity, linearity, precision, accuracy and LOQ in accordance with the requirements of SANTE/2020/12830 Rev. 1. The LOQ is set at 0.01 mg/kg for each analyte.

Extraction efficiency: Method BPL19-0032 uses 1% formic acid in acetonitrile and water for the extraction of residues from the samples. The radiolabelled metabolism studies in the DAR used acetonitrile: water in various ratios, sometimes in the presence of an acid, as the extraction solvent. Therefore, the extraction efficiency of method BPL19-0032 has not been fully addressed. However, the weight of evidence from the DAR studies indicates that acetonitrile is efficient in extracting residues of flonicamid and its metabolites (TFNA and TFNG). As 1% formic acid in acetonitrile was used as the primary extraction solvent in the residue trials in potato, the extraction efficiency can be considered sufficiently addressed. The lack of specific data to address the extraction efficiency is unlikely to impact the MRL calculated or the outcome of the consumer risk assessment. Therefore, no further data are required at this time.

Additional validation data for potato matrix (Study RDE-20-44808)
Table C.1.3.1-3 Recovery results in potato (study RDE-20-44808)

Analyte (m/z ratio transition)	level (mg/kg)	No samples per level	Recovery range (%)	Mean recovery (%)	RSD (%)	Comments
Potato						
Flonicamid Quantification (230 > 203)	0.01	3	84 – 100	93	9.3	-
	0.1	3	91 – 103	99	6.8	
Flonicamid confirmation (230 >148)	0.01	3	74 – 99	90	15.3	-
	0.1	3	92 – 110	103	9.2	
TFNA Quantification (189.9 > 98)	0.01	3	73 – 96	86	14.1	-
	0.1	3	86 – 105	97	10.2	
TFNA Confirmation (189.9 > 148)	0.01	3	86 – 102	96	9.1	-
	0.1	3	90 – 109	101	9.5	
TFNG	0.01	3	70 – 92	83	13.3	-

Analyte (m/z ratio transition)	level (mg/kg)	No samples per level	Recovery range (%)	Mean recovery (%)	RSD (%)	Comments
Quantification (246.9 >203)	0.1	3	88 – 108	99	10.0	
TFNG Confirmation (246.9 > 148)	0.01	3	69 – 86	78	11.1	-
	0.1	3	87 – 110	101	12.1	

Further validation data in the potato matrix (Study RDE-21-50691)

The method used to support study RDE-21-50691 uses a slight variation of the method and therefore full validation data has been provided in the potato matrix.

Reference:	Magnitude of the residues of flonicamid and its metabolites TFNA, TFNG and TFNA-AM in potato (RAC tubers) and processed fractions, following one or two foliar applications of IBE 3894 (IKI-220 50% WG) with or without oil-based product in Southern and Northern Europe –2021. Study No.RDE-21-50691
Method ID:	Analytical Phase Code: S21-06672-L1 (based on BPL19-0032)
GLP:	Yes
Acceptability of the method:	Acceptable

Principle of the method and sample preparation:

The sample preparation is identical to Method BPL19-0032 as described above, with 8mL water being added to the potato samples after homogenisation and fortification (if required).

Results and discussion:

Table C.1.3.1-4 Recovery results of flonicamid and metabolites in potato

Analyte (m/z ratio transition)	level (mg/kg)	No samples per level	Recovery range (%)	Mean recovery (%)	RSD (%)	Comments
Potato						
Flonicamid Quantification (230 > 203)	0.01	14	82.9 - 122	90.3	11	-
	0.1	15	79.4 - 103	91.3	7.3	
	1.0	2	92.4 – 93.7	93.1	-	
Flonicamid confirmation (230 >148)	0.01	14	83.0 - 118	90.4	10	-
	0.1	15	79.9 – 103	91.4	6.9	
	1.0	2	93.4 – 94.3	93.9	-	
TFNA Quantification (189.9 > 69)	0.01	14	78.2 – 96.5	86.4	6.9	-
	0.1	15	73.2 - 100	88.7	8.1	
	1.0	2	81.6 – 87.3	84.5	-	
TFNA Confirmation (189.9 > 146)	0.01	14	78.0 – 94.2	86.5	6.9	-
	0.1	15	73.9 – 99.5	88.6	7.9	
	1.0	2	85.2 – 87.3	86.3	-	
TFNG Quantification (246.9 >146)	0.01	14	80.2 - 115	97.6	10	-
	0.1	15	86.3 - 118	104	9.0	
	1.0	2	112-114	113	-	
TFNG Confirmation (246.9 > 163)	0.01	14	83.6 - 115	98.6	11	-
	0.1	15	86.7 - 120	106	9.1	
	1.0	2	111 - 114	113	-	

Table C.1.3.1-5 Characteristics of the analytical method for the quantitation of flonicamid and metabolite residues in potatoes

	Flonicamid	TFNG	TFNA
Chromatographic method	LC-MS/MS	LC-MS/MS	LC-MS/MS

	Flonicamid	**TFNG**	**TFNA**
Specificity demonstrated (yes/no, by…)	Yes. Representative chromatograms were provided for all crop matrices fortified at 0.01 mg/kg (LOQ) and 0.1mg/kg (10 x LOQ), matrix matched standards, and treated/untreated residues trial samples. No significant interference was noted at the retention time of interest.	Yes. Representative chromatograms were provided for all crop matrices fortified at 0.01 mg/kg (LOQ) and 0.1mg/kg (10 x LOQ), matrix matched standards, and treated/untreated residues trial samples. No significant interference was noted at the retention time of interest.	Yes. Representative chromatograms were provided for all crop matrices fortified at 0.01 mg/kg (LOQ) and 0.1mg/kg (10 x LOQ), matrix matched standards, and treated/untreated residues trial samples. No significant interference was noted at the retention time of interest.
Linearity demonstrated (yes/no)	Yes	Yes	Yes
Calibration			
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.15 – 15 ng/mL, equivalent to 0.003-0.3 mg/kg.	0.15 – 15 ng/mL, equivalent to 0.003-0.3 mg/kg.	0.15 – 15 ng/mL, equivalent to 0.003-0.3 mg/kg.
Calibration consists of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes (5)	Yes (5)	Yes (5)

	Flonicamid	**TFNG**	**TFNA**
Matrix effects	Significant matrix effects were not noted for flonicamid, however, matrix-matched standards were used for quantification.	Significant matrix effects were not noted for TFNG, however, matrix-matched standards were used for quantification.	Significant matrix effects were noted for TFNA and therefore matrix-matched standards were used for quantification.
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

Some mean recovery values at the higher fortification level of 1.0 mg/kg exceed the 110% threshold. As these deviations are minor, this considered acceptable.

The analytical procedure has been successfully validated with regards to specificity, linearity, precision, accuracy and LOQ in accordance with the requirements of SANTE/2020/12830 Rev. 1. The LOQ is set at 0.01 mg/kg for each analyte.

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

No additional studies submitted.

C.1.5 Methods for risk assessment for toxicological studies

No additional studies submitted.

C.2 Mammalian toxicology

No additional studies submitted.

C.3 Residue data

C.3.1 Nature and magnitude of residues in primary crops

C.3.1.1 Nature of residues

No additional studies submitted.

C.3.1.2 Magnitude of residues

C.3.1.2.1.1 Potato (Study 1)

Reference:	Magnitude of the residues of flonicamid and its metabolites TFNA, TFNG and TFNA-AM in potato (RAC tubers) following two foliar applications of IBE 3894 (IKI-220 50% WG) with or without oil-based adjuvant in Northern Europe –2020, [redacted] Report No. RDE-20-44808
Guideline(s):	ENV/JM/MONO(2011)50, OECD TG 509, SANCO/3029/99 rev. 4, SANCO/825/00 rev. 8.1, ENV/JM/MONO(2007)17
Deviations:	No
GLP:	Yes
Validity of the study:	Acceptable

Materials and methods

8 trials on potato were conducted in Austria, Germany, France, GB, The Netherlands, and Poland (NEU) using 'IBE 3894', a WG formulation containing 500 g/kg flonicamid (identical to 'Teppeki'), in the 2020 growing season.

'IBE 3894' was applied as a foliar spray at a rate of 80 g/ha flonicamid in 150-400 L/ha of water (target 300 L/ha). 2 applications (target of 21 day interval†) were made 0-85 days before harvest (equating to a final application at or after BBCH 55) on various plots at each site. The applications were within 25% of the proposed critical GAP (2 x 80 g/ha, up to BBCH 55)

While not the standard approach, the trials can be considered as reverse decline trials, where samples of potato were taken at 69-71, 54-57, 41-44, 13-16 and 0 days after last application from individual plots in each trial. Samples containing at least 2 kg were collected from both treated and control plots. Samples were frozen within 24 hours, and stored at ≤- 16.4 ºC until analysis. The maximum storage interval between harvest and analysis was 158 days. Data was considered in the DAR which demonstrates stability of flonicamid and metabolites for this period of time in high starch crops when stored at ≤-18 ºC.

† It was made clear within the study report that where crops developed faster or slower than anticipated, higher prioritisation was given to the BBCH growth stage of the potatoes at time of final application than the application interval of 21 days. This approach is agreed by HSE. It is noted that in trials AT01 and DE02, the application intervals were 8 days and 14 days rather than 21 as specified in the GAP. As BBCH growth stage is considered a

more important driver of residue values, and the PHI was 83-87 days, this deviation in application interval is not expected to have significantly impacted results. Furthermore, it is noted that in all trials with lower application intervals, the residue levels are similar to those with a ~21 day interval.

Results and discussions

Analysis was using LC-MS/MS method BPL19-0032. Full details and validation data for this method can be found in Section C.1.3. This method is considered satisfactorily validated in accordance with SANTE/2020/12830 Rev. 1 and further bolstered by a reduced data-set conducted in potatoes (see C.1.3.).

Acceptable procedural recovery data for flonicamid (and metabolites) using an appropriate number of samples were presented.

Residues of TFNG and TFNA within the sum of flonicamid 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.3.1.2.1.1-1 below.

8 independent trials were conducted outdoors in Austria, Germany, France, GB, The Netherlands, and Poland, 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, TFNG and TFNA expressed as flonicamid in potato tubers at harvest following final application at BBCH 55 (the proposed timing in the GAP) were 0.03 - 0.12 mg/kg.

Table C.3.1.2.1.1-1 Reverse decline residue trials on potatoes

Reference:	Magnitude of the residues of flonicamid and its metabolites TFNA, TFNG and TFNA-AM in potato (RAC tubers) following two foliar applications of IBE 3894 (IKI-220 50% WG) with or without oil-based adjuvant in Northern Europe –2020, [redacted] Report No. RDE-20-44808		
GLP:	Yes	Sample storage conditions:	Up to 153 days at ≤-16.4 ºC
Crop/crop group:	Potatoes (root crops)	Analytical method:	BPL19-0032 - 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	TFNA	TFNG	Sum		
			0.079 0.075	308 289	0.026 0.026	04/06/2020 12/06/2020	8	BBCH 35 BBCH 55	Tubers	<0.01	0.02	0.01	0.04	87	

RDE-20-44808 AT01 Gerhaus, Austria NEU 2020	Potato (Tosca)	1. 07/04/2020 2. 17/06/2020 to 27/07/2020 3. 07/09/2020	0.080 0.083	311 323	0.026 0.026	09/06/2020 30/06/2020	21	BBCH 39 BBCH 65	Tubers	<0.01	0.01	0.02	0.04	69	
			0.082 0.080	318 312	0.026 0.026	24/06/2020 15/07/2020	21	BBCH 65 BBCH 69	Tubers	<0.01	0.02	0.05	0.08	54	
			0.081 0.077	315 300	0.026 0.026	07/07/2020 27/07/2020	20	BBCH 68 BBCH 70	Tubers	<0.01	0.02	0.04	0.07	42	
			0.082 0.079	318 308	0.026 0.026	04/08/2020 25/08/2020	21	BBCH 95 BBCH 95	Tubers	<0.01	<0.01	<0.01	<0.03	13	
			0.084 0.083	326 322	0.026 0.026	18/08/2020 07/09/2020	20	BBCH 93-95 BBCH 97	Tubers	<0.01	<0.01	<0.01	<0.03	0	
RDE-20-44808 DE02 Forchheim, Germany NEU 2020	Potato / Ida	1. 24/04/2020 2. 26/06/2020 to 06/07/2020 3. 15/09/2020	0.076 0.076	297 297	0.026 0.026	10/06/2020 24/06/2020	14	BBCH 24 BBCH 55	Tubers	<u><0.01</u>	<u>0.03</u> 0.03	<u>0.06</u> 0.06	<u>0.10</u> 0.10	83	
			0.076 0.078	297 303	0.026 0.026	16/06/2020 07/07/2020	21	BBCH 27 BBCH 70	Tubers	<0.01	0.01	0.01	0.03	70	
			0.076 0.076	297 297	0.026 0.026	30/06/2020 21/07/2020	21	BBCH 69 BBCH 85	Tubers	<0.01	0.02	0.06	0.09	56	
			0.076 0.075	297 292	0.026 0.026	14/07/2020 05/08/2020	22	BBCH 75 BBCH 91	Tubers	<0.01	<0.01	0.01	0.03	41	
			0.076 0.073	297 282	0.026 0.026	10/08/2020 01/09/2020	22	BBCH 93 BBCH 97	Tubers	<0.01	<0.01	<0.01	<0.03	14	
			0.078 0.078	303 303	0.026 0.026	25/08/2020 15/09/2020	21	BBCH 95 BBCH 97	Tubers	<0.01	<0.01	<0.01	<0.03	0	
RDE-20-44808	Potato / Artemis	1. 23/04/2020 2. 25/06/2020	0.081 0.076	313 293	0.026 0.026	04/06/2020 25/06/2020	21	BBCH 23 BBCH 55	Tubers	<u><0.01</u>	<u>0.04</u> 0.05	<u>0.05</u> 0.05	<u>0.11</u> 0.11	70	
			0.085 0.078	327 300	0.026 0.026	04/06/2020 25/06/2020	21	BBCH 23 BBCH 55	Tubers	<0.01	0.04	0.06	0.11	70	

FR03 Inchy en Artois, northern France NEU 2020		to 05/07/2020 3. 03/09/2020	0.076 0.078	293 300	0.026 0.026	19/06/2020 09/07/2020	21	BBCH 51 BBCH 69	Tubers	<0.01	0.07	0.07	0.15	56	
			0.078 0.076	300 293	0.026 0.026	02/07/2020 22/07/2020	21	BBCH 69 BBCH 93	Tubers	<0.01	0.07	0.10	0.18	43	
			0.078 0.078	300 300	0.026 0.026	30/07/2020 19/08/2020	20	BBCH 93 BBCH 97	Tubers	<0.01	<0.01	0.01	0.03	15	
			0.078	300	0.026	12/08/2020	-	BBCH 95	Tubers	<0.01	<0.01	<0.01	<0.03	22**	
RDE-20-44808 FR04 Sault Saint Rémy, northern France NEU 2020	Potato / Jacky	1. 20/04/2020 2. 23/06/2020 to 08/07/2020 3. 17/08/2020	0.080 0.079	310 305	0.026 0.026	27/05/2020 13/06/2020	17	BBCH 21 BBCH 55	Tubers	<0.01	0.02	0.02	0.05	66	
			0.080 0.080	310 310	0.026 0.026	20/05/2020 10/06/2020	21	BBCH 10 BBCH 51	Tubers	<0.01	0.02	0.01	0.04	69	
			0.083 0.080	320 310	0.026 0.026	03/06/2020 23/06/2020	20	BBCH 23 BBCH 60	Tubers	<0.01	0.03	0.10	0.14	56	
			0.081 0.083	315 320	0.026 0.026	17/06/2020 08/07/2020	21	BBCH 59 BBCH 69	Tubers	<0.01	0.02	0.04	0.07	41	
			0.083 0.083	320 320	0.026 0.026	15/07/2020 05/08/2020	21	BBCH 71 BBCH 95	Tubers	<0.01	<0.01	<0.01	<0.03	13	
			0.084 0.083	325 320	0.026 0.026	29/07/2020 18/08/2020	20	BBCH 91 BBCH 97	Tubers	<0.01	<0.01	<0.01	<0.03	0	
RDE-20-44808	Potato / Maris Piper	1. 23/04/2020 2. 06/07/2020 to 15/08/2020 3. 14/09/2020	0.075 0.079	290 307	0.026 0.026	15/06/2020 06/07/2020	21	BBCH 16 BBCH 55	Tubers	<0.01	<0.01	0.02	0.04	70	
			0.074 0.079	283 307	0.026 0.026	15/06/2020 06/07/2020	21	BBCH 16 BBCH 55	Tubers	<0.01	<0.01	0.02	0.04	70	
			0.076 0.078	293 303	0.026 0.026	30/06/2020 20/07/2020	20	BBCH 19 BBCH 55	Tubers	<0.01	0.03	0.08	0.12	56	
			0.081	313	0.026	13/07/2020	21	BBCH 55	Tubers	<0.01	0.02	0.03	0.06	42	

GB05 Bucknell, UK NEU 2020			0.079	307	0.026	03/08/2020		BBCH 73							
			0.081 0.074	313 287	0.026 0.026	10/08/2020 01/09/2020	22	BBCH 73 BBCH 85	Tubers	<0.01	0.02	0.01	0.04	13	
			0.083 0.079	320 307	0.026 0.026	24/08/2020 14/09/2020	21	BBCH 85 BBCH 97	Tubers	<0.01	<0.01	<0.01	<0.03	0	
RDE-20-44808 NL06 Willemstad, The Netherlands NEU 2020	Potato / Melody	1. 14/04/2020 2. 24/06/2020 to 07/07/2020 3. 21/09/2020	0.073 0.080	283 310	0.026 0.026	03/06/2020 22/06/2020	19	BBCH 22 BBCH 55	Tubers	<u><0.01</u>	<u>0.01</u>	<u>0.02</u>	<u>0.04</u>	79	
			0.075 0.078	290 303	0.026 0.026	10/06/2020 30/06/2020	20	BBCH 28 BBCH 65	Tubers	<0.01	0.02	0.02	0.05	71	
			0.076 0.078	297 303	0.026 0.026	24/06/2020 15/07/2020	21	BBCH 60 BBCH 71	Tubers	<0.01	0.03	0.04	0.08	56	
			0.076 0.078	297 303	0.026 0.026	07/07/2020 29/07/2020	22	BBCH 69 BBCH 75	Tubers	<0.01	0.02	0.04	0.07	44	
			0.075 0.073	290 283	0.026 0.026	05/08/2020 27/08/2020	22	BBCH 80 BBCH 92	Tubers	<0.01	0.02	0.02	0.05	13	
			0.078 0.081	303 317	0.026 0.026	19/08/2020 09/09/2020	21	BBCH 90 BBCH 95	Tubers	<0.01	<0.01	<0.01	<0.03	0	
RDE-20-44808 PL07 Wola Książęca, Poland NEU 2020	Potato / Gala	1. 08/04/2020 2. 26/06/2020 to 12/07/2020 3. 27/08/2020	0.076 0.076	297 293	0.026 0.026	03/06/2020 17/06/2020	14	BBCH 29 BBCH 55	Tubers	<0.01	0.03	0.04	0.08	71	
			0.079 0.077	307 300	0.026 0.026	27/05/2020 17/06/2020	21	BBCH 27 BBCH 55	<u>Tubers</u>	<u><0.01</u>	<u>0.05</u>	<u>0.03</u>	<u>0.09</u>	71	
			0.077 0.079	300 307	0.026 0.026	10/06/2020 01/07/2020	21	BBCH 33 BBCH 65	Tubers	<0.01	0.05	0.05	0.11	57	
			0.076 0.076	297 293	0.026 0.026	24/06/2020 15/07/2020	21	BBCH 59 BBCH 70	Tubers	<0.01	0.02	<0.01	0.04	43	
			0.077	300	0.026	22/07/2020	20	BBCH 81	Tubers	<0.01	<0.01	0.01	<0.03	15	

			0.076	293	0.026	12/08/2020		BBCH 93							
			0.076 0.079	297 307	0.026 0.026	06/08/2020 27/08/2020	21	BBCH 91 BBCH 97	Tubers	<0.01	<0.01	<0.01	<0.03	0	
RDE-20-44808 PL08 Kajkowo, Poland NEU 2020	Potato / Tafjun	1. 16/04/2020 2. 25/06/2020 to 31/07/2020 3. 17/09/2020	0.076 0.078	293 303	0.026 0.026	12/06/2020 23/06/2020	11	BBCH 33 BBCH 55	Tubers	<0.01	<0.01	0.01	0.03	85	
			0.074 0.074	287 287	0.026 0.026	17/06/2020 07/07/2020	20	BBCH 38 BBCH 63	Tubers	<0.01	<0.01	0.01	0.03	71	
			0.084 0.078	323 303	0.026 0.026	01/07/2020 22/07/2020	21	BBCH 60 BBCH 75	Tubers	<0.01	0.03	0.03	0.07	56	
			0.078 0.078	300 300	0.026 0.026	15/07/2020 05/08/2020	21	BBCH 65 BBCH 81	Tubers	<0.01	0.03	0.07	0.11	42	
			0.081 0.076	313 293	0.026 0.026	12/08/2020 01/09/2020	20	BBCH 85 BBCH 93	Tubers	<0.01	0.01	<0.01	0.03	15	
			0.080	310	0.026	25/08/2020	-	BBCH 93	Tubers	<0.01	<0.01	<0.01	<0.03	22**	

(*) Residue value of the retain sample

(**) A second application was not performed because the crop had no more foliage. This explains the delay between application and sampling.

(a) TFNG and TFNA are expressed as themselves

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

C.3.1.2.1.2 Potato (Study 2)

Reference:	Magnitude of the residues of flonicamid and its metabolites TFNA, TFNG and TFNA-AM in potato (RAC tubers) and processed fractions, following one or two foliar applications of IBE 3894 (IKI-220 50% WG) with or without oil-based product in Southern and Northern Europe –2021., [redacted] Report No. RDE-21-50691
Guideline(s):	OECD TG 509, SANCO 7029/VI/95 rev.5, OECD TG 508, SANCO 7035/VI/95 rev.5, SANTE/2020/12830 Rev. 1, ENV/JM/MONO(2007)17
Deviations:	Yes – Trial NL06 removed
GLP:	Yes
Validity of the study:	Acceptable

Materials and methods

8 trials on potato were conducted in Austria, Germany, France, GB, The Netherlands, and Poland (NEU) using 'IBE 3894', a WG formulation containing 500 g/kg flonicamid (identical to 'Teppeki'), in the 2021 growing season.

'IBE 3894' was applied as a foliar spray at a rate of 80 g/ha flonicamid in 150-500 L/ha of water (target 300 L/ha). 2 applications (with a target 21 day interval†) were made between BBCH 15 and 71 (7 - 119 days before harvest) on various plots at each site. The applications were within 25% of the proposed critical GAP (2 x 80 g/ha, up to BBCH 55)

While the study design was not the standard approach, the trials can be considered as reverse decline trials, with final applications made at BBCH 15, BBCH 35-39, BBCH 51, BBCH 55 or BBCH 70-71 from different plots within the same trial. The crops were then harvested at maturity (BBCH 89) which equated to variable PHIs between 7 and 119 days. Samples containing at least 2 kg were collected from both treated and control plots. Samples were frozen within 24 hours, and stored at ≤- 18 ºC until analysis. The maximum storage interval between harvest and analysis was 83 days. Data was considered in the DAR which demonstrates stability of flonicamid and metabolites for this period of time in high starch crops when stored at ≤-18 ºC.

† It was made clear within the study report that where crops developed faster or slower than anticipated, higher prioritisation was given to the BBCH growth stage of the potatoes at time of final application than the application interval of 21 days. This approach is agreed by HSE. It is noted that in trials FR03 and GB05, the application intervals were 8 days and 9 days rather than 21 as specified in the GAP. As BBCH growth stage is considered a

more important driver of residue values, and the PHI was 22-93 days, this deviation in application interval is not expected to have significantly impacted results. Furthermore, it is noted that in all trials with lower application intervals, the residue levels are similar to those with a ~21 day interval.

Trial NL06 deviated significantly from the study plan as most applications were performed at double the planned application rate; 0.160 kg a.s./ha rather than 0.08 kg a.s./ha. As a sufficient number of trials are available to derive a robust MRL, this trial has been excluded from the set; as scaling residues performed at a higher rate is considered to have additional uncertainties compared to trials performed at the GAP. It is noted however that if the residue values were to be scaled appropriately, they would be within the expected range seen in other trials.

Results and discussions

Analysis was using LC-MS/MS method validated within the study report (Analytical phase report: S21-06672-L1). Full details and validation data for this method can be found in Section C.1.3. This method is considered satisfactorily validated in accordance with SANTE/2020/12830 Rev. 1 and further bolstered by a reduced data-set conducted in potatoes (see C.1.3.).

Acceptable procedural recovery data for flonicamid (and metabolites) using an appropriate number of samples were presented.

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.3.1.2.1.2-1 below.

Eight independent trials were undertaken outdoors in Austria, Germany, France, GB, and Poland, and five of 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, TFNG and TFNA expressed as flonicamid in potato tubers after final application at BBCH 55 (or earlier if residue value is higher) were 0.042 - 0.097 mg/kg.

Table C.3.1.2.1.2-1 Reverse decline residue trials on potatoes

Reference:	Magnitude of the residues of flonicamid and its metabolites TFNA, TFNG and TFNA-AM in potato (RAC tubers) and processed fractions, following one or two foliar applications of IBE 3894 (IKI-220 50% WG) with or without oil-based product in Southern and Northern Europe –2021., [redacted] Report No. RDE-21-50691		
GLP:	Yes	Sample storage conditions:	Up to 83 days at ≤-18 ºC
Crop/crop group:	Potatoes (root crops)	Analytical method:	S21-06672-L1 - 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	TFNA (a)	TFNG (a)	Sum (b)		
			0.076	289	0.026	24/06/2021	22	BBCH 51	Tubers	<0.01	0.013	0.048	0.071	81	

RDE-21-50691 AT01 Gerhaus, Austria NEU 2020	Potato / Kuras	1. 26/04/2021 2. 24/06/2021 to 16/07/2021 3. 20/09/2021	0.083	312	0.027	16/07/2021		BBCH 70							
			0.076 0.083	290 314	0.026 0.026	21/06/2021 12/07/2021	21	BBCH 19 BBCH 61	Tubers	<0.01	<0.01	0.022	0.042	85	
			0.079 0.079	299 300	0.026 0.026	18/06/2021 09/07/2021	21	BBCH 19 BBCH 51	Tubers	<0.01	<0.01	0.032	0.052	88	
			0.080 0.077	301 292	0.026 0.026	15/06/2021 06/07/2021	21	BBCH 19 BBCH 36	Tubers	<0.01	<0.01	0.046	0.066	91	
			0.084 0.076	318 287	0.026 0.026	21/05/2021 11/06/2021	21	BBCH 09 BBCH 19	Tubers	<0.01	<0.01	0.027	0.047	116	
RDE-21-50691 DE02 Forchheim, Germany NEU 2020	Potato / Bernina	1. 10/04/2021 2. 30/06/2021 to 07/07/2021 27/08/2021	0.081 0.080	305 300	0.027 0.027	15/06/2021 05/07/2021	20	BBCH 23 BBCH 71	Tubers	<0.01	0.035	0.014	0.059	49	
			0.080 0.080	300 300	0.027 0.027	10/06/2021 30/06/2021	20	BBCH 22 BBCH 55	Tubers	<0.01	0.035	<0.01	0.055	54	
			0.080 0.080	300 300	0.027 0.027	09/06/2021 28/06/2021	19	BBCH 22 BBCH 39-51	Tubers	<0.01	<0.01	<0.01	<0.03	56	
			0.081 0.080	305 300	0.027 0.027	07/06/2021 28/06/2021	21	BBCH 22 BBCH 39-51	Tubers	<0.01	<0.01	<0.01	<0.03	56	
			0.081 0.082	305 310	0.027 0.026	27/04/2021 28/05/2021	31	BBCH 03 BBCH 15	Tubers	<0.01	<0.01	<0.01	<0.03	87	
RDE-21-	Potato / Montana	1. 22/04/2021 2. 26/06/2021 to	0.080 0.082	302 309	0.026 0.027	23/06/2021 16/07/2021	23	BBCH 23 BBCH 71	Tubers	<0.01	0.039	0.098	0.15	59	
			0.077 0.077	291 291	0.026 0.026	15/06/2021 23/06/2021	8	BBCH 22 BBCH 55	Tubers	<0.01	0.021	0.048	0.079	82	

50691 FR03 Inchy en Artois, northern France NEU 2020		05/07/2021 3. 15/09/2021	0.080 0.084	302 316	0.026 0.027	10/06/2021 21/06/2021	11	BBCH 22 BBCH 39-51	Tubers	<0.01	<0.01	<0.01	<0.03	84	
			0.083 0.082	313 309	0.027 0.027	10/06/2021 28/06/2021	18	BBCH 22 BBCH 39-51	Tubers	<0.01	<0.01	<0.01	<0.03	77	
			0.081 0.082	305 309	0.027 0.027	20/05/2021 07/06/2021	18	BBCH 03 BBCH 15	Tubers	<0.01	<0.01	<0.01	<0.03	98	
RDE-21-50691 FR04 Sault Saint Rémy, northern France NEU 2020	Potato / Chateau	1. 22/04/2021 2. 09/07/2021 to 14/07/2021 3. 23/07/2021	0.083 0.079	313 300	0.027 0.026	24/06/2021 16/07/2021	22	BBCH 39 BBCH 70	Tubers	<0.01	0.036	0.014	0.060	7	
			0.077 0.081	292 308	0.026 0.026	17/06/2021 07/07/2021	20	BBCH 35 BBCH 55	Tubers	<0.01	0.031	<0.01	0.051	16	
			0.080 0.081	307 308	0.026 0.026	10/06/2021 01/07/2021	21	BBCH 16 BBCH 50	Tubers	<u><0.01</u>	<u>0.038</u>	<u>0.010</u>	<u>0.058</u>	22	
			0.079 0.079	300 300	0.026 0.026	28/05/2021 17/06/2021	20	BBCH 15 BBCH 35	Tubers	<0.01	0.012	<0.01	0.032	36	
			0.079 0.086	300 325	0.026 0.026	06/05/2021 28/05/2021	22	BBCH 03 BBCH 15	Tubers	<0.01	<0.01	<0.01	<0.03	56	
RDE-21-50691 GB05 Bucknell, UK NEU 2020	Potato / Marfona	1. 31/05/2021 2. 01/08/2021 to 15/08/2021 3. 18/10/2021	0.078 0.079	295 300	0.026 0.026	10/08/2021 31/08/2021	21	BBCH 69 BBCH 91	Tubers	<0.01	0.035	0.018	0.063	41	
			0.084 0.079	320 300	0.026 0.026	22/07/2021 29/07/2021	7	BBCH 19 BBCH 55	Tubers	<0.01	<0.01	0.014	0.034	74	
			0.079 0.076	300 290	0.026 0.026	14/07/2021 23/07/2021	9	BBCH 17 BBCH 51	Tubers	<u><0.01</u>	<u>0.022</u>	<u>0.029</u>	<u>0.061</u>	80	
			0.087 0.082	320 310	0.027 0.026	08/07/2021 29/07/2021	21	BBCH 15 BBCH 55	Tubers	<0.01	<0.01	<0.01	<0.03	74	

			0.080 0.082	305 310	0.026 0.026	25/06/2021 08/07/2021	13	BBCH 08 BBCH 15	Tubers	<0.01	<0.01	<0.01	<0.03	95	
RDE-21-50691 NL06 Willemstad, The Netherlands NEU 2020	Potato / Agria	1. 27/04/2021 2. 12/07/2021 to 30/07/2021 3. 23/10/2021	0.079 0.080	299 303	0.026 0.026	08/07/2021 27/07/2021	19	BBCH 57 BBCH 70-71	Tubers	<0.01	0.058	0.094	0.16	79	
			0.157 0.079	298 298	0.053 0.027	29/06/2021 08/07/2021	9	BBCH 51 BBCH 55	Tubers	<0.01	0.076	0.13	0.21	98	Not included due to incorrect application rate
			0.166 0.160	315 305	0.053 0.052	24/06/2021 29/06/2021	5	BBCH 39 BBCH 51	Tubers	<0.01	0.069	0.034	0.11	107	
			0.158 0.166	300 315	0.053 0.053	17/06/2021 24/06/2021	7	BBCH 15 BBCH 39	Tubers	<0.01	0.067	0.043	0.12	112	
			0.169 0.163	320 310	0.053 0.053	10/06/2021 17/06/2021	7	BBCH 11-13 BBCH 15	Tubers	<0.01	0.034	0.031	0.075	119	
RDE-21-50691 PL07 Wola Książęca, Poland	Potato / Ignacy	1. 27/04/2021 2. 28/06/2021 to 25/07/2021 3. 08/09/2021	0.080 0.081	300 307	0.027 0.026	25/06/2021 19/07/2021	24	BBCH 59 BBCH 71	Tubers	<0.01	0.031	0.045	0.086	50	
			0.081 0.080	307 300	0.026 0.027	14/06/2021 21/06/2021	7	BBCH 17 BBCH 55	Tubers	<0.01	0.014	0.017	0.041	78	
			0.081 0.075	307 283	0.026 0.027	11/06/2021 18/06/2021	7	BBCH 15 BBCH 51	Tubers	<0.01	0.014	0.017	0.041	81	
			0.085	320	0.027	09/06/2021	19	BBCH 14	Tubers	<0.01	0.012	0.020	0.042	71	

NEU 2020			0.079	297	0.027	28/06/2021		BBCH 39							
			0.082 0.082	310 310	0.026 0.026	24/05/2021 11/06/2021	18	BBCH 08 BBCH 15	Tubers	<0.01	<0.01	<0.01	<0.03	88	
RDE-21-50691 PL08 Kajkowo, Poland NEU 2020	Potato / Eurostar	1. 24/04/2021 2. 05/07/2021 to 3. 20/07/2021 06/10/2021	0.080 0.082	300 310	0.027 0.026	28/06/2021 20/07/2021	22	BBCH 33 BBCH 71	Tubers	<0.01	<0.01	0.044	0.064	78	
			0.078 0.080	295 300	0.026 0.027	14/06/2021 05/07/2021	21	BBCH 15-16 BBCH 55	Tubers	<0.01	<0.01	0.077	0.097	93	
			0.081 0.078	305 295	0.027 0.026	11/06/2021 02/07/2021	21	BBCH 15 BBCH 51	Tubers	<0.01	0.01	0.031	0.051	96	
			0.081 0.080	305 300	0.027 0.027	08/06/2021 28/06/2021	20	BBCH 14-15 BBCH 33	Tubers	<0.01	<0.01	0.034	0.054	100	
			0.082 0.083	310 314	0.026 0.026	26/05/2021 14/06/2021	19	BBCH 09 BBCH 15-16	Tubers	<0.01	<0.01	0.01	0.030	114	

(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

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	Submitter
[redacted]	2020	Validation Of Residue Analytical Method for Determination of Flonicamid (IKI-220) And Its Metabolites TFNA, TFNA-AM And TFNG in Wheat Grain and Straw, Sugar Beet Root, Oil Seed Rape Seed, Orange Whole Fruit And Lettuce SGS Report No. BPL19-0032 GLP Unpublished	ISK
[redacted]	2020	Independent Laboratory Validation of the Multi-Residue Method for the Determination of Flonicamid (IKI-220) and its Metabolites TFNA, TFNA-AM and TFNG in Wheat Grain and Lettuce Eurofins Agroscience Services EcoChem GmbHReport No. S20-03573 GLP Unpublished	ISK
[redacted]	2021	Magnitude of the residues of flonicamid and its metabolites TFNA, TFNG and TFNA-AM in potato (RAC tubers) following two foliar applications of IBE 3894 (IKI-220 50% WG) with or without oil-based adjuvant in Northern Europe –2020. STAPHYT Report No. RDE-20-44808 GLP Unpublished	ISK
[redacted]	2022	Magnitude of the residues of flonicamid and its metabolites TFNA, TFNG and TFNA-AM in potato (RAC tubers) and processed fractions, following one or two foliar applications of IBE 3894 (IKI-220 50% WG) with or without oil-based product in Southern and Northern Europe –2021. Report No. RDE-21-50691 GLP Unpublished	ISK