

# **The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers**

## **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 202500879 and 202501652

**April 2026**



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## Summary

In accordance with Article 6 of Assimilated Regulation 396/2005,<sup>1</sup> HSE received two applications, one on 22 July 2025 (outdoor uses), and the second on 19 November 2025 (protected uses) to amend the existing MRLs for the active substance cyantraniliprole in or on various commodities. The applications were to support an extension of authorisation for minor uses.

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.<sup>2</sup>

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

Sufficiently validated analytical methods for the determination of cyantraniliprole in products of plant and animal origin, in line with the residue definitions for enforcement, are available to support the uses under consideration in the MRL application.

Toxicological reference values were established for the approval of the active substance: an ADI of 0.01 mg/kg bw/day and no ARfD allocated or required.

The metabolism of cyantraniliprole in primary crops was investigated in the cereal/grass crops, leafy crops, pulses and oilseeds and fruit crop groups following foliar and soil applications for the approval of the active substance (EFSA, 2014). As a consistent metabolic pathway was observed across crops from four crop groups, the available data are sufficient to support all crop groups. The crops included in this MRL application are, therefore, covered by the metabolism studies available.

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<sup>1</sup> Retained [Regulation \(EC\) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin](#) (as it applies in Great Britain, pursuant to the European Union (Withdrawal) Act 2018 and European Union (Withdrawal Agreement Act 2020). Great Britain ("GB") refers to England, Scotland and Wales.

<sup>2</sup> Retained [Regulation \(EC\) No 1107/2009 concerning the placing of plant protection products on the market](#) (as it applies in Great Britain, pursuant to the European Union (Withdrawal) Act 2018 and European Union (Withdrawal Agreement Act 2020). Great Britain ("GB") refers to England, Scotland and Wales.

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

- Cyantraniliprole

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

- Cyantraniliprole

No new trials have been submitted to support the proposed MRLs. Trials supporting the on-label authorisations of Minecto One on outdoor lettuce, and additional EAMU authorisations on protected lettuce have been considered and extrapolated to support the proposed use on leafy crops, spinach and similar leaves, and herbs and edible flowers.

For the outdoor uses, eight NEU trials on open-leaf varieties of lettuce were previously evaluated to support the proposed MRLs. For indoor uses, Sixteen residues trials were available, with eight considered acceptable to support the proposed MRLs. Trials are supported by validated analytical methods and storage stability data.

Hydrolysis of cyantraniliprole under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrate that cyantraniliprole is stable under conditions representative of pasteurisation and sterilisation. However, degradation under conditions representative of baking/brewing/boiling was observed, with metabolites IN-J9Z38, IN-F6L99 and IN-N5M09 identified.

The residue definition for risk assessment (RD-RA) for processed commodities is:

- Sum of cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole

The EFSA Conclusion (EFSA, 2014) identified a data gap to assess the toxicological properties of IN-N5M09 and IN-F6L99. Data and information to address this data gap was considered in the ER/RO (HSE, 2022).

It was concluded that the Cramer Class III TTC values of 1.5 µg/kg bw/d is applicable for the chronic dietary risk assessment and 5 µg/kg bw is applicable for the acute dietary risk assessment.

Consideration has been given to the available relevant data on magnitude of residues in processed commodities, and processing factors applied to the crops considered in the current evaluation and previous approved uses to estimate the expected dietary exposure to IN-N5M09 and IN-F6L99. The dietary exposures have been compared to the TTC values and no chronic or acute risk intake concerns have been identified for metabolites IN-N5M09 and IN-F6L99.

No consideration has been given to residues in rotational crops. While crops may be grown in rotation, the cGAP is equivalent to that considered in the GB ER-RO on various commodities (HSE, 2023). No increase is expected to residues in rotational crops. See the ER-RO related to GB MRL 2023/005 for further details.

None of the crops in the proposed GAPs are used for animal feed. Therefore, no further consideration of residues in products of animal origin is required.

Two separate consumer risk assessments have been considered under Scenario 1, and Scenario 2.

### Scenario 1

Scenario 1 includes values related to the CXLs that apply to the commodities under consideration.

The highest UK NEDI was 150% of the ADI (Toddler). The highest PRIMo IEDI was 133% of the ADI (NL toddler). Therefore, a chronic intake concern has been identified from exposure to cyantraniliprole from all dietary sources.

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

Chronic intake concerns have been identified, this is driven by the inputs for lettuces and salad plants (except cress/land cress), and spinaches and similar leaves as such the CXL cannot be adopted for these commodities. The inputs for cress/land cress and chervil have low relevance to the overall exposure; the CXL input applied to these three commodities does not result in chronic exceedances. As such, the CXL has been included in scenario 2 for cress and other sprouts and shoots, land cress, and chervil in scenario 2.

### Scenario 2

The highest UK NEDI was 99.3% of the ADI (Infant). The highest PRIMo IEDI was 92% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with cyantraniliprole.

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

### Conclusion

HSE concludes that the CXL for leafy vegetables may not be adopted for most commodities under consideration due to identified chronic consumer concerns as detailed under Scenario 1.

The CXL for leafy vegetables may be adopted for: cresses and other sprouts and shoots (0251040), land cresses (0251050), and chervil (0256010) as no consumer concerns were identified under Scenario 2.

Sufficient data have been provided to support the setting of new MRLs for the proposed uses of cyantraniliprole on lettuces and salad plants (except lettuces), spinaches, purslanes, chards/beet leaves and herbs and edible flowers. These will not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected.

HSE recommends that the MRLs outlined in Table 0.1 are amended in the GB MRL Statutory Register.

**Table 0.1 MRLs recommended by HSE**

**Enforcement residue definition for products of plant origin: Cyantraniliprole**

| <b>Product code</b> | <b>Product</b>                               | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>Comments</b>                                                                          |
|---------------------|----------------------------------------------|--------------------------------|--------------------------------------|------------------------------------------------------------------------------------------|
| 0251010             | Lamb's lettuce                               | 0.01*                          | 9.0                                  | The MRL is derived by extrapolation of residue trials on open-leaf varieties of lettuce. |
| 0251030             | Escaroles/ broad leaved endives              | 0.01*                          | 4.0                                  |                                                                                          |
| 0251040             | Cresses and other sprouts and shoots         | 0.01*                          | 20                                   |                                                                                          |
| 0251050             | Land cresses                                 | 0.01*                          | 20                                   | The MRL is based on protected trials.                                                    |
| 0251060             | Roman rocket/ rucolas                        | 0.01*                          | 9.0                                  |                                                                                          |
| 0251070             | Red mustards                                 | 0.01*                          | 9.0                                  |                                                                                          |
| 0251080             | Baby leaf crops (including brassica species) | 0.01*                          | 9.0                                  | No health effects are expected.                                                          |
| 0252010             | Spinaches                                    | 0.01*                          | 0.9                                  |                                                                                          |
| 0252020             | Purslanes                                    | 0.01*                          | 0.9                                  |                                                                                          |

| <b>Product code</b> | <b>Product</b>           | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>Comments</b>                                                                                                                                                              |
|---------------------|--------------------------|--------------------------------|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0252030             | Chards/beet leaves       | 0.01*                          | 0.9                                  | trials on open-leaf varieties of lettuce.<br><br>The MRL is based on outdoor NEU trials<br><br>No health effects are expected.                                               |
| 0256010             | Chervil                  | 0.02*                          | 20                                   | The MRL is based on the CXL                                                                                                                                                  |
| 0256020             | Chives                   | 0.02*                          | 4.0                                  | The MRL is derived by extrapolation of residue trials on open leaf varieties of lettuce.<br><br>The MRL is based on protected trials.<br><br>No health effects are expected. |
| 0256030             | Celery leaves            | 0.02*                          | 4.0                                  |                                                                                                                                                                              |
| 0256040             | Parsley                  | 0.02*                          | 4.0                                  |                                                                                                                                                                              |
| 0256050             | Sage                     | 0.02*                          | 4.0                                  |                                                                                                                                                                              |
| 0256060             | Rosemary                 | 0.02*                          | 4.0                                  |                                                                                                                                                                              |
| 0256070             | Thyme                    | 0.02*                          | 4.0                                  |                                                                                                                                                                              |
| 0256080             | Basil and edible flowers | 0.02*                          | 4.0                                  |                                                                                                                                                                              |
| 0256090             | Laural/ bay leaves       | 0.02*                          | 4.0                                  |                                                                                                                                                                              |
| 0256100             | Tarragon                 | 0.02*                          | 4.0                                  |                                                                                                                                                                              |
| 0256990             | Others - herbs           | 0.02*                          | 4.0                                  |                                                                                                                                                                              |

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

## Background

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

On 22 July 2025, HSE accepted an application to set new MRLs for cyantraniliprole in or on the following commodities based on outdoor uses: lettuces and salad plants (except lettuces), spinaches, purslanes, chards/beet leaves and herbs and edible flowers. HSE then accepted an application on 19 November 2025 to set new MRLs for cyantraniliprole in or on the following commodities based on indoor/protected uses: lettuces and salad plants (except lettuces), and herbs and edible flowers. The indoor and outdoor uses have been considered in the same ER-RO.

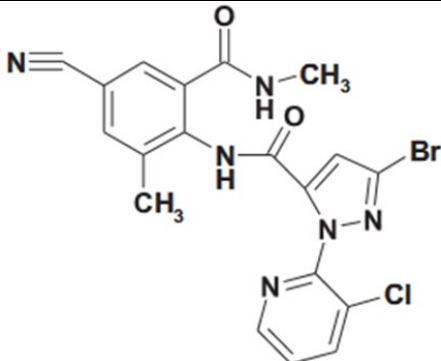
HSE evaluated the information submitted to uniform principles, as defined by Article 8 of Assimilated Regulation 396/2005 and prepared an Evaluation Report. HSE also took into account EFSA Reasoned Opinions and Conclusions on the peer review relating to decisions implemented in GB.

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

## The active substance and its use pattern

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

**Table 0.2 Information on the active substance**

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Common name (ISO)     | Cyantraniliprole                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Chemical name (IUPAC) | 3-bromo-1-(3-chloro-2-pyridyl)-4'-cyano-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide                                                                                                                                                                                                                                                                                                                                              |
| CAS number            | 736994-63-1                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Structural formula    |  <p>The chemical structure of Cyantraniliprole is shown. It features a central pyrazole ring. One nitrogen of the pyrazole is substituted with a 3-chloro-2-pyridyl group. The other nitrogen is substituted with a 3-bromo-4'-cyano-2'-methyl-6'-(methylcarbamoyl)phenyl group. The methylcarbamoyl group is represented as -C(=O)NHCH<sub>3</sub>.</p> |
| Molecular formula     | C <sub>19</sub> H <sub>14</sub> BrClN <sub>6</sub> O <sub>2</sub>                                                                                                                                                                                                                                                                                                                                                                           |
| Molecular mass        | 473.72 g/mol                                                                                                                                                                                                                                                                                                                                                                                                                                |

Cyantraniliprole is an approved active substance in GB. An EFSA Conclusion is available (EFSA, 2014). The MRLs for cyantraniliprole have not been reviewed under Article 12 of Regulation (EC) No 396/2005 as MRLs were established at the approval of the active substance. MRLs are established for cyantraniliprole in Part 2 of the GB MRL Statutory Register.

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

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

**Table 0.3 CXLs relevant to the proposed uses**

| Commodity                                 | CXL (mg/kg) | Comments                                                                                   | Year of adoption |
|-------------------------------------------|-------------|--------------------------------------------------------------------------------------------|------------------|
| Leafy Vegetables (excluding head lettuce) | 20          | The CXL is higher than the current GB MRL's for leafy crops. See below for further details | 2014             |

The CXL for leafy vegetables (excluding head lettuce) can be extrapolated to the following GB MRL codes:

- 0251000: Lettuce and salad plants
- 0252000: Spinaches and similar leaves
- 0256010: Chervil

The CXL has been considered for adoption in GB as part of the current assessment. HSE concluded that the CXL for leafy vegetables may not be adopted for lettuces and salad plants (0251000) (except cresses and other sprouts and shoots (0251040), land cresses (0251050)), and spinaches and similar leaves (0252000) due to identified chronic consumer concerns as detailed under Scenario 1.

The CXL for leafy vegetables may be adopted for: cresses and other sprouts and shoots (0251040), land cresses (0251050), and chervil (0256010) as no consumer concerns were identified under Scenario 2.

# 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 cyantraniliprole in plant commodities, in line with the enforcement residue definition for products of plant origin, were assessed for the approval of the active substance (EFSA, 2014).

The multi-residue DFG S19 LC-MS/MS method is validated for the high water (apple, peach, tomato, lettuce, cucumber), high acid (orange, lemon, lime), high oil (almond, rape seed), dry/high starch (wheat grain) and high water/starch (potato) commodity groups and in processed commodities (tomato paste and sun dried tomato) with an LOQ of 0.01 mg/kg. Acceptable ILV data are available.

The crops groups under consideration in the MRL application belong to the high water commodity group and are covered by the analytical methods available.

The analytical method for enforcement uses water followed by acetone for extraction. In the lettuce metabolism study from the approval of the active substance, following foliar treatment, 91.7 – 99.9 % TRR was extractable using acetone:1N formic acid (9:1, v:v). Cyantraniliprole (the enforcement residue definition for products of plant origin) represented 50.3-97.9% TRR. In the tomato metabolism study from the approval of the active substance, following foliar treatment, 99.7 – 100.0% TRR was extractable using acetone:1N formic acid (9:1, v:v). Cyantraniliprole represented 43.4-95.3% TRR (where 24.1% TRR was attributable to identified metabolites which are not included in the residue definition). Therefore, extraction efficiency has been adequately addressed in accordance with SANTE/2017/10632 rev.3

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

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

## 2 Mammalian toxicology

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

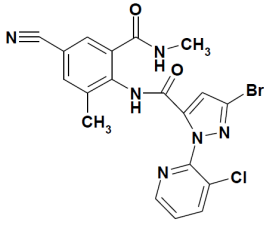
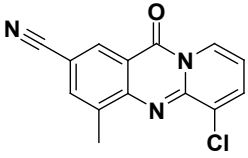
**Table 2.1 Overview of the toxicological reference values for cyantraniliprole**

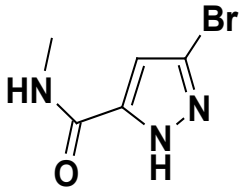
| TRVs | Source | Year | Value           | Study relied upon | Safety factor  |
|------|--------|------|-----------------|-------------------|----------------|
| ADI  | EFSA   | 2014 | 0.01 mg/kg bw/d | 1 year dog        | 100            |
| ARfD | EFSA   | 2014 | Not allocated   | No ARfD necessary | Not applicable |

### 2.1 Further toxicological studies

Data gaps were identified in the peer review of the pesticide risk assessment of the active substance cyantraniliprole relating to the toxicological profile of two metabolites found in processed commodities, IN-N5M09 and IN-F6L99 (EFSA, 2014). The following additional in vitro data was submitted and evaluated in the framework of the previous ER-RO for the setting of tMRLs on various commodities (HSE, 2022).

**Table 2.1-2 Summary overview of toxicological profile of IN-N5M09 and IN-F6L99**

| Metabolite No.   | Structure                                                                           | Toxicological assessment                                                                                                                                                                                                                                                                                    | Source     |
|------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Cyantraniliprole |  | Active substance<br>Full data package available.                                                                                                                                                                                                                                                            | EFSA, 2014 |
| IN-N5M09         |  | Not detected in ADME studies on parent. Structurally very different to parent.<br>Low acute oral toxicity (>5000 mg/kg bw in the mouse). Not genotoxic. No repeat dose toxicity data available<br><b>Cramer Class III TTC value of 1.5 µg/kg bw/d is applicable for the chronic dietary risk assessment</b> | HSE, 2022  |

|          |                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                              |           |
|----------|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
|          |                                                                                   | <b>and a value of 5 µg/kg bw is applicable for the acute dietary risk assessment.</b>                                                                                                                                                                                                                                                                                                                        |           |
| IN-F6L99 |  | <p>Not detected in ADME studies on parent. Structurally very different to parent.</p> <p>Low acute oral toxicity (&gt;2000 mg/kg bw in the mouse). Not genotoxic. No repeat dose toxicity data available</p> <p><b>Cramer Class III TTC value of 1.5 µg/kg bw/d is applicable for the chronic dietary risk assessment and a value of 5 µg/kg bw is applicable for the acute dietary risk assessment.</b></p> | HSE, 2022 |

## 3 Residues in plants

### 3.1 Nature of residues in primary crops

Metabolism in primary crops was investigated following foliar and soil treatments in rice (cereal/grass crops), lettuce (leafy crops), cotton (pulses and oilseeds) and tomato (fruit) for the approval of the active substance (EFSA Conclusion, 2014).

The following summary is presented by EFSA (2014):

*“For each crop, metabolism was investigated after either three foliar applications or three soil drench applications at 150 g/ha (except for rice where a single soil application at 300 g/ha was experimented). Separate tests were conducted for soil applications, using <sup>14</sup>Ccyantraniliprole either labelled on the cyano or pyrazole moieties, while foliar treatments were made using a mixture of both radiolabel forms in a 1:1 ratio. In this particular case, the use of mixed radiolabel forms was considered acceptable, since no extensive cleavage of the parent molecule was observed in the different studies.*

*In all plant matrices, total radioactive residue levels were at least one order of magnitude higher following foliar applications than soil drench applications. Irrespective of the mode of application, a similar metabolic profile was observed in the different crop groups, cyantraniliprole representing the major component of the residues, accounting for almost 25 % to more than 90 % TRR. Twenty different metabolites were identified, mostly below 5% TRR, the most abundant being the metabolite IN-J9Z38 representing 23% TRR at 32 day PHI in lettuce (0.007 mg/kg) and 6% to 28% TRR in rice foliage, straw and grain (0.03 to 0.09 mg/kg) following drench application.*

*As cyantraniliprole was shown to be the major component of the radioactive residues in the different plant studies, the residue definition for monitoring was limited to cyantraniliprole only. The inclusion of additional metabolites in the residue definition for risk assessment was considered. Having regard to the low residue levels observed in the supervised residues trials where all samples were analysed for a total of 6 to 7 metabolites, it was proposed to limit the residue definition for risk assessment to cyantraniliprole only, considering that the additional contribution of these metabolites to the overall consumer intake would be negligible”*

A summary of the available primary crop metabolism data is presented in the EFSA Conclusion, 2014 and copied below.

**Table 3.1-1 Summary of the primary plant metabolism studies**

| Crop group | Crop(s) | Applications | DAT <sup>(a)</sup> (days) |
|------------|---------|--------------|---------------------------|
|------------|---------|--------------|---------------------------|

|                     |         |                                                                          |                                            |
|---------------------|---------|--------------------------------------------------------------------------|--------------------------------------------|
| Fruit crops         | Tomato  | Foliar, 3 x 150 g/ha BBCH 14-61<br>Soil drench, 3 x 150 g/ha, BBCH 19-61 | 125 (leaves, fruits)                       |
| Root crops          | -       | -                                                                        | -                                          |
| Leafy crops         | Lettuce | Foliar, 3 x 100 g/ha, BBCH 50<br>Soil drench, 3 x 150 g/ha, BBCH 18-19   | 0, 7, 14, 32<br>7, 14, 32                  |
| Cereals/grass crops | Rice    | Foliar, 3 x 150 g/ha, BBCH 13-14<br>Soil granule, 1 x 300 g/ha, BBCH 13  | 140 (straw, grain)<br>175 (straw, grain)   |
| Pulses/Oilseeds     | Cotton  | Foliar, 3 x 150 g/ha, BBCH 16-19<br>Soil drench, 3 x 150 g/ha, BBCH 19   | 124 (leaves, bolls)<br>125 (leaves, bolls) |
| Miscellaneous       | -       |                                                                          |                                            |

(a) DAT where identification/characterisation of the residues has been investigated (*interim samplings with information limited to TRR levels only, can be omitted*)

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 and soil drench/granule, which is the same as the application type for the proposed use. The application rate in the primary crop metabolism studies is greater than to that in the proposed GAP (at least 3N). On this basis all proposed uses of 'Minecto One' are supported by the available metabolism data.

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

- Cyantraniliprole

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

- Cyantraniliprole

## 3.2 Magnitude of residues in primary crops

### Residue trials

No new trials have been submitted to support setting new GB MRLs on leafy vegetables and edible herbs. Reference is made to trials on lettuce previously considered in GB supporting product authorisation for cyantraniliprole on lettuces and extrapolating this data to additional crops. The data have been summarized in the appendix for completeness.

### Outdoor uses

The UK cGAP for use of 'Minecto One' is tabulated below:

| MRL code                                                      | Crop                                        | Application rate (g/ha) | Growth stage | No. of apps (and retreatment interval (RTI)) | PHI (days) | Water Volume (L/ha) |
|---------------------------------------------------------------|---------------------------------------------|-------------------------|--------------|----------------------------------------------|------------|---------------------|
| <b>0251000</b><br>(except <b>0251020</b> and <b>0251080</b> ) | Lettuces and salad plants (except lettuces) | 74                      | BBCH 12 – 49 | 2 (7)                                        | 7          | 300 - 1000          |
| <b>0251080</b>                                                | Baby leaf crops                             | 74                      | BBCH 12 - 18 | 2 (7)                                        | 7          | 300 - 1000          |
| <b>0252010</b> ,<br><b>0252020</b> ,<br><b>0252030</b>        | spinaches, purslanes, chards/beet leaves    | 74                      | BBCH 12 - 49 | 2 (7)                                        | 7          | 300 - 1000          |
| <b>0256000</b>                                                | Herbs and edible flowers                    | 74                      | BBCH 12 – 49 | 2 (7)                                        | 7          | 300 - 1000          |

Eight trials on open leaf varieties of lettuce are available and evaluated for the authorisation of Minecto One (COP 2015/01172), the residue data can be seen in Appendix C.3.1.2.

Trials were conducted using a WG formulation, with four of the trials having a second plot using an OD formulation. Two applications were made in the trials, with the first application ranging between 74 – 78 g a.s/ha, and the second 72 – 81 g a.s/ha. The water volume used in the trials ranged between 292 – 428 L water/ha.

For trials conducted with two separate plots with different formulation types (WG and OD), the residues between the two is shown to be comparable via T-test, therefore the highest residue between plots have been selected for risk assessment and MRL calculations.

All eight trials were decline with samples taken 0, 3, 7 - 9, 9 - 10 and 13-14 days after application. The final application was made at BBCH 43 – 49, with a RTI of 7 - 8 days between applications, which is acceptable to support the GAP.

It is noted that the latest application timing for baby leaf lettuce is BBCH 18, which is less critical than the latest stage of application on lettuce (BBCH 48). However, the relevant factor to consider for baby leaf crops is the PHI; the trials on lettuce can be considered representative for baby-leaf lettuce.

The cGAP on leafy vegetables and salad plants, spinaches and similar leaves and herbs and edible flowers (BBCH 49) is for an application after the formation of the edible part (BBCH 16), therefore half of the trials should be decline trials. As all trials were decline trials, this is considered acceptable.

No significant deviations were noted in the trials. All trials were conducted on open leaf varieties of lettuce.

### Protected/indoor uses

The UK cGAP for use of 'Minecto One' is tabulated below:

| MRL code                         | Crop                                                                               | Application rate (g/ha) | Growth stage | No. of apps (and retreatment interval (RTI)) | PHI (days) | Water Volume (L/ha) |
|----------------------------------|------------------------------------------------------------------------------------|-------------------------|--------------|----------------------------------------------|------------|---------------------|
| <b>0251030, 0251040, 0251050</b> | Escaroles/broad-leaved endives, Cresses and other sprouts and shoots, land cresses | 74                      | BBCH 12 - 49 | 7 (2)                                        | 10         | 300 - 1000          |
| <b>0251010, 0251060, 0251070</b> | Lamb's lettuce/ corn salads, Roman rocket/ rucola, red mustards                    | 74                      | BBCH 12 - 49 | 7 (2)                                        | 3          | 300 - 1000          |
| <b>0251080</b>                   | Baby leaf crops (including brassica species)                                       | 74                      | BBCH 12 - 18 | 7 (2)                                        | 3          | 300 - 1000          |
| <b>0256000</b>                   | Herbs and edible flowers                                                           | 74                      | BBCH 12 - 49 | 7 (2)                                        | 10         | 300 - 1000          |

Sixteen residue trials on protected open leaf lettuce were evaluated under COP 2025/00914. Residue data can be seen in Appendix C.3.1.2.

Eight of the trials were conducted within the SEU, and eight in the NEU. As trials were conducted in a protected environment, consideration on the different climates is not required and SEU trials can be considered to support new MRLs in GB.

Twelve of the available trials were conducted using a SC formulation, with the remaining four conducted with an OD formulation. For four of the SC trials and the four OD trials, three applications were made at a nominal rate of 75 g a.s/ha which is higher than the critical GAP (2 x 74 g a.s/ha). It is not possible to apply the proportionality principle to scale these trial results in this case as multiple applications were made, and it is not clear to what extent the final application is driving the residue.

For the remaining eight SC trials, two applications were made at an overdosed rate. The first application ranged from 121 – 135 g a.s/ha and the second from 116 – 132 g a.s/ha. The water volume used in the trials ranged from 279 – 404 L water/ha.

All eight trials were decline trials with samples taken 0, 3, 6 – 7, 10 – 11, and 13 – 14 days after application. The final application was made at BBCH 41 – 48, with a RTI of 7 days between applications, which is acceptable to support the GAPs.

The number of application is equivalent to the proposed GAPs, and while the application rate is overdosed, difference between application rates is overdosed by a consistent factor (nominal rate of 125 g a.s/ha vs 74 g a.s/ha). The scaling of such trials is outlined within the EFSA publication on the proportionality principle approach (EFSA, 2018a). Therefore, the proportionality principle has been applied to the eight trials for risk assessment and MRL calculations.

Residue values and scaled residues are presented below with scaling factors.

| Location, Trial No.,<br>Formulation                        | PHI (days) | Residue levels<br>(mg/kg) | Scales Residue<br>levels (mg/kg) | Scaling factor |
|------------------------------------------------------------|------------|---------------------------|----------------------------------|----------------|
| Languedoc-Rousillon,<br>France, S11-00591-01,<br>SC        | 0          | 3.95                      | 2.21                             | 0.561          |
|                                                            | <b>3</b>   | <b>4.62</b>               | <b>2.59</b>                      |                |
|                                                            | 7          | 2.36                      | 1.32                             |                |
|                                                            | 10         | 2.09                      | 1.17                             |                |
|                                                            | <u>13*</u> | <u>2.30<sup>(a)</sup></u> | <u>1.29<sup>(a)</sup></u>        |                |
| Emilia Romagna , Italy,<br>S11-00591-02, SC                | 0          | 4.58                      | 2.69                             | 0.587          |
|                                                            | <b>3</b>   | <b>5.19</b>               | <b>3.05</b>                      |                |
|                                                            | 7          | 2.77                      | 1.63                             |                |
|                                                            | <u>10</u>  | <u>2.07</u>               | <u>1.22</u>                      |                |
|                                                            | 13         | 1.42                      | 0.83                             |                |
| Conil de la Frontera,<br>Cádiz, Spain S11-<br>00591-03, SC | 0          | 9.34                      | 5.49                             | 0.587          |
|                                                            | <b>3</b>   | <b>4.64</b>               | <b>2.73</b>                      |                |
|                                                            | 7          | 4.28                      | 2.51                             |                |
|                                                            | <u>10</u>  | <u>2.97</u>               | <u>1.74</u>                      |                |
|                                                            | 14         | 2.09                      | 1.23                             |                |
| Andalucía, Cádiz, Spain,<br>S11-00591-04, SC               | 0          | 9.81                      | 5.67                             | 0.578          |
|                                                            | <b>3</b>   | <b>8.40</b>               | <b>4.86</b>                      |                |

|  |           |             |             |  |
|--|-----------|-------------|-------------|--|
|  | 7         | 3.68        | 2.13        |  |
|  | <u>11</u> | <u>2.83</u> | <u>1.64</u> |  |
|  | 14        | 2.15        | 1.24        |  |

(a) Residues of 13 day PHI have been selected over the sample taken at 10 day PHI due to higher residues

| Location, Trial No.,<br>Formulation      | PHI (days)              | Residue levels<br>(mg/kg) | Scaled Residue<br>levels (mg/kg) | Scaling factor |
|------------------------------------------|-------------------------|---------------------------|----------------------------------|----------------|
| Orientales, France, S12-<br>01416-01, SC | 0                       | 0.41                      | 0.23                             | 0.561          |
|                                          | <b>3</b>                | <b>0.43</b>               | <b>0.24</b>                      |                |
|                                          | 7                       | 0.19                      | 0.11                             |                |
|                                          | <u>10</u>               | <u>0.12</u>               | <u>0.07</u>                      |                |
|                                          | 14                      | 0.10                      | 0.06                             |                |
| Bologna, Italy, S12-<br>01416-02, SC     | 0                       | 4.80                      | 2.89                             | 0.602          |
|                                          | <b>3</b>                | <b>5.05</b>               | <b>3.04</b>                      |                |
|                                          | 7                       | 2.47                      | 1.49                             |                |
|                                          | 10                      | 1.46                      | 0.88                             |                |
|                                          | <u>14<sup>(a)</sup></u> | <u>1.80<sup>(a)</sup></u> | <u>1.08<sup>(a)</sup></u>        |                |
| Navarra, Spain, S12-<br>01416-03, SC     | 0                       | 3.54                      | 2.26                             | 0.638          |
|                                          | 3                       | 1.67                      | 1.07                             |                |
|                                          | <b>7<sup>(b)</sup></b>  | <b>2.39<sup>(b)</sup></b> | <b>1.52<sup>(b)</sup></b>        |                |
|                                          | <u>10</u>               | <u>0.40</u>               | <u>0.26</u>                      |                |
|                                          | 14                      | 0.19                      | 0.12                             |                |
| Latina, Italy, S12-01416-<br>04, SC      | 0                       | 0.96                      | 0.60                             | 0.627          |
|                                          | <b>3</b>                | <b>0.94</b>               | <b>0.59</b>                      |                |
|                                          | 7                       | 0.79                      | 0.50                             |                |
|                                          | <u>10</u>               | <u>0.76</u>               | <u>0.48</u>                      |                |
|                                          | 14                      | 0.59                      | 0.37                             |                |

(a) Value at 14 day PHI has been selected due to higher residues than those at PHI 10

(b) Value at PHI 7 has been selected as higher residues are seen than those at PHI 3

No significant deviations were noted in the trials. All trials were conducted on open leaf varieties of lettuce.

The cGAP on leafy vegetables and salad plants, and herbs and edible flowers (BBCH 49) is for an application after the formation of the edible part (BBCH 16), therefore half of the trials should be decline trials. As all trials were decline trials, this is considered acceptable.

‘Minecto One’ is an WG formulation, the trials were undertaken using either a SC or OD formulation. Extrapolation from SC to WG is permissible in accordance with the GB extrapolation guidance 2024. Trials conducted using an OD formulation were not acceptable as they are overdosed, and it is not considered appropriate to apply the proportionality principle to these trials, the extrapolation of OD trials to support an WG formulation has not been considered further.

### Consideration of the available residue data for indoor and outdoor uses.

The trials were conducted in accordance with the relevant guidance documents, and no significant deviations were noted in the trials.

As set out in the GB Extrapolations Guidance 2024 trials on open leaf lettuce can be extrapolated to support uses on whole group (a) lettuce and salad plants (0251000), Whole group (b) spinaches and similar leaves (0252000) and whole sub-group (f) herbs and edible flowers (0256000) when application is before or after the edible part of the crop.

All crops for the proposed use are minor crops, therefore four trials are required to extrapolate to support the proposed use when >LOQ residues are expected. As the eight trials are available and have been performed on open leaf lettuce, they are sufficient to support new MRLs.

The current GB MRLs for the crops under consideration are outlined below,

| Commodity                    | GB (GB MRL 2025/001) | Supported MRL (outdoor) | Supported MRL (Indoor) |
|------------------------------|----------------------|-------------------------|------------------------|
| 0251010 - Lamb's lettuce     | 0.01*                | 0.9                     | 9.0                    |
| 0251030 - Endive,            | 0.01*                |                         | 4.0                    |
| 0251040 - Cress,             | 0.01*                |                         | 4.0                    |
| 0251050 - Land cress,        | 0.01*                |                         | 4.0                    |
| 0251060 - Rocket,            | 0.01*                |                         | 9.0                    |
| 0251070 - Red mustard,       | 0.01*                |                         | 9.0                    |
| 0251080 - Baby leaf crops,   | 0.01*                |                         | 9.0                    |
| 0252010 – Spinaches          | 0.01*                |                         | -                      |
| 0252020 – Purslanes          | 0.01*                |                         | -                      |
| 0252030 – Chards/beet leaves | 0.01*                |                         | -                      |
| 0256010 – Chervil            | 0.02*                |                         | 4.0                    |
| 0256020 – Chives             | 0.02*                |                         | 4.0                    |
| 0256030 – Celery leaves      | 0.02*                |                         | 4.0                    |
| 0256040 – Parsley            | 0.02*                |                         | 4.0                    |
| 0256050 – Sage               | 0.02*                |                         | 4.0                    |
| 0256060 – Rosemary           | 0.02*                |                         | 4.0                    |
| 0256070 – Thyme              | 0.02*                |                         | 4.0                    |
| 0256080 – Basil              | 0.02*                |                         | 4.0                    |
| 0256090 – Laurel/bay leaves  | 0.02*                |                         | 4.0                    |
| 0256100 – Tarragon           | 0.02*                |                         | 4.0                    |
| 0256990 – Others - Herbs     | 0.02*                |                         | 4.0                    |

All MRL values reported in mg/kg.

## Storage stability

The freezer storage stability was addressed at the approval of cyantraniliprole; sufficient data are available to support the stability of cyantraniliprole in all plant commodities for at least 18 months.

Samples were stored at -18 °C for maximum periods of eight months during the trials from sampling to analysis. The freezer storage stability data considered in the DAR for cyantraniliprole supports this period of storage.

Extract solutions stored for a maximum of 13 days during the trials before analysis. The stability of analytes in extracts was demonstrated by corresponding procedural recovery specimens which were stored under the same conditions as the sample extracts.

## Analytical methods

Samples were analysed using company method 'DuPont-15736'. The method was considered and accepted during the EU approval of the active substance (UK, DAR, 2013). The method is suitable for determination of residues in crops of high water content.

Additional validation data has been considered for lettuce under Section C.1.1 demonstrating the method meets the criteria outlined in Section 4.2 of SANTE/2020/12830 Rev 1.

Method DuPont-15736 uses acetonitrile/water (90/10) as an extraction solvent, with the aid of ball bearings. The extraction procedure of DuPont-15736 was investigated at the approval of the active substance by comparing the extractability to that of the available metabolism study using radio-labelled samples. Extractability was investigated from lettuce leaf, beet foliage, wheat grain and wheat hay. The following conclusion was made;

*“The residue profiles obtained were compared with those obtained for the same samples in the plant metabolism study. The levels of the parent and metabolites obtained using the residue method were within 89 to 100% of those found in the metabolism study as reported in the table below, which indicates that the residue method provides acceptable extraction efficiency.”*

Therefore, extraction efficiency is sufficiently addressed for method DuPont-15636.

**Table 3.2 Overview of the available residue trials data**

| Commodity                                  | Region/<br>Indoor<br>(a) | Residue levels<br>(mg/kg) observed<br>in the trials<br>representative<br>for the intended<br>GAPs<br>(b) | Recommendations/<br>comments<br>(OECD calculations)                                                                                                                                                                                                                                                                                                                                                                                               | MRL<br>proposals<br>(mg/kg) | HR<br>(mg/kg)<br>(c) | STMR<br>(mg/kg)<br>(d) |
|--------------------------------------------|--------------------------|----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|------------------------|
| <b>RD-RA/<br/>RD-Enf: Cyantraniliprole</b> |                          |                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                             |                      |                        |
| Lettuce                                    | GB / outdoor             | 2 x 0.05, 0.10,<br>0.11, 0.14, 0.15,<br>0.17, 0.60                                                       | <p>Trials conducted on open-leaf lettuce, extrapolation to:</p> <p><b>0251000 – lettuce and salad plants (excluding lettuce)</b></p> <p>Endive, cress, land cress, lamb's lettuce, rocket, red mustard, spinach, spinach beet, purslane</p> <p><b>025200 – Spinaches and similar leaves</b></p> <p><b>0256000 – Herbs and edible flowers.</b></p> <p>OECD MRL calculation:</p> <p><b>Unrounded:</b> 0.886 mg/kg<br/><b>Rounded:</b> 0.9 mg/kg</p> | <b>0.9</b>                  | 0.6                  | 0.125                  |
|                                            | GB / Indoor              | 0.24, 0.59, <b>1.52</b> ,<br>2.59, 2.73, 3.04,<br>3.05, 4.86                                             | Trials conduction on open-leaf lettuce.                                                                                                                                                                                                                                                                                                                                                                                                           | <b>9.0</b>                  | 4.856                | 2.658                  |

|  |                                                                     |                                                                                                                                                                                                                                                                                                                                                                                  |            |       |       |
|--|---------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-------|-------|
|  |                                                                     | <p>Residues selected to support the GAP of <u>3 day PHI</u>. Value in <b>bold</b> taken from a later PHI.</p> <p>Trials on open-leaf lettuce extrapolated to;</p> <p><b>0251000 – lettuce and salad plants</b></p> <p>lamb's lettuce, rocket, red mustard, baby leaf crops</p> <p>- OECD MRL calculation:</p> <p><b>Unrounded:</b> 8.310 mg/kg<br/><b>Rounded:</b> 9.0 mg/kg</p> |            |       |       |
|  | <p>0.07, 0.26, 0.48, <b>1.08</b>, 1.22, <b>1.29</b>, 1.64, 1.74</p> | <p>Residues selected to support the GAP of <u>10 day PHI</u>. Value in <b>bold</b> taken from a later PHI</p> <p>Trials on open-leaf lettuce extrapolated to:</p> <p><b>0251000 – lettuce and salad plants</b></p> <p>Endive, cress, land cress</p> <p><b>0256000 – Herbs and edible flowers.</b></p> <p>- OECD MRL calculation:</p>                                             | <b>4.0</b> | 1.744 | 1.149 |

|  |  |  |                                                            |  |  |  |
|--|--|--|------------------------------------------------------------|--|--|--|
|  |  |  | <b>Unrounded:</b> 3.495 mg/kg<br><b>Rounded:</b> 4.0 mg/kg |  |  |  |
|--|--|--|------------------------------------------------------------|--|--|--|

- (a) GB or the country for an import tolerance and whether the GAP is for an outdoor use or an indoor/protected/glasshouse use.
- (b) Residue levels in trials conducted according to GAPs reported in ascending order. When residue definitions for enforcement and risk assessment differ, **Enf/RA** differentiate data expressed according to the residue definition for **Enforcement** and **Risk Assessment**.
- (c) **HR**: Highest residue, according to the residue for risk assessment, (within brackets when expressed according to the residue definition for enforcement: HR<sub>Enf</sub>)
- (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<sub>Enf</sub>)

### 3.3 Conversion factors for risk assessment for products of plant origin

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

### 3.4 Effect of industrial processing and/or household preparation

#### 3.4.1 Nature of the residues in processed commodities

Hydrolysis of cyantraniliprole under representative conditions of pasteurisation; baking, brewing and boiling; and sterilisation was evaluated for the approval of the active substance (EFSA, 2014).

*“Cyantraniliprole was stable under standard hydrolysis conditions simulating pasteurisation and sterilisation, but under boiling conditions, slightly degraded to IN-J9Z38 (12-14 % AR) via cyclisation and, to a lesser extent, to metabolites IN-N5M09 and IN-F6L99 (5-8% AR) resulting from the cleavage of the parent compound. The degradation of cyantraniliprole under boiling conditions was confirmed in several processing studies where metabolite IN-J9Z38 was observed in higher quantities than cyantraniliprole.*

*The residue definition in processed commodities for risk assessment is sum of cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole.”*

The EFSA Conclusion (EFSA, 2014) identified a data gap to assess the toxicological properties of IN-N5M09 and IN-F6L99. Data and information to address this data gap was considered in a previous GB ER-RO (HSE, 2022).

The conditions simulating boiling/baking/brewing are relevant to the proposed uses therefore the risk posed by IN-N5M09 and IN-F6L99 has been addressed below.

**Table 3.4.1 Overview of the available hydrolysis studies**

| Conditions          | Stable?      | Comment                                                                 |
|---------------------|--------------|-------------------------------------------------------------------------|
| 20 min, 90°C, pH 4  | Yes          | -                                                                       |
| 60 min, 100°C, pH 5 | See comments | Degraded to IN-J9Z38 (12-14% AR) and to IN-F6L99 and IN-N5M09 (5-8% AR) |
| 20 min, 120°C, pH 6 | Yes          | -                                                                       |

#### **Residue definitions for processed commodities (EFSA, 2014)**

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

- Sum cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole for processed commodities

The above RD-RA for processed commodities is applicable, provided that the dietary exposures to the metabolites IN-F6L99 and IN-N5M09 are below the TTC for both chronic and acute exposure.

The residue definition for enforcement of cyantraniliprole takes into account processed commodities.

### 3.4.2 Magnitude of the residues in processed commodities

Studies investigating the effect of processing on the magnitude of residues have been assessed during the peer review and processing factors were proposed for a number of commodities.

According to the OECD guidance on magnitude of residues in processed commodities (No. 96), the processed fractions which are important for the estimation of dietary exposure of the proposed uses are:

- Spinaches, purslane, chard/beet leaves: Cooking/steaming (cat 2)
- Herbs, fresh and chives: Dehydration (cat 2)

No consideration of the magnitude of residues in processed commodities is required for lettuce and salad plants (except lettuce) as these commodities are primarily consumed raw.

As the residue definitions for risk assessment for processed and unprocessed commodities differ, the following were calculated for the approval of the active substance:

- Processing factors (Pf) (parent only) based on ratio between residue levels of cyantraniliprole in processed commodities and residue levels of cyantraniliprole in raw commodities,
- Conversion factors (CF) based on ratio between residue levels of sum of cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole in processed commodities and residue levels of cyantraniliprole in processed commodities.

The relevant Pf (parent only) and CFs derived for the approval of the active substance are given in Table 3.4.2-1

**Table 3.4.2-1 – Overview of the available relevant processing studies.**

| Crop (RAC) / processed product | Number of trials | Processing factor (Pf) (parent only) <sup>(a)</sup> |           | CF for RA <sup>(b)</sup> |           | Reference  |
|--------------------------------|------------------|-----------------------------------------------------|-----------|--------------------------|-----------|------------|
|                                |                  | Individual values                                   | Median Pf | Individual values        | Median CF |            |
| Spinach / leaves cooked        | 3                | 0.09, 0.16, 0.17                                    | 0.2       | 5.55, 8.01, 11.63        | 8.0       | EFSA, 2014 |

(a) The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

(b) The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study

(c) Not reliable, as residue levels in raw potato close to the LOQ (0.014 and 0.020 mg/kg) and ≤0.01 mg/kg in all processed fractions

Further consideration is given to metabolites IN-N5M09 & IN-F6L99 below.

## **IN-N5M09 & IN-F6L99**

### **Introduction**

As stated in Section 3.4.1, the EFSA Conclusion (2014) identified a data gap to assess the toxicological properties of processing degradation products IN-N5M09 and IN-F9L99. Toxicological data and information for IN-N5M09 and IN-F6L99 was submitted for the ER-RO for the setting of tMRLs on raspberries and blackberries (HSE, 2022).

It was concluded that the Cramer Class III TTC values of 1.5 µg/kg bw/d is applicable for the chronic dietary risk assessment and 5 µg/kg bw is applicable for the acute dietary risk assessment. The residue levels of IN-N5M09 and IN-F6L99 in processed commodities have been estimated to perform an estimation of the dietary exposure to these metabolites and compared these dietary exposures to the TTC.

Provided the dietary exposures for both metabolites are below the TTC, the metabolites do not need to be included in the RD-RA for processed commodities. Further data on the magnitude of residues and/or tox data will not be required.

### **Estimation of residue levels for the crops under consideration in this assessment**

#### **Herbs, fresh**

No processing data is available on herbs and edible flowers. Consideration has been given to the available processing studies which include dehydration steps to determine the potential formation of metabolites IN-N5M09 and IN-F6L99 in herbs after dehydration.

Data is available on apple / dry pomace, tomato / dry pomace, grapes / raisins, grapes / dry pomace, and potato / flakes, all of which include the dehydration step.

Based on the residue levels of cyantraniliprole found in RAC and dehydrated processed commodities a production factor can be calculated:

Production factor = Level of metabolite in the processed commodity (mg/kg) / level of cyantraniliprole in RAC (mg/kg)

The median production factor, for each metabolite, has then been applied to the STMR/HR of cyantraniliprole for the residue trials supporting the proposed uses. This gives the residue levels of the metabolites following for the proposed uses. These values can then be used to estimate the dietary exposure to the metabolites from the consumption of processed commodities

The residue levels of cyantraniliprole, IN-N5M09 and IN-F6L99 found after dehydration are summarised in Table 3.4.2-2

**Table 3.4.2-2 Production factors for IN-N5M09 and IN-F6L99 in dehydrated commodities**

| Trial    | Matrix       | Residues (mg/kg) |          |          | Production factor IN-N5M09 | Production factor IN-F6L99 |
|----------|--------------|------------------|----------|----------|----------------------------|----------------------------|
|          |              | Cyantraniliprole | IN-N5M09 | IN-F6L99 |                            |                            |
| Trial 06 | Grapes (RAC) | 0.16 (a)         | N/A      | N/A      | -                          | -                          |
|          | Dry Pomace   | 1.4              | 0.018    | ND       | <b>0.113</b>               | -                          |
|          | Raisins      | 0.26             | N/A      | N/A      | -                          | -                          |
| Trial 07 | Grapes (RAC) | 0.12 (a)         | N/A      | N/A      | -                          | -                          |
|          | Dry Pomace   | 0.73             | 0.006    | N/D      | <b>0.05</b>                | -                          |
|          | Raisins      | 0.096            | N/A      | N/A      | -                          | -                          |
| Trial 08 | Grapes (RAC) | 0.11 (a)         | N/A      | N/A      | -                          | -                          |
|          | Dry Pomace   | 0.17             | N/D      | N/D      | -                          | -                          |
|          | Raisins      | 0.15             | N/A      | N/A      | -                          | -                          |
| Trial 03 | Apple (RAC)  | 0.075            | 0.01     | 0.01     | -                          | -                          |
|          | Dry pomace   | 0.300            | 0.01     | 0.01     | 0.133                      | 0.133                      |
| Trial 10 | Apple (RAC)  | 0.263            | 0.01     | 0.01     | -                          | -                          |
|          | Dry pomace   | 0.680            | 0.01     | 0.01     | 0.038                      | 0.038                      |
| Trial 14 | Apple (RAC)  | 0.260            | 0.01     | 0.01     | -                          | -                          |
|          | Dry pomace   | 0.520            | 0.01     | 0.01     | 0.039                      | 0.039                      |
| Trial 8  | Orange (RAC) | 0.130            | 0.01     | 0.01     | -                          | -                          |
|          | Dry pulp     | 0.110            | 0.01     | 0.01     | 0.077                      | 0.077                      |
| Trial 25 | Orange (RAC) | 0.087            | 0.01     | 0.01     | -                          | -                          |
|          | Dry pulp     | 0.024            | 0.01     | 0.01     | 0.115                      | 0.115                      |
| Trial 26 | Orange (RAC) | 0.170            | 0.01     | 0.01     | -                          | -                          |
|          | Dry pulp     | 0.065            | 0.01     | 0.01     | 0.059                      | 0.059                      |
| Trial 14 | Plum (RAC)   | 0.183            | 0.01     | 0.01     | -                          | -                          |
|          | Prunes       | 0.350            | 0.01     | 0.01     | 0.055                      | 0.055                      |
| Trial    | Plum (RAC)   | 0.240            | 0.01     | 0.01     | -                          | -                          |

| Trial    | Matrix       | Residues (mg/kg) |          |          | Production factor IN-N5M09 | Production factor IN-F6L99 |
|----------|--------------|------------------|----------|----------|----------------------------|----------------------------|
|          |              | Cyantraniliprole | IN-N5M09 | IN-F6L99 |                            |                            |
| 16       | Prunes       | 0.370            | 0.01     | 0.01     | 0.042                      | 0.042                      |
| Trial 20 | Plum (RAC)   | 0.040            | 0.01     | 0.01     | -                          | -                          |
|          | Prunes       | 0.050            | 0.01     | 0.01     | 0.2                        | 0.2                        |
| Trial 1  | Tomato (RAC) | 0.130            | 0.01     | 0.01     | -                          | -                          |
|          | Dried Pomace | 0.230            | 0.01     | 0.01     | 0.077                      | 0.077                      |
| Trial 2  | Tomato (RAC) | 0.200            | 0.01     | 0.01     | -                          | -                          |
|          | Dried Pomace | 0.500            | 0.013    | 0.01     | <b>0.065</b>               | 0.05                       |
| Trial 3  | Tomato (RAC) | 0.120            | 0.01     | 0.01     | -                          | -                          |
|          | Dried Pomace | 0.120            | 0.01     | 0.01     | 0.083                      | 0.083                      |
| Trial 10 | Potato (RAC) | 0.01             | 0.01     | 0.01     | -                          | -                          |
|          | Flakes       | 0.01             | 0.01     | 0.01     | 1                          | 1                          |
| Trial 11 | Potato (RAC) | 0.014            | 0.01     | 0.01     | -                          | -                          |
|          | Flakes       | 0.01             | 0.01     | 0.01     | 0.714                      | 0.714                      |
| Trial 12 | Potato (RAC) | 0.020            | 0.01     | 0.01     | -                          | -                          |
|          | Flakes       | 0.01             | 0.01     | 0.01     | 0.5                        | 0.5                        |

(a) Calculated as a mean between three individual values

N/A = Not applicable.

N/D = Not detected.

The above data demonstrated that metabolite IN-F6L99 was not observed in any dehydrated commodity (n=21), and as such no further consideration has been made of this metabolite in dried herbs.

For metabolite IN-N5M09, >LOQ residues are observed in 3 of the 21 relevant trials/processed fractions: grapes/dry pomace (n=2), and tomato/dry pomace (n=1). It is noted that these are waste products/animal feed commodities, and data on other consumed dried commodities (raisins, potato flakes, prunes) may be more relevant to the dehydration of herbs. Nevertheless, and in order to capture the worst case formation fraction, the production factor for IN-N5M09 has been calculated based on grape and tomato dry pomace.

**Table 3.4.2-3 Production factors for IN-N5M09 and IN-F6L99 in grapes / dry pomace, and tomato / dry pomace.**

| Trial    | Matrix       | Residues (mg/kg) |          |          | Production factor IN-N5M09 |
|----------|--------------|------------------|----------|----------|----------------------------|
|          |              | Cyantraniliprole | IN-N5M09 | IN-F6L99 |                            |
| Trial 06 | Grapes (RAC) | 0.16 (a)         | N/A      | N/A      | -                          |
|          | Dry Pomace   | 1.4              | 0.018    | ND       | 0.113                      |
| Trial 07 | Grapes (RAC) | 0.12 (a)         | N/A      | N/A      | -                          |
|          | Dry Pomace   | 0.73             | 0.006    | N/D      | 0.05                       |
| Trial 2  | Tomato (RAC) | 0.200            | 0.01     | 0.01     | -                          |

| Trial  | Matrix       | Residues (mg/kg) |          |          | Production factor IN-N5M09 |
|--------|--------------|------------------|----------|----------|----------------------------|
|        |              | Cyantraniliprole | IN-N5M09 | IN-F6L99 |                            |
|        | Dried Pomace | 0.500            | 0.013    | 0.01     | 0.065                      |
| Median | Production   | Factor:          |          |          | 0.065                      |

(a) Calculated as a mean of three individual values.

Taking into account the median production factor calculated in the table above, STMR-P and HR-P values have been derived in the table below for IN-N5M09. The STMR-P and HR-P values are obtained by applying the production factor to the STMR and HR in the RAC. The STMR-P represents the median residues of IN-N5M09 arising in the processed commodity.

**Table 3.4.2-4 Herbs, fresh – inputs for dietary risk assessment for metabolites IN-N5M09 & IN-F6L99**

| Commodity                         | Metabolite | Median production factor | STMR RAC (mg/kg) | STMR-P (mg/kg) | HR RAC (mg/kg) | HR-P (mg/kg) |
|-----------------------------------|------------|--------------------------|------------------|----------------|----------------|--------------|
| Herbs, fresh (except chervil) (a) | IN-N5M09   | 0.065                    | 1.149            | <b>0.075</b>   | 1.744          | <b>0.113</b> |
| Chervil (b)                       |            |                          | 4.7              | <b>0.306</b>   | 19             | <b>1.235</b> |

(a) STMR and HR calculated from the supporting residue trials (Section 3.2)

(b) STMR and HR taken from the supporting CXL (FAO, 2014)

### Spinach and similar leaves

The levels of the two metabolites in processed spinach and similar leaves needs to be estimated. A processing study for spinach was assessed in the DAR for the approval of the active substance. The residue levels of cyantraniliprole, IN-N5M09 and IN-F6L99 found in spinach and cooked leaves are summarised in Table 3.4.2-5.

**Table 3.4.2-5 Production factors for IN-N5M09 and IN-F6L99 in cooked spinach**

| Trial    | Matrix      | Residues (mg/kg) |          |          | Production factor IN-N5M09 | Production factor IN-F6L99 |
|----------|-------------|------------------|----------|----------|----------------------------|----------------------------|
|          |             | Cyantraniliprole | IN-N5M09 | IN-F6L99 |                            |                            |
| Trial 35 | Spinach RAC | 4.600            | 0.010    | 0.010    | -                          | -                          |

| Trial                     | Matrix          | Residues (mg/kg) |          |          | Production factor IN-N5M09 | Production factor IN-F6L99 |
|---------------------------|-----------------|------------------|----------|----------|----------------------------|----------------------------|
|                           |                 | Cyantraniliprole | IN-N5M09 | IN-F6L99 |                            |                            |
|                           | Leaves – cooked | 0.800            | 0.020    | 0.010    | 0.004                      | 0.002                      |
| Trial 36                  | Spinach RAC     | 5.300            | 0.010    | 0.010    | -                          | -                          |
|                           | Leaves – cooked | 0.860            | 0.047    | 0.010    | 0.009                      | 0.002                      |
| Trial 37                  | Spinach RAC     | 10.00            | 0.010    | 0.010    | -                          | -                          |
|                           | Leaves – cooked | 0.900            | 0.085    | 0.015    | 0.009                      | 0.002                      |
| Median production factor: |                 |                  |          |          | 0.009                      | 0.002                      |

Taking into account the median production factors calculated in the table above, STMR-P and HR-P values have been derived in the table below for IN-N5M09 and IN-F6L99. The STMR-P and HR-P values are obtained by applying the production factor to the STMR and HR in the RAC. The STMR-P represents the median residues of IN-N5M09 and IN-F6L99 arising in the processed commodity.

**Table 3.4.2-6 Spinach – inputs for dietary risk assessment for metabolites IN-N5M09 & IN-F6L99**

| Commodity                                    | Metabolite | Median production factor | STMR RAC (mg/kg) | STMR-P (mg/kg)  | HR RAC (mg/kg) | HR-P (mg/kg)  |
|----------------------------------------------|------------|--------------------------|------------------|-----------------|----------------|---------------|
| Spinaches<br>Purslanes<br>Chards/beet leaves | IN-N5M09   | 0.009                    | 0.125            | <b>0.001125</b> | 0.6            | <b>0.0054</b> |
|                                              | IN-F6L99   | 0.002                    | 0.125            | <b>0.00025</b>  | 0.6            | <b>0.0012</b> |

#### Other commodities

The residue levels of IN-N5M09 and IN-F6L99 arising in processed commodities from other uses of cyantraniliprole have been estimated to perform chronic dietary risk assessments which account for all potential sources of the degradation products. All authorised uses of cyantraniliprole which may lead to the formation of IN-N5M09 and IN-F6L99 in processed commodities have been considered. The inputs are given in Table 3.4.2-7 with an explanation of the production factors used.

Commodities where the MRL is set at the limit of quantification/detection have not been included.

**Table 3.4.2-7 Inputs for all uses of cyantraniliprole for dietary risk assessment.**

| Commodity                | STMR RAC (mg/kg) | STMR-P (IN-N5M09) (mg/kg) | STMR-P (IN-F6L99) (mg/kg) | Comments                                                                                                                                                                                                                                    |
|--------------------------|------------------|---------------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Grapefruits              | 0.16             | 0.032                     | 0.022                     | There are relevant processed citrus fractions formed upon heating for fruits e.g. marmalade, therefore the production factors for apple sauce have been applied.                                                                            |
| Oranges                  | 0.16             | 0.032                     | 0.022                     |                                                                                                                                                                                                                                             |
| Lemons                   | 0.16             | 0.032                     | 0.022                     |                                                                                                                                                                                                                                             |
| Limes                    | 0.16             | 0.032                     | 0.022                     |                                                                                                                                                                                                                                             |
| Mandarins                | 0.16             | 0.032                     | 0.022                     |                                                                                                                                                                                                                                             |
| Others - Citrus Fruit    | 0.16             | 0.032                     | 0.022                     |                                                                                                                                                                                                                                             |
| Tree Nuts                | 0.01             | -                         | -                         | Whilst there are relevant processed fractions formed upon heating for tree nuts e.g. roasted/fried and oil, in both the olive and cotton seed processing studies, IN-N5M09 and IN-F6L99 were not detected/quantified in raw or refined oil. |
| Apples                   | 0.16             | 0.032                     | 0.022                     | The production factors for apple sauce have been used for all pome fruit.                                                                                                                                                                   |
| Pears                    | 0.16             | 0.032                     | 0.022                     |                                                                                                                                                                                                                                             |
| Quinces                  | 0.16             | 0.032                     | 0.022                     |                                                                                                                                                                                                                                             |
| Medlars                  | 0.16             | 0.032                     | 0.022                     |                                                                                                                                                                                                                                             |
| Loquats/Japanese medlars | 0.16             | 0.032                     | 0.022                     |                                                                                                                                                                                                                                             |
| Others - Pome fruit      | 0.16             | 0.032                     | 0.022                     |                                                                                                                                                                                                                                             |
| Cherries (sweet)         | 0.93             | 0.188                     | 0.128                     | Stone fruit can undergo boiling during processing therefore production factors for apple sauce have been applied.                                                                                                                           |
| Peaches                  | 0.34             | 0.069                     | 0.047                     |                                                                                                                                                                                                                                             |
| Plums                    | 0.12             | 0.024                     | 0.017                     |                                                                                                                                                                                                                                             |
| Table grapes             | 0.26             | 0.053                     | 0.036                     | Table grapes can undergo boiling during processing (relevant processed fractions e.g. jam/jelly) therefore production factors for apple sauce have been applied.                                                                            |
| Wine grapes              | 0.32             | -                         | -                         | In the grape processing study from the approval of the active substance, IN-N5M09 and IN-F6L99 were not detected in any wine fractions.                                                                                                     |

| <b>Commodity</b>                                     | <b>STMR<br/>RAC<br/>(mg/kg)</b> | <b>STMR-P<br/>(IN-<br/>N5M09)<br/>(mg/kg)</b> | <b>STMR-P<br/>(IN-<br/>F6L99)<br/>(mg/kg)</b> | <b>Comments</b>                                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------|---------------------------------|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Strawberries                                         | 0.455                           | 0.092                                         | 0.063                                         | Berries and small fruits can undergo boiling during processing (relevant. processed fractions e.g. jam/jelly) therefore production factors for apple sauce have been applied                                                                                                                                    |
| Blackberries                                         | 0.346                           | 0.07                                          | 0.048                                         |                                                                                                                                                                                                                                                                                                                 |
| Raspberries                                          | 0.346                           | 0.07                                          | 0.048                                         |                                                                                                                                                                                                                                                                                                                 |
| Blueberries                                          | 0.75                            | 0.152                                         | 0.104                                         |                                                                                                                                                                                                                                                                                                                 |
| Cranberries                                          | 0.012                           | 0.002                                         | 0.002                                         |                                                                                                                                                                                                                                                                                                                 |
| Currants<br>(black, red<br>and white)                | 0.75                            | 0.152                                         | 0.104                                         |                                                                                                                                                                                                                                                                                                                 |
| Gooseberries<br>(green, red<br>and yellow)           | 0.75                            | 0.152                                         | 0.104                                         |                                                                                                                                                                                                                                                                                                                 |
| Rose hips                                            | 0.75                            | 0.152                                         | 0.104                                         |                                                                                                                                                                                                                                                                                                                 |
| Azaroles/Medi<br>terranean<br>medlars                | 0.16                            | 0.032                                         | 0.022                                         |                                                                                                                                                                                                                                                                                                                 |
| Table olives                                         | 0.27                            | 0.055                                         | 0.037                                         | These fruit may undergo heating hence the production factors for apple sauce have been applied.                                                                                                                                                                                                                 |
| Kaki/Japanese<br>persimmons                          | 0.16                            | 0.032                                         | 0.022                                         |                                                                                                                                                                                                                                                                                                                 |
| Avocados                                             | 0.03                            | 0.006                                         | 0.004                                         |                                                                                                                                                                                                                                                                                                                 |
| Mangoes                                              | 0.01                            | 0.002                                         | 0.001                                         |                                                                                                                                                                                                                                                                                                                 |
| Root and<br>tuber<br>vegetables                      | 0.01                            | -                                             | -                                             | Whilst cooked vegetables are a relevant processed fraction, in the potato processing study from the approval of the active substance, IN-N5M09 and IN-F6L99 were not detected/quantified in any processed fractions and residues were <0.01 mg/kg in the majority of the supporting residue trials (FAO, 2013). |
| Garlic                                               | 0.02                            | 0.0002                                        | 0.00004                                       | There are no processing data which can be directly extrapolated to bulb vegetables. However, these vegetables can be subject to cooking hence the production factors for cooked spinach have been applied.                                                                                                      |
| Onions                                               | 0.02                            | 0.0002                                        | 0.00004                                       |                                                                                                                                                                                                                                                                                                                 |
| Shallots                                             | 0.02                            | 0.0002                                        | 0.00004                                       |                                                                                                                                                                                                                                                                                                                 |
| Spring<br>onions/green<br>onions and<br>Welsh onions | 1.3                             | 0.012                                         | 0.003                                         |                                                                                                                                                                                                                                                                                                                 |
| Others - bulb<br>vegetables                          | 0.02                            | 0.0002                                        | 0.00004                                       |                                                                                                                                                                                                                                                                                                                 |
| Tomatoes                                             | 0.17                            | 0.034                                         | 0.024                                         | For fruiting vegetables, the                                                                                                                                                                                                                                                                                    |

| <b>Commodity</b>                   | <b>STMR<br/>RAC<br/>(mg/kg)</b> | <b>STMR-P<br/>(IN-<br/>N5M09)<br/>(mg/kg)</b> | <b>STMR-P<br/>(IN-<br/>F6L99)<br/>(mg/kg)</b> | <b>Comments</b>                                                                                                           |
|------------------------------------|---------------------------------|-----------------------------------------------|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Sweet peppers/bell peppers         | 0.14                            | 0.028                                         | 0.019                                         | productions factors for apple sauce have been applied given these relate to processing of a fruit commodity.              |
| Aubergines/eggplants               | 0.14                            | 0.028                                         | 0.019                                         |                                                                                                                           |
| Okra/lady's fingers                | 0.14                            | 0.028                                         | 0.019                                         |                                                                                                                           |
| Others - Solanacea                 | 0.14                            | 0.028                                         | 0.019                                         |                                                                                                                           |
| Cucumbers                          | 0.08                            | 0.016                                         | 0.011                                         |                                                                                                                           |
| Gherkins                           | 0.08                            | 0.016                                         | 0.011                                         |                                                                                                                           |
| Courgettes                         | 0.08                            | 0.016                                         | 0.011                                         |                                                                                                                           |
| Others - Cucurbits-edible peel     | 0.08                            | 0.016                                         | 0.011                                         |                                                                                                                           |
| Melons                             | 0.06                            | 0.012                                         | 0.008                                         |                                                                                                                           |
| Pumpkins                           | 0.06                            | 0.012                                         | 0.008                                         |                                                                                                                           |
| Watermelons                        | 0.06                            | 0.012                                         | 0.008                                         |                                                                                                                           |
| Others - Cucurbits - inedible peel | 0.06                            | 0.012                                         | 0.008                                         |                                                                                                                           |
| Broccoli                           | 0.56                            | 0.005                                         | 0.001                                         | Cooked brassicas are a relevant processed fraction therefore the production factors for cooked spinach have been applied. |
| Cauliflowers                       | 0.56                            | 0.005                                         | 0.001                                         |                                                                                                                           |
| Others - Flowering Brassicas       | 0.56                            | 0.005                                         | 0.001                                         |                                                                                                                           |
| Brussels sprouts                   | 0.56                            | 0.005                                         | 0.001                                         |                                                                                                                           |
| Head cabbages                      | 0.56                            | 0.005                                         | 0.001                                         |                                                                                                                           |
| Others - Head Brassicas            | 0.56                            | 0.005                                         | 0.001                                         |                                                                                                                           |
| Chinese Cabbage                    | 2.7                             | 0.024                                         | 0.005                                         |                                                                                                                           |
| Kales                              | 1.075                           | 0.0097                                        | 0.0022                                        |                                                                                                                           |
| Kohlrabies                         | 0.56                            | 0.005                                         | 0.001                                         |                                                                                                                           |
| Lettuces                           | 0.79                            | -                                             | -                                             | Lettuce is not commonly consumed cooked.                                                                                  |
| Beans (with pods)                  | 0.29                            | 0.003                                         | 0.0006                                        | Cooked legume vegetables are a relevant processed fraction                                                                |

| <b>Commodity</b>                                                 | <b>STMR<br/>RAC<br/>(mg/kg)</b> | <b>STMR-P<br/>(IN-<br/>N5M09)<br/>(mg/kg)</b> | <b>STMR-P<br/>(IN-<br/>F6L99)<br/>(mg/kg)</b> | <b>Comments</b>                                                                                                                                                                                                  |
|------------------------------------------------------------------|---------------------------------|-----------------------------------------------|-----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Beans<br>(without pods)                                          | 0.07                            | 0.001                                         | 0.0001                                        | therefore the production factors for cooked spinach have been applied.                                                                                                                                           |
| Peas (with pods)                                                 | 0.7                             | 0.006                                         | 0.001                                         |                                                                                                                                                                                                                  |
| Peas (without pods)                                              | 0.07                            | 0.001                                         | 0.0001                                        |                                                                                                                                                                                                                  |
| Celeries                                                         | 2                               | 0.018                                         | 0.004                                         | Cooked stem vegetables are a relevant processed fraction therefore the production factors for cooked spinach have been applied.                                                                                  |
| Globe artichokes                                                 | 0.03                            | 0.0003                                        | 0.00006                                       |                                                                                                                                                                                                                  |
| Leek                                                             | 0.055                           | 0.000495                                      | 0.00011                                       |                                                                                                                                                                                                                  |
| Beans (dry)<br>Lentis (dry)<br>Peas (dry)<br>Lupins/lupini beans | 0.032                           | 0.0003                                        | 0.00006                                       | Cooked pulses are a relevant processed fraction therefore the production factors for cooked spinach have been applied.                                                                                           |
| Soyabean                                                         | 0.032                           | 0.0003                                        | 0.00006                                       | Whilst IN-N5M09 and IN-F6L99 are not expected to be relevant for soyabean oil; soyabeans may also be cooked and consumed in other forms. Therefore, the production factors for cooked spinach have been applied. |
| Sunflower seeds                                                  | 0.067                           | -                                             | -                                             | In the olive and cotton seed processing studies from the approval of the active substance, IN-N5M09 and IN-F6L99 were not detected/quantified in raw or refined oil.                                             |
| Rapeseeds/canola seeds                                           | 0.077                           | -                                             | -                                             |                                                                                                                                                                                                                  |
| Cotton seeds                                                     | 0.16                            | -                                             | -                                             |                                                                                                                                                                                                                  |
| Olives for oil production                                        | 0.27                            | -                                             | -                                             |                                                                                                                                                                                                                  |
| Rice                                                             | 0.01                            | -                                             | -                                             | Whilst rice can be cooked, in the supporting residues trials on rice all residues were <0.01 mg/kg (EFSA, 2016a).                                                                                                |
| Teas                                                             | 4.05                            | -                                             | -                                             | Whilst infusions from tea are relevant processed fractions, the processing studies from the approval of the active substance indicate that IN-N5M09 and IN F6L99 are not formed in potato cooking water.         |

| Commodity                         | STMR<br>RAC<br>(mg/kg) | STMR-P<br>(IN-<br>N5M09)<br>(mg/kg) | STMR-P<br>(IN-<br>F6L99)<br>(mg/kg) | Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------|------------------------|-------------------------------------|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Coffee beans                      | 0.01                   | -                                   | -                                   | Whilst coffee beans can be processed (including brewing), the processing studies from the approval of the active substance indicate that IN-N5M09 and IN-F6L99 are not formed in potato cooking water or spinach cooking water (which are considered the most relevant fractions for brewed coffee). (One residue of IN-F6L99 was detected at 0.011 mg/kg in spinach cooking water but the RAC was 10 mg/kg hence the production factor would be 0.0011 which, when applied to an LOQ STMR of 0.01 mg/kg, would lead to a negligible input). |
| Herbal infusions from dried roots | 0.08                   | -                                   | -                                   | Whilst infusions from dried roots are relevant processed fractions, the processing studies from the approval of the active substance indicate that IN-N5M09 and IN-F6L99 are not formed in potato cooking water.                                                                                                                                                                                                                                                                                                                             |
| Liquorice                         | 0.08                   | -                                   | -                                   | In the potato processing study from the approval of the active substance, IN-N5M09 and IN-F6L99 were not detected/quantified in any processed fractions and residues were <0.01 mg/kg in the majority of the supporting residue trials (FAO, 2013). The STMR is derived from application of a dehydration factor to the RAC in which STMR was at the LOQ (0.01 mg/kg).                                                                                                                                                                       |
| Turmeric/curcuma                  | 0.08                   | -                                   | -                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Others - Roots or rhizome         | 0.08                   | -                                   | -                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Sugar beet roots                  | 0.01                   | -                                   | -                                   | In the potato processing study from the approval of the active substance, IN-N5M09 and IN-F6L99 were not detected/quantified in any processed fractions and residues were <0.01 mg/kg in the majority of the supporting residue trials (FAO, 2013).                                                                                                                                                                                                                                                                                          |
| Chicory roots                     | 0.01                   | -                                   | -                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

## **Dietary exposure estimated for IN-N5M09 and IN-F6L99**

Exposure to each metabolite independently has been estimated on the basis of the STMR-P and HR-P values derived above and the consumption data in the UK model and the EFSA PRIMo model. In principle, processing data related to the MRLs already established for cyantraniliprole should be provided. However, the extrapolations applied to estimate metabolite levels are regarded as appropriate on the assumption that all commodities are consumed processed.

For the chronic exposure assessment using UK consumption data, the chronic assessment uses the 97.5<sup>th</sup> percentile consumption level of 'consumer only' for the two commodities which give the highest intake, and for the remaining commodities, the mean consumption of the total population group is used.

### **IN-N5M09**

The chronic exposure to IN-N5M09 is 1.121 µg/kg bw/day (Toddler) using UK consumption data and 0.89 µg/kg bw/day (DE child) using PRIMo consumption data.

The acute exposure to IN-N5M09 is 1.48 µg/kg bw/day (vegetarian / parsley (surrogate input for herbs) using UK consumption data and 1.6 µg/kg bw (children / chervil) using PRIMo consumption data.

### **IN-F6L99**

The chronic exposure to IN-F6L99 is 0.764 µg/kg bw/day (Toddler) using UK consumption data and 0.598 µg/kg bw (DE child) using PRIMo consumption data.

The acute exposure to IN-F6L99 is 0.00681 µg/kg bw (4-6 year old child/spinach) using UK consumption data and 0.037 µg/kg bw (Children / Chards/beet leaves / boiled) using PRIMo consumption data.

## **Conclusion on exposure to IN-N5M09 & IN-F6L99**

It was concluded in the ER/RO (HSE, 2022) that for both IN-N5M09 and IN-F6L99 the Cramer Class III TTC value of 1.5 µg/kg bw/d is applicable for the chronic dietary risk assessment and a value of 5 µg/kg bw is applicable for the acute dietary risk assessment, and that exposures do not need to be combined for IN-N5M09 and IN-F6L99 due to low plausibility for additive toxicity.

The calculated chronic exposures for both compounds, are lower than the TTC limits set for Cramer Class III substances. The acute exposures, for both compounds, are below the threshold value of 5 µg/kg bw that can be used for in compounds in Cramer Class III.

As the exposure estimates are all below the Cramer Class III TTC value of 1.5 µg/.kg bw/d for chronic dietary risk assessment and the threshold value of 5 µg/kg bw for acute dietary risk assessment, no chronic or acute health effects are expected from the consumption of processed commodities containing the metabolites IN-N5M09 and IN-F6L99.

The conclusion is only applicable to the uses considered in this application and in the previous assessments; the exposure estimates would need to be reconsidered for any additional uses or raised MRLs.

It is noted CXLs are available which would apply to spinach, purslane, and chards/beet leaves. As chronic consumer concerns are noted in Section 7, and the CXLs will not be adopted at this time in GB, no consideration of intake of IN-N5M09 and IN-F6L99 as a result of the CXL has been given. Should these CXLs be adopted at a later time consideration of processed metabolites will be required.

### 3.5 Rotational crops

The maximum DT<sub>90</sub> for cyantraniliprole from the approval of the active substance is 376 days and the maximum DT<sub>90</sub> values for several metabolites exceeds 500 days as shown in Table 3.2-1.

The DT<sub>50</sub>s and DT<sub>90</sub>s derived during the approval of the active substance for parent and several soil metabolites are presented in Table 3.2-1.

**Table 3.5-1 DT<sub>50</sub> and DT<sub>90</sub> values for cyantraniliprole and soil metabolites**

| Analyte          | DT <sub>50</sub> (days) | DT <sub>90</sub> (days) |
|------------------|-------------------------|-------------------------|
| Cyantraniliprole | 91.9                    | 376                     |
| IN-J9Z38         | 610                     | 2027                    |
| IN-JCZ38         | 133                     | 442                     |
| IN-JSE76         | 343                     | 1319                    |
| IN-K5A77         | 328                     | 1680                    |
| IN-K5A78         | 977                     | 3244                    |
| IN-K5A79         | 130                     | 432                     |
| IN-PLT97         | 711                     | 2363                    |

The crops under consideration may be grown in rotation.

Residues in rotational crops were considered in a previous GB ER-RO (HSE, 2023), where a GAP of 148 g/ha, with a 25% interception rate was considered. This is equivalent to the crops under consideration noting “Minecto One” is restricted to two applications per year.

No MRL issues are expected from rotation crops based on the previous evaluation. For further consideration of residues in rotational crop see the previously published ER-RO on various commodities (HSE, 2023)

## 4 Residues in livestock

No consideration of residues in products of animal origin is required as the crops are not used as animal feedstuffs. It was noted that residues may arise in feed commodities grown in rotation. However, no increase in residues in feed commodities grown in rotation is expected from the proposed cGAP.

For further consideration of residues in livestock, see the previously published ER-RO on various commodities (HSE, 2023)

## **5 Residues in honey**

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

## **6 MRLs for products not covered in Sections 3 and 4**

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 model and the EFSA PRIMo.

Chronic dietary exposures have been estimated based on the uses of cyantraniliprole considered in this application, the uses considered in previous assessments supporting existing GB MRLs (GB ER-RO (2023/005), GB ER-RO (2025/001), and, for the remaining commodities, the existing MRLs established in the GB MRL Statutory Register.

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

Two scenarios have been presented for the consumer risk assessment to investigate both the recommended MRLs supposed in the current assessment, and the impact of adopting the available CXLs relevant to the commodities under consideration

- **Scenario 1:** Consumer risk assessment with CXLs
- **Scenario 2:** Consumer risk assessment with supported GB MRLs.

#### **Scenario 1: Consumer risk assessment with consideration of CXLs**

##### **UK NEDIs**

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

- For the NEDIs, the 'Rees-Day' approach is taken which sums the two highest 97.5<sup>th</sup> 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.

As there is no consumption data for lamb lettuce, baby leaf lettuce, fresh herbs, and dewberries in the UK models, the consumption data for lettuce, parsley, and loganberries has been used, respectively, to ensure that appropriate consumption values are used in the consumer risk assessments.

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**

**Plant risk assessment residue definition:** cyantraniliprole

**Animal risk assessment residue definition:** sum of cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole

| Commodity          | Chronic risk assessment |                                     |
|--------------------|-------------------------|-------------------------------------|
|                    | Input (mg/kg)           | Comment                             |
| <b>Cress</b>       | <b>4.7</b>              | <b>FAO, 2014</b>                    |
| <b>Lettuce (a)</b> | <b>4.7</b>              | <b>FAO, 2014</b>                    |
| <b>Spinach</b>     | <b>4.7</b>              | <b>FAO, 2014</b>                    |
| <b>Chicory</b>     | <b>4.7</b>              | <b>FAO, 2014</b>                    |
| <b>Parsley (b)</b> | <b>4.7</b>              | <b>FAO, 2014</b>                    |
| Grapefruit         | 0.016                   | STMR (0.16) x PF (0.1) (EFSA, 2014) |
| Lemons             | 0.016                   | STMR (0.16) x PF (0.1) (EFSA, 2014) |
| Limes              | 0.016                   | STMR (0.16) x PF (0.1) (EFSA, 2014) |
| Mandarins          | 0.016                   | STMR (0.16) x PF (0.1) (EFSA, 2014) |
| Oranges            | 0.016                   | STMR (0.16) x PF (0.1) (EFSA, 2014) |
| Almonds            | 0.01                    | STMR (FAO, 2015)                    |
| Brazil nuts        | 0.01                    | STMR (FAO, 2015)                    |
| Cashew nuts        | 0.01                    | STMR (FAO, 2015)                    |
| Chestnuts          | 0.01                    | STMR (FAO, 2015)                    |
| Coconuts           | 0.01                    | STMR (FAO, 2015)                    |
| Hazelnuts          | 0.01                    | STMR (FAO, 2015)                    |
| Pecan nuts         | 0.01                    | STMR (FAO, 2015)                    |
| Pistachios         | 0.01                    | STMR (FAO, 2015)                    |
| Walnuts            | 0.01                    | STMR (FAO, 2015)                    |
| Peanuts            | 0.01                    | STMR (FAO, 2015)                    |
| Apples             | 0.16                    | STMR (FAO, 2013)                    |
| Pears              | 0.16                    | STMR (FAO, 2013)                    |
| Peaches            | 0.34                    | STMR (FAO, 2013)                    |

| Commodity      | Chronic       | risk assessment                   |
|----------------|---------------|-----------------------------------|
|                | Input (mg/kg) | Comment                           |
| Plums          | 0.12          | STMR (EFSA, 2014)                 |
| Cherries       | 0.93          | STMR (FAO, 2013)                  |
| Table grapes   | 0.26          | STMR (EFSA, 2016b)                |
| Wine grapes    | 0.32          | STMR x PF x YF (0.7) (EFSA, 2014) |
| Strawberries   | 0.46          | STMR (FAO, 2018)                  |
| Blackberries   | 0.346         | STMR (HSE, 2022)                  |
| Raspberries    | 0.346         | STMR (HSE, 2022)                  |
| Gooseberries   | 0.75          | STMR (FAO, 2013)                  |
| Blackcurrants  | 0.75          | STMR (FAO, 2013)                  |
| Red currants   | 0.75          | STMR (FAO, 2013)                  |
| White currants | 0.75          | STMR (FAO, 2013)                  |
| Avocadoes      | 0.03          | STMR (HSE,2025)                   |
| Mangoes        | 0.01          | STMR (FAO, 2018)                  |
| Olives         | 0.27          | STMR (EFSA, 2014)                 |
| Garlic         | 0.02          | STMR (FAO, 2013)                  |
| Onions         | 0.02          | STMR (FAO, 2013)                  |
| Spring onions  | 1.3           | STMR (FAO, 2013)                  |
| Tomatoes       | 0.17          | STMR (EFSA, 2014)                 |
| Peppers        | 0.14          | STMR (EFSA, 2014)                 |
| Aubergines     | 0.14          | STMR (EFSA, 2014)                 |
| Marrows        | 0.08          | STMR (EFSA, 2014)                 |
| Cucumbers      | 0.08          | STMR (EFSA, 2014)                 |
| Gourd          | 0.08          | STMR (EFSA, 2014)                 |
| Courgettes     | 0.08          | STMR (EFSA, 2014)                 |
| Melons         | 0.06          | STMR (EFSA, 2014)                 |
| Broccoli       | 0.56          | STMR (FAO, 2013)                  |
| Cauliflower    | 0.56          | STMR (FAO, 2013)                  |

| Commodity                  | Chronic       | risk assessment                                             |
|----------------------------|---------------|-------------------------------------------------------------|
|                            | Input (mg/kg) | Comment                                                     |
| Brussels sprouts           | 0.56          | STMR (FAO, 2013)                                            |
| Kale → Head cabbage (c)    | 1.72          | STMR (1.075) x Pf (0.2) x CF (8) (HSE, 2023)                |
| Chinese cabbage            | 4.32          | STMR <sub>Enf</sub> (2.7) x Pf (0.2) x CF (8) (HSE, 2023)   |
| Kohl Rabi                  | 0.56          | STMR (FAO, 2013)                                            |
| Beans with pods            | 0.29          | STMR (FAO, 2015)                                            |
| Runner beans               | 0.29          | STMR (FAO, 2015)                                            |
| Beans without pods         | 0.07          | STMR (FAO, 2015)                                            |
| Peas with pods             | 0.7           | STMR (FAO, 2015)                                            |
| Peas without pods          | 0.07          | STMR (FAO, 2015)                                            |
| Celery                     | 2.0           | STMR (FAO, 2013)                                            |
| Globe artichokes           | 0.03          | STMR (EFSA, 2015)                                           |
| Leeks                      | 0.088         | STMR <sub>Enf</sub> (0.055) x Pf (0.2) x CF (8) (HSE, 2023) |
| Beans                      | 0.032         | STMR (HSE, 2025)                                            |
| Lentils                    | 0.032         | STMR (HSE, 2025)                                            |
| Dried peas                 | 0.032         | STMR (HSE, 2025)                                            |
| Oilseeds                   | 0.27          | STMR (EFSA, 2014) – based on olives for oil production      |
| Potatoes                   | 0.01          | STMR (FAO, 2013)                                            |
| Tea (dried leaves)         | 4.05          | STMR (HSE, 2025)                                            |
| Sugar beet                 | 0.01          | STMR (FAO, 2013)                                            |
| Poultry                    | 0.0039        | STMR (FAO, 2015) (d)                                        |
| Meat fat                   | 0.1           | STMR (FAO, 2015) (d)                                        |
| Meat excl. poultry & offal | 0.041         | STMR (FAO, 2015) (d)                                        |
| All types of kidney        | 0.38          | STMR (FAO, 2015) (d)                                        |
| All types of Liver         | 0.38          | STMR (FAO, 2015) (d)                                        |
| Other types of offal       | 0.38          | STMR (FAO, 2015) (d)                                        |

| Commodity                          | Chronic risk assessment                                |                      |
|------------------------------------|--------------------------------------------------------|----------------------|
|                                    | Input (mg/kg)                                          | Comment              |
| Eggs                               | 0.048                                                  | STMR (HSE, 2025) (d) |
| Milk                               | 0.05                                                   | STMR (HSE, 2023)     |
| Other plant and animal commodities | GB MRL Statutory Register and GB decision no. 2025/001 |                      |

**In bold** uses proposed as part of the current assessment.

(a) For lamb lettuce, and baby-leaf lettuce, the available consumption data is limited in the UK models. Therefore lettuce has been used to ensure that appropriate consumption values are used in the consumer risk assessment.

(b) For herbs and edible flowers, the available consumption data is limited in the UK models. Therefore parsley has been used to ensure that appropriate consumption values are used in the consumer risk assessment.

(c) For kale, the available consumption data is limited in the UK models. Therefore, head cabbage has been used to ensure that appropriate consumption values are used in the consumer risk assessments.

(d) Residue values in the FAO (2013, 2015 & HSE 2025) estimations of STMRs in products of animal origin are the sum of cyantraniliprole and metabolites IN-N7B69, IN-J9Z38, IN-MLA84 and IN-MYX98, expressed as cyantraniliprole. The range of metabolites in the FAO estimated STMRs is broader than the GB risk assessment residue definition; however, these values are considered appropriate for use in the exposure calculation.

Model outputs for the UK chronic calculator (versions 1.1) is presented in Appendix B.

### PRIMo

The PRIMo IEDIs 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

**Plant risk assessment residue definition:** cyantraniliprole

**Animal risk assessment residue definition:** sum of cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole

| Commodity                                    | Chronic       | risk assessment                   |
|----------------------------------------------|---------------|-----------------------------------|
|                                              | Input (mg/kg) | Comment                           |
| Lamb's lettuce/corn salads                   | 4.7           | FAO, 2014                         |
| Escaroles/broad-leaved endives               | 4.7           | FAO, 2014                         |
| Cress and other sprouts and shoot            | 4.7           | FAO, 2014                         |
| Land cress                                   | 4.7           | FAO, 2014                         |
| Roman rocket/rucola                          | 4.7           | FAO, 2014                         |
| Red mustard                                  | 4.7           | FAO, 2014                         |
| Baby leaf crops (including brassica species) | 4.7           | FAO, 2014                         |
| Spinaches                                    | 4.7           | FAO, 2014                         |
| Purslanes                                    | 4.7           | FAO, 2014                         |
| Chards/beet leaves                           | 4.7           | FAO, 2014                         |
| Herbs and edible flowers (except chervil)    | 1.149         | STMR (Current Assessment)         |
| Chervil                                      | 4.7           | FAO, 2014                         |
| Citrus fruit                                 | 0.016         | STMR x PF (EFSA, 2014)            |
| Tree nuts                                    | 0.01          | STMR (FAO, 2015)                  |
| Pome fruit                                   | 0.16          | STMR (FAO, 2013)                  |
| Cherries                                     | 0.93          | STMR (FAO, 2013)                  |
| Peaches                                      | 0.34          | STMR (FAO, 2013)                  |
| Plums                                        | 0.12          | STMR (EFSA, 2014)                 |
| Table grapes                                 | 0.26          | STMR (EFSA, 2016b)                |
| Wine grapes                                  | 0.32          | STMR x PF x YF (0.7) (EFSA, 2014) |
| Strawberries                                 | 0.46          | STMR (FAO, 2018)                  |
| Blackberries                                 | 0.346         | STMR (HSE, 2022)                  |
| Raspberries (red and yellow)                 | 0.346         | STMR (HSE, 2022)                  |
| Blueberries                                  | 0.75          | STMR (FAO, 2013)                  |

| Commodity                            | Chronic       | risk assessment                                             |
|--------------------------------------|---------------|-------------------------------------------------------------|
|                                      | Input (mg/kg) | Comment                                                     |
| Cranberries                          | 0.012         | STMR (FAO, 2018)                                            |
| Currants (black, red and white)      | 0.75          | STMR (FAO, 2013)                                            |
| Gooseberries (green, red and yellow) | 0.75          | STMR (FAO, 2013)                                            |
| Rose hips                            | 0.75          | STMR (FAO, 2013)                                            |
| Azarole/Mediterranean medlars        | 0.16          | STMR (FAO, 2013)                                            |
| Table olives                         | 0.27          | STMR (EFSA, 2014)                                           |
| Kaki/Japanese persimmons             | 0.16          | STMR (FAO, 2013)                                            |
| Mangoes                              | 0.01          | STMR (FAO, 2018)                                            |
| Avocadoes                            | 0.03          | STMR (HSE, 2025)                                            |
| Root and tuber vegetables            | 0.01          | STMR (FAO, 2013)                                            |
| Garlic                               | 0.02          | STMR (FAO, 2013)                                            |
| Onions                               | 0.02          | STMR (FAO, 2013)                                            |
| Shallots                             | 0.02          | STMR (FAO, 2013)                                            |
| Spring onions/green onions and Welsh | 1.3           | STMR (FAO, 2013)                                            |
| Other bulb vegetables                | 0.02          | STMR (FAO, 2013)                                            |
| Tomatoes                             | 0.17          | STMR (EFSA, 2014)                                           |
| Sweet peppers/bell peppers           | 0.14          | STMR (EFSA, 2014)                                           |
| Aubergines/egg plants                | 0.14          | STMR (EFSA, 2014)                                           |
| Okra/lady's fingers                  | 0.14          | STMR (EFSA, 2014)                                           |
| Other solanacea                      | 0.14          | STMR (EFSA, 2014)                                           |
| Cucurbits – edible peel              | 0.08          | STMR (EFSA, 2014)                                           |
| Cucurbits – inedible peel            | 0.06          | STMR (EFSA, 2014)                                           |
| Flowering brassica                   | 0.56          | STMR (FAO, 2013)                                            |
| Head brassica                        | 0.56          | STMR (FAO, 2013)                                            |
| Chinese cabbages/pe-tsai             | 4.32          | STMR <sub>Enf</sub> (2.7) x Pf (0.2) x CF (8) (HSE, 2023)   |
| Kales                                | 1.72          | STMR <sub>Enf</sub> (1.075) x Pf (0.2) x CF (8) (HSE, 2023) |

| Commodity                                                                         | Chronic       | risk assessment                                             |
|-----------------------------------------------------------------------------------|---------------|-------------------------------------------------------------|
|                                                                                   | Input (mg/kg) | Comment                                                     |
| Kohlrabies                                                                        | 0.56          | STMR (FAO, 2013)                                            |
| Lettuces                                                                          | 0.79          | STMR (FAO, 2013)                                            |
| Beans (with pods)                                                                 | 0.29          | STMR (FAO, 2015)                                            |
| Beans (without pods)                                                              | 0.07          | STMR (FAO, 2015)                                            |
| Peas (with pods)                                                                  | 0.7           | STMR (FAO, 2015)                                            |
| Peas (without pods)                                                               | 0.07          | STMR (FAO, 2015)                                            |
| Celeries                                                                          | 2.00          | STMR (FAO, 2013)                                            |
| Globe artichokes                                                                  | 0.03          | STMR (EFSA, 2015)                                           |
| Leeks                                                                             | 0.088         | STMR <sub>Enf</sub> (0.055) x Pf (0.2) x CF (8) (HSE, 2023) |
| Beans                                                                             | 0.032         | STMR (HSE, 2025)                                            |
| Lentils                                                                           | 0.032         | STMR (HSE, 2025)                                            |
| Peas                                                                              | 0.032         | STMR (HSE, 2025)                                            |
| Lupins/lupini beans                                                               | 0.032         | STMR (HSE, 2025)                                            |
| Sunflower seeds                                                                   | 0.067         | STMR (FAO, 2015)                                            |
| Rapeseeds/canola seeds                                                            | 0.077         | STMR (FAO, 2015)                                            |
| Soyabeans                                                                         | 0.032         | STMR (HSE, 2025)                                            |
| Cotton seeds                                                                      | 0.16          | STMR (FAO, 2015)                                            |
| Olives for oil production                                                         | 0.27          | STMR (EFSA, 2014)                                           |
| Tea (dried leaves)                                                                | 4.05          | STMR (HSE, 2025)                                            |
| Coffee beans                                                                      | 0.01          | STMR (EFSA, 2016a)                                          |
| Herbal infusion (dried roots)                                                     | 0.08          | STMR (EFSA, 2015)                                           |
| Spices (roots or rhizome)                                                         | 0.08          | STMR (EFSA, 2015)                                           |
| Sugar beet root                                                                   | 0.01          | STMR (FAO, 2013)                                            |
| Chicory root                                                                      | 0.01          | STMR (FAO, 2013)                                            |
| Swine, bovine, sheep, goat, equine, other farmed terrestrial animals: muscle/meat | 0.041         | STMR (FAO, 2015) (a)                                        |

| Commodity                                                                                          | Chronic                                                | risk assessment      |
|----------------------------------------------------------------------------------------------------|--------------------------------------------------------|----------------------|
|                                                                                                    | Input (mg/kg)                                          | Comment              |
| Swine, bovine, sheep, goat, equine, other farmed terrestrial animals: fat                          | 0.1                                                    | STMR (FAO, 2015) (a) |
| Swine, bovine, sheep, goat, equine, other farmed terrestrial animals: liver, kidney, edible offals | 0.38                                                   | STMR (FAO, 2015) (a) |
| Poultry: muscle/meat                                                                               | 0.0039                                                 | STMR (FAO, 2015) (a) |
| Poultry: fat                                                                                       | 0.0083                                                 | STMR (FAO, 2015) (a) |
| Poultry: liver, kidney, edible offals                                                              | 0.0321                                                 | STMR (FAO, 2015) (a) |
| Milk: Cattle                                                                                       | 0.05                                                   | STMR (HSE, 2023)     |
| Milk: Sheep                                                                                        | 0.03                                                   | STMR (HSE, 2023)     |
| Milk: Goat                                                                                         | 0.03                                                   | STMR (HSE, 2023)     |
| Milk: Horse                                                                                        | 0.03                                                   | STMR (HSE, 2023)     |
| Milk: Others                                                                                       | 0.03                                                   | STMR (HSE, 2023)     |
| Birds eggs                                                                                         | 0.048                                                  | STMR (HSE, 2025) (a) |
| Other plant and animal commodities                                                                 | GB MRL Statutory Register and GB decision no. 2025/001 |                      |

\* indicates residue at LOQ

(a) Residue values in the FAO (2013, 2015 & HSE, 2025) estimations of STMRs in products of animal origin are the sum of cyantraniliprole and metabolites IN-N7B69, IN-J9Z38, IN-MLA84 and IN-MYX98, expressed as cyantraniliprole. The range of metabolites in the FAO estimated STMRs is broader than the GB risk assessment residue definition; however, these values are considered appropriate for use in the exposure calculation.

**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 150% of the ADI (Toddler). The highest PRIMo IEDI was 133% of the ADI (NL toddler). Therefore, a chronic intake concern has been identified from exposure to cyantraniliprole from all dietary sources.

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

Chronic intake concerns have been identified, this is driven by the inputs for lettuces and salad plants (except cress/land cress), and spinaches and similar leaves as such the CXL cannot be adopted for these commodities. The inputs for cress/land cress and chervil have low relevance to the overall exposure; the CXL input applied to these three commodities does not result in chronic exceedances. As such, the CXL has been included in scenario 2 for cress and other sprouts and shoots, land cress, and chervil in scenario 2.

## **Scenario 2: Consumer risk assessment with consideration of the supported GB MRLs & CXLs for cresses and other sprouts, lands cress and chervils**

### **UK NEDIs**

The UK NEDIs for the active substance and commodities listed in Table 7.1-3 have been estimated for ten consumer groups using the UK chronic (versions 1.1 as detailed in Regulatory Update 21/2005). The following assumptions have been made:

- For the NEDIs, the 'Rees-Day' approach is taken which sums the two highest 97.5<sup>th</sup> 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 7.1-3.
- There is no loss of residue during transport, storage or processing of foods prior to consumption.

As there is no consumption data for lamb lettuce, baby leaf lettuce, fresh herbs, and dewberries in the UK models, the consumption data for lettuce, parsley, and loganberries has been used, respectively, to ensure that appropriate consumption values are used in the consumer risk assessments.

The input values for the UK consumer risk assessment are given in Table 7.1-3.

**Table 7.1-3 Input values for the UK consumer risk assessment**

**Plant risk assessment residue definition:** cyantraniliprole

**Animal risk assessment residue definition:** sum of cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole

| Commodity          | Chronic risk assessment |                                  |
|--------------------|-------------------------|----------------------------------|
|                    | Input (mg/kg)           | Comment                          |
| <b>Cress</b>       | <b>4.7</b>              | <b>FAO, 2014</b>                 |
| <b>Lettuce (a)</b> | <b>2.658</b>            | <b>STMR (Current assessment)</b> |
| <b>Spinach</b>     | <b>0.125</b>            | <b>STMR (Current assessment)</b> |
| <b>Chicory</b>     | <b>1.149</b>            | <b>STMR (Current assessment)</b> |

| Commodity          | Chronic       | risk assessment                     |
|--------------------|---------------|-------------------------------------|
|                    | Input (mg/kg) | Comment                             |
| <b>Parsley (b)</b> | <b>4.7</b>    | <b>FAO, 2014</b>                    |
| Grapefruit         | 0.016         | STMR (0.16) x PF (0.1) (EFSA, 2014) |
| Lemons             | 0.016         | STMR (0.16) x PF (0.1) (EFSA, 2014) |
| Limes              | 0.016         | STMR (0.16) x PF (0.1) (EFSA, 2014) |
| Mandarins          | 0.016         | STMR (0.16) x PF (0.1) (EFSA, 2014) |
| Oranges            | 0.016         | STMR (0.16) x PF (0.1) (EFSA, 2014) |
| Almonds            | 0.01          | STMR (FAO, 2015)                    |
| Brazil nuts        | 0.01          | STMR (FAO, 2015)                    |
| Cashew nuts        | 0.01          | STMR (FAO, 2015)                    |
| Chestnuts          | 0.01          | STMR (FAO, 2015)                    |
| Coconuts           | 0.01          | STMR (FAO, 2015)                    |
| Hazelnuts          | 0.01          | STMR (FAO, 2015)                    |
| Pecan nuts         | 0.01          | STMR (FAO, 2015)                    |
| Pistachios         | 0.01          | STMR (FAO, 2015)                    |
| Walnuts            | 0.01          | STMR (FAO, 2015)                    |
| Peanuts            | 0.01          | STMR (FAO, 2015)                    |
| Apples             | 0.16          | STMR (FAO, 2013)                    |
| Pears              | 0.16          | STMR (FAO, 2013)                    |
| Peaches            | 0.34          | STMR (FAO, 2013)                    |
| Plums              | 0.12          | STMR (EFSA, 2014)                   |
| Cherries           | 0.93          | STMR (FAO, 2013)                    |
| Table grapes       | 0.26          | STMR (EFSA, 2016b)                  |
| Wine grapes        | 0.32          | STMR x PF x YF (0.7) (EFSA, 2014)   |
| Strawberries       | 0.46          | STMR (FAO, 2018)                    |
| Blackberries       | 0.346         | STMR (HSE, 2022)                    |
| Raspberries        | 0.346         | STMR (HSE, 2022)                    |
| Gooseberries       | 0.75          | STMR (FAO, 2013)                    |

| Commodity               | Chronic       | risk assessment                                           |
|-------------------------|---------------|-----------------------------------------------------------|
|                         | Input (mg/kg) | Comment                                                   |
| Blackcurrants           | 0.75          | STMR (FAO, 2013)                                          |
| Red currants            | 0.75          | STMR (FAO, 2013)                                          |
| White currants          | 0.75          | STMR (FAO, 2013)                                          |
| Avocadoes               | 0.03          | STMR (HSE,2025)                                           |
| Mangoes                 | 0.01          | STMR (FAO, 2018)                                          |
| Olives                  | 0.27          | STMR (EFSA, 2014)                                         |
| Garlic                  | 0.02          | STMR (FAO, 2013)                                          |
| Onions                  | 0.02          | STMR (FAO, 2013)                                          |
| Spring onions           | 1.3           | STMR (FAO, 2013)                                          |
| Tomatoes                | 0.17          | STMR (EFSA, 2014)                                         |
| Peppers                 | 0.14          | STMR (EFSA, 2014)                                         |
| Aubergines              | 0.14          | STMR (EFSA, 2014)                                         |
| Marrows                 | 0.08          | STMR (EFSA, 2014)                                         |
| Cucumbers               | 0.08          | STMR (EFSA, 2014)                                         |
| Gourd                   | 0.08          | STMR (EFSA, 2014)                                         |
| Courgettes              | 0.08          | STMR (EFSA, 2014)                                         |
| Melons                  | 0.06          | STMR (EFSA, 2014)                                         |
| Broccoli                | 0.56          | STMR (FAO, 2013)                                          |
| Cauliflower             | 0.56          | STMR (FAO, 2013)                                          |
| Brussels sprouts        | 0.56          | STMR (FAO, 2013)                                          |
| Kale → Head cabbage (c) | 1.72          | STMR (1.075) x Pf (0.2) x CF (8) (HSE, 2023)              |
| Chinese cabbage         | 4.32          | STMR <sub>Enf</sub> (2.7) x Pf (0.2) x CF (8) (HSE, 2023) |
| Kohl Rabi               | 0.56          | STMR (FAO, 2013)                                          |
| Beans with pods         | 0.29          | STMR (FAO, 2015)                                          |
| Runner beans            | 0.29          | STMR (FAO, 2015)                                          |
| Beans without pods      | 0.07          | STMR (FAO, 2015)                                          |

| Commodity                          | Chronic                                                | risk assessment                                             |
|------------------------------------|--------------------------------------------------------|-------------------------------------------------------------|
|                                    | Input (mg/kg)                                          | Comment                                                     |
| Peas with pods                     | 0.7                                                    | STMR (FAO, 2015)                                            |
| Peas without pods                  | 0.07                                                   | STMR (FAO, 2015)                                            |
| Celery                             | 2.0                                                    | STMR (FAO, 2013)                                            |
| Globe artichokes                   | 0.03                                                   | STMR (EFSA, 2015)                                           |
| Leeks                              | 0.088                                                  | STMR <sub>Enf</sub> (0.055) x Pf (0.2) x CF (8) (HSE, 2023) |
| Beans                              | 0.032                                                  | STMR (HSE, 2025)                                            |
| Lentils                            | 0.032                                                  | STMR (HSE, 2025)                                            |
| Dried peas                         | 0.032                                                  | STMR (HSE, 2025)                                            |
| Oilseeds                           | 0.27                                                   | STMR (EFSA, 2014) – based on olives for oil production      |
| Potatoes                           | 0.01                                                   | STMR (FAO, 2013)                                            |
| Tea (dried leaves)                 | 4.05                                                   | STMR (HSE, 2025)                                            |
| Sugar beet                         | 0.01                                                   | STMR (FAO, 2013)                                            |
| Poultry                            | 0.0039                                                 | STMR (FAO, 2015) (d)                                        |
| Meat fat                           | 0.1                                                    | STMR (FAO, 2015) (d)                                        |
| Meat excl. poultry & offal         | 0.041                                                  | STMR (FAO, 2015) (d)                                        |
| All types of kidney                | 0.38                                                   | STMR (FAO, 2015) (d)                                        |
| All types of Liver                 | 0.38                                                   | STMR (FAO, 2015) (d)                                        |
| Other types of offal               | 0.38                                                   | STMR (FAO, 2015) (d)                                        |
| Eggs                               | 0.048                                                  | STMR (HSE, 2025) (d)                                        |
| Milk                               | 0.05                                                   | STMR (HSE, 2023)                                            |
| Other plant and animal commodities | GB MRL Statutory Register and GB decision no. 2025/001 |                                                             |

**In bold** uses proposed as part of the current assessment.

(a) For lamb lettuce, and baby-leaf lettuce, the available consumption data is limited in the UK models. Therefore lettuce has been used to ensure that appropriate consumption values are used in the consumer risk assessment.

(b) For herbs and edible flowers, the available consumption data is limited in the UK models. Therefore parsley has been used to ensure that appropriate consumption values are used in the consumer risk assessment.

(c) For kale, the available consumption data is limited in the UK models. Therefore, head cabbage has been used to ensure that appropriate consumption values are used in the consumer risk assessments.

(d) Residue values in the FAO (2013, 2015 & HSE 2025) estimations of STMRs in products of animal origin are the sum of cyantraniliprole and metabolites IN-N7B69, IN-J9Z38, IN-MLA84 and IN-MYX98, expressed as cyantraniliprole. The range of metabolites in the FAO estimated STMRs is broader than the GB risk assessment residue definition; however, these values are considered appropriate for use in the exposure calculation.

Model outputs for the UK chronic calculator (versions 1.1) is presented in Appendix B.

## PRIMo

The PRIMo IEDIs for the active substance and commodities listed in Table 7.1-4 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 7.1-4.
- 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 7.1-4.

**Table 7.1-4 Input values for the PRIMo consumer risk assessment**

**Plant risk assessment residue definition:** cyantraniliprole

**Animal risk assessment residue definition:** sum of cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole

| Commodity                         | Chronic       | risk assessment           |
|-----------------------------------|---------------|---------------------------|
|                                   | Input (mg/kg) | Comment                   |
| Lamb's lettuce/corn salads        | 2.658         | STMR (Current Assessment) |
| Escaroles/broad-leaved endives    | 1.149         | STMR (Current Assessment) |
| Cress and other sprouts and shoot | 4.7           | FAO, 2014                 |
| Land cress                        | 4.7           | FAO, 2014                 |
| Roman rocket/rucola               | 2.658         | STMR (Current Assessment) |
| Red mustard                       | 2.658         | STMR (Current Assessment) |

| Commodity                                           | Chronic       | risk assessment                   |
|-----------------------------------------------------|---------------|-----------------------------------|
|                                                     | Input (mg/kg) | Comment                           |
| <b>Baby leaf crops (including brassica species)</b> | <b>2.658</b>  | <b>STMR (Current Assessment)</b>  |
| <b>Spinaches</b>                                    | <b>0.125</b>  | <b>STMR (Current Assessment)</b>  |
| <b>Purslanes</b>                                    | <b>0.125</b>  | <b>STMR (Current Assessment)</b>  |
| <b>Chards/beet leaves</b>                           | <b>0.125</b>  | <b>STMR (Current Assessment)</b>  |
| <b>Herbs and edible flowers (except chervil)</b>    | <b>1.149</b>  | <b>STMR (Current Assessment)</b>  |
| <b>Chervil</b>                                      | <b>4.7</b>    | <b>FAO, 2014</b>                  |
| Citrus fruit                                        | 0.016         | STMR x PF (EFSA, 2014)            |
| Tree nuts                                           | 0.01          | STMR (FAO, 2015)                  |
| Pome fruit                                          | 0.16          | STMR (FAO, 2013)                  |
| Cherries                                            | 0.93          | STMR (FAO, 2013)                  |
| Peaches                                             | 0.34          | STMR (FAO, 2013)                  |
| Plums                                               | 0.12          | STMR (EFSA, 2014)                 |
| Table grapes                                        | 0.26          | STMR (EFSA, 2016b)                |
| Wine grapes                                         | 0.32          | STMR x PF x YF (0.7) (EFSA, 2014) |
| Strawberries                                        | 0.46          | STMR (FAO, 2018)                  |
| Blackberries                                        | 0.346         | STMR (HSE, 2022)                  |
| Raspberries (red and yellow)                        | 0.346         | STMR (HSE, 2022)                  |
| Blueberries                                         | 0.75          | STMR (FAO, 2013)                  |
| Cranberries                                         | 0.012         | STMR (FAO, 2018)                  |
| Currants (black, red and white)                     | 0.75          | STMR (FAO, 2013)                  |
| Gooseberries (green, red and yellow)                | 0.75          | STMR (FAO, 2013)                  |
| Rose hips                                           | 0.75          | STMR (FAO, 2013)                  |
| Azarole/Mediterranean medlars                       | 0.16          | STMR (FAO, 2013)                  |
| Table olives                                        | 0.27          | STMR (EFSA, 2014)                 |
| Kaki/Japanese persimmons                            | 0.16          | STMR (FAO, 2013)                  |

| Commodity                            | Chronic       | risk assessment                                             |
|--------------------------------------|---------------|-------------------------------------------------------------|
|                                      | Input (mg/kg) | Comment                                                     |
| Mangoes                              | 0.01          | STMR (FAO, 2018)                                            |
| Avocadoes                            | 0.03          | STMR (HSE, 2025)                                            |
| Root and tuber vegetables            | 0.01          | STMR (FAO, 2013)                                            |
| Garlic                               | 0.02          | STMR (FAO, 2013)                                            |
| Onions                               | 0.02          | STMR (FAO, 2013)                                            |
| Shallots                             | 0.02          | STMR (FAO, 2013)                                            |
| Spring onions/green onions and Welsh | 1.3           | STMR (FAO, 2013)                                            |
| Other bulb vegetables                | 0.02          | STMR (FAO, 2013)                                            |
| Tomatoes                             | 0.17          | STMR (EFSA, 2014)                                           |
| Sweet peppers/bell peppers           | 0.14          | STMR (EFSA, 2014)                                           |
| Aubergines/egg plants                | 0.14          | STMR (EFSA, 2014)                                           |
| Okra/lady's fingers                  | 0.14          | STMR (EFSA, 2014)                                           |
| Other solanacea                      | 0.14          | STMR (EFSA, 2014)                                           |
| Cucurbits – edible peel              | 0.08          | STMR (EFSA, 2014)                                           |
| Cucurbits – inedible peel            | 0.06          | STMR (EFSA, 2014)                                           |
| Flowering brassica                   | 0.56          | STMR (FAO, 2013)                                            |
| Head brassica                        | 0.56          | STMR (FAO, 2013)                                            |
| Chinese cabbages/pe-tsai             | 4.32          | STMR <sub>Enf</sub> (2.7) x Pf (0.2) x CF (8) (HSE, 2023)   |
| Kales                                | 1.72          | STMR <sub>Enf</sub> (1.075) x Pf (0.2) x CF (8) (HSE, 2023) |
| Kohlrabies                           | 0.56          | STMR (FAO, 2013)                                            |
| Lettuces                             | 0.79          | STMR (FAO, 2013)                                            |
| Beans (with pods)                    | 0.29          | STMR (FAO, 2015)                                            |
| Beans (without pods)                 | 0.07          | STMR (FAO, 2015)                                            |
| Peas (with pods)                     | 0.7           | STMR (FAO, 2015)                                            |
| Peas (without pods)                  | 0.07          | STMR (FAO, 2015)                                            |
| Celeries                             | 2.00          | STMR (FAO, 2013)                                            |

| Commodity                                                                                          | Chronic       | risk assessment                                             |
|----------------------------------------------------------------------------------------------------|---------------|-------------------------------------------------------------|
|                                                                                                    | Input (mg/kg) | Comment                                                     |
| Globe artichokes                                                                                   | 0.03          | STMR (EFSA, 2015)                                           |
| Leeks                                                                                              | 0.088         | STMR <sub>Enf</sub> (0.055) x Pf (0.2) x CF (8) (HSE, 2023) |
| Beans                                                                                              | 0.032         | STMR (HSE, 2025)                                            |
| Lentils                                                                                            | 0.032         | STMR (HSE, 2025)                                            |
| Peas                                                                                               | 0.032         | STMR (HSE, 2025)                                            |
| Lupins/lupini beans                                                                                | 0.032         | STMR (HSE, 2025)                                            |
| Sunflower seeds                                                                                    | 0.067         | STMR (FAO, 2015)                                            |
| Rapeseeds/canola seeds                                                                             | 0.077         | STMR (FAO, 2015)                                            |
| Soyabeans                                                                                          | 0.032         | STMR (HSE, 2025)                                            |
| Cotton seeds                                                                                       | 0.16          | STMR (FAO, 2015)                                            |
| Olives for oil production                                                                          | 0.27          | STMR (EFSA, 2014)                                           |
| Tea (dried leaves)                                                                                 | 4.05          | STMR (HSE, 2025)                                            |
| Coffee beans                                                                                       | 0.01          | STMR (EFSA, 2016a)                                          |
| Herbal infusion (dried roots)                                                                      | 0.08          | STMR (EFSA, 2015)                                           |
| Spices (roots or rhizome)                                                                          | 0.08          | STMR (EFSA, 2015)                                           |
| Sugar beet root                                                                                    | 0.01          | STMR (FAO, 2013)                                            |
| Chicory root                                                                                       | 0.01          | STMR (FAO, 2013)                                            |
| Swine, bovine, sheep, goat, equine, other farmed terrestrial animals: muscle/meat                  | 0.041         | STMR (FAO, 2015) (a)                                        |
| Swine, bovine, sheep, goat, equine, other farmed terrestrial animals: fat                          | 0.1           | STMR (FAO, 2015) (a)                                        |
| Swine, bovine, sheep, goat, equine, other farmed terrestrial animals: liver, kidney, edible offals | 0.38          | STMR (FAO, 2015) (a)                                        |
| Poultry: muscle/meat                                                                               | 0.0039        | STMR (FAO, 2015) (a)                                        |
| Poultry: fat                                                                                       | 0.0083        | STMR (FAO, 2015) (a)                                        |
| Poultry: liver, kidney, edible offals                                                              | 0.0321        | STMR (FAO, 2015) (a)                                        |
| Milk: Cattle                                                                                       | 0.05          | STMR (HSE, 2023)                                            |

| Commodity                          | Chronic                                                | risk assessment      |
|------------------------------------|--------------------------------------------------------|----------------------|
|                                    | Input (mg/kg)                                          | Comment              |
| Milk: Sheep                        | 0.03                                                   | STMR (HSE, 2023)     |
| Milk: Goat                         | 0.03                                                   | STMR (HSE, 2023)     |
| Milk: Horse                        | 0.03                                                   | STMR (HSE, 2023)     |
| Milk: Others                       | 0.03                                                   | STMR (HSE, 2023)     |
| Birds eggs                         | 0.048                                                  | STMR (HSE, 2025) (a) |
| Other plant and animal commodities | GB MRL Statutory Register and GB decision no. 2025/001 |                      |

\* indicates residue at LOQ

(a) Residue values in the FAO (2013, 2015 & HSE, 2025) estimations of STMRs in products of animal origin are the sum of cyantraniliprole and metabolites IN-N7B69, IN-J9Z38, IN-MLA84 and IN-MYX98, expressed as cyantraniliprole. The range of metabolites in the FAO estimated STMRs is broader than the GB risk assessment residue definition; however, these values are considered appropriate for use in the exposure calculation.

**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 99.3% of the ADI (Infant). The highest PRIMo IEDI was 91% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with cyantraniliprole.

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

## 7.2 Other routes of exposure

Not applicable

## 8 The conclusion of the competent authority

Sufficiently validated analytical methods for the determination of cyantraniliprole in products of plant and animal origin, in line with the residue definitions for enforcement, are available to support the uses under consideration in the MRL application.

Toxicological reference values were established for the approval of the active substance: an ADI of 0.01 mg/kg bw/day and no ARfD allocated or required.

The metabolism of cyantraniliprole in primary crops was investigated in the cereal/grass crops, leafy crops, pulses and oilseeds and fruit crop groups following foliar and soil applications for the approval of the active substance (EFSA, 2014). As a consistent metabolic pathway was observed across crops from four crop groups, the available data are sufficient to support all crop groups. The crops included in this MRL application are, therefore, covered by the metabolism studies available.

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

- Cyantraniliprole

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

- Cyantraniliprole

No new trials have been submitted to support the proposed MRLs. Trials supporting the on-label authorisations of Minecto One on outdoor lettuce, and additional EAMU authorisations on protected lettuce have been considered and extrapolated to support the proposed use on leafy crops, spinach and similar leaves, and herbs and edible flowers.

For the outdoor uses, eight NEU trials on open-leaf varieties of lettuce were previously evaluated to support the proposed MRLs. For indoor uses, Sixteen residues trials were available, with eight considered acceptable to support the proposed MRLs. Trials are supported by validated analytical methods and storage stability data.

Hydrolysis of cyantraniliprole under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrate that cyantraniliprole is stable under conditions representative of pasteurisation and sterilisation. However, degradation under conditions representative of baking/brewing/boiling was observed, with metabolites IN-J9Z38, IN-F6L99 and IN-N5M09 identified.

The residue definition for risk assessment (RD-RA) for processed commodities is:

- Sum of cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole

The EFSA Conclusion (EFSA, 2014) identified a data gap to assess the toxicological properties of IN-N5M09 and IN-F6L99. Data and information to address this data gap was considered in the ER/RO (HSE, 2022).

It was concluded that the Cramer Class III TTC values of 1.5 µg/kg bw/d is applicable for the chronic dietary risk assessment and 5 µg/kg bw is applicable for the acute dietary risk assessment.

Consideration has been given to the available relevant data on magnitude of residues in processed commodities, and processing factors applied to the crops considered in the current evaluation and previous approved uses to estimate the expected dietary exposure to IN-N5M09 and IN-F6L99. The dietary exposures have been compared to the TTC values and no chronic or acute risk intake concerns have been identified for metabolites IN-N5M09 and IN-F6L99.

No consideration has been given to residues in rotational crops. While crops may be grown in rotation, the cGAP is equivalent to that considered in the GB ER-RO on various commodities (HSE, 2023). No increase is expected to residues in rotational crops. See the ER-RO related to GB MRL 2023/005 for further details.

None of the crops in the proposed GAPs are used for animal feed. Therefore, no further consideration of residues in products of animal origin is required.

Two separate consumer risk assessments have been considered under Scenario 1, and Scenario 2.

### Scenario 1

Scenario 1 includes values related to the CXLs that apply to the commodities under consideration.

The highest UK NEDI was 150% of the ADI (Toddler). The highest PRIMo IEDI was 133% of the ADI (NL toddler). Therefore, a chronic intake concern has been identified from exposure to cyantraniliprole from all dietary sources.

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

Chronic intake concerns have been identified, this is driven by the inputs for lettuces and salad plants (except cress/land cress), and spinaches and similar leaves as such the CXL cannot be adopted for these commodities. The inputs for cress/land cress and chervil have

low relevance to the overall exposure; the CXL input applied to these three commodities does not result in chronic exceedances. As such, the CXL has been included in scenario 2 for cress and other sprouts and shoots, land cress, and chervil in scenario 2.

## Scenario 2

The highest UK NEDI was 99.3% of the ADI (Infant). The highest PRIMo IEDI was 92% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with cyantraniliprole.

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

## Conclusion

HSE concludes that the CXL for leafy vegetables may not be adopted for most commodities under consideration due to identified chronic consumer concerns as detailed under Scenario 1.

The CXL for leafy vegetables may be adopted for: cresses and other sprouts and shoots (0251040), land cresses (0251050), and chervil (0256010) as no consumer concerns were identified under Scenario 2.

Sufficient data have been provided to support the setting of new MRLs for the proposed uses of cyantraniliprole on lettuces and salad plants (except lettuces), spinaches, purslanes, chards/beet leaves and herbs and edible flowers. These will not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected.

HSE recommends that the MRLs outlined in Table 8.1 are amended in the GB MRL Statutory Register.

**Table 8.1 MRLs recommended by HSE**

**Enforcement residue definition for products of plant origin: Cyantraniliprole**

| Product code | Product                              | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                                            |
|--------------|--------------------------------------|-------------------------|-------------------------------|---------------------------------------------------------------------------------------------------------------------|
| 0251010      | Lamb's lettuce                       | 0.01*                   | 9.0                           | The MRL is derived by extrapolation of residue trials on open-leaf varieties of lettuce.<br><br>The MRL is based on |
| 0251030      | Escaroles/ broad leaved endives      | 0.01*                   | 4.0                           |                                                                                                                     |
| 0251040      | Cresses and other sprouts and shoots | 0.01*                   | 20                            |                                                                                                                     |

| Product code | Product                                      | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                 |
|--------------|----------------------------------------------|-------------------------|-------------------------------|------------------------------------------------------------------------------------------|
| 0251050      | Land cresses                                 | 0.01*                   | 20                            | protected trials.                                                                        |
| 0251060      | Roman rocket/ rucolas                        | 0.01*                   | 9.0                           | No health effects are expected.                                                          |
| 0251070      | Red mustards                                 | 0.01*                   | 9.0                           |                                                                                          |
| 0251080      | Baby leaf crops (including brassica species) | 0.01*                   | 9.0                           |                                                                                          |
|              |                                              |                         |                               | The MRLs for 0251040 and 0251050 are based on the CXL.                                   |
| 0252010      | Spinaches                                    | 0.01*                   | 0.9                           | The MRL is derived by extrapolation of residue trials on open-leaf varieties of lettuce. |
| 0252020      | Purslanes                                    | 0.01*                   | 0.9                           |                                                                                          |
| 0252030      | Chards/beet leaves                           | 0.01*                   | 0.9                           |                                                                                          |
|              |                                              |                         |                               | The MRL is based on outdoor NEU trials                                                   |
|              |                                              |                         |                               | No health effects are expected.                                                          |
| 0256010      | Chervil                                      | 0.02*                   | 20                            | The MRL is based on the CXL                                                              |
| 0256020      | Chives                                       | 0.02*                   | 4.0                           | The MRL is derived by extrapolation of residue trials on open leaf varieties of lettuce. |
| 0256030      | Celery leaves                                | 0.02*                   | 4.0                           |                                                                                          |
| 0256040      | Parsley                                      | 0.02*                   | 4.0                           |                                                                                          |
| 0256050      | Sage                                         | 0.02*                   | 4.0                           | The MRL is based on protected trials.                                                    |
| 0256060      | Rosemary                                     | 0.02*                   | 4.0                           |                                                                                          |
| 0256070      | Thyme                                        | 0.02*                   | 4.0                           |                                                                                          |
| 0256080      | Basil and edible flowers                     | 0.02*                   | 4.0                           | No health effects are expected.                                                          |
| 0256090      | Laural/ bay leaves                           | 0.02*                   | 4.0                           |                                                                                          |
| 0256100      | Tarragon                                     | 0.02*                   | 4.0                           |                                                                                          |
| 0256990      | Others - herbs                               | 0.02*                   | 4.0                           |                                                                                          |

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

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## Appendix A – Outdoor GAPs notified in the MRL application

| Crop and/or situation (a)                                       | GB or Country For Import Tolerance | Product name | F,G or I (b) | Pests or Group of pests controlled (c) | Preparation |                | Application                               |                                     |                    |                                    | Application rate per treatment |                      |                       | PHI (days) (m) | Remarks |
|-----------------------------------------------------------------|------------------------------------|--------------|--------------|----------------------------------------|-------------|----------------|-------------------------------------------|-------------------------------------|--------------------|------------------------------------|--------------------------------|----------------------|-----------------------|----------------|---------|
|                                                                 |                                    |              |              |                                        | Type (d-f)  | Conc. a.s. (i) | method kind (f-h)                         | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | g a.s /hL min-max (l)          | Water (L/ha) min-max | g a.s./ha min-max (l) |                |         |
| Lettuces and salad plants (except lettuces and baby leaf crops) | GB                                 | A16971B      | F            | Insect pests****                       | WG          | 400 g/kg       | Horizontal boom and hand-held application | BBCH 12 - 49                        | 1 - 2              | 7 days                             | 7.4 – 24.6                     | 300 - 1000           | 74                    | 7              |         |
| Baby leaf crops                                                 | GB                                 | A16971B      | F            | Insect pests****                       | WG          | 400 g/kg       | Horizontal boom and hand-held application | BBCH 12 - 18                        | 1 - 2              | 7 days                             | 7.4 – 24.6                     | 300 - 1000           | 74                    | 7              |         |
| Spinaches and similar leaves                                    | GB                                 | A16971B      | F            | Insect pests****                       | WG          | 400 g/kg       | Horizontal boom and hand-held application | BBCH 12 - 49                        | 1 - 2              | 7 days                             | 7.4 – 24.6                     | 300 - 1000           | 74                    | 7              |         |
| Herbs and edible flowers                                        | GB                                 | A16971B      | F            | Insect pests****                       | WG          | 400 g/kg       | Horizontal boom and hand-held application | BBCH 12 - 49                        | 1 - 2              | 7 days                             | 7.4 – 24.6                     | 300 - 1000           | 74                    | 7              |         |

(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

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>(b) State if the use is outdoor, field use (F) or glasshouse (G) or indoor use (I).</p> <p>(c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008.</p> <p>Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>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).</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## Appendix B – Indoor GAPs notified in the MRL application

| Crop and/or situation (a)                                                          | GB or Country For Import Tolerance | Product name | F, G or I (b) | Pests or Group of pests controlled (c) | Preparation |                | Application                               |                                     |                    |                                    | Application rate per treatment |                      |                       | PHI (days) (m) | Remarks |
|------------------------------------------------------------------------------------|------------------------------------|--------------|---------------|----------------------------------------|-------------|----------------|-------------------------------------------|-------------------------------------|--------------------|------------------------------------|--------------------------------|----------------------|-----------------------|----------------|---------|
|                                                                                    |                                    |              |               |                                        | Type (d-f)  | Conc. a.s. (i) | method kind (f-h)                         | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | g a.s /hL min-max (l)          | Water (L/ha) min-max | g a.s./ha min-max (l) |                |         |
| Escaroles/broad-leaved endives, Cresses and other sprouts and shoots, land cresses | GB                                 | A16971B      | F             | Insect pests****                       | WG          | 400 g/kg       | Horizontal boom and hand-held application | BBCH 2 - 49                         | 1 - 2              | 7 days                             | 7.4 – 24.6                     | 300 - 1000           | 74                    | 10             |         |
| Baby leaf crops (including brassica species)                                       | GB                                 | A16971B      | F             | Insect pests****                       | WG          | 400 g/kg       | Horizontal boom and hand-held application | BBCH 2 - 18                         | 1 - 2              | 7 days                             | 7.4 – 24.6                     | 300 - 1000           | 74                    | 3              |         |
| Lamb's lettuce/ corn salads, Roman rocket/ rucola, red mustards                    | GB                                 | A16971B      | F             | Insect pests****                       | WG          | 400 g/kg       | Horizontal boom and hand-held application | BBCH 2 - 49                         | 1 - 2              | 7 days                             | 7.4 – 24.6                     | 300 - 1000           | 74                    | 3              |         |
| Herbs and edible flowers                                                           | GB                                 | A16971B      | F             | Insect pests****                       | WG          | 400 g/kg       | Horizontal boom and hand-held application | BBCH 2 - 49                         | 1 - 2              | 7 days                             | 7.4 – 24.6                     | 300 - 1000           | 74                    | 10             |         |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>(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)</p> <p>(b) State if the use is outdoor, field use (F) or glasshouse (G) or indoor use (I).</p> <p>(c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008.</p> <p>Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(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).</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
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## Appendix B – UK models and Pesticide Residues Intake Model (PRIMo)

**Table B.1 Chronic risk assessment undertaken using UK model version 1.1 – Scenario 1**

**Active substance:** Cyantraniliprole

**ADI:** 0.01 mg/kg bw/day

**Source:** Reg. (EU) No 2016/1414

|              | 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 | 0.00754                                 | 0.01178 | 0.01501 | 0.01057   | 0.00990    | 0.00644     | 0.00511     | 0.00857    | 0.00669            | 0.00544               |
| % of ADI     | 75%                                     | 118%    | 150%    | 106%      | 99%        | 64%         | 51%         | 86%        | 67%                | 54%                   |

| Commodity   | STMR (mg/kg) | P | COMMODITY INTAKES |         |         |         |         |         |         |         |         |         |
|-------------|--------------|---|-------------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
|             |              |   | (mg/kg bw/day)    |         |         |         |         |         |         |         |         |         |
| Grapefruit  | 0.016        |   | 0.00003           | 0.00003 | 0.00009 | 0.00008 | 0.00018 | 0.00003 | 0.00002 | 0.00004 | 0.00004 | 0.00003 |
| Lemons      | 0.016        |   | 0.00000           | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Limes       | 0.016        |   | 0.00000           | L/C     | 0.00003 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00001 |
| Mandarins   | 0.016        |   | 0.00002           | L/C     | 0.00010 | 0.00006 | 0.00005 | 0.00002 | 0.00003 | 0.00002 | 0.00003 | 0.00001 |
| Oranges     | 0.016        |   | 0.00006           | 0.00017 | 0.00026 | 0.00018 | 0.00013 | 0.00013 | 0.00011 | 0.00007 | 0.00006 | 0.00004 |
| Almonds     | 0.01         |   | 0.00000           | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Brazil nuts | 0.01         |   | 0.00000           | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Cashew nuts | 0.01         |   | 0.00000           | L/C     | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Chestnuts   | 0.01         |   | 0.00000           | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | 0.00000 | 0.00000 | L/C     |

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|                |       |  |         |         |         |         |         |         |         |         |         |         |
|----------------|-------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Coconuts       | 0.01  |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Hazelnuts      | 0.01  |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Pecan nuts     | 0.01  |  | 0.00000 | L/C     | 0.00000 | L/C     | 0.00000 | 0.00000 | L/C     | 0.00000 | 0.00000 | L/C     |
| Pistachios     | 0.01  |  | 0.00000 | L/C     | 0.00000 | L/C     | 0.00000 | L/C     | L/C     | 0.00000 | L/C     | L/C     |
| Walnuts        | 0.01  |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Peanuts        | 0.01  |  | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Apples         | 0.16  |  | 0.00043 | 0.00135 | 0.00238 | 0.00151 | 0.00120 | 0.00066 | 0.00057 | 0.00053 | 0.00035 | 0.00017 |
| Pears          | 0.16  |  | 0.00022 | 0.00041 | 0.00104 | 0.00058 | 0.00035 | 0.00030 | 0.00023 | 0.00030 | 0.00036 | 0.00019 |
| Apricots       | 0.01  |  | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 |
| Peaches        | 0.34  |  | 0.00046 | 0.00046 | 0.00107 | 0.00054 | 0.00040 | 0.00026 | 0.00015 | 0.00032 | 0.00032 | 0.00015 |
| Plums          | 0.12  |  | 0.00011 | 0.00006 | 0.00026 | 0.00016 | 0.00009 | 0.00003 | 0.00003 | 0.00008 | 0.00008 | 0.00002 |
| Cherries       | 0.93  |  | 0.00044 | 0.00133 | 0.00097 | 0.00140 | 0.00051 | 0.00066 | 0.00055 | 0.00049 | 0.00033 | 0.00008 |
| Table grapes   | 0.26  |  | 0.00034 | 0.00043 | 0.00122 | 0.00056 | 0.00067 | 0.00029 | 0.00016 | 0.00053 | 0.00035 | 0.00012 |
| Wine grapes    | 0.32  |  | 0.00315 | 0.00039 | 0.00028 | 0.00029 | 0.00010 | 0.00032 | 0.00113 | 0.00311 | 0.00213 | 0.00047 |
| Strawberries   | 0.46  |  | 0.00027 | 0.00088 | 0.00092 | 0.00062 | 0.00041 | 0.00032 | 0.00023 | 0.00045 | 0.00047 | 0.00024 |
| Blackberries   | 0.346 |  | 0.00004 | L/C     | 0.00067 | 0.00002 | 0.00011 | 0.00009 | 0.00003 | 0.00011 | 0.00009 | 0.00001 |
| Loganberries   | 0.01  |  | 0.00000 | 0.00001 | 0.00001 | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Raspberries    | 0.346 |  | 0.00014 | L/C     | 0.00082 | 0.00023 | 0.00035 | 0.00009 | 0.00002 | 0.00014 | 0.00029 | 0.00013 |
| Gooseberries   | 0.75  |  | 0.00019 | 0.00039 | 0.00049 | 0.00018 | 0.00018 | 0.00018 | 0.00014 | 0.00054 | 0.00062 | 0.00018 |
| Blackcurrants  | 0.75  |  | 0.00043 | 0.00089 | 0.00134 | 0.00135 | 0.00104 | 0.00077 | 0.00084 | 0.00027 | 0.00040 | 0.00021 |
| Red currants   | 0.75  |  | 0.00006 | L/C     | 0.00059 | L/C     | 0.00004 | 0.00009 | 0.00003 | 0.00003 | 0.00025 | L/C     |
| White currants | 0.75  |  | 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        | 0.01  |  | 0.00002 | 0.00007 | 0.00007 | 0.00004 | 0.00003 | 0.00002 | 0.00001 | 0.00002 | 0.00002 | 0.00002 |
| Dates          | 0.01  |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     | 0.00000 | 0.00001 | 0.00000 |
| Figs           | 0.01  |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 |

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|                      |      |  |         |         |         |         |         |         |         |         |         |         |
|----------------------|------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Kiwi fruit           | 0.01 |  | 0.00001 | L/C     | 0.00002 | 0.00002 | 0.00001 | 0.00001 | 0.00002 | 0.00001 | 0.00001 | 0.00000 |
| Lychees              | 0.01 |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Mangoes              | 0.01 |  | 0.00001 | L/C     | 0.00002 | 0.00001 | 0.00002 | 0.00001 | 0.00004 | 0.00001 | 0.00000 | L/C     |
| Olives               | 0.27 |  | 0.00007 | L/C     | 0.00016 | 0.00016 | L/C     | 0.00001 | L/C     | 0.00005 | 0.00012 | L/C     |
| Passion fruit        | 0.01 |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | L/C     | L/C     |
| Pineapples           | 0.01 |  | 0.00001 | 0.00005 | 0.00005 | 0.00007 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 |
| Pomegranates         | 0.01 |  | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00001 | 0.00001 | 0.00001 |
| Beetroot             | 0.01 |  | 0.00000 | L/C     | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Carrots              | 0.01 |  | 0.00001 | 0.00004 | 0.00002 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 |
| Celeriac             | 0.01 |  | 0.00000 | L/C     | L/C     | 0.00000 | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     |
| Horseradish          | 0.01 |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | L/C     |
| Jerusalem artichokes | 0.01 |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Parsnips             | 0.01 |  | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Radishes             | 0.01 |  | 0.00000 | L/C     | 0.00001 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Salsify              | 0.01 |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Swedes               | 0.01 |  | 0.00000 | 0.00003 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Turnips              | 0.01 |  | 0.00000 | L/C     | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Yam                  | 0.01 |  | 0.00003 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Garlic               | 0.02 |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Onions               | 0.02 |  | 0.00001 | 0.00002 | 0.00002 | 0.00002 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 |
| Spring onions        | 1.3  |  | 0.00033 | L/C     | 0.00021 | 0.00085 | 0.00024 | 0.00012 | 0.00014 | 0.00033 | 0.00033 | 0.00012 |
| Tomatoes             | 0.17 |  | 0.00023 | 0.00031 | 0.00045 | 0.00033 | 0.00031 | 0.00018 | 0.00023 | 0.00030 | 0.00025 | 0.00023 |
| Peppers              | 0.14 |  | 0.00005 | L/C     | 0.00011 | 0.00006 | 0.00009 | 0.00004 | 0.00004 | 0.00008 | 0.00008 | 0.00003 |
| Aubergines           | 0.14 |  | 0.00004 | L/C     | 0.00021 | 0.00011 | 0.00004 | 0.00007 | 0.00005 | 0.00009 | 0.00006 | L/C     |
| Marrows              | 0.08 |  | 0.00004 | L/C     | 0.00012 | 0.00003 | 0.00005 | 0.00005 | 0.00002 | 0.00004 | 0.00011 | 0.00005 |
| Cucumbers            | 0.08 |  | 0.00003 | 0.00002 | 0.00019 | 0.00012 | 0.00008 | 0.00004 | 0.00004 | 0.00004 | 0.00004 | 0.00001 |

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|                    |      |  |         |         |         |         |         |         |         |         |         |         |
|--------------------|------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Gourd              | 0.08 |  | 0.00004 | L/C     | L/C     | L/C     | L/C     | 0.00002 | L/C     | 0.00002 | L/C     | L/C     |
| Courgettes         | 0.08 |  | 0.00003 | 0.00012 | 0.00019 | 0.00010 | 0.00006 | 0.00003 | 0.00003 | 0.00004 | 0.00004 | 0.00004 |
| 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         | 0.01 |  | 0.00001 | 0.00001 | 0.00002 | 0.00001 | 0.00001 | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00000 |
| Broccoli           | 0.56 |  | 0.00036 | 0.00064 | 0.00096 | 0.00068 | 0.00059 | 0.00040 | 0.00035 | 0.00038 | 0.00054 | 0.00019 |
| Cauliflower        | 0.56 |  | 0.00049 | 0.00176 | 0.00122 | 0.00094 | 0.00048 | 0.00042 | 0.00048 | 0.00068 | 0.00064 | 0.00037 |
| Brussels sprouts   | 0.56 |  | 0.00034 | 0.00131 | 0.00100 | 0.00082 | 0.00041 | 0.00052 | 0.00035 | 0.00044 | 0.00054 | 0.00026 |
| Head cabbage       | 1.72 |  | 0.00094 | 0.00302 | 0.00293 | 0.00217 | 0.00129 | 0.00123 | 0.00091 | 0.00130 | 0.00199 | 0.00126 |
| Chinese cabbage    | 4.32 |  | 0.00215 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00216 | 0.00151 | L/C     |
| Kohl Rabi          | 0.56 |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Cress              | 4.7  |  | 0.00018 | L/C     | 0.00023 | 0.00032 | 0.00011 | 0.00020 | 0.00014 | 0.00036 | 0.00045 | 0.00019 |
| Lettuce            | 4.7  |  | 0.00291 | 0.00167 | 0.00402 | 0.00323 | 0.00341 | 0.00190 | 0.00208 | 0.00331 | 0.00252 | 0.00129 |
| Spinach            | 4.7  |  | 0.00247 | 0.00470 | 0.00736 | 0.00404 | 0.00412 | 0.00294 | 0.00164 | 0.00321 | 0.00264 | 0.00166 |
| Watercress         | 0.01 |  | 0.00000 | L/C     | L/C     | 0.00000 | 0.00000 | 0.00000 | L/C     | 0.00000 | 0.00000 | L/C     |
| Chicory            | 4.7  |  | 0.00035 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00034 | L/C     | L/C     |
| Parsley            | 4.7  |  | 0.00080 | L/C     | 0.00052 | L/C     | 0.00075 | 0.00020 | 0.00007 | 0.00080 | 0.00084 | 0.00172 |
| Beans with pods    | 0.29 |  | 0.00015 | 0.00035 | 0.00056 | 0.00038 | 0.00019 | 0.00010 | 0.00020 | 0.00012 | 0.00021 | 0.00009 |
| Runner Beans       | 0.29 |  | 0.00018 | L/C     | 0.00043 | 0.00014 | 0.00021 | 0.00017 | 0.00014 | 0.00044 | 0.00028 | 0.00016 |
| Beans without pods | 0.07 |  | 0.00003 | 0.00004 | 0.00017 | 0.00003 | 0.00007 | 0.00003 | 0.00003 | 0.00004 | 0.00006 | 0.00004 |
| Peas with pods     | 0.7  |  | 0.00020 | L/C     | 0.00033 | 0.00088 | 0.00016 | 0.00020 | 0.00012 | 0.00018 | 0.00036 | L/C     |
| Peas without pods  | 0.07 |  | 0.00005 | 0.00017 | 0.00014 | 0.00010 | 0.00007 | 0.00005 | 0.00006 | 0.00006 | 0.00007 | 0.00005 |
| Beansprouts        | 0.01 |  | 0.00000 | L/C     | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Asparagus          | 0.01 |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | 0.00001 | 0.00000 | L/C     |
| Bamboo shoots      | 0.01 |  | 0.00000 | L/C     | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Celery             | 2    |  | 0.00065 | 0.00085 | 0.00084 | 0.00058 | 0.00032 | 0.00050 | 0.00036 | 0.00092 | 0.00097 | 0.00022 |
| Fennel             | 0.01 |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|                            |        |  |         |         |         |         |         |         |         |         |         |         |
|----------------------------|--------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| 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                      | 0.088  |  | 0.00004 | L/C     | 0.00006 | 0.00003 | 0.00003 | 0.00003 | 0.00002 | 0.00004 | 0.00005 | 0.00003 |
| Rhubarb                    | 0.01   |  | 0.00000 | 0.00001 | 0.00001 | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Cultivated mushrooms       | 0.01   |  | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 |
| Beans                      | 0.032  |  | 0.00005 | 0.00019 | 0.00015 | 0.00011 | 0.00009 | 0.00007 | 0.00007 | 0.00006 | 0.00004 | 0.00003 |
| Lentils                    | 0.032  |  | 0.00002 | 0.00005 | 0.00006 | 0.00006 | 0.00002 | 0.00004 | 0.00002 | 0.00002 | 0.00002 | 0.00001 |
| dried Peas                 | 0.032  |  | 0.00002 | L/C     | 0.00006 | 0.00001 | 0.00002 | 0.00004 | 0.00002 | 0.00002 | 0.00003 | 0.00002 |
| Oilseeds                   | 0.27   |  | 0.00086 | 0.00170 | 0.00196 | 0.00193 | 0.00151 | 0.00109 | 0.00095 | 0.00126 | 0.00086 | 0.00104 |
| Potatoes                   | 0.01   |  | 0.00003 | 0.00011 | 0.00009 | 0.00008 | 0.00007 | 0.00005 | 0.00005 | 0.00004 | 0.00003 | 0.00003 |
| Tea (dried leaves)         | 4.05   |  | 0.00086 | 0.00289 | 0.00106 | 0.00065 | 0.00048 | 0.00045 | 0.00055 | 0.00090 | 0.00085 | 0.00093 |
| Hops (dried 0.25% of beer) | 0.05   |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Oats                       | 0.01   |  | 0.00000 | 0.00002 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00001 |
| Barley                     | 0.01   |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Millet                     | 0.01   |  | L/C     | L/C     | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Buckwheat                  | 0.01   |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Maize                      | 0.01   |  | 0.00000 | 0.00005 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Wheat                      | 0.01   |  | 0.00004 | 0.00003 | 0.00008 | 0.00009 | 0.00007 | 0.00005 | 0.00004 | 0.00004 | 0.00003 | 0.00003 |
| Rice                       | 0.01   |  | 0.00002 | 0.00003 | 0.00005 | 0.00004 | 0.00005 | 0.00004 | 0.00003 | 0.00002 | 0.00001 | 0.00000 |
| Rye                        | 0.01   |  | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 |
| Poultry                    | 0.0039 |  | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00000 |
| Meat fat                   | 0.1    |  | 0.00002 | 0.00004 | 0.00007 | 0.00004 | 0.00003 | 0.00003 | 0.00002 | 0.00001 | 0.00002 | 0.00002 |
| Meat excl. poultry & offal | 0.041  |  | 0.00008 | 0.00017 | 0.00017 | 0.00014 | 0.00013 | 0.00008 | 0.00009 | 0.00002 | 0.00007 | 0.00007 |
| All types of kidney        | 0.38   |  | 0.00011 | 0.00016 | 0.00051 | 0.00013 | 0.00009 | 0.00008 | 0.00011 | L/C     | 0.00018 | 0.00012 |
| All types of Liver         | 0.38   |  | 0.00018 | 0.00085 | 0.00091 | 0.00013 | 0.00016 | 0.00023 | 0.00011 | L/C     | 0.00026 | 0.00018 |
| Other types of offal       | 0.38   |  | 0.00026 | 0.00060 | 0.00083 | 0.00042 | 0.00036 | 0.00039 | 0.00018 | 0.00006 | 0.00029 | 0.00027 |
| Eggs                       | 0.048  |  | 0.00005 | 0.00023 | 0.00017 | 0.00011 | 0.00008 | 0.00007 | 0.00005 | 0.00005 | 0.00005 | 0.00007 |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|            |      |  |         |         |         |         |         |         |         |         |         |         |
|------------|------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| 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 | 0.01 |  | 0.00014 | 0.00033 | 0.00056 | 0.00034 | 0.00031 | 0.00020 | 0.00019 | 0.00012 | 0.00011 | 0.00015 |

\* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value  $\geq$ 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 – Scenario 1**

| Chronic risk assessment: JMPR methodology (IEDI/TMDI) |                                |                   |                                   |                                              |                                  |                                          |                                         |                                          |                                         |                                   |                                                |
|-------------------------------------------------------|--------------------------------|-------------------|-----------------------------------|----------------------------------------------|----------------------------------|------------------------------------------|-----------------------------------------|------------------------------------------|-----------------------------------------|-----------------------------------|------------------------------------------------|
|                                                       |                                |                   | No of diets exceeding the ADI : 1 |                                              |                                  |                                          |                                         |                                          |                                         |                                   | Exposure resulting from                        |
| TMDI/NEDI/IEDI calculation (based on average food)    | Calculated exposure (% of ADI) | MS Diet           | Exposure (µg/kg bw per day)       | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities        | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities        | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
|                                                       | 133.0 %                        | NL toddler        | 13.30                             | 33.7%                                        | Spinaches                        | 29.9%                                    | Milk: Cattle                            | 17.3%                                    | Apples                                  |                                   | 45.3%                                          |
|                                                       | 66.8%                          | DE child          | 6.68                              | 20.0%                                        | Apples                           | 9.9%                                     | Milk: Cattle                            | 9.4%                                     | Spinaches                               |                                   | 13.4%                                          |
|                                                       | 61.6%                          | NL child          | 6.16                              | 12.2%                                        | Milk: Cattle                     | 11.8%                                    | Spinaches                               | 9.2%                                     | Apples                                  |                                   | 16.6%                                          |
|                                                       | 40.7%                          | GEMS/Food G11     | 4.07                              | 5.6%                                         | Celeries                         | 4.3%                                     | Spinaches                               | 4.0%                                     | Lamb's lettuce/corn salads              |                                   | 10.7%                                          |
|                                                       | 40.6%                          | FR toddler 2 3 yr | 4.06                              | 14.6%                                        | Milk: Cattle                     | 7.4%                                     | Spinaches                               | 5.1%                                     | Apples                                  |                                   | 8.6%                                           |
|                                                       | 39.8%                          | GEMS/Food G10     | 3.98                              | 6.8%                                         | Chinese cabbages/pe-tsai         | 3.1%                                     | Cress and other sprouts and shoots      | 2.7%                                     | Milk: Cattle                            |                                   | 7.1%                                           |
|                                                       | 39.4%                          | SE general        | 3.94                              | 8.6%                                         | Chinese cabbages/pe-tsai         | 6.2%                                     | Milk: Cattle                            | 3.5%                                     | Head cabbages                           |                                   | 4.1%                                           |
|                                                       | 39.2%                          | IE adult          | 3.92                              | 5.9%                                         | Spinaches                        | 5.3%                                     | Tea (dried leaves of Camellia sinensis) | 4.0%                                     | Wine grapes                             |                                   | 6.4%                                           |
|                                                       | 36.8%                          | FR child 3 15 yr  | 3.68                              | 11.4%                                        | Milk: Cattle                     | 5.0%                                     | Spinaches                               | 2.7%                                     | Apples                                  |                                   | 5.6%                                           |
|                                                       | 36.3%                          | UK infant         | 3.63                              | 19.4%                                        | Milk: Cattle                     | 2.5%                                     | Apples                                  | 2.3%                                     | Tea (dried leaves of Camellia sinensis) |                                   | 0.5%                                           |
|                                                       | 36.0%                          | GEMS/Food G06     | 3.60                              | 6.1%                                         | Tomatoes                         | 2.7%                                     | Table grapes                            | 2.3%                                     | Spinaches                               |                                   | 5.9%                                           |
|                                                       | 35.6%                          | GEMS/Food G08     | 3.56                              | 3.4%                                         | Lamb's lettuce/corn salads       | 3.3%                                     | Wine grapes                             | 2.8%                                     | Milk: Cattle                            |                                   | 5.9%                                           |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|       |                   |      |       |                    |      |                                         |      |                    |       |
|-------|-------------------|------|-------|--------------------|------|-----------------------------------------|------|--------------------|-------|
| 34.4% | NL general        | 3.44 | 7.1%  | Spinaches          | 4.7% | Escaroles/broad-leaved endives          | 4.2% | Milk: Cattle       | 12.1% |
| 34.4% | GEMS/Food G07     | 3.44 | 4.7%  | Wine grapes        | 3.2% | Milk: Cattle                            | 2.6% | Celeries           | 3.6%  |
| 33.1% | FR infant         | 3.31 | 12.5% | Spinaches          | 8.4% | Milk: Cattle                            | 2.7% | Apples             | 14.1% |
| 32.5% | RO general        | 3.25 | 8.0%  | Head cabbages      | 5.8% | Milk: Cattle                            | 5.4% | Wine grapes        |       |
| 31.9% | GEMS/Food G15     | 3.19 | 4.6%  | Head cabbages      | 3.5% | Milk: Cattle                            | 3.2% | Wine grapes        | 1.2%  |
| 31.3% | ES child          | 3.13 | 6.2%  | Milk: Cattle       | 3.8% | Spinaches                               | 3.8% | Chards/beet leaves | 7.6%  |
| 29.9% | DE women 14-50 yr | 2.99 | 6.2%  | Milk: Cattle       | 4.1% | Apples                                  | 2.7% | Wine grapes        | 3.7%  |
| 28.7% | DE general        | 2.87 | 6.2%  | Milk: Cattle       | 3.9% | Apples                                  | 2.7% | Wine grapes        | 3.4%  |
| 28.1% | FR adult          | 2.81 | 7.4%  | Wine grapes        | 5.7% | Tea (dried leaves of Camellia sinensis) | 2.5% | Spinaches          | 3.9%  |
| 26.7% | UK toddler        | 2.67 | 10.3% | Milk: Cattle       | 2.7% | Apples                                  | 1.3% | Spinaches          | 1.3%  |
| 25.5% | ES adult          | 2.55 | 4.2%  | Lettuces           | 3.8% | Chards/beet leaves                      | 3.5% | Spinaches          | 7.3%  |
| 22.4% | DK child          | 2.24 | 6.3%  | Milk: Cattle       | 3.7% | Apples                                  | 1.3% | Cucumbers          | 0.0%  |
| 21.7% | PT general        | 2.17 | 8.0%  | Wine grapes        | 3.2% | Kales                                   | 1.7% | Apples             | 0.1%  |
| 21.0% | IT adult          | 2.10 | 4.5%  | Spinaches          | 3.0% | Lettuces                                | 3.0% | Chards/beet leaves | 8.8%  |
| 19.0% | IT toddler        | 1.90 | 2.8%  | Chards/beet leaves | 2.7% | Spinaches                               | 2.4% | Tomatoes           | 6.3%  |
| 16.8% | UK vegetarian     | 1.68 | 2.6%  | Wine grapes        | 2.0% | Tea (dried leaves of Camellia sinensis) | 1.6% | Milk: Cattle       | 1.7%  |
| 15.4% | FI 3 yr           | 1.54 | 3.1%  | Spinaches          | 1.7% | Strawberries                            | 1.5% | Apples             | 3.1%  |
| 14.9% | DK adult          | 1.49 | 3.1%  | Wine grapes        | 2.6% | Milk: Cattle                            | 1.5% | Apples             | 0.6%  |
| 14.5% | UK adult          | 1.45 | 3.5%  | Wine grapes        | 2.2% | Tea (dried leaves of Camellia sinensis) | 1.5% | Milk: Cattle       | 0.9%  |
| 12.7% | PL general        | 1.27 | 3.3%  | Apples             | 2.0% | Head cabbages                           | 1.5% | Tomatoes           | 0.5%  |
| 12.7% | FI 6 yr           | 1.27 | 2.6%  | Spinaches          | 1.4% | Chinese cabbages/pe-tsai                | 1.3% | Strawberries       | 2.6%  |
| 11.7% | LT adult          | 1.17 | 3.0%  | Apples             | 2.2% | Head cabbages                           | 2.0% | Milk: Cattle       |       |
| 9.4%  | FI adult          | 0.94 | 1.1%  | Lettuces           | 1.0% | Wine grapes                             | 0.9% | Tomatoes           | 0.7%  |
| 4.9%  | IE child          | 0.49 | 1.8%  | Milk: Cattle       | 0.5% | Apples                                  | 0.3% | Broccoli           | 0.2%  |

**Table B.3 Chronic risk assessment undertaken using UK model version 1.1 – Scenario 2**

**Active substance:** Cyantraniliprole

**ADI:** 0.01 mg/kg bw/day

**Source:** Reg. (EU) No 2016/1414

|              | 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 | 0.00700                                 | 0.00993 | 0.00820 | 0.00649   | 0.00511    | 0.00344     | 0.00366     | 0.00742    | 0.00549            | 0.00476               |
| % of ADI     | 70%                                     | 99%     | 82%     | 65%       | 51%        | 34%         | 37%         | 74%        | 55%                | 48%                   |

| Commodity   | STMR    | P | COMMODITY INTAKES |         |         |         |         |         |         |         |         |         |
|-------------|---------|---|-------------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
|             | (mg/kg) |   | (mg/kg bw/day)    |         |         |         |         |         |         |         |         |         |
| Grapefruit  | 0.016   |   | 0.00003           | 0.00003 | 0.00009 | 0.00008 | 0.00018 | 0.00003 | 0.00002 | 0.00004 | 0.00004 | 0.00003 |
| Lemons      | 0.016   |   | 0.00000           | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Limes       | 0.016   |   | 0.00000           | L/C     | 0.00003 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00001 |
| Mandarins   | 0.016   |   | 0.00002           | L/C     | 0.00010 | 0.00006 | 0.00005 | 0.00002 | 0.00003 | 0.00002 | 0.00003 | 0.00001 |
| Oranges     | 0.016   |   | 0.00006           | 0.00017 | 0.00026 | 0.00018 | 0.00013 | 0.00013 | 0.00011 | 0.00007 | 0.00006 | 0.00004 |
| Almonds     | 0.01    |   | 0.00000           | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Brazil nuts | 0.01    |   | 0.00000           | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Cashew nuts | 0.01    |   | 0.00000           | L/C     | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Chestnuts   | 0.01    |   | 0.00000           | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Coconuts    | 0.01    |   | 0.00000           | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Hazelnuts   | 0.01    |   | 0.00000           | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Pecan nuts  | 0.01    |   | 0.00000           | L/C     | 0.00000 | L/C     | 0.00000 | 0.00000 | L/C     | 0.00000 | 0.00000 | L/C     |
| Pistachios  | 0.01    |   | 0.00000           | L/C     | 0.00000 | L/C     | 0.00000 | L/C     | L/C     | 0.00000 | L/C     | L/C     |
| Walnuts     | 0.01    |   | 0.00000           | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Peanuts     | 0.01    |   | 0.00000           | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |

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|                |       |  |         |         |         |         |         |         |         |         |         |         |
|----------------|-------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Apples         | 0.16  |  | 0.00043 | 0.00135 | 0.00238 | 0.00151 | 0.00120 | 0.00066 | 0.00057 | 0.00053 | 0.00035 | 0.00017 |
| Pears          | 0.16  |  | 0.00022 | 0.00041 | 0.00104 | 0.00058 | 0.00035 | 0.00030 | 0.00023 | 0.00030 | 0.00036 | 0.00019 |
| Apricots       | 0.01  |  | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 |
| Peaches        | 0.34  |  | 0.00046 | 0.00046 | 0.00107 | 0.00054 | 0.00040 | 0.00026 | 0.00015 | 0.00032 | 0.00032 | 0.00015 |
| Plums          | 0.12  |  | 0.00011 | 0.00006 | 0.00026 | 0.00016 | 0.00009 | 0.00003 | 0.00003 | 0.00008 | 0.00008 | 0.00002 |
| Cherries       | 0.93  |  | 0.00044 | 0.00133 | 0.00097 | 0.00140 | 0.00051 | 0.00066 | 0.00055 | 0.00049 | 0.00033 | 0.00008 |
| Table grapes   | 0.26  |  | 0.00034 | 0.00043 | 0.00122 | 0.00056 | 0.00067 | 0.00029 | 0.00016 | 0.00053 | 0.00035 | 0.00012 |
| Wine grapes    | 0.32  |  | 0.00315 | 0.00039 | 0.00028 | 0.00029 | 0.00010 | 0.00032 | 0.00113 | 0.00311 | 0.00213 | 0.00047 |
| Strawberries   | 0.46  |  | 0.00027 | 0.00088 | 0.00092 | 0.00062 | 0.00041 | 0.00032 | 0.00023 | 0.00045 | 0.00047 | 0.00024 |
| Blackberries   | 0.346 |  | 0.00004 | L/C     | 0.00067 | 0.00002 | 0.00011 | 0.00009 | 0.00003 | 0.00011 | 0.00009 | 0.00001 |
| Loganberries   | 0.01  |  | 0.00000 | 0.00001 | 0.00001 | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Raspberries    | 0.346 |  | 0.00014 | L/C     | 0.00082 | 0.00023 | 0.00035 | 0.00009 | 0.00002 | 0.00014 | 0.00029 | 0.00013 |
| Gooseberries   | 0.75  |  | 0.00019 | 0.00039 | 0.00049 | 0.00018 | 0.00018 | 0.00018 | 0.00014 | 0.00054 | 0.00062 | 0.00018 |
| Blackcurrants  | 0.75  |  | 0.00043 | 0.00089 | 0.00134 | 0.00135 | 0.00104 | 0.00077 | 0.00084 | 0.00027 | 0.00040 | 0.00021 |
| Red currants   | 0.75  |  | 0.00006 | L/C     | 0.00059 | L/C     | 0.00004 | 0.00009 | 0.00003 | 0.00003 | 0.00025 | L/C     |
| White currants | 0.75  |  | 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        | 0.01  |  | 0.00002 | 0.00007 | 0.00007 | 0.00004 | 0.00003 | 0.00002 | 0.00001 | 0.00002 | 0.00002 | 0.00002 |
| Dates          | 0.01  |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     | 0.00000 | 0.00001 | 0.00000 |
| Figs           | 0.01  |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 |
| Kiwi fruit     | 0.01  |  | 0.00001 | L/C     | 0.00002 | 0.00002 | 0.00001 | 0.00001 | 0.00002 | 0.00001 | 0.00001 | 0.00000 |
| Lychees        | 0.01  |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Mangoes        | 0.01  |  | 0.00001 | L/C     | 0.00002 | 0.00001 | 0.00002 | 0.00001 | 0.00004 | 0.00001 | 0.00000 | L/C     |
| Olives         | 0.27  |  | 0.00007 | L/C     | 0.00016 | 0.00016 | L/C     | 0.00001 | L/C     | 0.00005 | 0.00012 | L/C     |
| Passion fruit  | 0.01  |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | L/C     | L/C     |
| Pineapples     | 0.01  |  | 0.00001 | 0.00005 | 0.00005 | 0.00007 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|                      |      |  |         |         |         |         |         |         |         |         |         |         |
|----------------------|------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Pomegranates         | 0.01 |  | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00001 | 0.00001 | 0.00001 |
| Beetroot             | 0.01 |  | 0.00000 | L/C     | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Carrots              | 0.01 |  | 0.00001 | 0.00004 | 0.00002 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 |
| Celeriac             | 0.01 |  | 0.00000 | L/C     | L/C     | 0.00000 | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     |
| Horseradish          | 0.01 |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | L/C     |
| Jerusalem artichokes | 0.01 |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Parsnips             | 0.01 |  | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Radishes             | 0.01 |  | 0.00000 | L/C     | 0.00001 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Salsify              | 0.01 |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Swedes               | 0.01 |  | 0.00000 | 0.00003 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Turnips              | 0.01 |  | 0.00000 | L/C     | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Yam                  | 0.01 |  | 0.00003 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Garlic               | 0.02 |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Onions               | 0.02 |  | 0.00001 | 0.00002 | 0.00002 | 0.00002 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 |
| Spring onions        | 1.3  |  | 0.00033 | L/C     | 0.00021 | 0.00085 | 0.00024 | 0.00012 | 0.00014 | 0.00033 | 0.00033 | 0.00012 |
| Tomatoes             | 0.17 |  | 0.00023 | 0.00031 | 0.00045 | 0.00033 | 0.00031 | 0.00018 | 0.00023 | 0.00030 | 0.00025 | 0.00023 |
| Peppers              | 0.14 |  | 0.00005 | L/C     | 0.00011 | 0.00006 | 0.00009 | 0.00004 | 0.00004 | 0.00008 | 0.00008 | 0.00003 |
| Aubergines           | 0.14 |  | 0.00004 | L/C     | 0.00021 | 0.00011 | 0.00004 | 0.00007 | 0.00005 | 0.00009 | 0.00006 | L/C     |
| Marrows              | 0.08 |  | 0.00004 | L/C     | 0.00012 | 0.00003 | 0.00005 | 0.00005 | 0.00002 | 0.00004 | 0.00011 | 0.00005 |
| Cucumbers            | 0.08 |  | 0.00003 | 0.00002 | 0.00019 | 0.00012 | 0.00008 | 0.00004 | 0.00004 | 0.00004 | 0.00004 | 0.00001 |
| Gourd                | 0.08 |  | 0.00004 | L/C     | L/C     | L/C     | L/C     | 0.00002 | L/C     | 0.00002 | L/C     | L/C     |
| Courgettes           | 0.08 |  | 0.00003 | 0.00012 | 0.00019 | 0.00010 | 0.00006 | 0.00003 | 0.00003 | 0.00004 | 0.00004 | 0.00004 |
| 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           | 0.01 |  | 0.00001 | 0.00001 | 0.00002 | 0.00001 | 0.00001 | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00000 |
| Broccoli             | 0.56 |  | 0.00036 | 0.00064 | 0.00096 | 0.00068 | 0.00059 | 0.00040 | 0.00035 | 0.00038 | 0.00054 | 0.00019 |
| Cauliflower          | 0.56 |  | 0.00049 | 0.00176 | 0.00122 | 0.00094 | 0.00048 | 0.00042 | 0.00048 | 0.00068 | 0.00064 | 0.00037 |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|                      |       |  |         |         |         |         |         |         |         |         |         |         |
|----------------------|-------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Brussels sprouts     | 0.56  |  | 0.00034 | 0.00131 | 0.00100 | 0.00082 | 0.00041 | 0.00052 | 0.00035 | 0.00044 | 0.00054 | 0.00026 |
| Head cabbage         | 1.72  |  | 0.00094 | 0.00302 | 0.00293 | 0.00217 | 0.00129 | 0.00123 | 0.00091 | 0.00130 | 0.00199 | 0.00126 |
| Chinese cabbage      | 4.32  |  | 0.00215 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00216 | 0.00151 | L/C     |
| Kohl Rabi            | 0.56  |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Cress                | 4.7   |  | 0.00018 | L/C     | 0.00023 | 0.00032 | 0.00011 | 0.00020 | 0.00014 | 0.00036 | 0.00045 | 0.00019 |
| Lettuce              | 2.658 |  | 0.00165 | 0.00095 | 0.00227 | 0.00183 | 0.00193 | 0.00107 | 0.00117 | 0.00187 | 0.00142 | 0.00073 |
| Spinach              | 0.125 |  | 0.00007 | 0.00013 | 0.00020 | 0.00011 | 0.00011 | 0.00008 | 0.00004 | 0.00009 | 0.00007 | 0.00004 |
| Watercress           | 0.01  |  | 0.00000 | L/C     | L/C     | 0.00000 | 0.00000 | 0.00000 | L/C     | 0.00000 | 0.00000 | L/C     |
| Chicory              | 1.149 |  | 0.00009 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00008 | L/C     | L/C     |
| Parsley              | 4.7   |  | 0.00080 | L/C     | 0.00052 | L/C     | 0.00075 | 0.00020 | 0.00007 | 0.00080 | 0.00084 | 0.00172 |
| Beans with pods      | 0.29  |  | 0.00015 | 0.00035 | 0.00056 | 0.00038 | 0.00019 | 0.00010 | 0.00020 | 0.00012 | 0.00021 | 0.00009 |
| Runner Beans         | 0.29  |  | 0.00018 | L/C     | 0.00043 | 0.00014 | 0.00021 | 0.00017 | 0.00014 | 0.00044 | 0.00028 | 0.00016 |
| Beans without pods   | 0.07  |  | 0.00003 | 0.00004 | 0.00017 | 0.00003 | 0.00007 | 0.00003 | 0.00003 | 0.00004 | 0.00006 | 0.00004 |
| Peas with pods       | 0.7   |  | 0.00020 | L/C     | 0.00033 | 0.00088 | 0.00016 | 0.00020 | 0.00012 | 0.00018 | 0.00036 | L/C     |
| Peas without pods    | 0.07  |  | 0.00005 | 0.00017 | 0.00014 | 0.00010 | 0.00007 | 0.00005 | 0.00006 | 0.00006 | 0.00007 | 0.00005 |
| Beansprouts          | 0.01  |  | 0.00000 | L/C     | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Asparagus            | 0.01  |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | 0.00001 | 0.00000 | L/C     |
| Bamboo shoots        | 0.01  |  | 0.00000 | L/C     | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Celery               | 2     |  | 0.00065 | 0.00085 | 0.00084 | 0.00058 | 0.00032 | 0.00050 | 0.00036 | 0.00092 | 0.00097 | 0.00022 |
| Fennel               | 0.01  |  | 0.00000 | 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                | 0.088 |  | 0.00004 | L/C     | 0.00006 | 0.00003 | 0.00003 | 0.00003 | 0.00002 | 0.00004 | 0.00005 | 0.00003 |
| Rhubarb              | 0.01  |  | 0.00000 | 0.00001 | 0.00001 | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Cultivated mushrooms | 0.01  |  | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 |
| Beans                | 0.032 |  | 0.00005 | 0.00019 | 0.00015 | 0.00011 | 0.00009 | 0.00007 | 0.00007 | 0.00006 | 0.00004 | 0.00003 |
| Lentils              | 0.032 |  | 0.00002 | 0.00005 | 0.00006 | 0.00006 | 0.00002 | 0.00004 | 0.00002 | 0.00002 | 0.00002 | 0.00001 |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|                            |        |  |         |         |         |         |         |         |         |         |         |         |
|----------------------------|--------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| dried Peas                 | 0.032  |  | 0.00002 | L/C     | 0.00006 | 0.00001 | 0.00002 | 0.00004 | 0.00002 | 0.00002 | 0.00003 | 0.00002 |
| Oilseeds                   | 0.27   |  | 0.00086 | 0.00170 | 0.00196 | 0.00193 | 0.00151 | 0.00109 | 0.00095 | 0.00126 | 0.00086 | 0.00104 |
| Potatoes                   | 0.01   |  | 0.00003 | 0.00011 | 0.00009 | 0.00008 | 0.00007 | 0.00005 | 0.00005 | 0.00004 | 0.00003 | 0.00003 |
| Tea (dried leaves)         | 4.05   |  | 0.00086 | 0.00289 | 0.00106 | 0.00065 | 0.00048 | 0.00045 | 0.00055 | 0.00090 | 0.00085 | 0.00093 |
| Hops (dried 0.25% of beer) | 0.05   |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Oats                       | 0.01   |  | 0.00000 | 0.00002 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00001 |
| Barley                     | 0.01   |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Millet                     | 0.01   |  | L/C     | L/C     | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Buckwheat                  | 0.01   |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Maize                      | 0.01   |  | 0.00000 | 0.00005 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Wheat                      | 0.01   |  | 0.00004 | 0.00003 | 0.00008 | 0.00009 | 0.00007 | 0.00005 | 0.00004 | 0.00004 | 0.00003 | 0.00003 |
| Rice                       | 0.01   |  | 0.00002 | 0.00003 | 0.00005 | 0.00004 | 0.00005 | 0.00004 | 0.00003 | 0.00002 | 0.00001 | 0.00000 |
| Rye                        | 0.01   |  | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 |
| Poultry                    | 0.0039 |  | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00000 |
| Meat fat                   | 0.1    |  | 0.00002 | 0.00004 | 0.00007 | 0.00004 | 0.00003 | 0.00003 | 0.00002 | 0.00001 | 0.00002 | 0.00002 |
| Meat excl. poultry & offal | 0.041  |  | 0.00008 | 0.00017 | 0.00017 | 0.00014 | 0.00013 | 0.00008 | 0.00009 | 0.00002 | 0.00007 | 0.00007 |
| All types of kidney        | 0.38   |  | 0.00011 | 0.00016 | 0.00051 | 0.00013 | 0.00009 | 0.00008 | 0.00011 | L/C     | 0.00018 | 0.00012 |
| All types of Liver         | 0.38   |  | 0.00018 | 0.00085 | 0.00091 | 0.00013 | 0.00016 | 0.00023 | 0.00011 | L/C     | 0.00026 | 0.00018 |
| Other types of offal       | 0.38   |  | 0.00026 | 0.00060 | 0.00083 | 0.00042 | 0.00036 | 0.00039 | 0.00018 | 0.00006 | 0.00029 | 0.00027 |
| Eggs                       | 0.048  |  | 0.00005 | 0.00023 | 0.00017 | 0.00011 | 0.00008 | 0.00007 | 0.00005 | 0.00005 | 0.00005 | 0.00007 |
| 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                 | 0.01   |  | 0.00014 | 0.00033 | 0.00056 | 0.00034 | 0.00031 | 0.00020 | 0.00019 | 0.00012 | 0.00011 | 0.00015 |

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

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

**Table B.4 Chronic risk assessment undertaken using PRIMo revision 3.1 – Scenario 2**

| Chronic risk assessment: JMPR methodology (IEDI/TMDI)          |                                |                   |                                            |                                              |                                         |                                          |                                    |                                          |                                         |                                   |                                                |
|----------------------------------------------------------------|--------------------------------|-------------------|--------------------------------------------|----------------------------------------------|-----------------------------------------|------------------------------------------|------------------------------------|------------------------------------------|-----------------------------------------|-----------------------------------|------------------------------------------------|
|                                                                |                                |                   | No of diets exceeding the ADI :<br>--<br>- |                                              |                                         |                                          |                                    |                                          |                                         |                                   | Exposure resulting from                        |
|                                                                | Calculated exposure (% of ADI) | MS Diet           | Exposure (µg/kg bw per day)                | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities        | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities   | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities        | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
| TMDI/NEDI/IEDI calculation (based on average food consumption) | 91.5%                          | NL toddler        | 9.15                                       | 29.9%                                        | Milk: Cattle                            | 17.3%                                    | Apples                             | 6.9%                                     | Pears                                   |                                   | 3.8%                                           |
|                                                                | 56.5%                          | DE child          | 5.65                                       | 20.0%                                        | Apples                                  | 9.9%                                     | Milk: Cattle                       | 3.6%                                     | Table grapes                            |                                   | 3.0%                                           |
|                                                                | 46.5%                          | NL child          | 4.65                                       | 12.2%                                        | Milk: Cattle                            | 9.2%                                     | Apples                             | 2.7%                                     | Table grapes                            |                                   | 1.5%                                           |
|                                                                | 37.0%                          | GEMS/Food G10     | 3.70                                       | 6.8%                                         | Chinese cabbages/pe-tsai                | 3.1%                                     | Cress and other sprouts and shoots | 2.7%                                     | Milk: Cattle                            |                                   | 4.3%                                           |
|                                                                | 35.8%                          | UK infant         | 3.58                                       | 19.4%                                        | Milk: Cattle                            | 2.5%                                     | Apples                             | 2.3%                                     | Tea (dried leaves of Camellia sinensis) |                                   | 0.0%                                           |
|                                                                | 35.5%                          | SE general        | 3.55                                       | 8.6%                                         | Chinese cabbages/pe-tsai                | 6.2%                                     | Milk: Cattle                       | 3.5%                                     | Head cabbages                           |                                   | 0.3%                                           |
|                                                                | 33.5%                          | IE adult          | 3.35                                       | 5.3%                                         | Tea (dried leaves of Camellia sinensis) | 4.0%                                     | Wine grapes                        | 2.6%                                     | Celeries                                |                                   | 0.7%                                           |
|                                                                | 33.4%                          | GEMS/Food G11     | 3.34                                       | 5.6%                                         | Celeries                                | 3.9%                                     | Milk: Cattle                       | 3.3%                                     | Wine grapes                             |                                   | 3.3%                                           |
|                                                                | 32.8%                          | FR toddler 2 3 yr | 3.28                                       | 14.6%                                        | Milk: Cattle                            | 5.1%                                     | Apples                             | 2.3%                                     | Beans (with pods)                       |                                   | 0.8%                                           |
|                                                                | 32.5%                          | RO general        | 3.25                                       | 8.0%                                         | Head cabbages                           | 5.8%                                     | Milk: Cattle                       | 5.4%                                     | Wine grapes                             |                                   |                                                |
|                                                                | 32.3%                          | GEMS/Food G06     | 3.23                                       | 6.1%                                         | Tomatoes                                | 2.7%                                     | Table grapes                       | 2.1%                                     | Tea (dried leaves of Camellia sinensis) |                                   | 2.1%                                           |
|                                                                | 32.2%                          | GEMS/Food G08     | 3.22                                       | 3.3%                                         | Wine grapes                             | 2.8%                                     | Milk: Cattle                       | 2.5%                                     | Head cabbages                           |                                   | 2.6%                                           |
|                                                                | 32.1%                          | GEMS/Food G07     | 3.21                                       | 4.7%                                         | Wine grapes                             | 3.2%                                     | Milk: Cattle                       | 2.6%                                     | Celeries                                |                                   | 1.2%                                           |
|                                                                | 31.8%                          | FR child 3 15 yr  | 3.18                                       | 11.4%                                        | Milk: Cattle                            | 2.7%                                     | Apples                             | 1.4%                                     | Tomatoes                                |                                   | 0.6%                                           |
|                                                                | 31.2%                          | GEMS/Food G15     | 3.12                                       | 4.6%                                         | Head cabbages                           | 3.5%                                     | Milk: Cattle                       | 3.2%                                     | Wine grapes                             |                                   | 0.5%                                           |
|                                                                | 27.1%                          | DE women 14-50 yr | 2.71                                       | 6.2%                                         | Milk: Cattle                            | 4.1%                                     | Apples                             | 2.7%                                     | Wine grapes                             |                                   | 0.9%                                           |
|                                                                | 26.1%                          | DE general        | 2.61                                       | 6.2%                                         | Milk: Cattle                            | 3.9%                                     | Apples                             | 2.7%                                     | Wine grapes                             |                                   | 0.8%                                           |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|       |               |      |       |                          |      |                                         |      |                                         |      |
|-------|---------------|------|-------|--------------------------|------|-----------------------------------------|------|-----------------------------------------|------|
| 25.4% | UK toddler    | 2.54 | 10.3% | Milk: Cattle             | 2.7% | Apples                                  | 1.1% | Tea (dried leaves of Camellia sinensis) | 0.0% |
| 25.0% | FR adult      | 2.50 | 7.4%  | Wine grapes              | 5.7% | Tea (dried leaves of Camellia sinensis) | 2.2% | Milk: Cattle                            | 0.7% |
| 23.9% | ES child      | 2.39 | 6.2%  | Milk: Cattle             | 3.3% | Lettuces                                | 2.0% | Olives for oil production               | 0.2% |
| 23.8% | NL general    | 2.38 | 4.2%  | Milk: Cattle             | 2.3% | Apples                                  | 1.9% | Wine grapes                             | 1.5% |
| 22.4% | DK child      | 2.24 | 6.3%  | Milk: Cattle             | 3.7% | Apples                                  | 1.3% | Cucumbers                               | 0.0% |
| 21.7% | PT general    | 2.17 | 8.0%  | Wine grapes              | 3.2% | Kales                                   | 1.7% | Apples                                  | 0.1% |
| 19.5% | FR infant     | 1.95 | 8.4%  | Milk: Cattle             | 2.7% | Apples                                  | 1.5% | Cauliflowers                            | 0.5% |
| 18.4% | ES adult      | 1.84 | 4.2%  | Lettuces                 | 2.5% | Milk: Cattle                            | 1.3% | Tomatoes                                | 0.2% |
| 15.2% | UK vegetarian | 1.52 | 2.6%  | Wine grapes              | 2.0% | Tea (dried leaves of Camellia sinensis) | 1.6% | Milk: Cattle                            | 0.1% |
| 14.4% | DK adult      | 1.44 | 3.1%  | Wine grapes              | 2.6% | Milk: Cattle                            | 1.5% | Apples                                  | 0.0% |
| 13.7% | UK adult      | 1.37 | 3.5%  | Wine grapes              | 2.2% | Tea (dried leaves of Camellia sinensis) | 1.5% | Milk: Cattle                            | 0.0% |
| 13.2% | IT toddler    | 1.32 | 2.4%  | Tomatoes                 | 2.3% | Lettuces                                | 1.4% | Apples                                  | 0.5% |
| 12.9% | IT adult      | 1.29 | 3.0%  | Lettuces                 | 2.0% | Tomatoes                                | 1.3% | Peaches                                 | 0.8% |
| 12.4% | FI 3 yr       | 1.24 | 1.7%  | Strawberries             | 1.5% | Apples                                  | 1.0% | Tomatoes                                | 0.1% |
| 12.3% | PL general    | 1.23 | 3.3%  | Apples                   | 2.0% | Head cabbages                           | 1.5% | Tomatoes                                | 0.1% |
| 11.7% | LT adult      | 1.17 | 3.0%  | Apples                   | 2.2% | Head cabbages                           | 2.0% | Milk: Cattle                            |      |
| 10.1% | FI 6 yr       | 1.01 | 1.4%  | Chinese cabbages/pe-tsai | 1.3% | Strawberries                            | 0.9% | Apples                                  | 0.1% |
| 8.8%  | FI adult      | 0.88 | 1.1%  | Lettuces                 | 1.0% | Wine grapes                             | 0.9% | Tomatoes                                | 0.0% |
| 4.8%  | IE child      | 0.48 | 1.8%  | Milk: Cattle             | 0.5% | Apples                                  | 0.3% | Broccoli                                | 0.0% |

**Table B.5 Chronic risk assessment undertaken using UK model version 1.1 – IN-N5M09**

Active substance:

ADI: 0.0015 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 | 0.00027                                 | 0.00070 | 0.00112 | 0.00079   | 0.00077    | 0.00047     | 0.00043     | 0.00034    | 0.00029            | 0.00024               |
| % of ADI     | 18%                                     | 46%     | 75%     | 52%       | 52%        | 31%         | 28%         | 22%        | 19%                | 16%                   |

| STMR         |         | P | COMMODITY INTAKES |         |         |         |         |         |         |         |         |         |
|--------------|---------|---|-------------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Commodity    | (mg/kg) |   | (mg/kg bw/day)    |         |         |         |         |         |         |         |         |         |
| Grapefruit   | 0.03232 |   | 0.00006           | 0.00005 | 0.00019 | 0.00017 | 0.00037 | 0.00007 | 0.00005 | 0.00008 | 0.00008 | 0.00006 |
| Lemons       | 0.03232 |   | 0.00000           | 0.00002 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00001 | 0.00000 |
| Limes        | 0.03232 |   | 0.00001           | L/C     | 0.00005 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00002 |
| Mandarins    | 0.03232 |   | 0.00005           | L/C     | 0.00021 | 0.00012 | 0.00009 | 0.00005 | 0.00005 | 0.00004 | 0.00005 | 0.00002 |
| Oranges      | 0.03232 |   | 0.00012           | 0.00035 | 0.00053 | 0.00036 | 0.00027 | 0.00026 | 0.00021 | 0.00015 | 0.00012 | 0.00009 |
| Apples       | 0.03232 |   | 0.00009           | 0.00027 | 0.00048 | 0.00030 | 0.00024 | 0.00013 | 0.00012 | 0.00011 | 0.00007 | 0.00003 |
| Pears        | 0.03232 |   | 0.00005           | 0.00008 | 0.00021 | 0.00012 | 0.00007 | 0.00006 | 0.00005 | 0.00006 | 0.00007 | 0.00004 |
| Peaches      | 0.06868 |   | 0.00009           | 0.00009 | 0.00022 | 0.00011 | 0.00008 | 0.00005 | 0.00003 | 0.00006 | 0.00006 | 0.00003 |
| Plums        | 0.02424 |   | 0.00002           | 0.00001 | 0.00005 | 0.00003 | 0.00002 | 0.00001 | 0.00001 | 0.00002 | 0.00002 | 0.00001 |
| Cherries     | 0.18786 |   | 0.00009           | 0.00027 | 0.00020 | 0.00028 | 0.00010 | 0.00013 | 0.00011 | 0.00010 | 0.00007 | 0.00002 |
| Table grapes | 0.05252 |   | 0.00007           | 0.00009 | 0.00025 | 0.00011 | 0.00014 | 0.00006 | 0.00003 | 0.00011 | 0.00007 | 0.00002 |
| Strawberries | 0.09191 |   | 0.00005           | 0.00018 | 0.00018 | 0.00012 | 0.00008 | 0.00006 | 0.00005 | 0.00009 | 0.00009 | 0.00005 |
| Blackberries | 0.07    |   | 0.00001           | L/C     | 0.00014 | 0.00000 | 0.00002 | 0.00002 | 0.00001 | 0.00002 | 0.00002 | 0.00000 |
| Raspberries  | 0.07    |   | 0.00003           | L/C     | 0.00017 | 0.00005 | 0.00007 | 0.00002 | 0.00000 | 0.00003 | 0.00006 | 0.00003 |
| Gooseberries | 0.1515  |   | 0.00004           | 0.00008 | 0.00010 | 0.00004 | 0.00004 | 0.00004 | 0.00003 | 0.00011 | 0.00012 | 0.00004 |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|                  |          |  |         |         |         |         |         |         |         |         |         |         |
|------------------|----------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Blackcurrants    | 0.1515   |  | 0.00009 | 0.00018 | 0.00027 | 0.00027 | 0.00021 | 0.00016 | 0.00017 | 0.00005 | 0.00008 | 0.00004 |
| Red currants     | 0.1515   |  | 0.00001 | L/C     | 0.00012 | L/C     | 0.00001 | 0.00002 | 0.00001 | 0.00001 | 0.00005 | L/C     |
| White currants   | 0.1515   |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Avocados         | 0.006    |  | 0.00000 | L/C     | 0.00001 | L/C     | L/C     | L/C     | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Mangoes          | 0.00202  |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 | L/C     |
| Olives           | 0.055    |  | 0.00001 | L/C     | 0.00003 | 0.00003 | L/C     | 0.00000 | L/C     | 0.00001 | 0.00002 | L/C     |
| Garlic           | 0.0002   |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Onions           | 0.0002   |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Spring onions    | 0.0117   |  | 0.00000 | L/C     | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Tomatoes         | 0.03434  |  | 0.00005 | 0.00006 | 0.00009 | 0.00007 | 0.00006 | 0.00004 | 0.00005 | 0.00006 | 0.00005 | 0.00005 |
| Peppers          | 0.02828  |  | 0.00001 | L/C     | 0.00002 | 0.00001 | 0.00002 | 0.00001 | 0.00001 | 0.00002 | 0.00002 | 0.00001 |
| Aubergines       | 0.02828  |  | 0.00001 | L/C     | 0.00004 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00002 | 0.00001 | L/C     |
| Marrows          | 0.01616  |  | 0.00001 | L/C     | 0.00003 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00001 | 0.00002 | 0.00001 |
| Cucumbers        | 0.01616  |  | 0.00001 | 0.00000 | 0.00004 | 0.00002 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00000 |
| Gourd            | 0.01616  |  | 0.00001 | L/C     | L/C     | L/C     | L/C     | 0.00000 | L/C     | 0.00000 | L/C     | L/C     |
| Courgettes       | 0.01616  |  | 0.00001 | 0.00002 | 0.00004 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 |
| Melons           | 0.01212  |  | 0.00003 | 0.00004 | 0.00006 | 0.00004 | 0.00004 | 0.00003 | 0.00003 | 0.00003 | 0.00004 | 0.00001 |
| Broccoli         | 0.00504  |  | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Cauliflower      | 0.00504  |  | 0.00000 | 0.00002 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00001 | 0.00000 |
| Brussels sprouts | 0.00504  |  | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Head cabbage     | 0.005    |  | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Chinese cabbage  | 0.024    |  | 0.00001 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00001 | 0.00001 | L/C     |
| Kohl Rabi        | 0.005    |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Spinach          | 0.001125 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Parsley          | 0.306    |  | 0.00005 | L/C     | 0.00003 | L/C     | 0.00005 | 0.00001 | 0.00000 | 0.00005 | 0.00005 | 0.00011 |
| Beans with pods  | 0.00261  |  | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |

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|                    |          |  |         |         |         |         |         |         |         |         |         |         |
|--------------------|----------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Runner Beans       | 0.00261  |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Beans without pods | 0.00063  |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Peas with pods     | 0.0063   |  | 0.00000 | L/C     | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Peas without pods  | 0.00063  |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Celery             | 0.018    |  | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00001 | 0.00000 |
| Globe artichokes   | 0.0003   |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | L/C     | L/C     |
| Leeks              | 0.000495 |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Beans              | 0.0003   |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Lentils            | 0.0003   |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| dried Peas         | 0.0003   |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Oilseeds           | 0.0003   |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |

\* 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.6 Chronic risk assessment undertaken using PRIMo revision 3.1 – IN-N5M09**

| Chronic risk assessment: JMPR methodology (IEDI/TMDI)          |                                |                   |                                 |                                              |                                  |                                          |                                  |                                          |                                  |                                   |                                                |
|----------------------------------------------------------------|--------------------------------|-------------------|---------------------------------|----------------------------------------------|----------------------------------|------------------------------------------|----------------------------------|------------------------------------------|----------------------------------|-----------------------------------|------------------------------------------------|
|                                                                |                                |                   | No of diets exceeding the ADI : |                                              |                                  |                                          |                                  |                                          | Exposure resulting from          |                                   |                                                |
|                                                                | Calculated exposure (% of ADI) | MS Diet           | Exposure (µg/kg bw per day)     | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
| TMDI/NEDI/IEDI calculation (based on average food consumption) | 59.2%                          | DE child          | 0.887441                        | 26.9%                                        | Apples                           | 8.7%                                     | Oranges                          | 4.8%                                     | Table grapes                     |                                   | 0.7%                                           |
|                                                                | 58.4%                          | NL toddler        | 0.88                            | 23.2%                                        | Apples                           | 9.3%                                     | Pears                            | 5.4%                                     | Table grapes                     |                                   | 0.1%                                           |
|                                                                | 33.9%                          | NL child          | 0.51                            | 12.5%                                        | Apples                           | 3.6%                                     | Table grapes                     | 3.1%                                     | Oranges                          |                                   | 0.0%                                           |
|                                                                | 25.5%                          | GEMS/Food G06     | 0.38                            | 8.2%                                         | Tomatoes                         | 3.7%                                     | Table grapes                     | 2.2%                                     | Oranges                          |                                   | 0.2%                                           |
|                                                                | 19.2%                          | FR child 3 15 yr  | 0.29                            | 7.3%                                         | Oranges                          | 3.6%                                     | Apples                           | 1.9%                                     | Tomatoes                         |                                   | 0.1%                                           |
|                                                                | 18.6%                          | DE women 14-50 yr | 0.28                            | 5.6%                                         | Apples                           | 4.1%                                     | Oranges                          | 1.7%                                     | Tomatoes                         |                                   | 0.1%                                           |
|                                                                | 16.4%                          | DE general        | 0.25                            | 5.2%                                         | Apples                           | 3.4%                                     | Oranges                          | 1.5%                                     | Tomatoes                         |                                   | 0.1%                                           |
|                                                                | 16.1%                          | IE adult          | 0.24                            | 2.2%                                         | Oranges                          | 1.5%                                     | Apples                           | 1.5%                                     | Grapefruits                      |                                   | 0.2%                                           |
|                                                                | 15.7%                          | FR toddler 2 3 yr | 0.24                            | 6.8%                                         | Apples                           | 3.1%                                     | Oranges                          | 1.7%                                     | Mandarins                        |                                   | 0.1%                                           |
|                                                                | 15.5%                          | GEMS/Food G15     | 0.23                            | 2.7%                                         | Tomatoes                         | 2.4%                                     | Apples                           | 1.4%                                     | Oranges                          |                                   | 0.2%                                           |
|                                                                | 15.2%                          | UK toddler        | 0.23                            | 4.3%                                         | Oranges                          | 3.7%                                     | Apples                           | 1.3%                                     | Tomatoes                         |                                   | 0.0%                                           |
|                                                                | 14.7%                          | RO general        | 0.22                            | 4.4%                                         | Tomatoes                         | 3.1%                                     | Apples                           | 1.7%                                     | Cherries (sweet)                 |                                   |                                                |
|                                                                | 14.6%                          | GEMS/Food G10     | 0.22                            | 3.1%                                         | Tomatoes                         | 2.4%                                     | Oranges                          | 1.6%                                     | Apples                           |                                   | 0.2%                                           |
|                                                                | 14.5%                          | GEMS/Food G08     | 0.22                            | 2.6%                                         | Apples                           | 2.6%                                     | Tomatoes                         | 1.2%                                     | Table grapes                     |                                   | 0.2%                                           |
|                                                                | 14.4%                          | ES child          | 0.22                            | 4.7%                                         | Oranges                          | 2.5%                                     | Apples                           | 2.2%                                     | Tomatoes                         |                                   | 0.0%                                           |
|                                                                | 13.6%                          | GEMS/Food G11     | 0.20                            | 3.3%                                         | Apples                           | 2.1%                                     | Tomatoes                         | 1.6%                                     | Oranges                          |                                   | 0.1%                                           |

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|                                                                                                                                                                                                  |               |      |      |              |      |                                 |      |              |      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|------|------|--------------|------|---------------------------------|------|--------------|------|
| 13.6%                                                                                                                                                                                            | GEMS/Food G07 | 0.20 | 3.0% | Oranges      | 2.5% | Tomatoes                        | 2.2% | Apples       | 0.2% |
| 13.3%                                                                                                                                                                                            | DK child      | 0.20 | 5.0% | Apples       | 1.8% | Cucumbers                       | 1.5% | Pears        | 0.0% |
| 12.6%                                                                                                                                                                                            | SE general    | 0.19 | 2.3% | Apples       | 1.8% | Tomatoes                        | 1.6% | Oranges      | 0.1% |
| 12.4%                                                                                                                                                                                            | FI 3 yr       | 0.19 | 2.2% | Strawberries | 2.0% | Apples                          | 1.3% | Tomatoes     | 0.0% |
| 12.4%                                                                                                                                                                                            | IT toddler    | 0.19 | 3.3% | Tomatoes     | 1.9% | Apples                          | 1.6% | Peaches      | 0.1% |
| 11.3%                                                                                                                                                                                            | PL general    | 0.17 | 4.4% | Apples       | 2.0% | Tomatoes                        | 1.1% | Table grapes | 0.1% |
| 11.3%                                                                                                                                                                                            | UK infant     | 0.17 | 3.4% | Apples       | 2.8% | Oranges                         | 1.3% | Strawberries | 0.0% |
| 10.9%                                                                                                                                                                                            | PT general    | 0.16 | 2.3% | Apples       | 2.0% | Tomatoes                        | 1.6% | Peaches      | 0.0% |
| 10.7%                                                                                                                                                                                            | NL general    | 0.16 | 3.1% | Apples       | 2.2% | Oranges                         | 1.0% | Tomatoes     | 0.0% |
| 10.6%                                                                                                                                                                                            | IT adult      | 0.16 | 2.7% | Tomatoes     | 1.7% | Peaches                         | 1.7% | Apples       | 0.1% |
| 10.6%                                                                                                                                                                                            | ES adult      | 0.16 | 2.8% | Oranges      | 1.8% | Tomatoes                        | 1.7% | Apples       | 0.0% |
| 9.2%                                                                                                                                                                                             | FI 6 yr       | 0.14 | 1.7% | Strawberries | 1.3% | Apples                          | 1.0% | Tomatoes     | 0.0% |
| 7.6%                                                                                                                                                                                             | LT adult      | 0.11 | 4.0% | Apples       | 1.4% | Tomatoes                        | 0.4% | Cucumbers    |      |
| 7.4%                                                                                                                                                                                             | FR infant     | 0.11 | 3.6% | Apples       | 1.1% | Strawberries                    | 0.5% | Oranges      | 0.1% |
| 7.4%                                                                                                                                                                                             | FR adult      | 0.11 | 1.7% | Apples       | 1.3% | Oranges                         | 1.1% | Tomatoes     | 0.1% |
| 7.1%                                                                                                                                                                                             | UK vegetarian | 0.11 | 1.9% | Oranges      | 1.4% | Tomatoes                        | 1.3% | Apples       | 0.0% |
| 6.7%                                                                                                                                                                                             | DK adult      | 0.10 | 2.1% | Apples       | 1.2% | Tomatoes                        | 0.7% | Pears        | 0.0% |
| 6.4%                                                                                                                                                                                             | FI adult      | 0.10 | 1.3% | Tomatoes     | 1.3% | Apples                          | 0.9% | Oranges      | 0.0% |
| 4.8%                                                                                                                                                                                             | UK adult      | 0.07 | 1.2% | Oranges      | 1.0% | Tomatoes                        | 0.9% | Apples       | 0.0% |
| 2.0%                                                                                                                                                                                             | IE child      | 0.03 | 0.7% | Apples       | 0.3% | Currants (red, black and white) | 0.2% | Table grapes | 0.0% |
| <b>Conclusion:</b><br>The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.<br>The long-term intake of residues of IN-N5M09 is unlikely to present a public health concern. |               |      |      |              |      |                                 |      |              |      |



**Table B.7 Acute risk assessment undertaken using UK model version 1.2 – IN-N5M09**

| commodity | HR   | P | adult   |       | infant  |       | toddler |       | 4-6 year old child |       | 7-10 year old child |       |
|-----------|------|---|---------|-------|---------|-------|---------|-------|--------------------|-------|---------------------|-------|
|           |      |   | NESTI   | %ARfD | NESTI   | %ARfD | NESTI   | %ARfD | NESTI              | %ARfD | NESTI               | %ARfD |
| Spinach   | 0.01 |   | 0.00001 | 0.3   | 0.00003 | 0.6   | 0.00002 | 0.4   | 0.00003            | 0.6   | 0.00002             | 0.3   |
| Parsley   | 1.24 |   | 0.00081 | 16.2  | 0.00000 | 0.0   | 0.00038 | 7.7   | 0.00036            | 7.2   | 0.00135             | 27.0  |

| commodity | HR   | P | 11-14 year old child |       | 15-18 year old child |       | vegetarian |       | Elderly - own home |       | Elderly - residential |       |
|-----------|------|---|----------------------|-------|----------------------|-------|------------|-------|--------------------|-------|-----------------------|-------|
|           |      |   | NESTI                | %ARfD | NESTI                | %ARfD | NESTI      | %ARfD | NESTI              | %ARfD | NESTI                 | %ARfD |
| Spinach   | 0.01 |   | 0.00002              | 0.3   | 0.00001              | 0.2   | 0.00002    | 0.4   | 0.00001            | 0.2   | 0.00001               | 0.2   |
| Parsley   | 1.24 |   | 0.00036              | 7.2   | 0.00012              | 2.5   | 0.00148    | 29.6  | 0.00054            | 10.7  | 0.00052               | 10.3  |

Pesticide

ARfD 0.005 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.8 Acute risk assessment undertaken using PRIMo revision 3.1 – IN-N5M09**

| Unprocessed commodities | <b>Results for children</b><br>No. of commodities for which ARfD/ADI is exceeded (IESTI):                 |                          |                            |                     | <b>Results for adults</b><br>No. of commodities for which ARfD/ADI is exceeded (IESTI): |                          |                            |                     |
|-------------------------|-----------------------------------------------------------------------------------------------------------|--------------------------|----------------------------|---------------------|-----------------------------------------------------------------------------------------|--------------------------|----------------------------|---------------------|
|                         | ---                                                                                                       |                          |                            |                     | ---                                                                                     |                          |                            |                     |
|                         | <b>IESTI</b>                                                                                              |                          |                            |                     | <b>IESTI</b>                                                                            |                          |                            |                     |
|                         | 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) |
|                         | 31.92%                                                                                                    | Chervil                  | 0 / 1.24                   | 1.5957865           | 2.71%                                                                                   | Parsley                  | 0 / 0.11                   | 0.14                |
|                         | 2.47%                                                                                                     | Parsley                  | 0 / 0.11                   | 0.12                | 2.04%                                                                                   | Chards/beet leaves       | 0 / 0.01                   | 0.10                |
|                         | 2.44%                                                                                                     | Spinaches                | 0 / 0.01                   | 0.12                | 1.99%                                                                                   | Chervil                  | 0 / 1.24                   | 0.10                |
|                         | 1.85%                                                                                                     | Chives                   | 0 / 0.11                   | 0.09                | 0.74%                                                                                   | Celery leaves            | 0 / 0.11                   | 0.04                |
|                         | 1.71%                                                                                                     | Sage                     | 0 / 0.11                   | 0.09                | 0.45%                                                                                   | Sage                     | 0 / 0.11                   | 0.02                |
|                         | 1.69%                                                                                                     | Chards/beet leaves       | 0 / 0.01                   | 0.08                | 0.43%                                                                                   | Spinaches                | 0 / 0.01                   | 0.02                |
|                         | 1.65%                                                                                                     | Basil and edible flowers | 0 / 0.11                   | 0.08                | 0.38%                                                                                   | Chives                   | 0 / 0.11                   | 0.02                |
|                         | 1.08%                                                                                                     | Celery leaves            | 0 / 0.11                   | 0.05                | 0.28%                                                                                   | Basil and edible flowers | 0 / 0.11                   | 0.01                |
|                         | 0.14%                                                                                                     | Thyme                    | 0 / 0.11                   | 0.01                | 0.23%                                                                                   | Rosemary                 | 0 / 0.11                   | 0.01                |
|                         | 0.07%                                                                                                     | Rosemary                 | 0 / 0.11                   | 0.00                | 0.23%                                                                                   | Rosemary                 | 0 / 0.11                   | 0.01                |
|                         | 0.02%                                                                                                     | Laurel/bay leaves        | 0 / 0.11                   | 0.00                | 0.23%                                                                                   | Rosemary                 | 0 / 0.11                   | 0.01                |
|                         |                                                                                                           |                          |                            |                     | 0.23%                                                                                   | Rosemary                 | 0 / 0.11                   | 0.01                |
|                         |                                                                                                           |                          |                            |                     | 0.21%                                                                                   | Purslanes                | 0 / 0.01                   | 0.01                |
|                         | Expand/collapse list                                                                                      |                          |                            |                     |                                                                                         |                          |                            |                     |
|                         | <b>Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)</b> |                          |                            |                     |                                                                                         |                          |                            |                     |

| Processed commodity | <b>Results for children</b><br>No of processed commodities for which ARfD/ADI is exceeded (IESTI): |  |  |  | <b>Results for adults</b><br>No of processed commodities for which ARfD/ADI is exceeded (IESTI): |  |  |  |
|---------------------|----------------------------------------------------------------------------------------------------|--|--|--|--------------------------------------------------------------------------------------------------|--|--|--|
|                     | ---                                                                                                |  |  |  | ---                                                                                              |  |  |  |
|                     | <b>IESTI</b>                                                                                       |  |  |  | <b>IESTI</b>                                                                                     |  |  |  |

|                      | Highest % of ARfD/ADI | Processed commodities       | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |  | Highest % of ARfD/ADI | Processed commodities       | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
|----------------------|-----------------------|-----------------------------|----------------------------|---------------------|--|-----------------------|-----------------------------|----------------------------|---------------------|
|                      | 3.4%                  | Chards/beet leaves / boiled | 0 / 0.01                   | 0.17                |  | 1.4%                  | Chards/beet leaves / boiled | 0 / 0.01                   | 0.07                |
|                      | 1.5%                  | Spinaches / frozen; boiled  | 0 / 0.01                   | 0.08                |  | 0.89%                 | Spinaches / frozen; boiled  | 0 / 0.01                   | 0.04                |
|                      | #NUM!                 | #NUM!                       | #NUM!                      | #NUM!               |  | 0.45%                 | Purslanes / boiled          | 0 / 0.01                   | 0.02                |
| Expand/collapse list |                       |                             |                            |                     |  |                       |                             |                            |                     |

**Table B.9 Chronic risk assessment undertaken using UK model version 1.1 – IN-F6L99**

Active substance:

ADI: 0.0015 mg/kg bw/day

| 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                            | 0.00018 | 0.00047 | 0.00076 | 0.00053   | 0.00053    | 0.00032     | 0.00029     | 0.00023    | 0.00020            | 0.00013               |
| % of ADI                                | 12%     | 32%     | 51%     | 36%       | 35%        | 21%         | 19%         | 15%        | 13%                | 9%                    |

| STMR       |         | P | COMMODITY INTAKES |         |         |         |         |         |         |         |         |         |
|------------|---------|---|-------------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Commodity  | (mg/kg) |   | (mg/kg bw/day)    |         |         |         |         |         |         |         |         |         |
| Grapefruit | 0.02208 |   | 0.00004           | 0.00004 | 0.00013 | 0.00012 | 0.00025 | 0.00005 | 0.00003 | 0.00005 | 0.00005 | 0.00004 |
| Lemons     | 0.02208 |   | 0.00000           | 0.00002 | 0.00001 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 |
| Limes      | 0.02208 |   | 0.00001           | L/C     | 0.00004 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00001 |
| Mandarins  | 0.02208 |   | 0.00003           | L/C     | 0.00014 | 0.00008 | 0.00006 | 0.00003 | 0.00004 | 0.00003 | 0.00003 | 0.00001 |
| Oranges    | 0.02208 |   | 0.00009           | 0.00024 | 0.00036 | 0.00025 | 0.00018 | 0.00018 | 0.00015 | 0.00010 | 0.00008 | 0.00006 |
| Apples     | 0.02208 |   | 0.00006           | 0.00019 | 0.00033 | 0.00021 | 0.00017 | 0.00009 | 0.00008 | 0.00007 | 0.00005 | 0.00002 |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|                |         |  |         |         |         |         |         |         |         |         |         |         |
|----------------|---------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Pears          | 0.02208 |  | 0.00003 | 0.00006 | 0.00014 | 0.00008 | 0.00005 | 0.00004 | 0.00003 | 0.00004 | 0.00005 | 0.00003 |
| Peaches        | 0.04692 |  | 0.00006 | 0.00006 | 0.00015 | 0.00007 | 0.00006 | 0.00004 | 0.00002 | 0.00004 | 0.00004 | 0.00002 |
| Plums          | 0.01656 |  | 0.00002 | 0.00001 | 0.00004 | 0.00002 | 0.00001 | 0.00000 | 0.00000 | 0.00001 | 0.00001 | 0.00000 |
| Cherries       | 0.12834 |  | 0.00006 | 0.00018 | 0.00013 | 0.00019 | 0.00007 | 0.00009 | 0.00008 | 0.00007 | 0.00005 | 0.00001 |
| Table grapes   | 0.03588 |  | 0.00005 | 0.00006 | 0.00017 | 0.00008 | 0.00009 | 0.00004 | 0.00002 | 0.00007 | 0.00005 | 0.00002 |
| Strawberries   | 0.06279 |  | 0.00004 | 0.00012 | 0.00013 | 0.00008 | 0.00006 | 0.00004 | 0.00003 | 0.00006 | 0.00006 | 0.00003 |
| Blackberries   | 0.048   |  | 0.00001 | L/C     | 0.00009 | 0.00000 | 0.00002 | 0.00001 | 0.00000 | 0.00001 | 0.00001 | 0.00000 |
| Raspberries    | 0.048   |  | 0.00002 | L/C     | 0.00011 | 0.00003 | 0.00005 | 0.00001 | 0.00000 | 0.00002 | 0.00004 | 0.00002 |
| Gooseberries   | 0.1035  |  | 0.00003 | 0.00005 | 0.00007 | 0.00003 | 0.00002 | 0.00002 | 0.00002 | 0.00007 | 0.00009 | 0.00002 |
| Blackcurrants  | 0.1035  |  | 0.00006 | 0.00012 | 0.00019 | 0.00019 | 0.00014 | 0.00011 | 0.00012 | 0.00004 | 0.00006 | 0.00003 |
| Red currants   | 0.1035  |  | 0.00001 | L/C     | 0.00008 | L/C     | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00003 | L/C     |
| White currants | 0.1035  |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Avocados       | 0.004   |  | 0.00000 | L/C     | 0.00001 | L/C     | L/C     | L/C     | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Mangoes        | 0.00138 |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00000 | 0.00000 | L/C     |
| Olives         | 0.037   |  | 0.00001 | L/C     | 0.00002 | 0.00002 | L/C     | 0.00000 | L/C     | 0.00001 | 0.00002 | L/C     |
| Garlic         | 0.00004 |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Onions         | 0.00004 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Spring onions  | 0.003   |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Tomatoes       | 0.02346 |  | 0.00003 | 0.00004 | 0.00006 | 0.00005 | 0.00004 | 0.00003 | 0.00003 | 0.00004 | 0.00003 | 0.00003 |
| Peppers        | 0.01932 |  | 0.00001 | L/C     | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00000 |
| Aubergines     | 0.01932 |  | 0.00001 | L/C     | 0.00003 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | L/C     |
| Marrows        | 0.01104 |  | 0.00001 | L/C     | 0.00002 | 0.00000 | 0.00001 | 0.00001 | 0.00000 | 0.00001 | 0.00002 | 0.00001 |
| Cucumbers      | 0.01104 |  | 0.00000 | 0.00000 | 0.00003 | 0.00002 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00001 | 0.00000 |
| Gourd          | 0.01104 |  | 0.00001 | L/C     | L/C     | L/C     | L/C     | 0.00000 | L/C     | 0.00000 | L/C     | L/C     |
| Courgettes     | 0.01104 |  | 0.00000 | 0.00002 | 0.00003 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00001 | 0.00001 | 0.00000 |
| Melons         | 0.00828 |  | 0.00002 | 0.00003 | 0.00004 | 0.00003 | 0.00003 | 0.00002 | 0.00002 | 0.00002 | 0.00002 | 0.00001 |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|                    |         |  |         |         |         |         |         |         |         |         |         |         |
|--------------------|---------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Broccoli           | 0.00112 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Cauliflower        | 0.00112 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Brussels sprouts   | 0.00112 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Head cabbage       | 0.00112 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Chinese cabbage    | 0.005   |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | 0.00000 | L/C     |
| Kohl Rabi          | 0.00112 |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Spinach            | 0.00025 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Beans with pods    | 0.00058 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Runner Beans       | 0.00058 |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Beans without pods | 0.00014 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Peas with pods     | 0.0014  |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | L/C     |
| Peas without pods  | 0.00014 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Celery             | 0.004   |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Globe artichokes   | 0.00006 |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | L/C     | L/C     |
| Leeks              | 0.00011 |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Beans              | 0.00006 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Lentils            | 0.00006 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| dried Peas         | 0.00006 |  | 0.00000 | L/C     | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |
| Oilseeds           | 0.00006 |  | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 | 0.00000 |

\* 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.10 Chronic risk assessment undertaken using PRIMo revision 3.1 – IN-F6L99**

| Chronic risk assessment: JMPR methodology (IEDI/TMDI)          |                                |                   |                                         |                                              |                                  |                                             |                                  |                                             |                                  |                                   |                                                |
|----------------------------------------------------------------|--------------------------------|-------------------|-----------------------------------------|----------------------------------------------|----------------------------------|---------------------------------------------|----------------------------------|---------------------------------------------|----------------------------------|-----------------------------------|------------------------------------------------|
|                                                                |                                |                   | No of diets exceeding the ADI : --<br>- |                                              |                                  |                                             |                                  |                                             |                                  | Exposure resulting from           |                                                |
|                                                                | Calculated exposure (% of ADI) | MS Diet           | Exposure (µg/kg bw per day)             | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor or to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor or to MS diet (in % of ADI) | Commodity / group of commodities | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
| TMDI/NEDI/IEDI calculation (based on average food consumption) | 39.8%                          | DE child          | 0.597651821                             | 18.4%                                        | Apples                           | 5.9%                                        | Oranges                          | 3.3%                                        | Table grapes                     |                                   | 0.0%                                           |
|                                                                | 39.5%                          | NL toddler        | 0.59                                    | 15.9%                                        | Apples                           | 6.4%                                        | Pears                            | 3.7%                                        | Table grapes                     |                                   | 0.0%                                           |
|                                                                | 23.0%                          | NL child          | 0.34                                    | 8.5%                                         | Apples                           | 2.5%                                        | Table grapes                     | 2.1%                                        | Oranges                          |                                   | 0.0%                                           |
|                                                                | 17.1%                          | GEMS/Food G06     | 0.26                                    | 5.6%                                         | Tomatoes                         | 2.5%                                        | Table grapes                     | 1.5%                                        | Oranges                          |                                   | 0.0%                                           |
|                                                                | 12.9%                          | FR child 3 15 yr  | 0.19                                    | 5.0%                                         | Oranges                          | 2.5%                                        | Apples                           | 1.3%                                        | Tomatoes                         |                                   | 0.0%                                           |
|                                                                | 12.6%                          | DE women 14-50 yr | 0.19                                    | 3.8%                                         | Apples                           | 2.8%                                        | Oranges                          | 1.2%                                        | Tomatoes                         |                                   | 0.0%                                           |
|                                                                | 11.1%                          | DE general        | 0.17                                    | 3.6%                                         | Apples                           | 2.3%                                        | Oranges                          | 1.0%                                        | Tomatoes                         |                                   | 0.0%                                           |
|                                                                | 10.6%                          | IE adult          | 0.16                                    | 1.5%                                         | Oranges                          | 1.0%                                        | Apples                           | 1.0%                                        | Grapefruits                      |                                   | 0.0%                                           |
|                                                                | 10.5%                          | FR toddler 2 3 yr | 0.16                                    | 4.7%                                         | Apples                           | 2.1%                                        | Oranges                          | 1.2%                                        | Mandarins                        |                                   | 0.0%                                           |
|                                                                | 10.3%                          | UK toddler        | 0.15                                    | 2.9%                                         | Oranges                          | 2.5%                                        | Apples                           | 0.9%                                        | Tomatoes                         |                                   | 0.0%                                           |
|                                                                | 10.2%                          | GEMS/Food G15     | 0.15                                    | 1.9%                                         | Tomatoes                         | 1.6%                                        | Apples                           | 1.0%                                        | Oranges                          |                                   | 0.0%                                           |
|                                                                | 9.8%                           | RO general        | 0.15                                    | 3.0%                                         | Tomatoes                         | 2.1%                                        | Apples                           | 1.1%                                        | Cherries (sweet)                 |                                   |                                                |
|                                                                | 9.8%                           | ES child          | 0.15                                    | 3.2%                                         | Oranges                          | 1.7%                                        | Apples                           | 1.5%                                        | Tomatoes                         |                                   | 0.0%                                           |
|                                                                | 9.6%                           | GEMS/Food G08     | 0.14                                    | 1.8%                                         | Apples                           | 1.8%                                        | Tomatoes                         | 0.8%                                        | Table grapes                     |                                   | 0.0%                                           |
|                                                                | 9.5%                           | GEMS/Food G10     | 0.14                                    | 2.1%                                         | Tomatoes                         | 1.7%                                        | Oranges                          | 1.1%                                        | Apples                           |                                   | 0.0%                                           |
|                                                                | 9.1%                           | DK child          | 0.14                                    | 3.4%                                         | Apples                           | 1.2%                                        | Cucumbers                        | 1.0%                                        | Pears                            |                                   | 0.0%                                           |
|                                                                | 9.0%                           | GEMS/Food G11     | 0.13                                    | 2.3%                                         | Apples                           | 1.4%                                        | Tomatoes                         | 1.1%                                        | Oranges                          |                                   | 0.0%                                           |
|                                                                | 8.9%                           | GEMS/Food G07     | 0.13                                    | 2.1%                                         | Oranges                          | 1.7%                                        | Tomatoes                         | 1.5%                                        | Apples                           |                                   | 0.0%                                           |
|                                                                | 8.4%                           | FI 3 yr           | 0.13                                    | 1.5%                                         | Strawberries                     | 1.4%                                        | Apples                           | 0.9%                                        | Tomatoes                         |                                   | 0.0%                                           |
|                                                                | 8.3%                           | IT toddler        | 0.12                                    | 2.2%                                         | Tomatoes                         | 1.3%                                        | Apples                           | 1.1%                                        | Peaches                          |                                   | 0.0%                                           |
|                                                                | 8.2%                           | SE general        | 0.12                                    | 1.5%                                         | Apples                           | 1.2%                                        | Tomatoes                         | 1.1%                                        | Oranges                          |                                   | 0.0%                                           |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|                                                                                                                                                                                         |      |               |      |      |              |      |                                 |      |              |      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---------------|------|------|--------------|------|---------------------------------|------|--------------|------|
|                                                                                                                                                                                         | 7.6% | UK infant     | 0.11 | 2.3% | Apples       | 1.9% | Oranges                         | 0.9% | Strawberries | 0.0% |
|                                                                                                                                                                                         | 7.6% | PL general    | 0.11 | 3.0% | Apples       | 1.4% | Tomatoes                        | 0.8% | Table grapes | 0.0% |
|                                                                                                                                                                                         | 7.4% | PT general    | 0.11 | 1.5% | Apples       | 1.4% | Tomatoes                        | 1.1% | Peaches      |      |
|                                                                                                                                                                                         | 7.2% | ES adult      | 0.11 | 1.9% | Oranges      | 1.2% | Tomatoes                        | 1.1% | Apples       | 0.0% |
|                                                                                                                                                                                         | 7.2% | NL general    | 0.11 | 2.1% | Apples       | 1.5% | Oranges                         | 0.7% | Tomatoes     | 0.0% |
|                                                                                                                                                                                         | 7.1% | IT adult      | 0.11 | 1.8% | Tomatoes     | 1.2% | Peaches                         | 1.2% | Apples       | 0.0% |
|                                                                                                                                                                                         | 6.2% | FI 6 yr       | 0.09 | 1.2% | Strawberries | 0.9% | Apples                          | 0.7% | Tomatoes     | 0.0% |
|                                                                                                                                                                                         | 5.1% | LT adult      | 0.08 | 2.7% | Apples       | 1.0% | Tomatoes                        | 0.3% | Cucumbers    |      |
|                                                                                                                                                                                         | 4.9% | FR adult      | 0.07 | 1.1% | Apples       | 0.9% | Oranges                         | 0.7% | Tomatoes     | 0.0% |
|                                                                                                                                                                                         | 4.9% | FR infant     | 0.07 | 2.5% | Apples       | 0.7% | Strawberries                    | 0.4% | Oranges      | 0.0% |
|                                                                                                                                                                                         | 4.8% | UK vegetarian | 0.07 | 1.3% | Oranges      | 1.0% | Tomatoes                        | 0.9% | Apples       | 0.0% |
|                                                                                                                                                                                         | 4.6% | DK adult      | 0.07 | 1.4% | Apples       | 0.8% | Tomatoes                        | 0.5% | Pears        | 0.0% |
|                                                                                                                                                                                         | 4.3% | FI adult      | 0.06 | 0.9% | Tomatoes     | 0.9% | Apples                          | 0.6% | Oranges      | 0.0% |
|                                                                                                                                                                                         | 3.2% | UK adult      | 0.05 | 0.8% | Oranges      | 0.7% | Tomatoes                        | 0.6% | Apples       | 0.0% |
|                                                                                                                                                                                         | 1.4% | IE child      | 0.02 | 0.5% | Apples       | 0.2% | Currants (red, black and white) | 0.1% | Table grapes | 0.0% |
| <b>Conclusion:</b><br>The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.<br>The long-term intake of residues of is unlikely to present a public health concern. |      |               |      |      |              |      |                                 |      |              |      |

**Table B.11 Acute risk assessment undertaken using UK model version 1.2 – IN-F6L99**

|           |      |   | 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 |
| Spinach   | 0.00 |   | 0.00000 | 0.1   | 0.00001 | 0.1   | 0.00000 | 0.1   | 0.00001            | 0.1   | 0.00000             | 0.1   |

|           |      |   | 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 |
| Spinach   | 0.00 |   | 0.00000              | 0.1   | 0.00000              | 0.0   | 0.00000    | 0.1   | 0.00000            | 0.1   | 0.00000               | 0.0   |

Pesticide

ARfD 0.005 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.12 Acute risk assessment undertaken using PRIMo revision 3.1 – IN-F6L99**

|                                                                                                           |                                                                                           |                    |                            |                     |                                                                                         |                    |                            |                     |
|-----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|--------------------|----------------------------|---------------------|-----------------------------------------------------------------------------------------|--------------------|----------------------------|---------------------|
| Unprocessed commodities                                                                                   | <b>Results for children</b><br>No. of commodities for which ARfD/ADI is exceeded (IESTI): |                    |                            |                     | <b>Results for adults</b><br>No. of commodities for which ARfD/ADI is exceeded (IESTI): |                    |                            |                     |
|                                                                                                           | ---                                                                                       |                    |                            |                     | ---                                                                                     |                    |                            |                     |
|                                                                                                           | <b>IESTI</b>                                                                              |                    |                            |                     | <b>IESTI</b>                                                                            |                    |                            |                     |
|                                                                                                           | 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) |
|                                                                                                           | 0.54%                                                                                     | Spinaches          | 0 / 0                      | 0.0271213           | 0.45%                                                                                   | Chards/beet leaves | 0 / 0                      | 0.02                |
|                                                                                                           | 0.37%                                                                                     | Chards/beet leaves | 0 / 0                      | 0.02                | 0.10%                                                                                   | Spinaches          | 0 / 0                      | 0.00                |
|                                                                                                           |                                                                                           |                    |                            |                     | 0.05%                                                                                   | Purslanes          | 0 / 0                      | 0.00                |
| Expand/collapse list                                                                                      |                                                                                           |                    |                            |                     |                                                                                         |                    |                            |                     |
| <b>Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)</b> |                                                                                           |                    |                            |                     |                                                                                         |                    |                            |                     |

| Processed commodities | Results for children                                                |                             |                            |                     | Results for adults                                                  |                             |                            |                     |
|-----------------------|---------------------------------------------------------------------|-----------------------------|----------------------------|---------------------|---------------------------------------------------------------------|-----------------------------|----------------------------|---------------------|
|                       | No of processed commodities for which ARfD/ADI is exceeded (IESTI): |                             |                            |                     | No of processed commodities for which ARfD/ADI is exceeded (IESTI): |                             |                            |                     |
|                       | ---                                                                 |                             |                            |                     | ---                                                                 |                             |                            |                     |
|                       | IESTI                                                               |                             |                            |                     | IESTI                                                               |                             |                            |                     |
|                       | Highest % of ARfD/ADI                                               | Processed commodities       | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI                                               | Processed commodities       | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
|                       | 0.7%                                                                | Chards/beet leaves / boiled | 0 / 0                      | 0.037               | 0.3%                                                                | Chards/beet leaves / boiled | 0 / 0                      | 0.02                |
|                       | 0.3%                                                                | Spinaches / frozen; boiled  | 0 / 0                      | 0.02                | 0.20%                                                               | Spinaches / frozen; boiled  | 0 / 0                      | 0.01                |
| #NUM!                 | #NUM!                                                               | #NUM!                       | #NUM!                      | 0.10%               | Purslanes / boiled                                                  | 0 / 0                       | 0.00                       |                     |
| Expand/collapse list  |                                                                     |                             |                            |                     |                                                                     |                             |                            |                     |

## 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

No new data had been submitted as part of the current assessment. Method DuPont-15738 was used in all supporting residue trials. DuPont-15738 was validated as part of the approval of the active substance in the following report

- *Analytical Method for the Determination of DPX-HGW86 and Metabolites in Crop Using LC/MS/MS,” DuPont-15736,* [REDACTED]

Additional validation data is available in the following trials and has been reported for completeness.

- *Cyantraniliprole - Residue Study on Protected Lettuce in Northern Europe in 2010,* [REDACTED] *report no. TK0025418*
- *Cyantraniliprole - Residue Study on Protected Lettuce in Spain in 2010,* [REDACTED] *report no. TK0025415*
- *Cyantraniliprole and Acibenzolar-S-methyl - Residue Study on Protected Lettuce in Southern France, Italy and Spain in 2011 - 2012.,* [REDACTED] *report no. S11-00591*
- *Cyantraniliprole and Acibenzolar-S-methyl - Residue Study on Protected Lettuce in Southern France, Italy and Spain in 2012,* [REDACTED] *report no. S12-01416*

The method (DuPont-15736) was previously validated for the determination of cyantraniliprole and its metabolites in a range of plant matrices, in the EU DAR (UK, 2013).

Additional validation data supporting the use of the method with lettuce was presented in the study reports listed above and is summarised below:

Summary of method Dupont-15736 (DAR, UK, 2013):

A 10 g sample is extracted twice with 20 mL of a 90:10 mixture of acetonitrile: water solution and shaken at 700 cycles per minute for 2 minutes. The extract is centrifuged at 3000 RPM for 5 minutes and the supernatant is decanted into a clean 50-mL centrifuge tube. An additional 20 mL of 90:10 acetonitrile: water is added to the sample and shaken at 700 cycles per minute for 2 minutes, the extract is centrifuged at 3000 RPM for 5 minutes. The supernatant is combined into the same 50-mL centrifuge tube used previously in the process. The extract is diluted to 50 mL using 90:10 acetonitrile: water and vigorously mixed. Approximately 1 mL of extract is filtered with a 3-mL syringe and a 0.2-µm PTFE filter into a 13-mL centrifuge tube. Then, 0.10 mL of the filtered extract is pipetted into a HPLC vial and an additional 0.40 mL of methanol and 0.50 mL of de-ionized water are pipetted and mixed well (total volume of 1 mL). Samples are then analyzed using LC-MS/MS (ESI MRM positive mode).

The resulting sample concentration is 0.02 g sample/mL. Residues of active substance are determined by LC-MS/MS against matrix matched standards using the following conditions:

Parameters for LC-MS/MS were not presented in the DAR for the method Dupont-15736 but were included in the studies considered in this evaluation. There are noted differences in the parameters between the studies, however, due to divergences in the columns used (diameter and particle size), other parameters (flow rate and injection volume) have been adjusted accordingly.

Mobile phases remain similar except for ammonium formate being omitted in mobile phase B for studies S11-00591 and S12-01416. Ammonium formate is typically used as a pH buffer and as formic acid is already present in higher concentrations across all mobile phases and mobile phase A (the majority mobile phase) remains consistent in all studies it is concluded that the difference will have minimal impact and is acceptable. This is confirmed by the chromatograms provided which show a good response at LOQ concentrations (0.01 mg/kg) and similar elution times (11.3 minutes vs 11.5 minutes).

Although the method was previously validated in the DAR for cyantraniliprole in lettuce, confirmatory data has been provided and is presented in the table below:

## Results and discussion

### Table C.1.1.1-1 Recovery Results in lettuce

*Study TK0025418*

| Matrix  | level (mg/kg) | No samples per level | Range of recoveries (%) | Mean recovery | RSD (%) | Comments |
|---------|---------------|----------------------|-------------------------|---------------|---------|----------|
| Lettuce | 0.01          | 3                    | 85 - 111                | 100.7         | 13.7    | -        |
|         | 0.1           | 2                    | 100 - 115               | 107.5         | 9.9     | -        |
|         | 2.5           | 2                    | 101 - 105               | 103.0         | 2.7     | -        |

*Study TK0025415*

| Matrix  | level (mg/kg) | No samples per level | Range of recoveries (%) | Mean recovery | RSD (%) | Comments |
|---------|---------------|----------------------|-------------------------|---------------|---------|----------|
| Lettuce | 0.01          | 2                    | 88 - 106                | 97.0          | 13.1    | -        |
|         | 0.1           | 2                    | 89 - 101                | 95.0          | 8.9     | -        |
|         | 1.0           | 1                    | 91                      | -             | -       | -        |
|         | 2.0           | 1                    | 92                      | -             | -       | -        |

*Study. S11-00591*

| Matrix  | level (mg/kg) | No samples per level | Range of recoveries (%) | Mean recovery | RSD (%) | Comments |
|---------|---------------|----------------------|-------------------------|---------------|---------|----------|
| Lettuce | 0.01          | 2                    | 95 - 109                | 102           | 9.7     | -        |
|         | 0.1           | 1                    | 103                     | -             | -       | -        |
|         | 10.0          | 1                    | 91                      | -             | -       | -        |

*Study. S12-01416*

| Matrix  | level (mg/kg) | No samples per level | Range of recoveries (%) | Mean recovery | RSD (%) | Comments |
|---------|---------------|----------------------|-------------------------|---------------|---------|----------|
| Lettuce | 0.01          | 1                    | 108                     | -             | -       | -        |
|         | 1.0           | 1                    | 100                     | -             | -       | -        |
|         | 5.0           | 1                    | 88                      | -             | -       | -        |

Combined validation data

| Matrix  | level (mg/kg) | No samples per level | Range of recoveries (%) | Mean recovery | RSD (%) | Comments   |
|---------|---------------|----------------------|-------------------------|---------------|---------|------------|
| Lettuce | 0.01          | 8                    | 85 - 111                | 101           | 10.1    | Acceptable |
|         | 0.1           | 5                    | 89 - 115                | 101.6         | 9.12    | Acceptable |
|         | 1.0           | 2                    | 91 - 100                | 95.5          | 6.66    | NA         |
|         | 2             | 1                    | 92                      | -             | -       | NA         |
|         | 2.5           | 2                    | 101 - 105               | 103.0         | 2.7     | NA         |
|         | 5.0           | 1                    | 88                      | -             | -       | NA         |

|  |    |   |    |   |   |    |
|--|----|---|----|---|---|----|
|  | 10 | 1 | 91 | - | - | NA |
|--|----|---|----|---|---|----|

**Table C.1.1.1-2 Characteristics of the analytical method for the quantitation of cyantraniliprole residues in lettuce**

|                                                                                                    | <b>Cyantraniliprole</b>                                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chromatographic method                                                                             | HPLC-MS/MS,                                                                                                                                                                                |
| Specificity demonstrated (yes/no, by...)                                                           | Yes, by MS ions<br>475.1 – 266.1 (quantifier)<br>475.1 – 440.0 (qualifier)                                                                                                                 |
| Linearity demonstrated (yes/no)                                                                    | Yes                                                                                                                                                                                        |
| Calibration                                                                                        |                                                                                                                                                                                            |
| Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)                         | 0.131 – 5.58 ng/ml (0.00655 – 0.279 mg/kg (a)<br>0.105 – 5.54 ng/ml (0.00552 – 0.277 mg/kg). (b)<br>0.1 – 20 pg/µL (0.005 – 1.0 mg/kg) (c)<br>0.0001 – 0.02 µg/mL (0.005 – 1.0 mg/kg) (d). |
| Calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/no) | Seven single points (a)<br>Ten single points (b)<br>Eight single points (c) (d)                                                                                                            |
| Matrix effects                                                                                     | Not investigated, see below.                                                                                                                                                               |
| Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)                       | Yes                                                                                                                                                                                        |
| Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ration? (yes/no)                  | Yes                                                                                                                                                                                        |
| <b>LOQ</b> (mg/kg)                                                                                 | 0.01                                                                                                                                                                                       |

(a) TK0025418

(b) TK0025415

(c) S11-00591

(d) S12-01416

## **Conclusion**

### **Specificity:**

Specificity was demonstrated across all studies by retention time match with a reference standard and analysis of unfortified control samples and reagent blanks demonstrated no significant interference (> 30% of the LOQ) at the retention times of interest.

Confirmation of analyte identity is not required for risk assessment methods.

### **Matrix Effects:**

Matrix-matched standards were used for recoveries across all studies. For linearity, studies S11-00591 and S12-01416 used matrix matched standards however studies TK0025418 and TK0025415 used standards in solvent (50:50 methanol:water). From the chromatograms provided it is observed that the response in both matrix and solvent is roughly proportional (0.0056 mg/kg cyantraniliprole, intensity: 5500 in solvent, 0.01 mg/kg cyantraniliprole, intensity: 9500 in matrix, [REDACTED] 2011) therefore matrix effects are considered addressed and there is minimal effect.

### **Linearity:**

As the method has been previously validated linearity is not required for method confirmation however it has been provided across all studies. The initial method was found linear between 0.1 and 20 ng/mL (equivalent to 0.005 – 1 mg/kg).

Linearity was demonstrated by the analysis of at least 7 standards of increasing concentration. The maximum range of standard concentrations used was equivalent to 0.005 – 1.0 mg/kg cyantraniliprole in the samples. The response was linear with a correlation coefficient ( $r$ ) > 0.998 for all studies.

Highest concentration used for the linear range does not cover the highest recorded residues (9.81 mg/kg, S12-01416), however, recoveries within this range (10.0 mg/kg) have been provided and are acceptable. There is sufficient confidence that samples containing higher concentrations can be quantified and will be diluted appropriately; the chromatograms presented include some samples containing residues of cyantraniliprole above the upper limit of the linear range presented (TK0025418, figure 5, residue = 1.68 mg/kg, and S12-01416, figure 10, residue = 4.28 mg/kg) showing clear peaks and an appropriate dilution factor in the title (e.g. 20-fold diluted).

### **Accuracy and Precision:**

Recovery samples were prepared by spiking blank homogenized lettuce with cyantraniliprole standard and analysing them by the method described. The spike concentrations were in the range 0.01 to 10.0 mg/kg. A minimum of 3 recoveries total were provided for each study, this number is acceptable in accordance with SANTE/2020/12830, Rev.1 (minimum validation requirement for the assessment of existing methods for risk assessment, a minimum of three recovery samples, with at least one of them at the LOQ level). All recovery levels were within the range 85-111% for fortification level of 0.01 mg/kg and are acceptable (60-120%). For fortification levels of 0.1 and >0.1 mg/kg the recoveries fell within the ranges of 70-120% and 70-110% respectively therefore are acceptable.

Precision is not required for use of the method in a new crop from an already validated matrix group in accordance with SANTE/2020/12830, Rev.1 however, precision was determined from the accuracy recovery data where a sufficient number of recoveries were

provided at a single concentration. The % RSD was < 20% for all the relevant data therefore acceptable.

#### **Extraction efficiency:**

Extraction efficiency was considered as part of the active substance assessment for a similar method (DAR, UK, 2013, method DuPont-24754). This showed that extraction of residues of cyantraniliprole from lettuce leaf, beet foliage, wheat grain, and wheat hay therefore extraction efficiency is considered sufficiently addressed.

#### **Conclusion**

The DAR (UK, 2013) states that the analytical method Du-Pont-15736 is fully validated for the determination of cyantraniliprole and its metabolites in plants (LOQ = 0.01 mg/kg) for cucumbers, tomatoes, limes, almonds, grapes, apples, peaches, tomatoes, lettuce, potatoes, lemons, rape seed, wheat grain and wheat straw. The provided further validation data was evaluated in accordance with SANTE/2020/12830, Rev.1, minimum validation requirement for the assessment of existing methods for risk assessment. The data was concluded to have sufficiently demonstrated linearity, selectivity and specificity, and acceptable recovery. The method Du-Pont-15736 is therefore acceptable for the determination of cyantraniliprole in lettuce in the considered studies.

### **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

All studies detailed in section C.3.1.2 have all been evaluated in GB for previous authorisations: COP 2015/01172 & 2025/00914.

#### C.3.1.2.1 Lettuce – Study 1 - Outdoor

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Cyantraniliprole – Residue Study on Lettuce in Germany, Northern France and the United Kingdom in 2011, [REDACTED] 2012, S11-00606                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Guideline(s):          | Yes <ul style="list-style-type: none"><li>• FAO Guidelines on Producing Pesticide Residues Data from Supporting Residue trials (Rome, 1990)</li><li>• Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials: 7029/VI/95 (rev. 5, working document).</li><li>• Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex II of Directive 91/414/EEC (Article 5.3 and 8.2), 1996.</li></ul> |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Validity of the study: | Acceptable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

#### Materials and methods

Four trials on crop were conducted in Germany, Northern France, and the United Kingdom (NEU). Each trial site contained three plots. One plot was for control samples. For the other two plots, each was treated with a different formulation. For plot 2, cyantraniliprole was applied as a WG formulation. For plot 3, cyantraniliprole was applied as an OD formulation.

Plot 2: 'A16971B' was applied as a foliar spray at a target rate of 2 x 75 g/ha active in 300 L/ha of water. Actual applications ranged between 74 – 77 g/ha for the first application, and 73 – 76 g/ha for the second. The water volume used in the trials ranged from 292 – 360 L water/ha. An interval of 7-8 days separated applications, with the last application made at BBCH. Samples were taken 0, 3, 7, 9-10, 13-14 days after application. The applications were within 25% of (2 x 74 g/ha, 7 day interval, 7 day PHI).

Plot 3: 'A15929A' was applied as a foliar spray at a target rate of 2 x 75 g/ha active in 300 L/ha of water. Actual applications ranged between 74 – 78 g/ha for the first application, and 72 – 78 g/ha for the second. Water volume in the trials ranged from 291 – 348 L water/ha. Samples were taken 0, 3, 7, 9-10, 13-14 days after application. The applications were within 25% of (2 x 74 g/ha, 7 day interval, 7 day PHI).

Weather data were reported for the trials and no exceptional events were noted. The trials were decline, samples of crop part were taken at 0, 3, 7, 9 - 10, and 13 - 14 days after last

application. Samples containing at least 1 kg were collected from both treated and control plots. Samples were frozen within five hours, and stored at  $\leq -18$  °C until analysis. The maximum storage interval between harvest and analysis was four months. Data was considered in the DAR which demonstrates stability of cyantraniliprole for this period of time in high water crops when stored at  $\leq -20$  °C. While samples were stored slightly above the temperature where stability was demonstrated, it has little impact on the study as the difference is minor and the sample would be deep frozen during storage.

Extracts were stored for up to 13 days. Stability of extracts was demonstrated by concurrent procedural recoveries.

### **Analytical Method**

Analysis was performed using HPLC-MS/MS method DuPont-15736. The analytical method was satisfactorily validated in accordance with SANCO 3029/99 rev. 4 for the approval of the active substance in/on representative high water crops. Extraction efficiency has been adequately addressed for method DuPont-15736 in accordance with SANTE 2017/10632 rev.3.

Additional validation data has been considered under Section C.1.1 demonstrating the method meets the criteria outlined in Section 4.2 of SANTE/2020/12830 Rev 1.

Analysis of the following metabolites was also conducted: IN-JCZ38, IN-MLA84, IN-K7H19, IN-J9Z38, IN-K5A79, IN-N7B69 and IN-MYX98. These metabolites are not in the RD-RA or the RD-Enf and have not been reported in table C.3.1.2.1-1. All metabolites were <LOQ for all trials at all PHIs.

### **Results and Discussion**

The analytical method (DuPont-15736) was satisfactorily validated in accordance with SANCO 3029/99 rev. 4. The LOQ of the method is 0.01 mg/kg. Acceptable procedural recovery data for cyantraniliprole, using an appropriate number of samples were presented.

No residues were detected in control samples for all trials.

A summary of the residues trials is given in Table C.3.1.2.1-1.

**Table C.3.1.2.1-1 Residue trials on lettuce**

|                              |                                                                                                         |                                  |                  |
|------------------------------|---------------------------------------------------------------------------------------------------------|----------------------------------|------------------|
| Reference:                   | Cyantraniliprole - Residue Study on Lettuce in Germany, Northern France and the United Kingdom in 2011. |                                  |                  |
| GLP:                         | Yes                                                                                                     | Sample storage conditions:       | -18 °C           |
| Crop/crop group:             | Lettuce, open leaf                                                                                      | Analytical method:               | DuPont-15736     |
| Indoor/outdoor:              | Outdoor                                                                                                 | Limit of Quantification (mg/kg): | 0.01             |
| Formulation:                 | WG, OD                                                                                                  | Residues as:                     | calculated Mg/kg |
| Content of active substance: | 400 g/kg, 100 g/L                                                                                       |                                  |                  |

| Trial No<br>Location<br>Year                                                | Commodity<br>Variety        | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate per |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues<br>(mg/kg)                         | PHI<br>(days)                  | Remarks |
|-----------------------------------------------------------------------------|-----------------------------|----------------------------------------------------------------|----------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------------------------------|--------------------------------|---------|
|                                                                             |                             |                                                                | g a.s./ ha           | Water<br>(L/ha) | g a.s./<br>hL    |                                                           |                                               |                                         |                     | Parent                                      |                                |         |
| S11-00606<br>S11-<br><br>00606-01<br>UNITED<br>KINGDOM<br>(Europe<br>North) | Lettuce<br>(Lollo<br>rosso) | 1.<br>20/06/2011                                               | -                    | -               | -                | -                                                         | -                                             | -                                       | Lettuce,<br>Head    | <0.01                                       | 7                              | Control |
|                                                                             |                             | 2. NA<br>3. 07/2011                                            | 77.00<br>73.00       | 308<br>292      | 237.16<br>213.16 | 12 Jul<br>2011<br>19 Jul<br>2011                          | 7                                             | 37 – 39<br>45 - 47                      | Lettuce,<br>Head    | 0.47<br>0.42<br>0.14<br>0.07<br>0.04        | 0<br>3<br>7<br>10<br>14        | WG      |
|                                                                             |                             |                                                                | 78.00<br>73.00       | 312<br>291      | 243.36<br>212.43 | 12 Jul<br>2011<br>19 Jul<br>2011                          | 7                                             | 37 – 39<br>45 - 47                      | Lettuce,<br>Head    | 0.59<br>0.67<br><u>0.15</u><br>0.04<br>0.04 | 0<br>3<br><u>7</u><br>10<br>14 | OD      |
| S11-00606<br>S11-<br><br>00606-02<br>UNITED<br>KINGDOM<br>(Europe<br>North) | Lettuce<br>(Maureen)        | 1.<br>31/08/2011                                               | -                    | -               | -                | -                                                         | -                                             | -                                       | Lettuce,<br>Head    | < 0.01                                      | 7                              | Control |
|                                                                             |                             | 2. NA<br>3. 10/2011                                            | 77.00<br>75.00       | 306<br>298      | 235.62<br>223.5  | 27 Sep<br>2011<br>4 Oct<br>2011                           | 7                                             | 47 – 48<br>49                           | Lettuce,<br>Head    | 1.07<br>0.52<br><u>0.14</u><br>0.06<br>0.04 | 0<br>3<br><u>7</u><br>10<br>14 | WG      |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

| Trial No<br>Location<br>Year                                      | Commodity<br>Variety   | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate per<br>treatment |            |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues<br>(mg/kg)                         | PHI<br>(days)                 | Remarks |
|-------------------------------------------------------------------|------------------------|----------------------------------------------------------------|-----------------------------------|------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------------------------------|-------------------------------|---------|
|                                                                   |                        |                                                                |                                   |            |                  |                                                           |                                               |                                         |                     |                                             |                               |         |
|                                                                   |                        |                                                                | 76.00<br>76.00                    | 302<br>302 | 229.52<br>229.52 | 27 Sep<br>2011<br>4 Oct<br>2011                           |                                               | 47 – 48<br>49                           | Lettuce,<br>Head    | 0.58<br>0.20<br>0.06<br>0.02<br><0.01       | 0<br>3<br>7<br>10<br>14       | OD      |
| S11-00606<br>S11-<br><br>00606-03<br>GERMANY<br>(Europe<br>North) | Lettuce<br>(Oak Leaf)  | 1. 14/05/<br>2011                                              | -                                 | -          | -                | -                                                         | -                                             | -                                       | Lettuce,<br>Head    | < 0.01                                      | 7                             | Control |
|                                                                   |                        | 2. NA<br>3. 07/2011                                            | 77.00<br>75.00                    | 360<br>350 | 277.2<br>262.5   | 29 Jun<br>2011<br>06 Jul<br>2011                          | 7                                             | 45<br>47                                | Lettuce,<br>Head    | 1.51<br>0.13<br>0.04<br>0.03<br><0.01       | 0<br>3<br>7<br>9<br>13        | WG      |
|                                                                   |                        |                                                                | 75.00<br>72.00                    | 348<br>338 | 261<br>243.36    | 29 Jun<br>2011<br>06 Jul<br>2011                          | 7                                             | 45<br>47                                | Lettuce,<br>Head    | 1.38<br>0.16<br><u>0.05</u><br>0.03<br>0.02 | 0<br>3<br><u>7</u><br>9<br>13 | OD      |
| S11-00606<br>S11-<br><br>00606-04<br>FRANCE<br>(Europe<br>North)  | Lettuce<br>(Kiriniere) | 1. 01/07/2011                                                  | -                                 | -          | -                | -                                                         | -                                             | -                                       |                     | <0.01                                       | 7                             | Control |
|                                                                   |                        | 2. NA<br>3. 07/2011                                            | 74.00<br>76.00                    | 308<br>313 | 227.92<br>237.88 | 12 Jul<br>2011<br>20 Jul<br>2011                          | 8                                             | 19<br>45 - 46                           |                     | 2.37<br>0.20<br>0.04<br>0.01<br><0.01       | 0<br>3<br>7<br>9<br>14        | WG      |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate per |            |                | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues<br>(mg/kg)                          | PHI<br>(days)                 | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|----------------------|------------|----------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|----------------------------------------------|-------------------------------|---------|
|                              |                      |                                                                |                      |            |                |                                                           |                                               |                                         |                     |                                              |                               |         |
|                              |                      |                                                                | 74.00<br>78.00       | 305<br>320 | 225.7<br>249.6 | 12 Jul<br>2011<br>20 Jul<br>2011                          | 8                                             | 19<br>45 - 46                           |                     | 2.93<br>0.40<br><u>0.05</u><br>0.02<br><0.01 | 0<br>3<br><u>7</u><br>9<br>14 | OD      |

### C.3.1.2.2 Lettuce – Study 2 - Outdoor

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Cyantraniliprole – Residue study on Field Lettuce in Northern France and the United Kingdom in 2012, [REDACTED] 2013, S12-03305                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Guideline(s):          | Yes <ul style="list-style-type: none"> <li>• FAO Guidelines on Producing Pesticide Residues Data from Supporting Residue trials (Rome, 1990)</li> <li>• Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials: 7029/VI/95 (rev. 5, working document).</li> <li>• Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossier for the Inclusion of Active Substances in Regulations (EU) 544/2011 and 545/2011 implementing Regulation (EC) 1107/2009</li> <li>• European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/41, SANCO/3029/99 revision 4 (11 Jul 2000)</li> <li>• European Commission Guidance Document on Residue Analytical Method, SANCO/825/00 revision 8.1 (16 Nov 2010)</li> <li>• The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9.</li> </ul> |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Validity of the study: | Acceptable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

### Materials and methods

Four trials on open leaf lettuce were conducted in Northern France and the United Kingdom (NEU). Each trial site contained two plots. One plot was for control samples. For plot 2, cyantraniliprole was applied as a WG formulation.

Plot 2: 'A16971B' was applied as a foliar spray at a target rate of 2 x 75 g/ha active in 300 L/ha of water. Actual applications ranged between 74 – 78 g/ha for the first application, and 73 – 81 g/ha for the second. The water volume used in the trial ranged between 292 – 428 L water/ha. An interval of 7 days separated applications with the final application made at BBCH 43 - 49. Samples were taken 0, 3, 7-9, 10, and 14 days after application. The applications were within 25% of (2 x 74 g/ha, 7 day RTI, 7 day PHI).

Weather data were reported for the trials and no exceptional events were noted. The trials were decline, samples of crop part were taken at 0, 3, 7-9, 10, and 14 days after last application. Samples containing at least 1 kg were collected from both treated and control plots. Samples were frozen within four hours, and stored at ≤-18 °C until analysis. The

maximum storage interval between harvest and analysis was four months. Data was considered in the DAR which demonstrates stability of cyantraniliprole for this period of time in high water crops when stored at  $\leq -20$  °C. While samples were stored slightly above the temperature where stability was demonstrated, it has little impact on the study as the difference is minor and the sample would be deep frozen during storage.

Extracts were stored for up to 10 days. Stability of extracts was demonstrated by concurrent procedural recoveries.

## **Analytical Method**

Analysis was performed using HPLC-MS/MS method DuPont-15736. The analytical method was satisfactorily validated in accordance with SANCO 3029/99 rev. 4 for the approval of the active substance in/on representative high water crops. Extraction efficiency has been adequately addressed for method DuPont-15736 in accordance with SANTE 2017/10632 rev.3.

Additional validation data has been considered under Section C.1.1 demonstrating the method meets the criteria outlined in Section 4.2 of SANTE/2020/12830 Rev 1.

Analysis of the following metabolites was also conducted: IN-JCZ38, IN-MLA84, IN-K7H19, IN-J9Z38, IN-K5A79, IN-N7B69 and IN-MYX98. These metabolites are not in the RD-RA or the RD-Enf and have not been reported in table C.3.1.2.1-1. All metabolites were <LOQ for all trials at all PHIs.

## **Results and Discussion**

The analytical method (DuPont-15736) was satisfactorily validated in accordance with SANCO 3029/99 rev. 4. The LOQ of the method is 0.01 mg/kg. Acceptable procedural recovery data for cyantraniliprole, using an appropriate number of samples were presented.

Relevant deviations noted in the study:

- In trial S12-03305-04, treated lettuce samples S12-03305-04-007 and S12-03305-04-008 taken at 7 DALA (NCH) were not transferred to the freezer within 24 hours of sampling in error. Therefore, these specimens were not analysed but additional treated samples S12-03305-04-007a and S12-03305-04-008a were taken at 9 DALA for analysis.

No residues were detected in control samples for all trials.

A summary of the residues trials is given in Table C.3.1.2.2-1

**Table C.3.1.2.2-1 Residue trials on lettuce**

|                              |                                                                                                                                 |                                  |                  |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------|
| Reference:                   | Cyantraniliprole – Residue study on Field Lettuce in Northern France and the United Kingdom in 2012, [REDACTED] 2013, S12-03305 |                                  |                  |
| GLP:                         | Yes                                                                                                                             | Sample storage conditions:       | -18 °C           |
| Crop/crop group:             | Lettuce, open leaf                                                                                                              | Analytical method:               | DuPont-15736     |
| Indoor/outdoor:              | Outdoor                                                                                                                         | Limit of Quantification (mg/kg): | 0.01             |
| Formulation:                 | WG                                                                                                                              | Residues as:                     | calculated Mg/kg |
| Content of active substance: | 400 g/kg                                                                                                                        |                                  |                  |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

| Trial No<br>Location<br>Year                                                    | Commodity<br>Variety         | Date of<br>1.Sowing<br>or planting<br>2.Flowerin<br>g<br>3.Harvest | Application rate per |                      |                          | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>application<br>s (days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analyse<br>d | Residue<br>s<br>(mg/kg)                     | PHI<br>(days<br>)              | Remarks |
|---------------------------------------------------------------------------------|------------------------------|--------------------------------------------------------------------|----------------------|----------------------|--------------------------|-----------------------------------------------------------|------------------------------------------------|-----------------------------------------|-------------------------|---------------------------------------------|--------------------------------|---------|
|                                                                                 |                              |                                                                    | g a.s./ ha           | Water<br>r<br>(L/ha) | g a.s./<br>hL            |                                                           |                                                |                                         |                         | Parent                                      |                                |         |
| S12-<br>03305<br>S12-<br>03305-01<br>FRANCE<br>(Europe<br>North)                | Lettuce<br>(Abbice)          | 1.<br>02/08/2012<br>2. NA<br>3.<br>10/09/2012                      | 74.00<br>80.00       | 295<br>318           | 218.3<br>254.4           | 17 Aug<br>2012<br>24 Aug<br>2012                          | 7                                              | 42 - 45<br>43 - 47                      | Lettuce,<br>Head        | 0.64<br>0.26<br><u>0.17</u><br>0.14<br>0.11 | 0<br>3<br><u>7</u><br>10<br>14 | SC      |
| S12-<br>03305<br>S12-<br>03305-02<br>FRANCE<br>(Europe<br>North)                | Lettuce<br>(Gourmandine<br>) | 1.<br>31/08/2012<br>2. NA<br>3. 09/2011                            | 78.00<br>81.00       | 413<br>428           | 322.1<br>4<br>346.6<br>8 | 27 Aug<br>2012<br>03 Sep<br>2012                          | 7                                              | 45 – 46<br>47 - 48                      | Lettuce,<br>Head        | 1.20<br>0.77<br><u>0.60</u><br>0.18<br>0.19 | 0<br>3<br><u>7</u><br>10<br>14 | SC      |
| S12-<br>03305<br>S12-<br>03305-03<br>UNITED<br>KINGDO<br>M<br>(Europe<br>North) | Lettuce<br>(Expedition)      | 1.<br>22/08/2012<br>2. NA<br>3. 09/2012                            | 76.00<br>76.00       | 407<br>402           | 309.3<br>2<br>305.5<br>2 | 07 Sep<br>2012<br>14 Sep<br>2012                          | 7                                              | 46 – 48<br>47 - 49                      | Lettuce,<br>Head        | 1.52<br>0.21<br><u>0.10</u><br>0.03<br>0.03 | 0<br>3<br><u>7</u><br>10<br>14 | SC      |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

| Trial No<br>Location<br>Year                                                   | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowerin<br>g<br>3.Harvest | Applicatio<br>n<br>treatment | rate       | per               | Dates of<br>treatmen<br>t<br>or<br>number<br>and last<br>date | Interval<br>between<br>applicatio<br>s (days) | Growth<br>stage at<br>last<br>treatmen<br>t | Portion<br>analyse<br>d | Residue<br>s<br>(mg/kg)                     | PHI<br>(days<br>)              | Remark<br>s |
|--------------------------------------------------------------------------------|----------------------|--------------------------------------------------------------------|------------------------------|------------|-------------------|---------------------------------------------------------------|-----------------------------------------------|---------------------------------------------|-------------------------|---------------------------------------------|--------------------------------|-------------|
| S12-<br>03305<br>S12-<br>03305-04<br>UNITED<br>KINGDO<br>M<br>(Europe<br>North | Lettuce<br>(Batavia) | 1.<br>03/09/2012<br>2. NA<br>3. 10/2012                            | 75.00<br>73.00               | 300<br>292 | 225<br>213.1<br>6 | 10 Oct<br>2012<br>17 Oct<br>2012                              | 7                                             | 43 – 46<br>46 - 48                          | Lettuce,<br>Head        | 2.34<br>0.27<br><u>0.11</u><br>0.05<br>0.05 | 0<br>3<br><u>9</u><br>10<br>14 | SC          |

#### C.3.1.2.3 Lettuce – Study 3 - Protected

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Cyantraniliprole and Acibenzolar-S-methyl – Residue Study on Protected Lettuce in Southern France, Italy and Spain in 2011 – 2012, [REDACTED] 2012, S11-00591                                                                                                                                                                                                                                                                                                                                                                                                     |
| Guideline(s):          | Yes <ul style="list-style-type: none"><li>• FAO Guidelines on Producing Pesticide Residues Data from Supporting Residue trials (Rome, 1990)</li><li>• Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials: 7029/VI/95 (rev. 5, working document).</li><li>• Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex II of Directive 91/414/EEC (Article 5.3 and 8.2), 1996.</li></ul> |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Validity of the study: | Acceptable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

#### Materials and methods

Four trials on open leaf lettuce were conducted in southern France, Italy and Spain (SEU). Each trial site contained two plots. One plot was for control samples. For plot 2, cyantraniliprole was applied as a WG formulation.

Trials were conducted in protected environments.

Plot 2: 'A18351B' was applied as a foliar spray at a target rate of 2 x 125 g/h. Actual applications ranged between 122 - 128 g/ha for the first application, and 126 - 132 g/ha for the second. The water volume in the trials ranged from 293 – 404 L water/ha. An interval of 7 days separated applications with the final application made at BBCH 41 - 48. Samples were taken 0, 3, 6-7, 10-11, and 13-14 days after application. The applications were overdosed compared to the proposed GAP (2 x 74 g/ha, 7 day RTI, 3 – 10 day PHI).

Environmental conditions were reported trials and no exceptional events were noted. The trials were decline, samples of crop part were taken at 0, 3, 6-7, 10-11, and 13-14 days after last application. Samples containing at least 1 kg were collected from both treated and control plots. In some cases, a smaller sample was taken for the retained samples (0.54 kg), due to smaller plant growth, but these samples were not relied upon.

Samples were frozen within 11 hours, and stored at  $\leq -18$  °C until analysis. The maximum storage interval between harvest and analysis was eight months. Data was considered in the DAR which demonstrates stability of cyantraniliprole for this period of time in high water crops when stored at  $\leq -20$  °C. While samples were stored slightly above the temperature where stability was demonstrated, it has little impact on the study as the difference is minor and the sample would be deep frozen during storage.

Extracts were stored for up to five days. Stability of extracts was demonstrated by concurrent procedural recoveries.

### **Analytical Method**

Analysis was performed using HPLC-MS/MS method DuPont-15736. The analytical method was satisfactorily validated in accordance with SANCO 3029/99 rev. 4 for the approval of the active substance in/on representative high water crops. Extraction efficiency has been adequately addressed for method DuPont-15736 in accordance with SANTE 2017/10632 rev.3.

Additional validation data has been considered under Section C.1.1 demonstrating the method meets the criteria outlined in Section 4.2 of SANTE/2020/12830 Rev 1.

Analysis of the following metabolites was also conducted: IN-JCZ38, IN-MLA84, IN-K7H19, IN-J9Z38, IN-K5A79, IN-N7B69 and IN-MYX98. These metabolites are not in the RD-RA or the RD-Enf and have not been reported in table C.3.1.2.1-1. Metabolites IN-MLA84 and IN-J9Z38 were found above LOQ, with maximum individual values of 0.01 and 0.04 mg/kg, respectively.

### **Results and Discussion**

The analytical method (DuPont-15736) was satisfactorily validated in accordance with SANCO 3029/99 rev. 4. The LOQ of the method is 0.01 mg/kg. Acceptable procedural recovery data for cyantraniliprole, using an appropriate number of samples were presented.

Relevant deviations noted in the study:

- Trials S11-00591-01 and S11-00591-02: soil pH and OM were not recorded however as soil type has been recorded this is acceptable.
- Trials S11-00591-03 and S11-00591-04 specimens were kept deep frozen at or below -18°C, except for 71 hours up to -4.5°C. As the sample remained frozen (protected from thawing) and were homogenised before analysis (accounting for migration of moisture) this is acceptable.
- Trials S11-00591-03 and S11-00591-04 were only 1.9 km apart instead of 15 km however in accordance with SANTE/2019/12752 and GB Extrapolation Guidance 2024, there is no requirement for a minimum distance between the different facilities/locations in protected trials.

No residues were detected in control samples for all trials.

A summary of the residues trials is given in Table C.3.1.2.3

Table C.3.1.2.3-1 Residue trials on lettuce

|                              |                                                                                                                                                               |                                  |                  |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------|
| Reference:                   | Cyantraniliprole and Acibenzolar-S-methyl – Residue Study on Protected Lettuce in Southern France, Italy and Spain in 2011 – 2012, [REDACTED] 2012, S11-00591 |                                  |                  |
| GLP:                         | Yes                                                                                                                                                           | Sample storage conditions:       | -18 °C           |
| Crop/crop group:             | Lettuce, open leaf                                                                                                                                            | Analytical method:               | DuPont-15736     |
| Indoor/outdoor:              | Indoor                                                                                                                                                        | Limit of Quantification (mg/kg): | 0.01             |
| Formulation:                 | SC                                                                                                                                                            | Residues as:                     | calculated Mg/kg |
| Content of active substance: | 100 g/L                                                                                                                                                       |                                  |                  |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

| Trial No<br>Location<br>Year                                | Commodity<br>Variety  | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest | Application rate per<br>treatment |                 |                  | Dates of<br>treatment<br>or number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues<br>(mg/kg)                                | PHI<br>(days)                         | Remarks |
|-------------------------------------------------------------|-----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|--------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|----------------------------------------------------|---------------------------------------|---------|
|                                                             |                       |                                                                | g a.s./ ha                        | Water<br>(L/ha) | g a.s./<br>hL    |                                                        |                                               |                                         |                     | Parent                                             |                                       |         |
| S11-00591-01<br>France,<br>Gard,<br>Languedoc-<br>Rousillon | Lettuce,<br>Altero    | 1)<br>05/10/2011<br>2) N/A<br>3) 11/2011                       | 127<br>132                        | 382<br>397      | 485.14<br>524.04 | 08/11/2011<br>15/11/2011                               | 7                                             | 45 - 46<br>47 - 48                      | Lettuce,<br>Head    | 3.95<br><b>4.62</b><br>2.36<br>2.09<br><u>2.30</u> | 0<br><b>3</b><br>7<br>10<br><u>13</u> | SC      |
| S11-00591-02<br>Italy,<br>Castenaso,<br>Emilia<br>Romagna   | Lettuce,<br>Gentilina | 1)<br>21/9/2011<br>2) N/A<br>3) 10/2011                        | 124<br>126                        | 399<br>404      | 494.76<br>509.04 | 17/10/2011<br>24/10/2011                               | 7                                             | 41 - 43<br>45 - 47                      | Lettuce,<br>Head    | 4.58<br><b>5.19</b><br>2.77<br><u>2.07</u><br>1.42 | 0<br><b>3</b><br>7<br><u>10</u><br>14 | SC      |
| S11-00591-03<br>Spain,<br>Conil de la<br>Frontera,<br>Cádiz | Lettuce,<br>Candela   | 1)<br>31/12/2011<br>2) N/A<br>3) 02/2012                       | 128<br>126                        | 309<br>303      | 395.52<br>381.24 | 20/01/2012<br>27/01/2012                               | 7                                             | 18 – 19<br>41                           | Lettuce,<br>Head    | 9.34<br><b>4.64</b><br>4.28<br><u>2.97</u><br>2.09 | 0<br><b>3</b><br>6<br><u>10</u><br>14 | SC      |
| S11-00591-04<br>Spain,<br>Andalucía,<br>Cádiz               | Lettuce,<br>Candela   | 1)<br>07/01/2012<br>2) N/A<br>3) 02/2012                       | 122<br>128                        | 293<br>308      | 357.36<br>394.24 | 23/01/2012<br>30/01/2012                               | 7                                             | 18 – 19<br>41                           | Lettuce,<br>Head    | 9.81<br><b>8.40</b><br>3.68<br><u>2.83</u><br>2.15 | 0<br><b>3</b><br>7<br><u>11</u><br>14 | SC      |

#### C.3.1.2.4 Lettuce – Study 4 - Protected

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Cyantraniliprole and Acibenzolar-S-methyl – Residue Study on Protected Lettuce in Southern France, Italy and Spain in 2012, [REDACTED] 2013, S12-01416                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Guideline(s):          | Yes <ul style="list-style-type: none"><li>• FAO Guidelines on Producing Pesticide Residues Data from Supporting Residue trials (Rome, 1990)</li><li>• Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials: 7029/VI/95 (rev. 5, working document).</li><li>• Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 544/2011 and 545/2011 implementing Regulation (EC) 1107/2009.</li><li>• European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000).</li><li>• European Commission Guidance Document on Residue Analytical Method, SANCO/825/00 revision 8.1 (16 Nov 2010).</li><li>• The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO(2002)9.</li></ul> |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Validity of the study: | Acceptable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

#### Materials and methods

Four trials on open leaf lettuce were conducted in France, Italy and Spain (SEU). Each trial site contained two plots. One plot was for control samples. For plot 2, cyantraniliprole was applied as a SC formulation.

Trials were conducted in protected environments.

Plot 2: 'A18351B' was applied as a foliar spray at a target rate of 2 x 125 g/h. Actual applications ranged between 121 - 135 g/ha for the first application, and 116 - 132 g/ha for the second. The water volume used in the trials ranged from 279 – 400 L water/ha. An interval of 7 days separated applications with the final application made at BBCH 43 - 48. Samples were taken 0, 3, 7, 10, and 14 days after application. The applications were overdosed compared to the proposed GAP (2 x 74 g/ha, 7 day RTI 7, 3 – 10 day PHI).

Environmental conditions were reported for the trials and no exceptional events were noted. The trials were decline, samples of crop part were taken at 0, 3, 7, 10, and 14 days

after last application. Samples containing at least 1 kg were collected from both treated and control plots. Samples were frozen within six hours, and stored at  $\leq -18$  °C until analysis. The maximum storage interval between harvest and analysis was five months. Data was considered in the DAR which demonstrates stability of cyantraniliprole for this period of time in high water crops when stored at  $\leq -20$  °C. While samples were stored slightly above the temperature where stability was demonstrated, it has little impact on the study as the difference is minor and the sample would be deep frozen during storage.

Extracts were stored for up to three days. Stability of extracts was demonstrated by concurrent procedural recoveries.

### **Analytical Method**

Analysis was performed using HPLC-MS/MS method DuPont-15736. The analytical method was satisfactorily validated in accordance with SANCO 3029/99 rev. 4 for the approval of the active substance in/on representative high water crops. Extraction efficiency has been adequately addressed for method DuPont-15736 in accordance with SANTE 2017/10632 rev.3.

Additional validation data has been considered under Section C.1.1 demonstrating the method meets the criteria outlined in Section 4.2 of SANTE/2020/12830 Rev 1.

Analysis of the following metabolites was also conducted: IN-JCZ38, IN-MLA84, IN-K7H19, IN-J9Z38, IN-K5A79, IN-N7B69 and IN-MYX98. These metabolites are not in the RD-RA or the RD-Enf and have not been reported in table C.3.1.2.4-1. Metabolites IN-MLA84 and IN-J9Z38 were found above LOQ, with maximum individual values of 0.02 and 0.05 mg/kg, respectively.

### **Results and Discussion**

The analytical method (DuPont-15736) was satisfactorily validated in accordance with SANCO 3029/99 rev. 4. The LOQ of the method is 0.01 mg/kg. Acceptable procedural recovery data for cyantraniliprole, using an appropriate number of samples were presented.

No residues were detected in control samples for all trials.

A summary of the residues trials is given in Table C.3.1.2.4-1

Table C.3.1.2.4-1 Residue trials on lettuce

|                              |                                                                                                                                                        |                                  |                  |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------|
| Reference:                   | Cyantraniliprole and Acibenzolar-S-methyl – Residue Study on Protected Lettuce in Southern France, Italy and Spain in 2012, [REDACTED] 2013, S11-01416 |                                  |                  |
| GLP:                         | Yes                                                                                                                                                    | Sample storage conditions:       | -20 °C           |
| Crop/crop group:             | Lettuce, open leaf                                                                                                                                     | Analytical method:               | DuPont-15736     |
| Indoor/outdoor:              | Indoor                                                                                                                                                 | Limit of Quantification (mg/kg): | 0.01             |
| Formulation:                 | SC                                                                                                                                                     | Residues as:                     | calculated Mg/kg |
| Content of active substance: | 100 g/L                                                                                                                                                |                                  |                  |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

| Trial No<br>Location<br>Year                                    | Commodity<br>Variety             | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate per<br>treatment |                 |                  | Dates of<br>treatment<br>or number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues<br>(mg/kg)                                | PHI<br>(days)           | Remarks |
|-----------------------------------------------------------------|----------------------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|--------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|----------------------------------------------------|-------------------------|---------|
|                                                                 |                                  |                                                                | g a.s./ ha                        | Water<br>(L/ha) | g a.s./<br>hL    |                                                        |                                               |                                         |                     | Parent                                             |                         |         |
| S12-<br>01416-01<br>France,<br>Pyrénées-<br>Orientales<br>(SEU) | Lettuce,<br>Kinshasa             | 1)<br>11/10/2012<br>2) N/A<br>3)<br>15/11/2012                 | 131<br>132                        | 369<br>372      | 483.39<br>491.04 | 23/10/2012<br>30/10/2012                               | 7                                             | 19 – 41<br>43                           | Leaf                | 0.41<br><b>0.43</b><br>0.19<br><u>0.12</u><br>0.10 | 0<br>3<br>7<br>10<br>14 | SC      |
| S12-<br>01416-02<br>Italy,<br>Bologna                           | Lettuce,<br>Foglia di<br>quercia | 1)<br>25/10/2012<br>2) N/A<br>3)<br>02/11/2012                 | 121<br>123                        | 387<br>395      | 468.27<br>485.85 | 26/10/2012<br>02/11/2012                               | 7                                             | 45 – 46<br>47                           | Leaf                | 4.80<br><b>5.05</b><br>2.47<br>1.46<br><u>1.80</u> | 0<br>3<br>7<br>10<br>14 | SC      |
| S12-<br>01416-03<br>Spain,<br>Navarra                           | Lettuce,<br>Arab                 | 1)<br>14/07/2012<br>2) N/A<br>3) 08/2012                       | 135<br>116                        | 326<br>279      | 440.1<br>323.64  | 06/09/2012<br>13/09/2012                               | 7                                             | 43 – 45<br>45                           | Leaf                | 3.54<br>1.67<br><b>2.39</b><br><u>0.40</u><br>0.19 | 0<br>3<br>7<br>10<br>14 | SC      |
| S12-<br>01416-04                                                | Lettuce,<br>Volturno             | 1)<br>03/09/2012<br>2) N/A<br>3)<br>16/10/2012                 | 125<br>118                        | 400<br>377      | 500<br>444.86    | 02/10/2012<br>09/10/2012                               | 7                                             | 41<br>47                                | Leaf                | 0.96<br><b>0.94</b><br>0.79<br><u>0.76</u><br>0.59 | 0<br>3<br>7<br>10<br>14 | SC      |

#### C.3.1.2.5 Lettuce – Study 5 - Protected

|                        |                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Cyantraniliprole – Residue Study on Lettuce in Northern Europe in 2010, [REDACTED] 2011, TK0025418                                                                                                                                                                                                                                                                               |
| Guideline(s):          | Yes <ul style="list-style-type: none"><li>• FAO Guidelines on Producing Pesticide Residues Data from Supporting Residue trials (Rome, 1990)</li><li>• Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996.</li></ul> |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                               |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                              |
| Validity of the study: | Acceptable.                                                                                                                                                                                                                                                                                                                                                                      |

#### Materials and methods

Two trials on open leaf lettuce were conducted in UK and Germany. Each trial site contained three plots. One plot was for control samples. For the other two plots, each was treated with a different formulation. For plot 2, cyantraniliprole was applied as a SC formulation. For plot 3, cyantraniliprole was applied as an OD formulation.

Trials were conducted in protected environments.

Plot 2: 'A16968A' was applied as a foliar spray at a target rate of 3 x 75 g/ha. Actual applications ranged between 72 - 77 g/ha for the first application, 74 - 76 g/ha for the second application, and 73 - 74 g/ha for the third. The water volume used ranged from 573 - 820 L water/ha. An interval of 7 days separated applications with the final application made at BBCH 45-49. Samples were taken 0, 1, 3 - 6, and 7 days after application. The applications were overdosed compared to the proposed GAP (2 x 74 g/ha, 7 day RTI, 3 - 10 day PHI).

Plot 3: 'A15929A' was applied as a foliar spray at a target rate of 3 x 75 g/ha. Actual applications ranged between 75 - 77 g/ha for the first application, 73 - 74 g/ha for the second application, and 75 g/ha for the third. The water volume used ranged from 590 - 823 L water/ha. An interval of 7 days separated applications with the final application made at BBCH 45-49. Samples were taken 0, 1, 3 - 6, and 7 days after application. The applications were overdosed compared to the proposed GAP (2 x 74 g/ha, 7 day RTI, 3 - 10 day PHI).

Environmental data were reported for the trials, with deviations noted (see deviations below). The trials were decline, samples of crop part were taken at 0, 1, 3 - 6, and 7 days after last application. Samples containing at least 1 kg were collected from both treated and control plots. Samples were frozen within 12 hours, and stored at  $\leq -18$  °C until analysis. The maximum storage interval between harvest and analysis was four months. Data was considered in the DAR which demonstrates stability of cyantraniliprole for this period of time in high water crops when stored at  $\leq -20$  °C. While samples were stored

slightly above the temperature where stability was demonstrated, it has little impact on the study as the difference is minor and the sample would be deep frozen during storage.

Extracts were stored for up to two days. It is not reported in the study how stability of extracts is addressed, however stability is sufficiently addressed in the other available studies for Method DuPont-15736.

## **Analytical Method**

Analysis was performed using HPLC-MS/MS method DuPont-15736. The analytical method was satisfactorily validated in accordance with SANCO 3029/99 rev. 4 for the approval of the active substance in/on representative high water crops. Extraction efficiency has been adequately addressed for method DuPont-15736 in accordance with SANTE 2017/10632 rev.3.

Additional validation data has been considered under Section C.1.1 demonstrating the method meets the criteria outlined in Section 4.2 of SANTE/2020/12830 Rev 1.

Analysis of the following metabolites was also conducted: IN-JCZ38, IN-MLA84, IN-K7H19, IN-J9Z38, IN-K5A79, IN-N7B69 and IN-MYX98. These metabolites are not in the RD-RA or the RD-Enf and have not been reported in table C.3.1.2.5-1. Metabolites IN-MLA84 and IN-J9Z38 were found above LOQ, with maximum individual values of 0.02 and 0.05 mg/kg, respectively.

## **Results and Discussion**

The analytical method (DuPont-15736) was satisfactorily validated in accordance with SANCO 3029/99 rev. 4. The LOQ of the method is 0.01 mg/kg. Acceptable procedural recovery data for cyantraniliprole, using an appropriate number of samples were presented.

Relevant deviations/deficiencies in the study:

- For both trials soil pH and OM not recorded however as soil type has been recorded this is acceptable.
- For both trials the daily temperatures for the greenhouse was not recorded, however, weather data from the nearest meteorological station was provided. Environmental conditions at application were recorded (temperature and humidity), values were consistent across application dates and there is confidence that the test conditions are representative of growing conditions for protected lettuce in the UK.

No residues were detected in control samples for all trials.

A summary of the residues trials is given in Table C.3.1.2.5-1

**Table C.3.1.2.5-1 Residue trials on lettuce**

Reference: Cyantraniliprole – Residue Study on Lettuce in Northern Europe in 2010, [REDACTED] 2011, TK0025418

GLP: Yes Sample storage conditions: -18 °C

Crop/crop group: Lettuce, open leaf Analytical method: DuPont-15736

Indoor/outdoor: Indoor Limit of Quantification (mg/kg): 0.01

Formulation: SC, OD Residues calculated as: Mg/kg

Content of active substance: 100 g/L

| Trial No<br>Location<br>Year                           | Commodity<br>Variety | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest | Application rate per |                   |                  | Dates of<br>treatment<br>or number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues<br>(mg/kg)          | PHI<br>(days)    | Remarks |
|--------------------------------------------------------|----------------------|----------------------------------------------------------------|----------------------|-------------------|------------------|--------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|------------------------------|------------------|---------|
|                                                        |                      |                                                                | g a.s./ ha           | Water<br>(L/ha)   | g<br>a.s./<br>hL |                                                        |                                               |                                         |                     | Parent                       |                  |         |
| S10-01060-01,<br>United Kingdom,<br>Lancashire<br>2010 | Lettuce,<br>Charles  | 1. NA<br>2. NA<br>3. 10/2010                                   | -                    | -                 | -                | -                                                      | -                                             | -                                       | -                   | <0.01                        |                  | Control |
|                                                        |                      |                                                                | 72<br>74<br>74       | 573<br>593<br>593 |                  | 23/09/2010<br>30/10/2010<br>07/10/2010                 | 7                                             | 41 – 43<br>43 – 45<br>45 - 48           | Leaf                | 2.20<br>1.86<br>1.84<br>1.77 | 0<br>1<br>3<br>7 | SC      |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|                                                   |                    |                                   |                |                   |   |                                        |   |                               |      |                              |                  |         |
|---------------------------------------------------|--------------------|-----------------------------------|----------------|-------------------|---|----------------------------------------|---|-------------------------------|------|------------------------------|------------------|---------|
|                                                   |                    |                                   | 75<br>74<br>75 | 597<br>590<br>599 |   | 23/09/2010<br>30/10/2010<br>07/10/2010 | 7 | 41 – 43<br>43 – 45<br>45 – 48 | Leaf | 2.37<br>2.92<br>2.18<br>2.46 | 0<br>1<br>3<br>7 | OD      |
| S10-01060-02.<br>Germany,<br>Württemberg,<br>2010 | Lettuce,<br>Kitare | 1. 09/2010<br>2. NA<br>3. 12/2010 | -              | -                 | - | -                                      | - | -                             | -    |                              |                  | Control |
|                                                   |                    |                                   | 77<br>76<br>73 | 820<br>807<br>784 |   | 02/11/2010<br>09/10/2010<br>16/10/2010 | 7 | 44 – 45<br>46 – 47<br>48 – 49 | Leaf | 2.08<br>1.97<br>1.65<br>2.14 | 0<br>1<br>6<br>7 | SC      |
|                                                   |                    |                                   | 77<br>73<br>75 | 823<br>783<br>804 |   | 02/11/2010<br>09/10/2010<br>16/10/2010 | 7 | 44 – 45<br>46 – 47<br>48 – 49 | Leaf | 1.45<br>2.23<br>1.68<br>2.25 | 0<br>1<br>6<br>7 | OD      |

#### C.3.1.2.6 Lettuce – Study 6 – Protected

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Cyantraniliprole – Residue Study on Protected Lettuce in Spain 2010, [REDACTED] TK0025415                                                                                                                                                                                                                                                                                                                                                              |
| Guideline(s):          | Yes <ul style="list-style-type: none"><li>• Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).</li><li>• Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996.</li></ul> |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Validity of the study: | Acceptable.                                                                                                                                                                                                                                                                                                                                                                                                                                            |

#### Materials and methods

Two trials on open leaf lettuce were conducted in Spain. Each trial site contained three plots. One plot was for control samples. For the other two plots, each was treated with a different formulation. For plot 2, cyantraniliprole was applied as a SC formulation. For plot 3, cyantraniliprole was applied as an OD formulation.

Trials were conducted in protected environments.

Plot 2: 'A16968A' was applied as a foliar spray at a target rate of 3 x 75 g/ha. Actual applications ranged between 74 – 82 g/ha for the first application, 74 – 77 g/ha for the second, and 70 – 76 g/ha for the third. The water volume used ranged from 752 – 876 L water/ha. An interval of 7 days separated applications with the final application made at BBCH 48 – 49. Samples were taken 0, 1, 3, and 7 days after application. The applications were overdosed compared to the proposed GAPs (2 x 74 g/ha, 7 day interval 3 – 10 day PHI).

Plot 3: 'A15929A' was applied as a foliar spray at a target rate of 3 x 75 g/ha. Actual applications ranged between 75 – 81 g/ha for the first application, 72 – 76 g/ha for the second application, and 71 – 73 g/ha for the third. The water volume used ranged from 755 – 866 L water/ha. An interval of 7 days separated applications with the final application made at BBCH 45-49. Samples were taken 0, 1, 3, and 7 days after application. The applications were overdosed compared to the proposed GAPs (2 x 74 g/ha, 7 day RTI, 3 – 10 day PHI).

Environmental conditions were reported for the trials and no exceptional events were noted. The trials were decline, samples of crop part were taken at 0, 1, 3, and 7 days after last application. Samples containing at least 1 kg were collected from both treated and control plots. Samples were frozen within five hours, and stored at  $\leq -18^{\circ}\text{C}$  until analysis. The maximum storage interval between harvest and analysis was four months. Data was considered in the DAR which demonstrates stability of cyantraniliprole for this period of

time in high water crops when stored at  $\leq -20$  °C. While samples were stored slightly above the temperature where stability was demonstrated, it has little impact on the study as the difference is minor and the sample would be deep frozen during storage.

Extracts were stored for up to two days. It is not reported in the study how stability of extracts is addressed, however stability is sufficiently addressed in the other available studies for Method DuPont-15736 for a longer period.

### **Analytical Method**

Analysis was performed using HPLC-MS/MS method DuPont-15736. The analytical method was satisfactorily validated in accordance with SANCO 3029/99 rev. 4 for the approval of the active substance in/on representative high water crops. Extraction efficiency has been adequately addressed for method DuPont-15736 in accordance with SANTE 2017/10632 rev.3.

Additional validation data has been considered under Section C.1.1 demonstrating the method meets the criteria outlined in Section 4.2 of SANTE/2020/12830 Rev 1.

Analysis of the following metabolites was also conducted: IN-JCZ38, IN-MLA84, IN-K7H19, IN-J9Z38, IN-K5A79, IN-N7B69 and IN-MYX98. These metabolites are not in the RD-RA or the RD-Enf and have not been reported in table C.3.1.2.5-1. Metabolites IN-J9Z38 were found above LOQ, with maximum individual values of 0.02 mg/kg.

### **Results and Discussion**

The analytical method (DuPont-15736) was satisfactorily validated in accordance with SANCO 3029/99 rev. 4. The LOQ of the method is 0.01 mg/kg. Acceptable procedural recovery data for cyantraniliprole, using an appropriate number of samples were presented.

Relevant deviations/deficiencies in the study:

- Trials S10-01061-01 and S10-01061-02 soil pH and OM (%) were not recorded however as soil type has been recorded this is acceptable.

No residues were detected in control samples for all trials.

A summary of the residues trials is given in Table C.3.1.2.6-1

**Table C.3.1.2.6-1 Residue trials on lettuce**

Reference: Cyantraniliprole – Residue Study on Protected Lettuce in Spain 2010, [REDACTED] 2011, TK0025415

GLP: Yes Sample storage conditions: -18 °C

Crop/crop group: Lettuce, open leaf Analytical method: DuPont-15736

Indoor/outdoor: Indoor Limit of Quantification (mg/kg): 0.01

Formulation: SC, OD Residues calculated as: Mg/kg

Content of active substance: 100 g/L

| Trial No<br>Location<br>Year                 | Commodity<br>Variety | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest | Application rate per<br>treatment |                   |                  | Dates of<br>treatment<br>or number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues<br>(mg/kg)          | PHI<br>(days)    | Remarks |
|----------------------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-------------------|------------------|--------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|------------------------------|------------------|---------|
|                                              |                      |                                                                | g a.s./ ha                        | Water<br>(L/ha)   | g<br>a.s./<br>hL |                                                        |                                               |                                         |                     | Parent                       |                  |         |
| S10-01061-<br>01, Spain,<br>Navarra,<br>2010 | Lettuce,<br>Pravia   | 1.15/09/2010<br>2.NA<br>3.01/2011                              | -                                 | -                 | -                | -                                                      | -                                             | -                                       | -                   | <0.01                        |                  | Control |
|                                              |                      |                                                                | 74<br>77<br>70                    | 785<br>824<br>752 |                  | 04/01/2011<br>11/01/2011<br>18/01/2011                 | 7                                             | 45<br>45 – 47<br>49                     | Leaf                | 0.03<br>0.01<br>0.19<br>0.01 | 0<br>1<br>3<br>7 | SC      |

The evaluation of new MRLs for cyantraniliprole in or on various leaf vegetables, herbs and edible flowers

|                                      |                  |                                      |                |                   |   |                                        |   |                               |      |                                     |                         |         |
|--------------------------------------|------------------|--------------------------------------|----------------|-------------------|---|----------------------------------------|---|-------------------------------|------|-------------------------------------|-------------------------|---------|
|                                      |                  |                                      | 75<br>76<br>71 | 798<br>808<br>755 |   | 04/01/2011<br>11/01/2011<br>18/01/2011 | 7 | 45<br>45 – 47<br>49           | Leaf | 0.44<br>0.08<br><u>2.8</u><br>2.1   | 0<br>1<br><u>3</u><br>7 | OD      |
| S10-01061-02, Spain, Andalucia, 2010 | Lettuce, Carolus | 1. 06/11/2010<br>2. NA<br>3. 01/2011 | -              | -                 | - | -                                      | - | -                             | -    | <0.01                               |                         | Control |
|                                      |                  |                                      | 82<br>74<br>76 | 876<br>793<br>806 |   | 13/12/2010<br>20/12/2010<br>27/12/2010 | 7 | 45 – 46<br>46 – 47<br>48 – 49 | Leaf | 0.70<br>0.76<br><u>0.82</u><br>0.88 | 0<br>1<br><u>3</u><br>7 | SC      |
|                                      |                  |                                      | 81<br>72<br>73 | 866<br>773<br>776 |   | 13/12/2010<br>20/12/2010<br>27/12/2010 | 7 | 45 – 46<br>46 – 47<br>48 – 49 | Leaf | 1.2<br>1.9<br>1.0<br>1.2            | 0<br>1<br>3<br>7        | OD      |

### **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

All endpoints remained unchanged. The full list of endpoints is outlined in the EFSA Reasoned Opinion (EFSA, 2019). See the previous evaluation for tMRLs for details on additional processing factors (HSE, 2022)

## **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 <sub>90</sub>  | Period required for 90% dissipation (define method of estimation)                          |
| DT <sub>50</sub>  | 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<br>(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 <sub>50</sub>         | Lethal concentration, median                                                                                                                                                                                                                                                                                                                                                             |
| LD <sub>50</sub>         | 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<br><br><b>NB</b> the limit of quantification and limit of determination are the same.<br><br>Assimilated Regulation 396/2005 refers to the limit of determination<br><br>Assimilated Regulation 1107/2009 refers to the limit of quantification<br><br>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**

No additional data considered.



