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Modification of the existing maximum residue level for apricots and setting of import tolerances for cyantraniliprole in various crops

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants FMC International and Syngenta Crop Protection submitted two requests to the competent national authority in France, respectively, to set import tolerances for the active substance cyantraniliprole in various crops and to modify the existing maximum residue levels (MRLs) in apricots. The data submitted in support of the requests were found sufficient to derive MRL proposals for apricots, potatoes, tropical root and tuber vegetables, cucurbits (inedible peel), lettuces and salad plants, Chinese cabbage and other leafy brassica (except kale), spinaches and similar leaves (except spinach), parsley and minor oilseeds. Based on the risk assessment results, EFSA concluded that the dietary intake of residues resulting from the uses of cyantraniliprole according to the reported agricultural practices is unlikely to present a risk to consumer health for the parent compound. A definitive conclusion on the risk for consumers cannot be derived for the degradation products IN-N5M09 and IN-F6L99 which are formed during cooking/boiling. For both compounds, the concerns on genotoxicity have been ruled out, but the general toxicity has not been addressed. The indicative exposure calculated by the EMS and EFSA for these compounds is affected by non-standard uncertainties but can support risk managers to take an informed decision on the requested modification of the existing MRLs for the crops under assessment.

Keywords: cyantraniliprole, various crops, import tolerance, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, FMC International submitted an application to the competent national authority in France (evaluating Member State) to set several import tolerances for the active substance cyantraniliprole in various crops reflecting existing uses in Canada and the United States.

In addition, the applicant Syngenta Crop Protection submitted in accordance with Article 6 of Regulation (EC) No 396/2005 an application to France to modify the existing maximum residue levels (MRLs) for the active substance cyantraniliprole in various commodities.

The EMS, France, drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 11 October 2016 and on 26 April 2018, respectively. The EMS proposed to raise the existing MRLs for various crops imported from Canada and United States and, based on the intended Southern European (SEU) use, to raise the existing MRL for apricots.

EFSA assessed the applications and evaluation reports as required by Article 10 of the MRL regulation. For both MRL applications, EFSA identified various data gaps and points which needed further clarification, and which were requested from the EMS. It is noted that, in accordance with Guidance Document SANTE/2015/10595 Rev. 4, in cases where missing information has been identified for specific parts of the application, the applicant could also take the decision to take forward only those uses that are fully supported by data and inform the EMS and EFSA accordingly. In line with the above-mentioned procedure, both original applications were modified by the applicants, and certain uses were no longer supported. The most recent revised Evaluation reports were submitted to EFSA in December 2021 and replaced the previously submitted evaluation reports.

Based on the conclusions derived by EFSA in the framework of the EU pesticides peer review, the data evaluated under previous MRL assessments, and the additional data provided in the framework of these applications, the following conclusions are derived.

The metabolism of cyantraniliprole following either foliar or soil application was investigated in primary crops belonging to the groups of fruit crops (tomato), leafy crops (lettuce), cereals/grass (rice) and pulses/oilseeds (cotton). Residues were mainly composed of the parent compound. Investigation of residues in rotational crops is not required for the present assessment since the two MRL applications refer to import tolerance requests and a proposed use on a permanent crop, respectively. Studies investigating the effect of processing on the nature of cyantraniliprole (hydrolysis studies) demonstrated that cyantraniliprole was stable under pasteurisation and sterilisation conditions but degraded to IN-J9Z38 (14% applied radioactivity, AR), IN-N5M09 (8% AR) and IN-F6L99 (5% AR) during processes simulating baking/brewing/boiling.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products and the capabilities of the analytical methods for enforcement, the residue definition for enforcement and risk assessment for unprocessed plant products was proposed by the EU pesticides peer review as 'cyantraniliprole'. The residue definition for risk assessment in processed products was agreed to be the 'sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole'. EFSA concluded that for the crops assessed in these applications, metabolism of cyantraniliprole in primary crops has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC-MS/MS) are available to quantify residues in the crops assessed in these applications according to the enforcement residue definition at or above 0.01 mg/kg in the crops assessed (LOQ). The available residue trials are sufficient to derive MRL proposals for all crops under consideration.

Specific studies investigating the magnitude of cyantraniliprole, IN-J9Z38, IN-N5M09 and IN-F6L99 residues in processed commodities were assessed during the EU pesticides peer review where several processing factors according to the risk assessment residue definition in processed commodities were derived. Under the present assessment, new processing studies were not submitted and would be required to properly estimate not only the magnitude of cyantraniliprole but also to estimate the formation of cyantraniliprole degradation products IN-J9Z38, IN-N5M09 and IN-F6L99 in processed products. Since hydrolysis degradation products IN-N5M09 and IN-F6L99 were observed at significant levels in some processed commodities the EU pesticides peer review set a data gap to address their toxicity.

The toxicity data submitted for IN-N5M09 and IN-F6L99 confirm that both compounds are unlikely to be genotoxic. The general toxicity of these compounds has not been assessed. The available

processing studies indicate that the highest formation of degradation product IN-N5M09 was observed in apple sauce (0.07 mg/kg), cooked leaves of spinach (0.09 mg/kg), tomato dry pomace (0.013 mg/kg) and grape dry pomace (0.02 mg/kg). Degradation product IN-F6L99 was only observed in apple sauce (0.04 mg/kg) and in cooked spinach leaves (0.015 mg/kg). In other processed commodities, the degradation products were below the LOQ/LOD. In order to estimate the relevance of these degradation products in risk assessment, the EMS calculated the potential consumer exposure to IN-N5M09 and IN-F6L99 from the intake of all commodities that can be processed. In the absence of toxicological reference values of these compounds, the EMS proposed to use the Threshold of Toxicological Concern (TTC).

The possible occurrence of cyantraniliprole residues in commodities of animal origin was investigated and indicated that there is currently no need to modify the existing EU MRLs for animal commodities.

The toxicological profile of cyantraniliprole was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary. The metabolite IN-J9Z38, included in the risk assessment residue definition for processed commodities, is of a similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The chronic consumer exposure assessment for parent cyantraniliprole was performed using the median residue value (STMR) as derived from supervised trials on the crops under consideration. For the commodities for which EU MRLs are set, the STMR values derived in the EU pesticides peer review, from previous MRL applications and from the evaluations by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) were selected as input values.

The calculated chronic exposure to cyantraniliprole residues accounted for a maximum of 72% of the ADI (NL toddler diet). EFSA concluded that the proposed use of cyantraniliprole as well as the import tolerances on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health for the parent compound.

In order to estimate the human exposure to hydrolysis degradation products IN-N5M09 and IN-F6L99 in the absence toxicological reference values, the EMS calculated potential intake of each degradation product individually, using PRIMo rev.3.1. The input values were those of cyantraniliprole (in unprocessed commodities) multiplied by the processing factors derived to account for formation of IN-N5M09 and IN-F6L99 in various processed commodities. The processing factors were calculated as the ratio of the residue concentration of either IN-N5M09 or IN-F6L99 in the processed product and the residue concentration of cyantraniliprole in the unprocessed product. Where processing factors were not available, these were extrapolated to commodities subject to similar processing conditions. The calculated chronic exposure was then compared to the TTC for Cramer Class III compounds of 1.5 μg/kg bw per day. The calculated individual exposure accounted for 18% and 54% of IN-N05M09 and IN-F6L99, respectively, from the threshold exposure of 1.5 μg/kg bw per day. The EMS concluded that the exposure to these degradation products is not a safety concern.

EFSA highlights that the TTC approach (proposed in the EFSA PPR Guidance on the Residue Definition for risk assessment) has not been endorsed by the European Commission and the Member States, and therefore in principle cannot be applied. In order to verify the conclusion by the EMS, EFSA carried out an indicative estimate of the consumer exposure to each degradation product using the PRIMo rev.3.1. EFSA converted the STMR values available for cyantraniliprole in raw agricultural commodity to the respective degradation product equivalent and then applied the processing factors as derived for each metabolite. The calculated long-term exposure accounted for 0.67 μg/kg bw per day for IN-N05M09 and 0.47 μg/kg bw per day for IN-F6L99 and, in principle, confirms the low estimated exposure by the EMS. EFSA notes that this calculation is just a rough estimate and is affected by multiple uncertainties outlined throughout the assessment, which individually may over- or underestimate the actual exposure.

The calculated exposure still has a wide margin of safety and currently does not give an indication that the existing risk assessment residue definition in processed commodities would need to be modified.

EFSA therefore proposes that a risk management decision is taken to conclude whether in the absence of a general toxicological assessment of hydrolysis degradation products IN-N5M09 and IN-F6L99, the low calculated exposure is a sufficient argument to conclude that the existing risk assessment residue definition for processed products does not need to be modified and that the estimated exposure related to both degradation products is unlikely to be of safety concern for the crops under assessment.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Cyantraniliprole				
140010	Apricots	0.01*	0.7[(b)]	The intended SEU use is sufficiently supported by data. Risk for consumers unlikely for the parent compound. Further risk management discussions required since the product can undergo boiling as a processing step.
211000	Potatoes	0.05	0.15[(b)]	The requested import tolerances are sufficiently supported by data. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 0.15 mg/kg. Further risk management discussions required since the products can undergo boiling as a processing step.
212000	Tropical root and tuber vegetables	0.05	0.15[(b)]	
230000	Cucurbits with inedible peel	0.3	0.4[(b)]	The requested import tolerance is sufficiently supported by data. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 0.7 mg/kg. Further risk management discussions required since the products can undergo boiling as a processing step.
243010	Chinese cabbages/ pe-tsai	0.01*	30[(b)]	The requested import tolerances are sufficiently supported by data. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 30 mg/kg. Further risk management discussions required since the products can undergo boiling as a processing step.
243990	Others, leafy brassica			
251000 (except 251020 and 251030	Lettuces and salad plants (except lettuces and escaroles)	0.01*	15	The requested import tolerances are sufficiently supported. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 20 mg/kg.
251020	Lettuces	5	15 or 10	The requested import tolerance is sufficiently supported by data. Further risk management discussions required on the appropriate MRL proposal between 15 mg/kg, derived from a data set of residue trials on open leaf lettuces only, or 10 mg/kg, derived according to the EU rules from a combined data set of closed and open leaf lettuces. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 20 mg/kg.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
251030	Escaroles/ broad-leaved endives	0.01*	15[(b)]	The requested import tolerance sufficiently supported. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 20 mg/kg. Further risk management discussions required since the product can undergo boiling as a processing step.
252000 (except 252010)	Purslane, chard/beet leaves and other spinaches and similar leaves (except spinach)	0.01*	20[(b)]	The requested import tolerances are sufficiently supported by data. Risk for consumers unlikely. MRL in the countries of origin is set at 30 mg/kg. Further risk management discussions required since the products can undergo boiling as a processing step.
256040	Parsley	0.02*		
401010 401030 401040 401080 401100 401110 401120 401130 401140 401150	Linseed Poppy seed Sesame seed Mustard seed Pumpkin seed Safflower seed Borage seed Gold of pleasure Hemp seed Castor beans	0.01*	1.5	The requested import tolerance is sufficiently supported by data. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 1.5 mg/kg.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Further risk management consideration is required to decide whether the argument of the low exposure is acceptable to waive the need to submit the data on the general toxicity of IN-N5M09 and IN-F6L99 (relevant for processed commodities that undergo cooking/boiling) for the requested modification of the existing MRLs.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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Assessment

The European Food Safety Authority (EFSA) received two applications for the active substance cyantraniliprole, respectively, to set import tolerances in various crops and to modify the existing maximum residue level (MRL) in apricots. The detailed description of the authorised uses in United States and Canada, and of the intended SEU uses of cyantraniliprole on apricots, which are the basis for the current MRL applications, are reported in Appendix A.[1]

Cyantraniliprole is the ISO common name for 3-bromo-1-(3-chloro-2-pyridyl)-4′-cyano-2′-methyl-6′-(methylcarbamoyl)-1*H*-pyrazole-5-carboxanilide (IUPAC). The chemical structures of the active substance and its main metabolites and degradation products are reported in Appendix E.

Cyantraniliprole was evaluated in the framework of Regulation (EC) No 1107/2009[2] with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses of foliar applications on various crops. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2014). Cyantraniliprole was approved[3] for the use as insecticide on 14 September 2016. The process of renewal of the first approval has not yet been initiated.

The EU MRLs for cyantraniliprole are established in Annex II of Regulation (EC) No 396/2005[4]. After completion of the EU pesticides peer review, EFSA has issued several reasoned opinions on the modification of MRLs for cyantraniliprole. The proposals from these reasoned opinions have been considered in MRL regulations.[5] Furthermore, Codex maximum residue limits (CXLs) were also implemented in the EU legislation by the Commission Regulations.[4]

The review of MRLs for this active substance in accordance with Article 12 of Regulation (EC) No 396/2005 is not required (EFSA, 2017b), since the MRLs were established in the context of the first approval of the active substance (EFSA, 2014) or by subsequent MRL applications which were assessed by EFSA.

In accordance with Article 6 of Regulation (EC) No 396/2005, FMC International submitted an application to the competent national authority in France (evaluating Member State) to set several import tolerances for the active substance cyantraniliprole in various crops reflecting existing uses in Canada and the United States.

In addition, the applicant Syngenta Crop Protection submitted in accordance with Article 6 of Regulation (EC) No 396/2005 a second application to France to modify the existing maximum residue levels (MRLs) for the active substance cyantraniliprole in various commodities.

The EMS, France drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 11 October 2016 and on 26 April 2018, respectively. The EMS proposed to raise the existing MRLs for various crops imported from Canada and United States, and to raise the existing MRL for apricots.

EFSA assessed both applications and evaluation reports as required by Article 10 of the MRL regulation. For both applications, EFSA identified various data gaps and points which needed further clarification and were requested from the EMS. It is noted that, in accordance with Guidance Document SANTE/2015/10595 Rev. 4 (European Commission, 2015), in cases where missing information has been identified for specific parts of the application, the applicant could also take the decision to take forward only those uses that are fully supported by data and inform the EMS and EFSA accordingly. In line with the above-mentioned procedure, both original applications were modified by the applicants, and certain uses were no longer supported. The most recent revised

[1] It is noted that in the MRL application for the import tolerances, the GAPs were presented in accordance with the US food classification (see footnotes to Appendix A). Normally, MRL applications are assessed individually for the crops for which MRLs are requested, following the EU food classification. In this case, the crops for which the import tolerance request is made, were identified by the EMS and the applicant and specified in the MRL application and the Evaluation report (France, 2016).

[2] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[3] Commission Implementing Regulation (EU) 2016/1414 of 24 August 2016 approving the active substance cyantraniliprole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 230, 25.8.2016, p. 16–19.

[4] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

[5] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

Evaluation reports were submitted to EFSA on 7 December 2021 (France, 2016, 2018), which replaced the previously submitted evaluation reports.

For reasons of consistency EFSA assessed both applications in a single reasoned opinion.

EFSA based its assessment on the evaluation reports submitted by the EMS (France, 2016, 2018), the draft assessment report (DAR) (United Kingdom, 2013) prepared under Regulation (EC) No 1107/2009, the Commission review report on cyantraniliprole (European Commission, 2016), the conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole (EFSA, 2014), the conclusions from previous EFSA opinions on cyantraniliprole (EFSA, 2015, 2016a,b, 2017a, 2018a, 2019a, b 2021) and the evaluations of cyantraniliprole by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) (FAO, 2013, 2015, 2019).

For these applications, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the applications to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; 2019, OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[7].

A selected list of end points of the studies assessed by EFSA in the framework of these MRL applications including the end points of relevant studies assessed previously is presented in Appendix B.

The two evaluation reports submitted by the EMS (France, 2016, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Mammalian toxicology

The toxicological profile of cyantraniliprole was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day (European Commission, 2016). An acute reference dose (ARfD) was not required (EFSA, 2014).

The toxicological relevance of the plant metabolite IN-J9Z38 (included in the risk assessment residue definition for processed commodities) was discussed in the EU pesticides peer review, and it was considered covered by the reference values derived for cyantraniliprole (EFSA, 2014).

In the framework of a previous MRL assessment (EFSA, 2021), additional information on the toxicological profile for the degradation products IN-N5M09 and IN-F6L99 observed in the standard hydrolysis studies were provided. These studies were also appraised by the EMS in the present assessments (France, 2016, 2018). Based on experimental data, IN-N5M09 and IN-F6L99 are considered unlikely to be genotoxic. These two degradation products are not considered structurally similar to parent cyantraniliprole (EFSA, 2021). Studies to investigate the general toxicity of the degradation products are still not available.

2. Residues in plants

2.1. Nature of residues and methods of analysis in plants

2.1.1. Nature of residues in primary crops

The metabolism of cyantraniliprole following either foliar or soil applications in primary crops belonging to the fruit (tomatoes), leafy (lettuces), cereals/grass (rice), pulses/oilseeds (cotton) crop groups has been investigated in the framework of the EU pesticides peer review (EFSA, 2014). In the crops tested, parent compound was the main residue, accounting for almost 25% to more than 90% of the total radioactive residues (TRR). Twenty different metabolites were identified, mostly below 5% TRR, the most abundant being the metabolite IN-J9Z38 representing 23% TRR at 32-day preharvest interval (PHI) in lettuce (0.007 mg/kg) and 6–28% TRR in rice foliage, straw and grain (0.03–0.09 mg/kg)

[6] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

[7] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

following soil drench application. Due to low actual amounts of metabolite IN-J9Z38 present in plant matrices, the EU pesticides peer review considered cyantraniliprole to be the major component of residue in primary crops (EFSA, 2014). No additional studies were submitted in the current MRL application.

For the import tolerances and the intended use, the metabolic behaviour in primary crops is sufficiently addressed.

2.1.2. Nature of residues in rotational crops

Investigation of residues in rotational crops is not required for the present assessment since MRL applications refer to import tolerance requests and to the use on a permanent crop.

2.1.3. Nature of residues in processed commodities

The effect of processing on the nature of cyantraniliprole was investigated in the framework of the EU pesticides peer review (EFSA, 2014). Cyantraniliprole was stable under pasteurisation and sterilisation process conditions but degraded to IN-J9Z38 (up to 14% of the applied radioactivity, AR), IN-N5M09 (up to 8% AR) and IN-F6L99 (up to 5% AR) during processes simulating baking/brewing/boiling.

Based on standard hydrolysis studies, the residue definitions in processed commodities were proposed as 'cyantraniliprole' for enforcement and as the 'sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole' for risk assessment (EFSA, 2014). The toxicological relevance of the metabolite IN-J9Z38, observed also in plant metabolism (see Section 2.1.1) was considered covered by the toxicity of the parent (EFSA, 2014).

The two degradation products IN-N5M09 and IN-F6L99 were identified at quantifiable levels in cooked spinach, and therefore, additional toxicological data were requested for these compounds in the framework of the EU pesticides peer review (EFSA, 2014). The applicants provided some studies investigating the toxicity of degradation products in the framework of a previous MRL assessment (EFSA, 2021) (see Section 1).

2.1.4. Methods of analysis in plants

Analytical methods for the determination of cyantraniliprole residues were assessed during the EU pesticides peer review under Regulation (EC) No 1107/2009 (EFSA, 2014). The multiresidue DFG S19 method using liquid chromatography coupled with tandem mass spectrometry (LC–MS/MS) quantification and its independent laboratory validation (ILV) were concluded to be fully validated for the determination of residues of cyantraniliprole in high water (apples, peaches, tomatoes, lettuces, cucumbers, potatoes), high acid (oranges, lemons, limes), high oil (almonds, rapeseeds) content matrices and in dry commodities (wheat grain) at the limit of quantification (LOQ) of 0.01 mg/kg for each analyte. The methods are sufficiently validated for the determination of residues of cyantraniliprole in the crops under consideration at or above the LOQ of 0.01 mg/kg.

2.1.5. Stability of residues in plants

The storage stability of cyantraniliprole and the metabolites IN-J9Z38, IN-N5M09 and IN-F6L99 in plant commodities stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2014). It was demonstrated that in high oil content matrices, the residues of cyantraniliprole and IN-F6L99 were stable for 18 months and residues of IN-J9Z38 and IN-N5M09 were stable for at least 24 months when stored at −20°C. In high water content matrices, the storage stability of cyantraniliprole and respective metabolite and degradation products is demonstrated for more than 24 months, when stored at −20°C.

2.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of standard hydrolysis studies, the toxicological significance of metabolites and/or degradation products, the capabilities of enforcement analytical methods, the following residue definitions were proposed:

- Residue definition for risk assessment for primary crops: cyantraniliprole
- Residue definition for risk assessment in processed commodities: Sum cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole
- Residue definition for enforcement: cyantraniliprole

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

In some processed commodities, a formation of two degradation products, namely IN-N5M09 and IN-F6L99, in addition to IN-J9Z38 was observed in the magnitude of residue studies submitted for the EU pesticides peer review. Although for these degradation products the EU pesticides peer review set a data gap for the assessment of toxicological properties, the proposed risk assessment residue definition in processed commodities was confirmed (EFSA, 2014). Now, in order to demonstrate that there is no need to amend the existing risk assessment residue definition for processed commodities, the EMS estimated potential consumer exposure to these degradation products IN-N5M09 and IN-F6L99 from the intake of all commodities that can be processed (see Section 4).

For the commodities assessed in this application, EFSA concluded that the residue definitions derived by the EU pesticides peer review are appropriate and no modification is required.

2.2. Magnitude of residues in plants

In support of the MRL requests under assessment, the applicants submitted residue trials on apricots, peaches, potatoes, mustard greens, lettuces, spinaches, melons and cotton. The trial samples were analysed for cyantraniliprole and for metabolites IN-N7B69, IN-JCZ38, IN-K5A79, IN-MYX98, IN-MLA84, IN-J9Z38 and IN-K7H19. Since none of these metabolites are included in either enforcement or risk assessment residue definition in primary crops, these data were not taken into consideration. The available residue trials are summarised in Appendix B, Table B.2.2.1.

The residue trial samples were stored frozen prior to analysis for time intervals not exceeding the demonstrated storage stability periods for cyantraniliprole, and therefore, the residue data are considered valid with regard to storage stability. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (France, 2016, 2018). It is noted that when residue values were reported as 'ND – not detected, < LOD of 0.003 mg/kg', for the MRL setting these values were reported as '< 0.01 mg/kg' (below LOQ).

EFSA notes, that, according to Regulation (EC) No 544/2011, at least 50% of the residue trials shall be decline trials if a significant part of the consumable crop is present at the time of application. This requirement has not been fully respected for import tolerance requests (one or two decline trials are available) and EFSA asked the applicant to provide justification for this deviation. The applicant explained that the national registration rules in the exporting countries USA/Canada have been followed, which require that two decline trials are submitted for crops that require 16–20 trials, while only one decline trial is needed for crops requiring 5–12 trials (France, 2016). The applicant also referred to trials assessed in the EU pesticides peer review for cyantraniliprole which indicate that residue concentrations do not increase with time when the active substance is applied according to the GAP (France, 2016). Indeed, the available EU residue trials indicate that the preharvest intervals for cyantraniliprole GAPs have been properly set to account for the maximum residue concentration expected in the crop. This argument, however, is not fully justifying the lack of residue decline studies. Further aspects of residue decline are discussed below specifically for each crop or crop group.

EFSA acknowledges that for the assessment of present applications, the EU extrapolation rules in force at the time of the original submissions of MRL applications are applicable; however, since subsequent modifications of this guidance do not affect the outcome of the present assessment, EFSA applied the latest extrapolation rules set out in the Technical Guidelines SANTE/2019/12752 (European Commission, 2019).

Apricots

In support of the MRL application, the applicant submitted residue decline trials performed on apricots (four trials) and peaches (four trials). All trials were compliant with the intended GAP and were performed in 2015 in various EU countries: France, Italy, Spain and Greece. Given the widespread distribution of trials, the lack of trials being distributed over two growing seasons is considered a minor deviation. Decline trials indicate that residue concentrations decrease over time.

The applicant proposes to combine residue trials on peaches and apricots and extrapolate to apricots. Such an extrapolation is acceptable according to EU Technical Guidelines SANTE/2019/12752 (European Commission, 2019). The residue data indicate that an MRL of 0.7 mg/kg would be required to support the intended SEU use of cyantraniliprole.

Potatoes, tropical root and tuber vegetables

In support of the authorised GAPs in the United States and Canada, the applicant submitted 21 residue trial on potatoes. Trial plots were treated according to the following application patterns: seed treatment plus foliar application (21 plots), three times foliar application using OD formulation (20 plots), three times foliar application using SE formulation (bridging trials) (five plots) and in-furrow application plus foliar treatment application (one plot). Two samples were taken per plot and the average value was selected for the residue data set.

One of the trials was designed as decline trial investigating residue concentrations in potato prior to each application, but as residues at PHI intervals of 1, 5, and 7 days were below the LOD, decline could not be properly assessed. Although the data requirement for at least 50% of trials being decline trials was not fulfilled, EFSA agrees with the EMS that this could be considered as a minor deviation, given the fact that the overall residue data package for cyantraniliprole generally indicates residue decline along time. Given the time of transportation of treated potatoes to EU, it can be concluded that further reduction of residues in potatoes is expected.

Two pairs of the trials conducted in New Glasgow (Canada), in Jerome (USA) and in Payette (USA) were considered replicates by EFSA, and among these pairs of trials, the highest value was selected. Thus, 18 trials can be considered independent.

The treatment using seed application combined with foliar spraying resulted in a more critical residue situation in potatoes, and therefore, trials reflecting this use pattern were used to derive the MRL proposal of 0.15 mg/kg for potatoes. The applicant has proposed to extrapolate the residue data in potatoes to the whole group of tropical root and tuber vegetables. According to the Technical Guidelines SANTE/2019/12752, such an extrapolation is acceptable (European Commission, 2019).

The current CAN/US tolerance[8,9] for the group of crops corresponding to the EU group of tropical root and tuber vegetables and potatoes is 0.15 mg/kg.

Cucurbits with inedible peel

In support of the authorised foliar use the applicant provided in total nine GAP-compliant residue trials on melons. Trials were performed in 2008–2009 in the United States and Canada. For two trials conducted in Porterville (USA), the independency could not be demonstrated from submitted trial information, and therefore, EFSA considered them replicates and selected the highest value among these trials. Two samples per plot were taken of melon whole fruit; the data were provided separately for whole fruit, pulp and peel. In none of pulp samples, cyantraniliprole residues were present above the LOQ of 0.01 mg/kg.

In order to provide evidence that decline of cyantraniliprole residues is expected in cucurbits in general, one decline trial on cucumber, representing cucurbit wit edible peel crop group is available, indicating that at PHI intervals longer than 1 day the residues decrease. This is further confirmed by the EU residue trials assessed in the EU pesticides peer review, where a decline of residues was observed in melons for a similar foliar GAP at the PHI intervals of 3, 7 and 14 days.

In total, eight residue trials on melons are available to derive an MRL proposal of 0.4 mg/kg. The applicant has proposed to extrapolate the residue data in melons to the whole group of cucurbits with inedible peel. According to the Technical Guidelines SANTE/2019/12752, such an extrapolation is acceptable (European Commission, 2019).

The current CAN/US tolerance[8,9] for the group of crops corresponding to the EU group of cucurbits with inedible peel is 0.7 mg/kg.

Chinese cabbages/pe-tsai and other leafy brassica (except kale)

In support of the authorised use on Chinese cabbage and other leafy brassica (except kale) in the United States and Canada, the applicant provided 11 GAP-compliant residue trials on mustard greens.[10] The trials were conducted at different locations in the USA in 2008–2009.

Residue decline trials have not been provided. Instead, the EMS provided a decline trial on broccoli to confirm that residue decline will be expected in leafy brassica. Additionally, the metabolism study on

[8] US Federal Register- § 180.672 Cyantraniliprole; tolerances for residues. Available online (e-CFR): https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.672

[9] Health Canada. Maximum Residue Limits for Pesticides. Available online: https://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php

[10] Mustard greens (*Brassica juncea,* code 0243010-002), according to Part B of Annex I of Regulation (EC) No 396/2005 is attributed to the main representative product Chinese cabbages/pe-tsai in Part A of Annex I to Regulation (EC) No 396/2005.

lettuce confirm residue decline at longer PHI intervals. EFSA agrees with the EMS that there is sufficient evidence that residue decline over time is expected and concludes that for the present assessment, the lack of 50% of residue trials being decline, is considered a minor deviation.

The applicant proposes to extrapolate the residue data in mustard greens to Chinese cabbage which is acceptable according to the main extrapolation principles reported in the Technical Guidelines SANTE/2019/12752 (European Commission, 2019). In addition, the applicant requested the extrapolation to 'other' leafy brassica, but excluding kales, which also belongs to the crop group of leafy brassica. According to the Technical Guidelines SANTE/2019/12752 extrapolation to the whole group is possible only from kales (European Commission, 2019). The applicant was therefore asked by EFSA to provide an evidence-based justification (in terms of residue accumulation, consumption, cultivation and morphology) to support the extrapolation from mustard greens. In response to EFSA, the applicant informed that mustard greens in the USA and Canada is the representative crop of the brassica leafy greens with a cultivation area exceeding that of kale (nearly 1/3 more). Both crops 'share similar pest pressure, with cutworms, wireworms, aphids, leaf miners and leafhoppers as primary insects, the agronomic morphology of each crop is very similar, with the entire edible portion of the crop exposed to pesticide applications and both have large leaves, which contribute to higher residues than other leafy greens, based on the large leaf surface area' (France, 2016). Indeed, when compared to residue data in lettuces and spinaches for identical GAPs, the residues in mustard greens are higher.

EFSA is of the opinion, that the argumentation provided by the applicant is adequate and in the framework of the present assessment accepts to extrapolate the residue data in mustard greens to 'other' leafy brassica (except kale), with an MRL proposal of 30 mg/kg.

The current US/CAN[8,9] tolerance for the group of crops corresponding to the EU group of leafy brassica is 30 mg/kg.

Lettuces and other salad plants (lamb's lettuces/corn salad, lettuces, escaroles/ broad-leaved endives, cresses, land cresses, Roman rocket-rucola, red mustards, baby leaf crops, others lettuces and salad plants)

In support of the authorised GAP, the applicant provided in total 12 GAP-compliant residue trials on open leaf lettuce and 12 GAP-compliant trials on head lettuce. The trials were conducted at different locations in the USA and Canada in 2008–2009. In all trials crop received three times foliar treatment, using OD formulation. Some trials (six for open leaf lettuce and two for head lettuce) were designed as bridging trials – side-by-side plot received foliar treatment using SE formulation. Statistical test demonstrated that application of SE and OD formulations resulted in comparable residues, and therefore, the highest value was selected for the MRL calculation.

Residue decline trials have not been provided. However, the metabolism studies and EU residue trials on lettuce indicate that following foliar treatment, residues in lettuce decline over time. Thus, for the present assessment, the lack of 50% of residue trials being decline is considered a minor deviation.

Two pairs open leaf lettuce trials conducted in Porterville (USA) and in King City (USA) and two head lettuce trials conducted in Porterville (USA) were considered replicates by EFSA since a more detailed information was not available to conclude otherwise. From replicate trials, the highest residue value was selected. Thus, for open leaf lettuce, there are 10 and for head lettuce 11 independent trials available.

The applicant proposed to extrapolate residue data from leaf lettuce to the whole subgroup of lettuces and other salad plants. Such an extrapolation according to the Technical Guidelines SANTE/2019/12752 is considered acceptable (European Commission, 2019). The CAN/US[8,9] tolerance for the crops listed in the EU food group of lettuces and salad plants is set at a level of 20 mg/kg.

For **lettuces**, EFSA notes that, in principle, the available GAP-complaint residue data in open leaf lettuce and head lettuce shall be combined to derive an MRL proposal. The combined residue data set results in a lower MRL proposal of 10 mg/kg, while the residue data on leaf lettuce alone result in a higher MRL proposal of 15 mg/kg. Considering the ALARA principle and the above-mentioned EU rules which allow combining closed and open leaf lettuce varieties, EFSA proposes that a risk management decision is taken on the appropriate value for the MRL proposal in lettuces.

Purslanes, chards/beet leaves and other spinaches and similar leaves (except spinach); Parsley

In support of the authorised GAP, the applicant provided in total 10 GAP-compliant residue trials on spinaches. The trials were conducted at different locations in the USA in 2008–2009. In all trials crop received three times foliar treatment, using OD formulation; four trials were designed as bridging trials – side-by-side plot received foliar treatment using SE formulation. The residues in crop were slightly higher when OD formulation was used, and therefore, these data were selected for the MRL setting.

Residue decline trials have not been provided. However, the metabolism studies and the EU residue trials on lettuces indicate that following foliar treatment residues in lettuce decline over time. Thus, for the present assessment, the lack of 50% of residue trials being decline is considered a minor deviation.

The applicant proposes that the residue data in spinaches are extrapolated to the whole group of spinaches and similar leaves and to parsley. According to the Technical Guidelines SANTE/2019/12752, such an extrapolation is acceptable (European Commission, 2019). The number and quality of the trials is sufficient to derive an MRL of 20 mg/kg for the whole group of spinaches and similar leaves (except spinach) and for parsley.

The US/CAN[8,9] tolerance for the crops corresponding to spinaches and similar leaves and parsley is set at a level of 20 mg/kg.

Linseeds, poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans (minor oilseeds)[11]

In support of the authorised GAP on minor oilseeds, the applicant provided in total 13 GAP-compliant residue trials on cotton performed with foliar application using OD formulation. The trials were conducted at different locations in the USA in 2009. In one trial, the sample was taken 9 instead of 7 days after the last application and was therefore disregarded. One trial was designed as bridging trial where side-by-side plot was treated in-furrow, combined with foliar application. Residues in the crop from this trial were lower than with three foliar treatments. In two trials, the residue behaviour was investigated 1 and 5 days before harvest, indicating that residues generally decline. This information, however, is not fully satisfying the data requirement for 50% of trials being decline. Notwithstanding this shortcoming, EFSA considers the trials to be acceptable, since cyantraniliprole according to available residue trials and metabolism studies are not expected to accumulate or form other metabolites different than those identified and characterised in the metabolism studies in crops at longer PHI intervals.

It is therefore concluded that the number of trials is sufficient to support the authorised use. The applicant proposes to extrapolate residue data from cotton seed to minor oilseeds (linseeds, poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans). According to the Technical Guidelines SANTE/2019/12752 such an extrapolation is acceptable (European Commission, 2019). The MRL proposal of 1.5 mg/kg is derived for minor oilseeds. The current CAN/US[8,9] tolerance for oilseeds 1.5 mg/kg.

2.2.1. Magnitude of residues in rotational crops

Investigation of residues in rotational crops is not required for the present assessment since MRL applications refer to import tolerance requests and the use on a permanent crop.

2.2.2. Magnitude of residues in processed commodities

New studies to investigate the effect of processing on the magnitude of cyantraniliprole residues in processed products from the crops under consideration have not been submitted. Such studies would be required to properly estimate not only the magnitude of cyantraniliprole but also to estimate the formation of cyantraniliprole degradation products IN-J9Z38, IN-N5M09 and IN-F6L99 in processed products.

In order to investigate the relevance of degradation products IN-N5M09 and IN-F6L99 in the risk assessment of processed commodities, the EMS proposed to calculate the dietary exposure to these compounds from the intake of all food commodities which can be consumed processed. In order to

[11] Considered 'minor' according to the Technical Guidelines SANTE/2019/12752 (European Commission, 2019).

derive input values for the risk assessment, the production (formation) for IN-N5M09 and IN-F6L99 was derived by the EMS from the processing studies available for the EU pesticides peer review on oranges, apples, plums, grapes, potatoes, tomatoes, olives, cotton, spinaches (United Kingdom, 2013). It is noted that from these studies, the EU pesticides peer review had already derived various processing and conversion factors for cyantraniliprole and its metabolite IN-J9Z38, which are compiled in the EFSA conclusion (EFSA, 2014). The EU pesticides peer review also concluded that potato processing factors are not fully reliable since residue levels in raw commodity were close to LOQ (0.01–0.014 mg/kg) and in all processed potato commodities tested were < LOQ (EFSA, 2014). From recent EFSA assessment, the processing factors for olives are also available (EFSA, 2021).

According to the results of processing studies, the degradation product IN-N5M09 was present above the LOQ only in tomato pomace (one sample 0.013 mg/kg), apple sauce (all three samples, 0.014–0.07 mg/kg), dry grape pomace (one sample, 0.018 mg/kg) and in cooked spinach leaves (all three samples, 0.02–0.085 mg/kg). The degradation product IN-F6L99 was detected above the LOQ only in apple sauce (two samples, 0.04 mg/kg) and in cooked spinach leaves (one sample, 0.015 mg/kg). In remaining samples, the residues were either below the limit of detection (LOD) of 0.003 mg/kg or below the LOQ of 0.01mg/kg. On the basis of these studies, the applicant and the EMS derived tentative processing factors for both degradation products as a ratio of residues of these compounds in the processed commodity and concentrations of cyantraniliprole in raw agricultural commodity (RAC). The PFs derived by the EMS are reported in the table below (France, 2016, 2018).

Matrix	Overall PF IN-N5M09	Overall PF IN-F6L99
Sun-dried tomatoes	0.065*	0.035** (tomato paste)
Prune	0.021*	0.017*
Applesauce	0.269**	0.154**
Processed olives	0.016*	0.007*
Grape juice	0.025*	0.025*
Spinach cooked leaves	0.009**	0.002**

PF (processing factor) = degradation product residue processed commodity (mg/kg)/parent residues in RAC (mg/kg).
*: Derived average PF based on a single PF, as the compound was not detected in other trials.
**: Derived average PF based on the median of three PFs.

EFSA proposed to express cyantraniliprole residues in RAC as IN-N5M09 and IN-F6L99 equivalents, by applying the molecular weight conversion factors. The processing factors were then derived as a ratio between residues of a degradation product in processed commodity and the residues of cyantraniliprole (expressed as IN-N5M09 or IN-F6L99 equivalents) in RAC. It is noted that when residues of IN-N5M09 and IN-F6L99 were reported to be below the LOD of 0.003 mg/kg or were reported at actual values above the LOD but below the LOQ of 0.01 mg/kg (e.g. 0.006 mg/kg), the residues of degradation products were assumed to occur at the levels reported. EFSA acknowledges that it introduces additional uncertainties, but the approach to alternatively express these values at the LOQ would result in an overestimation of the formation of degradation products. The overview of the processing factors derived by EFSA is summarised in Appendix B.2.2.3.

2.2.3. Proposed MRLs

The available data are considered sufficient to propose modifications of the existing EU MRLs and to derive risk assessment values for the following crops: apricots, potatoes, tropical root and tuber vegetables, cucurbits (inedible peel), lettuces and salad plants, Chinese cabbages and other leafy brassica (except kale), spinaches and similar leaves (except spinach), parsley, linseeds, poppy seeds, sesame seeds, mustard seeds, safflower seeds, borage seeds, gold of pleasure, hempseeds and castor beans.

In Section 4, EFSA assessed whether cyantraniliprole residues in the crops for which an MRL amendment is proposed are likely to pose a consumer health risk. Additionally, an indicative consumer exposure to processing degradation products IN-N5M09 or IN-F6L99 was estimated.

3. Residues in livestock

Some of the crops under consideration or their by-products (potatoes, cassava, linseeds, safflower) can enter the EU livestock feed chain, and therefore, a potential carry-over of cyantraniliprole residues into food of animal origin has to be assessed.

The EU livestock dietary burden was calculated according to the currently used OECD methodology (OECD, 2013). For all feed crops for which the EU MRL in Commission Regulation (EU) No 2020/856[12] is set above the LOQ (including rice with an MRL of 0.01* mg/kg), the risk assessment values corresponding to the existing EU MRL were used as input values in the dietary burden calculator. For several crops, the processing factors as derived by the EU pesticides peer review were available to refine the exposure calculation. For the crops under consideration, the risk assessment values as derived from the submitted trials were used as input values.

The calculated livestock exposure exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all livestock diets, but the main contributor in all diets was head cabbage. However, as the most recent livestock exposure was calculated according to the EU methodology, EFSA further assessed whether the existing EU MRLs are still sufficient to account for potential residues in animal tissues.

3.1. Nature of residues and methods of analysis in livestock

The metabolism of cyantraniliprole was investigated in lactating goats and laying hens and a general residue definition for monitoring was proposed as 'cyantraniliprole' only. The residue definition for risk assessment was set as the 'sum of cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69 expressed as cyantraniliprole'. Furthermore, an overall conversion factor of 2 (except for meat and honey where a conversion factor of 1 was derived) was derived from the animal feeding studies considering the metabolites relevant for each animal matrix (EFSA, 2014). Methods of analysis have been previously assessed by EFSA and considered as sufficiently validated (EFSA, 2014).

3.2. Magnitude of residues in livestock

Feeding studies investigating the magnitude of cyantraniliprole residues in lactating goat and laying hen were reported in the framework of the EU pesticides peer review (EFSA, 2014). The livestock dietary burdens which were calculated in the present assessment were then compared with the feeding levels of livestock feeding studies to estimate the carry-over of cyantraniliprole residues into animal matrices from the intake of residues from the crops under consideration. According to the results of these studies, it is concluded that there is no need to modify the existing EU MRLs for cyantraniliprole for animal commodities, which reflect the implementation of the Codex MRLs into the EU legislation.

4. Consumer risk assessment

4.1. Exposure to cyantraniliprole

EFSA performed the dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018b, 2019b). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference value for cyantraniliprole used in the risk assessment (i.e. ADI of 0.01 mg/kg bw per day) was derived in the framework of the EU pesticides peer review (European Commission, 2016). The same toxicological reference value is applicable to the metabolite IN-J9Z38 (EFSA, 2014).

Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required (EFSA, 2014).

The long-term exposure assessment was performed taking into account the median residue value (STMR) derived from supervised trials on the crops under consideration. For the remaining

[12] Commission Regulation (EU) 2020/856 of 9 June 2020 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products.C/2020/3608. OJ L 195, 19.6.2020, p. 9–51.

commodities covered by the MRL regulation, the STMR values derived in the EU pesticides peer review (EFSA, 2014), previous MRL applications (EFSA, 2015, 2016a,b, 2017a, 2018a, 2019a,b, 2021) and evaluations by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) (FAO, 2013, 2015, 2019) were selected as input values. For melons and citrus fruits, the peeling factors as derived by the EU pesticides peer review were applied. For boiled purslane and beet leaves/chard, for canned table olives and for olive for oil production, the processing factors and conversion factors as derived in previous EFSA outputs (EFSA, 2014, 2021) were applied to estimate the exposure according to the risk assessment residue definition for processed commodities.

EFSA notes that for animal commodities for which the existing EU MRLs are set on the basis of CXLs, STMR values refer to the risk assessment residue definition derived by the JMPR (i.e. sum of cyantraniliprole and metabolites IN-N7B69, IN-J9Z38, IN-MLA84 and IN-MYX98, expressed as cyantraniliprole, FAO, 2015). The range of metabolites in the residue definition set by the JMPR is broader than the EU risk assessment residue definition; therefore, the calculated exposure is expected to be slightly overestimated. However, EFSA considered appropriate to use STMRs in the exposure calculation without adaptation.

The calculated chronic exposure accounted for a maximum of 72% of the ADI (NL toddler diet). Among the crops under consideration, the highest contribution to the long-term exposure was identified from the intake of lettuces and other salad plants (17%), Chinese cabbage (12%), parsley (2%), potatoes (1.7%) and was individually below 1% of the ADI for remaining crops. Further details on the contribution of residues expected in the commodities assessed in this application to the overall long-term exposure are provided in the report sheet of the PRIMo, which is presented in Appendix C.

EFSA concluded that the long-term intake of residues of cyantraniliprole resulting from the existing and intended uses is unlikely to present a risk to consumer health for the parent compound.

4.2. Indicative exposure to hydrolysis degradation products IN-N5M09 and IN-F6L99

In some processed commodities during boiling/cooking, a formation of two degradation products (IN-N5M09 and IN-F6L99) was observed in the magnitude of residue studies submitted for the EU pesticides peer review and in the absence of toxicological data of these compounds, their relevance in the consumer exposure was not assessed. Although the data gap was set by the EU pesticides peer review for the assessment of toxicological profile of these compounds, the derived residue definition for the risk assessment in processed commodities did not include these compounds (EFSA, 2014).

New toxicity studies were submitted in previous and present assessments of cyantraniliprole (EFSA, 2021; France, 2016, 2018), and confirm that both compounds are not genotoxic *in vitro*. However, regarding general toxicity, further toxicological data were not submitted to assess whether these degradation products are of qualitatively or/and quantitatively similar toxicity in comparison with the parent compound cyantraniliprole.

In the absence of general toxicity data, the applicant and the EMS proposed to apply the threshold of toxicological concern (TTC) approach to assess the relevance of IN-N5M09 and IN-F6L99 in the diet when consuming processed commodities and to investigate whether there is a need to modify the existing risk assessment residue definition in processed commodities. The EMS proposed to compare the calculated exposure to the TTC for Cramer Class III compounds value of 1.5 μg/kg bw per day.

The EMS calculated potential chronic consumer exposure from the intake of processed commodities expected to contain residues of IN-N5M09 and IN-F6L99. The exposure was calculated for each degradation product individually, using PRIMo rev.3.1. The medium residue values of cyantraniliprole were multiplied by the processing factor as derived from the processing studies (see Section 2.2.2). The input value was then compared with the consumption data for raw commodity and the TTC value of 1.5 μg/kg bw per day.

For all food commodities for which the consumption data are available and which can be consumed processed, the processing factors of degradation products IN-N5M09 and IN-F6L99 are not available. In order to cover all crops that can potentially undergo a boiling step, the EMS proposes to extrapolate the highest processing factors as derived for several processed commodities – apple sauce, tomato (dried pomace/tomato paste), processed olives, cooked spinach leaves and grape juice – to other crops which can be similarly processed and among which the extrapolation of processing factors could be acceptable according to OECD Guideline 508 (OECD, 2008).

The EMS applied the following processing (production) factors to raw commodity:

Raw agricultural commodity	Processed commodity for extrapolation of PF
Citrus fruits, pome fruits, stone fruits, strawberries, kaki, mangoes,	Apple sauce
Grapes, cane fruits, other small fruits and berries	Grape juice
Table olives, olives for oil production	Canned (whole olives)
Potatoes, tropical root and tuber vegetables, beetroots, carrots, celeriac, horseradishes, Jerusalem artichokes, parsnips garlic, onions, shallots, sugar beet roots, chicory roots	No factor applied as no concentration observed in processing studies
Parsley, radishes, salsifies, spring onions, okra, cucumbers, courgettes, pumpkins, flowering and head brassica, kohlrabies, spinaches and similar (except spinach), legumes, celeries, globe artichokes and dry beans	Cooked spinach leaves
Tomato	Dried tomato and tomato paste*
Sweet peppers, aubergines	Dried tomato or cooked spinach*
Melons, watermelons	None, products are eaten raw

*: Depending on degradation product.

The exposure calculated by the EMS was 18% for IN-N05M09 and 54% for IN-F6L99 from the threshold exposure of 1.5 μg/kg bw per day. The EMS concluded that since calculated exposures are below the TTC value, the exposure to these degradates is not a safety concern and the proposed modifications of cyantraniliprole MRLs will not have any impact on the consumer exposure to IN-N05M09 and IN-F6L99 (France, 2016).

In order to investigate whether the existing risk assessment residue definition for processed commodities would need to be modified by the inclusion of two degradation products, also EFSA carried out an indicative estimate of the consumer exposure to each degradation product using the EFSA PRIMo rev.3.1. However, a slightly different approach was used by EFSA to derive the input values: The STMR values available for cyantraniliprole in raw agricultural commodity were converted to the respective degradation product equivalent and then processing factors as derived for each degradation product (see Appendix B.2.2.3) were applied. To extent feasible, the extrapolation of processing factors was done in accordance with the OECD Guideline 508 (OECD, 2008). The details of the input values are presented in Appendix D.2.

The calculated long-term exposure accounted for 0.67 μg/kg bw per day for IN-N05M09 and 0.47 μg/kg bw per day for IN-F6L99 and, in principle, confirming the low estimated exposure by the EMS.

EFSA notes that this calculation is just a rough estimate and is affected by multiple uncertainties, which individually may over- or underestimate the actual exposure:

1) The long-term intake of residues is calculated on the basis of raw commodity consumption data under the assumption that crop is exclusively consumed in one form of a processed commodity, which is not necessarily the commodity expected to contain the highest residues of the degradation product
2) Where processing factors were unavailable or unreliable, EFSA assumed that cyantraniliprole residues in raw commodity are fully converted to a respective degradation product
3) Some of the derived tentative processing factors are subject to uncertainties (see Appendix B.2.2.3) or even contradictory. For example, the processing studies on apple sauce provide evidence that cyantraniliprole is partially degraded to IN-N5M09 and IN-F6L99 whilst in the studies for apple puree, these degradation products were not identified. Since both products are made from cooked apples and apple puree is a form of apple sauce, no explanation can be found (in the exposure calculation EMS considered and extrapolated to several other products the results observed in apple sauce)
4) Details for all processing studies (flowcharts, etc.) were not provided. It is therefore not known for many commodities how the samples were prepared (washed, peeled) and if conditions involving boiling actually occurred. For table olives, e.g. the canning involves only sterilisation (where degradation products are not formed)

5) Extrapolating results gained in processing studies from a commodity to other commodities should be made with care since processing techniques may be different
6) IN-F6L99 is a common hydrolysis degradate of cyantraniliprole and chlorantraniliprole. The contribution of IN-F6L99 in processed products from the use of the pesticide chlorantraniliprole to the exposure assessment via processed products was considered by the EMS only. It was calculated much lower (0.17 times lower) than the contribution from the cyantraniliprole uses (France, 2016) and was therefore not further considered in the framework of the present assessment
7) The acute toxicity potential of degradation products is not known, and therefore, the consumer exposure from the short-term intake of residues of IN-N5M09 and IN-F6L99 could not be assessed.

EFSA would support the EMS conclusion that although this dietary exposure estimate is affected by various uncertainties, it still has a wide margin of safety and does not give an indication that the existing risk assessment residue definition in processed commodities would need to be modified in the framework of the current assessment. However, it has to be highlighted that the TTC approach (proposed in the EFSA PPR Guidance on the Residue Definition for risk assessment (EFSA PPR Panel, 2016)) which has been used to reach this conclusion has not been endorsed by the European Commission and the Member States, and in principle cannot be applied.

EFSA therefore proposes that a risk management decision is taken to conclude whether in the absence of a general toxicological assessment of hydrolysis degradation products IN-N5M09 and IN-F6L99, the low calculated exposure is a sufficient argument to conclude that the existing risk assessment residue definition for processed products does not need to be modified and that the estimated exposure related to both degradation products is unlikely to be of safety concern for the crops under assessment.

5. Conclusion and Recommendations

The data submitted in support of this these MRL applications were found sufficient to derive an import tolerance for potatoes, tropical root and tuber vegetables, cucurbits with inedible peel, lettuces and salad plants, spinaches and similar leaves (except spinach), parsley, Chinese cabbage and other leafy brassica (except kale), minor oilseeds and to support the intended SEU use on apricots.

EFSA concluded that the long-term intake of residues of cyantraniliprole resulting from the existing and intended or notified uses is unlikely to pose a risk to consumers' health for the parent compound.

Based on an indicative consumer dietary exposure to degradation products IN-N5M09 and IN-F6L99 in processed commodities, the EMS concluded that the estimated chronic exposure is expected to be low (below TTC for Cramer class III compounds of 1.5 μg/kg bw per day) and the proposed modifications of cyantraniliprole MRLs will not have any impact on the consumer exposure to IN-N05M09 and IN-F6L99.

EFSA would support the EMS conclusions that the calculated exposure to IN-N5M09 and IN-F6L99 is low with a wide safety margin and currently does not give an indication that the existing EU risk assessment residue definition in processed commodities would need to be modified. This assumption, however, is based on the use of the TTC approach (EFSA PPR Panel, 2016) which has not been endorsed by the European Commission and the Member States and is not an agreed approach to decide whether toxicological studies can be waived for certain compounds. Furthermore, the exposure calculation is affected by non-standard uncertainties and the lack of actual concentrations of these compounds in many relevant processed products.

EFSA therefore proposes that a risk management decision is taken to conclude whether in the absence of a general toxicological assessment of hydrolysis degradation products IN-N5M09 and IN-F6L99, the low calculated exposure is a sufficient argument to conclude that the existing risk assessment residue definition for processed products does not need to be modified and that the estimated exposure related to both degradation products is unlikely to be of safety concern for the crops under assessment.

The MRL recommendations are summarised in Appendix B.5.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ArfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CIRCA	(EU) Communication & Information Resource Centre Administrator
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens

CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
Dw	dry weight
EC	emulsifiable concentrate
ECD	electron capture detector
EDI	estimated daily intake
EMS	evaluating Member State
Eq	residue expressed as a.s. equivalent
ESI	electrospray ionisation
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FLD	fluorescence detector
FPD	flame photometric detector
GAP	Good Agricultural Practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GC-ECD	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-FPD	gas chromatography with flame photometric detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GC-NPD	gas chromatography with nitrogen/phosphorous detector
GLP	Good Laboratory Practice
gpa	Gallons per acre
GR	Granule
GS	growth stage
HPLC	high performance liquid chromatography
HPLC-MS	high performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UVD	high performance liquid chromatography with ultra-violet detector
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient
LC	liquid chromatography
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector

MW	molecular weight
MW CF	molecular weight conversion factor
NEU	northern Europe
NOAEL	no observed adverse effect level
NPD	nitrogen/phosphorous detector
OD	Oil dispersion
OECD	Organisation for Economic Co-operation and Development
PAFF	Standing Committee on Plants, Animals, Food and Feed
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
Rber	statistical calculation of the MRL by using a non-parametric method
Rmax	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
RPF	relative potency factor
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SCPAFF	Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH)
SE	Suspo-emulsion
SEU	southern Europe
SG	water-soluble granule
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TAR	total applied radioactivity
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultraviolet (detector)
WG	water-dispersible granule
WHO	World Health Organization
WP	wettable powder
YF	yield factor
ZC	mixed CS and SC formulation

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS Or country	F G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s.	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate (max)			
Intended GAPs															
Apricot	SEU	F	*Cydia molesta; Anarsia lineatella; thrips*	WG	400	Foliar spray	BBCH 69–87	1	–	0.0083–0.0208 Kg a.s/hl	600–1,500	0.125	kg a.i./ha	3	
Authorised GAPs (for import tolerance MRLs)															
Vegetables, corm and tuberous[(1)]	US/CA	F	*L. decemlineata, O. nubilalis T. ni, M. persicae, M. euphorbiae, Epitrix* spp.	OD	100 g/L	High volume spray – broadcast by ground or overhead chemigation, low volume spray – by air	BBCH 10–89	1–9	5		187–935 (foliar) 20–100 gpa, 47–187 (aerial) 5–20 gpa	150	g/ha	7	According to the MRL application, the import tolerance request according to Annex I of Regulation (EC) No 396/2005 refers to uses on Tropical root and tuber vegetables. Maximum seasonal application rate per crop = 450 g ai/ha cGAP: foliar, 1 × 150 g/ha Can also be combined with soil application or seed treatment use of the 200 g/L SC formulation

Crop and/or situation	NEU, SEU, MS Or country	F G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s.	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate (max)			
Vegetables, corm and tuberous[(1)]	US/CA	F	*L. decemlineata, O. nubilalis, T. ni, Epitrix* spp.	SC	200 g/L	Soil application at-plant	BBCH 00	1	n/a		93–281 (at-plant soil) 10–30 gpa	200	g/ha	By growth*	According to the MRL application, the import tolerance request according to Annex I of Regulation (EC) No 396/2005 refers to uses on Tropical root and tuber vegetables. Maximum seasonal application rate per crop = 450 g ai/ha Can also be combined with foliar use of the 100 g/L OD formulation (1 × 150 g/ha) and PHI = 7 days in case of additional foliar treatment
Potatoes	US/CA	F	*L. decemlineata, O. nubilalis, T. ni, Epitrix* spp.	SC	200 g/L	Seed piece treatment	BBCH 00	1	n/a		n/a	200	g/ha	By growth*	Maximum seasonal application rate per crop = 450 g ai/ha Can also be combined with foliar use of the 100 g/L OD formulation (1 × 150 g/ha) and PHI = 7 days in case of additional foliar treatment

Crop and/or situation	NEU, SEU, MS Or country	F G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s.	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate (max)			
Vegetables, cucurbit[(2)]	US/CA	F	*D. hyalinata*, *D. nitidalis*, *Bemisia* spp., *Liriomyza* spp., *M. persicae*, *A. gossypii*, *T. ni*, *S. exigua*, *Epitrix* spp.	SE	100 g/L	High volume spray – broadcast by ground, low volume spray – by air	BBCH 11–89	1–9	5		93–935 (foliar) 10–100 gpa, 19–93 (aerial) 2–10 gpa	150	g/ha	1	According to the MRL application, the import tolerance request according to Annex I of Regulation (EC) No 396/2005 refers to uses on Cucurbits with inedible peel. Maximum seasonal application rate per crop = 450 g ai/ha; cGAP: 3 × 150 g/ha
Vegetables, leafy brassica[(3)]	US/CA	F	*S. exigua*, *P. xylostella*, *T. ni*, *S. frugiperda*, *M. persicae*, *H. zea*, *Bemisia spp.*, *B. brassicae*, *Phyllotreta* spp.	SE	100 g/L	High volume spray – broadcast by ground, low volume spray – by air	BBCH 11–89	1–9	5		93–935 (foliar) 10–100 gpa, 19–93 (aerial) 2–10 gpa	150	g/ha	1	According to the MRL application, the import tolerance request according to Annex I of Regulation (EC) No 396/2005 refers to uses on Chinese cabbage and other leafy brassica (except kale). Maximum seasonal application rate per crop = 450 g ai/ha cGAP: 3 × 150 g/ha

Crop and/or situation	NEU, SEU, MS Or country	F G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s.	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate (max)			
Vegetables, leafy except brassica[(4)]	US/CA	F	*S. exigua, T. ni, S. frugiperda, M. persicae, H. zea, Bemisia* spp., *M. euphorbiae, Liriomyza* spp.	SE	100 g/L	High volume spray – broadcast by ground, low volume spray – by air	BBCH 11–89	1–9	5		93–935 (foliar) 10–100 gpa, 19–93 (aerial) 2–10 gpa	150	g/ha	1	According to the MRL application, the import tolerance request according to Annex I of Regulation (EC) No 396/2005 refers to uses on Lettuces and other salad plants, Spinaches and similar leaves; Parsley Maximum seasonal application rate per crop = 450 g ai/ha cGAP: 3 × 150 g/ha
Oil seeds[(5)]	US/CA	F	*H. electellum, S. helianthana, P. cruciferae, P. xylostella, M. configurata*	OD	100 g/L	High volume spray – broadcast by ground, low volume spray – by air	BBCH 10–89	1–9	7		187–935 (foliar) 20–100 gpa, 47–187 (aerial) 5–20 gpa	150	g/ha	7	According to the MRL application, the import tolerance request according to Annex I of Regulation (EC) No 396/2005 refers to uses on linseeds, poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure, hempseed and castor beans (minor oilseeds). Maximum seasonal application rate per crop = 450 g ai/ha cGAP: 3 × 150 g/ha

NEU: northern European Union; SEU: southern European Union; MS: Member State; OD: Oil dispersion; SC: Suspension concentrate; SE: Suspo-emulsion; GPA: Change in gallons per acre.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(c): PHI – minimum preharvest interval.

(1): Crop subgroup 1C includes the following: Arracacha; Arrowroot; Artichoke, Chinese; Artichoke, Jerusalem; Canna, edible; Cassava, bitter and sweet; Chayote (root); Chufa; Dasheen (taro); Ginger; Leren; Potato; Sweet potato; Tanier; Turmeric; Yam bean; Yam, true.

(2): Crop group 9 includes the following: Chayote (fruit); Chinese wax gourd (Chinese preserving melon); Citron melon; Cucumber; Gherkin; Gourd, edible (includes hyotan, cucuzza, hechima, Chinese okra); Momordica spp. (includes balsam apple, balsam pear, bitter melon, Chinese cucumber); Muskmelon (hybrids and/or cultivars of Cucumis melo) (includes cantaloupe); Pumpkin; Squash, summer; Squash, winter (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash); Watermelon

(3): Crop group 5 includes the following: Broccoli; Broccoli, Chinese (gai lan); Broccoli raab (rapini); Brussels sprouts; Cabbage; Cabbage, Chinese (bok choy); Cabbage, Chinese (napa); Cabbage, Chinese mustard (gai choy); Cauliflower; Cavalo broccoli; Collards; Kale; Kohlrabi; Mizuna; Mustard greens; Mustard spinach; Rape greens.

(4): Crop group 4 includes the following: Amaranth (Chinese spinach); Arugula (Roquette); Cardoon; Celery; Celery, Chinese; Celtuce; Chervil; Chrysanthemum, edible-leaved; Chrysanthemum, garland; Corn salad; Cress, garden; Cress, upland; Dandelion; Dock (sorrel); Endive (escarole); Fennel, Florence; Lettuce, head and leaf; Orach; Parsley; Purslane, garden; Purslane, winter; Radicchio (red chicory); Rhubarb; Spinach; Spinach, New Zealand; Spinach, vine; Swiss chard.

(5): Crop group 20 includes the following: Borage; Calendula; Castor oil plant; Chinese tallowtree; Cottonseed; Crambe; Cuphea; Echium; Euphorbia; Evening Primrose; Flax seed; Gold of Pleasure; Hare's ear mustard; Jojoba; Lesquerella; Lunaria; Meadowfoam; Milkweed; Mustard seed; Niger seed; Oil radish; Poppy seed; Rapeseed (canola); Rose hip; Safflower; Sesame; Stokes aster; Sunflower; Sweet rocket; Tallowwood; Tea oil plant; Vernonia.

Appendix B – List of end points

B.1. Mammalian toxicology

Studies performed on metabolites or impurities

	IN-F6L99, Unlikely to be genotoxic based on experimental data Not considered structurally similar to parent cyantraniliprole Studies to investigate the general toxicity of the degradation products are still not available
	IN-N5M09 Unlikely to be genotoxic based on experimental data Not considered structurally similar to parent cyantraniliprole Studies to investigate the general toxicity of the degradation products are still not available

B.2. Residues in plants

B.2.1. Nature of residues and methods of analysis in plants

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crops**	**Applications**	**Sampling**	**Comment/Source**
	Fruit crops	Tomatoes	Foliar, 3 × 150 g/ha, BBCH 14–61	125 DALA (leaves, fruits)	Radiolabelled active substance: Foliar applications:^{14}C-cyano and ^{14}C-pyrazole cyantraniliprole in a 1:1 mixture formulation; Soil applications: Separate studies with each label (EFSA, 2014)
			Soil drench, 3 × 150 g/ha, BBCH 19–61	125 DALA (leaves, fruits)	
	Leafy crops	Lettuces	Foliar, 3 × 150 g/ha, BBCH 50	0, 7, 14, 32 DALA	
			Soil drench, 3 × 150 g/ha, BBCH 18–19	7, 14, 32 DAT	
	Cereals/grass	Rice	Foliar, 3 × 150 g/ha, BBCH 13–14	140 DALA (straw, grain)	
			Soil granule, 1 × 300 g/ha, BBCH 13	175 DALA (straw, grain)	
	Pulses/ oilseeds	Cotton	Foliar, 3 × 150 g/ha, BBCH 16–19)	124 DALA (leaves, bolls)	
			Soil drench (3 × 150 g/ha, BBCH 19)	125 DAT (leaves, bolls)	

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI** (DAT)	**Comment/Source**
	Root/tuber crops	Red beet	Bare soil application, 1 × 300 g a.s./ha Pilot study not conducted under GLP	30, 120	Radiolabelled active substance: [cyano-^{14}C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole; [Pyrazole carbonyl-14C]-cyantraniliprole in pilot study (EFSA, 2014)
	Cereal (small grain)	Wheat			
	Pulses and oil seeds	Soya beans			
	Leafy crops	Lettuces	Bare soil application, 1 × 450 g a.s./ha	30, 120	
	Cereal (small grain)	Wheat		30, 120, 365	
	Pulses and oil seeds	Soya bean		25, 120	
Processed commodities (hydrolysis study)	**Conditions**	**Stable?**			**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes			Cyantraniliprole was stable under pasteurisation and sterilisation processes but degraded to IN-J9Z38 (up to 14% AR), IN-N5M09 (up to 8% AR) and IN-F6L99 (up to 5% AR) during processes simulating baking/brewing/boiling (EFSA, 2014)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	No			
	Sterilisation (20 min, 120°C, pH 6)	Yes			

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2014)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2014)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No	EFSA (2014)
Plant residue definition for monitoring (RD-Mo)	Cyantraniliprole	
Plant residue definition for risk assessment (RD-RA)	Primary crops: Cyantraniliprole Processed commodities: Sum cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole Rotational crops: Open	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	LC–MS/MS LOQ = 0.01 mg/kg for cyantraniliprole in plants (high water-, high oil-, high acid- content matrices). ILV is also available. (EFSA 2014, 2015)	

DAT: days after treatment; a.s.: acitve substance; DALA: days after last application; BBCH: growth stages of mono- and dicotyledonous plants; PBI: plant-back interval; GLP: Good Laboratory Practice; AR: applied radioactivity; LOQ: limit of quantification; LC–MS/MS: liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation.

B.2.1.2. Stability of residues in plants

Plant product (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	High water content	Apples	–20	≥ 24	month	Cyantraniliprole, IN-J9Z38, IN-N5M09, IN-F6L99	EFSA (2014)
	High acid content	Grapes	–20	≥ 24	month	Cyantraniliprole, IN-J9Z38, IN-N5M09, IN-F6L99	EFSA (2014)
	High starch content	Potatoes	–20	≥ 24	month	Cyantraniliprole, IN-J9Z38, IN-N5M09, IN-F6L99	EFSA (2014)
	High protein content	Dry beans	–20	18	month	Cyantraniliprole	EFSA (2014)
		Dry beans	–20	≥ 24	month	IN-J9Z38, IN-N5M09, IN-F6L99	EFSA (2014)
	High oil content	Peanuts	–20	18	month	Cyantraniliprole, IN-F6L99	EFSA (2014)
		Peanuts	–20	≥ 24	month	IN-J9Z38, IN-N5M09	EFSA (2014)

B.2.2. Magnitude of residues in plants

B.2.2.1. Summary of residues data from the supervised residue trials

Commodity	Region/ Indoor[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)
Enforcement and risk assessment residue definition: Cyantraniliprole						
Apricots	SEU	Peaches: 0.06; 0.07[(d)]; 0.20; 0.43 Apricots: 0.03; 0.10; 0.15; 0.22[(d)]	Residue trials on apricots (4 trials) and peaches (4 trials) compliant with GAP. Extrapolation from a merged residue data set to apricots possible.	0.7	0.43	0.13
Potato and tropical root and tuber vegetables	US/CAN	5 × < 0.01; 0.01; 0.011; 2 × 0.014; 0.02; 2 × 0.023; 0.027; 0.028; 0.031; 0.052; 0.072; 0.11	Residue trials on potatoes compliant with US/Canadian GAP. Extrapolation to tropical roots and tuber vegetables acceptable. Residue trials with results reported as ND or in values lower than the LOQ of 0.01 mg/kg, are reported here as < 0.01 mg/kg.	0.15	0.11	0.017
Cucurbits with inedible peel	US/CAN	0.063, 0.101, 0.105, 0.113, 0.12, 0.127, 0.161, 0.185	Residue trials on melon compliant with US/Canadian GAP. Extrapolation to the group cucurbits with inedible peel acceptable.	0.4	0.185	0.117
Chinese cabbage and other leafy brassica (except kale)	US/CAN	2.4, 3.4, 3.9, 5.5, 5.8, 6.0, 7.1, 7.2, 8.0, 13.0, 19.0	Residue trials on mustard greens *(Brassica juncea)* compliant with US/Canadian GAP. The extrapolation of residue data from mustard greens to Chinese cabbage is possible. In the specific case of this assessment, the extrapolation of residue data from mustard greens to 'others' leafy brassica (except kales) was accepted on the basis of an evidence-based justification provided by the applicant (France, 2016).	30	19.00	6.00
Lettuces and other salad plants (lamb's lettuce/corn salad, lettuces, escaroles/broad-leaved endives, cresses, land cresses, Roman rocket/rucola, red mustards, baby leaf crops)	US/CAN	1.2, 2 × 2.4, 2.5, 3.2, 3.3, 4.0, 5.3, 2 × 6.8	Residue trials on open leaf lettuce compliant with US/Canadian GAP. Extrapolation to the group lettuces and other salad plants acceptable.	15	6.8	3.25

Commodity	Region/ Indoor[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)
Lettuces	US/CAN	Open leaf lettuce: 1.2, 2 × 2.4, 2.5, 3.2, 3.3, 4.0, 5.3, 2 × 6.8 Head lettuce: 0.084; 0.16; 0.18; 0.64; 0.75; 0.83; 1.3; 1.6; 1.8; 2.1; 2.7	Residue trials on open leaf and head lettuce compliant with US/Canadian GAP combined to derive an MRL proposal for lettuce.	10	6.8	2.1
Purslanes, chards/beet leaves, other spinaches and similar leaves (except spinaches), Parsley	US/CAN	3.8, 4.1, 4.2, 4.6, 4.7, 4.9, 5.8, 8.2, 10.0, 13.0	Residue trials on spinaches compliant with US/Canadian GAP. Extrapolation to the group spinaches and similar leaves and to parsley acceptable. For spinaches, the applicant has not requested a modification of the existing MRL.	20	13.0	4.8
Linseed, poppy seed, sesame seed, mustard seed, pumpkin seed, safflower, borage, gold of pleasure, hempseed and castor beans	US/CAN	0.01, 0.03, 0.04, 2 × 0.12, 0.14, 0.18, 0.20, 0.22, 0.26, 0.29, 0.99	Residue trials on cotton compliant with US/ Canadian GAP. Extrapolation to minor oilseeds (linseed, poppy seed, sesame seed, mustard seed, pumpkin seed, safflower, borage, gold of pleasure, hempseed and castor beans) possible.	1.5	0.99	0.16

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials. US: United States of America, CAN: Canada.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Residues higher at a longer PHI interval of 7 days.

B.2.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	The present MRL applications are on permanent crops and imported products For information: Cyantraniliprole residues > 0.01 mg/kg not expected. Insufficient information was provided to address the transfer of the very persistent soil metabolites in rotational crops (data gap). Long-term rotational crop studies are required to investigate the magnitude of residues of cyantraniliprole and its most persistent metabolites (EFSA, 2014).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	The present MRL applications are on permanent crops and imported products For information: Long-term rotational crop studies are required to investigate the magnitude of residues of cyantraniliprole and its most persistent metabolites (EFSA, 2014).

MRL: maximum residue level.

B.2.2.3. Processing factors

Processed commodity	Number of valid studies[(a)]	Processing Factor (PF)		CF_P[(b)]	Comment/ Source
		Individual values	Median PF		
Melon, pulp	12	0.10; 0.13; 0.14; 0.16; 0.17; 0.20; 0.20; 0.23; 0.24; 0.26; 0.32; 0.33	0.2	1	EFSA (2014)
Melon, pulp	9	< 0.06; < 0.09; < 0.1; < 0.2; < 0.05; < 0.16; < 0.10; 2 × < 0.08	< 0.1	1	France (2016)

n.d.: not detected.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

The available processing studies assessed in the EU pesticides peer review are reported in the EFSA conclusion (EFSA, 2014) and in the DAR (United Kingdom, 2013). Additional data on the formation of cyantraniliprole metabolites IN-N5M09 and IN-F6L99 in various processed commodities submitted under present MRL applications (France, 2016, 2018) and summary details are reported in the table below.

Processed commodity	No of valid studies[(a)]	CYAN in RAC, expressed as IN-N5M09[(b)] (mg/kg)	CYAN in RAC, expressed as IN-F6L99[(c)] (mg/kg)	Residues in processed commodity		Median processing factors (tentative)	
				IN-N5M09 (mg/kg)	IN-F6L99 (mg/kg)	IN-N5M09	IN-F6L99
Tomato, wet pomace	3	0.114; 0.074; 0.068	0.086; 0.056; 0.052	0.005; 2 × < 0.003	3 × < 0.003	< 0.044	< 0.054
Tomato, dry pomace	3	0.074; 0.114; 0.068	0.056; 0.086; 0.052	0.008; 0.013; 0.005	3 × < 0.003	0.108	< 0.054
Tomato, paste	3	0.074; 0.114 0.068	0.056; 0.086; 0.052	0.005; 0.005; 0.004	0.004; 0.005; 0.004	< 0.059	< 0.071
Apples, sauce	3	0.043; 0.148; 0.148	0.032; 0.112; 0.112	0.014; 0.053; 0.07	0.009; 0.04; 0.036	0.359	0.322

Processed commodity	No of valid studies[(a)]	CYAN in RAC, expressed as IN-N5M09[(b)] (mg/kg)	CYAN in RAC, expressed as IN-F6L99[(c)] (mg/kg)	Residues in processed commodity		Median processing factors (tentative)	
				IN-N5M09 (mg/kg)	IN-F6L99 (mg/kg)	IN-N5M09	IN-F6L99
Apples, Juice	3	0.043; 0.148; 0.148	0.032; 0.112; 0.112	3 × < 0.003	3 × < 0.003	< 0.02	< 0.027
Apples, canned	3	0.043; 0.148; 0.148	0.032; 0.112; 0.112	3 × < 0.003	3 × < 0.003	< 0.02	< 0.027
Oranges, juice	3	0.074; 0.049; 0.097	0.056; 0.037; 0.073	3 × < 0.003	3 × < 0.003	< 0.041	< 0.054
Olives, canned (whole)	3	0.312; 0.148; 0.165	0.237; 0.112; 0.125	0.009; 2 × < 0.003	0.004; 2 × < 0.003	< 0.02	< 0.02
Olives, raw oil	3	0.31; 0.148; 0.165	0.237; 0.112; 0.125	3 × < 0.003	3 × < 0.003	< 0.018	< 0.024
Cotton, raw oil	3	0.295; 0.403; 0.91	0.22; 0.31; 0.69	3 × < 0.003	3 × < 0.003	< 0.007	< 0.01
Grapes, wet pomace	3	0.09; 0.068; 0.062	0.069; 0.05; 0.047	0.007; 2 × < 0.003	3 × < 0.003	< 0.048	< 0.058
Grapes, dry pomace	3	0.09; 0.068; 0.062	0.069; 0.052; 0.047	0.018; 0.006; 0.003	3 × < 0.003	0.088	< 0.058
Grapes, Juice	3	0.09; 0.068; 0.032	0.069; 0.052; 0.047	0.004; 2 × < 0.003	0.004; 2 × < 0.003	< 0.044	< 0.058
Spinaches, cooked leaves	3	2.61; 3.01; 5.68	1.98; 2.28; 4.03	0.02; 0.047; 0.085	0.003; 0.008; 0.015	0.015	< 0.003

PF: processing factor; CYAN: cyantraniliprole.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Molecular weight (MW) of IN-N5M09 (269 g/mol)/MW of cyantraniliprole (473.72 g/mol).
(c): Molecular weight (MW) of IN-F6L99 (204 g/mol)/MW of cyantraniliprole (473.72 g/mol).

B.3. Residues in livestock

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[(a)]	Most critical commodity[(b)]		Trigger exceeded 0.1 mg/kg (Y/N)
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all)	0.034	0.059	0.88	1.54	Dairy cattle	Cabbage, heads	Leaves	Yes
Cattle (dairy only)	0.034	0.059	0.88	1.54	Dairy cattle	Cabbage, heads	Leaves	Yes
Sheep (all)	0.025	0.039	0.75	1.15	Ram/Ewe	Cabbage, heads	Leaves	Yes
Sheep (ewe only)	0.025	0.038	0.75	1.15	Ram/Ewe	Cabbage, heads	Leaves	Yes
Swine (all)	0.012	0.023	0.51	1.00	Swine (breeding)	Cabbage, heads	Leaves	Yes
Poultry (all)	0.023	0.035	0.33	0.51	Poultry layer	Cabbage, heads	Leaves	Yes
Poultry (layer only)	0.023	0.035	0.33	0.51	Poultry layer	Cabbage, heads	Leaves	Yes

(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.3.1. Nature of residues and methods of analysis in livestock

B.3.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	**Animal**	**Dose (mg/kg bw per d)**	**Duration (days)**	**Comment/Source**
	Goat	0.44	7	1. [CN-14C]-cyantraniliprole (EFSA, 2014) 2. [PC-14C]-cyantraniliprole (EFSA, 2014)
	Poultry	1.07	14	1. [CN-14C]-cyantraniliprole (EFSA, 2014) 2. [PC-14C]-cyantraniliprole (EFSA, 2014)

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 14	EFSA (2014)
	Eggs: 27	EFSA (2014)
Metabolism in rat and ruminant similar	Yes	EFSA (2014)
Can a general residue definition be proposed for animals?	Yes	EFSA (2014)
Animal residue definition for monitoring (RD-Mo)	Cyantraniliprole	
Animal residue definition for risk assessment (RD-RA)	Sum of cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole Conversion factor (CF) of 2: all animal commodities, except meat and honey, for which CF of 1 is applicable (EFSA, 2014)	
Fat soluble residues	No	EFSA (2014)
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	LC–MS/MS LOQ = 0.01 mg/kg for cyantraniliprole in foodstuff of animal origin (milk, eggs, liver, kidney, meat and fat) ILV is available (EFSA, 2014)	

LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation

B.3.2. Magnitude of residues in livestock

B.3.2.1. Summary of the residue data from livestock feeding studies

Animal commodity	**Residues at the closet feeding level (mg/kg)**		**Estimated value at 1N level**		**MRL proposal (mg/kg)**	**CF**	**STMR (mg/kg)**	**HR (mg/kg)**
	Mean	**Highest**	**$STMR_{Mo}$ (mg/kg)[(a)]**	**HR_{Mo} (mg/kg)[(b)]**				
Cattle (all diets)								
Closest feeding level[(c)]:	0.088 mg/kg bw 1.5 N Dairy cattle (highest diet)							
Muscle	0.01	0.01	0.00	0.01	**0.01***	n.c.	0.00	0.01
Fat	0.01	0.02	0.01	0.01	**0.01**	n.c.	0.01	0.01
Liver	0.06	0.07	0.02	0.04	**0.05**	n.c.	0.02	0.04
Kidney	0.03	0.03	0.01	0.02	**0.02**	n.c.	0.01	0.02

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)	CF	STMR (mg/kg)	HR (mg/kg)
	Mean	Highest	$STMR_{Mo}$ (mg/kg)[(a)]	HR_{Mo} (mg/kg)[(b)]				
Cattle (dairy only)								
Closest feeding level[(c)]:	0.088	mg/kg bw	1.5	N Dairy cattle				
Milk[(d)]	0.03	0.03	0.01	0.02	**0.02**	n.c.	0.01	0.02
Sheep (all diets)[(e)]								
Closest feeding level[(c)]:	0.088 mg/kg bw 2.2 N Lamb (highest diet)							
Muscle	0.01	0.01	0.00	0.00	**0.01***	n.c.	0.00	0.00
Fat	0.01	0.02	0.00	0.01	**0.01***	n.c.	0.00	0.01
Liver	0.06	0.07	0.02	0.03	**0.03**	n.c.	0.02	0.03
Kidney	0.03	0.03	0.01	0.01	**0.015**	n.c.	0.01	0.01
Sheep (dairy only)[(e)]								
Closest feeding level[(c)]:	0.088 mg/kg bw 2.3 N Ewe							
Milk[(d)]	0.03	0.03	0.01	0.01	**0.015**	n.c.	0.01	0.01
Swine[(e)]								
Closest feeding level[(c)]:	0.088 mg/kg bw 3.8 N Breeding (highest diet)							
Muscle	0.01	0,01	0.00	0.00	**0.01***	n.c.	0.00	0.00
Fat	0.01	0.02	0.00	0.00	**0.01***	n.c.	0.00	0.00
Liver	0.06	0.07	0.01	0.02	**0.02**	n.c.	0.01	0.02
Kidney	0.03	0.03	0.00	0.01	**0.01***	n.c.	0.00	0.01
Poultry (all diets)								
Closest feeding level[(c)]:	0.24 mg/kg bw 6.9 N Layer (highest diet)							
Muscle	0.00	0.01	0.00	0.00	**0.01***	n.c.	0.00	0.00
Fat	0.01	0.01	0.00	0.00	**0.01***	n.c.	0.00	0.00
Liver	0.02	0.03	0.00	0.00	**0.01***	n.c.	0.00	0.00
Poultry (layer only)								
Closest feeding level[(c)]:	0.24 mg/kg bw 6.9 N Layer							
Eggs	0.08	0.08	0.01	0.01	**0.015**	n.c.	0.01	0.01

*: Indicates that the MRL is proposed at the limit of quantification.
(a): The mean residue level for milk and the mean residue levels for eggs and tissues were recalculated at the 1N rate for the median dietary burden.
(b): The mean residue level in milk and the highest residue levels in eggs and tissues, were recalculated at the 1N rate for the maximum dietary burden.
(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): Highest residue level from day 1 to day 28 (daily mean of 3 cows).
(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

B.4. Consumer risk assessment

B.4.1. Cyantraniliprole

ARfD	ARfD unnecessary (European Commission, 2016)
Highest IESTI, according to EFSA PRIMo	Acute risk assessment not required since an ARfD is considered unnecessary
Assumptions made for the calculations	–

ADI	0.01 mg/kg bw per day (European Commission, 2016)
Highest IEDI, according to EFSA PRIMo	72% ADI (NL toddler diet) Highest contribution of crops assessed:
	Lettuces and other salad plants: 17% of ADI (ES adult) maximum for lettuce Chinese cabbages: 12% of the ADI (SE general population) Parsley: 2% of the ADI (GEMS/Food G10) Potatoes 1.7% of ADI (PT general population) Tropical root and tuber vegetables: 0.7% of ADI (IE adult), maximum for cassava Apricots: 0.49% of the ADI (DE child diet) Cucurbits with inedible peel: 0.26% of ADI (WHO cluster diet B), maximum for watermelons Minor oilseeds: individually < 0.5% of ADI
Assumptions made for the calculations	For the crops under consideration, the calculation is based on the median residue levels (STMR) in raw agricultural commodities (RAC) as derived from the submitted residue trials. For commodities of plant and animal origin, the STMR values as available from previous EFSA outputs or JMPR assessments were used as input values. For cucurbits (inedible peel) and citrus fruits, the peeling factors of 0.2 and 0.1, respectively, as derived by the EU pesticides peer review were applied to refine the exposure calculation. For boiled purslane and beet leaves/chard, for canned table olives and for olive for oil production, the processing factors and conversion factors as derived in previous EFSA outputs were applied to estimate the exposure according to the risk assessment residue definition for processed commodities (EFSA, 2014, 2021). The contribution of commodities where no GAP was reported in the framework of applications to set MRLs for this active substance or for which no CXL was implemented in the EU legislation was not included in the calculation. The calculation was performed using PRIMo rev.3.1

ARfD: acute reference dose; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; bw: body weight; GAP: Good Agricultural Practice; MRL: maximum residue level

B.4.2. IN-N5M09 and IN-F6L99

ARfD	Not available
Highest IESTI, according to EFSA PRIMo	–
Assumptions made for the calculations	–

ADI	Not available EMS France proposed to compare each exposure with 1.5 μg/kg bw per day (TTC for Cramer Class III compounds)
Highest IEDI, according to EFSA PRIMo	**IN-N05M09** Maximum exposure 0.67 μg/kg bw per day (NL toddler diet) **IN-F6L99** Maximum exposure 0.47 μg/kg bw per day (NL toddler diet)

Assumptions made for the calculations	The calculation is performed using the STMR values available for cyantraniliprole residues in unprocessed commodity and expressed as IN-N5M09 or IN-F6L99 equivalents by applying the individual molecular weight conversion factors; to these values tentative processing factors were then applied (see Appendix B.2.2.3). The overall considerations were as follows: –The products which are normally consumed raw were excluded from the exposure calculation: lettuces and other salad plants (except escarole), watermelons, melons, tree nuts – For pumpkins, the peeling factor of 0.2 was applied –The products for which no cyantraniliprole GAP was reported in the framework of MRL applications or no CXL was implemented in the EU legislation were excluded from the calculation –The products for which the main processing process does not involve boiling/cooking steps and for which no residues of the degradation products were identified in processed commodity (oilseeds, olives) were also excluded from the calculation, assuming the degradation products are not formed –For root and tuber vegetables, bulb vegetables (except spring onions), roots of herbal infusions and spices, sugar beet and chicory roots, the processing studies on potatoes were not considered fully valid (low residues in RAC) and therefore for these commodities it was assumed that cyantraniliprole residues present in RAC are fully converted to the respective degradation products –For rice and coffee beans, in the absence of processing studies, it was assumed that all cyantraniliprole residues present in RAC are converted to respective degradation products To extent feasible, the extrapolation of processing factors was done in accordance with the OECD Guideline 508 (OECD, 2008) and are in detail reported in Appendix E2. The calculation was performed using PRIMo rev.3.1

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; GAP: Good Agricultural Practice; MRL: maximum residue level; CXL: codex maximum residue limit; RAC: raw agricultural commodities; STMR: supervised trials median residue.

B.5. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Cyantraniliprole				
140010	Apricots	0.01*	0.7[(b)]	The intended SEU use is sufficiently supported by data. Risk for consumers unlikely for the parent compound. Further risk management discussions required since the product can undergo boiling as a processing step.
211000	Potatoes	0.05	0.15[(b)]	The requested import tolerances are sufficiently supported by data. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 0.15 mg/kg. Further risk management discussions required since the products can undergo boiling as a processing step.
212000	Tropical root and tuber vegetables	0.05	0.15[(b)]	
230000	Cucurbits with inedible peel	0.3	0.4[(b)]	The requested import tolerance is sufficiently supported by data. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 0.7 mg/kg. Further risk management discussions required since the products can undergo boiling as a processing step.
243010	Chinese cabbages/ pe-tsai	0.01*	30[(b)]	The requested import tolerances are sufficiently supported by data. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 30 mg/kg. Further risk management discussions required since the products can undergo boiling as a processing step.
243990	Others, leafy brassica			
251000 (except 251020 and 251030	Lettuces and salad plants (except lettuces and escaroles)	0.01*	15	The requested import tolerances are sufficiently supported. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 20 mg/kg.
251020	Lettuces	5	15 or 10	The requested import tolerance is sufficiently supported by data. Further risk management discussions required on the appropriate MRL proposal between 15 mg/kg, derived from a data set of residue trials on open leaf lettuces only, or 10 mg/kg, derived according to the EU rules from a combined data set of closed and open leaf lettuces. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 20 mg/kg.
251030	Escaroles/ broad-leaved endives	0.01*	15[(b)]	The requested import tolerance sufficiently supported. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 20 mg/kg. Further risk management discussions required since the product can undergo boiling as a processing step.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
252000 (except 252010)	Purslane, chard/beet leaves and other spinaches and similar leaves (except spinach)	0.01*	20[(b)]	The requested import tolerances are sufficiently supported by data. Risk for consumers unlikely. MRL in the countries of origin is set at 30 mg/kg. Further risk management discussions required since the products can undergo boiling as a processing step.
256040	Parsley	0.02*		
401010 401030 401040 401080 401100 401110 401120 401130 401140 401150	Linseed Poppy seed Sesame seed Mustard seed Pumpkin seed Safflower seed Borage seed Gold of pleasure Hemp seed Castor beans	0.01*	1.5	The requested import tolerance is sufficiently supported by data. Risk for consumers unlikely for the parent compound. MRL in the countries of origin is set at 1.5 mg/kg.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Further risk management consideration is required to decide whether the argument of the low exposure is acceptable to waive the need to submit the data on the general toxicity of IN-N5M09 and IN-F6L99 (relevant for processed commodities that undergo cooking/boiling) for the requested modification of the existing MRLs.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Xyantraniliprole			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	Not applicable
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2016	Year of evaluation:	2016

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
72%	NL toddler	7.22	17%	Apples	10%	Milk: Cattle	8%	Escaroles/broad-leaved endives		72%
50%	DE child	5.03	20%	Apples	4%	Table grapes	4%	Cherries (sweet)		50%
46%	GEMS/Food G10	4.55	11%	Lettuces	9%	Chinese cabbages/pe-tsai	2%	Head cabbages		46%
45%	SE general	4.47	13%	Lettuces	12%	Chinese cabbages/pe-tsai	4%	Head cabbages		45%
40%	NL child	3.95	9%	Apples	4%	Milk: Cattle	3%	Escaroles/broad-leaved endives		40%
39%	IE adult	3.91	11%	Other leafy brassica	4%	Wine grapes	3%	Lettuces		39%
37%	GEMS/Food G08	3.73	6%	Lettuces	4%	Olives for oil production	3%	Wine grapes		37%
35%	IT adult	3.52	12%	Lettuces	5%	Other lettuce and other salad plants	3%	Other spinach and similar		35%
35%	ES child	3.51	14%	Lettuces	4%	Olives for oil production	4%	Chards/beet leaves		35%
35%	GEMS/Food G07	3.50	8%	Lettuces	5%	Wine grapes	3%	Celeries		35%
35%	ES adult	3.47	17%	Lettuces	4%	Chards/beet leaves	2%	Olives for oil production		35%
33%	GEMS/Food G11	3.27	6%	Celeries	3%	Wine grapes	3%	Lamb's lettuce/corn salads		33%
32%	GEMS/Food G06	3.18	6%	Tomatoes	3%	Lettuces	3%	Table grapes		32%
32%	GEMS/Food G15	3.16	5%	Head cabbages	4%	Lettuces	3%	Wine grapes		32%
30%	IT toddler	3.01	9%	Lettuces	4%	Other lettuce and other salad plants	3%	Chards/beet leaves		30%
28%	RO general	2.82	8%	Head cabbages	5%	Wine grapes	3%	Tomatoes		28%
27%	FR child 3 15 yr	2.68	4%	Milk: Cattle	4%	Other lettuce and other salad plants	3%	Apples		27%
25%	DE women 14-50 yr	2.45	4%	Apples	4%	Lettuces	3%	Wine grapes		25%
24%	FR adult	2.36	7%	Wine grapes	5%	Other lettuce and other salad plants	1%	Apples		24%
23%	FR toddler 2 3 yr	2.34	5%	Apples	5%	Milk: Cattle	2%	Beans (with pods)		23%
23%	DE general	2.30	4%	Apples	3%	Lettuces	3%	Wine grapes		23%
23%	NL general	2.28	3%	Escaroles/broad-leaved endives	3%	Lettuces	2%	Apples		23%
22%	PT general	2.19	8%	Wine grapes	3%	Lettuces	2%	Apples		22%
20%	DK child	2.05	5%	Lettuces	4%	Apples	2%	Milk: Cattle		20%
20%	UK infant	1.99	6%	Milk: Cattle	3%	Apples	1%	Cauliflowers		20%
17%	UK toddler	1.69	3%	Milk: Cattle	3%	Apples	1%	Tomatoes		17%
15%	UK vegetarian	1.54	5%	Lettuces	3%	Wine grapes	1%	Tomatoes		15%
15%	FR infant	1.50	3%	Milk: Cattle	3%	Apples	1%	Cauliflowers		15%
14%	DK adult	1.41	3%	Wine grapes	3%	Lettuces	2%	Apples		14%
13%	PL general	1.33	3%	Apples	2%	Head cabbages	2%	Tomatoes		13%
13%	UK adult	1.32	4%	Lettuces	3%	Wine grapes	0.7%	Tomatoes		13%
13%	FI 3 yr	1.28	2%	Strawberries	2%	Apples	1%	Chinese cabbages/pe-tsai		13%
12%	FI adult	1.24	5%	Lettuces	1%	Chinese cabbages/pe-tsai	1.0%	Wine grapes		12%
12%	FI 6 yr	1.20	3%	Lettuces	2%	Chinese cabbages/pe-tsai	1%	Strawberries		12%
12%	LT adult	1.19	3%	Apples	2%	Head cabbages	2%	Lettuces		12%
3%	IE child	0.35	0.6%	Milk: Cattle	0.5%	Apples	0.3%	Broccoli		3%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of cyantraniliprole is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

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)

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 11

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 9

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)
9941%	Escaroles/broad-leaved endives/boiled	15/15	994	3072%	Celeries/boiled	15/9.1	307
1245%	Chards/beet leaves/boiled	20/4	124	3066%	Escaroles/broad-leaved endives/boiled	15/15	307
867%	Broccoli/boiled	2/1.1	87	501%	Chards/beet leaves/boiled	20/4	50
766%	Cauliflowers/boiled	2/1.1	77	458%	Cauliflowers/boiled	2/1.1	46
355%	Pumpkins/boiled	0.4/0.4	35	265%	Broccoli/boiled	2/1.1	26
244%	Peaches/canned	1.5/0.94	24	234%	Kohlrabies/boiled	2/1.1	23
214%	Currants (red, black and white)/juice	4/0.75	21	221%	Pumpkins/boiled	0.4/0.4	22
188%	Beans (with pods)/boiled	1.5/1.5	19	165%	Purslanes/boiled	20/4	16
140%	Potatoes/fried	0.15/0.15	14	142%	Wine grapes/wine	1.5/1.5	14
140%	Wine grapes/juice	1.5/0.32	14	96%	Currants (red, black and white)/juice	4/0.75	9.6
112%	Brussels sprouts/boiled	2/1.1	11	86%	Table grapes/raisins	1.5/7.05	8.6
87%	Apples/juice	0.8/0.16	8.7	77%	Peaches/canned	1.5/0.94	7.7
84%	Oranges/juice	0.9/0.16	8.4	68%	Peas (with pods)/boiled	2/2	6.8
78%	Courgettes/boiled	0.4/0.22	7.8	67%	Wine grapes/juice	1.5/0.32	6.7
76%	Sweet potatoes/boiled	0.15/0.15	7.6	53%	Apples/juice	0.8/0.16	5.3

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of cyantraniliprole is unlikely to present a public health risk.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

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EFSA PRIMo revision 3.1; 2021/01/06

IN-F6L99

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.0015	ARfD (mg/kg bw):	Not necessary
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2016	Year of evaluation:	2016

Input values
Details – chronic risk assessment
Supplementary results – chronic risk assessment
Details – acute risk assessment/children
Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
31%	NL toddler	0.47	16%	Apples	6%	Pears	2%	Potatoes		31%
29%	DE child	0.43	18%	Apples	3%	Cherries (sweet)	1%	Potatoes		29%
18%	NL child	0.27	9%	Apples	2%	Sugar beet roots	2%	Pears		18%
10%	DE women 14-50 yr	0.14	4%	Apples	1%	Sugar beet roots	1%	Cherries (sweet)		10%
9%	DE general	0.13	4%	Apples	1%	Sugar beet roots	0.9%	Cherries (sweet)		9%
9%	RO general	0.13	2%	Apples	2%	Potatoes	1%	Cherries (sweet)		9%
9%	PT general	0.13	3%	Potatoes	2%	Apples	1%	Wine grapes		9%
9%	FR toddler 2 3 yr	0.13	5%	Apples	0.9%	Potatoes	0.8%	Sugar beet roots		9%
9%	IE adult	0.13	2%	Sweet potatoes	1%	Potatoes	1%	Apples		9%
8%	GEMS/Food G06	0.13	1%	Apples	1%	Tomatoes	1.0%	Potatoes		8%
8%	FR child 3 15 yr	0.12	2%	Apples	1%	Sugar beet roots	0.8%	Oranges		8%
8%	GEMS/Food G15	0.12	2%	Potatoes	2%	Apples	0.9%	Cherries (sweet)		8%
8%	GEMS/Food G08	0.12	2%	Potatoes	2%	Apples	0.7%	Peaches		8%
7%	UK toddler	0.11	3%	Apples	2%	Potatoes	0.9%	Sugar beet roots		7%
7%	GEMS/Food G11	0.11	2%	Apples	2%	Potatoes	0.5%	Wine grapes		7%
7%	DK child	0.11	3%	Apples	1%	Potatoes	1%	Pears		7%
7%	PL general	0.11	3%	Apples	2%	Potatoes	0.8%	Cherries (sweet)		7%
7%	UK infant	0.11	2%	Apples	2%	Potatoes	0.6%	Cherries (sweet)		7%
7%	GEMS/Food G07	0.11	2%	Potatoes	2%	Apples	0.8%	Wine grapes		7%
7%	GEMS/Food G10	0.10	1%	Potatoes	1%	Apples	0.5%	Peaches		7%
7%	SE general	0.10	2%	Potatoes	2%	Apples	0.5%	Pears		7%
6%	NL general	0.10	2%	Apples	1%	Potatoes	0.8%	Sugar beet roots		6%
6%	ES child	0.09	2%	Apples	0.9%	Potatoes	0.8%	Cherries (sweet)		6%
6%	FI 3 yr	0.09	2%	Potatoes	1%	Apples	0.4%	Peaches		6%
5%	IT toddler	0.08	1%	Apples	1%	Peaches	0.8%	Cherries (sweet)		5%
5%	LT adult	0.08	3%	Apples	2%	Potatoes	0.2%	Pears		5%
5%	FR infant	0.07	2%	Apples	0.9%	Potatoes	0.4%	Sugar beet roots		5%
5%	FR adult	0.07	1%	Wine grapes	1%	Apples	0.4%	Peaches		5%
5%	ES adult	0.07	1%	Apples	0.7%	Peaches	0.6%	Cherries (sweet)		5%
5%	FI 6 yr	0.07	2%	Potatoes	0.9%	Apples	0.3%	Peaches		5%
5%	IT adult	0.07	1%	Peaches	1%	Apples	0.5%	Cherries (sweet)		5%
4%	FI adult	0.06	2%	Coffee beans	0.9%	Apples	0.6%	Potatoes		4%
4%	DK adult	0.06	1%	Apples	0.6%	Potatoes	0.5%	Wine grapes		4%
3%	UK vegetarian	0.05	0.9%	Apples	0.7%	Potatoes	0.4%	Wine grapes		3%
3%	UK adult	0.04	0.7%	Potatoes	0.6%	Apples	0.6%	Wine grapes		3%
1%	IE child	0.02	0.5%	Apples	0.3%	Potatoes	0.1%	Rice		1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of IN-F6L99 is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

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

Conclusion:

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European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

IN-N05M09

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.0015	ARfD (mg/kg bw):	Not necessary
Source of ADI:	TTC Cramer	Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
45%	NL toddler	0.67	24%	Apples	9%	Pears	3%	Potatoes		45%
41%	DE child	0.62	27%	Apples	5%	Cherries (sweet)	2%	Potatoes		41%
26%	NL child	0.38	13%	Apples	3%	Sugar beet roots	3%	Pears		26%
13%	DE women 14-50 yr	0.20	6%	Apples	2%	Sugar beet roots	2%	Cherries (sweet)		13%
12%	IE adult	0.18	2%	Sweet potatoes	2%	Apples	1%	Potatoes		12%
12%	RO general	0.18	3%	Apples	2%	Potatoes	2%	Cherries (sweet)		12%
12%	DE general	0.18	5%	Apples	2%	Sugar beet roots	1%	Cherries (sweet)		12%
12%	FR toddler 2 3 yr	0.18	7%	Apples	1%	Potatoes	1%	Sugar beet roots		12%
12%	PT general	0.17	3%	Potatoes	2%	Apples	2%	Peaches		12%
11%	GEMS/Food G06	0.17	2%	Apples	1%	Cherries (sweet)	1%	Tomatoes		11%
11%	FR child 3 15 yr	0.16	4%	Apples	1%	Sugar beet roots	1.0%	Potatoes		11%
11%	GEMS/Food G15	0.16	2%	Apples	2%	Potatoes	1%	Cherries (sweet)		11%
11%	GEMS/Food G08	0.16	3%	Apples	3%	Potatoes	1%	Peaches		11%
10%	DK child	0.16	5%	Apples	2%	Potatoes	1%	Pears		10%
10%	GEMS/Food G11	0.16	3%	Apples	3%	Potatoes	0.5%	Wine grapes		10%
10%	PL general	0.15	4%	Apples	2%	Potatoes	1%	Cherries (sweet)		10%
10%	UK toddler	0.15	4%	Apples	2%	Potatoes	1%	Sugar beet roots		10%
10%	UK infant	0.15	3%	Apples	2%	Potatoes	0.9%	Cherries (sweet)		10%
10%	SE general	0.15	3%	Potatoes	2%	Apples	0.7%	Pears		10%
10%	GEMS/Food G07	0.14	2%	Potatoes	2%	Apples	0.8%	Wine grapes		10%
9%	GEMS/Food G10	0.14	2%	Potatoes	2%	Apples	0.8%	Peaches		9%
9%	NL general	0.13	3%	Apples	2%	Potatoes	1%	Sugar beet roots		9%
9%	ES child	0.13	2%	Apples	1%	Potatoes	1%	Cherries (sweet)		9%
8%	FI 3 yr	0.12	3%	Potatoes	2%	Apples	0.5%	Peaches		8%
8%	IT toddler	0.12	2%	Apples	2%	Peaches	1%	Cherries (sweet)		8%
8%	LT adult	0.11	4%	Apples	2%	Potatoes	0.3%	Pears		8%
7%	FR infant	0.11	4%	Apples	1%	Potatoes	0.5%	Sugar beet roots		7%
7%	IT adult	0.11	2%	Peaches	2%	Apples	0.8%	Cherries (sweet)		7%
7%	ES adult	0.10	2%	Apples	1.0%	Peaches	0.8%	Cherries (sweet)		7%
6%	FI 6 yr	0.10	3%	Potatoes	1%	Apples	0.5%	Peaches		6%
6%	FR adult	0.09	2%	Apples	1%	Wine grapes	0.6%	Peaches		6%
6%	FI adult	0.08	2%	Coffee beans	1%	Apples	0.8%	Potatoes		6%
5%	DK adult	0.08	2%	Apples	0.8%	Potatoes	0.7%	Pears		5%
5%	UK vegetarian	0.07	1%	Apples	0.9%	Potatoes	0.4%	Wine grapes		5%
4%	UK adult	0.06	0.9%	Potatoes	0.9%	Apples	0.6%	Wine grapes		4%
2%	IE child	0.03	0.7%	Apples	0.4%	Potatoes	0.1%	Rice		2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of IN-N05M09 is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

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

Conclusion:

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cabbage, heads (leaves)	0.56	STMR (FAO, 2013)	0.95	HR (FAO, 2013)
Carrot culls, swede roots, turnip roots	0.01	STMR (EFSA, 2015)	0.014	HR (EFSA, 2015)
Cassava/tapioca	0.017	STMR	0.11	HR
Potato culls	0.017	STMR	0.11	HR
Bean seed (dry)	0.01	STMR (FAO, 2015)	0.01	STMR (FAO, 2015)
Cotton seed	0.16	STMR (FAO, 2015)	0.16	STMR (FAO, 2015)
Soybean seed	0.033	STMR (FAO, 2015)	0.033	STMR (FAO, 2015)
Apple, wet pomace	0.16	STMR × PF × CF (1) (FAO, 2013)	0.16	STMR × PF × CF (1) (FAO, 2013)
Sugar beet, dried pulp	0.18	STMR (FAO, 2015)	0.18	STMR (FAO, 2015)
Sugar beet, ensiled pulp	0.03	STMR (FAO, 2015)	0.03	STMR (FAO, 2015)
Sugar beet, molasses	0.28	STMR (FAO, 2015)	0.28	STMR (FAO, 2015)
Citrus, dried pulp	0.077	STMR (0.16) × PF (0.4) × CF (1.2) (EFSA, 2014)	0.077	STMR (0.16) × PF (0.4) × CF (1.2) (EFSA, 2014)
Cotton, meal	0.02	STMR (0.16) (FAO, 2015) × PF (0.1) (EFSA, 2014)	0.02	STMR (0.16) (FAO, 2015) × PF (0.1) (EFSA, 2014)
Linseed, meal	0.32	STMR (0.16) × default PF (2)	0.32	STMR (0.16) × default PF (2)
Potato, process waste	0.02	STMR × PF (1)[(a)]	0.02	STMR × PF (1)[(a)]
Potato, dried pulp	0.76	STMR × default PF (38)	0.76	STMR × default PF (38)
Rice bran, pollard	0.01	STMR (EFSA, 2016a)	0.01	STMR (EFSA, 2016a)
Rapeseed, meal	0.15	STMR (0.077) (FAO, 2015) × default PF (2)	0.15	STMR (0.077) (FAO, 2015) × default PF (2)
Safflower, meal	0.32	STMR (0.16) × default PF (2)	0.32	STMR (0.16) × default PF (2)
Soybean, meal	0.04	STMR (FAO, 2015) × default PF (1.3)	0.04	STMR (FAO, 2015) × default PF (1.3)
Soybean, hull	0.43	STMR (FAO, 2015) × default PF (13)	0.43	STMR (FAO, 2015) × default PF (13)
Sunflower, meal	0.13	STMR (0.067) (FAO, 2015) × default PF (2) (EFSA, 2014)	0.13	STMR (0.067) (FAO, 2015) × default PF (2) (EFSA, 2014)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

(a): The potato processing studies indicate no concentration of residues in process waste and therefore the processing factor of 1 was applied. Although the processing study has deficiencies related to low residues in RAC (0.01–0.02 mg/kg), this deficiency was not considered a major data gap since the trials were performed according to the authorised use pattern in the USA at the authorised application rate. A new processing study in principle would be required.

D.2. Consumer risk assessment

Cyantraniliprole

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Cyantraniliprole				
Citrus fruit	0.016	STMR × PeF (EFSA, 2014)	Acute risk assessment not required as an ARfD is not necessary (EFSA, 2014).	
Tree nuts	0.01	STMR (FAO, 2015)		
Pome fruit	0.16	STMR (FAO, 2013)		
Apricots	0.13	STMR		
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 (EFSA, 2016b)		
Strawberries	0.455	STMR (FAO,2019)		
Blueberries (bush berries)	0.75	STMR (FAO, 2013)		
Cranberries	0.012	STMR (FAO,2019)		
Currants (black, red, white)	0.75	STMR (FAO, 2013)		
Gooseberries (green, red & yellow)	0.75	STMR (FAO, 2013)		
Rose hips	0.75	STMR (FAO, 2013)		
Azarole/Mediterranean medlars	0.16	STMR (FAO, 2013)		
Table olives	0.53	STMR (EFSA, 2021)		
Mango	0.01	STMR (FAO, 2019)		
Kaki/Japanese persimmons	0.16	STMR (FAO, 2013)		
Potatoes	0.017	STMR		
Tropical roots and tuber vegetables	0.017	STMR		
Other root and tuber vegetables	0.01	STMR (FAO, 2013)		
Garlic, onions, shallots	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)		
Okra, lady's fingers	0.14	STMR (EFSA, 2014)		
Cucurbits, edible peel	0.08	STMR (EFSA, 2014)		
Cucurbits, inedible peel	0.023	STMR × PF (0.2) (EFSA, 2014)		
Flowering brassica	0.56	STMR (FAO, 2013)		
Head brassica	0.56	STMR (FAO, 2013)		
Chinese cabbage, other leafy brassica (except kale)	6	STMR		
Kohlrabies	0.56	STMR (FAO, 2013)		
Lettuce and other salad plants including Brassicaceae	3.25	STMR[(a)]		
Spinach and similar leaves (except spinaches)	4.8	STMR		
Parsley	4.8	STMR		
Beans with pods	0.29	STMR (FAO, 2015)		
Peas with pods	0.7	STMR (FAO, 2015)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Beans without pods	0.07	STMR (FAO, 2015)		
Peas without pods	0.07	STMR (FAO, 2015)		
Celeries	2	STMR (FAO, 2013)		
Globe artichokes	0.03	STMR (EFSA, 2015)		
Sunflower seed	0.067	STMR (FAO, 2015)		
Rapeseed	0.077	STMR (FAO, 2015)		
Soybeans	0.033	STMR (FAO, 2015)		
Cotton seeds	0.16	STMR (FAO, 2015)		
Minor oilseeds (linseeds, peanuts, poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans)	0.16	STMR		
Olives for oil production	0.53	(EFSA, 2021)		
Rice	0.01	STMR (EFSA, 2016a)		
Coffee beans	0.01	STMR (EFSA, 2016a)		
Herbal infusions from roots	0.08	STMR (EFSA, 2015)		
Liquorice, turmeric,	0.08	STMR (EFSA, 2015)		
Sugar beet root	0.01	STMR (FAO, 2013)		
Chicory root	0.01	STMR (FAO, 2013)		
Risk assessment residue definition: Sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole				
Meat of swine, bovine, sheep, goat, equine	0.041	STMR (FAO, 2015)[(b)]	Acute risk assessment not required as an ARfD was deemed unnecessary (EFSA, 2014).	
Fat of swine, bovine, sheep, goat, equine	0.1			
Liver, kidney, edible offal of swine, bovine, sheep, goat, equine	0.38			
Poultry: muscle	0.004			
Poultry: fat	0.008			
Poultry: liver, kidney, edible offal	0.032			
Milk	0.016			
Eggs	0.043			

(a): Pending risk management decision, the higher STMR derived from the dataset of open leaf verities (MRL proposal 0.15 mg/kg) instead of the STMR of 2.1 mg/kg derived from a combined dataset of open and close leaf varieties (MRL proposal of 10 mg/kg) was tested.

(b): Residue values in the FAO (2015) estimation 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 EU risk assessment residue definition, however these values were considered appropriate for use in the exposure calculation without adaptation (EFSA, 2016c).

Degradation product IN-N5M09 (indicative exposure)

Commodity	Input value (mg/kg)	Comment[(a)]	Source of the tentative processing factor applied
Grapefruits	0.004	STMR-RAC × MW CF × PF	Orange juice
Oranges			
Lemons			
Limes			
Mandarins			
Other citrus fruit			
Apples	0.0323	STMR-RAC × MW CF × PF	Apple sauce
Pears			
Quinces			
Medlar			
Loquats/Japanese medlars			
Other pome fruit			
Apricots	0.027		
Cherries (sweet)	0.19		
Peaches	0.07		
Plums	0.025		
Table grapes	0.007	STMR-RAC × MW CF × PF	Grape juice
Wine grapes	0.008		
Strawberries	0.011		
Blueberries	0.019		
Cranberries	0.0003		
Currants (red, black and white)	0.019		
Gooseberries (green, red and yellow)	0.019		
Rose hips	0.019		
Azarole/Medit. medlar	0.004		
Kaki/Japanese persimmons	0.03	STMR-RAC × MW CF × PF	Apple sauce
Mangoes	0.002		
Potatoes	0.01	STMR-RAC × MW CF	Derived PFs for potatoes not fully reliable. Residues in RAC expressed as IN-N5M09 equivalents
Cassava roots/manioc			
Sweet potatoes			
Yams			
Arrowroots			
Other tropical root and tuber vegetables			

Commodity	Input value (mg/kg)	Comment[(a)]	Source of the tentative processing factor applied
Beetroots	0.006	STMR-RAC × MW CF	Derived PFs for potatoes not fully reliable. Residues in RAC expressed as IN-N5M09 equivalents
Carrots			
Celeriacs/turnip-rooted celeries			
Horseradishes			
Jerusalem artichokes			
Parsnips			
Parsley roots/Hamburg roots parsley			
Radishes			
Salsifies			
Swedes/rutabagas			
Turnips			
Other root and tuber vegetables			
Garlic	0.011	STMR-RAC × MW CF	Derived PFs for potatoes not fully reliable. Residues in RAC expressed as IN-N5M09 equivalents
Onions			
Shallots			
Spring onions/green onions and Welsh onions	0.011	STMR-RAC × MW CF × PF	Cooked spinach
Other bulb vegetables	0.02		
Tomatoes	0.006		
Sweet peppers/bell peppers	0.001	STMR-RAC × MW CF × PF	Cooked spinach
Aubergines/egg plants			
Okra/lady’s fingers			
Other solanaceae			
Cucumbers	0.0007	STMR-RAC × MW CF × PF	Cooked spinach
Gherkins			
Courgettes			
Other cucurbits – edible peel			
Pumpkins	0.0002	STMR-RAC × MW CF × PF × PeF (0.2)	Cooked spinach
Broccoli	0.005	STMR-RAC × MW CF × PF	Cooked spinach
Cauliflowers			
Other flowering brassica			
Brussels sprouts			
Head cabbages			
Other head brassica			
Chinese cabbages/pe-tsai	0.05	STMR-RAC × MW CF × PF	
Other leafy brassica	0.05	STMR-RAC × MW CF × PF	
Kohlrabies	0.005	STMR-RAC × MW CF × PF	
Escaroles/broad-leaved endives	0,.028	STMR-RAC × MW CF × PF	
Purslanes	0.04	STMR-RAC × MW CF × PF	
Chards/beet leaves	0,04	STMR-RAC × MW CF × PF	
Other spinach and similar	0.04	STMR-RAC × MW CF × PF	
Parsley	0.04	STMR-RAC × MW CF × PF	
Beans (with pods)	0.0025	STMR-RAC × MW CF × PF	
Beans (without pods)	0.0006	STMR-RAC × MW CF × PF	
Peas (with pods)	0.006	STMR-RAC × MW CF × PF	
Peas (without pods)	0.0006	STMR-RAC × MW CF × PF	

Commodity	Input value (mg/kg)	Comment[(a)]	Source of the tentative processing factor applied
Celeries	0.017	STMR-RAC × MW CF × PF	
Globe artichokes	0.0003	STMR-RAC × MW CF × PF	
Beans	+0.0001	STMR-RAC × MW CF × PF	
Rice	0.006	STMR-RAC × MW CF	No PF available. Residues in RAC expressed as IN-N5M09 equivalents.
Coffee beans	0.006	STMR-RAC × MW CF	
Valerian root	0.05	STMR-RAC × MW CF	Derived PFs for potatoes not fully reliable. Residues in RAC expressed as IN-N5M09 equivalents.
Ginseng root			
Other herbal infusions (dried roots)			
Liquorice			
Turmeric/curcuma			
Other spices (roots)			
Sugar beet roots	0.006	STMR-RAC × MW CF	
Chicory roots	0.006	STMR-RAC × MW CF	

(a): The STMR values reported in table correspond to the STMR for cyantraniliprole, expressed as IN-N5M09 equivalents by applying the molecular weight conversion factor of 0.57 and multiplied by the processing factor, where available, as reported in Appendix B.2.2.3.

Degradation product IN-F6L99 (indicative exposure)

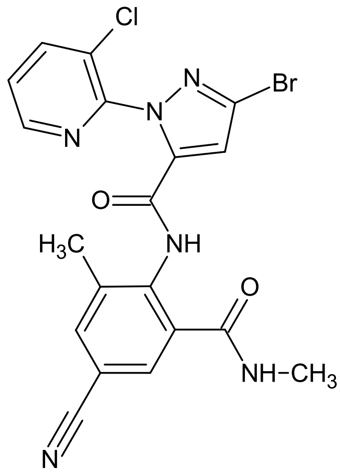
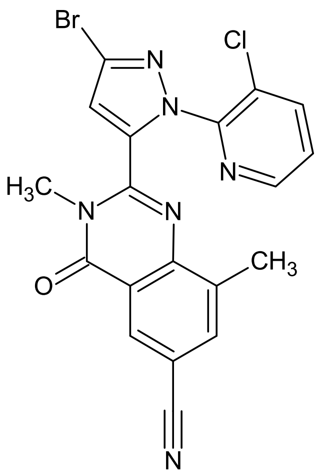
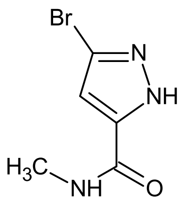
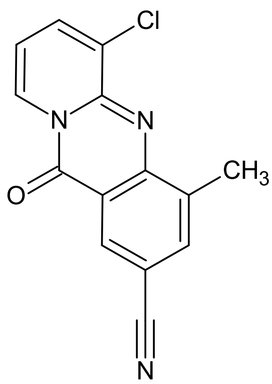
Commodity	Input value (mg/kg)	Comment[(a)]	Source of the processing factor
Grapefruits	0.004	STMR-RAC × MW CF × PF	Orange juice
Oranges			
Lemons			
Limes			
Mandarins			
Other citrus fruit			
Apples	0.022	STMR-RAC × MW CF × PF	Apple sauce
Pears			
Quinces			
Medlar			
Loquats/Japanese medlars			
Other pome fruit			
Apricots	0.018	STMR-RAC × MW CF × PF	
Cherries (sweet)	0.129	STMR-RAC × MW CF × PF	
Peaches	0.047	STMR-RAC × MW CF × PF	
Plums	0.017	STMR-RAC × MW CF × PF	
Table grapes	0.006	STMR-RAC × MW CF × PF	Grape juice
Wine grapes	0.008	STMR-RAC × MW CF × PF	
Strawberries	0.011	STMR-RAC × MW CF × PF	Apple sauce
Blueberries	0.019	STMR-RAC × MW CF × PF	
Cranberries	0.0003	STMR-RAC × MW CF × PF	
Currants (red, black and white)	0.019	STMR-RAC × MW CF × PF	
Gooseberries (green, red and yellow)			
Rose hips			
Azarole/Mediterranean medlar	0.004	STMR-RAC × MW CF × PF	
Kaki/Japanese persimmons	0.022	STMR-RAC × MW CF × PF	
Mangoes	0.0014	STMR-RAC × MW CF × PF	

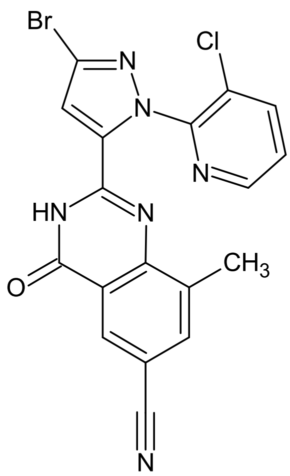
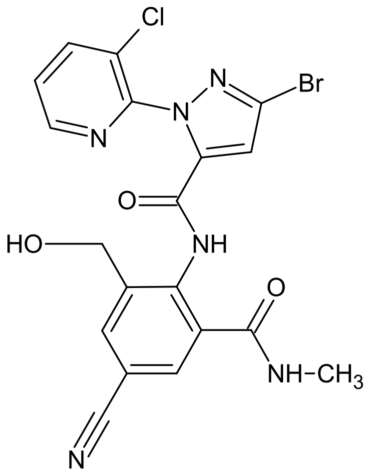
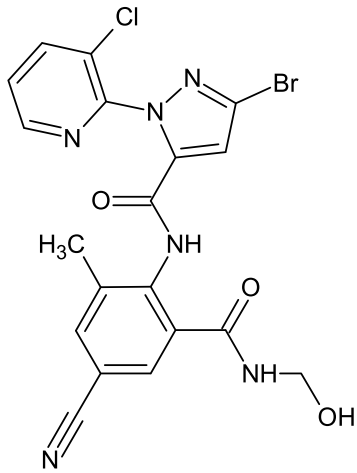
Commodity	Input value (mg/kg)	Comment[(a)]	Source of the processing factor
Potatoes	0.007	STMR-RAC × MW CF	Derived PFs for potatoes not fully reliable. Residues in RAC expressed as IN-F6L99 equivalents
Cassava roots/manioc			
Sweet potatoes			
Yams			
Arrowroots			
Other tropical root and tuber vegetables			
Beetroots	0.004	STMR-RAC × MW CF	
Carrots			
Celeriacs/turnip rooted celeries			
Horseradishes			
Jerusalem artichokes			
Parsnips			
Parsley roots/Hamburg roots parsley			
Radishes			
Salsifies			
Swedes/rutabagas			
Turnips			
Other root and tuber vegetables			
Garlic	0.009	STMR-RAC × MW CF × PF	Derived PFs for potatoes not fully reliable. Residues in RAC expressed as IN-F6L99 equivalents
Onions			
Shallots			
Spring onions/green onions and Welsh onions	0.002	STMR-RAC × MW CF × PF	Cooked spinach
Tomatoes	0.005	STMR-RAC × MW CF × PF	Tomato paste
Sweet peppers/bell peppers	0.0002	STMR-RAC × MW CF × PF	Cooked spinach
Aubergines/egg plants			
Okra/lady's fingers			
Other solanaceae			
Cucumbers	0.0001	STMR-RAC × MW CF × PF	
Gherkins			
Courgettes			
Other cucurbits – edible peel			
Pumpkins	0.00003	STMR-RAC × MW CF × PF × PeF (0.2)	
Broccoli	0.0007	STMR-RAC × MW CF × PF	
Cauliflowers			
Other flowering brassica			
Brussels sprouts			
Head cabbages			
Other head brassica			
Chinese cabbages/pe-tsai	0.0077	STMR-RAC × MW CF × PF	Cooked spinach
Other leafy brassica	0.0077	STMR-RAC × MW CF × PF	
Kohlrabies	0.0007	STMR-RAC × MW CF × PF	
Escaroles/broad-leaved endives	0.004	STMR-RAC × MW CF × PF	

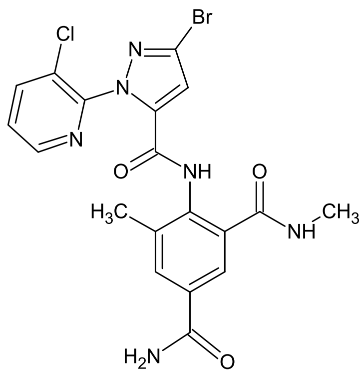
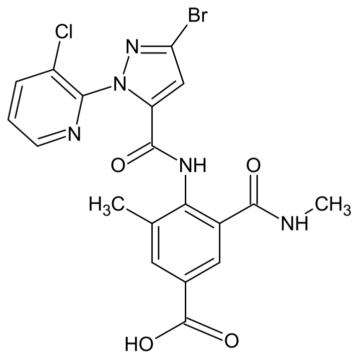
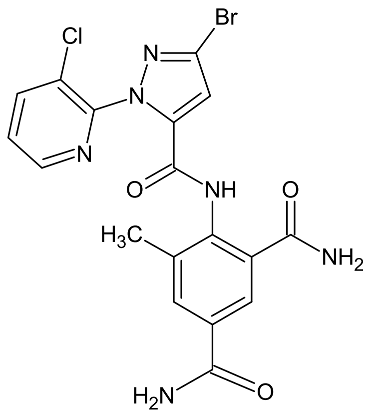
Commodity	Input value (mg/kg)	Comment[(a)]	Source of the processing factor
Purslanes	0.006	STMR-RAC × MW CF × PF	
Chards/beet leaves			
Other spinach and similar			
Parsley			
Beans (with pods)	0.0004	STMR-RAC × MW CF × PF	
Beans (without pods)	0.0001	STMR-RAC × MW CF × PF	
Peas (with pods)			
Peas (without pods)			
Celeries	0.003	STMR-RAC × MW CF × PF	
Globe artichokes	0.00003	STMR-RAC × MW CF × PF	
Beans	0.00001	STMR-RAC × MW CF × PF	
Rice	0.004	STMR-RAC × MW CF	No PF available. Residues in RAC expressed as IN-F6L99 equivalents
Coffee beans	0.004	STMR-RAC × MW CF	
Valerian root	0.03	STMR-RAC × MW CF	Derived PFs for potatoes not fully reliable. Residues in RAC expressed as IN-F6L99 equivalents.
Ginseng root			
Other herbal infusions (dried roots)			
Liquorice			
Turmeric/curcuma			
Other spices (roots)			
Sugar beet roots	0.004	STMR-RAC × MW CF	
Chicory roots	0.004	STMR-RAC × MW CF	

(a): The STMR values reported in table correspond to the STMR for cyantraniliprole, expressed as IN-F6L99 equivalents by applying the molecular weight conversion factor of 0.43 and multiplied by the processing factor, where available, as reported in Appendix B.2.2.3.

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
Cyantraniliprole	3-bromo-1-(3-chloro-2-pyridyl)-4′-cyano-2′-methyl-6′-(methylcarbamoyl)-1*H*-pyrazole-5-carboxanilide CNC(=O)c1cc(C#N)cc(C)c1NC(=O)c1cc(Br) nn1c1ncccc1Cl DVBUIBGJRQBEDP-UHFFFAOYSA-N	
IN-J9Z38	2-[3-bromo-1-(3-chloropyridin-2-yl)-1*H*-pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carbonitrile Cc1cc(C#N)cc2c1N=C(c1cc(Br) nn1c1ncccc1Cl)N(C)C2=O WHYZZHSKSZLNRP-UHFFFAOYSA-N	
IN-F6L99	3-bromo-*N*-methyl-1*H*-pyrazole-5-carboxamide O = C(NC)c1cc(Br)n[NH]1 LOYJZLKXTLAMJX-UHFFFAOYSA-N	
IN-N5M09	6-chloro-4-methyl-11-oxo-11*H*-pyrido[2,1-*b*] quinazoline-2-carbonitrile Cc1cc(C#N)cc2c1N=C1C(Cl)=CC=CN1C2=O MZOZXXSPJGMFBK-UHFFFAOYSA-N	

Code/trivial name[(a)]	IUPAC name/SMILES notation/ InChiKey[(b)]	Structural formula[(c)]
IN-MLA84	2-[3-bromo-1-(3-chloropyridin-2-yl)-1*H*-pyrazol-5-yl]-8-methyl-4-oxo-3,4-dihydroquinazoline-6-carbonitrile Cc1cc(C#N)cc2c1N=C(NC2=O)c1cc(Br) nn1c1ncccc1Cl XOWPMRVDJYWVNL-UHFFFAOYSA-N	
IN-N7B69	3-bromo-1-(3-chloropyridin-2-yl)-*N*-[4-cyano-2-(hydroxymethyl)-6-(methylcarbamoyl)phenyl]-1*H*-pyrazole-5-carboxamide CNC(=O)c1cc(C#N)cc(CO)c1NC(=O)c1cc(Br) nn1c1ncccc1Cl HIRGCCGVBWDKSH-UHFFFAOYSA-N	
IN-MYX98	3-bromo-1-(3-chloropyridin-2-yl)-*N*-{4-cyano-2-[(hydroxymethyl)carbamoyl]-6-methylphenyl}-1*H*-pyrazole-5-carboxamide OCNC(=O)c1cc(C#N)cc(C)c1NC(=O)c1cc(Br) nn1c1ncccc1Cl FLLWEQACDZRMFC-UHFFFAOYSA-N	

Code/trivial name[(a)]	IUPAC name/SMILES notation/ InChiKey[(b)]	Structural formula[(c)]
IN-JCZ38	4-{[3-bromo-1-(3-chloropyridin-2-yl)-1*H*-pyrazole-5-carbonyl]amino}-N^3,5-dimethylbenzene-1,3-dicarboxamide NC(=O)c1cc(C)c(NC(=O)c2cc(Br) nn2c2ncccc2Cl)c(c1)C(=O)NC JFIAYQGSZXIMCY-UHFFFAOYSA-N	
IN-K5A79	4-{[3-bromo-1-(3-chloropyridin-2-yl)-1*H*-pyrazole-5-carbonyl]amino}-3-methyl-5-(methylcarbamoyl)benzoic acid O = C(O)c1cc(C)c(NC(=O)c2cc(Br) nn2c2ncccc2Cl)c(c1)C(=O)NC KYFCNLOMKNWSJD-UHFFFAOYSA-N	
IN-K7H19	4-{[3-bromo-1-(3-chloropyridin-2-yl)-1*H*-pyrazole-5-carbonyl]amino}-5-methylbenzene-1,3-dicarboxamide NC(=O)c1cc(C)c(NC(=O)c2cc(Br) nn2c2ncccc2Cl)c(c1)C(N)=O OPRSISXZVGQMIT-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 07 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).