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## Modification of the existing maximum residue levels for cyantraniliprole in olives

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### Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant FMC International Switzerland Sarl (FISSarl) submitted a request to the competent national authority in France to modify the existing maximum residue level (MRL) for the active substance cyantraniliprole in table olives and olives for oil production. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the intended uses of cyantraniliprole in olives. Adequate analytical methods for enforcement are available to control the residues of cyantraniliprole in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the intake of residues resulting from the uses of cyantraniliprole according to the reported agricultural practices is unlikely to present a risk to consumer health.

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## Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant FMC International Switzerland Sarl (FISSarl) submitted a request to the competent national authority in France (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance cyantraniliprole in table olives and olives for oil production. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 26 April 2018. To accommodate for the intended uses of cyantraniliprole, the EMS proposed to raise the existing MRLs for table olives and olives for oil production from 1.5 to 3 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested to the EMS. On 17 May 2021, the EMS submitted the requested information in a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of cyantraniliprole following either foliar or soil drench 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.

As the proposed uses of cyantraniliprole are on permanent crops, investigations of residues in rotational crops are not required.

Studies investigating the effect of processing on the nature of cyantraniliprole (hydrolysis studies) demonstrated that cyantraniliprole was stable under pasteurisation and sterilisation processes, but degraded to IN-J9Z38 (14% applied radioactivity (AR)), IN-N5M09 (8% AR) and IN-F6L99 (5% AR) during processes simulating baking/brewing/boiling. The metabolite IN-J9Z38, included in the risk assessment residue definition for processed commodities, is of a similar toxicity as the parent active substance. Based on the experimental data provided by the applicant in the context of the current MRL application, it was concluded that IN-N5M09 and IN-F6L99 are unlikely to be genotoxic. The general toxicity of these compounds was not assessed. Considering the lack of genotoxicity potential and the fact that these degradation products are not expected to be present in significant concentrations in processed or unprocessed olives treated with cyantraniliprole according to the intended GAP, IN-N5M09 and IN-F6L99 were not further considered for the consumer exposure assessment.

Sufficiently validated analytical methods based on liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS) are available to quantify cyantraniliprole residues at or above the limit of quantification (LOQ) of 0.01 mg/kg in the commodities assessed in this application.

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 for processed products was agreed to be the 'sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole'.

EFSA concluded that for the crops assessed in this application, metabolism of cyantraniliprole in primary crops and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

The available residue trials are sufficient to derive an MRL proposal of 3 mg/kg for table olives and olives for oil production in support of the intended southern Europe (SEU) uses of cyantraniliprole. It should be highlighted that olive samples were taken only from the treated part of the tree and does not reflect the overall residue concentration of the plot (treated and untreated parts of the crop); hence, lower residues may be expected in samples from the untreated side of the tree. The derived MRL proposal and corresponding risk assessment values might therefore be overestimated.

Studies investigating the effect of processing have been assessed in the framework of the EU pesticides peer review and indicated that canning reduces cyantraniliprole residues by factors of 0.4 in olives with stone and 0.6 in olives without stone; refined oil extraction reduces residues by a factor of 0.7 and cold pressing increases residues by a factor of 1.2. These studies confirm that the residues of hydrolysis degradation products IN-N5M09 and IN-F6L99 are not present at significant levels in processed olives.

Residues of cyantraniliprole in commodities of animal origin were not assessed since olives are normally not fed to livestock.

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 consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). The estimated long-term dietary exposure to cyantraniliprole accounted for up to 67% of the ADI (NL toddler diet). The contribution of residues expected in the commodities assessed in the present MRL application to the overall long-term exposure were 4.3% of the ADI (GEMS/Food G08 diet) for olives for oil production and 0.3% of the ADI (IE adult diet) for table olives.

The risk assessment is affected by additional, non-standard uncertainties related to animal products, table olives and olives for oil production, for which the exposure is likely to be overestimated due to conservative approaches used to derive the input values for the exposure calculations. Additional uncertainties are linked to the lack of toxicological reference values for the two degradation products IN-N5M09 and IN-F6L99, found in quantifiable concentrations in certain processed products, e.g. cooked spinach. However, since in processed olive products these degradation products were not identified, this uncertainty is not directly linked to the intended use in olives.

EFSA concluded that the proposed uses of cyantraniliprole on olives do not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

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 to D.

| Code <sup>(a)</sup>                                     | Commodity                 | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification  |
|---|---------------------------|-------------------------|-------------------------|--|
| <b>Enforcement residue definition: Cyantraniliprole</b> |                           |                         |                         |  |
| 0161030   | Table olives              | 1.5                     | 3                       | The submitted data are sufficient to derive MRL proposals for the SEU uses. Risk for consumers unlikely. |
| 0402010   | Olives for oil production | 1.5                     | 3                       |  |

MRL: maximum residue level; SEU: southern Europe.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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## Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for cyantraniliprole in olives. The detailed description of the intended use of cyantraniliprole, which are the basis for the current MRL application, is reported in Appendix A.

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 are reported in Appendix E.

Cyantraniliprole was evaluated in the framework of Regulation (EC) No 1107/2009<sup>1</sup> with the United Kingdom designated as rapporteur Member State (RMS); the representative uses assessed were foliar applications on various crops. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2014b). Cyantraniliprole was approved<sup>2</sup> for a period of ten years 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<sup>3</sup>. 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 recent MRL regulations.<sup>4</sup> Furthermore, Codex maximum residue limits (CXLs) were also implemented in the EU legislation by the Commission Regulations<sup>4</sup>. 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, 2014b) or following subsequent MRL applications which were assessed by EFSA.

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant FMC International Switzerland Sarl (FISSarl) submitted a request to the competent national authority in France (EMS) to modify the existing MRLs for the active substance cyantraniliprole in table olives and olives for oil production. The EMS drafted the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 26 April 2018. To accommodate for the intended uses of cyantraniliprole, the EMS proposed to raise the existing MRLs for olives (table olives and oil production) from 1.5 to 3 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested to the EMS. On 17 May 2021, the EMS submitted the requested information in a revised evaluation report (France, 2018), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2018), the DAR (United Kingdom, 2013) prepared under Regulation (EC) 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, 2014b), as well as the conclusions from previous EFSA outputs on cyantraniliprole (EFSA, 2014a, 2015, 2016a,b,c, 2017a, 2018a, 2019b,c).

For this application, the data requirements established in Regulation (EU) No 544/2011<sup>5</sup> and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011). 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<sup>6</sup>.

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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, 16.3.2005, p. 1–16.

<sup>4</sup> 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>

<sup>5</sup> 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.

<sup>6</sup> 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.

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

The evaluation report submitted by the EMS (France, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2018b, 2019a) 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, 2014b).

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, where it was considered to be covered by the reference values derived for cyantraniliprole (EFSA, 2014b).

In the framework of the current assessment, the applicant provided additional information on the toxicological profile for the degradation products IN-N5M09 and IN-F6L99 observed in the standard hydrolysis studies; these new studies were assessed by the EMS (France, 2018). Based on experimental data, metabolites IN-N5M09 and IN-F6L99 are considered unlikely to be genotoxic. These two degradation products are not considered structurally similar to parent cyantraniliprole. Studies to investigate the general toxicity of the degradation products are 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 (tomato), leafy (lettuce), cereals/grass (rice), pulses/oilseeds (cotton) crop groups has been investigated in the framework of the EU pesticides peer review (EFSA, 2014b). No additional studies were submitted in the current MRL application.

In the crops tested, parent compound was the main residue, accounting for almost 25% to more than 90% of the total radioactive residues (TRRs). 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% to 28% TRR in rice foliage, straw and grain (0.03 to 0.09 mg/kg) following soil drench application (EFSA, 2014b).

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.

#### 2.1.2. Nature of residues in rotational crops

As the proposed uses of cyantraniliprole are on permanent crops, investigations of residues in rotational crops are not required.

#### 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, 2014b). Cyantraniliprole was stable under pasteurisation and sterilisation processes 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, 2014b).

The toxicological relevance of the plant metabolite IN-J9Z38 was considered to be covered by the parent (EFSA, 2014b). 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. Further details on the toxicological assessment of these degradation products are reported in Section 1. In the framework of



the first approval of cyantraniliprole in 2014, these two degradation products were not suggested to be included in the residue definition for processed products (EFSA, 2014b).

#### 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, 2014b). 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 and its metabolite IN-J9Z38 in high water (apples, peaches, tomatoes, lettuces, cucumbers), high acid (oranges, lemons, limes), high oil (almonds, rape seeds) content commodities, dry/starch (wheat grain, potatoes) matrices and in processed commodities (tomato paste and sun dried tomatoes) at the limit of quantification (LOQ) of 0.01 mg/kg for each analyte (EFSA, 2014b, 2015).

Table olives and olives for oil production belong to the high oil content commodity group; therefore, sufficiently validated analytical methods are available for the determination of residues of cyantraniliprole in the commodities under consideration.

#### 2.1.5. Storage 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, 2014b). It was demonstrated that for commodities belonging to the high oil content group, 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  $-20^{\circ}\text{C}$ .

#### 2.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products, the capabilities of enforcement analytical methods, the following residue definitions were proposed in the framework of the EU pesticide peer review (EFSA, 2014b):

- Residue definition for risk assessment for primary crops (raw agricultural commodities): cyantraniliprole.
- Residue definition for risk assessment for processed commodities: sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole.
- Residue definition for enforcement (primary crops and processed commodities): cyantraniliprole.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition. Taking into account the proposed uses assessed in this application, EFSA concluded that these residue definitions are appropriate and no modification is required. Since in processed olives and their products, the degradation products IN-N5M09 and IN-F6L99 do not occur in significant concentrations, the previously derived residue definition for processed commodities is applicable also for olives.

## 2.2. Magnitude of residues in plants

### 2.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted 9 residue trials performed on olives in SEU.

The trials were conducted according to the intended critical Good Agricultural Practice (GAP) in France, Greece, Italy and Spain during the 2014 growing season. The treatment consisted of three foliar applications on 1 m<sup>2</sup> of foliage in the south side of the treated tree (resulting in three application rates of 15 g a.i./ha), at BBCH 79–89 with a 7-day interval between applications and in combination with a bait for fruit fly. Cyantraniliprole residues were measured in olive fruit samples harvested from the treated sector of olive trees.

The trials have been carried out over one growing season, whereas two seasons would generally be required according to Commission Regulation (EC) No 544/2011. Considering the wide geographical



distribution of trial locations, it can be assumed that the range of different conditions is covered, therefore the lack of trials covering two growing seasons can be considered as a minor deficiency.

Trials from two experimental sites were considered by EFSA as non-independent being conducted on sites located at a distance of less than 20 km from each other, on the same crop variety and on close treatment dates (< 30 days apart). The trial with the lower residue level measured (Venterol) was therefore disregarded. Finally, data from 8 experimental locations were selected to derive MRL proposals and risk assessment values.

Decline studies were not available. However, a rapid residue decline between the second and the third application was observed and the lack of decline studies was therefore considered a minor deficiency.

The samples were analysed for the parent compound in accordance with the residue definitions for enforcement and risk assessment and stored under conditions for which integrity of the samples has been demonstrated. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (France, 2018).

The number and quality of trials are sufficient to derive an MRL proposal of 3 mg/kg for the intended SEU uses on table olives and olives for oil production. It should be highlighted that the sampling method used does not reflect the overall residue concentration of the plot (treated and untreated parts of the crop) but focussed only on the treated sector; hence, lower residues may be expected in samples from the untreated side of the tree. Overall, this may lead to an overestimation of the residue levels in the commodity and to a higher MRL proposal.

The available residues data from the GAP-compliant supervised residue trials is summarised in Appendix B, Table B.2.2.1.

### 2.2.2. Magnitude of residues in rotational crops

Not relevant as olives are not grown in rotation with other crops.

### 2.2.3. Magnitude of residues in processed commodities

Studies investigating the effect of processing on the magnitude of cyantraniliprole residues in processed olives and various other products were assessed in the context of the EU pesticides peer review (EFSA, 2014b). The processed commodities were analysed for the residues of cyantraniliprole and its degradation products IN-J9Z38, IN-N5M09 and IN-F6L99. The risk assessment residue definition in processed commodities differs from the risk assessment residue definition in raw agricultural commodities (RAC) and therefore the conversion factors were derived.

The three field trials on olives used for processing studies were significantly overdosed compared to the GAP under assessment. The number and quality of the processing studies is sufficient to derive robust processing factors (PFs) for canned olives and raw and refined olive oil. The results from these studies suggest that residues of cyantraniliprole concentrate in raw olive oil (PF: 1.2) and decrease in refined olive oil (PF: 0.7) and canned olives with stone (PF: 0.4) and without stone (PF: 0.6).

Residues of IN-N5M09 and IN-F6L99 were not detected in raw and refined olive oil (the first one being the only product where concentration of residues was observed) and were reported to be negligible (levels up to 0.013 mg/kg for IN-N5M09 and < 0.01 mg/kg for IN-F6L99) in canned olives, thus confirming no need to consider these compounds in the residue definition in processed olive products. As regards IN-J9Z38, a significant amount of the parent compound was found to be converted to the degradation product, which confirms the decision to include this degradation product in the residue definition for risk assessment (EFSA, 2014b).

The processing factors relevant for the commodities assessed in this assessment are reported in Appendix B, B.2.2.3.

### 2.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B.2.2.1). In Section 4, EFSA assessed whether cyantraniliprole residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

## 3. Residues in livestock

Not relevant as olives are not used for feed purposes.

## 4. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018b, 2019a). 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 values are applicable to the metabolite IN-J9Z38 (EFSA, 2014b). Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required (EFSA, 2014b).

The long-term exposure assessment was performed taking into account the median residue values (STMR) derived from supervised trials for the commodities assessed in this application. For the remaining commodities covered by the MRL regulation, the STMR values derived in the EU pesticides peer review (EFSA, 2014b), previous MRL applications (EFSA, 2015, 2016a,b, 2017a, 2018a, 2019c) and evaluations by the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) (FAO, 2014, 2015, 2019) were selected as input values.

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, 2019). 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.

The complete list of input values is presented in Appendix D.2.

The highest estimated long-term dietary intake accounted for 67% of the ADI (NL toddler diet). The contributions of residues expected in the commodities assessed in the present MRL application to the overall long-term exposure were 4.3% of the ADI (GEMS/Food G08 diet) for olives for oil production and 0.3% of the ADI (IE adult diet) for table olives (see Appendix B.4).

The risk assessment is affected by additional, non-standard uncertainties related to animal products, table olives and olives for oil production. The contribution of animal products to the dietary exposure is likely to be overestimated, since the input values used in the exposure calculation cover additional metabolites which are not part of the EU residue definition. For olives, the expected exposure to residues present in bulked and blended olive products derived from orchards treated in accordance with the intended GAP (spot or band application) is likely to be lower since the input values derived from the supervised field trials used in the exposure assessment are representative for the part of the orchard that was treated with cyantraniliprole (see Section 2.2.1); after bulking, the harvested olives from an orchard treated according to the intended GAP are likely to contain lower residues, since part of the olives would not have been exposed to the direct treatment with cyantraniliprole. Additional uncertainties are linked to the lack of toxicological reference values for two degradation products IN-N5M09 and IN-F6L99 found in quantifiable concentrations in certain processed products, e.g. cooked spinach. However, since in processed olive products these degradation products were not identified, this uncertainty is not directly linked to the intended use in olives.

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

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

## 5. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for olives (table olives and olives for oil production).

EFSA concluded that the proposed uses of cyantraniliprole on the crop under consideration does not result in a consumer exposure exceeding the toxicological reference values and, therefore, is unlikely to pose a risk to consumers' health.

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   |
| CF       | conversion factor for enforcement to risk assessment residue definition |
| CXL      | Codex maximum residue limit   |
| DAR      | draft assessment report   |
| DAT      | days after treatment  |
| EMS      | evaluating Member State   |
| FAO      | Food and Agriculture Organization of the United Nations                 |
| GAP      | Good Agricultural Practice  |
| GLP      | Good Laboratory Practice  |
| HR       | highest residue   |
| IEDI     | international estimated daily intake                                    |
| ISO      | International Organisation for Standardisation                          |
| IUPAC    | International Union of Pure and Applied Chemistry                       |
| JMPR     | Joint FAO/WHO Meeting on Pesticide Residues                             |
| LC–MS/MS | liquid chromatography with tandem mass spectrometry                     |
| LOQ      | limit of quantification   |
| MRL      | maximum residue level   |

|       |  |
|-------|--|
| MS    | Member States  |
| NEU   | northern Europe  |
| OECD  | Organisation for Economic Co-operation and Development |
| PF    | processing factor                                      |
| PHI   | preharvest interval                                    |
| PRIMo | (EFSA) Pesticide Residues Intake Model                 |
| RA    | risk assessment  |
| RAC   | raw agricultural commodity                             |
| RD    | residue definition                                     |
| RMS   | rapporteur Member State                                |
| SANCO | Directorate-General for Health and Consumers           |
| SEU   | southern Europe  |
| SE    | suspoemulsion  |
| STMR  | supervised trials median residue                       |
| TRR   | total radioactive residue                              |
| WHO   | World Health Organization                              |

## 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 <sup>(a)</sup> | Pests or group of pests controlled | Preparation         |            | Application   |  |                |                                  | Application rate per treatment |                    |   | Unit      | PHI (days) <sup>(d)</sup> | Remarks  |
|-----------------------|-------------------------|-------------------------|------------------------------------|---------------------|------------|---|--|----------------|----------------------------------|--------------------------------|--------------------|---|-----------|---------------------------|--|
|                       |                         |                         |                                    | Type <sup>(b)</sup> | Conc. a.s. | Method kind   | Range of growth stages & season <sup>(c)</sup> | Number min–max | Interval between application min | g a.s./hL min–max              | Water L/ha min–max | Rate  |           |                           |  |
| Olives                | SEU                     | F                       | Fruit fly: <i>Bactrocera oleae</i> | SE                  | 100 g/L    | Foliar spot application with a conventional sprayer (only 1 nozzle left) or a backpack sprayer. | BBCH 81–89 (Aug–Dec)                           | 3              | 7                                | 25–150                         | 5–30               | 15 for a treatment on each tree or 7.5 on every other row | g a.s./ha | 7                         | Spot or band application with the addition of an attractive bait for fruit fly (hydrolysed proteins, i.e. Levex <sup>®</sup> at 1.25 L/ha). Application to be done on a small part of each tree (e.g. 1 m <sup>2</sup> per tree treated) |

NEU: northern European Union; SEU: southern European Union; MS: Member State; SE: suspoemulsion; a.s.: active substance.

(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.

(d): PHI: minimum preharvest interval.



## Appendix B – List of end points

### B.1. Mammalian toxicology

Studies performed on metabolites or impurities

IN-N5M09

Unlikely to be genotoxic.

No conclusion on general toxicity.

IN-F6L99

Unlikely to be genotoxic.

No conclusion on general toxicity.

### 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<br>(available studies) | Crop groups     | Crop(s)  | Application(s)                         | Sampling<br>(DAT)  | Comment/<br>Source  |
|--------------------------------------|-----------------|----------|--|--|---|
|                                      | Fruit crops     | Tomatoes | Foliar (3 × 150 g/ha, BBCH 14–61)      | 0, 7, 14 DAT (leaves); 125 DAT (leaves, fruits)                    | Radiolabelled active substance: Foliar applications: <sup>14</sup> C-cyano and <sup>14</sup> C-pyrazole cyantraniliprole in a 1:1 mixture formulation<br>Soil applications: Separate studies with each label (United Kingdom, 2013; EFSA, 2014b). |
|                                      |                 |          | Soil drench (3 × 150 g/ha, BBCH 19–61) | 7, 14 DAT (leaves); 125 DAT (leaves, fruits)                       |   |
|                                      | Leafy crops     | Lettuces | Foliar (3 × 150 g/ha, BBCH 33–36)      | 0, 7, 14, 32 DAT   |   |
|                                      |                 |          | Soil drench (3 × 150 g/ha, BBCH 36–38) | 7, 14, 32 DAT  |   |
|                                      | Cereals/grass   | Rice     | Foliar (3 × 150 g/ha, BBCH 13–14)      | 140 DAT (straw, grain)   |   |
|                                      |                 |          | Soil granule (1 × 300 g/ha, BBCH 13)   | 175 DAT (straw, grain)   |   |
|                                      | Pulses/oilseeds | Cotton   | Foliar (3 × 150 g/ha, BBCH 16–19)      | 0, 7, 13–14 DAT (leaves); 124–125 DAT (gin by-product, lint, seed) |   |
|                                      |                 |          | Soil drench (3 × 150 g/ha, BBCH 19–51) | 7, 13–14 DAT (leaves); 124–125 DAT (gin by-product, lint, seed)    |   |

| <b>Rotational crops</b><br>(available studies)     | <b>Crop groups</b>                                | <b>Crop(s)</b> | <b>Application(s)</b>                                    | <b>PBI (DAT)</b> | <b>Comment/Source</b>   |
|--|---|----------------|--|------------------|---|
|  | Cereals   | Wheat          | 1 × 450 g a.s./ha  | 30, 120, 365     | All studies conducted with bare soil application. Radiolabelled active substance: [cyano- <sup>14</sup> C]-cyantraniliprole and [pyrazole carbonyl- <sup>14</sup> C]-cyantraniliprole for wheat; [pyrazole carbonyl- <sup>14</sup> C]-cyantraniliprole for soya bean (United Kingdom, 2013; EFSA, 2014b). |
|  | Root crops  | Red beet       |  | 30, 120          |   |
|  | Leafy crops                                       | Lettuce        |  | 30, 120          |   |
|  | Pulses and oil seeds                              | Soya bean      | 1 × 300 g a.s./ha<br>Pilot study not conducted under GLP | 25, 120          |   |
| <b>Processed commodities</b><br>(hydrolysis study) | <b>Conditions</b>                                 |                |  | <b>Stable?</b>   |   |
|  | Pasteurisation (20 min, 90°C, pH 4)               |                |  | Yes              | EFSA (2014b)  |
|  | Baking, brewing and boiling (60 min, 100°C, pH 5) |                |  | See comment      | Degraded to IN-J9Z38 (12–14% AR) and to IN-N5M09 (8% AR) and IN-F6L99 (5% AR) under baking/boiling/brewing conditions (EFSA, 2014b).  |
|  | Sterilisation (20 min, 120°C, pH 6)               |                |  | Yes              | EFSA (2014b)  |

|  |  |              |
|--|--|--------------|
| Can a general residue definition be proposed for primary crops?                          | Yes  | EFSA (2014b) |
| Rotational crop and primary crop metabolism similar?                                     | Open   | EFSA (2019c) |
| Residue pattern in processed commodities similar to residue pattern in raw commodities?  | No   | EFSA (2014b) |
| Plant residue definition for monitoring (RD-Mo)  | Cyantraniliprole   |              |
| Plant residue definition for risk assessment (RD-RA)                                     | Primary crops (raw agricultural commodities): Cyantraniliprole<br>Processed commodities: Sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole<br>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- and high starch content matrices).<br>ILV is also available (EFSA, 2014b).               |              |

DAT: days after treatment; 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. Storage stability of residues in plants

| Plant products (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 and IN-F6L99 | EFSA (2014b)    |
|                                    | High acid content    | Grapes    | -20    | ≥ 24             | Month | Cyantraniliprole, IN-J9Z38, IN-N5M09 and IN-F6L99 | EFSA (2014b)    |
|                                    | High starch content  | Potatoes  | -20    | ≥ 24             | Month | Cyantraniliprole, IN-J9Z38, IN-N5M09 and IN-F6L99 | EFSA (2014b)    |
|                                    | High protein content | Dry beans | -20    | 18               | Month | Cyantraniliprole                                  | EFSA (2014b)    |
|                                    | High protein content | Dry beans | -20    | ≥ 24             | Month | IN-J9Z38, IN-N5M09 and IN-F6L99                   | EFSA (2014b)    |
|                                    | High oil content     | Peanuts   | -20    | 18               | Month | Cyantraniliprole, IN-F6L99                        | EFSA (2014b)    |
|                                    | High oil content     | Peanuts   | -20    | ≥ 24             | Month | IN-J9Z38, IN-N5M09                                | EFSA (2014b)    |

### B.2.2. Magnitude of residues in plants

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

| Commodity | Region/ Indoor <sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg)  | Comments/ Source   | Calculated MRL (mg/kg) | HR <sup>(b)</sup> (mg/kg) | STMR <sup>(c)</sup> (mg/kg) | CF <sup>(d)</sup> |
|-----------|-------------------------------|---|--|------------------------|---------------------------|-----------------------------|-------------------|
| Olives    | SEU                           | Whole olive fruit: 0.15; 0.27; 0.37; 0.53; 0.53; 0.95; 0.97; 1.20 | Residue trials on olives compliant with the intended GAP. Residue data extrapolated among table olives and olives for oil production | 3                      | 1.20                      | 0.53                        | –                 |

MRL: maximum residue level; GAP: Good Agricultural Practice.

(a): EU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.

(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): Conversion factor to recalculate residues according to the proposed residue definition for monitoring to the residue definition for risk assessment.

### B.2.2.2. Residues in rotational crops

|   |      |   |
|---|------|---|
| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Open | 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, 2014b). |
| Residues in rotational and succeeding crops expected based on field rotational crop study?    | Open | Field rotational crop studies at 450 g/ha. Long-term rotational crop studies are required to investigate the magnitude of residues of cyantraniliprole and its most persistent metabolites (EFSA, 2014b).   |

### B.2.2.3. Processing factors

Processing studies were not submitted in the framework of the present MRL application. Processing studies in olives were assessed in the framework of the EU pesticide peer review (EFSA, 2014b).

| Crop/processed product               | Number of valid studies | Processing factors       |                   | Comments/Source                     |
|--------------------------------------|-------------------------|--------------------------|-------------------|-------------------------------------|
|                                      |                         | Median PF <sup>(a)</sup> | CF <sup>(b)</sup> |                                     |
| Olives/Processed (flesh)             | 3                       | 0.6                      | 1.6               | United Kingdom (2013), EFSA (2014b) |
| Olives/Processed (whole, with stone) | 3                       | 0.4                      | 1.6               |                                     |
| Olives/raw oil                       | 3                       | 1.2                      | 1.1               |                                     |
| Olives/refined oil                   | 2                       | 0.7                      | 1.4               |                                     |

PF: processing factor.

(a): Processing factor derived as a ratio of residues in processed commodity according to enforcement residue definition and residues in raw agricultural commodity (RAC) according to enforcement residue definition.

(b): Conversion factor for risk assessment derived as a ratio of residues in processed commodity according to risk assessment residue definition and residues in raw commodity according to enforcement assessment residue definition.

### B.3. Residues in livestock

Not relevant.

## B.4. Consumer risk assessment

Acute consumer risk assessment not relevant since no ARfD has been considered necessary (European Commission, 2016).

|                                       |   |
|---------------------------------------|---|
| ADI                                   | 0.01 mg/kg bw per day (European Commission, 2016)   |
| Highest IEDI, according to EFSA PRIMo | 67% of ADI (NL toddler diet)<br>Contribution of crops assessed:<br>Table olives: 0.32% (IE adult diet)<br>Olives for oil production: 4.3% (GEMS/Food G08 diet)  |
| Assumptions made for the calculations | Calculations performed with PRIMo revision 3.1 (EFSA, 2018a, 2019a).<br>The calculation is based on the median residue levels derived for crops under consideration (STMR values) as derived from the submitted residue trials according to the risk assessment residue definition.   |
|                                       | For the remaining commodities covered by the MRL regulation, the STMR values derived in the EU pesticides peer review, previous MRL applications and, where relevant, in the evaluations by the JMPR were selected as input values.<br><br>For animal commodities, for which the existing EU MRLs are set on the basis of CXLs, STMR values are derived according to risk assessment residue definition set by the JMPR (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 are considered appropriate for use in the exposure calculation.<br><br>The crops on which no uses have been reported in the EU pesticides peer review or in subsequent EFSA outputs, were not included in the exposure calculation. |

ARfD: acute reference dose; ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; MRL: maximum residue level; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; CXL: codex maximum residue limit; FAO: Food and Agriculture Organization of the United Nations.

## B.5. Recommended MRLs

| Code <sup>(a)</sup>                                     | Commodity                 | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification  |
|---|---------------------------|-------------------------|-------------------------|--|
| <b>Enforcement residue definition: Cyantraniliprole</b> |                           |                         |                         |  |
| 161030  | Table olives              | 1.5                     | 3                       | The submitted data are sufficient to derive an MRL proposal for the SEU uses. Risk for consumers unlikely. |
| 402010  | Olives for oil production | 1.5                     | 3                       |  |

MRL: maximum residue level; SEU: southern Europe.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

### Appendix C – Pesticide Residue Intake Model (PRIMo)



| Cyantranilprole                |      |                     |                |
|--------------------------------|------|---------------------|----------------|
| LOQs (mg/kg) range from:       | 0.01 | to:                 | 0.05           |
| Toxicological reference values |      |                     |                |
| ADI (mg/kg bw per day):        | 0.01 | ARID (mg/kg bw):    | not applicable |
| Source of ADI:                 | EC   | Source of ARID:     | 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 – acuterisk assessment/adults

| Chronic risk assessment: JMPR methodology (IEDI/TMDI) |                   |                             |  |                                 |  |                                 |  |                                 |                                   |  |                         |
|---|-------------------|-----------------------------|--|---------------------------------|--|---------------------------------|--|---------------------------------|-----------------------------------|--|-------------------------|
| No of diets exceeding the ADI : ---                   |                   |                             |  |                                 |  |                                 |  |                                 |                                   |  | Exposure resulting from |
| Calculated exposure (% of ADI)                        | MS Diet           | Exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |                         |
|   |                   |                             |  |                                 |  |                                 |  |                                 |                                   |  |                         |
| 51%   | DE child          | 5.13                        | 20%  | Apples                          | 6%                                       | Oranges                         | 4%                                       | Table grapes                    |                                   | 51%  |                         |
| 37%   | NL child          | 3.65                        | 9%   | Apples                          | 4%                                       | Milk: Cattle                    | 3%                                       | Table grapes                    |                                   | 37%  |                         |
| 29%   | GEMS/Food G07     | 2.92                        | 5%   | Wine grapes                     | 3%                                       | Celeries                        | 2%                                       | Oranges                         |                                   | 29%  |                         |
| 29%   | GEMS/Food G08     | 2.91                        | 4%   | Olives for oil production       | 3%                                       | Wine grapes                     | 3%                                       | Head cabbages                   |                                   | 29%  |                         |
| 29%   | GEMS/Food G15     | 2.85                        | 5%   | Head cabbages                   | 3%                                       | Wine grapes                     | 2%                                       | Tomatoes                        |                                   | 29%  |                         |
| 29%   | RO general        | 2.85                        | 8%   | Head cabbages                   | 5%                                       | Wine grapes                     | 3%                                       | Tomatoes                        |                                   | 29%  |                         |
| 28%   | IE adult          | 2.82                        | 4%   | Wine grapes                     | 3%                                       | Celeries                        | 2%                                       | Oranges                         |                                   | 28%  |                         |
| 28%   | GEMS/Food G11     | 2.76                        | 6%   | Celeries                        | 3%                                       | Wine grapes                     | 2%                                       | Apples                          |                                   | 28%  |                         |
| 27%   | GEMS/Food G06     | 2.73                        | 6%   | Tomatoes                        | 3%                                       | Table grapes                    | 2%                                       | Olives for oil production       |                                   | 27%  |                         |
| 27%   | FR child 3 15 yr  | 2.66                        | 5%   | Oranges                         | 4%                                       | Milk: Cattle                    | 3%                                       | Apples                          |                                   | 27%  |                         |
| 25%   | GEMS/Food G10     | 2.52                        | 3%   | Lettuces                        | 2%                                       | Head cabbages                   | 2%                                       | Tomatoes                        |                                   | 25%  |                         |
| 24%   | FR toddler 2 3 yr | 2.40                        | 5%   | Apples                          | 5%                                       | Milk: Cattle                    | 2%                                       | Oranges                         |                                   | 24%  |                         |
| 24%   | ES child          | 2.38                        | 4%   | Olives for oil production       | 3%                                       | Oranges                         | 3%                                       | Lettuces                        |                                   | 24%  |                         |
| 23%   | DE women 14-50 yr | 2.34                        | 4%   | Apples                          | 3%                                       | Oranges                         | 3%                                       | Wine grapes                     |                                   | 23%  |                         |
| 23%   | SE general        | 2.29                        | 4%   | Head cabbages                   | 3%                                       | Lettuces                        | 2%                                       | Milk: Cattle                    |                                   | 23%  |                         |
| 22%   | DE general        | 2.18                        | 4%   | Apples                          | 3%                                       | Wine grapes                     | 3%                                       | Oranges                         |                                   | 22%  |                         |
| 21%   | UK infant         | 2.14                        | 6%   | Milk: Cattle                    | 3%                                       | Apples                          | 2%                                       | Oranges                         |                                   | 21%  |                         |
| 20%   | PT general        | 1.98                        | 8%   | Wine grapes                     | 2%                                       | Apples                          | 2%                                       | Tomatoes                        |                                   | 20%  |                         |
| 19%   | UK toddler        | 1.94                        | 3%   | Milk: Cattle                    | 3%                                       | Oranges                         | 3%                                       | Apples                          |                                   | 19%  |                         |
| 19%   | ES adult          | 1.93                        | 4%   | Lettuces                        | 2%                                       | Olives for oil production       | 2%                                       | Oranges                         |                                   | 19%  |                         |
| 18%   | FR adult          | 1.77                        | 7%   | Wine grapes                     | 1%                                       | Apples                          | 0.9%                                     | Oranges                         |                                   | 18%  |                         |
| 18%   | NL general        | 1.76                        | 2%   | Apples                          | 2%                                       | Wine grapes                     | 2%                                       | Oranges                         |                                   | 18%  |                         |
| 17%   | DK child          | 1.68                        | 4%   | Apples                          | 2%                                       | Milk: Cattle                    | 1%                                       | Cucumbers                       |                                   | 17%  |                         |
| 13%   | FR infant         | 1.35                        | 3%   | Milk: Cattle                    | 3%                                       | Apples                          | 1%                                       | Cauliflowers                    |                                   | 13%  |                         |
| 13%   | IT toddler        | 1.28                        | 2%   | Tomatoes                        | 2%                                       | Lettuces                        | 1%                                       | Apples                          |                                   | 13%  |                         |
| 13%   | UK vegetarian     | 1.28                        | 3%   | Wine grapes                     | 1%                                       | Oranges                         | 1%                                       | Lettuces                        |                                   | 13%  |                         |
| 12%   | IT adult          | 1.24                        | 3%   | Lettuces                        | 2%                                       | Tomatoes                        | 1%                                       | Peaches                         |                                   | 12%  |                         |
| 12%   | DK adult          | 1.22                        | 3%   | Wine grapes                     | 2%                                       | Apples                          | 0.9%                                     | Tomatoes                        |                                   | 12%  |                         |
| 11%   | PL general        | 1.14                        | 3%   | Apples                          | 2%                                       | Head cabbages                   | 2%                                       | Tomatoes                        |                                   | 11%  |                         |
| 11%   | FI 3 yr           | 1.11                        | 2%   | Strawberries                    | 2%                                       | Apples                          | 1.0%                                     | Tomatoes                        |                                   | 11%  |                         |
| 10%   | UK adult          | 1.10                        | 3%   | Wine grapes                     | 0.9%                                     | Lettuces                        | 0.9%                                     | Oranges                         |                                   | 11%  |                         |
| 10%   | LT adult          | 1.02                        | 3%   | Apples                          | 2%                                       | Head cabbages                   | 1%                                       | Tomatoes                        |                                   | 10%  |                         |
| 8%  | FI adult          | 0.85                        | 1%   | Lettuces                        | 1.0%                                     | Wine grapes                     | 0.9%                                     | Tomatoes                        |                                   | 8%   |                         |
| 8%  | FI 6 yr           | 0.85                        | 1%   | Strawberries                    | 0.9%                                     | Apples                          | 0.7%                                     | Tomatoes                        |                                   | 8%   |                         |
| 3%  | IE child          | 0.34                        | 0.6%   | Milk: Cattle                    | 0.5%                                     | Apples                          | 0.3%                                     | Broccoli                        |                                   | 3%   |                         |

**Conclusion:**  
 The estimated long-term dietary intake (TMDI/IEDI) was below the ADI.  
 The long-term intake of residues of cyantranilprole 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.



|  |  |
|--|--|
| <b>Acute risk assessment /children</b>           | <b>Acute risk assessment/adults/general population</b> |
| <b>Details – acute risk assessment /children</b> | <b>Details – acute risk assessment/adults</b>          |

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**

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

|                              |   |                       |                          |                     |                             |                       |                          |                     |
|------------------------------|---|-----------------------|--------------------------|---------------------|-----------------------------|-----------------------|--------------------------|---------------------|
| <b>Processed commodities</b> | <b>Results for children</b>   |                       |                          |                     | <b>Results for adults</b>   |                       |                          |                     |
|                              | No of processed commodities for which ARfD/ADI is exceeded (IESTI): |                       |                          |                     | 8                           |                       |                          |                     |
|                              | <b>IESTI</b>  |                       |                          |                     | <b>IESTI</b>                |                       |                          |                     |
|                              | Highest % of ARfD/ADI   | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI       | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|                              | 867%  | Broccoli/boiled       | 2/1.1                    | 87                  | 3072%                       | Celeries/boiled       | 15/9.1                   | 307                 |
| 766%                         | Cauliflowers/boiled   | 2/1.1                 | 77                       | 458%                | Cauliflowers/boiled         | 2/1.1                 | 46                       |                     |
| 266%                         | Pumpkins/boiled   | 0.3/0.3               | 27                       | 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 whii                                       | 4/0.75                | 21                       | 166%                | Pumpkins/boiled             | 0.3/0.3               | 17                       |                     |
| 188%                         | Beans (with pods)/boiled  | 1.5/1.5               | 19                       | 142%                | Wine grapes/wine            | 1.5/1.5               | 14                       |                     |
| 140%                         | Wine grapes/juice   | 1.5/0.32              | 14                       | 96%                 | Currants (red, black and    | 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                      |                     |
| 56%                          | Peaches/juice   | 1.5/0.34              | 5.6                      | 53%                 | Apples/juice                | 0.8/0.16              | 5.3                      |                     |
| 52%                          | Pears/juice   | 0.8/0.16              | 5.2                      | 53%                 | Head cabbages/canned        | 2/0.56                | 5.3                      |                     |
| 51%                          | Gherkins/pickled  | 0.4/0.22              | 5.1                      | 50%                 | Courgettes/boiled           | 0.4/0.22              | 5.0                      |                     |
| 47%                          | Potatoes/fried  | 0.05/0.05             | 4.7                      | 24%                 | Okra, lady's fingers/boiled | 1.5/1.5               | 2.4                      |                     |
| 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.

## Appendix D – Input values for the exposure calculations

### D.1. Livestock dietary burden calculations

Not relevant to the present MRL application.

### D.2. Consumer risk assessment

| Commodity   | Existing/<br>proposed MRL<br>(mg/kg) | Source       | Chronic risk assessment |  |
|---|--------------------------------------|--------------|-------------------------|--|
|   |                                      |              | Input value<br>(mg/kg)  | Comment  |
| <b>Risk assessment residue definition: Cyantraniliprole</b> |                                      |              |                         |  |
| Table olives  | 3                                    | Proposed MRL | 0.53                    | STMR-RAC   |
| Olives for oil production                                   | 3                                    | Proposed MRL | 0.53                    | STMR-RAC   |
| Citrus fruit  | 0.9                                  | EFSA (2014b) | 0.16                    | STMR-RAC   |
| Tree nuts   | 0.04                                 | FAO (2015)   | 0.01                    | STMR-RAC   |
| Pome fruits   | 0.8                                  | FAO (2014)   | 0.16                    | STMR-RAC   |
| Cherries  | 6                                    | FAO (2014)   | 0.93                    | STMR-RAC   |
| Peaches   | 1.5                                  | FAO (2014)   | 0.34                    | STMR-RAC   |
| Plums   | 0.7                                  | EFSA (2014b) | 0.12                    | STMR-RAC   |
| Table grapes  | 1.5                                  | EFSA (2016b) | 0.26                    | STMR-RAC   |
| Wine grapes   | 1.5                                  | EFSA (2016b) | 0.32                    | STMR-RAC × PF × YF <sup>(a)</sup><br>(EFSA, 2014b, 2015) |
| Strawberries  | 1.5                                  | FAO (2019)   | 0.455                   | STMR-RAC   |
| Blueberries (bush berries)                                  | 4                                    | FAO (2014)   | 0.75                    | STMR-RAC   |
| Cranberries   | 0.08                                 | FAO (2019)   | 0.012                   | STMR-RAC   |
| Currants (red, black and white)                             | 4                                    | FAO (2014)   | 0.75                    | STMR-RAC   |
| Gooseberries (green, red & yellow)                          | 4                                    | FAO (2014)   | 0.75                    | STMR-RAC   |
| Rose hips   | 4                                    | FAO (2014)   | 0.75                    | STMR-RAC   |
| Azarole/Mediterranean medlars                               | 0.8                                  | FAO (2014)   | 0.16                    | STMR-RAC   |
| Kaki/Japanese persimmons                                    | 0.8                                  | FAO (2014)   | 0.16                    | STMR-RAC   |
| Mangoes   | 0.7                                  | FAO (2019)   | 0.01                    | STMR-RAC   |
| Root and tuber vegetables<br>(except sugar beet)            | 0.05                                 | FAO (2014)   | 0.01                    | STMR-RAC (EFSA, 2014a)                                   |
| Garlic  | 0.05                                 | FAO (2014)   | 0.02                    | STMR-RAC   |
| Onions  | 0.05                                 | FAO (2014)   | 0.02                    | STMR-RAC   |
| Shallots  | 0.05                                 | FAO (2014)   | 0.02                    | STMR-RAC   |
| Spring onions   | 8                                    | FAO (2014)   | 1.3                     | STMR-RAC   |
| Other bulb vegetables                                       | 0.05                                 | FAO (2014)   | 0.02                    | STMR-RAC   |
| Tomatoes  | 1                                    | EFSA (2014b) | 0.17                    | STMR-RAC   |
| Peppers   | 1.5                                  | EFSA (2014b) | 0.14                    | STMR-RAC   |
| Aubergines  | 1                                    | EFSA (2014b) | 0.14                    | STMR-RAC   |
| Okra, lady's fingers  | 1.5                                  | EFSA (2014b) | 0.14                    | STMR-RAC   |
| Other solanaceae  | 1.5                                  | EFSA (2014b) | 0.14                    | STMR-RAC   |
| Cucurbits with edible peel                                  | 0.4                                  | EFSA (2014b) | 0.08                    | STMR-RAC   |
| Cucurbits with inedible peel                                | 0.3                                  | FAO (2014)   | 0.06                    | STMR-RAC (EFSA, 2014b)                                   |
| Brassica vegetables (ex. leafy<br>brassica)                 | 2                                    | FAO (2014)   | 0.56                    | STMR-RAC   |
| Lettuces  | 5                                    | FAO (2014)   | 0.79                    | STMR-RAC   |
| Beans (with pods)   | 1.5                                  | FAO (2015)   | 0.29                    | STMR-RAC   |
| Beans (without pods)  | 0.3                                  | FAO (2015)   | 0.07                    | STMR-RAC   |
| Peas (with pods)  | 2                                    | FAO (2015)   | 0.7                     | STMR-RAC   |

| Commodity   | Existing/<br>proposed MRL<br>(mg/kg) | Source       | Chronic risk assessment |                         |
|---|--------------------------------------|--------------|-------------------------|-------------------------|
|   |                                      |              | Input value<br>(mg/kg)  | Comment                 |
| Peas (without pods)   | 0.3                                  | FAO (2015)   | 0.07                    | STMR-RAC                |
| Celeries  | 15                                   | FAO (2014)   | 2                       | STMR-RAC                |
| Globe artichokes  | 0.1                                  | EFSA (2015)  | 0.03                    | STMR-RAC                |
| Beans (dry)   | 0.3                                  | FAO (2015)   | 0.01                    | STMR-RAC                |
| Sunflower seeds   | 0.5                                  | FAO (2015)   | 0.067                   | STMR-RAC                |
| Rapeseeds/canola seeds  | 0.8                                  | FAO (2015)   | 0.077                   | STMR-RAC                |
| Soya beans  | 0.4                                  | FAO (2015)   | 0.033                   | STMR-RAC                |
| Cotton seeds  | 1.5                                  | FAO (2015)   | 0.16                    | STMR-RAC                |
| Rice  | 0.01*                                | EFSA (2016a) | 0.01                    | STMR-RAC                |
| Coffee beans  | 0.05                                 | EFSA (2016a) | 0.01                    | STMR-RAC                |
| Herbal infusions (dried roots)  | 0.2                                  | EFSA (2015)  | 0.08                    | STMR-RAC                |
| Liquorice   | 0.2                                  | EFSA (2015)  | 0.08                    | STMR-RAC                |
| Turmeric/curcuma  | 0.2                                  | EFSA (2015)  | 0.08                    | STMR-RAC                |
| Other spices (roots)  | 0.2                                  | EFSA (2015)  | 0.08                    | STMR-RAC                |
| Sugar beet roots  | 0.05                                 | FAO (2014)   | 0.01                    | STMR-RAC                |
| Chicory roots   | 0.05                                 | FAO (2014)   | 0.01                    | STMR-RAC                |
| <b>Risk assessment residue definition:</b> Sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole |                                      |              |                         |                         |
| Mammalian terrestrial animals: meat   | 0.2                                  | FAO (2015)   | 0.041                   | STMR-RAC <sup>(b)</sup> |
| Mammalian terrestrial animals: fat  | 0.5                                  | FAO (2015)   | 0.1                     | STMR-RAC <sup>(b)</sup> |
| Mammalian terrestrial animals: liver, kidney, edible offal  | 1.5                                  | FAO (2015)   | 0.38                    | STMR-RAC <sup>(b)</sup> |
| Poultry: meat   | 0.02                                 | FAO (2015)   | 0.004                   | STMR-RAC <sup>(b)</sup> |
| Poultry: fat  | 0.04                                 | FAO (2015)   | 0.008                   | STMR-RAC <sup>(b)</sup> |
| Poultry: liver, kidney, edible offal  | 0.15                                 | FAO (2015)   | 0.032                   | STMR-RAC <sup>(b)</sup> |
| Milk  | 0.02                                 | FAO (2014)   | 0.016                   | STMR-RAC <sup>(b)</sup> |
| Eggs  | 0.15                                 | FAO (2015)   | 0.043                   | STMR-RAC <sup>(b)</sup> |

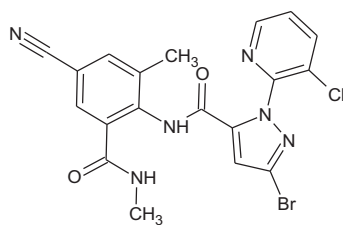
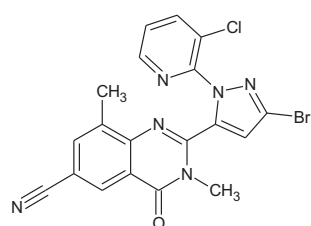
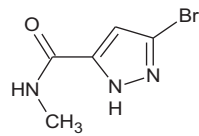
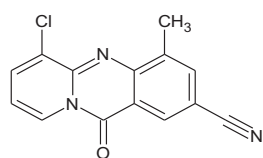
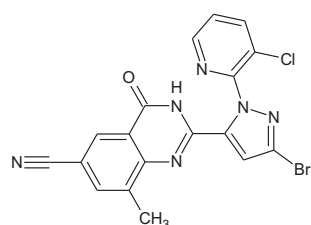
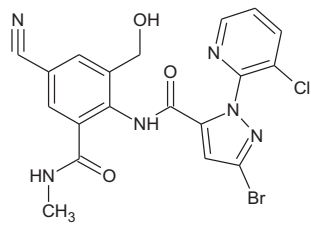
STMR-RAC: supervised trials median residue – raw agriculture commodity; PF: processing factor; YF: yield factor.

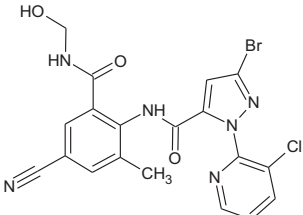
\*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

(a): Consumption figure in the PRIMo model is expressed for the raw commodity (grape). A yield factor (YF) of 0.7 is therefore considered to estimate the consumption figure for wine.

(b): Residue values in the FAO (2015). Estimation of STMRs in products of animal origin is the sum of cyantraniliprole and metabolites IN-N7B69, IN-J9Z38, IN-MLA84 and IN-MYX98, expressed as cyantraniliprole.

## Appendix E – Used compound codes

| Code/trivial name <sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey <sup>(b)</sup>   | Structural formula <sup>(c)</sup>   |
|----------------------------------|--|---|
| Cyantraniliprole                 | 3-bromo-1-(3-chloro-2-pyridyl)-4'-cyano-2'-methyl-6'-(methylcarbamoyl)-1 <i>H</i> -pyrazole-5-carboxanilide<br><br><chem>CNC(=O)c1cc(C#N)cc(C)c1NC(=O)c1cc(Br)nn1c1ncccc1Cl</chem><br><br>DVBUIBGJRQBEDP-UHFFFAOYSA-N                          |    |
| IN-J9Z38                         | 2-[3-bromo-1-(3-chloropyridin-2-yl)-1 <i>H</i> -pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carbonitrile<br><br><chem>Cc1cc(C#N)cc2c1N=C(c1cc(Br)nn1c1ncccc1Cl)N(C)C2=O</chem><br><br>WHYZZHKSZLNRP-UHFFFAOYSA-N                 |    |
| IN-F6L99                         | 3-bromo- <i>N</i> -methyl-1 <i>H</i> -pyrazole-5-carboxamide<br><br><chem>O=C(NC)c1cc(Br)n[nH]1</chem><br><br>LOYJZLKXTLAMJX-UHFFFAOYSA-N  |   |
| IN-N5M09                         | 6-chloro-4-methyl-11-oxo-11 <i>H</i> -pyrido[2,1- <i>b</i> ]quinazoline-2-carbonitrile<br><br><chem>Cc1cc(C#N)cc2c1N=C1C(Cl)=CC=CN1C2=O</chem><br><br>MZOZXXSPJGMFBK-UHFFFAOYSA-N  |  |
| IN-MLA84                         | 2-[3-bromo-1-(3-chloropyridin-2-yl)-1 <i>H</i> -pyrazol-5-yl]-8-methyl-4-oxo-1,4-dihydroquinazoline-6-carbonitrile<br><br><chem>Cc1cc(C#N)cc2c1N=C(NC2=O)c1cc(Br)nn1c1ncccc1Cl</chem><br><br>XOWPMRVDJYWVNL-UHFFFAOYSA-N                       |  |
| IN-N7B69                         | 3-bromo-1-(3-chloropyridin-2-yl)- <i>N</i> -[4-cyano-2-(hydroxymethyl)-6-(methylcarbamoyl)phenyl]-1 <i>H</i> -pyrazole-5-carboxamide<br><br><chem>CNC(=O)c1cc(C#N)cc(CO)c1NC(=O)c1cc(Br)nn1c1ncccc1Cl</chem><br><br>HIRGCCGVBDKSH-UHFFFAOYSA-N |  |

| Code/trivial name <sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey <sup>(b)</sup>  | Structural formula <sup>(c)</sup>   |
|----------------------------------|---|---|
| IN-MYX98                         | 3-bromo-1-(3-chloropyridin-2-yl)- <i>N</i> -{4-cyano-2-[(hydroxymethyl)carbamoyl]-6-methylphenyl}-1 <i>H</i> -pyrazole-5-carboxamide<br><br><chem>OCNC(=O)c1cc(C#N)cc(C)c1NC(=O)c1cc(Br)nn1c1ncccc1Cl</chem><br><br>FLLWEQACDZRMFC-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 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).