REASONED OPINION

EFSA Journal

ADOPTED: 25 October 2019

doi: 10.2903/j.efsa.2019.5903

Modification of the existing maximum residue levels for cyantraniliprole in Chinese cabbages, blackberries and raspberries

European Food Safety Authority (EFSA),
Maria Anastassiadou, Alba Brancato, Luis Carrasco Cabrera, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Alejandro Rojas, Angela Sacchi, Miguel Santos, Alois Stanek, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

In accordance with Article 53 of Regulation (EC) 1107/2009, the United Kingdom granted two 120-day emergency authorisations for the use of plant protection products containing the active substance cyantraniliprole in Chinese cabbages, raspberries and blackberries. The applicants (Agriculture & Horticulture Development Board (AHDB)) and FMC Agro Ltd) requested the setting of temporary maximum residue levels (MRLs) for cyantraniliprole in Chinese cabbages, raspberries and blackberries. The United Kingdom, as evaluating Member State (EMS), summarised the data provided by the applicants in two evaluation reports which were submitted to the European Commission and forwarded to EFSA. Adequate analytical methods for enforcement are available to control the residues of cyantraniliprole on the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Sufficient residue trials were submitted to calculate MRL proposals for the crops under assessment. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of parent cyantraniliprole in crops under assessment according to the reported emergency agricultural practice is unlikely to present a risk to consumer health. Due to data gaps related to the toxicological profile of degradation products generated during processing, the risk assessment for processed products could not be finalised.

Keywords: cyantraniliprole, raspberries, blackberries, Chinese cabbages, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question Numbers: EFSA-Q-2019-00473 and EFSA-Q-2019-00540

Correspondence: pesticides.mrl@efsa.europa.eu

Acknowledgments: EFSA wishes to acknowledge the contribution of Trainees Marianna Raczyk and Silvia Ruocco to this opinion.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2019. Reasoned Opinion on the modification of the existing maximum residue levels for cyantraniliprole in Chinese cabbages, blackberries and raspberries. EFSA Journal 2019;17(11):5903, 27 pp. https://doi.org/10.2903/j.efsa.2019.5903

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

In accordance with the provisions of Article 53 of Regulation (EC) 1107/2009, the United Kingdom granted two 120-day emergency authorisations for the use of plant protection products containing the active substance cyantraniliprole for limited and controlled use in Chinese cabbages, raspberries and blackberries. The emergency uses are expected to lead to residues exceeding the existing maximum residue level (MRLs). In accordance with Article 18(4) of Regulation (EC) No 396/2005 (hereinafter referred to as 'the MRL Regulation'), such authorisations should be immediately notified to the other Member States, the European Commission and European Food Safety Authority (EFSA), together with an appropriate risk assessment with a view to setting a temporary MRL for a specified period or taking any other necessary measure in relation to such products.

In order to establish temporary MRLs for the uses of cyantraniliprole according to the authorised good agricultural practices (GAPs), two applications were submitted, under Article 6(2) of the MRL Regulation, for the setting/modification of the MRLs for cyantraniliprole in Chinese cabbages (application by the Agriculture & Horticulture Development Board (AHDB)) and in raspberries and blackberries (application by the FMC Agro Ltd), respectively.

The United Kingdom, as evaluating Member State (EMS), assessed the data provided by the applicants and drafted two evaluation reports (ER) in accordance with Article 8 of the MRL Regulation, which were submitted to the European Commission and forwarded to EFSA on 17 July and 20 August 2019. To accommodate for the intended uses of cyantraniliprole, the EMS proposed to raise the existing MRL for Chinese cabbages from the limit of quantification (LOQ) 0.01 mg/kg to 8 mg/kg and for raspberries and blackberries from 0.9 mg/kg to 1.5 mg/kg.

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation.

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

The metabolism of cyantraniliprole following either foliar or soil applications in primary crops belonging to the fruit, leafy, cereals/grass, pulses/oilseeds crop groups has been investigated in the framework of the European Union (EU) pesticides peer review. For the uses under assessment in this application, the metabolic behaviour of the active substance in the primary crops under consideration is sufficiently addressed.

According to the EFSA peer review, multiple years of consecutive applications of cyantraniliprole in rotational crops may lead to accumulation of several persistent metabolites. Therefore, long-term rotational crop studies are required to investigate the magnitude of residues of the active substance and its most persistent metabolites. Regarding the crops under assessment, raspberries and blackberries are not grown in rotation with other plants but Chinese cabbages are. However, since the GAP for Chinese cabbages was granted for a limited period of 120 days, the requested long-term rotational crop studies are of low relevance for this application. In line with its previous assessments, EFSA recommends Member States to consider this point when granting national authorisations and where relevant, to take appropriate risk mitigation measures in order to avoid the presence of residues of cyantraniliprole and relevant metabolites in rotational crops.

Studies investigating the effect of processing on the nature of cyantraniliprole (hydrolysis studies) demonstrated that the active substance is hydrolytically stable under the representative pasteurisation and sterilisation conditions. Under boiling conditions, however, cyantraniliprole mainly converts to IN-J9Z38 via cyclisation and, at a lower extent, to the following degradation products: IN-F6L99 and IN-N5M09. These substances were quantified in processing studies with cooked spinaches, being representative commodity for Chinese cabbages and in certain processing studies that are representative for raspberries and blackberries. A data gap on the toxicological relevance of these two degradation products was identified in the previous EFSA assessments. According to the United Kingdom, these data are currently under assessment at national level in the framework of other MRL applications.

Based on the currently available scientific knowledge, EFSA concluded that for the crops assessed in this application, the metabolism of cyantraniliprole in primary crops and its possible degradation in processed products have been sufficiently addressed and that the previously derived residue definitions are applicable. If, however, new scientific evidence on the toxicological relevance of IN-F6L99 and IN-N5M09 becomes available, the residue definition for risk assessment in processed commodities may need to be reconsidered.

Sufficiently validated analytical methods based on LC-MS/MS are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are in line with the data requirements and would allow to derive MRL proposals for parent cyantraniliprole covering the emergency uses in Chinese cabbages, raspberries and blackberries.

Residues of cyantraniliprole in commodities of animal origin were not assessed since the crops under consideration in this MRL application 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 metabolite IN-J9Z38, included in the residue definition for processed commodities, is of similar toxicity as the parent active substance.

The consumer risk assessment for the parent compound was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The estimated long-term exposure to cyantraniliprole accounted for up to 62% of the ADI for NL toddler. The contribution of residues expected in (i) raspberries is up to the 0.7% of the ADI for FI 3 yr, (ii) blackberries up to the 0.4% of the ADI for IE adult and (iii) Chinese cabbages up to the 3.7% of the ADI for SE general.

The identified data gaps on IN-F6L99 and IN-N5M09 do not allow to finalise the risk characterisation and, consequently, the risk assessment for processed products cannot be finalised. Data to address the data gaps on the toxicity of substances have been submitted in the framework of other MRL applications. The data are currently under assessment by the competent national authority.

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				
153010	Blackberries	0.9[(ft)]	Further risk management considerations are required	The number of residue trials submitted is in line with the data requirements and would allow to calculate an MRL of 1.5 mg/kg for the emergency use of parent cyantraniliprole in blackberries and raspberries Since the hazard characterisation for two degradation products that may be formed in processed products is not finalised, the risk assessment for IN-F6L99 and IN-N5M09 cannot be finalised
153030	Raspberries (red and yellow)	0.9[(ft)]		
243010	Chinese cabbages/ pe-tsai	0.01*	Further risk management considerations are required	The number of residue trials submitted is in line with the data requirements and would allow to calculate an MRL of 8 mg/kg for the emergency use of parent cyantraniliprole in Chinese cabbages Since the hazard characterisation for two degradation products that may be formed in processed products is not finalised, the risk assessment for IN-F6L99 and IN-N5M09 cannot be finalised

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(ft): MRL applicable until 30 June 2021, after that date 0.01 (*) mg/kg will be applicable unless modified by a Regulation.

Table of Contents

Assessment

In accordance with Article 53 of Regulation (EC) 1107/2009, the United Kingdom granted two emergency authorisations for the use of plant protection products containing the active substance cyantraniliprole in Chinese cabbages (applicant: Agriculture & Horticulture Development Board (AHDB) and in raspberries and blackberries (applicant: FMC Agro Ltd). The detailed description of the emergency uses of cyantraniliprole which are the basis for the current assessment 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.

In the framework of Regulation (EC) No 1107/2009,[1] cyantraniliprole was evaluated for a number of foliar applications on various crops with the United Kingdom designated as rapporteur Member State (RMS). The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2014). Cyantraniliprole was approved[2] for the use as insecticide on 14 September 2016 (European Commission, 2016).

The EU MRLs for cyantraniliprole have been established in Annex II of Regulation (EC) No 396/2005[3] by Commission Regulations (EU) 2015/845[4] and 2017/171[5] which covered all representative uses assessed in the EFSA peer review and MRL proposals derived in succeeding MRL applications assessed by EFSA (EFSA, 2014, 2015, 2016a,b). In Commission Regulation (EU) 2017/626[6], certain Codex MRLs assessed by JMPR in 2015 (FAO, 2015) were taken over in the EU legislation. Temporary MRLs have been set for leeks, raspberries and blackberries[7] with Commission Regulation (EU) 2018/832[8], following emergency authorisations granted by the United Kingdom (EFSA, 2017a, 2018a). An MRL review under Article 12 of Regulation (EC) No 396/2005 is not foreseen, since the EU MRLs have been established in the framework of the approval of the active substance (EFSA, 2017b).

The current assessment for the modification of MRLs for cyantraniliprole in Chinese cabbages, raspberries and blackberries is based on the evaluation reports submitted by the EMS (United Kingdom, 2019a,b), the draft assessment report (DAR) on cyantraniliprole prepared under Regulation (EC) 1107/2009 (United Kingdom, 2013), the EFSA conclusions on the peer review of the active substance (EFSA, 2014), the Commission's review report on cyantraniliprole (European Commission, 2016) and previous reasoned opinions related to MRL applications on cyantraniliprole (EFSA, 2015, 2016a,b, 2017a, 2018a).

[1] 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.

[2] 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.

[3] Regulation (EC) No 396/2005 of the European 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.

[4] Commission Regulation (EU) 2015/845 of 27 May 2015 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 azoxystrobin, chlorantraniliprole, cyantraniliprole, dicamba, difenoconazole, fenpyroximate, fludioxonil, glufosinate-ammonium, imazapic, imazapyr, indoxacarb, isoxaflutole, mandipropamid, penthiopyrad, propiconazole, pyrimethanil, spirotetramat and trinexapac in or on certain products. OJ L 138, 4.6.2015, p. 1–69.

[5] Commission Regulation (EU) 2017/171 of 30 January 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, azoxystrobin, cyantraniliprole, cyflufenamid, cyproconazole, diethofencarb, dithiocarbamates, fluazifop-P, fluopyram, haloxyfop, isofetamid, metalaxyl, prohexadione, propaquizafop, pyrimethanil, Trichoderma atroviride strain SC1 and zoxamide in or on certain products. OJ L 30, 3.2.2017, p. 45–111.

[6] Commission Regulation (EU) 2017/626 of 31 March 2017 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 acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products. OJ L 96, 7.4.2017, p. 1–43.

[7] Previous emergency authorisation for raspberries and blackberries was for an indoor use.

[8] Commission Regulation (EU) 2018/832 of 5 June 2018 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cymoxanil, deltamethrin, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products. OJ L 140, 6.6.2018, p. 38–86.

For both applications, the data requirements established in Regulation (EU) No 540/2011[9] 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; 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.[10]

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, are presented in Appendix B.

The evaluation reports submitted by the EMS (United Kingdom, 2019a,b) and the exposure calculations using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2018b) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of cyantraniliprole following either foliar or soil applications in primary crops belonging to the fruit, leafy, cereals/grass, pulses/oilseeds crop groups has been investigated in the framework of the EU pesticide peer review (EFSA, 2014). No additional studies were submitted in the current MRL application.

For the uses under assessment, the metabolic behaviour in primary crops is sufficiently elucidated.

1.1.2. Nature of residues in rotational crops

For raspberries and blackberries investigations of residues in rotational crops are not required since these crops are not grown in rotation with other crops.

Chinese cabbages can be grown in rotation with other crops and, therefore, the nature of possible residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that cyantraniliprole is of moderate to high persistence, with a maximum DT_{90} of 376 days, whilst several metabolites demonstrated a moderate to very high persistence with DT_{90} values estimated to be in the range of 4–9 years (EFSA, 2014).

In the framework of the peer review (EFSA, 2014), rotational crop studies in wheat, soybeans, radishes and lettuces were provided. All metabolites identified in primary crops were also detected in the rotational crops investigated. As for primary crops, cyantraniliprole was identified as the main component of the residues in rotational crops (*ca.* 20% to 60% total radioactive residue (TRR)). Several metabolites (IN-J9Z38, IN-JCZ38, IN-MLA84, IN-N7B69) were observed in proportions above 25% TRR in some plant matrices.

With the current MRL application, no additional information on the nature of residues in rotational crops was provided.

1.1.3. 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. It was concluded that under the representative pasteurisation and sterilisation conditions, the active substance is hydrolytically stable. Under boiling conditions, however, cyantraniliprole mainly converts to IN-J9Z38 via cyclisation and, to a lower extent, to the following degradation products: IN-F6L99 and IN-N5M09. The need to investigate the toxicological relevance of the latter two degradation products was already highlighted by EFSA (EFSA, 2014).[11] Information on the toxicological profile for IN-F6L99 and IN-N5M09 has been provided by the applicant in the framework of other MRL applications and it is currently under assessment at national level.

[9] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

[10] 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.

[11] It is noted that the identified data gap on the toxicological relevance of the degradation products identified after processing (boiling) has been raised also in previous MRL applications, currently under clock stop for additional information. The assessment of these applications has been suspended until the information will be provided.

1.1.4. 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; the methods were fully validated in high water-, high oil-, high acid- and high starch content matrices for the determination of residues of cyantraniliprole and its metabolite IN-J9Z38 at an LOQ of 0.01 mg/kg for each analyte (EFSA, 2014).

1.1.5. Storage stability of residues in plants

The storage stability of cyantraniliprole residues in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2014). It was demonstrated that for commodities belonging to the group characterised by a high water content (which includes Chinese cabbages), and high acid content (which includes raspberries and blackberries), residues were stable for at least 24 months when stored at −20°C.

1.1.6. Proposed residue definitions

Based on the pattern for the metabolism of cyantraniliprole in plants, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products and the capabilities of enforcement analytical methods, the following residue definitions were proposed (EFSA, 2014):

- Residue definition for risk assessment for primary crops: 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 products): Cyantraniliprole

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

EFSA would like to reiterate the need to characterise the toxicological properties of two degradation products formed during processing/boiling of cyantraniliprole (i.e. IN-F6L99 and IN-N5M09). This information is currently under assessment at national level in the framework of other MRL applications.

In this case, the residue definition for risk assessment in processed commodities may need to be reconsidered depending on the outcome of the new toxicological data.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

1.2.1.1. Raspberries and blackberries

In support of the MRL application for raspberries and blackberries, the applicant submitted five outdoor residue trials on raspberries, conducted in the northern France (United Kingdom, 2017a) and Germany (United Kingdom, 2019b). The trials were performed in three growing seasons (2012, 2013 and 2015) with two foliar spray applications at an application rate of 75 g a.s./ha.

The samples were analysed 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.

The trials were conducted at a lower application rate (75 g a.s./ha) than the maximum application rate authorised for the emergency use (90 g a.s./ha), but they were within the acceptable deviation range of ± 25%. Thus, the trials were acceptable for deriving an MRL proposal for cyantraniliprole in raspberries and blackberries.

Extrapolation from raspberries to blackberries is possible according to the European Commission Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

1.2.1.2. Chinese cabbages

In support of the MRL application for Chinese cabbages, the applicant referred to four outdoor residue trials on kale conducted in Germany, the Netherlands and the United Kingdom that were submitted in the framework of a previous MRL application (United Kingdom, 2017c). An oil adjuvant was added to the spray mix in all trials which increased the adhesion of the pesticide to foliage and increased rainfastness. For the purpose of the emergency authorisation granted for Chinese cabbages,

the trials were considered acceptable for deriving an MRL proposal for cyantraniliprole in Chinese cabbages.

The samples were analysed 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.

According to the European Commission Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017), extrapolation from kale to the whole subgroup 'leafy brassica' including Chinese cabbages is possible.

The residue trials representative for the emergency uses on Chinese cabbages, raspberries and blackberries are summarised in Appendix B.1.2.1.

1.2.2. Magnitude of residues in rotational crops

As raspberries and blackberries are not grown in rotation with other crops, this section is relevant for Chinese cabbages only.

In the context of the peer review, EFSA considered that an accumulation of several persistent metabolites is expected following multiple years of consecutive applications. The trials submitted in the peer review were conducted with a single seasonal application rate and were, therefore, not fully appropriate to address the possible transfer of residues in rotational crops resulting from the use of cyantraniliprole on primary crops (EFSA, 2014). The peer review concluded that long-term rotational crop studies are required to investigate the magnitude of residues of cyantraniliprole and its most persistent metabolites.

The current MRL application on Chinese cabbages did not provide any new information on the magnitude of residues in rotational crops. Considering that the GAP on Chinese cabbage was granted for a limited period of 120 days, the requested long-term rotational crop studies are considered of low relevance in the context of the present assessment.

1.2.3. Magnitude of residues in processed commodities

1.2.3.1. Raspberries and blackberries

Studies investigating the effect of processing on the magnitude of cyantraniliprole residues in products derived from crops which are of high acidity were assessed during the peer review process (EFSA, 2014). No new studies on the processing of raspberries and blackberries have been submitted in the framework of the current assessment.

In the EFSA peer review, processing factors (PFs) and conversion factors were derived for a number of processed fruits with high acid content (see Appendix B.1.2.3) (EFSA, 2014).

The processing studies on apple sauce provided 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 (EFSA, 2014). Since the details on the processing conditions are not reported, the reasons for the contradictive results cannot be explained.

For raspberries and blackberries, the formation of IN-N5M09 and IN-F6L99 cannot currently be excluded. Hence, the toxicological characterisation of these degradation products would be required to allow a conclusion on possible consumer health risks. Alternatively, specific processing studies should be presented which demonstrate that the degradation products are not present in processed products derived from raspberries and blackberries.

1.2.3.2. Chinese cabbages

Processing studies on cooked spinach leaves have been assessed in the framework of the EU peer review (EFSA, 2014). A PF of 0.2 was calculated for the residue definition for enforcement. In addition, a CF of 8 was derived which indicates that the parent compound is converted to the cyclisation product of cyantraniliprole (IN-J9Z38).

The study with spinach provided evidence that cyantraniliprole is partially converted to IN-J9Z38 (cyclisation product) and, to a lower extent, to the degradation products IN-N5M09 and IN-F6L99 for which the toxicological profile is not fully characterised (EFSA, 2014).

To address the magnitude of IN-N5M09 and IN-F6L99 in processed Chinese cabbages, the applicant used results from a previously submitted study on head cabbages (United Kingdom, 2017c). Starting from raw (inner) cabbage leaves containing the active substance at the level of LOQ (= 0.01 mg/kg),

parent cyantraniliprole and IN-J9Z38 were not detected in the cooked leaves. Because of the low residue level in the unprocessed cabbage leaves, reliable processing and conversion factors could not be derived through this study. Additionally, IN-N5M09 and IN-F6L99 were not analysed in the unprocessed and then processed cabbage leaves. The study does not address the question whether the degradation products are formed in processed Chinese cabbages and, therefore, was not taken into consideration in the current assessment.

For Chinese cabbages, currently the formation of IN-N5M09 and IN-F6L99 cannot be excluded. Hence, the toxicological characterisation of these degradation products would be required to allow a conclusion on possible consumer health concerns. Alternatively, specific processing studies should be presented which demonstrate that the degradation products are not present in processed products derived from Chinese cabbages.

1.2.4. Proposed MRLs

The number and quality of the residue trials were considered in line with the data requirements and allow to calculate MRL proposals for the parent cyantraniliprole in Chinese cabbages, raspberries and blackberries grown in northern Europe (NEU) in accordance with the emergency authorised GAPs.

EFSA noted that the data gaps related to the toxicological profile of the degradation products IN-N5M09 and IN-F6L99 that may be formed in processed products are of relevance for the risk assessment (see Section 3).

2. Residues in livestock

The assessment of residues in livestock is not relevant to the present application as raspberries, blackberries and Chinese cabbages are not used for animal feed purposes.

3. Consumer risk assessment

3.1. Parent cyantraniliprole and IN-J9Z38

EFSA performed a dietary risk assessment for the agreed residue definitions using revision 3.1 of the EFSA PRIMo (EFSA, 2018b, 2019). 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).

Cyantraniliprole did not show evidence of acute toxicity in the available studies (EFSA, 2014) and, therefore, the setting of an ARfD was not required. Consequently, a short-term risk assessment was not carried out.

The ADI value of 0.01 mg/kg body weight (bw) per day derived for cyantraniliprole (EFSA, 2014; European Commission, 2016) was used in the chronic (long-term) risk assessment. The same toxicological reference value was found appropriate for the degradation product/metabolite IN-J9Z38 (EFSA, 2014) which was included in the residue definition for risk assessment (processed products).

For raspberries and blackberries, the long-term exposure assessment was performed taking into account the supervised trials median residue (STMR) values derived for raspberries (United Kingdom, 2019b). For Chinese cabbages, the STMR value derived from studies on kales (United Kingdom, 2017c, 2019a) was used. For commodities for which MRL applications have been previously assessed and for CXLs that were taken over in the EU MRL legislation, STMR values derived by EFSA and JMPR were selected as input values (FAO, 2013, 2018; EFSA, 2014, 2015, 2016a,b, 2018a). The complete list of input values is presented in Appendix D.

The estimated long-term exposure to cyantraniliprole accounted for up to 62% of the ADI for NL toddler. The contribution of residues expected in (i) raspberries is up to the 0.7% of the ADI for FI 3 yr, (ii) blackberries up to the 0.4% of the ADI for IE adult and (iii) Chinese cabbages up to the 3.7% of the ADI for SE general. For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo 3.1 is presented in Appendix C.

EFSA concluded that the long-term intake of residues of cyantraniliprole resulting from the existing uses and the emergency authorised uses in Chinese cabbages, raspberries and blackberries does not exceed the ADI for cyantraniliprole.

3.2. IN-F6L99 and IN-N5M09

The hazard characterisation for the two degradation products IN-F6L99 and IN-N5M09 is not finalised (see Sections 1.1.3, 1.1.6 and 1.2.3). Thus, toxicological reference values are not available to perform a risk assessment. Requests for data on the toxicity of these substances generated during processing (boiling) of cyantraniliprole have been raised in the framework of four applications related to the setting of MRLs for cyantraniliprole in various crops (including leafy brassica) which are currently on clock-stop. Data to address this data gap have been submitted to the competent national authorities. The result of this assessment is expected to be available in due time.

4. Conclusion and Recommendations

In accordance with Article 53 of Regulation (EC) 1107/2009, the United Kingdom granted 120-day emergency authorisations for the use of cyantraniliprole in Chinese cabbages, raspberries and blackberries.

Adequate analytical methods for enforcement are available to control the residues of cyantraniliprole in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

The residue trials submitted in support of the current applications were found to be sufficient to calculate MRL proposals for residues generated in primary crops and to derive input values for the dietary risk assessment (for the residue definition covering the parent compound and its cyclisation product IN-J9Z38). The estimated long-term exposure to cyantraniliprole accounted for up to 62% of the ADI. The contribution of residues expected in the crops under consideration was in the range of 0.4% up to the 3.7% of the ADI.

In processed products derived from Chinese cabbages, raspberries and blackberries, the occurrence of IN-F6L99 and IN-N5M09 cannot be excluded. Since data are missing to finalise the toxicological characterisation for these degradation products, the risk assessment cannot be finalised.

The overall recommendations are summarised in Appendix B.4.

References

EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole. EFSA Journal 2014;12(9):3814, 249 pp. https://doi.org/10.2903/j.efsa.2014.3814

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing maximum residue levels for cyantraniliprole in various crops. EFSA Journal 2015;13(10):4263, 25 pp. https://doi.org/10.2903/j.efsa.2015.4263

EFSA (European Food Safety Authority), 2016a. Reasoned opinion on the modification of the maximum residue levels for cyantraniliprole in rice and coffee. EFSA Journal 2016;14(4):4447, 14 pp. https://doi.org/10.2903/j.efsa.2016.4447

EFSA (European Food Safety Authority), 2016b. Reasoned opinion on the modification of the existing maximum residue level for cyantraniliprole in table grapes. EFSA Journal 2016;14(7):4553, 14 pp.https://doi.org/10.2903/j.efsa.2016.4553

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017a. Reasoned opinion on the setting of maximum residue levels for cyantraniliprole in raspberries and blackberries. EFSA Journal 2017;15(11):5061, 24 pp. https://doi.org/10.2903/j.efsa.2017.5061

EFSA (European Food Safety Authority), 2017b. Statement on pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(12):5080, 8 pp. https://doi.org/10.2903/j.efsa.2017.5080

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2018a. Reasoned Opinion on the setting of a maximum residue level for cyantraniliprole in leeks. EFSA Journal 2018;16(1):5124, 24 pp. https://doi.org/10.2903/j.efsa.2018.5124

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018b. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), 2018c. Recommendations on the use of the proportionality approach in the framework of risk assessment for pesticide residues. EFSA supporting publication 2017:EN-1503, 18 pp. https://doi.org/10.2903/sp.efsa.2017.en-1503
EFSA (European Food Safety Authority), 2019. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1. EFSA supporting publication 2019; 6(3):EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.en-1605
European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.
European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.
European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.
European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.
European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.
European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.
European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals.7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.
European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2016. Final review report for the active substance cyantraniliprole finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 12 July 2016 in view of the approval of cyantraniliprole as active substance in accordance with Regulation (EC) No 1107/2009. SANTE/00111/2015 rev1, 12 July 2016
European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.
FAO (Food and Agriculture Organization of the United Nations), 2013. Cyantraniliprole. In: Pesticide residues in food – 2013. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 219.
FAO (Food and Agriculture Organization of the United Nations), 2015. Pesticide residues in food, Joint FAO/WHO Meeting on Pesticide Residues. Report 2015. FAO Plant Production and Protection Paper 223, 647 pp.
FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Ed. FAO Plant Production and Protection Paper 225, 298 pp.
FAO (Food and Agriculture Organization of the United Nations), 2018. Pesticide residues in food 2018 – Report 2018 - Joint FAO/WHO Meeting on Pesticide Residues. FAO Plant Production and Protection Paper no. 234, Rome, 668 pp. Licence: CC BY-NC-SA 3.0 IGO.
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org
OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.
United Kingdom, 2013. Draft assessment report on the active substance cyantraniliprole prepared by the rapporteur Member State the United Kingdom in the framework of Regulation (EC) No. 1107/2009, May 2013. Available online: www.efsa.europa.eu
United Kingdom, 2017a. Evaluation report on the setting of MRL(s) of cyantraniliprole in raspberries and blackberries. August 2017, 29 pp.
United Kingdom, 2017b. United Kingdom, 2017. Evaluation report on the setting of MRL(s) of cyantraniliprole in leeks. 1 September 2017, 27 pp.
United Kingdom, 2017c. Evaluation report on the setting of MRL(s) of cyantraniliprole in kale, cattle milk, horse milk and other terrestrial animal milk. October 2017, 34 pp (assessment currently under clock stop for additional data request).
United Kingdom, 2019a. Evaluation report on the modification of MRLs for cyantraniliprole in Chinese cabbage. 12 July 2019, 30 pp.
United Kingdom, 2019b. Evaluation report on the modification of MRLs for cyantraniliprole in raspberries and blackberries. 16 July 2019, 42 pp.

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AHDB	Agriculture & Horticulture Development Board
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
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
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
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
NEU	northern Europe
OD	Oil Dispersion
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
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
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization
YF	yield factor

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

Code	Crop name	Region/ country	Outdoor/ Indoor[a]	Pests controlled	Active substance (a.s.)	Formulation type[b]	a.s. conc. in formulation (g/kg or g/L)	Appl. method	Growth stage	No of appl.	Interval (days) Minim.	Water amount (L/ha)	Max. appl. Rate (g a.s./ ha)	PHI (days) [d]	Comments
0153010 0153030	Blackberries Raspberries	NEU/UK	Outdoor	Spotted Wing Drosophila (Drosophila suzukii insect, DROSSU)	Cyantraniliprole	SE	100	Foliar treatment – broadcast spraying	BBCH 71–87	2	7–10	500–1500	90	3	Emergency authorisation under Article 53 of Regulation (EC) No 1107/ 2009. Reported appl. rate from 75 to 90 g a.s./ha
0243010	Chinese cabbages/ pre-tsai	NEU/UK	Outdoor	Diamond Back Moth (Plutella xylostella)	Cyantraniliprole	OD	100	Foliar treatment broadcast – spraying	See comments	2	7	300–800	75	3	Emergency authorisation under Article 53 of Regulation (EC) No 1107/ 2009 Growth stage June to October; second appl. after BBCH 40

NEU: northern European Union; SEU: southern European Union; MS: Member State.
(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. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Tomatoes	Foliar (3 × 150 g/ha, BBCH 14–61)	125 DAT (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)		
	Leafy crops	Lettuces	Foliar (1 × 100 g/ha, BBCH 50)	0, 7, 14, 32 DAT	
			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 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)	124 DAT (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**
	Cereals	Wheat	1 × 450 g a.s./ha	30, 120, 365	All studies conducted with bare soil application Radiolabelled active substance: [cyano-14C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole for wheat; [Pyrazole carbonyl-14C]-cyantraniliprole for soya bean (United Kingdom, 2013)
	Root crops	Radishes		30, 120	
	Leafy crops	Lettuces		30, 120	
	Pulses and oil seeds	Soya beans	1 × 300 g a.s./ha Pilot study not conducted under GLP	25, 120	

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	EFSA (2014)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	See comments	Degraded to IN-J9Z38 (12–14% AR) and to IN-F6L99 and IN-N5M09 (5–8% AR) under baking/boiling/brewing conditions (EFSA, 2014)
	Sterilisation (20 min, 120°C, pH 6)	Yes	EFSA (2014)

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

DAT: days after treatment; BBCH: growth stages of mono- and dicotyledonous plants; a.s: active substance; PBI: plant-back interval; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. 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	Months	Cyantraniliprole, IN-J9Z38, IN-MLA84, IN-N5M09, IN-F6L99	EFSA (2014)
	High acid content	Grapes	−20	≥ 24	Months	Cyantraniliprole, IN-J9Z38, IN-MLA84, IN-N5M09, IN-F6L99	EFSA (2014)
	High starch content	Potatoes	−20	≥ 24	Months	Cyantraniliprole, IN-J9Z38, IN-MLA84, IN-N5M09, IN-F6L99	EFSA (2014)
	High protein content	Dry beans	−20	18	Months	Cyantraniliprole	EFSA (2014)
	High protein content	Dry beans	−20	≥ 24	Months	IN-J9Z38, IN-MLA84, IN-N5M09, IN-F6L99	EFSA (2014)
	High oil content	Peanuts	−20	18	Months	Cyantraniliprole, IN-F6L99	EFSA (2014)
		Peanuts	−20	≥ 24	Months	IN-J9Z38, IN-MLA84, IN-N5M09	EFSA (2014)

B.1.2. Magnitude of residues in plants

B.1.2.1. 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)	CF(d)
Raspberries blackberries	NEU	**Mo/RA:** 0.200, 0.340, 0.346, 0.347, 0.632	Residue trials in raspberries compliant with the GAP (within the 25% deviation). Extrapolation from raspberries to blackberries possible	1.5	0.63	0.35	–
Chinese cabbages/ pe-tsai	NEU	**Mo/RA:** 0.4, 1.1, 2.6, 3.8	Residue trials in kale compliant with the GAP. Extrapolation to Chinese cabbages	8.0	3.8	1.85	–

*: Indicates that the MRL is proposed at the limit of quantification.
(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.
(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 residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. 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, 2014)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Open	Field rotational crop studies at 450 g/ha (3N compared to emergency authorised GAP). Long-term rotational crop studies are required to investigate the magnitude of residues of cyantraniliprole and its most persistent metabolites (EFSA, 2014) Considering that the GAP under assessment was granted for a limited period of 120 days, the requested long-term rotational crop studies are of low relevance for this assessment. In general, EFSA recommends that Member States should consider this point when granting national authorisations and, where relevant, to take appropriate risk mitigation measures in order to avoid the presence of residues of cyantraniliprole and relevant metabolites in rotational crops. The contribution of persistent metabolites generated from other approved, structurally related pesticides (e.g. chlorantraniliprole) would also need to be considered in this context

GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

New processing studies were not submitted in the framework of the current MRL application.

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/ Source
		Individual values (mg/kg)	Median PF		
Head cabbages/leaves cooked	–	n.d.; n.d.; < 0.01	< 0.1	1.0	Not valid studies[a],[c] United Kingdom, 2017c
Spinach/leaves cooked	3	–	0.2	8.0	EFSA (2014)
Citrus/pulp	16	–	0.1	1.0	EFSA (2014)
Citrus/peel	16	–	3.7	1.0	EFSA (2014)
Orange/juice	3	–	0.1	1.0	EFSA (2014)
Orange/wet pulp	3	–	0.2	1.0	EFSA (2014)
Orange/dry pulp	3	–	0.4	1.2	EFSA (2014)
Orange/meal	3	–	0.4	1.2	EFSA (2014)
Orange/marmalade	3	0.06; 0.08; 0.12	0.1	1.0	EFSA (2014)
Orange/oil	3	–	6.2	1.2	EFSA (2014)
Orange/canned	3	–	0.1	1.0	EFSA (2014)
Apple/washed	3	–	0.6	1.0	EFSA (2014)
Apple/puree	3	–	1.1	1.0	EFSA (2014)
Apple/canned	3	0.04; 0.12; 0.13	0.1	1.0	EFSA (2014)
Apple/juice	3	–	0.3	1.0	EFSA (2014)
Apple/wet pomace	3	–	1.0	1.0	EFSA (2014)
Apple/dry pomace	3	–	2.6	1.0	EFSA (2014)

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/ Source
		Individual values (mg/kg)	Median PF		
Apple sauce	3	–	1.4	2.0	EFSA (2014)
Plums/prunes	3	–	1.5	1.1	EFSA (2014)
Grape juice	3	0.81; 0.83; 1.56	0.8	1.0	EFSA (2014)
Grape/raisins	3	–	1.4	1.0	EFSA (2014)

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.
(c): Despite raw cabbage contains up to 1.7 mg/kg cyantraniliprole (United Kingdom, 2017a,b,c), EFSA noted that most of the active substance occurs in the outer leaves which are removed before cooking; the levels of cyantraniliprole on the raw commodity to be processed (i.e. inner leaves) and its processed fractions are at or below the LOQ (≤0.01 mg/kg) and, therefore, were disregarded.

B.2. Residues in livestock

Not triggered based on the intended use because Chinese cabbages, raspberries and blackberries are not used for feed purposes.

Animal residue definition for monitoring (RD-Mo)	Cyantraniliprole
Animal residue definition for risk assessment (RD-RA)	Sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole

B.3. Consumer risk assessment

B.3.1. Parent cyantraniliprole

Acute consumer assessment not relevant since no ARfD has been considered necessary.

ADI	0.01 mg/kg bw per day (EFSA, 2014; European Commission, 2016)
Highest IEDI, according to EFSA PRIMo	62% ADI (NL toddler) Chinese cabbages: 3.7% of ADI (SE general) Raspberries: 0.7% of ADI (FI 3yr) Blackberries: 0.4% of ADI (IE adult)
Assumptions made for the calculations	The calculation was performed with revision 3.1 of the EFSA PRIMo (EFSA, 2018b, 2019). It is based on the median residue levels in the raw agricultural commodities, except for wine grapes for which relevant PF and YF were applied The exposure estimate was updated with information on strawberries, cranberries and mango, based on the revised CXLs for cyantraniliprole in these commodities (FAO, 2018) and data from new trials on Chinese cabbages and raspberries

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; PF: processing factor; YF: yield factor; CXL: Codex maximum residue limit.

B.3.2. Degradation products IN-F6L99 and IN-N5M09

ADI	Hazard characterisation not finalised ADI/ARfD value currently not available
ARfD	
Comments	Due to data gaps on hazard characterisation, the risk assessment cannot be finalised

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Cyantraniliprole				
153010	Blackberries	0.9(ft)	Further risk management considerations are required	The number of residue trials submitted is in line with the data requirements and would allow to calculate an MRL of 1.5 mg/kg for the emergency use of parent cyantraniliprole in blackberries and raspberries Since the hazard characterisation for two degradation products that may be formed in processed products is not finalised, the risk assessment for IN-F6L99 and IN-N5M09 cannot be finalised
153030	Raspberries (red and yellow)	0.9(ft)		
243010	Chinese cabbages/ pe-tsai	0.01*	Further risk management considerations are required	The number of residue trials submitted is in line with the data requirements and would allow to calculate an MRL of 8 mg/kg for the emergency use of parent cyantraniliprole in Chinese cabbages Since the hazard characterisation for two degradation products that may be formed in processed products is not finalised, the risk assessment for IN-F6L99 and IN-N5M09 cannot be finalised

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(ft): MRL applicable until 30 June 2021, after that date 0.01 (*) mg/kg will be applicable unless modified by a Regulation.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Cyantraniliprole

LOQs (mg/kg) range from:	0.01	to:	15.0
Toxicological reference values			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	Not necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2014	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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	62%	NL toddler	6.19	17%	Apples	10%	Milk: Cattle	7%	Pears		62%
	50%	DE child	5.01	20%	Apples	6%	Oranges	4%	Table grapes		50%
	34%	NL child	3.36	9%	Apples	4%	Milk: Cattle	3%	Table grapes		34%
	27%	RO general	2.65	8%	Head cabbages	5%	Wine grapes	3%	Tomatoes		27%
	25%	IE adult	2.49	4%	Wine grapes	3%	Celeries	2%	Oranges		25%
	24%	GEMS/Food G15	2.38	5%	Head cabbages	3%	Wine grapes	2%	Tomatoes		24%
	24%	SE general	2.35	4%	Chinese cabbages/pe-tsai	4%	Head cabbages	3%	Lettuces		24%
	23%	GEMS/Food G11	2.30	6%	Celeries	3%	Wine grapes	2%	Apples		23%
	23%	GEMS/Food G06	2.30	6%	Tomatoes	3%	Table grapes	2%	Oranges		23%
	22%	GEMS/Food G07	2.25	5%	Wine grapes	3%	Celeries	2%	Oranges		22%
	22%	FR child 3 15 yr	2.24	5%	Oranges	4%	Milk: Cattle	3%	Apples		22%
	22%	GEMS/Food G10	2.22	3%	Chinese cabbages/pe-tsai	3%	Lettuces	2%	Head cabbages		22%
	22%	DE women 14-50 yr	2.21	4%	Apples	3%	Oranges	3%	Wine grapes		22%
	21%	GEMS/Food G08	2.15	3%	Wine grapes	3%	Head cabbages	2%	Apples		21%
	20%	DE general	2.04	4%	Apples	3%	Wine grapes	3%	Oranges		20%
	20%	FR toddler 2 3 yr	2.00	5%	Apples	5%	Milk: Cattle	2%	Oranges		20%
	19%	UK infant	1.90	6%	Milk: Cattle	3%	Apples	2%	Oranges		19%
	18%	UK toddler	1.83	3%	Milk: Cattle	3%	Oranges	3%	Apples		18%
	18%	PT general	1.77	8%	Wine grapes	2%	Apples	2%	Tomatoes		18%
	17%	ES child	1.70	3%	Oranges	3%	Lettuces	2%	Milk: Cattle		17%
	16%	NL general	1.57	2%	Apples	2%	Wine grapes	2%	Oranges		16%
	16%	FR adult	1.55	7%	Wine grapes	1%	Apples	0.9%	Oranges		16%
	15%	ES adult	1.50	4%	Lettuces	2%	Oranges	1%	Tomatoes		15%
	15%	DK child	1.46	4%	Apples	2%	Milk: Cattle	1%	Lettuces		15%
	13%	UK vegetarian	1.25	3%	Wine grapes	1%	Oranges	1%	Lettuces		13%
	12%	IT toddler	1.24	2%	Tomatoes	2%	Lettuces	1%	Apples		12%
	12%	IT adult	1.18	3%	Lettuces	2%	Tomatoes	1%	Peaches		12%
	12%	PL general	1.18	3%	Apples	2%	Head cabbages	2%	Tomatoes		12%
	12%	FR infant	1.17	3%	Milk: Cattle	3%	Apples	1%	Cauliflowers		12%
	12%	FI 3 yr	1.16	2%	Strawberries	2%	Apples	1.0%	Tomatoes		12%
	11%	DK adult	1.09	3%	Wine grapes	2%	Apples	0.9%	Tomatoes		11%
	10%	UK adult	1.04	3%	Wine grapes	0.9%	Lettuces	0.9%	Oranges		10%
	9%	LT adult	0.93	3%	Apples	2%	Head cabbages	1%	Tomatoes		9%
	9%	FI 6 yr	0.91	1%	Strawberries	0.9%	Apples	0.7%	Tomatoes		9%
	9%	FI adult	0.88	1%	Lettuces	1.0%	Wine grapes	0.9%	Tomatoes		9%
	3%	IE child	0.30	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.

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

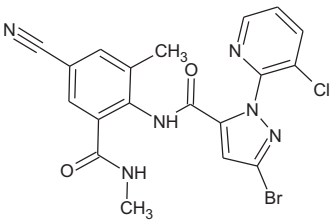
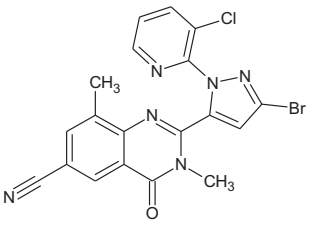
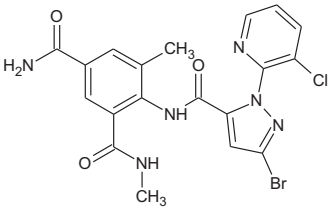
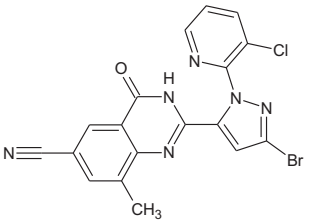
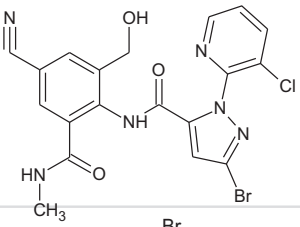
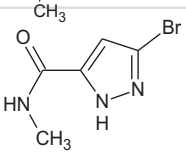
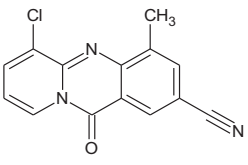
Consumer risk assessment

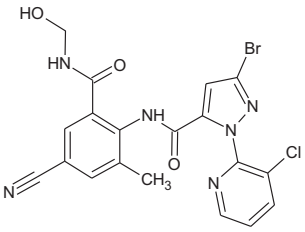
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Cyantraniliprole				
Blackberries, raspberries	0.35	STMR Emergency authorisation under Article 53 of Regulation (EC) No 1107/2009	–	Acute risk assessment not required as an ARfD is not necessary (EFSA, 2014)
Chinese cabbages	1.85	STMR Emergency authorisation under Article 53 of Regulation (EC) No 1107/2009		
Citrus fruit	0.16	STMR (EFSA, 2014)		
Pome fruit	0.16	STMR (FAO, 2013)		
Cherries	0.93	STMR (FAO, 2013)		
Peaches	0.34	STMR (FAO, 2013)		
Plums	0.12	STMR (EFSA, 2014)		
Table grapes	0.26	STMR (EFSA, 2016b)		
Wine grapes	0.32	STMR × PF × YF[(a)] (EFSA, 2014)		
Strawberries	0.46	STMR (FAO, 2018)		
Blueberries (bush berries)	0.75	STMR (FAO, 2013)		
Cranberries	0.012	STMR (FAO, 2018)		
Currants (black, red and 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	0.27	STMR (EFSA, 2014)		
Kaki/Japanese persimmons	0.16	STMR (FAO, 2013)		
Mangoes	0.01	STMR (FAO, 2018)		
Root and tuber vegetables	0.01	STMR (FAO, 2013)		
Garlic, onions, shallots	0.02	STMR (FAO, 2013)		
Spring onions, Welsh 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 (ex. cucumbers)	0.08	STMR (EFSA, 2014)		
Cucumbers	0.065	STMR (FAO, 2013)		
Cucurbits with inedible peel (ex. melon)	0.01	STMR (FAO, 2013)		
Melon	0.06	STMR (EFSA, 2014)		
Flowering brassica	0.56	STMR (FAO, 2013)		
Head brassica	0.56	STMR (FAO, 2013)		
Kohlrabies	0.56	STMR (FAO, 2013)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Head lettuce	0.79	STMR (FAO, 2013)		
Beans without pods	0.01	STMR (EFSA, 2015)		
Peas without pods	0.01	STMR (EFSA, 2015)		
Celeries	2	STMR (FAO, 2013)		
Globe artichokes	0.03	STMR (EFSA, 2015)		
Leeks	0.075	STMR-scaled[(b)] Emergency authorisation under Article 53 of Regulation (EC) No 1107/2009 (EFSA, 2018a)		
Rice	0.01	STMR (EFSA, 2016a)		
Coffee beans	0.01	STMR (EFSA, 2016a)		
Herbal infusions from roots	0.08	STMR (EFSA, 2015)		
Root and rhizome spices	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				
Mammalian terrestrial animals: meat	0.002	STMR (FAO, 2013)[(c)]	–	Acute risk assessment not required as an ARfD is not necessary (EFSA, 2014)
Mammalian terrestrial animals: fat	0.007	STMR (FAO, 2013)[(c)]		
Mammalian terrestrial animals: liver, kidney, edible offal	0.026	STMR (FAO, 2013)[(c)]		
Poultry: meat	0	STMR (FAO, 2013)[(c)]		
Poultry: fat	0	STMR (FAO, 2013)[(c)]		
Poultry: liver, kidney, edible offal	0.004	STMR (FAO, 2013)[(c)]		
Milk	0.016	STMR (FAO, 2013)[(c),(d)]		
Eggs	0.01	STMR (FAO, 2013)[(c)]		

*: Indicates that the input value is proposed at the limit of quantification.
(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): STMR-scaled: residue trial values scaled assuming proportionality for estimation of residues at the GAP target application rate.
(c): Residue values in the FAO (2013) 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 are considered appropriate for use in the exposure calculation.
(d): The EU MRL for cyantraniliprole in milk (Regulation (EU) 2017/626) is the same value as the 2013 CXL for cyantraniliprole in milk (0.02 mg/kg); and therefore the 2013 FAO STMR value for milk is used for the exposure calculation.

Appendix E – Used compound codes

Code/trivial name	Chemical name/SMILES notation[a]	Structural formula[b]
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-JCZ38	4-({[3-bromo-1-(3-chloropyridin-2-yl)-1*H*-pyrazol-5-yl]carbonyl}amino)-N^3,5-dimethylisophthalamide NC(=O)c1cc(C)c(NC(=O)c2cc(Br)nn2c2ncccc2Cl)c(c1)C(=O)NC JFIAYQGSZXIMCY-UHFFFAOYSA-N	
IN-MLA84	2-[3-bromo-1-(3-chloropyridin-2-yl)-1*H*-pyrazol-5-yl]-8-methyl-4-oxo-1,4-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-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	Chemical name/SMILES notation[a]	Structural formula[b]
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	

(a): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019)
(b): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).