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Modification of the existing maximum residue levels for cyantraniliprole in various crops

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), France, received an application from Du Pont de Nemours and Syngenta Crop protection AG to modify the existing maximum residue levels (MRLs) for the active substance cyantraniliprole in various crops. In order to accommodate for the intended uses of cyantraniliprole, France proposed to modify the MRLs for cyantraniliprole on cherries, strawberries, carrots, other root and tuber vegetables except sugar beet, Brussels sprouts, beans and peas (without pods), globe artichokes, herbal infusions from roots and root and rhizome spices. An import tolerance based on the US/Canadian good agricultural practices is also requested for cucumbers. France 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 EFSA. The intended uses on the crops under consideration, except for cucumbers are adequately supported by residue data and MRL proposals can therefore be derived. Adequate analytical enforcement methods are available to control the residues of cyantraniliprole on the relevant crop commodities. Based on the risk assessment results, EFSA concludes that the proposed use of cyantraniliprole on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

Keywords: cyantraniliprole, MRL application, pesticide, insecticide, maximum residue level, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), France, received an application from Du Pont de Nemours and Syngenta Crop protection AG to modify the existing maximum residue levels for cyantraniliprole in various crops. In order to accommodate for the intended uses of cyantraniliprole, France proposed to raise the existing MRLs from the limit of quantification of 0.01 mg/kg to 0.5 mg/kg on strawberries, to 0.15 mg/kg on beans and peas (without pods), to 0.1 mg/kg on globe artichokes and to 0.03 mg/kg on herbal infusions from roots and root and rhizome spices (extrapolated from residue trials on carrots); to decrease the MRL on carrots and other root and tuber vegetables, except sugar beet from 0.05 mg/kg to 0.03 mg/kg, from 2 mg/kg to 0.3 mg/kg on Brussels sprouts and to increase the MRL on cucumbers from 0.3 mg/kg to 0.4 mg/kg. The MRL proposal of 6 mg/kg on cherries (sweet) remained unchanged. France 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 28 January 2015.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) prepared under Regulation (EC) 1107/2009, the conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole and the JMPR Evaluation report.

The toxicological profile of cyantraniliprole was assessed in the framework of the 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 bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of cyantraniliprole in primary crops was investigated in the fruit, leafy, cereal/grass and pulses/oilseeds crop groups following foliar and soil applications. From these studies the peer review established the residue definition as cyantraniliprole for monitoring and risk assessment. For the uses on the crops under consideration, EFSA concludes that the metabolism of cyantraniliprole in primary crops has been sufficiently addressed and that the residue definitions derived are applicable.

EFSA concludes that the submitted residue trials are sufficient to propose an MRL of 0.5 mg/kg on strawberries, 0.2 mg/kg on the crop groups "herbal infusions from roots" and "root and rhizome spices", 0.04 mg/kg on beans without pods, 0.15 mg/kg on peas without pods and 0.1 mg/kg on globe artichokes. No MRL modification is proposed for cherries, carrots, root and tuber vegetables and Brussels sprouts, since the GAPs supported in the framework of this MRL application result in lower MRL proposals than the MRLs currently into force under Regulation (EC) No 396/2005. Sufficient residue trials have not been submitted to derive an import tolerance for cucumbers according to the US/Canadian GAPs. Adequate analytical enforcement methods are available to monitor the residues of cyantraniliprole in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

Studies investigating the nature of cyantraniliprole residues under standard hydrolysis conditions were assessed during the peer review and showed the active substance to be stable under pasteurisation and sterilisation, but slightly degraded to metabolites IN J9Z38, IN N5M09 and IN F6L99 under boiling conditions. Therefore for processed commodities the residue definition was proposed as cyantraniliprole only for enforcement and as the sum of cyantraniliprole and IN J9Z38 expressed as cyantraniliprole for risk assessment. It is however highlighted that toxicological data were requested for metabolites IN-N5M09 and IN-F6L99 since these compounds were recovered at significant levels in cooked spinach leaves only (up to 0.09 mg/kg). These compounds were either not detected or recovered at a very low level (close to the LOQ of 0.01 mg/kg) in other processed commodities (grapes, tomato, olive, citrus fruit, apple, plum and cotton).

Specific studies to assess the magnitude of cyantraniliprole residues in processed cherries and strawberries commodities are not required since these crops are considered as covered by the available processing studies on fruit crops assessed during the peer review. Since the TMDI is less than 10 % of the ADI with regard to the other crops, processing studies on cooked commodities of these crops are not triggered.

The occurrence of cyantraniliprole residues in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature and magnitude of residues, it was concluded that the rotational crop studies were not fully appropriate to address the transfer of the

persistent soil metabolites in plants and that long term rotational crop studies considering cyantraniliprole and its most persistent metabolites following several years of consecutive applications are required. Meanwhile, Member States should consider this point when granting authorisations and where relevant, take appropriate risk mitigation measures in order to avoid the presence of residues of cyantraniliprole and relevant metabolites in rotational crops.

As swedes and turnips are used as feed products as well as citrus/apple pomace and potatoes, a potential carry-over into food of animal origin was assessed. The calculated dietary burden indicated that the trigger value of 0.1 mg/kg dry matter (DM) was exceeded for ruminants and pigs. However, based on the cattle feeding study, no residues above the LOQ are expected in animal matrices and the setting of MRLs is therefore not necessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The CXLs that have been recently transposed in the EU legislation were taken into account in the long-term consumer intake calculation and compared with respectively the MRL proposals on the crops under consideration in this MRL application and the MRLs derived from the representative uses assessed during the peer review.

The total chronic intake calculated accounted for up to 45 % of the ADI (DE child) when these MRLs were considered. The contribution of residues in the crops under consideration to the total consumer exposure was negligible.

EFSA concludes that the proposed use of cyantraniliprole on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a health risk to consumers.

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: cyantraniliprole				
0140020	Cherries	6	6	No change. The EU GAP results in a lower MRL proposal (0.5 mg/kg) than the CXL of 6 mg/kg transposed in Reg. (EU) 2015/845
0152000	Strawberries	0.01*	0.5	Indoor and NEU uses
0210000	Root & tuber vegetables	0.05	0.05	No change. The EU GAPs result in a lower MRL proposals on carrots (0.03 mg/kg) and on the "Other root and tuber vegetables" crops (0.02 mg/kg) than the CXL of 0.05 mg/kg transposed in Reg. (EU) 2015/845
0232010	Cucumbers	0.3	0.3	No change. Additional trials requested to propose an import tolerance according to the US/Canadian GAP.
0242010	Brussels sprouts	2	2	No change. The EU GAP results in a lower MRL proposal (0.3 mg/kg) than the CXL of 2 mg/kg transposed in Reg. (EU) 2015/845
0260020	Beans without pods	0.01*	0.04	NEU and SEU uses
0260040	Peas without pods	0.01*	0.15	NEU and SEU uses
0270050	Globe artichokes	0.01*	0.1	SEU uses
0633000	Herbal infusions from roots	0.01*	0.2	Extrapolation from NEU and SEU trials on carrots, using a dehydration factor of 8
0840000	Root and rhizome spices	0.01*	0.2	

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005
(*): indicates that the MRL is set at the limit of analytical quantification (LOQ)

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Background

Regulation (EC) No 396/2005[1] establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC,[2] repealed by Regulation (EC) No 1107/2009,[3] shall submit to a Member State, when appropriate, an application to set a MRL and to set an import tolerance in accordance with the provisions of Article 7 of the Regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from the company Du Pont de Nemours[4] and Syngenta[5] to modify the existing MRLs in various crops for the active substance cyantraniliprole and to set an import tolerance on cucumbers. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission and to EFSA on 28 January 2015. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00076 and the following subject:

cyantraniliprole: Setting of MRLs for cyantraniliprole in various commodities

France proposed to raise the existing MRLs from the limit of quantification of 0.01 mg/kg to 0.5 mg/kg on strawberries, to 0.15 mg/kg on beans and peas (without pods), to 0.1 mg/kg on globe artichokes and to 0.03 mg/kg on herbal infusions from roots and root and rhizome spices (extrapolated from residue trials on carrots); to decrease the MRL on carrots and other root and tuber vegetables, except sugar beet from 0.05 mg/kg to 0.03 mg/kg, from 2 mg/kg to 0.3 mg/kg on Brussels sprouts and to increase the MRL on cucumbers from 0.3 mg/kg to 0.4 mg/kg. The MRL proposal of 6 mg/kg on cherries (sweet) remained unchanged.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the EMS, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of the Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The active substance and its use pattern

Cyantraniliprole is the ISO common name for 3-bromo-1-(3-chloro-2-pyridyl)-4′-cyano-2′-methyl-6′-(methylcarbamoyl)pyrazole-5-carboxanilide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in appendix C. Cyantraniliprole has been approved for the uses as insecticide.

Cyantraniliprole is a new active substance currently not yet approved under Regulation (EC) No 1107/2009, for which the European Commission has established the completeness of the application dossier and the date of admissibility of the application was recognised as being 10 August 2011;

[1] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.
[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32
[3] 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.
[4] Du Pont de Nemours GmbH, Hugenottenallee 173-175, 63263, Neu-Isenburg, Germany
[5] Syngenta Crop Protection AG, Schwarzwaldallee 215, 4002, Basel, Switzerland

according to the transitional measures provided for in Regulation (EC) No 1107/2009 and Commission Regulation (EU) No 188/2011[6], the procedure of Council Directive 91/414/EEC shall continue to apply.

The representative uses evaluated in the peer review were foliar applications on various crops. The draft assessment report (DAR) has been peer reviewed by EFSA (EFSA, 2014). The DAR included a proposal to set MRLs, in accordance with Article 11(2) of the Regulation. MRLs were assessed on oranges, mandarins, apples/pears, peaches, apricots, plums, vine grapes, potatoes, tomatoes, peppers, aubergines, cucumbers/courgettes, melon, lettuce, beans and olives but MRLs on citrus fruit, plums, wine grapes, tomatoes, peppers, aubergines, cucumbers, courgettes and table olives are not yet implemented in the current European legislation. The peer review has been finalised, but a final decision concerning the approval under Regulation (EC) No 1107/2009 is pending.

The EU MRLs for cyantraniliprole are established in Annex IIIA of Regulation (EC) No 396/2005. The EU MRLs for cyantraniliprole are established at the default MRL of 0.01 mg/kg according to article 18(1)(b) of Regulation (EC) No 396/2005 on the crops for which no CXL was proposed.

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure	Considered by Regulation	Remarks
Conclusion on the peer review	Not yet implemented	The DAR included proposal to set MRLs, in accordance with Article 11(2) of the Regulation
Implementation of CXLs	(EU) No 2015/845	FAO, 2014

Codex Alimentarius has established maximum residue limits (CXLs) for a wide range of commodities, including the crops under consideration for which the CXLs are set at 6 mg/kg for cherries (sweet), 0.3 mg/kg for fruiting vegetables and cucurbits, 0.05 mg/kg for root and tuber vegetables and 2 mg/kg for Brassica vegetables (flowering and head brassica, kohlrabies). The adopted CXLs were included in Regulation (EC) No 396/2005 as MRLs by Regulation (EU) No 2015/845, except those on which the Union presented a reservation to the Codex Committee on Pesticides Residues (CCPR) (leafy vegetables, except lettuce head; fruiting vegetables other than cucurbits). The MRL established in North America for cyantraniliprole in cucumbers is 0.4 mg/kg[7].

The details of the intended/authorised GAPs for cyantraniliprole are given in Appendix A.

Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (France, 2015), the DAR prepared under Regulation (EC) No 1107/2009 (United Kingdom, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole (EFSA, 2014) and the JMPR Evaluation report (FAO, 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[8] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a, b, 2011; OECD, 2011).

[6] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ L 53, 26.02.2011, p. 51–55.

[7] Include source of information, e.g. US Code of Federal Regulations 40 CFR §180.672 cyantraniliprole: tolerances for residues.

[8] 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, 11.06.2011, p. 127–175.

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of cyantraniliprole residues in plant commodities were assessed during the peer review under Regulation (EC) No 1107/2009 (EFSA, 2014). The multi-residue DFG S19 method using LC-MS/MS quantification and its ILV were concluded to be fully validated for the determination of cyantraniliprole and its metabolite IN-J9Z38 residues in high water (apple, peach, tomato, lettuce, cucumber), high acid (orange, lemon, lime), high oil (almond, rape seed) content commodities, dry/starch (wheat grain, potato) matrices and in processed commodities (tomato paste and sun dried tomato) at the LOQ of 0.01 mg/kg for each analyte.

As the commodities under consideration belong to the group of high water and high acid content commodities, EFSA concludes that a sufficiently validated analytical method for enforcing the proposed MRLs for cyantraniliprole on the crops under consideration is available.

1.2. Methods for enforcement of residues in food of animal origin

An analytical method for the determination of residues of cyantraniliprole and its metabolites in commodities of animal origin was evaluated during the peer review under Regulation (EC) No 1107/2009 (EFSA, 2014). The multi-residue DFG S19 method using LC-MS/MS quantification and its ILV were concluded to be fully validated for the determination of cyantraniliprole and its metabolites IN-J9Z38, IN-MLA84 and IN-N7B69 residues in milk, eggs and tissues at the LOQ of 0.01 mg/kg for each analyte.

EFSA concludes that a sufficiently validated analytical method for enforcing the proposed MRLs for cyantraniliprole in food of animal origin is available.

2. Mammalian toxicology

The toxicological profile of the active substance cyantraniliprole was assessed in the framework of the peer review under Regulation (EC) No 1107/2009 (EFSA, 2014). The data were sufficient to derive toxicological reference values compiled in Table 2.

Table 2: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Cyantraniliprole					
ADI	EFSA	2014	0.01 mg/kg bw per day	One year dog	100
ARfD	EFSA	2014	Not allocated. Not necessary	-	-

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of cyantraniliprole in primary crops was evaluated in the framework of the peer review under Regulation (EC) No 1107/2009 (EFSA, 2014) in the fruit, leafy, cereal and pulses/oilseeds crop groups. An overview of the available metabolism studies is presented in Table 3.

Table 3: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling[(a)] (day, DAT)	Comments
Fruit	Tomato	Foliar (3x 150 g/ha, BBCH 14-61)	125 DAT_3 (leaves, fruits)	**Foliar applications**: ^{14}C-Cyano and ^{14}C-pyrazole cyantraniliprole in a 1:1 mixture formulation. **Soil applications:** Separate studies with each label.
		Soil drench (3x 150 g/ha, BBCH 19-61)		
Leafy	Lettuce	Foliar (3x 150 g/ha, BBCH 14-18)	0, 7, 14, 32 DAT_3	
		Soil drench (3x 150 g/ha, BBCH 18-19)	7, 14, 32 DAT_3	
Cereals / Grass	Rice	Foliar (3x 150 g/ha, BBCH 13/14)	140 DAT_3 (straw, grain)	
		Soil granule (1x 300 g/ha, BBCH 13)	175 DAT (straw, grain)	
Pulses / Oilseeds	Cotton	Foliar (3x 150 g/ha, BBCH 16-19)	124 DAT_3 (leaves, bolls)	
		Soil drench (3x 150 g/ha, BBCH 19)	125 DAT_3 (leaves, bolls)	

(a): DATx, days after treatment x

Based on these metabolism studies, the residue definition was proposed as cyantraniliprole for monitoring and risk assessment in the conclusion of the peer review (EFSA, 2014). The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

For the uses on the crops under consideration, EFSA concludes that the metabolism of cyantraniliprole is sufficiently addressed and the residue definition for enforcement and risk assessment agreed during the peer review is applicable.

3.1.1.2. Magnitude of residues

In support of the MRL application, residue trials conducted on cherries, carrots, Brussels sprouts, beans, peas and globe artichokes according to the GAPs proposed for northern and/or southern Europe were provided. In addition, indoor trials performed on cucumbers in the USA and Canada according to the North American GAPs were submitted in support to an import tolerance request. All samples were analysed for the determination of cyantraniliprole residues only.

Since similar residue levels were observed in the samples collected in the northern and southern residue trials conducted on cherries, carrots, beans and peas, the northern and southern datasets were merged together to derive MRL proposals. For strawberries, the MRL was proposed from the trials conducted under indoor conditions with foliar applications, since resulting in higher residue levels compared to the outdoor foliar uses and the indoor uses of the active substance by drip soil applications. MRLs were also derived for the crop groups "herbal infusions from roots" and "root and rhizome spices" by extrapolation from trials conducted on carrot, considering a default dehydration factor of 8 (based on a dry matter content of *ca.* 12 % in carrot and *ca.* 90 % in dried root), since the MRLs apply to the dried commodity.

Cucumber is a major crop and therefore, an import tolerance based on the US/Canadian GAPs was not proposed for cucumbers, since only 5 trials were made available, while a total of 8 trials are required for a major crop (European Commission, 2011).

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 4. When more than one use has been assessed for a crop, EFSA proposes the MRL derived from the more critical residue situation is highlighted in bold in Table 4.

The stability of cyantraniliprole residues in plant matrices under storage conditions prior to analysis was assessed during the peer review under Regulation (EC) No 1107/2009 (EFSA, 2014). Residues of cyantraniliprole were found to be stable at ≤- 20°C for up to 24 months in high water-, high acid- and dry/starch content matrices and up to 18 months in high oil- and dry/protein content matrices. As the trial samples were stored for a maximum period of 12 months under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical methods used to analyse the residue trial samples have been sufficiently validated and were proven to be fit for the purpose (France, 2014).

EFSA concludes that, based on the EU GAPs, the data are sufficient to derive the following MRL proposals:

– 0.5 mg/kg on cherries in NEU and SEU

– 0.5 mg/kg on strawberries in NEU and indoor conditions

– 0.03 mg/kg on carrots in NEU and SEU

– 0.02 mg/kg on other root and tuber vegetables, except sugar beet, in NEU and SEU (by extrapolation from trials on carrots)

– 0.3 mg/kg on Brussels sprouts in NEU and SEU

– 0.04 mg/kg on beans without pods in NEU and SEU

– 0.15 mg/kg on peas without pods in NEU and SEU

– 0.1 mg/kg on globe artichokes in SEU

– 0.2 mg/kg on herbal infusions from roots and root and rhizome spices in NEU and SEU (extrapolation from trials on carrots and considering a dehydration factor of 8)

However, it should be noted that a large number of CXLs adopted by the Codex Alimentarius Commission (FAO, 2014) have been recently transposed in the EU legislation by Regulation (EU) No 2015/845 of 27 may 2015, of which MRLs of:

- 6 mg/kg on cherries,

- 2 mg/kg on Brussels sprouts,

- 0.05 mg/kg for the whole group "Root and tuber vegetables"

Since the EU GAPs assessed in the framework of this MRL application result in lower MRL proposals for cherries, carrots and Brussels sprouts, EFSA would not recommend a modification of the MRLs for these crops and the CXLs transposed by Regulation (EU) No 2015/845 remain applicable.

Table 4: Overview of the available residues trials data

Crop (GAPs)	Region/ Indoor[a]	Residue levels observed in the supervised residue trials[b] (mg/kg)	Recommendations/comments[c]	MRL proposal (mg/kg)	HR[d] (mg/kg)	STMR[e] (mg/kg)
Cherries (2x 100 g/ha, PHI 3 d)	NEU	0.065, 0.092, 0.10, 0.12, 0.13, 0.14, 2x 0.24	MRL, STMR and HR derived from the merged datasets., MRL_{OECD} = 0.49/0.50	0.50	0.26	0.16
	SEU	0.18, 0.19, 0.20, 0.26				
Strawberries (2x 75 g/ha, PHI 1 d) Drip soil applications	NEU	5x <0.01		0.01*	0.01	0.01
Strawberries (4x 75 g/ha, PHI 1 d) Drip soil applications	Indoor	5x <0.01		0.01*	0.01	0.01
Strawberries (2x 75 g/ha, PHI 1 d) Foliar applications	NEU	0.04, 0.043, 0.045, 0.051, 0.054, 0.054, 0.1, 0.12	MRL_{OECD}: 0.19/0.20	0.20	0.12	0.05
Strawberries (4x 75 g/ha, PHI 1 d) Foliar applications	Indoor	0.05, 2x 0.13, 0.14, 0.16, 0.17, 0.23, 0.23, 0.26	MRL_{OECD}: 0.50	**0.50**	0.26	0.16
Carrots (2x 75 g/ha, PHI 14 d)	NEU	13x <0.01, 3x 0.01	MRL, STMR and HR derived from the merged datasets. **- Extrapolation to the whole group of "other root and tuber vegetables except sugar beet".** **- Extrapolation to herbal infusions from roots and root and rhizome spices crop groups** (considering a default dehydration factor of 8).	0.02	0.01	0.01
	SEU	15x <0.01, 0.01		0.2 (dried)	0.08 (dried)	0.08 (dried)
Carrots (2x 75 g/ha, PHI 7 d)	NEU	6x <0.01, 2x 0.01, 0.01, 0.01, 0.02	MRL, STMR and HR derived from the merged datasets. MRL_{OECD}: 0.02/0.03	0.03	0.02	0.01
	SEU	10x <0.01, 0.01, 0.02				
Cucumbers (3x 150 g/ha, PHI 1 d)	Indoor (USA, Canada)	0.03, 0.043, 0.18, 0.19, 0.33	US/Canadian GAP. Maximum seasonal rate: 450 g/ha No MRL proposal due to incomplete residue data set.	-	-	-
Brussels sprouts (2x 75 g/ha, PHI 3 d)	NEU	3x 0.02, 0.03, 2x 0.04	MRL_{OECD}: 0.09	0.09	0.04	0.03
	SEU	0.06, 2x 0.08, 0.10	MRL_{OECD}: 0.24/0.30	**0.30**	0.10	0.08
Bean without pods (2x 75 g/ha, PHI 3 d)	NEU	5x <0.01, 0.02, 0.03	MRL, STMR and HR derived from the merged datasets. MRL_{OECD}: 0.02/0.04	0.04	0.03	0.01
	SEU	7x <0.01, 0.02				

Crop (GAPs)	**Region/ Indoor**[a]	**Residue levels observed in the supervised residue trials**[b] (mg/kg)	**Recommendations/comments**[c]	**MRL proposal** (mg/kg)	**HR**[d] (mg/kg)	**STMR**[e] (mg/kg)
Pea without pods (2x 75 g/ha, PHI 3 d)	NEU	5x <0.01, 0.04, 0.05, 0.08	MRL, STMR and HR derived from the merged datasets. MRL_{OECD}: 0.05/0.15	0.15	0.08	0.01
	SEU	3x <0.01, 2x 0.01, 0.01, 0.04, 0.05				
Globe artichokes (2x 50 g/ha, PHI 7 d)	SEU	0.016, 0.019, 0.033, 0.038, 0.050	MRL_{OECD}: 0.09/0.10	0.1	0.05	0.03

(*): Indicates that the MRL is proposed at the limit of analytical quantification (LOQ).
(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): Individual residue levels considered for MRL calculation are reported in ascending order (2x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.10, 0.15, 0.17), Underlined values: samples taken at a PHI longer than the intended PHI
(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values)
(d): HR: Highest residue level according to the residue definition for risk assessment.
(e): STMR: Median residue level according to residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the nature of cyantraniliprole residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the conclusion of the peer review (EFSA, 2014). It was concluded that the active substance is hydrolytically stable under the representative conditions of pasteurisation and sterilisation, but slightly degraded under boiling conditions to IN J9Z38 (12 to 14 % AR) and to metabolites IN N5M09 and IN F6L99 (5 to 8 % AR), resulting from the cleavage of the parent compound. The residue definitions in processed commodities were therefore proposed as cyantraniliprole for enforcement and as the sum of cyantraniliprole and IN J9Z38 expressed as cyantraniliprole for risk assessment (EFSA, 2014). It is however highlighted that toxicological data were requested for metabolites IN-N5M09 and IN-F6L99 since these compounds were recovered at significant levels in cooked spinach leaves (up to 0.09 mg/kg) whilst they were either not detected or recovered at a very low level (close to the LOQ of 0.01 mg/kg) in other processed commodities (grapes, tomato, olive, citrus fruit, apple, plum and cotton).

Studies investigating the effect of processing on the magnitude of cyantraniliprole residues in processed products were assessed during the peer review and processing factors (PF) were proposed for processed commodities of citrus fruits, apples, plums, grapes, tomatoes, melons, spinaches, olives and cotton seeds (EFSA, 2014). Specific studies to assess the magnitude of cyantraniliprole residues in processed cherries and strawberries commodities are not required since these crops are considered as covered by the available processing studies on fruit crops assessed during the peer review. Regarding root and tuber vegetables, Brussels sprouts, legume vegetables and globe artichokes, since the residue levels in the raw agricultural commodity (RAC) do not exceed the trigger value of 0.1 mg/kg and the contribution of these crops to the chronic intake is less than 10 % of the ADI, processing studies on cooked commodities of these crops are considered as not triggered (European Commission, 1997d).

3.1.2. Rotational crops

The crops under consideration, except cherries, can be grown in rotation with other plants and therefore the possible occurrence of 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 to 9 years (EFSA, 2014). Thus, further studies on rotational crops are required (European Commission, 1997c).

Studies on the nature and magnitude of cyantraniliprole residues in rotational crops were assessed in the framework of the peer review and it was concluded that the residue definitions set for primary crops are also applicable to rotational crops. Field rotational crop studies with a total seasonal application rate of 450 g/ha were also available (1.5 N and 4.5 N compared to the intended indoor and outdoor GAPs). However, since accumulation of several very persistent metabolites is expected following multiple years of consecutive applications, EFSA concludes that the rotational crops field trials conducted with a single application rate are not fully appropriate to address the transfer of cyantraniliprole residues in rotational crops. The peer review concluded that long term rotational crop studies considering the magnitude of residues of cyantraniliprole and its most persistent metabolites were needed. Meanwhile, EFSA concludes that Member States should consider this point when granting authorisations and where relevant, take appropriate risk mitigation measures in order to avoid the presence of residues of cyantraniliprole and relevant metabolites in rotational crops.

3.2. Nature and magnitude of residues in livestock

The use of cyantraniliprole resulted in quantifiable residue levels in swedes and turnips which might be fed to livestock.

3.2.1. Dietary burden of livestock

The median and maximum dietary burden for livestock was calculated using the agreed European methodology (European Commission, 1996). The input values for the dietary burden calculation were

selected according to the current FAO recommendations (FAO, 2009) considering the livestock intake from the feed items in this MRL application (swedes, turnips) and from the representative uses assessed under the peer review (citrus/apple pomace, potatoes).

To conduct the animal burden calculations, EFSA used the STMR and HR levels derived for swedes, turnips and potatoes and the STMR levels as well as the processing factors (PF) and conversion factors for risk assessment (CF) respectively for citrus and apple pomace derived in the framework of the peer review (EFSA, 2014) and the JMPR evaluation (FAO, 2013). The input values for the dietary burden calculation are summarised in Table 5.

Table 5: Input values for the dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Citrus, pomace	0.077	STMR x PF x CF (EFSA, 2014)	0.077	STMR x PF x CF (EFSA, 2014)
Apple, pomace	0.16	STMR x PF x CF (FAO, 2013)	0.16	STMR x PF x CF (FAO, 2013)
Potatoes	0.01	STMR (FAO, 2013)	0.044	HR (FAO, 2013)
Swedes	0.01	STMR (Table 4)	0.01	HR (Table 4)
Turnips	0.01	STMR (Table 4)	0.01	HR (Table 4)

The estimated animal dietary intakes taking into account the feed commodities listed in Table 5 are summarised in Table 6.

Table 6: Results of the dietary burden calculation

Animal	**Median burden** (mg/kg bw)	**Maximum burden** (mg/kg bw)	**Maximum burden** (mg/kg DM)	**>0.1 mg /kg DM** (Y/N)	**Highest contributing commodity**[(a)]
Dairy cattle	0.004	0.006	0.16	Y	Potatoes
Beef cattle	0.012	0.016	0.39	Y	Apple pomace
Poultry	0.001	0.004	0.06	N	Potatoes
Pigs	0.002	0.007	0.18	Y	Potatoes

(a): Considering the maximum dietary animal burden

Since the residue levels observed in the different animal matrices from the cattle feeding study conducted at a dose rate of 3 mg/kg DM (*ca*. 8N, based on the calculated dietary burden for beef cattle) were in the range of 0.01 mg/kg (muscle) to 0.07 mg/kg (liver), no residues above the LOQ are expected in animal matrices when considering the estimated animal intakes reported in Table 6 and based on the uses supported at EU level, the setting of MRLs is therefore not necessary.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population[9] (EFSA, 2007).

A large number of CXLs adopted by the Codex Alimentarius Commission (FAO, 2014) have been recently transposed in the EU legislation by Regulation (EU) No 2015/845. These MRLs were taken into account by EFSA in the long-term consumer intake calculation and compared with respectively the MRL proposals on the crops under consideration in this MRL application and the MRLs derived

[9] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

from the representative uses assessed during the peer review (EFSA, 2014). EFSA used the median residue values (STMR) derived from residue trials on the relevant crops assessed by the JMPR, the STMR values from the residue trials on strawberries, beans and peas, globe artichokes and carrots (extrapolated to herbal infusions from roots and root and rhizome spices, considering a dehydration factor of 8) and the STMR values from the trials on the representative uses. Input values resulting from this comparison are summarised in Table 7.

It is highlighted that for plant and animal commodities, the same residue definitions for enforcement and risk assessment were proposed at Codex and EU level. For animal commodities, the conversion factor for risk assessment of 2 (except for meat and honey: 1) proposed by EFSA in the conclusion of the peer review (EFSA, 2014) was also adopted by the JMPR for the purpose of the dietary intake calculations.

An acute consumer exposure assessment was not performed, since the setting of an ARfD was concluded to be unnecessary for cyantraniliprole.

The input values used for the dietary exposure calculation are summarised in Table 7.

Table 7: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment	
	Input (mg/kg)	**Comment**
Risk assessment residue definition: cyantraniliprole		
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)
Wine grapes	0.32	STMR x PF x YF[(a)] (EFSA, 2014)
Strawberries	0.16	STMR (Table 4)
Blueberries (bush berries)	0.75	STMR (FAO, 2013)
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)
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)

Commodity	Chronic exposure assessment	
	Input (mg/kg)	**Comment**
Risk assessment residue definition: cyantraniliprole		
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)
Head lettuce	0.79	STMR (FAO, 2013)
Beans without pods	0.01	STMR (Table 4)
Peas without pods	0.01	STMR (Table 4)
Celeries	2	STMR (FAO, 2013)
Globe artichokes	0.03	STMR (Table 4)
Coffee bean	0.01	STMR (FAO, 2013)
Herbal infusions from roots	0.08	STMR (Table 4)
Root and rhizome spices	0.08	STMR (Table 4)
Sugar beet root	0.01	STMR (FAO, 2013)
Chicory root	0.01	STMR (FAO, 2013)
Ruminant meat	0.003	0.8 x $STMR_{muscle}$ + 0.2 x $STMR_{fat}$ x CF[(b)] (FAO, 2013)
Ruminant fat	0.014	STMR x CF[(b)] (FAO, 2013)
Ruminant liver, kidney	0.052	STMR x CF[(b)] (FAO, 2013)
Ruminant edible offal	0.052	STMR x CF[(b)] (FAO, 2013)
Milk	0.032	STMR x CF[(b)] (FAO, 2013)
Eggs	0.02	STMR x CF[(b)] (FAO, 2013)
Other plant and animal commodities	MRL[(b)]	Default MRL of 0.01 mg/kg set according to Article 18(1)(b) of Regulation (EC) No 396/2005

(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): CF: Conversion factor for risk assessment of 2 (except for meat and honey: 1) has been proposed for animal commodities in the conclusion of the peer review (EFSA, 2014).

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo when the CXLs transposed in the EU legislation, the MRLs derived on strawberries, beans and peas (without pods), globe artichokes, "herbal infusions from roots" and "root and rhizome spices" crop groups and the MRLs derived from the representative uses assessed under the peer review were considered in the intake calculation. The total chronic intake calculated accounted for up to 45 % of the ADI (DE child). The inclusion of these MRLs in the exposure calculation did not indicate any risk for the European consumers.

Conclusions and recommendations

The information submitted was sufficient to propose the MRLs summarised in the table below:

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: cyantraniliprole				
0140020	Cherries	6	6	No change. The EU GAP results in a lower MRL proposal (0.5 mg/kg) than the CXL of 6 mg/kg transposed in Reg. (EU) 2015/845
0152000	Strawberries	0.01*	0.5	Indoor and NEU uses
0210000	Root & tuber vegetables	0.05	0.05	No change. The EU GAPs result in a lower MRL proposals on carrots (0.03 mg/kg) and on the "Other root and tuber vegetables" crops (0.02 mg/kg) than the CXL of 0.05 mg/kg transposed in Reg. (EU) 2015/845
0232010	Cucumbers	0.3	0.3	No change. Additional trials requested to propose an import tolerance according to the US/Canadian GAP.
0242010	Brussels sprouts	2	2	No change. The EU GAP results in a lower MRL proposal (0.3 mg/kg) than the CXL of 2 mg/kg transposed in Reg. (EU) 2015/845
0260020	Beans without pods	0.01*	0.04	NEU and SEU uses
0260040	Peas without pods	0.01*	0.15	NEU and SEU uses
0270050	Globe artichokes	0.01*	0.1	SEU uses
0633000	Herbal infusions from roots	0.01*	0.2	Extrapolation from NEU and SEU trials on carrots, using a dehydration factor of 8

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005
(*): indicates that the MRL is set at the limit of analytical quantification (LOQ)

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex maximum residue limit (Codex MRL)
d	day
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90 % dissipation (define method of estimation)
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GEMS	Global Environment Monitoring System
GS	growth stage
HPLC	high performance liquid chromatography
HR	highest residue
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
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry detector
MW	Molecular weight
NEU	northern Europe

OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RAC	raw agricultural commodity
RMS	rapporteur Member State
SE	suspo-emulsion
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Good Agricultural Practice (GAPs)

Crop [a]	MS or NEU/SEU or Country	FG or I [b]	Pest or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (days) [l]	Remarks [m]
				type [d-f]	conc. a.s.[i]	Method kind[f-h]	Growth stage & season[j]	Number min-max [k]	Inter-val	g /hL	Water L/ha min-max	g/ha min-max		
Cherries	EU Central	F	*Rhagoletis cerasi* *Drosophila suzukii*	SE	100 g/L	High pressure mist blower	BBCH 79-BBCH 87	2	10 days	-	300-1333	100	3	Minimum recommended rate: 750 mL product/ha. When low spray volume, apply the equivalent amount of product to 1000 L/ha. For improved performance, use with addition of adjuvant oil.
	SEU	F		SE	100 g/L		BBCH 79-BBCH 87	2	10 days	-	300-1500	112.5	3	
Cucumbers	USA, Canada	G	*Lepidopterans*	SE	100 g/L	Hydraulic ground directed boom	BBCH 10-BBCH 89	8	5 days	-	187-935 (foliar) 47-187 (aerial)	150	1	Maximum seasonal application rate per crop = 450 g/ha
Strawberries	EU Central	F	*Spodoptera exigua* *Thrips*	SE	100 g/L	Hydraulic ground directed boom	BBCH 12-BBCH 89	2	7 days	-	200-800	75	1	For improved performance use with the addition of a suitable adjuvant oil
	EU indoor	G		SE	100 g/L		BBCH 12-BBCH 89	4	7 days	-	300-800	75	1	
Carrots	EU Central SEU	F	*Psila rosae*	SE	100 g/L	Hydraulic ground directed boom	BBCH 11-BBCH 89	2	10 days	-	150-800	75	14	
Other root and tuber vegetables	EU Central SEU	F	*Lepidopterans*	SE	100 g/L	Hydraulic ground directed boom	BBCH 11-BBCH 89	2	10 days	-	150-800	75	14	
Herbal infusions from roots	EU Central SEU	F	*Lepidopterans*	SE	100 g/L	Hydraulic ground directed boom	BBCH 11-BBCH 89	2	10 days	-	150-800	75	14	
Root and rhizome spices	EU Central SEU	F	*Lepidopterans*	SE	100 g/L	Hydraulic ground directed boom	BBCH 11-BBCH 89	2	10 days	-	150-800	75	14	
Globe artichokes	EU South	F	*Lepidoptera* *Spodoptera*	SE	100 g/L	Hydraulic ground	BBCH 11-BBCH 89	2	10 days	-	300-1000	50	7	Minimum recommended rate: 400 mL product/ha. When

Crop [a]	MS or NEU/SEU or Country	F G or I [b]	Pest or group of pests controlled [c]	Formulation		Application				Application rate per treatment			PHI (days) [l]	Remarks [m]
				type [d-f]	conc. a.s. [i]	Method kind [f-h]	Growth stage & season [j]	Number min-max [k]	Inter-val	g /hL	Water L/ha min-max	g/ha min-max		
			exigua Spodoptera littoralis			directed boom								low spray volume, apply the equivalent amount of product to 1000 l water/ha.
Brussels sprouts	BE DE LU NL UK FR	F	*Mamestra brassicae spp; Pieris brassicae Pieris rapae; Plutella xylostella Plusia spp;*	SE	100 g/L	Hydraulic ground directed boom	1st BBCH 12-2nd BBCH 20-55	2	7 days	-	200-1000	75	3	
Carrots	BE DE LU NL UK FR	F	*Psila rosae*	SE	100 g/L	Hydraulic ground directed boom	BBCH 20-BBCH 49	2	7 days	-	200-1000	75	7	
Beans without pods	BE DE LU NL UK FR	F	*Heliothis armigera, Ostrinia nubilalis*	SE	100 g/L	Hydraulic ground directed boom	BBCH 20-BBCH 59 and 69-89	2	7 days	-	200-1000	75	3	
Peas without pods	BE DE LU NL UK FR	F	*Cydia nigrican*	SE	100 g/L	Hydraulic ground directed boom	BBCH 69-BBCH 79	2	7 days	-	200-1000	75	3	

Remarks:

(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil-born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), water soluble granule (WG)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) all abbreviations must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants. type of equipment used must be indicated
(i) g/kg or µg/L
(j) Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Appendix B – Pesticide Residue Intake Model (PRIMo)

Cyantraniliprole			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	n.n.
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2014	Year of evaluation:	2014

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment

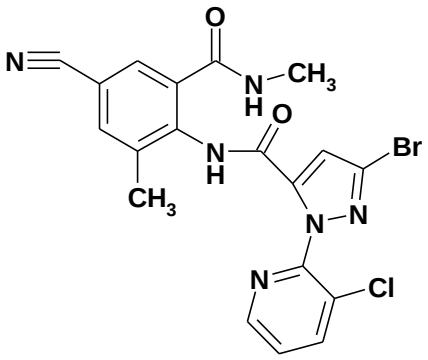
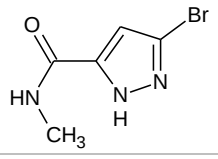
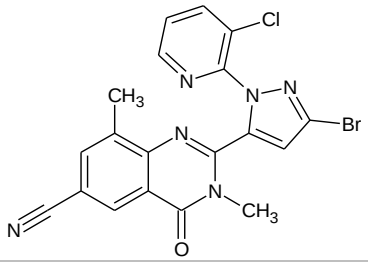
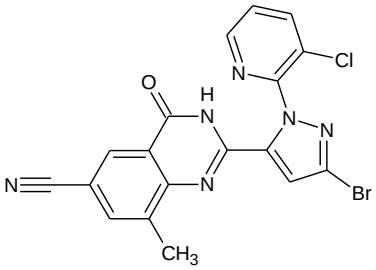
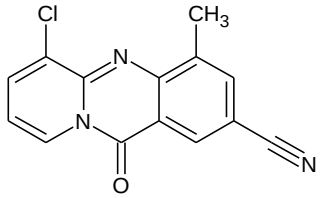
TMDI (range) in % of ADI minimum - maximum	
9	45
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	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	pTMRLs at LOQ (in % of ADI)
45.4	DE child	20.3	Pome fruit	7.4	Citrus fruit	4.6	Milk and cream,	
40.7	NL child	10.8	Pome fruit	9.4	Milk and cream,	6.5	Citrus fruit	
32.9	WHO Cluster diet B	5.7	Wine grapes	5.2	Tomatoes	2.8	Lettuce	
30.9	FR toddler	12.7	Milk and cream,	4.6	Pome fruit	4.4	Flowering brassica	
27.7	IE adult	4.3	Citrus fruit	4.0	Wine grapes	2.6	Celery	
26.2	UK Infant	12.4	Milk and cream,	2.9	Pome fruit	2.2	Citrus fruit	
23.0	UK Toddler	6.6	Milk and cream,	3.7	Citrus fruit	3.0	Pome fruit	
20.6	FR all population	12.8	Wine grapes	1.0	Citrus fruit	1.0	Pome fruit	
20.1	FR infant	8.2	Milk and cream,	4.5	Pome fruit	2.3	Flowering brassica	
19.7	ES child	4.0	Milk and cream,	3.7	Citrus fruit	3.3	Lettuce	
19.3	WHO cluster diet E	5.1	Wine grapes	2.8	Head brassica	1.6	Pome fruit	
18.7	SE general population 90th percentile	4.0	Milk and cream,	3.7	Head brassica	2.3	Pome fruit	
18.5	WHO regional European diet	3.0	Lettuce	2.3	Head brassica	1.9	Tomatoes	
16.8	NL general	3.0	Citrus fruit	2.2	Pome fruit	2.1	Milk and cream,	
16.6	DK child	4.8	Pome fruit	4.0	Milk and cream,	1.1	Lettuce	
16.6	PT General population	8.0	Wine grapes	2.3	Pome fruit	1.5	Tomatoes	
16.2	ES adult	4.2	Lettuce	2.3	Citrus fruit	1.8	Pome fruit	
15.9	WHO cluster diet D	4.1	Head brassica	1.7	Tomatoes	1.6	Milk and cream,	
15.8	WHO Cluster diet F	2.6	Head brassica	2.4	Lettuce	1.9	Wine grapes	
13.4	UK vegetarian	2.6	Wine grapes	1.7	Citrus fruit	1.1	Flowering brassica	
12.7	IT kids/toddler	2.4	Tomatoes	2.3	Lettuce	2.0	Pome fruit	
11.9	IT adult	3.0	Lettuce	2.0	Tomatoes	1.6	Pome fruit	
11.4	DK adult	4.5	Wine grapes	1.7	Milk and cream,	1.6	Pome fruit	
11.3	UK Adult	3.5	Wine grapes	1.1	Citrus fruit	1.0	Milk and cream,	
10.5	PL general population	3.7	Pome fruit	2.1	Head brassica	1.5	Tomatoes	
10.1	LT adult	3.2	Pome fruit	2.2	Head brassica	1.3	Milk and cream,	
9.0	FI adult	1.8	Milk and cream,	1.8	Citrus fruit	1.0	Wine grapes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Cyantraniliprole is unlikely to present a public health concern.

Appendix C – Used compound codes

Code/Trivial name	Chemical name	Structural formula
cyantraniliprole	3-bromo-1-(3-chloro-2-pyridyl)-4′-cyano-2′-methyl-6′-(methylcarbamoyl)pyrazole-5-carboxanilide MW: 473.72 g/mol	
IN-F6L99	3-bromo-N-methyl-1H-pyrazole-5-carboxamide	
IN-J9Z38	2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol- 5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline- 6-carbonitrile	
IN-MLA84	2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol- 5-yl]-8-methyl-4-oxo-1,4-dihydroquinazoline-6- carbonitrile	
IN-N5M09	6-chloro-4-methyl-11-oxo-11H-pyrido[2,1-b]quinazoline-2-carbonitrile	
IN-N7B69	3-bromo-1-(3-chloropyridin-2-yl)-N-[4-cyano-2- (hydroxymethyl)-6-(methylcarbamoyl)phenyl]- 1H-pyrazole-5-carboxamide