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## Setting of maximum residue levels for cyantraniliprole in raspberries and blackberries

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### Abstract

In accordance with Article 53 of Regulation (EC) 1107/2009, the United Kingdom granted a 120-day emergency authorisation for the use of cyantraniliprole in raspberries and blackberries. In order to accommodate for the new uses, the Agriculture & Horticulture Development Board submitted an application to raise the existing maximum residue level (MRL) for the crops concerned. The United Kingdom, as evaluating Member State, summarised the data provided by the applicant in an evaluation report which was submitted to the European Commission and forwarded to EFSA. Sufficient residue trials are available to derive an MRL proposal of 0.9 mg/kg for raspberries and blackberries grown under indoor/greenhouse conditions. For the NEU outdoor use on raspberries/blackberries, the available information was insufficient to derive an MRL proposal. Adequate analytical methods for enforcement are available to control the residues of cyantraniliprole in the commodities under consideration. Based on the risk assessment results, EFSA concluded that intake of residues resulting from the use of cyantraniliprole according to the reported agricultural practices (indoor/greenhouse use) is unlikely to present a risk to consumer health.

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## Summary

In accordance with the provisions of Article 53 of Regulation (EC) 1107/2009, the United Kingdom granted an emergency authorisation for the placing on the market of a plant protection product containing the active substance cyantraniliprole, for a period not exceeding 120 days, for limited and controlled use in raspberries and blackberries. The emergency use is expected to lead to residues exceeding the existing maximum residue level (MRL) and the United Kingdom has authorised the placing on the market within its territory of treated raspberries and blackberries not complying with the existing EU MRL, in accordance with Article 18(4) of Regulation (EC) No 396/2005 (hereinafter referred to as 'the MRL Regulation'). In order to accommodate the use of cyantraniliprole according to the authorised good agricultural practices (GAPs), the Agriculture & Horticulture Development Board submitted an application under Article 6(2) of the MRL Regulation to set specific MRLs for cyantraniliprole in raspberries and blackberries.

The United Kingdom, as evaluating Member State (EMS), assessed the data provided by the applicant and drafted an evaluation report in accordance with Article 8 of the MRL Regulation, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA). The EMS proposed that a temporary MRL in the framework of Article 16 of the MRL Regulation is justified since it is based on an emergency authorisation of a plant protection product in accordance with Article 53 of Regulation (EC) 1107/2009, and the products concerned constitute a minor component of consumers' diet and the expected residues following the emergency use do not pose an unacceptable risk to consumers or animals. The EMS proposed to raise the existing MRLs of cyantraniliprole in raspberries and blackberries from the limit of quantification (LOQ) of 0.01 to 0.9 mg/kg.

EFSA has based its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) prepared under Regulation (EC) No 1107/2009, the European Commission review report on cyantraniliprole, the conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole, the JMPR evaluation reports, as well as the conclusions from previous EFSA opinions on cyantraniliprole.

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 pesticides peer review.

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

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

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC-MS/MS) are available to quantify residues in the crops assessed in 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 submitted trials on indoor raspberries were performed at lower total application rates than the target application rate for the emergency authorised GAPs and EFSA applied the proportionality approach to estimate the residues values expected at the GAP target application rate.

The number and quality of the trials on indoor raspberries is sufficient to derive a MRL of 0.9 mg/kg for raspberries and blackberries grown under indoor/greenhouse conditions. The available data are insufficient to support the outdoor/field use GAPs for the crops under consideration.

Specific studies investigating the magnitude of cyantraniliprole residues in processed commodities are not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI).

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 ADI of 0.01 mg/kg body weight (bw) per day. The setting of an acute reference dose (ARfD) has been deemed unnecessary and therefore a short-term dietary risk assessment is not required.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRiMo). The estimated long-term dietary intake was in the range of 8.9–73.6% of the ADI and the maximum contribution of residues expected in blackberries and raspberries is < 1% of ADI.

EFSA concluded that the proposed use of cyantraniliprole on raspberries and blackberries will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumer health.

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

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
<b>Enforcement residue definition:</b> Cyantraniliprole				
153010	Blackberries	0.01*	0.9	The submitted data are sufficient to derive an MRL proposal of 0.9 mg/kg for the indoor/greenhouse use GAP on raspberries with an extrapolation to indoor/greenhouse blackberries. A consumer health concern is unlikely. For the NEU field use GAP, the available data were found to be insufficient to derive an MRL proposal. Considering that the emergency authorisation on these crops is granted for a limited period of time (120 days), further risk management considerations are required to decide whether the proposed MRLs should be established for a limited time period.
153030	Raspberries	0.01*	0.9	

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern Europe.

\*: 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.

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## Background

In accordance with the provisions of Article 53 of Regulation (EC) 1107/2009<sup>1</sup>, the United Kingdom granted an emergency authorisation for the placing on the market of a plant protection product containing the active substance cyantraniliprole, for a period not exceeding 120 days, for limited and controlled use in raspberries and blackberries, on the basis that such a measure appears necessary because of a danger which cannot be contained by any other reasonable means. The emergency use is expected to lead to residues exceeding the existing maximum residue level (MRL) and the United Kingdom has authorised the placing on the market within its territory of treated raspberries and blackberries not complying with the existing EU MRL, in accordance with Article 18(4) of Regulation (EC) No 396/2005<sup>2</sup> (hereinafter referred to as 'the MRL Regulation'). In order to accommodate the use of cyantraniliprole according to the authorised good agricultural practices, the Agriculture & Horticulture Development Board<sup>3</sup> submitted an application under Article 6(2) of the MRL Regulation to set specific MRLs for cyantraniliprole in raspberries and blackberries.

The United Kingdom, as evaluating Member State (EMS), assessed the data provided by the applicant and drafted an evaluation report in accordance with Article 8 of the MRL Regulation, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 29 August 2017. The EMS proposed that a temporary MRL in the framework of Article 16 of the MRL Regulation is justified since it is based on an emergency authorisation of a plant protection product in accordance with Article 53 of Regulation (EC) 1107/2009, and the products concerned constitute a minor component of consumers' diet and the expected residues following the emergency use do not pose an unacceptable risk to consumers or animals (United Kingdom, 2017).

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2017-00640 and the following subject:

*Cyantraniliprole – MRLs in raspberries and blackberries.*

The EMS proposed to raise the existing MRLs of cyantraniliprole in raspberries and blackberries from the limit of quantification (LOQ) of 0.01 to 0.9 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

## Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- An assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- The anticipated LOQ for the pesticide/product combination;
- An assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- The contribution to the intake due to the residues in the product for which the MRLs was requested;
- Any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within three months from the date of receipt of the application.

The evaluation report submitted by the EMS (United Kingdom, 2017) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

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

<sup>2</sup> Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

<sup>3</sup> Agriculture & Horticulture Development Board, Stoneleigh Park, Kenilworth, CV8 2TL, Warwickshire, United Kingdom.

## The active substance and its use pattern

The detailed description of the intended uses of cyantraniliprole which are the basis for the current MRL application is reported in Appendix A.

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

Cyantraniliprole was evaluated as a new active substance in the framework of Regulation (EC) No 1107/2009 with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as foliar applications on various crops. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2014).

Cyantraniliprole was approved<sup>4</sup> for the use as an insecticide on 14 September 2016.

The EU MRLs for cyantraniliprole are established in Annex II of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed. EFSA has issued several reasoned opinions on the modification of MRLs for cyantraniliprole (EFSA, 2015, 2016a,b). The proposals from these reasoned opinions have been considered in regulations<sup>5</sup> for EU MRL legislation.

## Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (United Kingdom, 2017), the DAR prepared under Regulation (EC) No 1107/2009 (United Kingdom, 2013), the European Commission review report on cyantraniliprole (European Commission, 2016), the conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole (EFSA, 2014), the JMPR evaluation reports (FAO, 2013, 2016), as well as the conclusions from previous EFSA opinions on cyantraniliprole (EFSA, 2015, 2016a,b).

For this application, the data requirements established in Regulation (EU) No 544/2011<sup>6</sup> and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a,b,c,d,e,f,g, 2000, 2010a,b, 2016; OECD, 2011, 2016). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011<sup>7</sup>.

A selected list of end points of the studies assessed by EFSA in the framework of EU pesticides peer review, including the end points of studies submitted in support of the current MRL application, are presented in Appendix B.

### 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 pesticides peer review (EFSA, 2014). No additional studies were submitted in the current MRL application.

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

<sup>4</sup> Commission Implementing Regulation (EU) 2016/1414 of 24 August 2016 approving the active substance cyantraniliprole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 230, 25.8.2016, p. 16–19.

<sup>5</sup> 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, fluzifop-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.

<sup>6</sup> COMMISSION REGULATION (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, pp. 1–155.

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



### 1.1.2. Nature of residues in rotational crops

As the proposed uses of cyantraniliprole are on permanent crops, investigations of residues in rotational crops are not required. However, residues in rotational crops were investigated in the framework of the peer review and metabolism in rotational crops was found to be similar to primary crops (EFSA, 2014).

### 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 (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 and in a minor proportion, to metabolites IN-N5M09 and IN-F6L99 resulting from the cleavage of the parent compound. Therefore, the residue definitions in processed commodities were proposed as cyantraniliprole for enforcement and as the sum of cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole for risk assessment (EFSA, 2014).

### 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 (EFSA, 2014) and were shown to be fully validated in high water-, high oil-, high acid- and high dry/starch content matrices.

The multiresidue DFG S19 method using liquid chromatography with tandem mass spectrometric (LC-MS/MS) quantification and its independent laboratory validation (ILV) were concluded to be fully validated for the determination of residues of cyantraniliprole and its metabolite IN-J9Z38 in high water (apples, peaches, tomatoes, lettuces, cucumbers), high acid (oranges, lemons, limes), high oil (almonds, rape seeds) content commodities, dry/starch (wheat grain, potatoes) matrices and in processed commodities (tomato paste and sun dried tomatoes) at the LOQ of 0.01 mg/kg for each analyte (EFSA, 2015).

The methods are sufficiently validated for residues of cyantraniliprole in the crops under consideration. The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg for each analyte in crops belonging to the high water content commodities.

### 1.1.5. Stability of residues in plants

The storage stability of cyantraniliprole in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2014). It was demonstrated that in crops assessed in the framework of this application, residues were stable for at least 24 months when stored at  $-20^{\circ}\text{C}$ .

### 1.1.6. Proposed residue definitions

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

- Residue definition for risk assessment for primary crops: Cyantraniliprole (except for processed commodities)
- Residue definition for risk assessment for processed commodities: Sum cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole
- Residue definition for enforcement: Cyantraniliprole.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition. Taking into account the proposed use assessed in this application, EFSA concluded that these residue definitions are appropriate and no modification is required.



## 1.2. Magnitude of residues in plants

### 1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials performed in outdoor raspberries (one trial; northern France) and indoor raspberries (five trials; conducted in Germany, the Netherlands and the United Kingdom). The samples were analysed for the parent compound cyantraniliprole in accordance with the residue definitions for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The five trials on indoor raspberries were conducted at total application rates which were lower than the target application rate for the emergency authorised GAPs, by factors of between 0.82 and 0.86. The other parameters of the trials on indoor raspberries are consistent with the GAP for indoor/greenhouse raspberries. Although the trials on indoor raspberries were within the acceptable deviation of 25% of the target application rate, EFSA applied the proportionality approach (CAC, 2013; OECD, 2016) since all trials were under dosed, leading to a systematic bias. Thus, to estimate the MRL proposal required for the indoor/greenhouse GAP, the trials were scaled up using scaling factors ranging from 1.17 to 1.22.

The trial on outdoor raspberries was conducted at a total application rate that was lower than the target application rate for the GAP reported in the application form, but within the acceptable deviation of 25% (0.84N). In accordance with the data requirements, a minimum of four GAP-compliant trials would be required for raspberries and blackberries.

The EMS proposed the establishment of temporary MRLs to accommodate the emergency authorised outdoor uses on raspberries and blackberries. According to the EMS, the indoor trials are expected to be more critical and therefore no additional trials would be required for the outdoor use; the MRL derived for the indoor use would be sufficient to cover the outdoor use (United Kingdom, 2017). To support this argumentation, the EMS referred to residue trials performed with cyantraniliprole on beans with pods, lettuce and strawberry which were performed under indoor and outdoor conditions. The EMS is of the opinion that the trials provide sufficient evidence that indoor uses lead to higher residues than outdoor uses.

EFSA compared the results of indoor and outdoor residue trials in beans with pods and strawberries. Using a statistical method (Mann–Whitney U-test), the indoor and outdoor trials were found to belong to similar populations. Thus, according to EFSA these data do not provide sufficient evidence to demonstrate that indoor trials are more critical than the outdoor use. For lettuce, the comparison of indoor and outdoor trials give an indication that lettuce grown under indoor conditions contain higher residues when treated with the same application rate and harvested at the same pre-harvest interval (PHI) than lettuce grown under outdoor conditions. However, lacking information whether the trials were performed on open leaf varieties or on head forming varieties, the identified difference is not necessarily related to the indoor/outdoor conditions.

EFSA concluded that the available data do not provide sufficient evidence to demonstrate that the indoor use conditions on raspberries and blackberries lead to higher residues than the outdoor use performed with the same application rate and PHI.

### 1.2.2. Magnitude of residues in rotational crops

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

### 1.2.3. Magnitude of residues in processed commodities

Studies investigating the effect of processing on the magnitude of cyantraniliprole residues in processed products were assessed during the peer review process and processing factors (PF) were proposed for several processed commodities (EFSA, 2014). New studies on the processing of raspberries and blackberries have not been submitted in the framework of the current application and are not necessary as the total theoretical maximum daily intake (TMDI) for raspberries and blackberries is less than 10% of the ADI (European Commission, 1997d).

#### 1.2.4. Proposed MRLs

The number and quality of the trials on indoor raspberries is sufficient to derive a MRL of 0.9 mg/kg for raspberries grown under indoor/greenhouse conditions, with possible extrapolation to blackberries in accordance with the EU extrapolation rules (European Commission, 2017).

Only one residue trial compliant with the NEU outdoor GAP for raspberries was provided, which showed a higher residue value compared to the indoor residue trials values. Based on the available information, EFSA does not share the view that the indoor use necessarily represents a more critical use than the outdoor use. The number of residue trials compliant with the NEU outdoor use on raspberries is insufficient to derive a MRL proposal for the outdoor use.

The available data which are considered appropriate to derive a MRL proposal and risk assessment values for the indoor uses on the commodities under evaluation are summarised in Appendix B.1.2.1. In Section 3, EFSA assessed whether residues on these crops are likely to pose a consumer health risk.

## 2. Residues in livestock

Not relevant as raspberries and blackberries are not used for feed purposes.

## 3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference value for cyantraniliprole used in the risk assessment (ADI value) was derived in the framework of the EU pesticides peer review (EFSA, 2014).

The long-term exposure assessment was performed taking into account the STMR scaled values derived for the commodities assessed in this application; for the remaining commodities covered by the MRL regulation, the existing EU MRLs and STMR values derived in previous MRL applications and JMPR evaluations were selected as input values (FAO, 2013; EFSA, 2014, 2015, 2016a,b). The complete list of input values is presented in Appendix D.1.

The estimated long-term dietary intake was in the range of 8.9–73.6% of the ADI and the maximum contribution of residues expected in blackberries and raspberries is < 1% of ADI. Further detail on the contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is provided in the report sheet of the PRIMo, which is presented in Appendix C.

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

## Conclusions and recommendations

Applying the proportionality approach, the number and quality of the trials on indoor raspberries is sufficient to derive a MRL of 0.9 mg/kg for raspberries grown under indoor/greenhouse conditions with a possible extrapolation to blackberries grown under indoor/greenhouse conditions.

The number of trials performed under outdoor use conditions is insufficient to support the outdoor/field use GAPs for the crops under consideration.

Only one residue trial compliant with the NEU outdoor GAP on raspberries was provided, which showed a higher residue value than the indoor residue trials. Based on the available data, it cannot be concluded that the indoor use represents the most critical scenario.

Considering that the emergency authorisation on these crops is granted for a limited period of time (120 days), further risk management considerations are required to decide whether the proposed MRLs should be established for a limited time period.

Adequate analytical methods for enforcement are available to control the residues of cyantraniliprole in plant matrices under consideration.

Based on the risk assessment results, EFSA concluded that the intake of residues resulting from the use of cyantraniliprole according to the emergency authorised agricultural practices is unlikely to present a risk to consumer health.

The MRL recommendations are summarised in Appendix B.4.

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## Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HR	highest residue
IEDI	international estimated daily intake
IENTI	international estimated short-term 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
Mo	monitoring
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
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SE	suspo-emulsion
SEU	southern Europe
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
UV	ultraviolet (detector)
WHO	World Health Organization
YF	yield factor

## Appendix A – Good Agricultural Practice (GAPs) triggering the application for setting a new MRL

Crop and/or situation	NEU, SEU, MS or country	F G or I <sup>(a)</sup>	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days) <sup>(d)</sup>	Remarks
				Type <sup>(b)</sup>	Conc. a.s.	Method kind	Range of growth stages & season <sup>(c)</sup>	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	g a.s./ha min–max		
Raspberry	UK	F	Spotted wing drosophila ( <i>Drosophila suzukii</i> , insect, DROSSU)	SE	100 g/L	Tractor mounted hydraulic sprayer	BBCH 71-87	2	7–10 days between applications	6–18	500–1,500	90 g a.s./ha (180 g a.s./ha total)	3	Emergency authorisation under Article 53 of Regulation (EC) No 1107/2009
Raspberry	UK	G/I	Spotted wing drosophila ( <i>Drosophila suzukii</i> , insect, DROSSU)	SE	100 g/L	Tractor mounted hydraulic sprayer	BBCH 71-87	2	7–10 days between applications	6–18	500–1,500	90 g a.s./ha (180 g a.s./ha total)	3	Emergency authorisation under Article 53 of Regulation (EC) No 1107/2009
Blackberry	UK	F	Spotted wing drosophila ( <i>Drosophila suzukii</i> , insect, DROSSU)	SE	100 g/L	Tractor mounted hydraulic sprayer	BBCH 71-87	2	7–10 days between applications	6–18	500–1,500	90 g a.s./ha (180 g a.s./ha total)	3	Emergency authorisation under Article 53 of Regulation (EC) No 1107/2009
Blackberry	UK	G/I	Spotted wing drosophila ( <i>Drosophila suzukii</i> , insect, DROSSU)	SE	100 g/L	Tractor mounted hydraulic sprayer	BBCH 71-87	2	7–10 days between applications	6–18	500–1,500	90 g a.s./ha (180 g a.s./ha total)	3	Emergency authorisation under Article 53 of Regulation (EC) No 1107/2009

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; MRL: maximum residue level; a.s.: active substance; SE: suspo-emulsion.

(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 pre-harvest 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)	
	Fruit crops	Tomato	Foliar (3 × 150 g/ha, BBCH 14-61)	125 DAT (leaves, fruits)	
			Soil drench (3 × 150 g/ha, BBCH 19-61)		
	Leafy crops	Lettuce	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)	
	Radiolabelled active substance: Foliar applications: <sup>14</sup> C-cyano and <sup>14</sup> C-pyrazole cyantraniliprole in a 1:1 mixture formulation; Soil applications: Separate studies with each label. Reference: EFSA (2014)				
	Rotational crops	Crop groups	Crop(s)	Application(s)	PBI (DAT)
Not required as the proposed uses of cyantraniliprole are on permanent crops					
Processed commodities (hydrolysis study)	Conditions			Investigated?	
	Pasteurisation (20 min, 90°C, pH 4)			Yes	
	Baking, brewing and boiling (60 min, 100°C, pH 5)			Yes	
	Sterilisation (20 min, 120°C, pH 6)			Yes	
Comment: Stable under sterilisation and pasteurisation conditions. Degraded to IN-J9Z38 (12–14% AR) and to IN-F6L99 and IN-N5M09 (5–8% AR) under boiling/baking/ brewing conditions. Reference: EFSA (2014)					

DAT: days after treatment; BBCH: growth stages of mono- and dicotyledonous plants; PBI: plant back interval; AR: applied radioactivity.



Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Yes
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 cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole
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 in plants (matrices with high water content, cereal and dry product, fatty product and acidic matrices) ILV is also available Reference: EFSA (2014)

#### B.1.1.2. Stability of residues in plants

Plant products	Category	Commodity	T (°C)	Stability (Months)
	High acid content	Grapes	–20	≥ 24
Reference: EFSA (2014)				



## B.1.2. Magnitude of residues in plants

### B.1.2.1. Summary of residues data from the supervised residue trials

Crop (supervised trials)	Region/ Indoor <sup>(a)</sup>	Residue levels observed in the supervised residue trials (mg/kg)	Comments (OECD calculations; unrounded/rounded result)	Crop (MRL application/request)	MRL proposals (mg/kg)	HR <sub>Mo</sub> <sup>(b)</sup> (mg/kg)	STMR <sub>Mo</sub> <sup>(c)</sup> (mg/kg)	CF <sup>(d)</sup>
Raspberry (RD-Mo=RD-RA, except for processed commodities)	NEU (Outdoor)	<b>Mo/RA:</b> 0.34	The residue trial was performed at a lower total application rate but within the '25% tolerance limit' rule	Raspberries	–	–	–	–
				Blackberries	–	–	–	–
	Indoor	<b>Mo/RA:</b> 0.12, 0.17, 0.25, 0.27, 0.32 <b>Mo/RA scaled:</b> 0.140, 0.200, 0.305, 0.325, 0.387	Residue trials compliant with the greenhouse /indoor application GAPs only. The residue trials were performed at lower total application rates and were scaled assuming proportionality for estimation of expected residues at the GAP target application rate; scaling factors: 1.17, 1.18, 1.22, 1.20 and 1.21, respectively. MRL <sub>OECD</sub> : 0.81/0.90 Possible extrapolation to blackberries (European Commission, 2017)	Raspberries	<b>0.9</b>	0.39	0.30	–
				Blackberries	<b>0.9</b>	0.39	0.30	–

OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; RD-Mo: residue definition for monitoring; RD-RA: residue definition for risk assessment; GAP: Good Agricultural Practice.

\*: 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 according to the residue definition for monitoring.

(c): Supervised trials median residue according to the residue definition for monitoring.

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

### B.1.2.2. Conversion factors for risk assessment in plant products

Not relevant.

### B.1.2.3. Residues in succeeding crops

Not required as the proposed uses of cyantraniliprole are on permanent crops.

### B.1.2.4. Processing factors

Studies on the processing of raspberries and blackberries are not provided and are not required as the total theoretical maximum daily intake (TMDI) for raspberries and blackberries is less than 10% of the ADI.

## B.2. Residues in livestock

Not triggered based on the intended uses on raspberries and blackberries, which 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

ARfD	ARfD has been considered unnecessary (EFSA, 2014)
Highest IESTI, according to EFSA PRIMo	Acute risk assessment not required since an ARfD is considered unnecessary (EFSA, 2014)
Assumptions made for the calculations	–
ADI	0.01 mg/kg bw per day (EFSA, 2014)
Highest IEDI, according to EFSA PRIMo	73.6 % ADI (WHO Cluster diet B) Maximum contribution of crops assessed: Blackberries: 0.4% of ADI (IE adult) Raspberries: 0.4% of ADI (NL child)
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities from the residue trials that were compliant with the greenhouse/indoor application GAPs. The residue values were scaled assuming proportionality for estimation of expected residues at the GAP target application rate. The median scaled residue level derived for raspberries was extrapolated to blackberries. For the remaining crops, the input values derived in previous assessments or the existing MRLs were used to estimate the overall long-term exposure

## B.4. Recommended MRLs

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
<b>Enforcement residue definition:</b> Cyantraniliprole				
153010	Blackberries	0.01*	0.9	The submitted data are sufficient to derive an MRL proposal of 0.9 mg/kg for the indoor/greenhouse use GAP on raspberries with an extrapolation to indoor/greenhouse blackberries. A consumer health concern is unlikely. For the NEU field use GAP, the available data were found to be insufficient to derive an MRL proposal. Considering that the emergency authorisation on these crops is granted for a limited period of time (120 days), further risk management considerations are required to decide whether the proposed MRLs should be established for a limited time period.
153030	Raspberries	0.01*	0.9	

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern Europe.

\*: 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.

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

<b>Cyantraniliprole</b>			
Status of the active substance:	Approved	Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
<b>Toxicological end points</b>			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	n.n.
Source of ADI:	EFSA 2014	Source of ARfD:	EFSA
Year of evaluation:	2014	Year of evaluation:	2014

Pesticides – Web Version – EU MRLs from Reg. (EU) 2017/626.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL).

The pTMRLs have been submitted to EFSA in September 2006.

<b>Chronic risk assessment – refined calculations</b>								
		TMDI (range) in % of ADI minimum – maximum						
		9	74					
<b>No of diets exceeding ADI:</b>								
Highest calculated TMDI values in % of ADI		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)
73.6	WHO Cluster diet B	28.8	Olives for oil production	5.7	Wine grapes	5.2	Tomatoes	2.3
49.4	DE child	19.3	Apples	6.1	Oranges	3.3	Cherries	1.4
46.4	NL child	10.1	Apples	7.6	Beans (with pods)	5.0	Oranges	1.8
42.1	FR toddler	16.6	Beans (with pods)	6.3	Milk and cream	4.2	Apples	1.6
37.7	WHO cluster diet E	5.1	Wine grapes	4.8	Rape seed	4.2	Beans (with pods)	1.5
34.1	IE adult	4.0	Wine grapes	2.6	Celery	2.5	Beans (with pods)	2.1
33.2	ES child	11.0	Olives for oil production	3.6	Beans (with pods)	3.5	Oranges	1.1
29.5	WHO regional European diet	4.7	Peas (with pods)	3.0	Beans (with pods)	3.0	Lettuce	1.1
28.6	FR infant	12.6	Beans (with pods)	4.1	Milk and cream	4.0	Apples	1.1
27.2	FR all population	12.8	Wine grapes	3.0	Olives for oil production	2.1	Beans (with pods)	0.7
25.8	ES adult	6.3	Olives for oil production	4.2	Lettuce	3.5	Beans (with pods)	0.6
24.2	PT General population	8.0	Wine grapes	3.8	Olives for oil production	1.7	Apples	1.3
23.2	UK Toddler	3.3	Milk and cream	3.2	Oranges	2.7	Apples	3.4
22.1	WHO Cluster diet F	2.6	Soya bean	2.5	Rape seed	2.4	Lettuce	1.3
21.9	UK Infant	6.2	Milk and cream	2.5	Apples	2.1	Oranges	2.3
20.5	NL general	3.8	Beans (with pods)	2.4	Oranges	2.0	Wine grapes	0.9
19.6	SE general population 90th percentile	3.5	Head cabbage	2.0	Milk and cream	1.7	Apples	1.3
18.3	WHO cluster diet D	2.5	Sunflower seed	1.7	Tomatoes	1.5	Soya bean	1.5
15.0	UK vegetarian	2.6	Wine grapes	1.4	Oranges	1.1	Lettuce	0.9
15.0	DK child	3.7	Apples	2.0	Milk and cream	1.1	Lettuce	1.7
14.8	IT adult	3.0	Lettuce	2.3	Beans (with pods)	2.0	Tomatoes	0.7
14.8	IT kids/toddler	2.4	Tomatoes	2.3	Lettuce	1.4	Beans (with pods)	1.1
12.3	UK Adult	3.5	Wine grapes	0.9	Lettuce	0.9	Oranges	0.9
11.5	PL general population	3.3	Apples	2.0	Head cabbage	1.5	Tomatoes	0.5
11.0	DK adult	4.5	Wine grapes	1.3	Apples	0.9	Milk and cream	0.6
9.6	LT adult	3.0	Apples	2.2	Head cabbage	1.1	Tomatoes	0.7
8.9	FI adult	1.6	Oranges	1.0	Wine grapes	0.9	Milk and cream	0.4

**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.

<b>Acute risk assessment/children – refined calculations</b>	<b>Acute risk assessment/adults/general population – refined calculations</b>
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Acute risk assessment is not necessary.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
	IESTI 1 *) **)			IESTI 2 *) **)			IESTI 1 *) **)			IESTI 2 *) **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
<b>No of critical MRLs (IESTI 1)</b>			---			<b>No of critical MRLs (IESTI 2)</b>			---			

Processed commodities	No of commodities for which ARfD/ADI is exceeded: ---			No of commodities for which ARfD/ADI is exceeded: ---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)

\*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

\*\*) pTMRL: provisional temporary MRL.

\*\*\*) pTMRL: provisional temporary MRL for unprocessed commodity.

**Conclusion:**

As no ARfD was considered necessary, it is concluded that the short-term intake of Cyantraniliprole residues is unlikely to present a public health concern.

## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition:</b> Cyantranilprole				
<b>Blackberries</b>	0.30	STMR-scaled <sup>(a)</sup> (indoor raspberries)	–	Acute risk assessment not required as an ARfD is not necessary (EFSA, 2014).
<b>Raspberries</b>	0.30	STMR-scaled <sup>(a)</sup> (indoor)		
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 <sup>(b)</sup> (EFSA, 2014)		
Strawberries	0.16	STMR (EFSA, 2015)		
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)		
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 (EFSA, 2015)		
Peas without pods	0.01	STMR (EFSA, 2015)		
Celeries	2	STMR (FAO, 2013)		
Globe artichokes	0.03	STMR (EFSA, 2015)		
Rice	0.01	STMR (EFSA, 2016a)		
Coffee beans	0.01	STMR (EFSA, 2016a)		
Herbal infusions from roots	0.08	STMR (EFSA, 2015)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Root and rhizome spices	0.08	STMR (EFSA, 2015)		
Sugar beet root	0.01	STMR (FAO, 2013)		
Chicory root	0.01	STMR (FAO, 2013)		
Other plant commodities	MRL	MRLs in Regulation (EU) 2017/626		
<b>Risk assessment residue definition:</b> Sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole				
Mammalian terrestrial animals: meat	0.002	STMR (FAO, 2013) <sup>(c)</sup>	–	Acute risk assessment not required as an ARfD is not necessary (EFSA, 2014)
Mammalian terrestrial animals: fat	0.007	STMR (FAO, 2013) <sup>(c)</sup>		
Mammalian terrestrial animals: liver, kidney, edible offal	0.026	STMR (FAO, 2013) <sup>(c)</sup>		
Poultry: meat	0	STMR (FAO, 2013) <sup>(c)</sup>		
Poultry: fat	0	STMR (FAO, 2013) <sup>(c)</sup>		
Poultry: liver, kidney, edible offal	0.004	STMR (FAO, 2013) <sup>(c)</sup>		
Milk	0.016	STMR (FAO, 2013) <sup>(c),(d)</sup>		
Eggs	0.01	STMR (FAO, 2013) <sup>(c)</sup>		
Other animal commodities	MRL	MRLs in Regulation (EU) 2017/626		

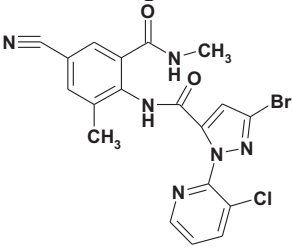
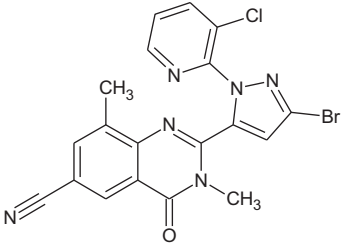
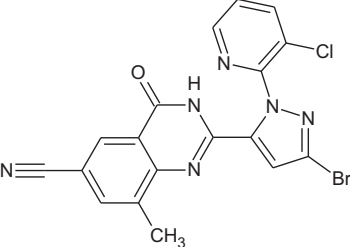
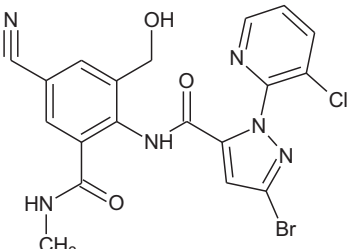
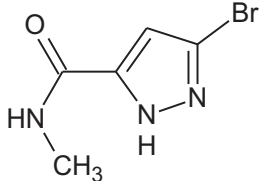
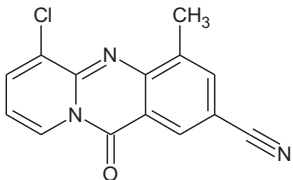
STMR: supervised trials median residue; MRL: maximum residue level; PF: processing factor.

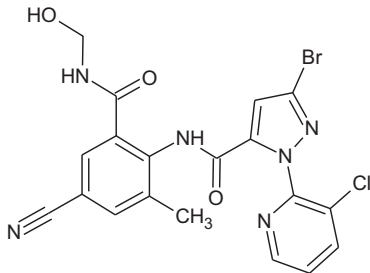
\*: Indicates that the input value is proposed at the limit of quantification.

- (a): STMR-scaled: residue trial values scaled assuming proportionality for estimation of residues at the GAP target application rate.
- (b): 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.
- (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 <sup>(a)</sup>	Structural formula <sup>(a)</sup>
Cyantraniliprole	3-bromo-1-(3-chloro-2-pyridyl)-4'-cyano-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide MW: 473.72 g/mol.	
IN-J9Z38	2-[3-bromo-1-(3-chloropyridin-2-yl)-1 <i>H</i> -pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carbonitrile	
IN-MLA84	2-[3-bromo-1-(3-chloropyridin-2-yl)-1 <i>H</i> -pyrazol-5-yl]-8-methyl-4-oxo-1,4-dihydroquinazoline-6-carbonitrile	
IN-N7B69	3-bromo-1-(3-chloropyridin-2-yl)- <i>N</i> -[4-cyano-2-(hydroxymethyl)-6-(methylcarbamoyl)phenyl]-1 <i>H</i> -pyrazole-5-carboxamide	
IN-F6L99	3-bromo- <i>N</i> -methyl-1 <i>H</i> -pyrazole-5-carboxamide	
IN-N5M09	6-chloro-4-methyl-11-oxo-11 <i>H</i> -pyrido[2,1- <i>b</i> ]quinazoline-2-carbonitrile	

Code/trivial name	Chemical name/SMILES notation <sup>(a)</sup>	Structural formula <sup>(a)</sup>
IN-MYX98	3-bromo-1-(3-chloropyridin-2-yl)- <i>N</i> -{4-cyano-2-[(hydroxymethyl)carbamoyl]-6-methylphenyl}-1 <i>H</i> -pyrazole-5-carboxamide	

SMILES: simplified molecular-input line-entry system; MW: molecular weight.

(a): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)).