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Setting of a maximum residue level for cyantraniliprole in leeks

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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 leek. In order to accommodate for the new use, the Agriculture & Horticulture Development Board submitted an application to raise the existing maximum residue level (MRL) for the crop 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 0.6 mg/kg for leeks in accordance with the emergency authorised good agricultural practice (GAP). 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 practice 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 leeks. 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 leeks not complying with the existing European Union (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 a specific MRLs for cyantraniliprole in leeks.

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 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 leeks from the limit of quantification (LOQ) of 0.01 mg/kg to 0.8 mg/kg on the basis of the combined northern Europe (NEU) and southern Europe (SEU) data set.

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.

The possible transfer of cyantraniliprole residues to crops that are grown in crop rotation has been assessed in EU pesticides peer review. Since the accumulation of very persistent metabolites is expected following multiple years of consecutive applications, the peer review concluded that long-term rotational crop studies are required to investigate the magnitude of residues of cyantraniliprole and its most persistent metabolites. Considering that the GAP under assessment was granted for a limited period of 120 days, the requested long-term rotational crop studies are of low relevance. In general, EFSA recommends 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.

On the basis of standard hydrolysis studies, the peer review proposed the residue definitions in processed commodities as cyantraniliprole for enforcement and as the sum of cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole for risk assessment. Considering that two additional degradation products were formed in significant levels in cooked spinach (i.e. IN-N5M09 and IN-F6L99), the peer review requested additional toxicological data for these compounds. The toxicological relevance of these metabolites should be further assessed, e.g. in the framework of the MRL review.

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 leeks were performed at higher total application rates than the target application rate for the emergency authorised GAP and EFSA applied the proportionality approach to estimate the residues values expected at the GAP target application rate. In contrast to the EMS, EFSA did not use the SEU trials to derive the MRL proposal, since the relevant GAP is authorised only in the UK.

The number and quality of the trials are sufficient to derive a MRL of 0.6 mg/kg for leeks in accordance with the emergency authorised GAP on the basis of the NEU residue trials.

Specific studies investigating the magnitude of cyantraniliprole residues in processed commodities were assessed during the peer review and a processing factor (PF) of 0.2 and a conversion factor for risk assessment (CF) of 8.0 derived for spinaches (leaves, cooked) are considered appropriate for extrapolation to leeks.

Residues of cyantraniliprole in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of cyantraniliprole was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day. 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 8.9–74% of the ADI and the maximum contribution of residues expected in leeks is 0.9% of ADI (FR toddler).

EFSA concluded that the proposed use of cyantraniliprole on leeks 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 ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Cyantraniliprole				
270060	Leeks	0.01*	0.6	The submitted data are sufficient to derive an MRL proposal of 0.6 mg/kg for the emergency authorised GAP on leeks on the basis of NEU residue trials. A consumer health concern is unlikely. Considering that the emergency authorisation was granted for a limited period of time (120 days); further risk management considerations are required to decide whether the proposed MRL should be established for a limited period of time. Some data gaps were identified in the peer review as regards processing and rotational crops that should be addressed, e.g. in the framework of the MRL review.

MRL: maximum residue level; 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) 1107/2009¹, 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 leeks, 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 leeks not complying with the existing European Union (EU) MRL, in accordance with Article 18(4) of Regulation (EC) No 396/2005² (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 Board³ submitted an application under Article 6(2) of the MRL Regulation to set specific MRLs for cyantraniliprole in leeks.

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 EFSA on 2 October 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-2017-00684 and the following subject:

Cyantraniliprole – MRL in leeks.

The EMS proposed to raise the existing MRLs of cyantraniliprole in leeks from the limit of quantification (LOQ) of 0.01–0.8 mg/kg on the basis of the combined northern Europe (NEU) and southern Europe (SEU) data set.

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 were 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 3 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.

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

² 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.

³ 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 use of cyantraniliprole which is 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 (EFSA, 2014).

Cyantraniliprole was approved⁴ 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, 2017). The proposals from these reasoned opinions have been considered in regulations⁵ 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, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011⁶ and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 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 546/2011.⁷

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.

⁴ 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.

⁵ For an overview of all MRL Regulations on this active substance, please consult: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN>.

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

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

1.1.2. Nature of residues in rotational crops

The crop under consideration can be grown in rotation with other plants, and therefore, the nature of possible residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that cyantraniliprole is of moderate to high persistence, with a maximum DT_{90} of 376 days, whilst several metabolites demonstrated a moderate to very high persistence with DT_{90} values estimated to be in the range of 4–9 years (EFSA, 2014), and therefore, studies on rotational crops are required (European Commission, 1997c).

Studies on the nature of cyantraniliprole residues in rotational crops were assessed in the framework of the peer review (EFSA, 2014). In the peer review, EFSA considered that the available studies on rotational crops were not fully appropriate to address the transfer of soil metabolites to plants, because they were conducted with a single application, while the DT_{90} values for several metabolites in soil were estimated to be in the range of 4–9 years and therefore open to accumulation following several years of consecutive applications. The current MRL application did not provide new information on the nature of residues in rotational crops.

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. On the basis of standard hydrolysis studies, the residue definitions in processed commodities were proposed as cyantraniliprole for enforcement and as the sum of cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole for risk assessment (EFSA, 2014). Considering that two additional degradation products were formed in significant levels in cooked spinach (i.e. IN-N5M09 and IN-F6L99), the peer review requested additional toxicological data for these compounds. The toxicological relevance of these metabolites should be further assessed, e.g. in the framework of the MRL review.

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

1.1.5. Stability of residues in plants

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

1.1.6. Proposed residue definitions

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

- Residue definition for risk assessment for primary crops: Cyantraniliprole (except for processed commodities)
- Residue definition for risk assessment for processed commodities: Sum of 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 eight GAP-compliant residue trials on NEU outdoor leeks conducted in the United Kingdom and northern France. The NEU trials were performed in two growing seasons (2010 and 2011). In addition, four outdoor residue trials on leeks conducted in SEU were submitted (southern France; 2011 growing season). All trials were performed with two foliar spray applications at a target application rate of 100 g a.s./ha with an oil dispersion formulation containing 100 g/L cyantraniliprole. In accordance with the GAP, an oil adjuvant was added to the spray mix in all trials.

In accordance with the data requirements, leek is considered a major crop in NEU for which a minimum of eight GAP-compliant trials are required (European Commission, 2017). Therefore, the number of trials compliant with the GAP is sufficient to support an MRL proposal. In contrast to the EMS, EFSA did not use the SEU trials to derive the MRL proposal, since the relevant GAP is authorised only in the UK.

The samples were analysed for the parent compound cyantraniliprole in accordance with the residue definitions for enforcement and risk assessment. Additional validation data for leeks were presented in the evaluation report and the analytical methods used were considered 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 measured total application rates in the NEU trials were higher than the target total application rate by factors ranging between 1.32N and 1.38N. The other parameters of the trials were consistent with the emergency authorised GAP for leeks. Since all trials were overdosed, leading to a systematic bias, EFSA (in contrast to the EMS) scaled down the residues values using the proportionality approach in order to estimate the MRL proposal required for the emergency authorised GAP (CAC, 2013; OECD, 2016).

1.2.2. Magnitude of residues in rotational crops

The possible transfer of cyantraniliprole residues to crops that are grown in crop rotation has been assessed in EU pesticides peer review. In the peer review, EFSA considered that since accumulation of several very persistent metabolites is expected following multiple years of consecutive applications, the submitted trials conducted with a single seasonal application rate are not fully appropriate to address the transfer of cyantraniliprole residues in rotational crops (EFSA, 2014). The peer review concluded that long-term rotational crop studies are required to investigate the magnitude of residues of cyantraniliprole and its most persistent metabolites. The current MRL application did not provide any new information on the magnitude of residues in rotational crops. Considering that the GAP under assessment was granted for a limited period of 120 days, the requested long-term rotational crop studies are of low relevance. In general, EFSA recommends 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.

1.2.3. Magnitude of residues in processed commodities

Processing studies were not submitted in the framework of the current MRL application. Although the levels of cyantraniliprole residues expected in the raw agricultural commodity (RAC) exceed the trigger value of 0.1 mg/kg, processing studies are not necessary considering that the expected dietary exposure via residues in leeks is low.

Studies investigating the effect of processing on the magnitude of cyantraniliprole residues were assessed during the peer review (EFSA, 2014). The processing factor (PF) of 0.2 and conversion factor for risk assessment (CF) of 8.0 derived for spinaches (leaves, cooked) are considered appropriate for extrapolation to leeks.

1.2.4. Proposed MRLs

The number and quality of the trials compliant with the NEU GAP are sufficient to derive a MRL of 0.6 mg/kg for leeks in accordance with the emergency authorised GAP. The available data which are considered appropriate to derive an MRL proposal and risk assessment values for the commodity 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

The assessment of residues in livestock is not relevant to the present application as leeks are not used for animal 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 subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference value for cyantraniliprole used in the risk assessment (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 scaled supervised trials median residue (STMR) 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, 2017). The complete list of input values is presented in Appendix D.1.

The estimated long-term dietary intake was in the range of 8.9–74% of the ADI and the maximum contribution of residues expected in leeks is 0.9% of ADI (FR toddler). 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 use on leeks is unlikely to present a risk to consumer health.

Conclusions and recommendations

The number and quality of the submitted trials are sufficient to derive a MRL of 0.6 mg/kg for leeks in accordance with the emergency authorised GAP.

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 practice is unlikely to present a risk to consumer health.

The MRL recommendation is 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
DM	dry matter

DT ₉₀	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
HR	highest residue
IEDI	international estimated daily intake
IESTI	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/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OD	oil dispersion
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WHO	World Health Organization
YF	yield factor

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

Crop and/or situation	NEU, SEU, MS or country	F G or I ^(a)	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days) ^(d)	Remarks
				Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	g a.s./ha min–max		
Leeks	NEU	F	<i>Thrips tabaci</i> <i>Frankliniella occidentalis</i> <i>Delia antiqua</i> <i>Phytomyza gymnostoma</i>	OD	100 g/L cyantraniliprole	Spray	BBCH 12–80	2	7 days	9.4–37.5	200–800	75	14	Emergency authorisation under Article 53 of Regulation (EC) No 1107/2009. A maximum of one treatment at the proposed GAP (two applications) may be made per year. For improved performance on sucking pests use with the addition of a suitable oil adjuvant.

NEU: northern Europe; SEU: southern Europe; MS; Member State; a.s.: active substance; OD: oil dispersion.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

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

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

(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	
Radiolabelled active substance: Foliar applications: ¹⁴ C-cyano and ¹⁴ C-pyrazole cyantraniliprole in a 1:1 mixture formulation; Soil applications: Separate studies with each label. Reference: EFSA (2014)	Fruit crops	Tomatoes	Foliar (3 × 150 g/ha, BBCH 14–61)	125 DAT (leaves, fruits)	
			Soil drench (3 × 150 g/ha, BBCH 19–61)		
	Leafy crops	Lettuces	Foliar (1 × 100 g/ha, BBCH 50)	0, 7, 14, 32 DAT	
			Soil drench (3 × 150 g/ha, BBCH 18–19)	7, 14, 32 DAT	
	Cereals/grass	Rice	Foliar (3 × 150 g/ha, BBCH 13–14)	140 DAT (straw, grain)	
			Soil granule (1 × 300 g/ha, BBCH 13)	175 DAT (straw, grain)	
	Pulses/oilseeds	Cotton	Foliar (3 × 150 g/ha, BBCH 16–19)	124 DAT (leaves, bolls)	
			Soil drench (3 × 150 g/ha, BBCH 19)	125 DAT (leaves, bolls)	
	Radiolabelled active substance: Foliar applications: ¹⁴ C-cyano and ¹⁴ C-pyrazole cyantraniliprole in a 1:1 mixture formulation; Soil applications: Separate studies with each label. Reference: EFSA (2014)				
	Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)
Comments: All studies conducted with bare soil application. Radiolabelled active substance: [cyano-14C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole for wheat; [Pyrazole carbonyl-14C]-cyantraniliprole for soya bean. Reference: United Kingdom (2013)	Cereals	Wheat	1 × 450 g a.s./ha	30, 120, 365	
	Root crops	Red beet		30, 120	
	Leafy crops	Lettuce		30, 120	
	Pulses and oil seeds	Soya bean	1 × 300 g a.s./ha Pilot study not conducted under GLP	25, 120	
	Comments: All studies conducted with bare soil application. Radiolabelled active substance: [cyano-14C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole for wheat; [Pyrazole carbonyl-14C]-cyantraniliprole for soya bean. Reference: United Kingdom (2013)				
Processed commodities (hydrolysis study)	Conditions			Investigated?	
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)	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; a.s.: active substance; GLP: Good Laboratory Practice; AR: applied radioactivity; LC: liquid chromatography; MS/MS: tandem mass spectrometry; ILV: independent laboratory validation.

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 of cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole Rotational crops: Open
Conversion factor (monitoring to risk assessment)	-
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	LC-MS/MS LOQ = 0.01 mg/kg for cyantraniliprole in plants (high water-, high oil-, high acid- and high starch content 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 water content	Apples	-20	≥ 24
	High acid content	Grapes	-20	≥ 24
	High starch content	Potatoes	-20	≥ 24
	High protein content	Dry beans	-20	18
	High oil content	Peanuts	-20	18
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 ^(a)	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 _{Mo} ^(b) (mg/kg)	STMR _{Mo} ^(c) (mg/kg)	CF ^(d)
Leeks (RD-Mo=RD-RA, except for processed commodities)	NEU	Mo/RA: 0.011, 0.012, 0.061, 0.090, 0.110, 0.240, 0.320, 0.380 Mo/RA scaled: 0.008, 0.009, 0.044, 0.068, 0.082, 0.177, 0.239, 0.287	The residue trials were performed at higher total application rates and were scaled down assuming proportionality for estimation of expected residues at the GAP target application rate; scaling factors: 0.740, 0.742, 0.727, 0.756, 0.747, 0.738, 0.748 and 0.754, respectively. MRL _{OECD} : 0.54/0.60	Leeks	0.6	0.287	0.075	–

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

(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. Residue trial values scaled assuming proportionality for estimation of residues at the GAP target application rate.

(c): Supervised trials median residue according to the residue definition for monitoring. Residue trial values scaled assuming proportionality for estimation of residues at the GAP target application rate.

(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

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Open	Cyantraniliprole residues >0.01 mg/kg not expected. No sufficient information was provided to address the transfer of the very persistent soil metabolites in rotational crops (data gap). Long-term rotational crop studies are required to investigate the magnitude of residues of cyantraniliprole and its most persistent metabolites (EFSA, 2014)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Open	Field rotational crop studies at 450 g/ha (3N compared to emergency authorised GAP). Long-term rotational crop studies are required to investigate the magnitude of residues of cyantraniliprole and its most persistent metabolites (EFSA, 2014)

B.1.2.4. Processing factors

Processing studies were not submitted in the framework of the current MRL application and are not required because the theoretical maximum daily intake (TMDI) from the consumption of leeks is less than 10% of the ADI (European Commission, 1997d). The processing factor derived for spinach (leaves, cooked) is considered appropriate for extrapolation to leeks.

Processed commodity	Number of valid Studies ^(a)	Processing Factor (PF)		CF _p ^(b)	Comment/Source
		Individual values	Median PF		
Spinach/leaves cooked	3	–	0.2	8.0	EFSA (2014)

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

B.2. Residues in livestock

Not triggered based on the intended use because leeks are not used for feed purposes.

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

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	74% ADI (WHO Cluster diet B) Maximum contribution of crop assessed: Leeks: 0.9% of ADI (FR toddler)
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodity from the NEU residue trials. Since the trials were overdosed, the residue values were scaled down assuming proportionality for residues at the target application rate. For the remaining crops, the input values derived in previous assessments, JMPR evaluations or the existing EU MRLs were used to estimate the overall long-term exposure

B.4. Recommended MRLs

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Cyantraniliprole				
270060	Leeks	0.01*	0.6	The submitted data are sufficient to derive an MRL proposal of 0.6 mg/kg for the emergency authorised GAP on leeks on the basis of NEU residue trials. A consumer health concern is unlikely. Considering that the emergency authorisation was granted for a limited period of time (120 days), further risk management considerations are required to decide whether the proposed MRL should be established for a limited period of time. Some data gaps were identified in the peer review as regards processing and rotational crops that should be addressed, e.g. in the framework of the MRL review

MRL: maximum residue level; 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)

Cyantraniliprole			
Status of the active substance:	Approved	Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per 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

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.

Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum – maximum						
		9		74				
No of diets exceeding ADI: ---								
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)		2nd contributor to MS diet (in % of ADI)		3rd contributor to MS diet (in % of ADI)		pTMRLs at LOQ (in % of ADI)
		Commodity/ group of commodities		Commodity/ group of commodities		Commodity/ group of commodities		
73.7	WHO Cluster diet B	28.8	Olives for oil production	5.7	Wine grapes	5.2	Tomatoes	2.3
49.5	DE child	19.3	Apples	6.1	Oranges	3.3	Cherries	1.4
46.6	NL child	10.1	Apples	7.6	Beans (with pods)	5.0	Oranges	1.8
42.9	FR toddler	16.6	Beans (with pods)	6.3	Milk and cream	4.2	Apples	1.5
37.8	WHO cluster diet E	5.1	Wine grapes	4.8	Rape seed	4.2	Beans (with pods)	1.5
34.4	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
29.1	FR infant	12.6	Beans (with pods)	4.1	Milk and cream	4.0	Apples	1.0
27.3	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
22.2	WHO Cluster diet F	2.6	Soya bean	2.5	Rape seed	2.4	Lettuce	1.2
21.9	UK Infant	6.2	Milk and cream	2.5	Apples	2.1	Oranges	2.3
20.7	NL general	3.8	Beans (with pods)	2.4	Oranges	2.0	Wine grapes	0.8
19.7	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
15.1	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
11.6	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.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations
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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 lead 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		Highest % of ARfD/ADI Commodities		Highest % of ARfD/ADI Commodities		Highest % of ARfD/ADI Commodities		
	pTMRL/ threshold MRL (mg/kg)		pTMRL/ threshold MRL (mg/kg)		pTMRL/ threshold MRL (mg/kg)		pTMRL/ threshold MRL (mg/kg)		
No of critical MRLs (IESTI 1)		---		No of critical MRLs (IESTI 2)		---			

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		Highest % of ARfD/ADI Processed commodities		
	pTMRL/ threshold MRL (mg/kg)		pTMRL/ threshold MRL (mg/kg)		
<p>*) 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.</p> <p>**) pTMRL: provisional temporary MRL.</p> <p>***) pTMRL: provisional temporary MRL for unprocessed commodity.</p>					
<p>Conclusion: As no ARfD was considered necessary, it is concluded that the short-term intake of Cyantranilprole residues is unlikely to present a public health concern.</p>					

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
Risk assessment residue definition: Cyantraniliprole				
Leeks	0.12	STMR-scaled ^(a) × PF × CF (0.075 × 0.2 × 8)	–	Acute risk assessment not required as an ARfD is not necessary EFSA (2014)
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 ^(b) EFSA (2014)		
Strawberries	0.16	STMR EFSA (2015)		
Blackberries, raspberries	0.30	STMR-scaled ^(a) (indoor raspberries) Emergency authorisation under Article 53 of Regulation (EC) No 1107/2009. EFSA (2017)		
Blueberries (bush berries)	0.75	STMR FAO (2013)		
Currants (black, red and white)	0.75	STMR (FAO, 2013)		
Gooseberries (green, red and 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)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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)		
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		
Risk assessment residue definition: Sum of cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole				
Mammalian terrestrial animals: meat	0.002	STMR FAO (2013) ^(c)	–	Acute risk assessment not required as an ARfD is not necessary EFSA (2014)
Mammalian terrestrial animals: fat	0.007	STMR FAO (2013) ^(c)		
Mammalian terrestrial animals: liver, kidney, edible offal	0.026	STMR FAO (2013) ^(c)		
Poultry: meat	0	STMR FAO (2013) ^(c)		
Poultry: fat	0	STMR FAO (2013) ^(c)		
Poultry: liver, kidney, edible offal	0.004	STMR FAO (2013) ^(c)		
Milk	0.016	STMR FAO (2013) ^{(c),(d)}		
Eggs	0.01	STMR FAO (2013) ^(c)		
Other animal commodities	MRL	MRLs in Regulation (EU) 2017/626		

STMR: supervised trials median residue; PF: processing factor; CF: conversion factor for enforcement to risk assessment residue definition; ARfD: acute reference dose; YF: yield factor; MRL: maximum residue level.

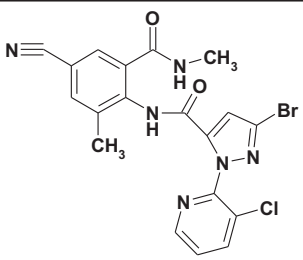
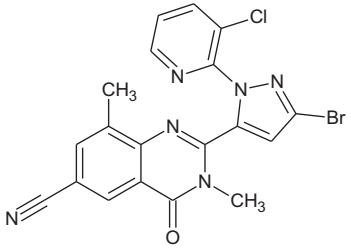
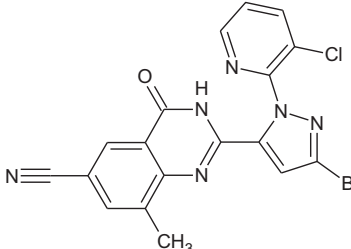
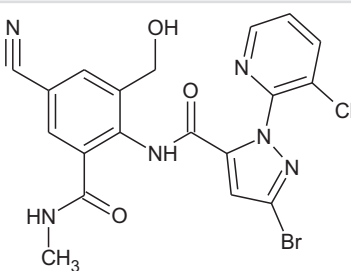
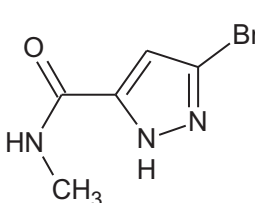
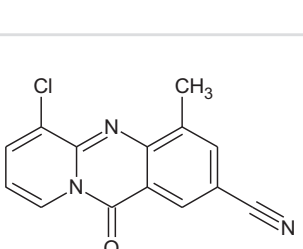
(a): STMR-scaled: residue trial values scaled assuming proportionality for estimation of residues at the GAP target application rate.

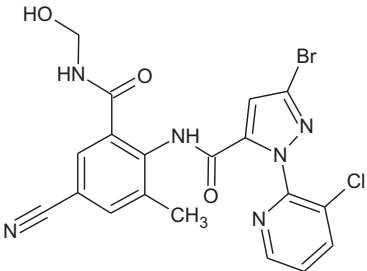
(b): Consumption figure in the PRIMo model is expressed for the raw commodity (grape). A yield factor (YF) of 0.7 is therefore considered to estimate the consumption figure for wine.

(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 ^(a)	Structural formula ^(a)
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)-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-dihydroquinazolin-6-carbonitrile	
IN-N7B69	3-bromo-1-(3-chloropyridin-2-yl)-N-[4-cyano-2-(hydroxymethyl)-6-(methylcarbamoyl)phenyl]-1H-pyrazole-5-carboxamide	
IN-F6L99	3-bromo-N-methyl-1H-pyrazole-5-carboxamide	
IN-N5M09	6-chloro-4-methyl-11-oxo-11H-pyrido[2,1-b]quinazolin-2-carbonitrile	

Code/trivial name	Chemical name/SMILES notation ^(a)	Structural formula ^(a)
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	 <p>The chemical structure shows a central benzene ring substituted with a cyano group (-C≡N) at the para position, a methyl group (-CH₃) at the meta position, and a carbonyl group (-C(=O)NH-) at the other meta position. This carbonyl group is further substituted with a hydroxymethyl group (-CH₂OH) on the nitrogen. The benzene ring is also connected to a pyrazole ring at its 1-position. The pyrazole ring has a bromine atom (-Br) at the 3-position and is linked to a 3-chloropyridin-2-yl group at its 5-position.</p>

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)).