

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

This scientific output, published on 28 May 2015, replaces the earlier version published on 11 November 2014³

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State the United Kingdom and the co-rapporteur Member State France for the pesticide active substance cyantraniliprole and the assessment of applications for maximum residue levels (MRLs) are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative uses of cyantraniliprole as an insecticide on various crops in agriculture and horticulture. MRLs were assessed in oranges, mandarins, apples/pears, peaches, apricots, plums, vine grapes, potatoes, tomatoes, cucumber/courgettes, melon, lettuce, beans and olives. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment and the proposed MRLs, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

© European Food Safety Authority, 2014

KEY WORDS

cyantraniliprole, peer review, risk assessment, pesticide, insecticide, maximum residue level

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

Available online: www.efsa.europa.eu/efsajournal

¹ On request from the European Commission, Question No EFSA-Q-2013-00588, approved on 13 August 2014.

² Correspondence: pesticides.peerreview@efsa.europa.eu

³.The ecotoxicology section of this Conclusion has been amended to provide the correct application rate of 2 x 12.5 g a.s./ha for use in potatoes in relation to the risk assessment for non-target arthropods (chapter 5 and list of end points). The overview tables on pages 32 and 34 have been amended to delete the reference to the issue not finalised on the consumer risk assessment (point 5 under 9.1.1) as the groundwater contamination is not relevant for the hydroponic representative uses. These changes do not affect the overall outcomes of the Conclusion. The original Conclusion is available on request as is a copy showing all the changes that were made.



SUMMARY

Cyantraniliprole is a new active substance for which in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (hereinafter referred to as 'the Regulation'), the rapporteur Member State (RMS) the United Kingdom and the co-rapporteur Member State (co-RMS) France received an application from DuPont Crop Protection and Syngenta Crop Protection on 29 June 2011 for approval. In accordance with Article 8(1)(g) of the Regulation, DuPont Crop Protection and Syngenta Crop Protection submitted applications for maximum residue levels (MRLs) as referred to in Article 7 of Regulation (EC) No 396/2005. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the co-RMS and the date of admissibility of the application was recognised as being 10 August 2011.

The RMS and the co-RMS provided its initial evaluation of the dossier on cyantraniliprole in the Draft Assessment Report (DAR), which was received by the EFSA on 31 May 2013. The DAR included a proposal to set MRLs, in accordance with Article 11(2) of the Regulation. The peer review was initiated on 20 June 2013 by dispatching the DAR for consultation of the Member States and the applicant DuPont Crop Protection and Syngenta Crop Protection.

Following consideration of the comments received on the DAR, it was concluded that additional information should be requested from the applicant and that the EFSA should conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology.

In accordance with Article 12 of the Regulation, the EFSA should adopt a conclusion on whether cyantraniliprole can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation and give a reasoned opinion concerning MRL applications as referred to in Article 10(1) of Regulation (EC) No 396/2005 as part of this conclusion.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of cyantraniliprole as an insecticide on various crops in agriculture and horticulture as proposed by the applicant. MRLs were assessed in oranges, mandarins, apples/pears, peaches, apricots, plums, vine grapes, potatoes, tomatoes, cucumber/courgettes, melon, lettuce, beans and olives. Full details of the representative uses and the proposed MRLs can be found in Appendix A to this report.

A data gap was identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites.

Sufficient data were submitted to conclude that the uses of cyantraniliprole according to the representative uses proposed at EU level result in a sufficient insecticidal efficacy against the target organisms.

In the area of identity a data gap was identified for a new technical specification.

In the area of mammalian toxicology, there is no critical area of concern. Data gaps were identified for further assessment of some metabolites.

The data were sufficient to propose plant and animal residue definitions for monitoring and risk assessment. No critical area of concern was identified in the residues section. Data gaps were identified for additional residue trials on lettuce, apricot and bean, conducted according to the representative uses proposed at EU level and for additional information to address the residues in rotational crops for the persistent metabolites. Data gap was identified for the setting of import tolerances that could not be taken into consideration in the conclusion.



The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level, with the notable exception that a data gap was identified for information on the effect of water treatment processes on the nature of residues of both the active substance and its identified metabolites potentially present in surface and groundwater, when surface water or groundwater are abstracted for drinking water. This gap leads to the consumer risk assessment from the consumption of drinking water being not finalised for all the representative uses. For a few of the representative uses environmental exposure assessments are missing leading to some data gaps and risk assessments not being finalised. On the basis of the available mammalian toxicology data for the groundwater metabolites IN-K5A78, IN-M2G98 and IN-K5A79, following the pertinent Commission guidance, the assessment of impact on groundwater quality could not be finalised as it is not clear if the parametric drinking water limit of $0.1~\mu g/L$ is applicable to these metabolites. I.e. the assessment of the groundwater relevance of these metabolites remains open for all the representative uses except crops grown using hydroponic cultivation systems.

In the area of ecotoxicology data gaps were identified to further address the risk to mammals, bees and non-target arthropods. The risk assessment could not be finalised for all non target organisms.



TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	4
Background	5
The active substance and the formulated product	7
Conclusions of the evaluation	7
1. Identity, physical/chemical/technical properties and methods of analysis	7
2. Mammalian toxicity	
3. Residues	9
3.1. Representative uses	9
3.2. Maximum residue levels	11
4. Environmental fate and behaviour	11
5. Ecotoxicology	14
6. Overview of the risk assessment of compounds listed in residue definitions triggering assess	ment
of effects data for the environmental compartments	19
6.1. Soil	19
6.2. Ground water	20
6.3. Surface water and sediment	22
6.4. Air	22
7. Data gaps	
7.1. Data gaps identified for the representative uses evaluated	23
7.2. Data gaps identified for the maximum residue level applications	24
8. Particular conditions proposed to be taken into account to manage the risk(s) identified	24
8.1. Particular conditions proposed for the representative uses evaluated	24
8.2. Particular conditions proposed for the maximum residue level applications	
9. Concerns	25
9.1. Concerns for the representative uses evaluated	
9.1.1. Issues that could not be finalised	
9.1.2. Critical areas of concern	
9.1.3. Overview of the concerns identified for each representative use considered	27
9.2. Issues related to the maximum residue level applications	
9.2.1. Issues not finalised under the maximum residue level applications	38
9.2.2. Consumer risk identified under the maximum residue level applications	38
References	
Appendices	42
Abbreviations	246



BACKGROUND

Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁴ (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant(s) for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of up to 150 days where additional information is required to be submitted by the applicant(s) in accordance with Article 12(3).

Cyantraniliprole is a new active substance for which in accordance with Article 7 of the Regulation, the rapporteur Member State (RMS) the United Kingdom (hereinafter referred to as the 'RMS') and the co-rapporteur Member State (co-RMS) France (hereinafter referred to as the 'co-RMS') received an application from DuPont Crop Protection and Syngenta Crop Protection on 29 June 2011 for approval of the active substance cyantraniliprole. In accordance with Article 8(1)(g) of the Regulation, DuPont Crop Protection and Syngenta Crop Protection submitted applications for maximum residue levels (MRLs) as referred to in Article 7 of Regulation (EC) No 396/2005⁵ as part of this conclusion. Complying with Article 9 of the Regulation, the RMS and the co-RMS checked the completeness of the dossier and the date of admissibility of the application was recognised as being 10 August 2011.

The RMS and the co-RMS provided its initial evaluation of the dossier on cyantraniliprole in the Draft Assessment Report (DAR), which was received by the EFSA on 31 May 2013 (United Kingdom, 2013). The DAR included a proposal to set MRLs, in accordance with Article 11(2) of the Regulation. The peer review was initiated on 20 June 2013 by dispatching the DAR for consultation of the Member States and the applicants DuPont Crop Protection and Syngenta Crop Protection for consultation and comments. EFSA also provided comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS and the co-RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The RMS and the co-RMS evaluated the comments and the applicant's response in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 10 October 2013. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicants, and that the EFSA should conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology.

The outcome of the telephone conference, together with the EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further

_

⁴ Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council 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.

⁵ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.



consideration, including those issues to be considered in an expert consultation, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert consultation where this took place, were reported in the final column of the Evaluation Table.

In accordance with Article 12 of the Regulation, the EFSA should adopt a conclusion on whether cyantraniliprole can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation and give a reasoned opinion concerning MRL applications as referred to in Article 10(1) of Regulation (EC) No 396/2005 as part of this conclusion. A final consultation on the conclusions arising from the peer review of the risk assessment and on the proposed MRLs took place with Member States via a written procedure in July 2014.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses of cyantranilprole as an insecticide on various crops in agriculture and horticulture as proposed by the applicant. MRLs were assessed in oranges, mandarins, apples/pears, peaches, apricots, plums, vine grapes, potatoes, tomatoes, cucumber/courgettes, melon, lettuce, beans and olives. A list of the relevant end points for the active substance as well as the formulation and the proposed MRLs is provided in Appendix A.

In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2014) comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the comments received on the DAR,
- the Reporting Table (11 October 2013),
- the Evaluation Table (29 July 2014),
- the report(s) of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its final addendum (compiled version of June 2014 containing all individually submitted files (United Kingdom, 2014)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.



THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

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 representative formulated products for the evaluation were 'DPX-HGW86 100 g/l OD' an oil dispersion formulation, 'DPX-HGW86 100 g/l SE' a suspo-emulsion, 'DPX-HGW86 200 g/l SC' a suspension concentrate and 'A16971 B' a water dispersible formulation (WG) containing 400 g/kg cyantraniliprole.

The formulations are all used as spray applications (except the SC formulation which is by drip irrigation or in hydroponics) to a wide range of outdoor and protected crops. Full details of the GAP can be found in the list of end points in Appendix A.

Sufficient data were submitted to conclude that the uses of cyantraniliprole according to the representative uses proposed at EU level result in a sufficient insecticidal efficacy against the target organisms, following the guidance document SANCO/10054/2013 - rev. 3 (European Commission, 2013).

A data gap has been identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier, to be conducted and reported in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011). Whilst the dossier contains information to address this point a transparent evaluation of the information was not provided by the RMS.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed during the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), Sanco/10597/2003 – rev. 10.1 (European Commission, 2012), SANCO/825/00 rev. 8.1 (European Commission, 2010).

The minimum purity of the active substance as manufactured is 940 g/kg. Impurities IN-Q6S09, IN-RYA13, methanesulfonic acid, acetonitrile, heptane and 3-picoline were considered relevant with no toxicological concern at the levels present in the technical material (see section 2). The levels should be considered provisional as a data gap has been identified for a revised technical specification.

The main data regarding the identity of cyantraniliprole and its physical and chemical properties are given in Appendix A.

The formulations were fully supported and no data gaps were identified.

The residue definition for all matrices is cyantraniliprole only. LC-MS/MS methods are available for products of animal and plant origin, soil, water and air. A method of analysis for body fluids and tissues is not required as the active substance is not proposed for classification as toxic or very toxic.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 rev. 10 - final (European Commission, 2003), SANCO/10597/2003 - rev. 10.1 (European Commission, 2012) and Guidance on Dermal Absorption (EFSA PPR Panel, 2012).

Cyantraniliprole was discussed during the Pesticides Peer Review meeting 114 on mammalian toxicology in May 2014.



With regard to the proposed technical specification, the levels of impurities in the batches used for the toxicological studies can be considered as representative of the levels in the technical specification. On the basis of their hazard (existing classification or toxic properties), the impurities IN-RYA13, IN-Q6S09, methanesulfonic acid, acetonitrile, n-heptane and 3-picoline are considered toxicologically relevant but of no concern up to the levels of the proposed specification.

The toxicokinetics of cyantraniliprole showed an oral absorption value of 70%, an extensive distribution in the body, no significant bioaccumulation, and an excretion occurring mainly within 48h after administration. Cyantraniliprole did not show evidence of acute toxicity in the available studies. In the short term studies with rats, mice and dogs, the critical effects for human health risk assessment were observed in the liver (increased relative organ weights, histopathological and clinical chemistry changes), the dog being the most sensitive species. In the 90-day and 1-year dog studies, the agreed NOAEL was 1 mg/kg bw per day (based on increased relative liver weights and altered clinical chemistry). At higher doses, increased incidences of vascular arteritis were also observed in dogs. In the available genotoxicity studies, cyantraniliprole did not exhibit any evidence of mutagenicity. In the long term studies with rats and mice, the liver was also the main target organ of toxicity (increased relative organ weights and histopathology). No adverse effect on the reproductive parameters was observed in the rat multigeneration study, and no teratogenic effect was observed in the developmental toxicity studies with rats and rabbits. In immunotoxicity studies, no adverse effects were observed in rats and mice up to the highest dose tested.

The toxicological relevance of the plant metabolite IN-J9Z38 was discussed in the meeting of experts and it was considered to be covered by the reference values derived for cyantraniliprole. For the metabolites IN-F6L99 and IN-N5M09 (found in processed commodities), an assessment of their toxicological properties is still missing (data gap). The groundwater metabolites IN-JSE76, IN-PLT97, IN-K5A79 and IN-M2G98 are not toxicologically relevant based on hazard assessment (step 3 of the Commission (2003) guidance). For IN-JSE76 and IN-PLT97, the reference values were discussed in the expert meeting, which concluded that due to their lower toxicity and lack of information of their effects in the dog (most sensitive species upon exposure to cyantraniliprole), the reference values of cyantraniliprole are applicable, whereas for IN-M2G98 and IN-K5A79, insufficient toxicological data were available to conclude on reference values (data gap). For the additional groundwater metabolite identified above $0.1~\mu g/L$ (IN-K5A78), insufficient data were available to establish the reference value for the consumer risk assessment.

It is noted that no recognised endocrine disrupting effects are observed *in vivo* and it is considered unlikely that any of the *in vitro* tests reported in the level 2 of the OECD Conceptual Framework (OECD, 2012) would add any relevant information; therefore cyantraniliprole is unlikely to be an endocrine disruptor according to the current scientific state-of-play (EFSA SC, 2013).

The acceptable daily intake (ADI) for cyantraniliprole is 0.01 mg/kg bw per day, based on the 1-year dog study and applying an uncertainty factor (UF) of 100. The acceptable operator exposure level (AOEL) is 0.007 mg/kg bw per day on the basis of the 1-year dog study, applying an UF of 100 and a correction for the oral absorption value (70%). On the basis of the available data, an acute reference dose (ARfD) is not required for cyantraniliprole.

Dermal absorption studies were provided for the four representative formulations containing cyantraniliprole. For the OD formulation, the dermal absorption values are 0.1% for both the concentrate and the dilution. For the SE formulation, the dermal absorption values are 0.4% for the concentrate and 2% for the dilution. For the SC formulation, the dermal absorption values are 0.1% for the concentrate and 0.6% for the dilution. For the WG formulation, the dermal absorption values are 0.02% for the concentrate, 3% for the dilution 1/534 (used for all exposure calculations for this formulation) and 0.6% for the dilution 1/1600.

For the OD formulation, the operator exposure estimates are not exceeding the AOEL. However, for the greenhouse uses, personal protective equipment (PPE) is required for the operators. For the SE



formulation, the operator exposure estimates with UK POEM for the tractor applications do include the need of PPE during mixing/loading (M/L) and application (A) when reduced volumes are applied, as well as a closed cab when high volumes are applied. For the knapsack applications, the exposure estimates with UK POEM trigger the need to use gloves during M/L and A to be below the AOEL. For the SC formulation, the operator exposure estimates during drip irrigation do not exceed the AOEL (without PPE). For tractor application of the WG formulation, the use of PPE (and closed cab) is required with the UK POEM to have exposure estimates below the AOEL; for knapsack application, the exposure estimates with UK POEM trigger the need for PPE during M/L and A. For all formulations, the exposure estimates for workers and bystanders/residents are below the AOEL.

3. Residues

The assessment in the residue section is based on the guidance documents listed in the guideline 1607/VI/97 rev.2 and the guideline on extrapolation SANCO 7525/VI/95 rev.9 (European Commission, 1999, 2011), the recommendations on livestock burden calculations stated in the JMPR reports (JMPR, 2004, 2007) and the OECD publication on MRL calculations (OECD, 2011).

3.1. Representative uses

Metabolism studies were conducted on four crop categories; on cereals (rice), leafy crops (lettuce), pulses/oilseeds (cotton) and fruit crops (tomato). For each crop, metabolism was investigated after either three foliar applications or three soil drench applications at 150 g/ha (except for rice where a single soil application at 300 g/ha was experimented). Separate tests were conducted for soil applications, using ¹⁴C-cyantraniliprole either labelled on the cyano or pyrazole moieties, while foliar treatments were made using a mixture of both radiolabel forms in a 1:1 ratio. In this particular case, the use of mixed radiolabel forms was considered acceptable, since no extensive cleavage of the parent molecule was observed in the different studies.

In all plant matrices, total radioactive residue levels were at least one order of magnitude higher following foliar applications than soil drench applications. Irrespective of the mode of application, a similar metabolic profile was observed in the different crop groups, cyantraniliprole representing the major component of the residues, accounting for almost 25 % to more than 90 % TRR. Twenty different metabolites were identified, mostly below 5% TRR, the most abundant being the metabolite IN-J9Z38 representing 23% TRR at 32 day PHI in lettuce (0.007 mg/kg) and 6% to 28% TRR in rice foliage, straw and grain (0.03 to 0.09 mg/kg) following drench application. All components identified in primary crops were also detected in the rotational crop studies conducted on wheat, soybean, redish and lettuce. As for primary crops, cyantraniliprole was identified as the main component of the residues in rotational crops (*ca.* 20% to 60% TRR). Several metabolites (IN-J9Z38, IN-JCZ38, IN-MLA84, IN-N7B69) were observed in proportions above 25% TRR in some plant matrices but representing less than 0.05 mg/kg. These rotational crop studies are however considered not fully appropriate to address the transfer of the soil metabolites in plants, as conducted with a single application, while the DT₉₀ in soil were estimated to be in the range of 4 to 9 years for several metabolites and therefore, open to accumulation following several years of consecutive applications.

As cyantraniliprole was shown to be the major component of the radioactive residues in the different plant studies, the residue definition for monitoring was limited to cyantraniliprole only. The inclusion of additional metabolites in the residue definition for risk assessment was considered. Having regard to the low residue levels observed in the supervised residues trials where all samples were analysed for a total of 6 to 7 metabolites, it was proposed to limit the residue definition for risk assessment to cyantraniliprole only, considering that the additional contribution of these metabolites to the overall consumer intake would be negligible.

Data were sufficient to derive MRLs for a total of 15 plant commodities according to the GAPs proposed at EU level, except for apricot, lettuce and bean (with pods) where trials conducted according to the representative GAPs were requested. All MRLs were derived from the trials conducted with foliar applications, since resulting in much higher residue levels than following drip



soil applications. Cyantraniliprole was stable under standard hydrolysis conditions simulating pasteurisation and sterilisation, but slightly degraded to IN-J9Z38 (12-14 % AR) and to metabolites IN-N5M09 and IN-F6L99 (5-8% AR) resulting from the cleavage of the parent compound, under boiling conditions. Degradation under boiling conditions was confirmed in several processing studies where metabolite IN-J9Z38 was observed in significant higher levels than cyantraniliprole. The residue definitions in processed commodities were therefore proposed as "cyantraniliprole" for enforcement and as "sum of cyantraniliprole and IN-J9Z39 expressed as cyantraniliprole" for risk assessment. Data were sufficient to propose Processing Factors (PF) and Conversion Factors (CF) for a large number of processed commodities. Since metabolites IN-N5M09 and IN-F6L99 were observed in significant levels in some processed commodities (up to 0.09 mg/kg) additional data to address the toxicity of these two metabolites are requested (see section 2).

Numerous field rotational crop studies conducted in the USA with a total seasonal application rate of 450 g/ha were submitted (1N and 2.5N compared to indoor and outdoor EU GAPs). As for primary crops, samples were analysed for cyantraniliprole and 6 metabolites. For a Plant Back Interval (PBI) of 14 to 30 days, positive residues (>0.01 mg/kg) of cyantraniliprole, IN-J9Z38, IN-JCZ38 and IN-MLA84 were observed in most of the feed commodities. In contrast, in food commodities, cyantraniliprole only was detected in radish roots (up to 0.015 mg/kg) and in mature lettuce (0.033 mg/kg). For intermediate PBI of 120 to 180 days, only cyantraniliprole and IN-JCZ38 residues were detected, mostly in cereal and oilseed forage and hay at levels up to 0.05 mg/kg. No residues above 0.01 mg/kg were measured in the one year PBI crops. As mentioned above, since accumulation of several very persistent metabolites is expected following multiple years of consecutive applications, EFSA is of the opinion that the submitted trials conducted with a single seasonal application rate, are not fully appropriate to address the transfer of cyantraniliprole residues in rotational crops. Long term rotational crop studies considering cyantraniliprole and its most persistent metabolites are requested.

The field data are supported by the storage stability studies where cyantraniliprole and IN-J9Z38, IN-JCZ38, IN-K7H19, IN-MLA84, IN-MYX98, IN-N7B69, IN-F6L99 and IN-N5M09 were shown to be stable at least 24 months in high water-, high acid-, high starch- and high protein-content matrices when stored frozen at -20°C (18 months for cyantraniliprole in high protein content matrices). In addition, most of the components were stable over two years in high oil-content matrices, except metabolite IN-N7B69 where a significant degradation was observed after a one year storage period, and for metabolites IN-JCZ38 and IN-K7H19 where recoveries after 1 month were below 70 %.

Goat and poultry metabolism studies conducted over 10 consecutive days at a feeding rate of 10 mg/kg feed were provided, using ¹⁴C-cyantraniliprole labelled either on the cyano or pyrazole moiety. The vast majority of administered radioactivity was excreted and less than 1% (poultry) and 2% (goat) of the radioactive residues were recovered in organs, tissues, milk or eggs. In addition to cyantraniliprole observed in all animal matrices, several other metabolites were identified in significant proportions and amounts in the different animal products; metabolites IN-J9Z38 and IN-MLA84 in eggs (13% to 27% TRR), metabolites IN-MYX98 and IN-N7B69 in milk (13% to 33% TRR). Based on these studies, the residue definition for products of animal origin was proposed as cyantraniliprole for monitoring and as the "sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69 expressed as cyantraniliprole" for risk assessment. An overall conversion factor of 2 (except for meat and honey were a conversion factor of 1 was derived) was derived from the animal feeding studies considering the metabolites relevant for each animal matrix. Having regard to the expected intakes calculated on the uses supported at EU level, the setting of MRLs for animal products was concluded to be not necessary.

No chronic intake consumer concern was identified. Considering the EFSA PRIMo model and the MRLs proposed according to the EU uses, the highest TMDI was calculated to be 139% of the ADI (WHO, cluster B). Refined estimation using the STMRs derived from the supervised residue trials, results in a highest IEDI value of 20% of the ADI (WHO, cluster B). As the setting of an ARfD was concluded to be not necessary for cyantraniliprole, an acute risk assessment was not conducted.



However, an additional contribution to the consumer intakes resulting from the presence of several groundwater metabolites above 0.75 μ g/L needs to be considered. Based on WHO consumption figures (WHO, 2011) and considering the outdoor uses defined with 2 foliar applications at 150 g/ha, this contribution is estimated to be 9%, 26% and 38% of the ADI for adult, child and infant respectively for the metabolite IN-JSE76, and 0.4%, 1% and 2% for the metabolite IN-PLT97. For child and infant, these contributions are above the 20% intake value recommended by the WHO guidelines. In contrast, all intakes are below 9% of the ADI when the outdoor use on lettuce of 2 applications at 75 g/ha is considered. Additional intakes resulting from the metabolites IN-K5A78, IN-K5A79 and IN-M2G98 expected to be present in groundwater in the range of 0.5 to 5.2 μ g/L, could not be considered, as insufficient data were available to derive toxicological reference values for these metabolites (see section 2).

3.2. Maximum residue levels

According to Article 11.2 of Regulation (EC) No. 1107/2009, an MRL application to set import tolerances based on the US and Canadian GAPs was included in the DAR for the approval of the active substance. However, the assessment of import tolerance requests was not conducted in the framework of the peer review, since evidence of the registration of cyantraniliprole as well as information on the GAPs and MRL values effectively adopted and published in the exporting countries were not submitted. Import tolerance assessment will be considered in a separate EFSA Reasoned Opinion once all outstanding information has been provided with a new MRL application under Regulation (EC) No 396/2005.

4. Environmental fate and behaviour

Cyantraniliprole was discussed in the Pesticides Peer Review experts' meeting 113 on fate and behaviour in May 2014.

In soil laboratory incubations under aerobic conditions in the dark, cyantraniliprole exhibited moderate to high persistence, forming the major (>10 % applied radioactivity (AR)) metabolites: IN-J9Z38 (max. 19 % AR which exhibited moderate to very high persistence), IN-JCZ38 (max. 40 % AR, low to high persistence), IN-JSE76 (max. 43 % AR, moderate to very high persistence), IN-K5A78 (max. 29 % AR, medium to very high persistence) and IN-PLT97 (max. 26 % AR, medium to very high persistence). The metabolites IN-K5A77, IN-K5A79 (both max. 9 % AR, moderate to very high persistence) and IN-M2G98 (max. 33 % AR in the aerobic degradation study dosed with IN-K5A79, high persistence) were concluded to be formed at levels triggering groundwater exposure assessments, in accordance with SANCO/221/2000 rev. 10 - final (European Commission, 2003) guidance. The rate of degradation of parent cyantraniliprole was concluded to be pH dependent with degradation being faster as soil pH increases. In these aerobic laboratory incubations mineralisation of the cyano and pyrazole carbonyl ¹⁴C radiolabels to carbon dioxide was limited accounting for not measureable to 2.2% AR after 90-100 days. The formation of unextractable residues (not extracted by calcium chloride, acidified acetone, acetone and acidified dichloromethane) for these radiolabels accounted for 5.1 – 17.8 % AR after 90-100 days. In anaerobic soil incubations cyantraniliprole transformed slightly quicker than under aerobic conditions, but did not form any novel metabolites compared to those formed in aerobic incubations, though higher levels of IN-J9Z38 (max. 72% AR) were formed. In moist soil laboratory photolysis experiments the major novel metabolites formed were IN-OKV54 and IN-RNU71 (max. 17 % and 14% AR respectively, both exhibiting moderate to very high persistence). The metabolite IN-NXX70 (max. 4.8 % AR, low persistence) was concluded to be formed at levels triggering groundwater exposure assessments, in accordance with SANCO/221/2000 rev. 10 - final (European Commission, 2003) guidance.

Cyantraniliprole exhibited high to medium mobility in soil, as did IN-JCZ38 and IN-RNU71. IN-QKV54 was indicated to exhibit slight mobility or be immobile. IN-J9Z38, IN-K5A77 and IN-NXX70 were indicated to exhibit low mobility or be immobile. IN-PLT97 exhibited medium to slight mobility and IN-K5A78 exhibited medium to low mobility. IN-JSE76 exhibited very high to high mobility and IN-M2G98 was predicted by QSAR estimates to exhibit high mobility. It was concluded that the



adsorption of these compounds was not pH dependent. IN-K5A79 exhibited very high to high mobility with adsorption being lower at soil pH above 6.5.

In satisfactory field dissipation studies carried out at 4 sites in Europe and 6 sites in North America (spray application to the soil surface on bare soil plots in late spring or early summer) cyantraniliprole exhibited moderate to medium persistence. Sample analyses were carried out for the parent cyantraniliprole, IN-J9Z38, IN-JCZ38, IN-JSE76, IN-K5A77, IN-K5A78, IN-K5A79, IN-PLT97 and at selected sites for the photoproducts IN-NXX70, IN-QKV54 and IN-RNU71. Field study DT₅₀ values for parent cyantraniliprole were accepted as being reasonable estimates of degradation and were normalised to FOCUS reference conditions (20°C and PF2 soil moisture) using the time step normalisation procedure in accordance with FOCUS (2006) kinetics guidance⁶. Kinetic analysis to derive DT values for the metabolites from the field studies were presented in the DAR, but have not been included in the list of agreed endpoints. The reason is that at some trial sites for some metabolites the data were either quite scattered, did not describe a clear decline phase, or were visually and statistically poor. The experts at the Pesticides Peer Review 113 meeting agreed that the laboratory and field data sets for the active substance cyantraniliprole should be combined to get DegradationT₅₀ for use in FOCUS modelling and that, to account for the pH dependence of degradation, the geomean for use in the FOCUS modelling exposure assessments should be all soils (6), that had a pH (H₂O) less than 7. This approach was considered defensible, as the soils overlying any vulnerable confined aquifer are considered unlikely to exhibit degradation rates representative of soils having a pH of less than or equal to 4.62 (which represents an alternative tier 1 approach, that would use the single lab DT_{50} from the experiment with the lowest soil pH (4.62)). Experts also noted that there was an information gap on degradation T₅₀ in the soil pH_(water) range 4.8-5.9 that means that some uncertainty remains regarding leaching potential when vulnerable aquifers are overlaid by predominantly acidic soils. This uncertainty is important as the modelling framework is sensitive to small changes in half life for parent cyantraniliprole. Therefore a data gap for such soil incubations (modelling cyantraniliprole DegradationT₅₀ endpoints at FOCUS reference conditions) for soils in the pH range 4.8-5.9, was agreed as appropriate and this data gap is indicated in section 7 of this conclusion.

In laboratory incubations in dark aerobic natural sediment water systems, cyantraniliprole exhibited moderate persistence at pH 6.1 and low persistence at pH 7.6, forming the major metabolite IN-J9Z38 (max. 48 % AR in water after 9 days and max. 77 % AR in sediment after 56 days, which exhibited high persistence). The unextractable sediment fraction (not extracted by acidified acetone, acetone and acidified dichloromethane: methanol) was a sink for the cyano and pyrazole carbonyl ¹⁴C radiolabels, accounting for 5.4 – 12.7 % AR at study end (100 days). Mineralisation of these radiolabels was minimal being below a value that could be measured at study end. The rate of decline of cyantraniliprole in a laboratory sterile natural water photolysis experiment was more rapid than occurred in the aerobic sediment water incubations with the major metabolites IN-NXX70 (max. 53 % AR) and IN-QKV54 (max. 85 % AR) being formed.

Surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) were carried out for the metabolites IN-J9Z38, IN-K5A77, IN-JCZ38, IN-JSE76, IN-K5A79, IN-K5A78, IN-PLT97, IN-RNU71, IN-QKV54, IN-NXX70 and IN-M2G98 using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 2.1 of the Steps 1-2 in FOCUS calculator). For the active substance cyantraniliprole, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available⁵. For selected uses to high crops FOCUS Step 3 based calculations were also provided for the metabolites IN-J9Z38, IN-RNU71 and IN-NXX70. The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 20 m being implemented for the drainage scenarios (representing a 91 – 93 % spray drift reduction), and combined no-spray buffer zones with vegetative buffer strips of up to 20 m (reducing solute flux in run-off by 80 % and erosion run-off by 95%) being implemented for the run-off scenarios. The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures in the

 $^{^6}$ Normalisation utilised the agreed Q_{10} of 2.58 (following EFSA PPR Panel, 2007) and Walker equation coefficient of 0.7



simulations. However, risk managers and others may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS (FOCUS, 2007) report acknowledges that for substances with KFoc < 2000 mL/g (i.e. cyantraniliprole), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds. A data gap (see section 7) has been identified for surface water exposure assessments for the requested field uses on melons, tomatoes, peppers and green beans with application by 'broadcast mist blower', as the available FOCUS surface water calculations for these situations used spray drift values from just standard hydraulic sprayers and not air assisted broadcast spraying equipment. For the representative protected uses, the necessary surface water and sediment exposure assessments were carried out using the FOCUS (2001) spray drift values to a 30cm deep static water body assuming a smallest distance between the spray cone and the water body of 5m. Additionally calculations assuming 0.2% emission to a static 30 cm water body, outlined as being an appropriate approach for glasshouse situations in FOCUS (2008) air guidance, when applications are made with ultra low volume application techniques, were provided.

Groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2009) scenarios and the models PEARL 4.4.4 and PELMO 4.4.3⁷ for the active substance cyantraniliprole. The potential for groundwater exposure from the representative uses by cyantraniliprole above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios, when considering that confined vulnerable aquifers would not often be overlaid by soils that have predominant pHs in the very acidic range below ca. 6 over a large proportion of their area. For situations where confined vulnerable aquifers are overlaid by soils having a pH_(water) around 4.62, groundwater exposure above 0.1 µg/L is indicated. For the 2x150 g a.s./ha application on nectarines (FOCUS surrogate crop apples), cyantraniliprole concentrations were $0.13 - 0.57 \mu g/L$. For the 2 x 75 g a.s. / ha application on lettuces, cyantraniliprole concentrations were $0.004 - 0.36 \mu g/L$, with 4 of 7 scenarios above 0.1 $\mu g/L$. For the metabolites IN-J9Z38, IN-JCZ38, IN-K5A77, IN-QV54 and IN-NXX70 it is possible to conclude that the potential for groundwater exposure from the representative uses would be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios. This was also the case for soil photolysis metabolite IN-RNU71 using tier 2 and 3 assessments where the formation amount of its precursor (IN-J9Z38) from field studies was incorporated in the assessments. For the metabolites IN-K5A78, IN-K5A79, IN-PLT97, IN-M2G98 and IN-JSE76, 0.1 µg/L is exceeded, triggering non relevance assessments. All also exceed 0.75 µg/L so consumer risk assessments are triggered for them. In addition for IN-JSE76 groundwater concentrations are predicted to be in the range 6.4-25.5 µg/L with between 4/7 and 7/9 FOCUS groundwater scenarios exceeding the SANCO/221/2000 rev. 10 final (European Commission, 2003) level of 10 µg/L. Groundwater exposure assessments were not available to cover the representative non hydroponic glasshouse uses on aubergines, tomatoes, cucurbits edible and inedible peel, peppers, green beans and lettuces (just drip irrigation assessment missing) or the foliar application to melons. This was therefore identified as a data gap (see section 7).

The applicant's dossier did not include any information to address the effect of water treatments processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water. This has been identified in section 7 as a data gap and as an assessment not finalised (see section 9.1.1). Article 4 (approval criteria for active substances) 3. (b) of Regulation (EC) No 1107/2009 indicates that information on this is needed for the decision making on EU level approval.

The PEC in soil, surface water, sediment, and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion, with the exception of the uses for which data gaps for an exposure assessment have been identified in section 7.

-

⁷ Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA PPR Panel, 2007) and Walker equation coefficient of 0.7



5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002), SETAC (2001), and EFSA (2009).

Some aspects of the risk assessment were discussed at the Pesticides Peer Review Meeting 115 (May 2014).

The acute and the long-term risks to **birds** via dietary exposure were assessed as low for the active substance and relevant plant metabolites with the screening step. The risks via consumption of contaminated water and via secondary poisoning were also assessed as low.

The acute risk to **mammals** was assessed as low for all the representative uses of cyantraniliprole. The long-term risk to mammals was considered as low for the uses in glasshouse and was assessed as low at the first tier only for the field representative uses in potatoes applied as ground directed spray and tomato and pepper applied as drip irrigation. Long-term risks to mammals were estimated as high for the other uses. Reanalysis of the toxicological data taking into account historical control data resulted in a NOAEL from the multi-generation rat study of 135.2 mg a.s./kg bw per day. However, the experts at the Pesticides Peer Review Meeting 115 (May 2014) agreed to use the lower endpoint of 25 mg a.s./kg bw per day from the rabbit developmental study as relevant for the mammalian long-term risk assessment, as was presented by the RMS. On the basis of this refinement the risk to herbivorous mammals was concluded as low, except for the representative uses (ground directed spray), in tomato, green bean, and pepper, and for the representative use (as spray) in citrus. A data gap was identified for further risk refinements for these uses and for melons (4 applications at 90 g a.s./ha).

The risk from the plant metabolites IN-J9Z38, IN-QKV54 and IN-NXX70 were considered to be low. The risks to mammals via consumption of contaminated water and via secondary poisoning were also concluded as low.

A number of studies were available on **aquatic organisms** with the active substance, the formulated products and the relevant metabolites. When the active substance is formulated appears to be more toxic than the technical. The risk assessment was driven by aquatic invertebrates. Since several acute toxicity studies with the active substance were available on aquatic organisms, the endpoints from reliable studies were used to construct an acute species sensitivity distribution (SSD) curve and to derive an HC_5 value. The experts at the meeting agreed on a HC_5 of 11. 8 μg a.s./L based on a bivalve toxicity endpoint as well as crustaceae and insect data. The agreed assessment factor (AF) was 3.

The risk of cyantraniliprole was low for fish, algae and aquatic plants with FOCUS step 1&2 PEC_{sw} values for all the representative uses, while a high risk was identified for invertebrates (both acute and chronic risk) and sediment dwelling organisms (chronic). For the higher tier acute risk assessment, the HC₅ of $11.8~\mu g$ a.s./L with the AF of 3 was used with the maximum PECsw values of FOCUS step 3&4. The higher tier chronic risk assessment was performed based on the standard endpoints from *Chironomus* (i.e. NOEC of $10~\mu g$ a.s./L and $24~\mu g$ a.s./kg sediment) and the trigger value of 10; the maximum PECsw values and PEC_{sed} values of FOCUS step 3&4 were used. This chronic risk assessment covers also the risk for aquatic invertebrates living in the water column, since the chronic endpoint for *Daphnia magna* is similar to the endpoint for *Chironomus*. Overall, the regulatory acceptable concentrations (RAC) were: $3.93~\mu g$ a.s./L (acute RAC); $1~\mu g$ a.s./L and $2.41~\mu g$ a.s./kg sediment (chronic RACs). Since the chronic RACs drives the risk assessment, only the outcome of the chronic risk assessments based on the worst-case exposure estimates for the representative uses is summarised below.

For the representative field uses (as ground directed spray) in lettuce, tomato, green bean, pepper and potatoes (critical GAP, 2 applications at 90 g a.s./ha), a low risk was identified at FOCUS step 3 for the drainage scenarios, except the D4 and the D6; a low risk was identified for the run-off scenarios, providing that mitigation measures comparable with vegetated buffer strips up to 20m are applied. For the representative spray field use in melon with 4 applications at 90 g a.s./ha, the risk assessment could



not be finalised, due to the lack of the exposure assessment (data gap). For the representative field uses (as directed spray) in apples, pears, peaches and apricots (critical GAPs, 2 applications at 90 g a.s./ha) a low risk was identified for the run-off and drainage scenarios (except D4), providing that mitigation measures comparable with no spray buffer zones up to 20 m and vegetated buffer strips up to 20 m are applied. For the representative use in plums (critical GAPs, 2 applications at 125 g a.s./ha) a low risk was identified for the run-off and drainage scenarios (except D4, D5, R1), providing that mitigation measures comparable with no spray buffer zones up to 20 m and vegetated buffer strips up to 20 m are applied. For the representative use in nectarines, citrus, mandarins and olives (critical GAPs, 2 applications at 150 g a.s./ha) a low risk was identified for the run-off and drainage scenarios, providing that mitigation measures comparable with no spray buffer zones up to 20 m and vegetated buffer strips up to 20 m are applied. For the representative use in grapes (critical GAPs, 2 applications at 112.5 g a.s./ha and) a low risk was identified for the run-off and drainage scenarios, providing that mitigation measures comparable with no spray buffer zones up to 10 m and vegetated buffer strips up to 10 m are applied. For the representative uses (as drip irrigation) in tomato and pepper a low risk was identified for the run-off and drainage scenarios, providing that mitigation measures comparable vegetated buffer strips up to 20 m are applied. The risk for the glasshouse uses was assessed as low. The risk for the metabolites IN-JCZ38 IN-PLT97 was assessed as low with FOCUS step1&2, and FOCUS step 3 for IN-J9Z38.

The toxicity of cyantraniliprole and its formulated products (Cyantraniliprole 100 g/L OD, Cyantraniliprole 100 g/L SE with and without Codacide Oil, Cyantraniliprole 200 g/L SC and A16971B) was investigated in acute oral and contact tests on **honeybees**. Oral toxicity tests were available also for the metabolites, IN-HGW87, IN-J9Z38, IN-K5A78 and IN-DBC80. Acute testing on honeybees demonstrated similar toxicities of the formulations. It is noted that the LD₅₀ values for the active substance were undefined values *i.e.* higher than the dosages tested, while the toxicity endpoints for the formulated products were defined values. The first-tier risk assessment based on the oral and contact HQ approach indicated a high risk for the active substance for all the representative uses. However, the HQs calculated based on the defined endpoints from the formulated products, indicated a low risk for the representative uses in potatoes (i.e. application rate of 12.5 g a.s./ha) and in mandarins with the application rate of 32 g a.s./ha while the risk for the other uses was indicated as high. It should be noted that for some representative uses (i.e. the drip irrigation in field tomato and pepper) the HQ approach is not applicable, since it was only validated for spray uses.

Numerous higher tier studies were available to address the risk to honeybees. The tests for the spray uses were carried out considering both applications, with and without mitigation measures, such as applications after daily bee flight. Only the studies carried out with application rates comparable to the representative uses were considered relevant for the risk assessment. Additional data were also available such as a foliage residue contact toxicity laboratory test, which indicated no treatment-related mortality over the 24-hour exposure to 3, 8, 24, 48, 72 hour aged residues, and several residue trials on bee matrices (e.g. nectar, pollen).

The RMS evaluated all the studies in detail in the revised DAR, Vol. 3 B.9 Part A (United Kingdom, 2014) and they were considered for risk assessment in the revised DAR vol. 3 B.9 Part B (United Kingdom, 2014).

Tunnel tests were performed in oilseed-rape, *Phacelia* and wheat (treated with sugar), apple and nectarine with treatment regimes including applications before flowering and/or applications during the flowering, either during or after the daily bee flight. Oilseed-rape and *Phacelia* are not in the GAP of the representative use, therefore, when extrapolating the results to other crops, the intrinsic differences between the plants in terms of residue translocation should be considered as source of uncertainty to the exposure to residues in pollen and nectar.

In the tunnel test performed in oilseed-rape, *Phacelia* and wheat, mortalities, signs of intoxication and flight activity reduction were observed for few days following applications during the flowering period, both during and after the daily bee flight. In the tunnel test performed in apple, mortality was



observed for one day following the application during flowering after the daily bee flight. Mortality was also observed in the tunnel test in nectarine, but it was not possible to establish the extent of this due to the lack of stable mortality in the control. No effects on behaviour were reported and also the flight activity was not affected but in the study in apple a low control flight activity was observed. In none of the semi-field tests, adverse effects were observed on honeybees following the pre-flowering applications. Furthermore, no effects were reported on colony and brood development, but this type of test is not appropriate for these assessments (i.e. short duration, no over-wintering assessment).

A bee brood test under semi-field conditions was available but during the experts' meeting it was considered as additional information only, because it was performed at a too high application rate (2 applications at 150 g a.s./ha each) and therefore due to a repellent effect, the amount of residues taken to the hive could have been low.

Three field studies were available: two performed in oilseed rape and one in melon. The field studies on oilseed rape indicated no adverse effects on honeybees following the pre-flowering applications. They also indicated no effects on mortalities following applications during the flowering period and after the daily bee flight. No effects were observed on colony strength and brood development, including over-wintering observations. The assessment of the effects on flight activity could not be concluded due to low flight activity in the control. Regarding the applications during flowering and bee-flight, adverse effects on mortality, flight activity and behaviour were observed. It has to be noted these studies were considered 'reliable with restriction' by the RMS due to some limitations regarding the compliance with the guideline. The field study in melon was discussed at the experts' meeting. The study was performed at application rate higher than the GAP (i.e. 150 g a.s./ha). The experts acknowledged the RMS's evaluation of this study regarding the reliability of the results due to e.g. low foraging activity in the crop (there was evidence of intensive foraging on wild flora) and Varroa infestation. However, the experts noted that the results regarding the effects (e.g. some increased mortality) were in-line with the results from other studies. Residue analysis of pollen, honey, wax and guttation fluid collected in the field studies confirmed the honeybees were exposed to cyantraniliprole during the studies and the residue decline was quite fast. The rapid residue decline (DT_{50} up to 6 days) was also confirmed by the data from the residue trials which showed high residue levels but relative rapid decline of cyantraniliprole. However, EFSA noted that residue levels in pollen higher than those detected in the field studies were reported from a trial in oilseed rape performed at slightly higher rate (120 g a.s./ha). Therefore, there might be uncertainty over whether the exposure in the field studies was worst-case. The residue analysis included also the metabolites, which were found below the limit of detection (i.e. LOD of 1.25 µg/kg).

Overall, on the basis of the available data, the following conclusions were drawn. For the representative uses as spray application on field vegetables with 2 applications at 90 g a.s./ha (i.e. field tomato, green bean, and field pepper, except melon), the experts argued that the risk to honeybees could be considered as low only if the first application is carried out before the flowering period and the second application is carried out during the flowering period but after daily bee flight (with minimum interval between application of 7 days). It is pointed out that this conclusion was based on the evidence from semi-field and field studies performed with crops not included in the GAP and from the field studies which were considered reliable with restriction. Therefore, further data would be needed to address these uncertainties, including information to confirm that the exposure in the field studies was worst-case. Furthermore, to better characterise the risk, the available measured residue levels might be used for estimating the honeybee residue intakes with the consumption of contaminated nectar and pollen. However, taking into account that these crops are not highly attractive to honeybees, the proposed use restriction can be considered sufficient to manage the risk. Since the available data covered only 2 applications at 90 g a.s./ha, it was not possible to draw a conclusion for the representative field use in melon with 4 applications at 90 g a.s./ha and a data gap was identified. The risk to honeybees for the representative use in lettuce (spray) was considered as low because it is not attractive to honeybees (i.e. it is not a flowering crop). However, for this representative use, applications during the bee flight should be avoided to prevent potential exposure via flowering weeds.



For the representative uses as <u>spray application</u> on apples, pears, nectarines peaches and apricots plums citrus, mandarins, olives, grapes a high risk could not be excluded with the available data. Considering the evidence that residual activity is likely to pose a low risk to bees, the experts argued that the risk to honeybees could be mitigated, particularly for application lower than 100 g a.s./ha, if the first application is carried out before the flowering and the second application is carried out during the flowering but after daily bee flight (with minimum interval between application of 19 days). However, on the basis of the residue data provided, EFSA noted that it was not possible to observe a clear trend for the residue decline. By taking into account that these crops may be highly attractive to honeybees, overall, EFSA considered that the risk assessment for cyantraniliprole and its metabolites for these representative uses should be further addressed (data gap). However, for the representative uses applied only after the flowering period, the risk can be considered as low, provided that risk mitigation measures are taken to avoid direct exposure of the bees foraging on flowering weeds.

Since the dossier was submitted and evaluated by the RMS before the adoption of the opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (EFSA PPR, 2012), the higher tier available studies (i.e. the field studies mentioned above) and the risk to bees were not evaluated by considering the recommendations of this opinion.

It is further noted that the available assessments for the all the field uses refer to honeybees and other pollinators such as wild bees are not covered.

A study on bumble bee in glasshouse was available and discussed during the experts' meeting. No effects on bumble bees (mortality, foraging activity and brood development) were observed, but a potentially treatment related effect on queen mortality was observed. It was noted that the study informed on the effects on bumble bee only for situations when the bumble bees are introduced into the glasshouses after application of cyantraniliprole. Therefore, this study alone cannot be considered sufficient to address the risk for bumble bees. Therefore risk mitigation measures such as covering or removing bumble bee colonies should be considered for the representative uses in glasshouse making use of these pollinators. EFSA noted that protection measures for the wild pollinators visiting the glasshouses should also be considered (e.g. by keeping the glasshouses closed).

Two semi-field studies were available to investigate the effects on honeybees following application via <u>drip irrigation</u> on melon. These studies were considered not fully reliable. Furthermore, the experts in the meeting agreed that data on melons cannot be extrapolated to the representative uses in tomato and pepper due to different attractiveness to bees and the intrinsic differences between the plants in terms of residue translocation. It has to be considered that residues levels were notably lower after soil drip application compared to foliar applications with a similar metabolic pattern. Furthermore, tomato and pepper are not highly attractive to honeybees. Nevertheless, further data would be needed to address the risk to bees for the representative uses as field drip irrigation for example to account for the residue intakes with the consumption of contaminated nectar and pollen.

As regards to the **non-target arthropods**, a low in- and off-field risk was indicated by the HQ values for the standard indicator species *T. pyri*, while the in-field and off-field HQ values for the standard indicator species *A. rhopalosiphi* were above the trigger (HQ values >2) for all the representative field uses. Additional extended laboratory tests (including natural substrate, field aging residue and semi-field testing) were therefore conducted with the standard species and additional species such as *Chrysoperla carnea* and *Coccinella septempunctata*. The higher tier extended lab and semi-field studies suggested there is still a high in-field and off-field risk for the representative field uses (as ground directed spray) in lettuce, tomato, green bean, pepper, and potatoes (high risk only for in-field areas) and for the representative uses as spray application on apples, pears, nectarines peaches and apricots plums citrus, mandarins, olives, grapes. The aged residue study and the study involving exposure of aphid mummies parasitized by *A. rhopalosiphi* indicate that the dissipation of residues in the field and a lack of effects on protected life stages might ensure the recovery of populations. There is also the potential for recolonisation or recovery of treated in-field areas by other relatively less sensitive flying and multivoltine insect species such as *C. carnea* and *C. septempunctata*, as



demonstrated by the aged residue studies on these species. However, these data were considered not sufficient to demonstrate the recovery and recolonisation of in-field areas within a year and off-field areas (except for the use on potatoes, 2 applications at 12.5 g a.s./ha) within an ecologically relevant timeframe for more sensitive species. Since the available data covered up to 2 applications at 90 g a.s./ha, it was not possible to draw any conclusion for the representative field use in melon with 4 applications at 90 g a.s./ha. A data gap was identified to further consider the risk to non-target arthropods for the representative field uses (as ground directed spray) in lettuce, tomato, green bean, pepper, and potatoes (only in-field risk), including melon (4 applications at 90 g a.s./ha) and for uses as spray application on apples, pears, nectarines peaches and apricots plums citrus, mandarins, olives, grapes.

For representative <u>outdoor drip irrigation uses in tomato and pepper</u>, extended laboratory studies on *Aleochara bilineata* and *Pardosa* were available. The study on *Pardosa* confirmed the low sensitivity of arachnids, therefore it cannot be considered relevant for the risk assessment of the most sensitive species. The extended lab study on *Aleochara bilineata* suggested that, based on ER₅₀ for reproduction there is still high risk for non-target arthropods inhabiting drip-irrigated areas. A study investigated the reproductive effects of aging soil residues of cyantraniliprole on *Aleochara bilineata* indicated no unacceptable effects following the exposure to soil aged for 1 month or longer after the 2nd application. Overall, by taking into account also the risk assessment on soil-macroorganism (see below), the risk to non-target arthropods for the representative outdoor drip irrigation uses in tomato and pepper can be considered as low.

The risk to non-target arthropods for glasshouse uses may need to be further considered within Integrated Pest Management (IPM).

The acute and chronic risk to **earthworms** was assessed as low for all the representative uses. Chronic tests were conducted to investigate the potential effects of cyantraniliprole and major soil metabolites on **soil macroorganisms** other than earthworms. A high first tier risk was indicated for *Folsomia candida* for cyantraniliprole based on the worst-case PECsoil. Field studies were submitted on collembolan populations. These indicated the potential for recovery within 1 year. Furthermore, no significant effects were observed on decomposition compared to the controls over the 6 month exposure period for the active substance or any of the tested metabolites in a litter bag study. Overall, the risk to soil macro-organisms for cyantraniliprole and its soil metabolites can be concluded as low for all the field representative uses. The risk to soil macroorganisms for glasshouse uses may need to be further considered within Integrated Pest Management (IPM), since the representative uses in glasshouses are not fully covered by the higher tier field data.

As regards to **soil microorganisms**, tests were conducted to investigate the potential effects of cyantraniliprole and major soil metabolites on carbon and nitrogen transformation. By comparing the PECsoil for cyantraniliprole and the soil metabolites to the soil concentrations at which no effects > 25 % were observed on nitrogen or carbon transformation, the risk to soil microorganisms was indicated as low for all the field representative uses. The risk for the metabolite IN-J9Z38 was indicated as high for glasshouse uses and may need to be further considered within Integrated Pest Management (IPM),

The risk to terrestrial non-target plants and organisms used in sewage treatment plants was assessed as low.



6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
cyantraniliprole	moderate to high persistence Biphasic kinetics DT ₅₀ 9-92 days (DT ₉₀ 66-376 days, 20-22°C 40-60% MWHC or 75% 1/3 bar) European field dissipation studies biphasic kinetics DT ₅₀ 14-28 days (DT ₉₀ 93-299 days)	Low risk for soil living organisms (high risk not excluded for collembola with the worst-
	North American field dissipation studies biphasic kinetics DT ₅₀ 10-44 days (DT ₉₀ 55-299 days) pH dependent, increasing persistence as pH decreases	case PECsoil from glasshouse uses)
IN-J9Z38	moderate to very high persistence Biphasic kinetics DT ₅₀ 51-610 days (DT ₉₀ 169-2027 days, 20-22°C 40-60% MWHC or 75% 1/3 bar)	Low risk for soil living organisms (high risk not excluded for microorganisms with the worst-case PECsoil form glasshouse uses)
IN-JCZ38	low to high persistence Biphasic kinetics DT ₅₀ 3.6-133 days (DT ₉₀ 19-442 days, 20-22°C 40-60% MWHC or 75% 1/3 bar)	Low risk for soil living organisms
IN-JSE76	moderate to very high persistence Biphasic kinetics DT ₅₀ 43-1249 days (DT ₉₀ 143-5929 days, 20°C 40-60% MWHC or 75% 1/3 bar)	Low risk for soil living organisms
IN-K5A78	medium to very high persistence Single first order kinetics DT ₅₀ 98-6x10 ⁵ days (20°C 40-60% MWHC or 75% 1/3 bar)	Low risk for soil living organisms
IN-PLT97	medium to very high persistence Single first order kinetics DT ₅₀ 70-1837 days (19-24°C 40-60% MWHC or 75% 1/3 bar)	Low risk for soil living organisms



IN-QKV54	moderate to very high persistence Biphasic kinetics DT ₅₀ 57-1187 days (DT ₉₀ 651-1595 days, 20°C 40-60% MWHC or 75% 1/3 bar)	Low risk for soil living organisms
IN-RNU71	moderate to very high persistence Biphasic kinetics DT_{50} 42-400 days (DT_{90} 139-2437 days, 20°C 40-60% MWHC or 75% 1/3 bar)	Low risk for soil living organisms

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter) Pesticidal activ		Toxicological relevance	Ecotoxicological activity
cyantraniliprole	high to medium mobility K_{Foc} 128-266 mL/mg	No when soils overlying a confined aquifer have pH predominantly above 4.6 When soils overlying a confined aquifer have pH below 6 over a high proportion of the area, groundwater exposure >0.1 µg/L is possible. (0.004-0.568 µg/L 4/7 and 9/9 FOCUS scenarios >0.1 µg/L, for representative lettuce and orchard uses respectively consequent from a DegT50 indicative of pH 4.6)	Yes	Yes	High risk to aquatic organisms in surface water for some representative uses. Mitigation measures were needed to manage the risk but were not sufficient for some FOCUS scenarios.
IN-J9Z38	low mobility to immobile K_{Foc} 2762-17978 mL/g	No	Assessment not triggered.	Major rat metabolite, assessment not triggered	Low risk to aquatic organisms in surface water
IN-JCZ38	high to medium mobility K_{Foc} 95-329 mL/g	No	Assessment not triggered.	No data available. Not required.	Low risk to aquatic organisms in surface water



IN-JSE76	very high to high mobility $$K_{Foc}$$ 13-52 mL/g	6.4-25.5 μg/L, between 4/7 and 7/9 FOCUS scenarios > 10 μg/L	No	Not relevant Reference values of cyantraniliprole: ADI 0.01 mg/kg bw per day, ARfD not required. Consumer intake up to 38% of the ADI	Low risk to aquatic organisms in surface water
IN-K5A77	low mobility to immobile K_{Foc} 1953-14677 mL/g	No	Assessment not triggered.	No data available. Not required.	Low risk to aquatic organisms in surface water
IN-K5A78	medium to low mobility K_{Foc} 269-1296 mL/g	0.33-0.99 μg/L	No	Data gap	Low risk to aquatic organisms in surface water
IN-K5A79	very high to high mobility K_{Foc} 21-72 mL/g pH dependent	1.9-5.22 μg/L	No	Not relevant based on hazard assessment, insufficient data to derive reference values, which are needed.	Low risk to aquatic organisms in surface water
IN-PLT97	medium to slight mobility K_{Foc} 423-3109 mL/g	0.48-1.28 μg/L	No	Not relevant Reference values of cyantraniliprole: ADI 0.01 mg/kg bw per day, ARfD not required. Consumer intake up to 2% of the ADI	Low risk to aquatic organisms in surface water
IN-QKV54	$\begin{array}{ccc} \text{slight} & \text{mobility} & \text{to} \\ \text{immobile} & \\ K_{Foc} \ 3482\text{-}14828 \ \text{mL/g} \end{array}$	No	Assessment not triggered.	No data available. Not required.	Low risk to aquatic organisms in surface water
IN-RNU71	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	No using tier 2 and tier 3 assessmemnts	Assessment not triggered.	No data available. Not required.	Low risk to aquatic organisms in surface water



IN-NXX70	low mobility to immobile based on structure read across from IN-J9Z38	No	Assessment not triggered.	No data available. Not required.	Low risk to aquatic organisms in surface water
IN-M2G98	high mobility QSAR K _{doc} 112 mL/g	0.64-4.1 μg/L	No	Not relevant based on hazard assessment, insufficient data to derive reference values, which are needed.	Low risk to aquatic organisms in surface water with sufficient margin to cover the higher concentration in groundwater

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
cyantraniliprole	High risk to aquatic organisms for some representative uses. Mitigation measures were needed to manage the risk but were not sufficient for some FOCUS scenarios.
IN-J9Z38	Low risk to aquatic organisms
IN-JCZ38	Low risk to aquatic organisms
IN-JSE76	Low risk to aquatic organisms
IN-K5A77	Low risk to aquatic organisms
IN-K5A78	Low risk to aquatic organisms
IN-PLT97	Low risk to aquatic organisms
IN-QKV54	Low risk to aquatic organisms
IN-RNU71	Low risk to aquatic organisms
IN-NXX70	Low risk to aquatic organisms

6.4. Air

Compound (name and/or code)	Toxicology
cyantraniliprole	Rat LC50 inhalation > 5.2 mg/L, 28-day rat NOAEC 0.1 mg/L



7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of the Regulation concerning information on potentially harmful effects).

7.1. Data gaps identified for the representative uses evaluated

- A search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of dossier, to be conducted and reported in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011), (relevant for all representative uses evaluated; The information is available but not transparently evaluated in the DAR).
- Revised technical specification (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Assessment of the toxicological properties of the metabolites IN-F6L99 and IN-N5M09 found in significant levels in some processed commodities (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2 and 3).
- Further toxicological assessment of groundwater metabolites: IN-M2G98 and IN-K5A79 for the derivation of reference values for the consumer's risk assessment; IN-K5A78 for its toxicological relevance (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).
- Supervised residue trials on apricot, lettuce and bean (with pods) conducted according to the representative GAPs supported at EU level (relevant for representative EU uses on apricot and lettuce; submission date proposed by the applicant: unknown; see section 3).
- Additional data to address the possible transfer in rotational crops, of the persistent soil metabolites, following multiple years of consecutive applications (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 3)
- Information from aerobic soil incubations (modelling cyantraniliprole DegT₅₀ at FOCUS reference conditions) for soils in the pH_(water) range 4.8-5.9 were not available. (relevant for all representative uses evaluated: submission date proposed by the applicant: unknown; see section 4).
- Surface water exposure assessments for field uses covering the requested uses where application is by 'broadcast mist blower' and consequent aquatic risk assessments were not available (relevant for the field uses evaluated on melons, tomatoes, peppers and green beans, where application by 'broadcast mist blower' was requested; submission date proposed by the applicant: unknown; see section 4 and 5).
- Groundwater exposure assessments were not available to cover the representative non hydroponic glasshouse uses on aubergines, tomatoes, cucurbits edible and inedible peel, peppers, green beans and lettuces (just drip irrigation assessment missing) or the foliar application to melons. (relevant for glasshouse uses on aubergines, tomatoes, cucurbits edible and inedible peel, peppers, green beans lettuces and melons; submission date proposed by the applicant: unknown; see section 4).
- Groundwater and surface water exposure assessments and consequent aquatic risk assessment were not available to cover the representative field uses on melons. (relevant for the southern



European field use of 4x 90g a.s./ha on melons); submission date proposed by the applicant: unknown; see section 4 and 5).

- The effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water (Article 4 (approval criteria for active substances) 3. (b) of Regulation (EC) No 1107/2009) has not been assessed. In the first instance, a consideration of the processes of ozonation and chlorination may be considered appropriate. If an argumentation is made that concentrations at the point of extraction for drinking water purposes will be low, this argumentation should cover metabolites predicted to be in groundwater and surface water, as well as the active substance. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).
- The long-term risks to herbivorous mammals needs to be further addressed (relevant for representative uses evaluated as ground directed spray in melon, tomato, green bean, and pepper, and for the representative use (as spray) in citrus; submission date proposed by the applicant: unknown; see section 5).
- The risk of cyantraniliprole and its metabolites to bees needs to be addressed (relevant for the southern European field use of 4x90g a.s./ha on melons; for the representative uses as spray application on apples, pears, nectarines peaches and apricots plums citrus, mandarins, olives, grapes, except those with applications only after the flowering period; for the representative uses as field drip irrigation on tomato and pepper; submission date proposed by the applicant: unknown; see section 5)
- The in-field and off field risk for non-target arthropods need to be further addressed to demonstrate the recovery and recolonisation of sensitive species (relevant for the representative field uses (as ground directed spray) in lettuce, tomato, green bean, and pepper, potatoes (only infield), including melon (4 applications at 90 g a.s./ha) and for uses as spray application on apples, pears, nectarines peaches and apricots plums citrus, mandarins, olives, grapes; submission date proposed by the applicant: unknown; see section 5)

7.2. Data gaps identified for the maximum residue level applications

• Documentation providing evidence of the registration of cyantraniliprole, as well as information on the GAPs and MRL values effectively adopted and published in the exporting countries were not available (relevant for all requested import tolerances; submission date proposed by the applicant: unknown; see section 3).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

8.1. Particular conditions proposed for the representative uses evaluated

- The operators should wear personal protective equipment during application of the OD formulation in greenhouses (see section 2).
- Mitigation measures such as no-spray buffer zone and/or vegetated buffer strips should be applied to manage the risk to aquatic organisms for the field representative uses.
- For the representative uses as spray application on field vegetables with 2 applications at 90 g a.s./ha (i.e. field tomato, green bean, and field pepper), the risk to honeybees could be considered as low only if the first application is carried out before the flowering period and the second application is carried out during the flowering period but after daily bee flight (with minimum interval between application of 7 days). For the representative field use in lettuce (spray) and for the representative spray uses in orchards and grapes applied only after the flowering periods,



applications during the bee flight should be avoided to prevent potential exposure via flowering weeds.

8.2. Particular conditions proposed for the maximum residue level applications

• No particular conditions are proposed for the MRL applications.

9. Concerns

9.1. Concerns for the representative uses evaluated

9.1.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011⁸ and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as an issue that could not be finalised where the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation for the representative uses assessed.

- 1. The environmental exposure (including groundwater exposure) and the consequent risk to non-target organisms could not be finalised for the southern European field use of 4x90g a.s./ha on melons.
- 2. Surface water exposure assessments for the field uses evaluated on melons, tomatoes, peppers and green beans where application is by 'broadcast mist blower' and consequent aquatic risk assessments could not be finalised.
- 3. The risk to bees for the representative uses as field drip irrigation on tomato and pepper could not be finalised.
- 4. The groundwater exposure assessment for the active substance and metabolites could not be finalised for the representative non hydroponic glasshouse uses on aubergines, tomatoes, cucurbits edible and inedible peel, peppers, green beans and lettuces (just drip irrigation assessment missing) or the foliar application to melons as the necessary assessments were not available.
- 5. The consumer risk assessment is not finalised with regard to the unknown nature of residues that might be present in drinking water, consequent to water treatment following abstraction of surface water and groundwater that might contain cyantraniliprole and its metabolites.
- 6. The available mammalian toxicological information was insufficient to conclude on the groundwater relevance of the metabolites IN-K5A78, IN-M2G98 and IN-K5A79. Consequently it is not clear if the parametric water quality drinking water limit of 0.1 μg/L is applicable to these metabolites that are indicated to be present in groundwater above this level. This assessment not being finalised applies to all the representative uses except hydroponic cultivation.

-

⁸ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127-175.



9.1.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where in the light of current scientific and technical knowledge using guidance documents available at the time of application the active substance is not expected to meet the approval criteria provided for in Article 4 of the Regulation.

• No issues identified in this category



9.1.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		Field melons spray 4x90g/ha	Field tomatoes spray 2x90g/ha	Field tomatoes drip 2x75g/ha	Field peppers spray 2x90g/ha	Field peppers drip 2x75g/ha
Operator risk	Risk identified Assessment not finalised					
Worker risk	Risk identified Assessment not finalised					
Bystander risk	Risk identified Assessment not finalised					
Consumer risk	Risk identified Assessment not finalised	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵
Risk to wild non target terrestrial vertebrates	Risk identified Assessment not finalised	X ¹	X		X	
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified Assessment not finalised	X ¹	X	X ³	X	X ³
Risk to aquatic organisms	Risk identified Assessment not finalised	X ^{1,2}	X (for D4, D6) X ²		X^2	X (for D4, D6)
Groundwater exposure active substance	Legal parametric value breached Assessment not finalised	X ¹				
Groundwater exposure metabolites	Legal parametric value breached ^(a) Parametric value of 10µg/L ^(b) breached Assessment not finalised	$X^{1,6}$	ca. 4/7 FOCUS scenarios X ⁶			
Comments/Rema	not finalised Comments/Remarks		when application by 'mist blower'		when application by 'mist blower'	



- (a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December.
- (b): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003.



Representative us	e	Field green beans 2x 90g/ha	Field lettuces spray 2x75g/ha	Potatoes 2x12.5g/ha
Operator risk	Risk identified Assessment not finalised			
Worker risk	Risk identified Assessment not finalised			
Bystander risk	Bystander risk Risk identified Assessment not finalised			
Consumer risk	Risk identified Assessment not finalised	X ⁵	X ⁵	X ⁵
Risk to wild non target terrestrial vertebrates	Assessment not finalised	X		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified Assessment not finalised	X	X	X
Risk to aquatic organisms	Risk identified Assessment not	X (for D4, D6) X ²	X (for D4, D6)	X (for D4, D6)
Groundwater exposure active substance	finalised Legal parametric value breached Assessment not finalised			
Groundwater exposure metabolites	Legal parametric value breached ^(a) Parametric value of 10µg/L ^(b) breached Assessment not finalised	ca. 4/7 FOCUS scenarios X ⁶	ca. 4/7 FOCUS scenarios X ⁶	<4/7 FOCUS scenarios X ⁶
Comments/Remai	² when application is by 'mist blower'			

⁽a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December.

⁽b): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003.



Representative	e use	Glasshouse aubergines spray 4x120g/ha	Glasshouse tomatoes spray 4x120g/ha	Glasshouse cucurbits edible peel spray 4x120g/ha	Glasshouse cucurbits inedible peel# spray 4x120g/ha	Glasshouse peppers spray 4x120g/ha	Glasshouse lettuces spray 2x75g/ha
	Risk						
Operator	identified						
risk	Assessment not finalised						
	Risk						
Wanlan	identified						
Worker risk	Assessment not finalised						
	Risk identified						
Bystander	Assessment						
risk	not						
	finalised						
Consumer	Risk identified						
risk	Assessment not	X^5	X^5	X^5	X^5	X^5	X^5
	finalised						
Risk to wild	Risk						
non target	identified						
terrestrial	Assessment not						
vertebrates	finalised						
Risk to wild non target	Risk identified						
terrestrial	Assessment						
organisms	not						
other than vertebrates	finalised						
vertebrates	Risk						
Risk to	identified						
aquatic	Assessment						
organisms	not finalised						
	Legal						
Groundwater	parametric						
exposure	value						
active	breached						
substance	Assessment not	X^4	X^4	X^4	X^4	X^4	
	finalised	71	71	71	71	71	
	Legal						
	parametric						
	value breached ^(a)						
Groundwater	Parametric						0 :: 4/7
exposure	value of						ca. 4/7 FOCUS
metabolites	10μg/L ^(b) breached						scenarios
	Assessment						
	not	$X^{4,6}$	$X^{4,6}$	$X^{4,6}$	$X^{4,6}$	$X^{4,6}$	X^6
	finalised						



Comments/Remarks		"crop group includes melons	

- (a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December.
- (b): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003.



Representative use		Glasshouse melons spray 4x90g/ha	Glasshouse green beans spray 4x90g/ha	Glasshouse aubergines drip 4x100g/ha	Glasshouse aubergines hydroponic 4x100g/ha	Glasshouse tomatoes drip 4x100g/ha	Glasshouse tomatoes hydroponic 4x100g/ha
Operator	Risk identified						
risk	Assessment not finalised						
***	Risk identified						
Worker risk	Assessment not finalised						
Bystander	Risk identified						
risk	Assessment not finalised						
Consumer	Risk identified						
risk	Assessment not finalised	X^5	X^5	X^5		X^5	
Risk to wild non target	Risk identified						
terrestrial vertebrates	Assessment not finalised						
Risk to wild non target	Risk identified						
terrestrial organisms other than vertebrates	Assessment not finalised						
Risk to	Risk identified						
aquatic organisms	Assessment not finalised						
Groundwater exposure	Legal parametric value breached						
active substance	Assessment not finalised	X^4	X^4	X^4		X ⁴	
Groundwater exposure metabolites	Legal parametric value breached ^(a)						
	Parametric value of 10µg/L ^(b) breached						
	Assessment not finalised	X ^{4,6}	$X^{4,6}$	X ^{4,6}		X ^{4,6}	



	-	-	-	-	
Comments/Remarks					

- (a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December.
- (b): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003.



Representative use		Glasshouse cucurbits edible peel drip 4x100g/ha	Glasshouse cucurbits edible peel hydroponic 4x100g/ha	Glasshouse cucurbits inedible drip 4x100g/ha	Glasshouse cucurbits inedible peel hydroponic 4x100g/ha	Glasshouse peppers drip 4x100g/ha	Glasshouse peppers hydroponic 4x100g/ha
Operator risk	Risk identified Assessment not finalised						
Worker risk	Risk identified Assessment not finalised						
Bystander risk	Risk identified Assessment not finalised						
Consumer risk	Risk identified Assessment not finalised	X ⁵		X ⁵		X ⁵	
Risk to wild non target terrestrial vertebrates	Risk identified Assessment not finalised						
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified Assessment not finalised						
Risk to aquatic organisms	Risk identified Assessment not finalised						
Groundwater exposure active substance	Legal parametric value breached						
	Assessment not finalised	X ⁴		X ⁴		X ⁴	
Groundwater exposure metabolites	Legal parametric value breached ^(a) Parametric value of						
	10µg/L ^(b) breached Assessment not finalised	X ^{4,6}		X ^{4,6}		X ^{4,6}	



Comments/Remarks			

- (a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December.
- (b): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003.



Representative use		Glasshouse melons drip 2x75g/ha	Glasshouse lettuces drip 3x100g/ha	Apples N2x75g/ha S2x90g/ha	Pears N2x75g/ha S2x90g/ha	Nectarines 2x150g/ha	Peaches 2x90g/ha
0 4 11	Risk identified						
Operator risk	Assessment not finalised						
Worker risk	Risk identified Assessment						
	not finalised						
Bystander risk	Risk identified Assessment						
	not finalised						
Consumer risk	Risk identified						
Consumer risk	Assessment not finalised	X^5	X^5	X^5	X^5	X^5	X^5
Risk to wild	Risk identified						
non target terrestrial vertebrates	Assessment not finalised						
Risk to wild non target	Risk identified			X	X	X	X
terrestrial organisms other than vertebrates	Assessment not finalised						
Risk to aquatic	Risk identified			X (for D4)	X (for D4)		X (for D4)
organisms	Assessment not finalised						
Groundwater exposure active	Legal parametric value breached						
substance	Assessment not finalised		X^4				
Groundwater exposure metabolites	Legal parametric value breached ^(a)						
	Parametric value of 10µg/L ^(b) breached	ca. 4/7 FOCUS scenarios		Between 4/7 and 7/9 FOCUS scenarios	Between 4/7 and 7/9 FOCUS scenarios	7/9 FOCUS scenarios	ca. ca. 4/7 FOCUS scenarios
	Assessment not finalised	X^6	$X^{4'6}$	X^6	X^6	X^6	X^6
Comments/Rem	arks						

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.

⁽a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December.

⁽b): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003.



Representative u	ise	Apricots 2x90g/ha	Plums 2x125g/ha	Citrus 2x150g/ha	Olives 2x150g/ha	Grape vines (wine) 2x112.5g/ha
	Risk identified					
Operator risk	Assessment not finalised					
	Risk identified					
Worker risk	Assessment not finalised					
	Risk identified					
Bystander risk	Assessment not finalised					
	Risk identified					
Consumer risk	Assessment not finalised	X^5	X^5	X^5	X^5	X^5
Risk to wild	Risk identified			X		
non target terrestrial vertebrates	Assessment not finalised					
Risk to wild	Risk identified	X	X	X	X	X
non target terrestrial organisms other than vertebrates	Assessment not finalised					
Risk to aquatic organisms	Risk identified	X (for D4)	X (for D4,D5, R1)			
or gamsms	Assessment not finalised					
Groundwater exposure active	Legal parametric value breached					
substance	Assessment not finalised					
Groundwater	Legal parametric value breached ^(a)					
exposure metabolites	Parametric value of 10µg/L ^(b) breached	ca. ca. 4/7 FOCUS scenarios	Between 4/7 and 7/9 FOCUS scenarios	7/9 FOCUS scenarios	7/9 FOCUS scenarios	Between 4/7 and 7/9 FOCUS scenarios
	Assessment not finalised	X^6	X^6	X^6	X^6	X^6
Comments/Rem	arks					

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.

⁽a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December.

⁽b): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003.



- 9.2. Issues related to the maximum residue level applications
- 9.2.1. Issues not finalised under the maximum residue level applications
- No issues identified in this category
- 9.2.2. Consumer risk identified under the maximum residue level applications
- No issues identified in this category



REFERENCES

- ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)
- EFSA (European Food Safety Authority), 2007. Opinion on a request from EFSA related to the default Q_{10} value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal 2007, 622, 1-32, doi:10.2903/j.efsa.2008.622
- EFSA (European Food Safety Authority), 2009. Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. doi:10.2903/j.efsa.2009.1438
- EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092, 49 pp. doi:10.2903/j.efsa.2011.2092
- EFSA SC (EFSA Scientific Committee), 2013. Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132, 84 pp. doi:10.2903/j.efsa.2013.3132
- EFSA (European Food Safety Authority), 2014. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance cyantraniliprole. Available online: www.efsa.europa.eu
- EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2012a. Guidance on Dermal Absorption. EFSA Journal 2012;10(4):2665, 30 pp. doi:10.2903/j.efsa.2012.2665
- EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2012b. Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus spp.* and solitary bees). EFSA Journal 2012; 10(5) 2668. [275 pp.] doi:10.2903/j.efsa.2012.2668. Available online: www.efsa.europa.eu/efsajournal.
- European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10 June 1999
- European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99 rev.4, 11 July 2000
- European Commission, 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002
- European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003
- European Commission, 2004. Guidance Document on Dermal Absorption. SANCO/222/2000 rev. 7, 19 March 2004
- European Commission, 2010. Guidance Document on residue analytical methods. SANCO/825/00 rev. 8.1, 16 November 2010
- European Commission, 2011. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95 rev.9. March 2011. pp.1-46



- European Commission, 2012. Guidance Document on the Assessment of the Equivalence of Technical Materials of Substances Regulated under Council Directive 91/414/EEC. SANCO/10597/2003 rev. 10.1, 13 July 2012
- European Commission, 2013. Guidance Document on data requirements on efficacy for the dossier to be submitted for the approval of new active substances contained in plant protection products. SANCO/10054/2013 rev. 3, 11 July 2013
- FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2001. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp., as updated by the Generic Guidance for FOCUS surface water scenarios, version 1.1 dated March 2012.
- FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2006. Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.
- FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2007. Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.
- FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2008. Pesticides in Air: Considerations for Exposure Assessment. Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006 Rev 2 June 2008
- FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2009. Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Workgroup, EC Document Reference SANCO/13144/2010-version.1. 604 pp, as outlined in Generic Guidance for Tier 1 FOCUS groundwater Assessment, version 2.0 dated January 2011
- JMPR (Joint Meeting on Pesticide Residues), 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004, Report 2004, 383 pp.
- JMPR (Joint Meeting on Pesticide Residues), 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, 18–27 September 2007, Report 2007, 164 pp.
- OECD (Organisation for Economic Co-operation and Development), 2006. Guidance Document on Overview of Residue Chemistry Studies. ENV/JM/MONO(2006)32, 10 October 2006
- OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues
- OECD (Organisation for Economic Co-operation and Development), 2012. Series on Testing and Assessment: No 150: Guidance document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption. ENV/JM/MONO(2012)22, 524 pp.
- SETAC (Society of Environmental Toxicology and Chemistry), 2001. Guidance Document on Regulatory Testing and Risk Assessment procedures for Plant Protection Products with Non-Target Arthropods. ESCORT 2
- United Kingdom, 2013. Draft Assessment Report (DAR) on the active substance cyantraniliprole prepared by the rapporteur Member State the United Kingdom in the framework of Regulation (EC) No. 1107/2009, May 2013. Available online: www.efsa.europa.eu



United Kingdom 2014. Final Addendum to the Draft Assessment Report (DAR) on cyantraniliprole, compiled by EFSA, June 2014. Available online: www.efsa.europa.eu

WHO (World Health Organization), 2011. WHO Guidelines for Drinking-water Quality, fourth edition, 564 pp.



APPENDICES

Active substance (ISO Common Name) ‡9

APPENDIX $\mathbf{A} - \mathbf{L}\mathbf{i}\mathbf{s}$ of end points for the active substance and the representative formulation

Cyantraniliprole

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Function (e.g. fungicide) Insecticide Rapporteur Member State United Kingdom (UK) Co-rapporteur Member State France (FR) **Identity (Annex IIA, point 1)** Chemical name (IUPAC) ‡ 3-bromo-1-(3-chloro-2-pyridyl)-4'-cyano-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide 3-bromo-1-(3-chloro-2-pyridinyl)-*N*-[4-cyano-2-methyl-Chemical name (CA) ‡ 6-[(methylamino)carbonyl]phenyl]-1*H*-pyrazole-5carboxamide CIPAC No ‡ Not assigned 736994-63-1 CAS No ‡ EC No (EINECS or ELINCS) ‡ Not assigned FAO Specification (including year of publication) ‡ None Minimum purity of the active substance as 940 g/kg

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured

Molecular formula ‡

manufactured ‡

Molar mass ‡

 9 ‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

473.72 g/mol



Structural formula ‡



Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	224 °C (98.4%, PAI) 217-219 °C (97.0%, TGAI)
Boiling point (state purity) ‡	The purified active decomposes prior to boiling at atmospheric pressure (98.4%, PAI)
Temperature of decomposition (state purity)	350 °C (98.4%, PAI)
Appearance (state purity) ‡	White fine powder solid with occasional aggregates (Munsell colour N 9.5/90%R) (98.4%, PAI) Off-white fine powder solid (Munsell colour 9.0, chroma of 0.5 and no hue) (97.0%, TGAI)
Vapour pressure (state temperature, state purity) ‡	The vapour pressure for cyantraniliprole was too low to be determined experimentally, estimated to be 5.133×10^{-15} Pa $(3.85 \times 10^{-17}$ mm Hg) at 20°C and 1.787×10^{-14} Pa $(1.34 \times 10^{-16}$ mm Hg) at 25°C (98.4%, PAI)
Henry's law constant ‡	$1.7 \times 10^{-13} \text{ Pa m}^3 \text{ mol}^{-1} (98.4\%, \text{PAI})$
Solubility in water (state temperature, state purity and pH) ‡	Milli-RO water 14.24 ± 0.55 mg/L pH 4: 17.43 ± 1.94 mg/L pH 7: 12.33 ± 0.61 mg/L . pH 9: 5.94 ± 0.61 mg/L All at 20°C and 98.4%, PAI
Solubility in organic solvents ‡ (state temperature, state purity)	acetone 6.54 g/L dichloromethane 5.05 g/L methanol 4.73 g/L acetonitrile 2.45 g/L ethyl acetate 1.96 g/L n-octanol 0.79 g/L o -xylene 0.29 g/L hexane 6.7 x 10^{-5} g/L All at 20°C and 97%, TGAI
Surface tension ‡ (state concentration and temperature, state purity)	69.43 \pm 0.21 mN/m (90 % saturated solution at 20 \pm 0.5 °C)(97%, TGAI)
Partition co-efficient ‡ (state temperature, pH and purity)	$\begin{array}{l} log \ P_{O/W} \ at \ 22 \ ^{\circ}C \ (98.4\%, PAI) \\ at \ pH \ 4 = 1.97 \pm 0.02 \\ at \ pH \ 7 = 2.02 \pm 0.00 \\ at \ pH \ 9 = 1.74 \pm 0.02 \\ Reagent \ grade \ water = 1.97 \pm 0.01 \end{array}$
Dissociation constant (state purity) ‡	$pKa_1 = 8.80 \pm 1.38 \text{ at } 20^{\circ}C (98.4\%, PAI)$



UV/VIS absorption (max.) incl. $\epsilon \ddagger$ (state purity, pH)

Extinction coefficients (all at 290 nm) were as follows (98.4%, PAI):

 ϵ = 12249 (log ϵ =4.088) mol $^{-1}$ cm $^{-1}$ in basic solution (13.14),

 $\epsilon = 7801 \text{ (log } \epsilon = 1.392) \text{ mol}^{-1} \text{ cm}^{-1} \text{ in neutral solution (MeOH),}$

 $\epsilon = 7262 \text{ (log } \epsilon = 1.861) \text{ mol}^{-1} \text{ cm}^{-1} \text{ in acidic solution (pH 0.86).}$

not flammable. (93.4%, TGAI)

not explosive (93.4%, TGAI)

not oxidising (94.5 %, TGAI)

Flammability ‡ (state purity)

Explosive properties ‡ (state purity)

Oxidising properties ‡ (state purity)



Summary of representative uses evaluated (*Cyantraniliprole*) Proposed GAPs as submitted by the applicants in their original dossiers Good Agricultural Practice (GAP) for Cyantraniliprole 100 g/L OD in the European Union

Crop			F	Pest or	Forn	nulation		Application	on			cation rat reatment		- РНІ	
and /or situation (a)	Country	Product name	G or I (b)	group of pests controlled (c)	Type (d-f)	Conc. of ai (g/L) (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/hL min max	water L/ha min max	g ai/ha max	(days) (l)	Remarks (m)
Aubergine, tomato	NEU, SEU	DPX- HGW86 100 g/L OD	G	Lepidoptera Liriomyza aphids	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-4	7-14	4.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil
Aubergine, tomato	NEU, SEU	DPX- HGW86 100 g/L OD	G	White fly Bemisia tabaci Trialeurodes vaporariorum	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-4	7-14	6.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil
Aubergine, tomato	NEU, SEU	DPX- HGW86 100 g/L OD	G	Thrips Frankliniella occidentalis Foliar thrips	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 51- BBCH 89	1-4	7-14	7.5-10.0	500- 1200	120	1	With addition of adjuvant oil
Field tomato	SEU	DPX- HGW86 100 g/L OD	F	Lepidoptera Liriomyza aphids	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-2	7-14	6.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil
Field tomato	SEU	DPX- HGW86 100 g/L OD	F	White fly Bemisia tabaci Trialeurodes vaporariorum	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-2	7-14	6.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil
Cucurbits edible and inedible peel	NEU, SEU	DPX- HGW86 100 g/L OD	G	Lepidoptera Liriomyza aphids	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-4	7-14	4.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil
Cucurbits edible and inedible peel	NEU, SEU	DPX- HGW86 100 g/L OD	G	White fly Bemisia tabaci Trialeurodes vaporariorum	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-4	7-14	6.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil



Good Agricultural Practice (GAP) for Cyantraniliprole 100 g/L OD in the European Union (continued)

Crop			F	Pest or	Form	nulation		Application	on			cation rat		РНІ	
and /or situation (a)	Country	Product name	G or I (b)	group of pests controlled (c)	Type (d-f)	Conc. of ai (g/L) (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/hL min max	water L/ha min max	g ai/ha max	(days) (l)	Remarks (m)
Cucurbits edible and inedible peel	NEU, SEU	DPX- HGW86 100 g/L OD	G	Thrips Frankliniella occidentalis Foliar thrips	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 51- BBCH 89	1-4	7-14	7.5-10.0	500- 1200	120	1	With addition of adjuvant oil
Melons (Melon & water melon)	SEU	DPX- HGW86 100 g/L OD	G + F	Lepidoptera Liriomyza aphids	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-4	7-14	4.0-7.5	500- 1200	90 (F+G) 120 (G)	1	With or without addition of adjuvant oil
Pepper	NEU, SEU	DPX- HGW86 100 g/L OD	G	Lepidoptera Liriomyza aphids	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-4	7-14	5.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil
Pepper	NEU, SEU	DPX- HGW86 100 g/L OD	G	White fly Bemisia tabaci Trialeurodes vaporariorum	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-4	7-14	6.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil
Pepper	NEU, SEU	DPX- HGW86 100 g/L OD	G	Thrips Frankliniella occidentalis Foliar thrips	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 51- BBCH 89	1-4	7-14	7.5-10.0	500- 1200	120	1	With addition of adjuvant oil
Field pepper	SEU	DPX- HGW86 100 g/L OD	F	Lepidoptera Liriomyza aphids	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-2	7-14	5.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil
Field pepper	SEU	DPX- HGW86 100 g/L OD	F	White fly Bemisia tabaci Trialeurodes vaporariorum	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-2	7-14	6.0-7.5	500- 1200	90	1	With addition of adjuvant oil
Green bean	SEU	DPX- HGW86 100 g/L OD	G	Lepidoptera liriomyza aphids	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-4	7-14	6.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil



Good Agricultural Practice (GAP) for Cyantraniliprole 100 g/L OD in the European Union (continued)

Crop			F	Pest or	Forn	nulation		Application	n			cation rat reatment	•	- РНІ	
and /or situation (a)	Country	Product name	G or I (b)	group of pests controlled (c)	Type (d-f)	Conc. of ai (g/L) (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/hL min max	water L/ha min max	g ai/ha max	(days) (l)	Remarks (m)
Green bean	SEU	DPX- HGW86 100 g/L OD	F	Lepidoptera liriomyza aphids	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-2	7-14	6.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil
Green bean	SEU	DPX- HGW86 100 g/L OD	G	Thrips Frankiniella occidentnalis Foliar thrips	OD	100 g/L	broadcast mist blower, hydraulic ground directed boom	BBCH 51- BBCH 89	1-4	7-14	7.5	500- 1200	90	1	With addition of adjuvant oil
Lettuce	SEU	DPX- HGW86 100 g/L OD	F + G	Lepidoptera Helicoverpa armigera Spodoptera exigua Spodoptera litoralis,	OD	100 g/L	hydraulic ground directed boom	When pest present	1-2	7-14	4.0- 7.5	500- 1000	75	1	With or without addition of adjuvant oil
Potatoes	NEU SEU	DPX- HGW86 100 g/L OD	F	L. decemlineata	OD	100 g/L	hydraulic ground directed boom	BBCH 31- BBCH 60	1-2	14	-	300- 600	12.5	14	With or without addition of adjuvant oil



Good Agricultural Practice (GAP) for Cyantraniliprole (DPX-HGW86) 100 g/L SE in the European Union

C			F	D4	Form	ılation		Appli	cation		Appli	ication rate pe	r treatment		
Crop and /or situation (a)	Country	Product name	G or I (b)	Pest or group of pests controlled (c)	Type (d-f)	Conc. of ai (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/hL min max	water L/ha min max	g ai/ha max	PHI (days) (l)	Remarks (m)
Apples, Pears	NEU SEU	DPX- HGW86 100 g/L SE	F	Cydia pomonella, Leafminers, Leafrollers (Pre-flowering Opherophtera brumata) Leafrollers Anthonomus pomorum	SE	100 g/L	High pressure mist blower	BBCH 70- BBCH 87 BBCH 31- 60	1-2	7 (14 amended to 7 in dossier upate)	4.0– 6.0	NEU 200-1250 SEU 700-1500	75 NEU 90 SEU	7	Minimum recommended application rate is 400 mL product/ha for <i>C. pommonella</i> . When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha
Nectarine	SEU	DPX- HGW86 100 g/L SE	F	Thrips, Franliniella occidentalis Thrips meridionalis	SE	100 g/L	High pressure mist blower	BBCH 59- BBCH 69	1-2	7-10	7.5- 10.0	700-1000	100	7	Minimum recommended application rate is 750 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha with addition of adjuvant oil



Good Agricultural Practice (GAP) for Cyantraniliprole (DPX-HGW86) 100 g/L SE in the European Union (continued)

Crop and /or	Countr	Product	F G	Pest or group of pests	Formu	ılation		Applica	tion		Applicat tre	tion rate atment	per	PHI (day s) (l)	Remarks (m)
situation (a)	y	name	or I (b)	controlled (c)	Type (d-f)	Conc. of ai (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/hL min max	water L/ha min max	g ai/h a max		
Nectarine	SEU	DPX- HGW86 100 g/L SE	F	Thrips, Franliniella occidentalis Thrips meridionalis	SE	100 g/L	High pressure mist blower	BBCH 69- BBCH 87	1-2	7-10	7.5-10.0	700- 1500	150	7	Minimum recommended application rate is 750 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha with addition of adjuvant oil
Nectarine, Peaches and Apricots	SEU	DPX- HGW86 100 g/L SE	F	Cydia molesta, Anarsia lineatella	SE	100 g/L	High pressure mist blower	BBCH 73- BBCH 85	1-2	10-14	5.0-6.0	700- 1500	90	7	Minimum recommended application rate is 500 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha
Citrus, mandarins	SEU	DPX- HGW86 100 g/L SE	F	Leafminers Ph. citrella Prays citri	SE	100 g/L	Mist blower	BBCH 31- BBCH 50	1-2	10-14	2.5-4.0	300- 800	32	n.a.	Adjuvant not essential but improves performance



Good Agricultural Practice (GAP) for Cyantraniliprole (DPX-HGW86) 100 g/L SE in the European Union (continued)

Crop			F G	Pest or	Form	ılation		Applica	ntion		Ap	plication rat treatment	-	РНІ	
and /or situation (a)	Country	Product name	or I (b)	group of pests controlled (c)	Type (d-f)	Conc. of ai (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/hL min max	water L/ha min max	g ai/ha max	(days) (l)	Remarks (m)
Citrus	SEU	DPX- HGW86 100 g/L SE	F	Aphids, Aphis spiricola, Aphis gossypii, Pexothrips kellianus Ceratitis capitata	SE	100 g/L	High pressure mist blower	BBCH 9-59 BBCH 69-89	1-2	7-14	7.5- 10.0	700-1500	150	7	Minimum recommended application rate is 750 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha with addition of adjuvant oil
Olives	SEU	DPX- HGW86 100 g/L SE	F	Moth, Pray oleae	SE	100 g/L	High pressure mist blower	BBCH 50- BBCH 80	1-2	10	2.0	700-2000	40	14	Minimum recommended application rate is 200 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha



Good Agricultural Practice (GAP) for Cyantraniliprole (DPX-HGW86) 100 g/L SE in the European Union (continued)

Crop			F G	Pest or	Formu	ılation		Applicat	ion		Ap	plication rate treatment	-	РНІ	
and /or situation (a)	Country	Product name	or I (b)	group of pests controlled (c)	Type (d-f)	Conc. of ai (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/hL min max	water L/ha min max	g ai/ha max	(days) (l)	Remarks (m)
Olives	SEU	DPX- HGW86 100 g/L SE	F	Fruit fly, Bractrocera oleae	SE	100 g/L	High pressure mist blower	BBCH 71- BBCH 85	1-2	10	5.0 (7.5)	700-3000 (2000)	150	14	Minimum recommended application rate is 500 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha
Grapes (wine)	NEU SEU	DPX- HGW86 100 g/L SE	F	Lobesia botrana, Eupoecilia ambiguella Empoasca vitis	SE	100 g/L	Mist blower	BBCH 55- BBCH 85	1-2	10 (14 changed to 10 during dossier update)	5.0- 7.5	700-1500	112.5	10	Minimum recommended application rate is 500 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha



Good Agricultural Practice (GAP) for Cyantraniliprole (DPX-HGW86) 200 g/L SC in the European Union

			F	·	For	mulation		Appli	cation		Applicati	on rate per	treatment		
Crop and /or situation (a)	Country	Product name	G or I (b)	Pest or group of pests controlled (c)	Type (d-f)	Conc. of ai	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/ha min max	water L/ha min max	g ai/ha max	PHI (days) (l)	Remarks (m)
Aubergine, tomato	NEU, SEU	DPX- HGW86 200 g/L SC	G	Lepidoptera Liriomyza aphids	SC	200 g/L	Drip	BBCH10- BBCH89	1-4	7-14	75 g ai/ha	n.a	75	1	
Aubergine, tomato	NEU, SEU	DPX- HGW86 200 g/L SC	G	White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Drip	BBCH10- BBCH89	1-4	7-14	75 -100 g ai/ha	n.a.	100	1	
Aubergine, tomato	NEU, SEU	DPX- HGW86 200 g/L SC	G	White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	hydroponic	BBCH10- BBCH89	1-4	7-14	75 -100 g ai/ha	n.a.	100	1	
Field tomato	SEU	DPX- HGW86 200 g/L SC	F	Lepidoptera Liriomyza aphids White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Drip	BBCH10- BBCH89	1-2	7-14	75 g ai/ha	n.a	75	1	
Cucurbits edible and inedible peel	NEU, SEU	DPX- HGW86 200 g/L SC	G	Lepidoptera Liriomyza aphids	SC	200 g/L	Drip	BBCH10- BBCH89	1-4	7-14	75 g ai/ha	n.a	75	1	
Cucurbits edible and inedible peel	NEU, SEU	DPX- HGW86 200 g/L SC	G	White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Drip	BBCH10- BBCH89	1-4	7-14	75 -100 g ai/ha	n.a.	100	1	
Cucurbits edible and inedible peel	NEU, SEU	DPX- HGW86 200 g/L SC	G	White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Hydroponic	BBCH10- BBCH89	1-4	7-14	75 -100 g ai/ha	n.a.	100	1	
Pepper	NEU, SEU	DPX- HGW86 200 g/L SC	G	Lepidoptera Liriomyza aphids	SC	200 g/L	Drip	BBCH10- BBCH89	1-4	7-14	75 g ai/ha	n.a	75	1	



Error! Reference source not found. (continued)

Crop			F	Pest or	For	mulation		Appli	cation		Applicati	on rate per	treatment		
and /or situation (a)	Country	Product name	G or I (b)	group of pests controlled (c)	Type (d-f)	Conc. of ai	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/ha min max	water L/ha min max	g ai/ha max	PHI (days) (l)	Remarks (m)
Pepper	NEU, SEU	DPX- HGW86 200 g/L SC	G	White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Drip	BBCH10- BBCH89	1-4	7-14	75 -100 g ai/ha	n.a.	100	1	
Pepper	NEU, SEU	DPX- HGW86 200 g/L SC	G	White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Hydroponic	BBCH10- BBCH89	1-4	7-14	75 -100 g ai/ha	n.a.	100	1	
Field pepper	SEU	DPX- HGW86 200 g/L SC	F	Lepidoptera Liriomyza aphids White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Drip	BBCH10- BBCH89	1-2	7-14	75 g ai/ha	n.a	75	1	
Melons (Melon & water melon)	SEU	DPX- HGW86 200 g/L SC	G	Lepidoptera Liriomyza aphids	SC	200 g/L	Drip	BBCH10- BBCH89	1-2	7-14	75 g ai/ha	n.a	75	1	
Lettuce	SEU	DPX- HGW86 200 g/L SC	G	Lepidoptera Helicoverpa armigera Spodoptera exigua Spodoptera littoralis	SC	200 g/L	Drip	When pest present	1-3	7-14	75-100 g ai/ha	n.a	100	1 - 3	



Good Agricultural Practice (GAP) for Cyantraniliprole (DPX-HGW86) 400 g/kg WG in the European Union

C			F G	Pests or	Form	ulation		Apj	plication		Applicat	tion rate per t	reatment	PHI	
Crop and/ or situation (a)	Country	Product name	or I (b)	Group of pests controlled (c)	Type (d-f)	Conc. of as g/kg (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applicatio ns (min)	g as/hL min max	water L/ha min max	g as/ha min max	(days)	Remarks: (m)
Apples	UK BE DE NL LU	A16971 B	F	Cydia pomonella	WG	400 g/kg	Foliar spray	73-87	2	10-14	5	300 to 1500	75	7	Rate from efficacy trials is 40 gai/10000 m2LWA in max of 18750 m2 LWA orchard. Application method: Tractor- mounter/trailed
Apples	FR	A16971 B	F	Cydia pomonella	WG	400 g/kg	Foliar spray	73-87	2	10-14	5	600 to 1500	75	7	Rate from efficacy trials is 40 gai/10000 m2LWA in max of 18750 m2 LWA orchard. Application method: Tractor- mounter/trailed
Pears	UK BE DE NL LU	A16971 B	F	Cydia pomonella	WG	400 g/kg	Foliar spray	73-87	2	10-14	5	300 to 1500	75	7	Rate from efficacy trials is 40 gai/10000 m2LWA in max of 18750 m2 LWA orchard. Application method: Tractor- mounter/trailed
Pears	FR	A16971 B	F	Cydia pomonella	WG	400 g/kg	Foliar spray	73-87	2	10-14	5	600 to 1500	75	7	Rate from efficacy trials is 40 gai/10000 m2LWA in max of 18750 m2 LWA orchard. Application method: Tractor- mounter/trailed



Good Agricultural Practice (GAP) for Cyantraniliprole (DPX-HGW86) 400 g/kg WG in the European Union (continued)

		00000		ur r ructice (Gr	,	0 5 00		- (0 (0 0			
Peach/ Nectarine	FR	A16971 B	F	Cydia molesta, Anarsia lineatella	WG	400 g/kg	Foliar spray	73-87	2	10-14	6-8	600 to 1500	125	7	Application method: Tractor- mounter/trailed broadcast air- assisted sprayer.
Plums	UK BE DE NL LU	A16971 B	F	Cydia funebrana	WG	400 g/kg	Foliar spray	73-87	2	10-14	6-8	300 to 1500	125	7	Application method: Tractor- mounter/trailed broadcast air- assisted sprayer.
Plums	FR	A16971 B	F	Cydia funebrana	WG	400 g/kg	Foliar spray	73-87	2	10-14	6-8	600 to 1500	125	7	Application method: Tractor- mounter/trailed broadcast air- assisted sprayer.

Remarks

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*eg.* fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) eg. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) eg. wettable powder (WP), emulsifiable concentrate (EC), granule (GR), Water dispersible granules (WG)
- (e) GCPF Codes GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, eg. high volume spraying, low volume spraying, spreading, dusting, drench

- (h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants type of equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at 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
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (1) PHI minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions



The following table is the **cGAP** considered in the Draft Assessment Report. A full breakdown of representative uses for the four representative formulations can be found above.

100 g/L OD: Field uses

Crop			F	Pest or	Forn	ıulation		Applicati	on			lication ra treatmen		РНІ	
and /or situation (a)	Country	Product name	G or I (b)	group of pests controlled (c)	Type (d-f)	Conc of ai (g/L) (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/hL min max	water L/ha min max	g ai/ha max	(days) (l)	Remarks (m)
Melons (Melon & water melon)	EU-S	DPX- HGW86 100 g/L OD	F	Lepidoptera Liriomyza aphids	OD	100 g/L	Broadcast mist blower* hydraulic ground directed boom	BBCH 10- BBCH 89 [early application timings only for surface water]	1-2	7	4.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil Included in the groundwater and surface water exposure assessment. Note this does not cover the applied for melon GAP that is 1-4x90g/ha.
Field tomato	EU-S	DPX- HGW86 100 g/L OD	F	Lepidoptera Liriomyza aphids White fly Bemisia tabaci Trialeurodes vaporariorum	OD	100 g/L	Broadcast mist blower* hydraulic ground directed boom	BBCH 10- BBCH 89 [early application timings only for surface water]	1-2	7	6.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil Included in the groundwater and surface water exposure assessment.
Field pepper	SEU	DPX- HGW86 100 g/L OD	F	Lepidoptera Liriomyza aphids White fly Bemisia tabaci Trialeurodes vaporariorum	OD	100 g/L	Broadcast mist blower* hydraulic ground directed boom	BBCH 10- BBCH 89 [early application timings only for surface water]	1-2	7-14	5.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil For white fly control use with adjuvant oil Considered covered by the field tomato use with regard to exposure in groundwater and surface water.



Green bean	EU-S	DPX- HGW86 100 g/L OD	F	Lepidoptera liriomyza aphids	OD	100 g/L	Broadcast mist blower* hydraulic ground directed boom	BBCH 10- BBCH 89 [early application timings only for surface water]	1-2	7	6.0-7.5	500- 1200	90	1	With or without addition of adjuvant oil Included in the groundwater and surface water exposure assessment.
Lettuce	EU-S	DPX- HGW86 100 g/L OD	F	Lepidoptera Helicoverpa armigera Spodoptera exigua Spodoptera litoralis,	OD	100 g/L	hydraulic ground directed boom	When pest present [early application timings only for surface water]	1-2	7	4.0-7.5	500- 1000	75 [90 g a.s./ha included in the environm ental assessme nt in groundw ater and surface water]	1	With or without addition of adjuvant oil Included in the groundwater and surface water exposure assessment.
Potatoes	NEU SEU	DPX- HGW86 100 g/L OD	F	L. decemlineata	OD	100 g/L	hydraulic ground directed boom	BBCH 31- BBCH 60	1-2	14	-	300- 600	12.5^	14	With or without addition of adjuvant oil Not included in groundwater or surface water assessment. Considered covered by the risk envelope set by the 2x90g/ha melon assessment.

^{*}The product is applied as ground directed spray. Note that for some uses in the requested GAPs from the applicant, the field grown crops are stated to be treated via broadcast mist blower. However such application methods have not been considered by the exposure assessment presented (and would not be covered by the standard FOCUS_{sw} assessment for the range of surrogate crops available to represent the intended uses, which all assume application by standard ground directed spray). Therefore a data gap has been identified for risk assessmenst to cover broadcast mist blower application.

[^]Lower use rates of 2 x 12.5 g a.s./ha on field grown potatoes haves not been specifically modelled for groundwater and surface water and exposure is assumed to be covered by the specific assessments at higher rates (e.g. the melon simulation which used potatoes as a surrogate crop at 2 x 90 g a.s./ha).



100 g/l OD: Glasshouse uses

Crop			F	Pest or	Form	ulation		Applicati	on		Applica	tion rate	per treatment		
and /or situation (a)	Country	Product name	G or I (b)	group of pests controlled (c)	Type (d-f)	Conc. of ai (g/L) (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/hL min max	water L/ha min max	g ai/ha max	PHI (days) (l)	Remarks (m)
Aubergine, tomato	EU-N, EU-S	DPX- HGW86 100 g/L OD	G	Thrips Frankliniella occidentalis Foliar thrips	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 51- BBCH 89	1-4	7-14	7.5-10.0	500- 1200	120*	1	With addition of adjuvant oil Assessed as an absolute worst case for PECsoil only for the glasshouse uses. Included in the surface water assessment. Not included the groundwater assessment.
Cucurbits edible and inedible peel	EU-N, EU-S	DPX- HGW86 100 g/L OD	G	Thrips Frankliniella occidentalis Foliar thrips	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 51- BBCH 89	1-4	7-14	7.5-10.0	500- 1200	120*	1	With addition of adjuvant oil Assessed as an absolute worst case for PECsoil only for the glasshouse uses. Included in the surface water assessment. Not included the groundwater assessment.



Pepper	EU-N, EU-S	DPX- HGW86 100 g/L OD	G	Thrips Frankliniella occidentalis Foliar thrips	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-4	7-14	5.0-10.0	500- 1200	120*	1	With addition of adjuvant oil Assessed as an absolute worst case for PECsoil only for the glasshouse uses. Included in the surface water assessment. Not included the groundwater assessment.
Lettuce	SEU	DPX- HGW86 100 g/L OD	G	Lepidoptera Helicoverpa armigera Spodoptera exigua Spodoptera litoralis,	OD	100 g/L	hydraulic ground directed boom	When pest present	1-2	7-14	4.0- 7.5	500- 1000	75	1	With or without addition of adjuvant oil Included in the surface water assessment.
Melons (Melon & water melon)	SEU	DPX- HGW86 100 g/L OD	G	Lepidoptera Liriomyza aphids	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-4	7-14	4.0-7.5	500- 1200	120*	1	With or without addition of adjuvant oil Assessed as an absolute worst case for PECsoil only for the glasshouse uses. Included in the surface water assessment. Not included the groundwater assessment.



Green bean	SEU	DPX- HGW86 100 g/L OD	G	Lepidoptera liriomyza aphids Thrips Frankiniella occidentnalis Foliar thrips	OD	100 g/L	Broadcast mist blower, hydraulic ground directed boom	BBCH 10- BBCH 89	1-4^	7-14	6.0-7.5	500- 1200	90*	1	With or without addition of adjuvant oil Assessed as an absolute worst case for PECsoil only for the glasshouse uses. Covered in the surface water assessment. Not included the groundwater assessment.
------------	-----	--------------------------------	---	--	----	---------	---	---------------------	------	------	---------	--------------	-----	---	---

^{*}Higher application rates and numbers of applications have been requested for glasshouse grown crops (up to 4 x 120 g a.s./ha compared to 2 x 90 g a.s./ha for field uses). However these glasshouse uses have not been considered further with regard to potential groundwater exposure. Therefore a data gap has been identified for groundwater exposure assessmenst to cover the glasshouse situation.

[^] Proposed GAP was for a max of 4 treatments but only 2 treatments supported by residues trials.



100 g/L SE: Field uses

Crop			F	Pest or	Form	ulation		Applicat	ion		Ap	plication rate treatment	e per	- PHI	
and /or situation (a)	Country	Product name	G or I (b)	group of pests controlled (c)	Type (d-f)	Conc. of ai (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/hL min max	water L/ha min max	g ai/ha max	(days)	Remarks (m)
Apples, Pears	NEU SEU	DPX- HGW86 100 g/L SE	F	Cydia pomonella, Leafminers, Leafrollers (Pre-flowering Opherophtera brumata) Leafrollers Anthonomus pomorum	SE	100 g/L	High pressure mist blower	BBCH 70- BBCH 87 BBCH 31-60	1-2	7	4.0- 6.0	NEU 200-1250 SEU 700-1500	75 NEU 90 SEU	7	Minimum recommended application rate is 400 mL product/ha for <i>C. pommonella</i> . When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha Included in the groundwater and surface water exposure assessment (higher rate only, early and late application addressed).
Nectarine	SEU	DPX- HGW86 100 g/L SE	F	Thrips, Franliniella occidentalis Thrips meridionalis	SE	100 g/L	High pressure mist blower	BBCH 59- BBCH 87	1-2	7-10	7.5- 10.0	700-1000	150	7	Minimum recommended application rate is 750 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha with addition of adjuvant oil Included in the groundwater and surface water exposure assessment (minimum interval only).



Nectarine, Peaches and Apricots	SEU	DPX- HGW86 100 g/L SE	F	Cydia molesta, Anarsia lineatella	SE	100 g/L	High pressure mist blower	BBCH 73- BBCH 85	1-2	10-14	5.0- 6.0	700-1500	90	7	Minimum recommended application rate is 500 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha Considered covered by the apple assessment with shorter interval of 7 d with regards surface water and groubndwater exposure.
Citrus, mandarins	SEU	DPX- HGW86 100 g/L SE	F	Leafminers Ph. citrella Prays citri	SE	100 g/L	Mist blower	BBCH 31- BBCH 50	1-2	10-14	2.5- 4.0	300-800	32	n.a.	Adjuvant not essential but improves performance Considered covered by the risk envelope set by the higher application rate assessment (150 g a.s./ha)
Citrus	SEU	DPX- HGW86 100 g/L SE	F	Aphids, Aphis spiricola, Aphis gossypii, Pexothrips kellianus Ceratitis capitata	SE	100 g/L	High pressure mist blower	BBCH 9-59 BBCH 69-89	1-2	7-14	7.5- 10.0	700-1500	150	7	Minimum recommended application rate is 750 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha with addition of adjuvant oil



Olives	SEU	DPX- HGW86 100 g/L SE	F	Moth, Pray oleae Fruit fly, Bractrocera oleae	SE	100 g/L	High pressure mist blower	BBCH 50- BBCH 80 BBCH 71- BBCH 85	1-2	10	2.0- 7.5	700-3000	150	14	Minimum recommended application rate is 200 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha Included in the groundwater and surface water exposure assessment (minimum interval only).
Grapes (wine)	NEU SEU	DPX- HGW86 100 g/L SE	F	Lobesia botrana, Eupoecilia ambiguella Empoasca vitis	SE	100 g/L	Mist blower	BBCH 55- BBCH 85	1-2	10	5.0- 7.5	700-1500	112.5	10	Minimum recommended application rate is 500 mL product/ha. When applying low spray volume equipment, apply the equivalent amount of product to 1000 L/ha Included in the groundwater and surface water exposure assessment



200 g/L SC: Field uses

Crop			F	Pest or	For	rmulation		Appli	cation		Applicati	on rate per	treatment		
and /or situation (a)	Country	Product name	G or I (b)	group of pests controlled (c)	Type (d-f)	Conc. of ai (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/ha min max	water L/ha min max	g ai/ha max	PHI (days) (l)	Remarks (m)
Field tomato (covering same use pattern on field pepper)	SEU	DPX- HGW86 200 g/L SC	F	Lepidoptera Liriomyza aphids White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Drip	BBCH10- BBCH89	1-2	7-14	75 g ai/ha	n.a	75	1	Product should be acidified to pH 4-6 at application. Dripper placement should be adjacent to plant roots Product should be applied in the first 3 _{rd} of the drip irrigation cycle. Included in the groundwater and surface water exposure assessment (minimal interval only)



200 g/L SC: Glasshouse uses

G.			F	D	For	mulation		Appli	cation		Applicati	on rate per	treatment		
Crop and /or situation (a)	Country	Product name	G or I (b)	Pest or group of pests controlled (c)	Type (d-f)	Conc. of ai	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g ai/ha min max	water L/ha min max	g ai/ha max	PHI (days) (l)	Remarks (m)
Aubergine, tomato	NEU, SEU	DPX- HGW86 200 g/L SC	G	Lepidoptera Liriomyza aphids White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Drip	BBCH10- BBCH89	1-4	7-14	75-100 g ai/ha	n.a	100*	1	Included in the surface water assessment (minimum intevral only). Not included the groundwater assessment.
Aubergine, tomato	NEU, SEU	DPX- HGW86 200 g/L SC	G	White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	hydroponic	BBCH10- BBCH89	1-4	7-14	75 -100 g ai/ha	n.a.	100	1	Included in the surface water assessment (minimum intevral only).
Cucurbits edible and inedible peel	NEU, SEU	DPX- HGW86 200 g/L SC	G	Lepidoptera Liriomyza aphids White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Drip	BBCH10- BBCH89	1-4	7-14	75-100 g ai/ha	n.a	100*	1	Included in the surface water assessment (minimum intevral only). Not included the groundwater assessment.
Cucurbits edible and inedible peel	NEU, SEU	DPX- HGW86 200 g/L SC	G	White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Hydroponic	BBCH10- BBCH89	1-4	7-14	75 -100 g ai/ha	n.a.	100	1	Included in the surface water assessment (minimum intevral only).
Pepper	NEU, SEU	DPX- HGW86 200 g/L SC	G	Lepidoptera Liriomyza aphids White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Drip	BBCH10- BBCH89	1-4	7-14	75-100 g ai/ha	n.a	100*	1	Included in the surface water assessment (minimum intevral only). Not included the groundwater assessment.
Pepper	NEU, SEU	DPX- HGW86 200 g/L SC	G	White fly Bemisia tabaci Trialeurodes vaporariorum	SC	200 g/L	Hydroponic	BBCH10- BBCH89	1-4	7-14	75 -100 g ai/ha	n.a.	100	1	Included in the surface water assessment (minimum intevral only).



Melons (Melon & water melon)	SEU	DPX- HGW86 200 g/L SC	G	Lepidoptera Liriomyza aphids	SC	200 g/L	Drip	BBCH10- BBCH89	1-2	7-14	75 g ai/ha	n.a	75	1	Considered covered by the risk envelope set by the other galss house uses for surface water.
Lettuce	SEU	DPX- HGW86 200 g/L SC	G	Lepidoptera Helicoverpa armigera Spodoptera exigua Spodoptera littoralis	SC	200 g/L	Drip	When pest present	1-3	7-14	75-100 g ai/ha	n.a	100*	1 - 3	Included in the surface water assessment (minimum intevral only). Not included the groundwater assessment.

^{*}Higher application rates and numbers of applications have been requested for glasshouse grown crops (up to 4 x 120 g a.s./ha compared to 2 x 90 g a.s./ha for field uses). However these glasshouse uses have not been considered further with regard to potential groundwater exposure. Therefore a data gap has been identified for groundwater exposure assessmenst to cover the glasshouse situation

400 g/kg WG: Field uses

Crop and/	rop and/		Formulation		Application			Application rate per treatment			- РНІ				
or situation (a)	Country	Product name	_	Group of pests controlled (c)	Type (d-f)	Conc. of as g/kg (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha min max	(days) (l)	Remarks: (m)
Apples	UK BE DE NL LU FR	A16971 B	F	Cydia pomonella	WG	400	Foliar spray	73-87	2	10-14	5	300 to 1500 (FR 600- 1500)	75*	7	Rate from efficacy trials is 40 gai/10000 m2LWA in max of 18750 m2 LWA orchard. Application method: Tractor- mounter/trailed
Pears	UK BE DE NL LU	A16971 B	F	Cydia pomonella	WG	400	Foliar spray	73-87	2	10-14	5	300 to 1500 (FR 600- 1500)	75*	7	Rate from efficacy trials is 40 gai/10000 m2LWA in max of 18750 m2 LWA orchard. Application method: Tractor- mounter/trailed



G			F	Pests or Group of pests controlled (c)	Formulation		Application			Application rate per treatment			DIII		
Crop and/ or situation (a)	Country	Product name	G or I (b)		Type (d-f)	Conc. of as g/kg (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha min max	PHI (days) (l)	Remarks: (m)
Peach/ Nectarine	FR	A16971 B	F	Cydia molesta, Anarsia lineatella	WG	400	Foliar spray	73-87	2	10-14	6-8	600 to 1500	125	7	Application method: Tractor- mounter/trailed broadcast air- assisted sprayer. Included in the surface water assessment. Groundwater covered by the risk envelope set by the higher application rates assessed for the 100g/1 SE formulation.
Plums	UK BE DE NL LU FR	A16971 B	F	Cydia funebrana	WG	400	Foliar spray	73-87	2	10-14	6-8	300 to 1500 (FR 600- 1500)	125	7	Application method: Tractor- mounter/trailed broadcast air- assisted sprayer. Included in the surface water assessment. Groundwater covered by the risk envelope set by the higher application rates assessed for the 100g/1 SE formulation.

^{*}Lower application rates are requested on some crops (e.g. apples at 2 x 75 g a.s./ha at 10 d intervals) than already assessed for the 100 g/l SE formulation. Additional surface water modelling at Member State level may be needed if any reduction in buffer zone or risk mitigation is requested as part of a future product authorisation applications. Surface water modelling was carried out based on the maximum rate of 2 x 125 g a.s./ha with an interval of 7 days between treatments.

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to



(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds	give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989	3-8263-3152-4), including where relevant, information on season at time of application
(f) All abbreviations used must be explained	(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	(1) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant-type of	instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
equipment used must be indicated	(m) PHI - minimum pre-harvest interval



Further information, Efficacy

Effectiveness

Efficacies in the range of 70 % to 100 % (% control) against thrips, whiteflies, aphids, lepidoptera, fruitflies, moths, leafminers... were observed in numerous efficacy trials on vegetable crops, vineyeards orchards... and using GAP compliant conditions.

Adverse effects on field crops

No symptoms or adverse effects were observed in any of the efficacy trials. No phytotoxicity has been observed on pome or stone fruits with the WG formulation, when applied at a double dose rate.

Observations on other undesirable or unintended side-effects

No undesirable or unintended side-effects reported.

Groundwater metabolites: Screening for biological activity

Activity against target organism

IN-JSE76	IN-K5A78	IN-K5A79	IN-PLT97	IN- M2G98
No	No	No	No	No



Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical a.s (analytical technique)

Impurities in technical a.s (analytical technique)

Plant protection product (analytical technique)

HPLC-UV (260 nm)

RPLC-UV, RPLC-MS/MS, RPLC-MS/MS, GC-FID, KFT, IC, ICP

HPLC-UV (260 or 254 nm)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin

Food of animal origin

Soil

Water surface

drinking/ground

Air

Cyantraniliprole

Cyantraniliprole

Cyantraniliprole

Cyantraniliprole

Cyantraniliprole

Cyantraniliprole

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)

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

Method and ILV is also available and validated at the same LOQ for some metabolites

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)

LC-MS/MS LOQ = 0.01 mg/kg for cyantraniliprole in foodstuff of animal origin (milk, eggs, liver, kidnay, meat and fat)

ILV is also available

Method and ILV is also available and validated at the same LOQ for some metabolites

Soil (analytical technique and LOQ)

LC-MS/MS LOQ = $1.0 \mu g/kg$ for cyantraniliprole

Method is also available and validated at the same LOQ for some environmental degradation products

Water (analytical technique and LOQ)

LC-MS/MS LOQ = $0.1 \mu g/L$ for cyantraniliprole

Method is also available and validated at the same LOQ for some environmental degradation products

Analytical methods are also available for the determination of cyantraniliprole and environmental degradation products in sediment with LOQ equal to 1.0 $\mu g/kg$ for each analyte



Air (analytical technique and LOQ)	LC-MS/MS LOQ = $0.9 \mu g/m^3$ for cyantraniliprole
	Method is also available and validated at the same LOQ for some environmental degradation products
Body fluids and tissues (analytical technique and LOQ)	Not required

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

RMS/peer review proposal

Active substance

None



Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Rapid and to a high degree. Cmax 2 h, 70% oral absorption at 10 mg/kg bw
Distribution ‡	Extensive; at Tmax, highest levels in liver, gastro-intestinal tract, adrenals, thyroid and plasma
Potential for accumulation ‡	No significant accumulation. Tissue: plasma ratios < 1.0 at 168 hours, highest residues in skin, gastro-intestinal content, liver and muscle.
Rate and extent of excretion ‡	Relatively rapid, predominantly via faeces (ca. 60%) and urine (ca. 30%) within 48 hours. Biliary excretion ca 15-30%
Metabolism in animals ‡	Extensive and comparable in single and repeat studies, by hydroxylation and glucuronidation (with or without ring closure). Major metabolites IN-N7B69, IN-MYX98, IN-MLA84 bis-hydroxy-cyantraniliprole.
Toxicologically relevant compounds ‡ (animals and plants)	Cyantraniliprole
Toxicologically relevant compounds ‡ (environment)	Cyantraniliprole

Acute toxicity (Annex IIA, point 5.2)

, r , r , r , r , r , r , r , r , r , r		
Rat LD ₅₀ oral ‡	> 5000 mg/kg bw	-
Rat LD ₅₀ dermal ‡	> 5000 mg/kg bw	-
Rat LC ₅₀ inhalation ‡	> 5.2 mg/L (nose-only, 4 h exposure)	-
Skin irritation ‡	Non-irritant	-
Eye irritation ‡	Non-irritant	-
Skin sensitisation ‡	Not a sensitiser (LLNA, Buehler and maximisation tests)	-

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver: increased relative organ weight, centrilobular hypertrophy and altered clinical chemistry (↑ ALP, ↑ALT, ↓ albumin, total protein).		
	Evidence of arteritis in dogs at dose levels above LOAEL for liver toxicity.		
Relevant oral NOAEL ‡	Rat 7 mg/kg bw per day (90-day study) Mouse 150 mg/kg bw per day (90-day study) Dog :1 mg/kg bw per day (90-day and 1-yr studies)	-	
Relevant dermal NOAEL ‡	> 1000 mg/kg bw per day (28-day rat, no	-	



Relevant inhalation NOAEL ‡

adverse systemic effects)	
> 0.1 mg/L (28-day rat)	-

Genotoxicity ‡ (Annex IIA, point 5.4)

Negative in-vi

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Liver: increased relative organ weight, histopatho (focal vacuolation, foci of cellular alteration (in rate centrilobular hypertrophy (in rats and mice))	0.0
Relevant NOAEL ‡	8.3 mg/kg bw per day (2-yr rat) 16 mg/kg bw per day (18-mo mouse)	
Carcinogenicity ‡	No evidence of tumours (rats, mice)	-

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Fertility: no adverse effect Parental: thyroid changes (increased organ weight, thyroid follicular hyperplasia and hypertrophy).' Offspring: decreased body and organ weights (thymus, spleen)	-
Relevant parental NOAEL ‡	1.2 mg/kg bw per day	-
Relevant reproductive NOAEL ‡	⇒ 1167 mg/kg bw per day	-
Relevant offspring NOAEL ‡	11.4 mg/kg bw per day	-

Developmental toxicity

Developmental target / critical effect ‡	Rat: no adverse effect in dams and foetuses Rabbit: decreased bodyweight (foetuses and dams), clinical signs and mortalities (dams)	-
Relevant maternal NOAEL ‡	Rat: 1000 mg/kg bw per day Rabbit: 25 mg/kg bw per day	-
Relevant developmental NOAEL ‡	Rat: 1000 mg/kg bw per day Rabbit: 100 mg/kg bw per day	-

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No adverse effect; NOAEL = 2000 mg/kg bw (rat)	-
Repeated neurotoxicity ‡	No adverse effect; NOAEL =1195 mg/kg bw	-



Delayed neurotoxicity ‡

per day (90-day rat)	
No data provided. No indication of delayed	-
neurotoxicity in other general studies	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡

Adrenals: no functional or histopathological effects (90-day mice)Thyroid: no in vitro inhibition of thyroid peroxidase, thyroid stimulation appears related to increase in hepatic enzyme activity; adrenal vesiculation not associated with cytotoxicity or functional effects (90-day rat)

Immunotoxicity: no immunosuppressive effect in rats or mice; 28-day rat NOAEL = 1699 mg/kg bw per day; 28-day mouse NOAEL = 1065 mg/kg bw per day.

Studies performed on metabolites or impurities ‡

IN-JSE76

acute oral toxicity : rat $LD_{50} > 5000$ mg/kg bw 28-day oral rat NOAEL = 1445 mg/kg bw per day (no adverse effect)

In-vitro bacterial reverse mutation assay (Ames): negative

In-vitro mammalian gene mutation: negative *In-vitro* mammalian chromosome aberration: negative

IN-PLT97

acute oral toxicity: mice $LD_{50} > 5000$ mg/kg bw 28-day oral rat NOAEL ≥ 1498 mg/kg bw per day (no adverse effect)

In-vitro bacterial reverse mutation assay (Ames): negative

In-vitro mammalian gene mutation: negative

In-vitro mammalian chromosome aberration: negative

IN-F6L99

acute oral toxicity: mice $LD_{50} > 5000$ mg/kg bw *In-vitro* bacterial reverse mutation assay (Ames): negative

IN-N5M09

acute oral toxicity: mice $LD_{50} > 5000$ mg/kg bw *In-vitro* bacterial reverse mutation assay (Ames): negative

IN-M2G98

In-vitro bacterial reverse mutation assay (Ames): negative

In-vitro mammalian gene mutation: negative

In-vitro mammalian chromosome aberration: negative

Medical data ‡ (Annex IIA, point 5.9)

New active substance, limited data available. No specific effects of poisoning are predicted, no reported accidental poisonings



Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI‡	0.01 mg/kg bw per day	One year dog	100
AOEL‡	0.007 mg/kg bw per day	One year dog	100 + correction for oral absorption 70%
ARfD ‡	Not necessary	-	-

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (Cyantraniliprole 100 g/L OD DuPont)	Concentrate & Dilution (1 g/L): 0.1%
Formulation (Cyantraniliprole 100 g/L SE DuPont)	Concentrate: 0.4% Dilution (1 g/L): 2%
Formulation (Cyantraniliprole 200 g/L SC DuPont)	Concentrate:0.1% Dilution (1 g/L): 0.6%
Formulation (400 g/kg WG A16971B Syngenta)	Concentrate (214 g/L): 0.02% Dilution 1/534 (0.624 g/L): 3% (used for all exposure calculations for this formulation) Dilution 1/1600 (0.207 g/L): 0.6%

Exposure scenarios (Annex IIIA, point 7.2)

Cyantraniliprole 100 g/l OD

Operator	Application method M		del/data	Operator protection	% of AOEL
	Field crop (boom)	German Model		No PPE	2%
	sprayer	UK	POEM	No PPE	18%
	Hand-held sprayer	Geri	man Model	No PPE	11%
	outdoors	UK	POEM	No PPE	16%
	Glasshouse sprayer	Gree	thern European enhouse Model rst case situation)	Coveralls and gloves during application	15%
Workers	kers Model/data		Task	% of AOEL	
	EUROPOEM worker reentry model (no PPE)		Crop inspection	1%	
			Hand harvesting	16%	
Bystanders	Application method		Model/data		% of AOEL
	Field crop (boom) sprayer (worst case)		Surrogate vapour exposure calculations (Siebers <i>et al</i>)		9%
			Measurements of to spray drift for Bell)	0.4%	
			Children's exposure to drift fallout (US EPA)		0.9%



Exposure scenarios (Annex IIIA, point 7.2)

Cyantraniliprole 100 g/l SE

Operator	Application method	Mod	lel/data	Operator protection	% of AOEL
	Broadcast air-	Geri	nan Model	No PPE.	63%
	assisted (orchard) sprayer (worst case)		POEM	Gloves when handling the concentrate or handling contaminated surfaces. Closed cab during application.	25%
	Hand-held sprayer	Geri	nan Model	No PPE.	61%
	outdoors (worst case)	UK POEM		Gloves when handling the concentrate and during application.	100%
Workers	Model/data		Task		% of AOEL
	EUROPOEM worker reentry model and DFR data (no PPE)				15%
Bystanders	Application method		Model/data		% of AOEL
	Broadcast air-assisted (orchard) sprayer (worst case)		Surrogate vapour exposure calculations (Siebers <i>et al</i>)		9%
			Measurements of simulated bystander exposure to spray drift for orchard sprayers (Lloyd and Cross)		7%
			Children's exposure to drift fallout (US EPA)		10%

Exposure scenarios (Annex IIIA, point 7.2)

Cyantraniliprole 200 g/l SC

Operator	Application method	Mod	lel/data	Operator protection	% of AOEL
	Drip irrigation or	Geri	nan Model	an Model No PPE	
	hydroponic systems	UK	POEM	No PPE	12%
Workers	Model/data		Task		% of AOEL
	EUROPOEM worker reentry model (no PPE)		Handling treated growing media		0.0003%
Bystanders	Application method		Model/data		% of AOEL
	Drip irrigation or hydroponic systems		Surrogate vapour exposure calculations (Siebers <i>et al</i>)		9%
			Drift exposure (negligible)		0%
			Fallout exposure (negligible)		0%



Exposure scenarios (Annex IIIA, point 7.2)

Cyantraniliprole 400 g/kg WG

Operator	Application method	Mod	del/data	Operator protection	% of AOEL
	Broadcast air-	Geri	man Model	No PPE.	76%
	assisted (orchard) sprayer	i IIKI		Gloves when handling the concentrate or handling contaminated surfaces. Closed cab during application.	81%
	Hand-held sprayer	Geri	man Model	No PPE	39%
	outdoors		POEM	Gloves when handling the concentrate. Coveralls and gloves during application.	70%
Workers	Model/data		Task		% of AOEL
	EUROPOEM worker re- entry model and DFR data (no PPE)				17%
Bystanders	Application method		Model/data		% of AOEL
	Broadcast air-assisted (orchard) sprayer (wors	st	Surrogate vapour exposure calculations (Siebers <i>et al</i>)		9%
	case)		Measurements of simulated bystander exposure to spray drift for orchard sprayers (Lloyd and Cross)		11%
			Children's exposure to drift fallout (US EPA)		10%

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Cyantraniliprole	None



Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Pulses/oilseeds (cotton) Leafy crops (lettuce) Fruit group (tomato) Cereals (rice) Soil and foliar applications
Rotational crops	Lettuce, radish, oats, soybean
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Pasteurization, Boiling/Baking/Brewing and Sterilization
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Stable under sterilization and pasteurization conditions. Degraded to IN-J9Z38 (12-14% AR) and to IN-F6L99 and IN-N5M09 (5-8% AR) under boiling/baking/ brewing conditions
Plant residue definition for monitoring	Cyantraniliprole
Plant residue definition for risk assessment	Cyantraniliprole
	Sum cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole for processed commodities
Conversion factor (monitoring to risk assessment)	Not, for raw commodities Proposed for some processed commodities

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Ruminants, poultry
Time needed to reach a plateau concentration in milk and eggs	Approx. 14 days (milk) and 27 days (eggs)
Animal residue definition for monitoring	Cyantraniliprole
Animal residue definition for risk assessment	Sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole
Conversion factor (monitoring to risk assessment)	2 (except for meat and honey :1)
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Cyantaniliprole residues >0.01 mg/kg not expected. No sufficient information was provided to address the transfert of the very persistent soil metabolites in rotational crops (data gap).



Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

When stored at -20°C, cyantraniliprole, IN-J9Z38; IN-JCZ38, IN-K7H19, IN-MLA84, IN-MYX98, IN-N7B69, IN-N5M09, IN-F6L99: stable ≥24 months in:

- high water- (apple)
- high acid- (grape)
- high starch- (potato)
- high protein- (dry bean), except cyantraniliprole; stable 18 months only

content matrices

0.05 (0.07) 0.02 (0.03) 0.01 (0.02) 0.03 (0.03)

In high oil content matrices (peanuts) residue stability was:

- >24 months for IN-J9Z38; IN IN-MLA84, IN-MYX98 and IN-N5M09,
- 18 months for cyantraniliprole, IN-F6L99 and IN-MYX98
- Not stable for IN-JCZ38 and IN-K7H19.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - levels)

Potential for accumulation (yes/no):

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)

Muscle
Liver
Kidney
Fat
Milk
Eggs

Ruminant:	Poultry:	Pig:					
Conditions of requirement of feeding studies							
Yes ¹	No ¹	No ¹					
(0.3 mg/kg DM for beef cattle)	(0.01 mg/kg DM)	(0.04 mg/kg DM)					
No	na	na					
Yes	na	na					
Residue levels in the cattle study at the feeding level of 3 mg/kg feed (dose group 1, <i>ca</i> 10N) (mean and (highest) mg/kg)							
<0.01 (0.01)	-	-					

^{1:} Animal burden calculations based on the EU uses



Summary of residues data according to the representative uses on agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop (GAP: Number x dose/ha, PHI)	Northern/ Southern Region field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to representativ e uses	HR (c)	STMR (b)
Orange/Mandarin (2x 150 g/ha; 7 d)	SEU	Whole fruit: 0.04; <u>0.09</u> ; <u>0.13</u> ; 0.14; <u>0.14</u> ; 3x 0.16; <u>0.16</u> ; <u>0.20</u> ; <u>0.21</u> ; <u>0.22</u> ; 0.23; <u>0.23</u> ; 0.38; 0.71 Pulp: 6x <0.01; 5x 0.02; 3x 0.03; 0.04; 0.08	Orange (8) and mandarin (8) datasets similar (Utest, 5%) and combined to derived MRL proposal. MRL _{OECD} : 0.82/0.9 Extrapolation to the Citrus group	0.90	0.71 0.08 (pulp)	0.16 0.02 (pulp)
Apples/pears (2x 75 g/ha; 7 d)	NEU	2x0.02; 0.03; 0.04; 2x 0.05; 3x 0.05; 0.055; 0.06; 3x 0.06; 0.08; 0.08; 0.10; 0.11; 0.12; 0.13	MRL proposal derived from SEU dataset, as leading to a higher MRL proposal.	_		
Apples/pears (2x 90 g/ha; 7 d)	SEU	2x <0.01; 0.02; 0.05; 0.06; 0.08; 0.09; 0.09; 0.10, 2x 0.10; 0.11; 0.12; 0.13; 0.15; 0.16; 0.18	Combined SEU dataset on apples (7) and <u>pears</u> (10). MRL _{OECD} : 0.29/0.3	0.30	0.18	0.10
Peaches/apricots (2x 150 g/ha; 7 d, GAP for peach and nectarine)	SEU	0.02; 0.03; <u>0.08</u> ; 0.11; 0.12; 0.13; 0.17; 2x 0.19; 0.21; 0.26 0.28; 0.29; 0.31; <u>0.32</u> ; <u>0.34</u> ; 0.35	Trials on peaches (14) and <u>apricots</u> (3) conducted according GAPs proposed for peaches (150 g/ha) taken into account to derived MRL for peaches and nectarines, MRL _{OECD} : 0.63/0.7	0.7	0.35	0.19
Apricots (2x 90 g/ha, 7 d)	SEU	No trials conducted according to GAP provided	Data gap: Trials conducted according to the intented GAP are required	No proposal		
Plums	NEU	0.01; 0.10; 0.11; 0.12; 0.17; 0.18; 0.31; 0.49	NEU and SEU datasets not significantly	0.7	0.49	0.12
(2x 125 g/ha; 7 d)	SEU	<0.01; 0.07; 0.08; 0.23	different (U-Test, 5%), MRL derived from the merged data. MRL _{OECD} : 0.7/0.7			
Wine grapes	NEU	0.07; 0.10; 0.14; 0.16; 0.24; <u>0.30</u> ; 0.33; 0.49; <u>0.68</u>	<u>Underlined values</u> : Trials conducted with a dose rate in the range of 144 to 152 g/ha (but	1.5	0.80	0.26

EFSA Journal 2014;12(9):3814



(2x 112.5 g/ha; 10 d)			considered as slightly exceeding the ±25%			
	SEU	0.07; <u>0.14</u> ; 0.19; <u>0.21</u> ; <u>0.28</u> ; <u>0.41</u> ; 0.48; <u>0.67</u> ; 0.80	tolerance). NEU and SEU data merged together for MRL calculation as not significantly different (U-Test, 5%). MRL _{OECD} : 1.2/1.5			
Potatoes	SEU	5x <0.01	Data considered sufficient to derive a MRL	0.01*	0.01	0.01
(2x 12.5 g/ha; 14 d)	NEU	5x <0.01	proposal, since all values <loq< td=""><td></td><td></td><td></td></loq<>			
Tomatoes (2x 90 g/ha, 1 d)	SEU	<0.01; 2x 0.02, 2x 0.08	Outdoor SEU GAPs, less critical than indoor GAPs	-		
Tomatoes (Normal size & cherry tomatoes) (4x 120 g/ha; 1 d)	Indoor	0.04; 0.05; 0.07;2x 0.14; <u>0.14</u> ; 0.15; 2x 0.18; 0.22; <u>0.40</u> ; <u>0.42</u> ; <u>0.59</u> ; <u>0.62</u>	MRL proposal derived from the combined indoor trials on normal size and cherry tomato (underlined)	1.0	0.62	0.17
Tomatoes (Normal size) (4x 120 g/ha; 1 d)	Indoor	0.04; 0.05; 0.07;2x 0.14; 0.15; 2x 0.18; 0.22	Indoor data on normal size tomatoes used extrapolate an MRL proposal for egg plant MRL _{OECD} : 0.39/0.4	0.40	0.22	0.14
Peppers (2x 90 g/ha; 1 d)	SEU	2x 0.07; 2x 0.08; 0.10; <u>0.13</u> ; <u>0.24</u> ; <u>0.32</u> ; <u>0.59</u> ; <u>0.82</u>	Trials on "hot pepper" underlined. Outdoor SEU GAPs, less critical than indoor GAPs	-		
Peppers (4x 120 g/ha; 1 d)	Indoor	0,08; <u>0.09</u> ; 0,10; 0,12; <u>0.12</u> ; 2x 0.13; 0,14; 0,15; 0,16; 0,17; <u>0.17</u> ; <u>0.34</u> ; <u>1.00</u>	MRL derived from the indoor trials (combined pepper and hot pepper). MRL _{OECD} : 1.2/1.5	1.5	1.00	0.14
Cucumber/courgette (2x 90 g/ha; 1 d)	SEU	2x 0.01; 0.02; 2x 0.03, 0.03, 0.04, 0.04; 0.10; 2x 0.10	Trials on cucumbers and <u>courgettes</u> (underlined). Outdoor SEU GAPs, less critical than indoor GAPs	-		
Cucumber and courgette (4x 120 g/ha; 1 d)	Indoor	0.03; 0.04; 0.05; 0.06; 0.08; 0.09; 2x 0.18; 0.22	MRL proposal derived from indoor trials. MRL _{OECD} : 0.39/0.4 Extrapolation to the whole group "Cucurbits edible peel".	0.40	0.22	0.08
Melon (2x 90 g/ha; 1 d)	SEU	0.03; 0.04; 2x 0.05; 0.07	Outdoor SEU GAPs, less critical than indoor GAPs	-		

EFSA Journal 2014;12(9):3814



Melon (4x 120 g/ha; 1 d)	Indoor		0.03; 2x 0.04; 0.05; 2x 0.06; 0.08; 0.10	MRL proposal derived from the indoor dataset. MRL _{OECD} : 0.17/0.2	0.20	0.10	0.06
		Pulp:	9x 0.01	Extrapolation to the whole group "Cucurbits inedible peel"		0.01 (pulp)	0.01 (pulp)
Lettuce	Indoor	Trials not conduct applications inste	cted according to GAP (3 ead of 2)	Data gap: Trials conducted according to the representative GAP are required	No proposal		
Beans (with pods) (2x 90 g/ha; 1 d)	Outdoor	NEU: 0.19 SEU: 0.13; 0.16;	, 0.22; 0.54	Number of outdoor trials not sufficient to derive an MRL on bean with pods (as major crop in NEU and SEU).	No proposal		
Beans (with pods) (4x 90 g/ha; 1 d)	Indoor	Trials not conduct applications only	cted according to GAP (2 v instead of 4)	Indoor trials not compliant with proposed GAP as conducted with 2 applications instead of 4.			
Olives (2x 150 g/ha; 14 d)	SEU	2x 0.21; 0.25; 0.2 1.10	26; 0.27; 0.36; 0.38; 0.47;	MRL _{OECD} : 1.5/1.5	1.5	1.10	0.27

⁽a) Numbers of trials in which particular residue levels were reported e.g. 3x < 0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.1, 2x 0.15, 0.17

EFSA Journal 2014;12(9):3814

⁽b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

⁽c) Highest residue



Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.01 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo model	Highest TMDI: 139 % ADI (WHO, cluster B) (EU representative uses only)
TMDI (% ADI) according to (national diets)	-
IEDI (% ADI) according to EFSA PRIMo model	Highest IEDI: 20% ADI (WHO Cluster B) (EU representative uses only)
NEDI (specify diet) (% ADI)	-
Factors included in IEDI and NEDI	STMR derived from residue trials
ARfD	Not proposed, not necessary
IESTI (% ARfD)	-
NESTI (% ARfD) according (to be specified)	-
Factors included in IESTI and NESTI	-

Additional contribution (% ADI) to the consumer intakes through drinking water resulting from groundwater metabolites expected to be present above 0.75 μ g/L (WHO, 2009)

Metabolites (expected concentration, μg/L)

IN-JSE76 (6.3 - 25.5 μ g/L) IN-PLT97 (0.74 - 1.28 μ g/L)

IN-K5A78, IN-K5A79 and IN-M2G98

Outde	oor (2x 15	0 g/ha)	Outdoor (2x 75 g/ha)				
Adult	Child	Infant	nt Adult Ch		Infant		
9%	26%	38%	2%	6%	9%		
0.4%	1%	2%	0.2%	1%	1%		

Insufficient information to derive toxicological reference values (data gap)



Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

	Number	Processing	factors	
Crop / processed product	of studies	Transfer factor	CF ¹	Comments
Citrus / pulp	16	0.1	n.n.	-
Citrus / peel	16	3.7	n.n.	_
Orange / juice	3	0.1	n.n.	-
Orange / wet pulp	3	0.2	n.n.	-
Orange / dry pulp	3	0.4	1.2	
Orange / meal	3	0.4	1.2	
Orange / marmalade	3	0.1	n.n.	
Orange / oil	3	6.2	1.2	-
Orange / canned	3	0.1	n.n.	-
Apple / washed	3	0.6	n.n.	_
Apple / puree	3	1.1	n.n.	-
Apple ;/ canned	3	0.1	n.n.	-
Apple / juice	3	0.3	n.n.	-
Apple / wet pomace	3	1.0	n.n.	-
Apple / dry pomace	3	2.6	n.n.	-
Apple / sauce	3	1.4	2.0	-
Plums / prunes	3	1.5	1.1	_
Grape / Bottled wine (red)	2	1.8	n.n.	-
Grape / Bottled wine (white)	1	0.6	n.n.	
Grape / Juice	3	0.8	n.n.	_
Grape / Raisins	3	1.4	n.n.	_
Potato / flakes	2	<0.6	-	NY / 12 11 2 1
Potato / peeled	2	<0.6	-	Not reliable, as residue
Potato / chips	2	<0.6	-	levels in raw potato close
Potato / fries	2	<0.6	_	to the LOQ (0.014 and
Potato / unpeeled boiled	2	<0.6	_	0.020 mg/kg) and \leq 0.01
Potato / unpeeled microwaved	2	<0.6	_	mg/kg in all processed fractions
Tomato / washed	3	0.2	n n	
Tomato / washed Tomato / peeled	3	0.2	n.n.	
Tomato / peeled Tomato / sundried	3	3.5	n.n. 1.1	
Tomato / canned	3	0.1		
Tomato / camed Tomato / juice	3	0.1	n.n. 1.3	
Tomato / paste		0.1	1.5	-
Tomato / paste Tomato / puree	3	0.0	1.5	
Melon / pulp	12	0.2		<u> </u>
Melon / peel	12	2.3	n.n.	
Spinach / leaves cooked	3	0.2	n.n. 8.0	-
Olives / Processed (flesh)	3			-
	3	0.6	1.6	-
Olives / Processed (whole)	3	0.4	1.6	
Olives / raw oil	2	1.2	1.1	-
Olives / refined oil		0.7	1.4	-
Cotton / raw oil (cold press)	2	0.3	n.n.	-
Cotton / refined oil (cold press)	2	0.01	5.7	-
Cotton / meal (cold press) CF: conversion factor for risk as	2	0.1	n.n.	-

1: CF: conversion factor for risk assessment

n.n.: not necessary



Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Code	Commodity		Proposed EU MRLs and comments
110000	Citrus fruit	0.9	SEU (extrapolation from orange/mandarin)
130010	Apple	0.3	NEU & SEU
130020	Pear	0.3	NEU & SEU
140010	Apricot	_	Data gap: Trials according to GAP required
140030	Peach/nectarine	0.7	SEU
140040	Plum	0.7	NEU & SEU
150010	Wine grapes	1.5	NEU & SEU
161030	Olives (table)	1.5	SEU
211000	Potato	0.01*	NEU & SEU
231010	Tomato	1.5	Indoor & SEU
231020	Peppers	1.5	Indoor & SEU
231030	Eggplant	0.4	Indoor & SEU
	other solanacea	1.5	Indoor & SEU
232000	Cucurbits edible peel	0.4	Indoor & SEU
233000	Cucurbits inedible peel	0.2	Indoor & SEU
251000	Lettuce, other salad plants		Data gap: Trials according to GAP required
260010	Beans (fresh with pods)	-	Data gap: Trials according to GAP required
402010	Olives (oil)	1.5	SEU

Proposed Import tolerances uses

Import tolerance proposals will be considered in a separate EFSA Reasoned Opinion, once documentation on registration in exporting countries will be submitted.



Route of degradation (aerobic) in soil (Annex IIA, OECD Point IIA 7.1.1)

Mineralisation after 100 days	20/22°C: <loq %="" (n="5)</th" -="" -2.2="" 90-100="" [¹⁴c-cn]="" after="" d,="" label=""></loq>
Non-extractable residues after 100 days	20/22°C: 5.6-15.9 % after 90-100 d, [¹⁴ C-CN] – label (n = 5) 5.08-17.8 % after 90-100 d, [¹⁴ C-PC] – label (n = 5) Report Nos. DuPont-15775 (22°C) and DuPont-17055 (20°C)
Metabolites requiring further consideration - name and/or code maximum % of applied	22°C (n = 5) [¹⁴ C-CN] and [¹⁴ C-PC] labels: IN-J9Z38, maximum 19.4% [day 120] IN-JCZ38, maximum 39.6% [day 120] IN-JSE76, maximum 42.9% [day 358] IN-K5A77, maximum 8.9% [day 100] IN-K5A78, maximum 28.8% [day 358] IN-K5A79, maximum 9.3% [day 41] IN-PLT97, maximum 26.3% [day 358] Report No. DuPont-15775 IN-M2G98, maximum of 32.9% in the IN-K5A79 dosed study n = number of soils

Route of degradation in soil – (anaerobic and photolysis) (Annex IIA, OECD Points IIA 7.1.2 and IIA 7.1.3)

Anaerobic degradation

inter object degradation	
Mineralisation after 100 days	20°C: not significant after 120 d, [14C-CN] and [14C-PC] – label, (n = 1)
	Report No. DuPont-17057
Non-extractable residues after 100 days	20°C: 5.52% after 120 d, [14C-CN] –label (n = 1) 20°C: 6.15% after 120 d, [14C-PC] –label (n = 1) Report No. DuPont-17057
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	20°C: (n = 1) [¹⁴ C-CN] and [¹⁴ C-PC] labels: IN-J9Z38, maximum 71.9% [day 30] IN-JCZ38, maximum 5.3% [day 10] IN-JSE76, maximum 5.8% [day 14] IN-K5A77, maximum 9.97% [day 60] IN-K5A78, maximum 16.2% [day 120] Report No. DuPont-17057



Soil photolysis

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)

Moist soil photolysis study, 20° C (n = 1) [14 C-CN] and [14 C-PC] labels

IN-QKV54, maximum 17.2% [day 15]

IN-RNU71, maximum 14.1% [day 30]

IN-NXX70, maximum 4.8% a [day 6]

IN-J9Z38*, maximum 54.8% [day 10]

IN-JCZ38*, maximum 3.4% [day 20]

IN-JSE76*, maximum 4.2% [day 30]

IN-K5A77*, maximum 1.95% [day 200]

IN-K5A79*, maximum 2.97% [day 30]

Report Nos. DuPont-28730 and DuPont-17056

technically IN-NXX70 did not breach any of the triggers for further assessment, however it has been included for completeness in the groundwater assessment as it is a precursor of the major soil photolysis metabolite IN-QKV54

^{*} Metabolites observed during soil photolysis were formed *via* aerobic soil degradation transformations concurrently with photodegradation reactions.



Rate of degradation in soil (Annex IIA, OECD Points IIA 7.2 and IIA 7.3; Annex IIIA, OECD Points IIIA 9.1 and IIIA 9.2)

Laboratory studies

Parent best fit – for use against regulatory triggers and in PECsoil calculations (non-normalised)

Study	Soil	DegT ₅₀	DegT ₉₀	Optimized parameters ± standard error	χ ² error	Model		
5775	Nambsheim at 22° C pH H ₂ O = 7.9	8.7	66.2	M0 (%)= 105.78 ± 1.7588 $\alpha = 1.168 \pm 0.1153$ $\beta = 10.716 \pm 1.7934$	4	FOMC		
DuPont-15775	Tama at 22° C pH H ₂ O = 6.2	37.1	328	M0 (%) = 106.56 ± 2.14 g = 0.56 k_1 (d ⁻¹) = $0.005 \pm$ 0.00027 k_2 (d ⁻¹) = $0.0647 \pm$ 0.0055	2.79	DFOP (Primary Reviewer fit)		
	Gross Umstadt at 10°C pH $\text{H}_2\text{O} = 7.04$	53.3ª	197ª	M0 (%) = 102.93 ± 1.3835 $g = 0.09161 \pm 0.0217$ k_1 (d^{-1}) = 0.16757 ± 0.0734 k_2 (d^{-1}) = 0.00434 ± 0.0003	1	DFOP		
DuPont-17055	Gross Umstadt at 20° C pH H ₂ O = 7.04		20°C 43.	43.7	235	M0 (%) = 102.89 ± 1.0783 $g = 0.2779 \pm 0.0162$ k_I (d^{-1}) = 0.20536 ± 0.0246 k_2 (d^{-1}) = 0.00842 ± 0.0004	1	DFOP
Du	Lleida at 20°C pH H ₂ O = 8.05	20.9	156	M0 (%)= 93.465 ± 1.6008 α = 1.1981 ± 0.1631 β = 26.66 ± 5.9727	6	FOMC		
	Sassafras at 20°C pH $H_2O = 4.62$	91.9	376	M0 (%) = 99.885 ± 1.4189 g = 0.15859 ± 0.0266 k_1 (d ⁻¹) = 0.13056 ± 0.039 k_2 (d ⁻¹) = 0.00567 ± 0.0004	2	DFOP		

^acorrected to 20°C using a Q₁₀ of 2.58

Note all rate constants (i.e. DFOP k_1 and k_2) were significantly different from zero on the basis of the t-test (p<0.05). Similarly all FOMC alpha and beta values were considered significantly different from zero on the basis of the reported confidence intervals.



Parent DegT50 – SFO fits for use in PECgw and PECsw calculations (normalised values)

		Experim	ental val	ues		Refer	ence values		
Study	Soil	DegT ₅₀	T (°C)	M (cc/cc)	T _{REF} (°C)	M _{REF} at 10kPa (cc/cc) ^a	Correction factor	Normalised DegT ₅₀	
DuPont-15775	Namb. (SFO)	12.4	22	0.200	20	0.238	1.0700	13.3	
DuF	Tama (SFO)	70.4	22	0.258	20	0.465	0.8002	56.3	
	Gross-U (SFO)	131	10	0.175	20	0.291	0.2715	35.6	
DuPont-17055	Gross-U (SFO)	55.6	20	0.175	20	0.291	0.7005	38.9	
DuPc	Lleida (SFO)	25.6	20	0.270	20	0.416	0.7389	18.9	
	Sass. (SFO)	92.5	20	0.196	20	0.214	0.9404	87.0	
Geomean								34.4	
Worst case	longest DT ₅₀							87.0	
Shortest SI	Shortest SFO DT ₅₀								

^aM_{REF} values were taken from experimental measurements of moisture content at 10kPa

The geomean values calculated for the Primary Reviewer selected values were derived based on the result from the Gross-Umstadt soil at 20° C only. During the Secondary Review stage GJR partners agreed that the the potential pH dependence of parent cyantraniliprole should be taken into account by running simulations with the worst case longest parent SFO DT₅₀ of 87.0 d to conservatively assess the leaching risk of parent. To assess the potential for faster parent degradation under neutral or alkaline conditions (and thus faster/higher formation of metabolites) it was agreed that additional simulations utilising the shortest SFO DT₅₀ of 13.3 d be used for the metabolite exposure assessments.



$Parent\ DegT50-SFO\ and\ DFOP\ for\ use\ in\ deriving\ PECgw\ and\ PECsw\ input\ parameters\ for\ metabolites\ IN-JCZ38\ and\ IN-J9Z38\ (normalised\ values)$

		E	xperime	ntal val	ues	Reference values											
Study	Soil	DegT_{50}		T (°C)	M (cc/cc)	T _{REF} (°C)	M _{REF} at 10kPa (cc/cc) ^a	Correction factor	Norm Deg	alised gT ₅₀							
DuPont-15775	Namb. (SFO)	12	2.4	22	0.200	20	0.238	1.0700	13	3.3							
DuPor	Tama (Primary Rev. DFOP fit)	10.7 132 (k1) (k2)		22	0.258	20	0.465	0.8002	8.6	106							
	Gross-U (SFO)	131		10	0.175	20	0.291	0.2715	35	5.6							
DuPont-17055	Gross-U (SFO)	55	55.6		0.175	20	0.291	0.7005	38	3.9							
DuPont	Lleida (Prim. Rev. DFOP fit)	5.1 48.6 (k2)		20	0.270	20	0.416	0.7389	3.8	35.9							
	Sass. (SFO)	92.5		20	0.196	20	0.214	0.9404	87	7.0							
			ed on eith	ner SFO	and fast pl	nase DFOP D	Primary Reviewer geomean (based on either SFO and fast phase DFOP DT ₅₀ or SFO and slow phase DFOP DT ₅₀ values) 17.1 44.3										

^aM_{REF} values were taken from experimental measurements of moisture content at 10kPa

The geomean values calculated for the Primary Reviewer selected values were derived based on the result from the Gross-Umstadt soil at 20°C only

The primary Reviewer geomean DT_{50} values include consideration of DFOP fits for the Tama and Lleida soils. The Primary Reviewer geomean DT50 values therefore include consideration of either fast phase (based on DFOP k1 rate constants) or slow phase (based on DFOP k2 rate constants) to give upper and lower limits to the geomean DT50 derived.



IN-JCZ38 best fit – for use against regulatory triggers and in PECsoil calculations (non-normalised)

Study	Soil	DegT ₅₀	DegT ₉₀	Optimized parameters ± standard error	Formation fraction	χ ² error	Model
75	Nambsheim at 22°C	14.8	49.3	k_JCZ38 = 0.046695 ± 0.008	0.39	20	FOMC-SFO
DuPont-15775	Tama at 22°C	37.0	123	k_JCZ38 = 0.018729 ± 0.003	0.41	21	FOMC-SFO (Applicant fit)
DuPor	Tama at 22°C	40.8	136	k_JCZ38 = 0.0170	0.39	19.3	DFOP-SFO (Primary Reviewer fit)
5	Gross Umstadt at 10°C	56.4ª	187ª	k_JCZ38 = 0.0047616 ± 0.004	0.39	11	DFOP-SFO
DuPont-17055	Gross Umstadt at 20°C	133	442	k_JCZ38 = 0.0052066 ± 0.001	0.31	4	DFOP-SFO
uPont	Lleida at 20°C	25.5	84.6	$k_JCZ38 = 0.027202$ ± 0.006	0.35	12	FOMC-SFO
D	Sassafras at 20°C	7E+4 ^b	2E+5 ^b	k_JCZ38 = 0.00001 ± 0.001	0.60	6	DFOP-SFO
	Gross Umstadt at 20°C	12.1	63.4	M0 (%)= 100.08 \pm 1.0396 α = 1.9739 \pm 0.21746 β = 28.673 \pm 4.1646	-	2	FOMC
	Lleida at 20°C	5.0	29.9	M0 (%)= 98.861 ± 1.077 α = 1.6056 ± 0.14177 β = 9.3501 ± 1.1223	-	4	FOMC
DuPont-17597	Nambsheim at 20°C	3.6	19.4	M0 (%)= 102.05 ± 1.5261 α = 1.8492 ± 0.27767 β = 7.8384 ± 1.555	-	5	FOMC
DuPo	Sassafras at 20°C	11.2	77.5	M0 (%)= 99.867 \pm 1.5044 α = 1.307 \pm 0.13392 β = 16.1 \pm 2.4886	-	5	FOMC
	Tama at 20°C	9.1	237	M0 (%) = 97.622 ± 0.98294 g = 0.82877 ± 0.02291 k_1 (d ⁻¹) = 0.10065 ± 0.00513 k_2 (d ⁻¹) = 0.0022719 ± 0.0017	-	3	DFOP

^acorrected to 20°C using a Q₁₀ of 2.58 ^bthe rate constant failed the significance test and was omitted from further consideration as an outlier. All other rate constants (i.e. SFO $k_{\rm J}CZ38$ and DFOP $k_{\rm l}$ and $k_{\rm 2}$) were significantly different from zero on the basis of the t-test (p<0.05; p<0.1 for Tama $k_{\rm 2}$). Similarly all FOMC alpha and beta values were considered significantly different from zero on the basis of the reported confidence intervals. Note that DuPont-15775 and DuPont-17055 were cyantraniliprole dosed studies; DuPont-17597 was the IN-JCZ38 dosed study. Hence no formation fractions are reported for DuPont-17597.



IN-JCZ38 DegT50 – for use in PECgw and PWCsw calculations (normalised values)

		-	Experimental	values			Reference values				
Study	Soil	DegT ₅₀	Formation fraction	T (°C)	M (cc/cc)	T _{REF} (°C)	M _{REF} at 10kPa (cc/cc) ^a	Correction factor	Normalised DegT ₅₀		
-15775	Namb. (SFO-SFO)	6.6	0.70	22	0.200	20	0.238	1.0700	7.1		
DuPont-15775	Tama (Prim.Rev. fit DFOP- SFO)	40.8	0.39	22	0.258	20	0.465	0.8002	32.6		
	Gross-U (SFO-SFO)	112	0.44	10	0.175	20	0.291	0.2715	30.4		
1055	Gross-U (SFO-SFO)	59.5	0.46	20	0.175	20	0.291	0.7005	41.7		
DuPont-17055	Lleida (Prim. Rev. fit DFOP- SFO)	33.6	0.26	20	0.270	20	0.416	0.7389	24.8		
	Sass. (SFO- SFO)	262	0.77	20	0.196	20	0.214	0.9404	246		
	Gross-U	13.4	-	20	0.220	20	0.309	0.7884	10.6		
76	Lleida	5.5	-	20	0.332	20	0.382	0.9065	5.0		
759	Namb.	3.9	-	20	0.197	20	0.191	1.00	3.9		
DuPont-17597	Sass.	12.5	-	20	0.177	20	0.217	0.8671	10.8		
DuPc	Tama (Prim. Rev. SFO fit)	10.1	-	20	0.312	20	0.432	0.7963	8.0		
Primary Reviewer average/geomean		0.51						15.7			

^aM_{REF} values were taken from experimental measurements of moisture content at 10kPa

Note that DuPont-15775 and DuPont-17055 were cyantraniliprole dosed studies; DuPont-17597 was the IN-JCZ38 dosed study. Hence no formation fractions are reported for DuPont-17597.

The geomean values calculated for the Primary Reviewer selected values were derived by calculating an average formation fraction or geomean DT_{50} for the replicated cyantraniliprole applied Gross-Umstadt soils first, and then deriving an overall average or geomean from the remaining values (n = 5 for formation fraction, n = 10 for DT_{50}).



IN-J9Z38 best fit – for use against regulatory triggers and in PECsoil calculations (non-normalised)

Study	Soil	DegT ₅₀	DegT ₉₀	Optimized parameters ± standard error	Formation fraction	χ² error	Model
75	Nambsheim at 22°C	224	743	k_J9Z38 = 0.0030977 ± 8E-04	0.13	34	FOMC-SFO
DuPont-15775	Tama at 22°C	610	2027	k_J9Z38 = 0.001136 ± 7E-04	0.15	11	FOMC-SFO (Applicant fit)
	Tama at 22°C	475	1578	k_J9Z38 = 0.0015	0.15	10	DFOP-SFO (Primary Reviewer fit)
5	Gross Umstadt at 10°C	47.7ª	158ª	k_J9Z38 = 0.0056337 ± 0.003	0.51	7	DFOP-SFO
DuPont-17055	Gross Umstadt at 20°C	90.5	301	k_J9Z38 = 0.0076585 ± 0.001	0.36	2	DFOP-SFO
uPont	Lleida at 20°C	78.9	262	k_J9Z38 = 0.0087862 ± 0.002	0.34	10	FOMC-SFO
D	Sassafras at 20°C	50.9	169	k_J9Z38 = 0.013622 ± 0.007	0.25	24	DFOP-SFO
	Gross Umstadt at 20°C	119	1117	M0 (%)= 95.952 \pm 0.60088 α = 0.9623 \pm 0.20554 β = 112 \pm 32.225	-	1	FOMC
	Lleida at 20°C	104	346	$M0 (\%) = 96.361 \pm 0.50166$ $k = 0.0066519 \pm 0.00014$	-	1	SFO
DuPont-17596	Nambsheim at 20°C	76.8	255	$M0 (\%) = 98.596 \pm 1.0421$ $k = 0.0090308 \pm 0.00032$	-	3	SFO
DuPont	Sassafras at 20°C	220	1168	$M0 (\%) = 97.728 \pm 1.0888$ $g = 0.27348 \pm 0.06267$ $k_1 (d^{-1}) = 0.043602 \pm 0.01229$ $k_2 (d^{-1}) = 0.0016973 \pm 0.00082$	-	2	DFOP
	Tama at 20°C	177	588	M0 (%)= 95.429 ± 0.53248 k = 0.003913 ± 0.00012	-	1	SFO

^acorrected to 20°C using a Q₁₀ of 2.58

All rate constants (i.e. SFO k_1 9238 and DFOP k_1 and k_2) were significantly different from zero on the basis of the t-test (p<0.05). Similarly all FOMC alpha and beta values were considered significantly different from zero on the basis of the reported confidence intervals.

Note that DuPont-15775 and DuPont-17055 were cyantraniliprole dosed studies; DuPont-17596 was the IN-J9Z38 dosed study. Hence no formation fractions are reported for DuPont-17596.



IN-J9Z38 DegT50 – for use in PECgw and PWCsw calculations (normalised values)

			Experimental	values			Re	ference values	rection actor Normalised DegT ₅₀ 0700 269 8002 380 2715 27.0		
Study	Soil	DegT ₅₀	Formation fraction	T (°C)	M (cc/cc)	T _{REF} (°C)	M _{REF} at 10kPa (cc/cc) ^a	Correction factor			
-15775	Namb. (SFO-SFO)	251	0.13	22	0.200	20	0.238	1.0700	269		
DuPont-15775	Tama (Prim.Rev. fit DFOP- SFO)	475	0.15	22	0.258	20	0.465	0.8002	380		
	Gross-U (SFO-SFO)	99.3	0.56	10	0.175	20	0.291	0.2715	27.0		
7055	Gross-U (SFO-SFO)	46.2	0.54	20	0.175	20	0.291	0.7005	32.4		
DuPont-17055	Lleida (Prim. Rev. fit DFOP- SFO)	101	0.27	20	0.270	20	0.416	0.7389	74.6		
	Sass. (SFO- SFO)	61.3	0.23	20	0.196	20	0.214	0.9404	57.6		
	Gross-U	110	-	20	0.176	20	0.309	0.6744	74.2		
969	Lleida	104	-	20	0.243	20	0.385	0.7238	75.3		
Pont-17596	Namb.	76.8	-	20	0.221	20	0.195	1.000	76.8		
DuPo	Sass.	139	-	20	0.211	20	0.243	0.9059	126		
	Tama	177	-	20	0.275	20	0.345	0.8541	151		
8	Primary Reviewer average/geomean		0.27			l			101		

^aM_{REF} values were taken from experimental measurements of moisture content at 10kPa

Note that DuPont-15775 and DuPont-17055 were cyantraniliprole dosed studies; DuPont-17596 was the IN-J9Z38 dosed study. Hence no formation fractions are reported for DuPont-17596.

The geomean values calculated for the Primary Reviewer selected values were derived by calculating an average formation fraction or geomean DT_{50} for the replicated cyantraniliprole applied Gross-Umstadt soils first, and then deriving an overall average or geomean from the remaining values (n = 5 for formation fraction, n = 10 for DT50).



IN-JSE76 best fit – for use against regulatory triggers and in PECsoil calculations (non-normalised)

Study	Soil	DegT ₅₀	DegT ₉₀	Optimized parameters ± standard error	Formation fraction	χ ² error	Model
	Gross Umstadt at 20°C	108	359	k_JSE76 = 0.0064069 ± 0.0004	0.91	3	FOMC-SFO
7597	Lleida at 20°C	129	427	k_JSE76 = 0.0053939 ± 0.00025	0.93	2	FOMC-SFO
DuPont-17597	Nambsheim at 20°C	43.2	143	k_JSE76 = 0.016063 ± 0.00068	0.86	4	FOMC-SFO
Dn	Sassafras at 20°C	108	357	k_JSE76 = 0.0064425 ± 0.00054	0.95	3	FOMC-SFO
	Tama at 20°C	120	399	k_JSE76 = 0.0057706 ± 0.00034	1.00	2	DFOP-SFO
	Gross Umstadt at 20°C	219	M0 (%)= 91.685 ±		-	2	SFO
	Lleida at 20°C	157	522	M0 (%)= 91.371 ± 0.57577 k = 0.0044084 ± 0.00014	-	1	SFO
∞	Nambsheim at 20°C	86.3	1089	M0 (%)= 90.971 ± 1.5647 α = 0.78229 ± 0.22765 β = 60.554 ± 26.958	-	3	FOMC
DuPont-17598	Sassafras at 20°C	343	1319	M0 (%) = 95.492 ± 1.504 g = 0.12004 ± 0.03895 k_I (d ⁻¹) = 0.08082 ± 0.04888 k_2 (d ⁻¹) = 0.0016484 ± 0.0005	-	1	DFOP
	Tama at 20°C	1249	5929	M0 (%) = 93.979 ± 0.68499 $g = 0.23055 \pm 0.0168$ $k_1 (d^{-1}) = 0.074546 \pm$ 0.01031 $k_2 (d^{-1}) = 0.00036471 \pm$ 0.00024	-	1	DFOP

Note that DuPont-17597 was the IN-JCZ38 dosed study and DuPont-17598 was the IN-JSE76 dosed study. Hence no formation fractions are reported for DuPont-17598.

All rate constants (i.e. SFO k_JCZ38 and DFOP k_1 and k_2) were significantly different from zero on the basis of the t-test (p<0.05; p<0.1 for Sassafras k_1 and Tama k_2). Similarly all FOMC alpha and beta values were considered significantly different from zero on the basis of the reported confidence intervals.



IN-JSE76 DegT50 – for use in PECgw and PWCsw calculations (normalised values; SFO-SFO for all

			Experimenta	l values			Re	ference values	
Study	Soil	DegT ₅₀	Formation fraction	T (°C)	M (cc/cc)	T _{REF} (°C)	M _{REF} at 10kPa (cc/cc) ^a	Correction factor	Normalised DegT ₅₀
	Gross- U	94.9	0.94	20	0.220	20	0.309	0.7884	74.8
<u> </u>	Lleida	139	0.89	20	0.332	20	0.382	0.9065	126
t-1759	Namb.	45.1	0.82	20	0.197	20	0.191	1.000	45.1
DuPont-17597	Sass.	93.2	0.96	20	0.177	20	0.217	0.8671	80.8
	Tama	89.6	1.00	20	0.312	20	0.432	0.7963	71.4
	Gross- U	219	-	20	0.200	20	0.309	0.7375	162
7598	Lleida	157	-	20	0.330	20	0.382	0.9026	142
DuPont-17598	Namb.	89.5	-	20	0.196	20	0.191	1.00	89.5
DuPe	Sass.	260	-	20	0.176	20	0.217	0.8636	225
	Tama	258	-	20	0.310	20	0.432	0.7927	205
Applica	nt average/	geomean	0.92		I	I	l		109

^aM_{REF} values were taken from experimental measurements of moisture content at 10kPa
Note that DuPont-17597 was the IN-JCZ38 dosed study and DuPont-17598 was the IN-JSE76 dosed study. Hence no formation fractions are reported for DuPont-17598.



IN-K5A79 best fit – for use against regulatory triggers and in PECsoil calculations (non-normalised)

Study	Soil	DegT ₅₀	DegT ₉₀	Optimized parameters ± standard error	Formation fraction	χ ² error	Model
	Gross Umstadt at 20°C	23.2	77.1	k_K5A79 = 0.029864 ± 0.01612	0.90	7	SFO-SFO
7598	Lleida at 20°C	40.5	135	$k_K5A79 = 0.017118$ ± 0.0096	0.37	14	SFO-SFO
DuPont-17598	Nambsheim at 20°C	37.6	125	$k_K5A79 = 0.018426$ ± 0.00871	0.42	11	FOMC- SFO
DuP	Sassafras at 20°C	116	384	$k_K5A79 = 0.0059954 \pm 0.00768$	0.32	6	DFOP- SFO
	Tama at 20°C	967	3211	$k_K5A79 = 0.000717$ ± 0.00122	0.47	5	DFOP- SFO
	Gross Umstadt at 24°C	t 42.8 142 M0 (%)=105.35 ± 0.94297 k = 0.016212 ± 0.00039		-	3	SFO	
8	Lleida at 24°C	16.4	54.6	M0 (%)= 102.34 ± 1.4244 $k = 0.042206 \pm 0.00146$	-	5	SFO
DuPont-18868	Nambsheim at 24°C	25.4	84.3	$M0 (\%)=103.23 \pm 1.7022$ $k = 0.027305 \pm 0.00098$	-	9	SFO
	Sassafras at 19°C	105	350	$M0 (\%) = 108.14 \pm \\ 1.1361$ $k = 0.0065743 \pm \\ 0.00027$	-	4	SFO
	Tama at 24°C	130	432	$M0 (\%) = 99.266 \pm 1.1544$ $k = 0.0053316 \pm 0.00028$	-	4	SFO

Note that DuPont-17598 was the IN-JSE76 dosed study and DuPont-18868 was the IN-K5A79 dosed study. Hence no formation fractions are reported for DuPont-18868.

All rate constants (i.e. SFO k_K5A79 and DFOP k_1 and k_2) were significantly different from zero on the basis of the t-test (p<0.05) except for the IN-JSE76 dosed Tama soil. Similarly all FOMC alpha and beta values were considered significantly different from zero on the basis of the reported confidence intervals.



IN-K5A79 DegT50 - for use in PECgw and PWCsw calculations (normalised values; SFO-SFO for all kinetic fits)

Kinetic	<u> </u>		Experimental	values			Re	ference values	
Study	Soil	DegT ₅₀	Formation fraction	T (°C)	M (cc/cc)	T _{REF} (°C)	M _{REF} at 10kPa (cc/cc) ^a	Correction factor	Normalised DegT ₅₀
&	Gross- U	40.4	0.48	20	0.200	20	0.309	0.7375	29.8
-1759	Lleida	32.7	0.41	20	0.330	20	0.382	0.9026	29.5
DuPont-17598	Namb.	21.8	0.59	20	0.196	20	0.191	1.00	21.8
Δ	Sass.	17.6	1.00	20	0.176	20	0.217	0.8636	15.2
	Gross- U	42.8	-	24	0.172	20	0.342	0.9030	38.6
898	Lleida	16.4	-	24	0.230	20	0.406	0.9817	16.1
DuPont-18868	Namb.	25.4	-	24	0.195	20	0.262	1.1871	30.2
DuP	Sass.	105	-	19	0.284	20	0.205	0.9096	95.5
	Tama	130	-	24	0.188	20	0.343	0.9591	125
Primary Reviewer average/geomean ^b			0.62						39

^aM_{REF} values were taken from experimental measurements of moisture content at 10kPa

Note that DuPont-17598 was the IN-JSE76 dosed study and DuPont-18868 was the IN-K5A79 dosed study. Hence no formation fractions

are reported for DuPont-18868. b Primary Reviewer average formation fraction and geomean DT₅₀ exclude the result from the Tama soil from DuPont-17598 as unacceptable. Individual geomean DT50 values were calculated for each replicated soil before the overall geomean DT50 was derived from the 5 remaining values.



IN-PLT97 best fit – for use against regulatory triggers and in PECsoil calculations (non-normalised)

Study	Soil	DegT ₅₀	DegT ₉₀	Optimized parameters ± standard error	Formation fraction	χ ² error	Model
	Gross Umstadt at 24°C	640	2126	k_PLT97 = 0.0010829 ± 0.00067	0.80	5	SFO- SFO
898	Lleida at 24°C	293	974	k_PLT97 = 0.0023653 ± 0.00053	0.79	3	SFO- SFO
DuPont-18868	Nambsheim at 24°C	236	783	k_PLT97 = 0.002941 ± 0.00051	1.00	3	SFO- SFO
DuP	Sassafras at 19°C	70.8	235	k_PLT97 = 0.0097971 ± 0.00631	0.39	4	SFO- SFO
	Tama at 24°C	0.42	8	SFO- SFO			
	Gross Umstadt at 20°C (Prim. Rev fit)	1638	5442	M0 (%)=92.101 k = 0.00042309	1	5	SFO
	Lleida at 20°C	439	1458	M0 (%)= 88.818 ± 14.12 $k = 0.0015791 \pm 0.0029561$	-	7	SFO
-1907	Nambsheim at 20°C	711	2363	M0 (%)= 93.161 ± 2.0301 k = 0.00097432 ± 2.0301	-	5	SFO
DuPont-19077	Sassafras at 20°C 1837 6103		6103	M0 (%)= 96.487 ± 1.3781 $k = 0.00037732 \pm 0.00024831$	-	3	SFO
				-	5	SFO	

Note that DuPont-18868 was the IN-K5A79 dosed study and DuPont-19077 was the IN-PLT97 dosed study. Hence no formation fractions are reported for DuPont-19077.

All rate constants (i.e. SFO k_PLT97 and SFO k) were significantly different from zero on the basis of the t-test (p<0.05) except for the IN-K5A76 dosed Tama soil. Similarly all FOMC alpha and beta values were considered significantly different from zero on the basis of the reported confidence intervals. Based on the good visual fit for the Tama soil this result was retained in the overall analysis.



IN-PLT97 DegT50 - for use in PECgw and PWCsw calculations (normalised values; SFO-SFO for all

kinetic			Experimenta	l values			Re	ference values	
Study	Soil	DegT ₅₀	Formation fraction	T (°C)	M (cc/cc)	T _{REF} (°C)	M _{REF} at 10kPa (cc/cc) ^a	Correction factor	Normalised DegT ₅₀
	Gross- U	640	0.80	24	0.172	20	0.342	0.9030	578
86	Lleida	293	0.79	24	0.230	20	0.406	0.9815	288
t-1886	Namb.	236	1.00	24	0.195	20	0.262	1.1881	280
DuPon	Sass.	70.8	0.39	19	0.284	20	0.205	0.9096	64.4
DuPont-18868	Tama	69.6	0.42	24	0.188	20	0.343	0.9591	66.8
	Gross- U	1744 ^b	-	20	0.193	20	0.342	0.6700	1168
770	Lleida	439	-	20	0.263	20	0.406	0.7379	324
nt-19(Namb.	711	-	20	0.164	20	0.286	0.6775	482
DuPont-19077	Sass.	1837	-	20	0.146	20	0.249	0.6882	1264
	Tama	429	-	20	0.238	20	0.460	0.6305	270
Applicant average/geomean		0.68		<u> </u>		1		323	

^aM_{REF} values were taken from experimental measurements of moisture content at 10kPa
Note that DuPont-18868 was the IN-K5A79 dosed study and DuPont-19077 was the IN-PLT97 dosed study. Hence no formation fractions are reported for DuPont-19077.

^bthe DT₅₀ value of 1744 was reported by the Applicant. The independent Primary Reviewer analysis resulted in a shorter DT₅₀ of 1638 d. However inclusion of this shorter DT₅₀ in the calculation of the geomean has a negligible effect (geomean DT₅₀ reduces from 323 to 321 d) and for simplicity the Applicant derived value has been retained.



IN-K5A77 best fit – for use against regulatory triggers and in PECsoil calculations (non-normalised)

				Optimized parameters	Formation	χ^2	
Study	Soil	DegT ₅₀	DegT ₉₀	± standard error	fraction	error	Model
	Gross Umstadt at 20°C	161	536	k_K5A77 = 0.0042955 ± 0.00124	0.89	4	FOMC- SFO
7596	Lleida at 20°C	42.0	140	k_K5A77 = 0.016499 ± 0.00217	0.86	5	SFO-SFO
DuPont-17596	Nambsheim at 20°C	74.1	246	k_K5A77 = 0.0093542 ± 0.00277	0.66	10	SFO-SFO
DuP	Sassafras at 20°C	644	2140	k_K5A77 = 0.0010759 ± 0.00157	0.70	3	DFOP- SFO
	Tama at 20°C	109	361	k_K5A77 = 0.0063722 ± 0.00084	1.00	7	SFO-SFO
	Gross Umstadt at 20°C	202	1216	M0 (%) = 98.659 ± 1.9481 g = 0.31163 ± 0.06013 k_1 (d ⁻¹) = 0.061427 ± 0.01756 k_2 (d ⁻¹) = 0.0015869 ± 0.00095	-	1	DFOP
2	Lleida at 20°C	27.4	154	M0 (%)= 98.127 ± 1.3907 α = 1.7542 ± 0.35314 β = 56.602 ± 15.293	-	2	FOMC
DuPont-17602	Nambsheim at 20°C	24.0	109	M0 (%)= 98.506 ± 2.8346 α = 2.828 ± 1.4154 β = 86.52 ± 53.716	-	2	FOMC
Δ	Sassafras at 20°C	328	1680	M0 (%) = 97.696 ± 2.732 g = 0.26141 ± 0.04095 k_1 (d ⁻¹) = 0.14633 ± 0.04071 k_2 (d ⁻¹) = 0.0011905 ± 0.00063	-	3	DFOP
	Tama at 20°C	79.0	1460	$M0 (\%) = 98.498 \pm 1.0908$ $\alpha = 0.63507 \pm 0.08554$ $\beta = 39.941 \pm 9.26$	-	2	FOMC

Most rate constants (i.e. SFO k_J9Z38 and DFOP k₁ and k₂) were significantly different from zero on the basis of the t-test (p<0.05; p<0.1 for k₂ Gross-Umstadt). Similarly all FOMC alpha and beta values were considered significantly different from zero on the basis of the reported confidence intervals. The only exception was the SFO k_K5A77 value for the Sassafras soil (DuPont-17596). Note that DuPont-17596 was the IN-J9Z38 dosed study; DuPont-17602 was the IN-K5A77 dosed study. Hence no formation fractions are reported for DuPont-17602.



IN-K5A77 DegT50 – for use in PECgw and PWCsw calculations (normalised values; SFO-SFO for all kinetic fits)

kinetic	IICS)		Experimental	values			Reference values				
Study	Soil	DegT ₅₀	Formation fraction	T (°C)	M (cc/cc)	T _{REF} (°C)	M _{REF} at 10kPa (cc/cc) ^a	Correction factor	Normalised DegT ₅₀		
	Gross- U	101	1.00	20	0.176	20	0.309	0.6744	68.1		
96	Lleida	42.0	0.86	20	0.243	20	0.385	0.7238	30.4		
t-1759	Namb.	74.1	0.66	20	0.221	20	0.195	1.000	74.1		
DuPont-17596	Sass.	93.1	1.00	20	0.211	20	0.243	0.9059	84.3		
Q	Tama	109	1.00	20	0.275	20	0.345	0.8541	93.1		
	Gross- U (App. fit)	117	-	20	0.172	20	0.309	0.6636	77.6		
7602	Lleida	32.2	-	20	0.242	20	0.385	0.7225	23.3		
DuPont-17602	Namb.	26.4	-	20	0.172	20	0.195	0.9159	24.2		
Dul	Sass. (App. fit)	153	-	20	0.204	20	0.243	0.8847	135		
	Tama	82.3	-	20	0.261	20	0.345	0.8226	67.7		
ave	Applican erage/geor		0.90			101		1	58.6		

^aM_{REF} values were taken from experimental measurements of moisture content at 10kPa Note that DuPont-17596 was the IN-J9Z38 dosed study and DuPont-17602 was the IN-K5A77 dosed study. Hence no formation fractions are reported for DuPont-17602.



IN-K5A78 best fit – for use against regulatory triggers and in PECsoil calculations (non-normalised)

Study	Soil	DegT ₅₀	DegT ₉₀	Optimized parameters ± standard error	Formation fraction	χ ² error	Model
	Gross Umstadt at 20°C	1066	3541	k_K5A78 = 0.0006503 ± 0.00187	0.80	5	DFOP-SFO
D. D	Lleida at 20°C	405	1347	k_K5A78 = 0.0017101 ± 0.00075	0.86	4	FOMC-SFO
DuPont- 17602	Nambsheim at 20°C	1397	4642	k_K5A78 = 0.0004961 ± 0.00125	0.93	1	FOMC-SFO
	Sassafras at 20°C	240	798	k_K5A78 = 0.0028863 ± 0.00234	0.91	13	DFOP-SFO
	Tama at 20°C	6E+5	2E+6	k_K5A78 = 0.000001 ± 0.00113	0.77	5	FOMC-SFO
	Gross Umstadt at 20°C	305	1013	M0 (%)= 95.645 ± 0.72255 k = 0.002274 ± 0.00015	-	2	SFO
	Lleida at 20°C	Lleida at 500		M0 (%)= 94.231 ± 0.50184 k = 0.0013857 ± 9.9 E-05	-	1	SFO
DuPont- 17599	Nambsheim at 20°C	977	3244	$M0 (\%) = 96.259 \pm 0.7408$ $k = 0.00070971 \pm 0.00014$	-	1	SFO
	Sassafras at 20°C	97.8	929	M0 (%)= 95.022 ± 1.6685 α = 0.95634 ± 0.44521 β = 91.851 ± 59.454	-	4	FOMC
	Tama at 20°C	237	788	M0 (%)= 94.372 ± 0.44917 k = 0.0029237 ± 9.7E-05	-	1	SFO

Note that DuPont-17602 was the IN-K5A77 dosed study; DuPont-17599 was the IN-K5A78 dosed study. Hence no formation fractions are reported for DuPont-17599.



IN-K5A78 DegT50 – for use in PECgw and PWCsw calculations (normalised values)

11 \-\\5	4/8 Deg 150		in PECgw and Experimental		sw calcula	ations (1	tions (normalised values) Reference values			
			2xperimentar	varacs			T(C)	terence varues		
Study	Soil	DegT ₅₀	Formation fraction	T (°C)	M (cc/cc)	T _{REF} (°C)	M _{REF} at 10kPa (cc/cc) ^a	Correction factor	Normalised DegT ₅₀	
	Gross-U (Prim. Rev. Fit DFOP- SFO)	305	0.89	20	0.172	20	0.309	0.6636	202	
	Lleida SFO-SFO	153	1.00	20	0.242	20	0.385	0.7225	111	
DuPont-17602	Namb. SFO-SFO	377	1.00	20	0.172	20	0.195	0.9159	345	
Q	Sass. (Prim. Rev. Fit DFOP- SFO)	240	0.91	20	0.204	20	0.243	0.8847	212	
	Tama SFO-SFO	151	1.00	20	0.261	20	0.345	0.8226	124	
	Gross-U	305	-	20	0.194	20	0.309	0.7219	220	
6	Lleida	500	-	20	0.261	20	0.385	0.7618	381	
DuPont-17599	Namb.	977	-	20	0.239	20	0.195	1.00	977	
DuPo	Sass.	93.3	-	20	0.229	20	0.243	0.9593	89.5	
	Tama	237	-	20	0.293	20	0.345	0.8919	211	
	Gross-U	89.6	0.52	20	0.200	20	0.309	0.7375	66.1	
865,	Lleida	37.7	0.60	20	0.330	20	0.382	0.9026	34.0	
DuPont-17598	Namb.	183.4	0.41	20	0.196	20	0.191	1	183.4	
Dul	Sass.	Statistica	ally robust DT50	could	not be de	rived				
	Tama	IN-K5A								
	rimary Reviewerage/geome		0.96 (IN-K5 0.51 (IN-JS						173.6	

^aM_{REF} values were taken from experimental measurements of moisture content at 10kPa
Note that DuPont-17602 was the IN-K5A77 dosed study, DuPont-17598 was the IN-JSE76 dosed study and DuPont-17599 was the IN-K5A78 dosed study. Hence no formation fractions are reported for DuPont-17599.



IN-RNU71 best fit – for use against regulatory triggers and in PECsoil calculations (non-normalised)

Study	Soil	DegT ₅₀	DegT ₉₀	Optimized parameters ± standard error	χ² error	Model
	Gross Umstadt at 20°C	107	356	M0 (%)= 84.7 \pm 1.8 k = 0.006 \pm 0.0003	3	SFO
	Lleida at 20°C	43	142	M0 (%)= 86.8 ± 1.4 k = 0.016 ± 0.001	3	SFO
59809	Nambsheim at 20°C	42	139	M0 (%)= 86.6 ± 1.6 k = 0.017 ± 0.001	4	SFO
DuPont-29809	Sassafras at 20°C (Prim. Rev. fit)	400	2437	M0 (%) = 91.72 ± 1.52 g = 0.314 k_1 (d ⁻¹) = 0.057 ± 0.016 k_2 (d ⁻¹) = 0.001 ± 0.001	2	DFOP
	Tama at 20°C (Prim. Rev. fit)	27.9	268	M0 (%) = 88.7 ± 1.5 g = 0.5 $k_1 (d^{-1}) = 0.061 \pm 0.012$ $k_2 (d^{-1}) = 0.006 \pm 0.002$	2	DFOP

All rate constants (i.e. SFO and DFOP k_1 and k_2) were significantly different from zero on the basis of the t-test (p<0.05) except the k_2 value for the Sassafras soil. The DFOP result for the Sassafras soil was accepted by the Primary Reviewer on the basis of the excellent visual fit.

IN-RNU71 DegT50 – for use in PECgw and PWCsw calculations (normalised values; all SFO except Tama where DFOP used)

	Soil	Experime	Reference values					
Study		DegT_{50}	T (°C)	M (cc/cc)	T _{REF} (°C)	M _{REF} at 10kPa (cc/cc) ^a	Correction factor	$\begin{array}{c} \textbf{Normalised} \\ \textbf{DegT}_{50} \end{array}$
	Gross- U	107	20	0.240	20	0.295	0.8653	92.6
DuPont-29809	Lleida	42	20	0.336	20	0.393	0.8959	37.6
	Namb.	175	20	0.266	20	0.261	1.0000	175
	Sass.	43	20	0.157	20	0.191	0.8722	37.5
	Tama (Prim. Rev. fit)	115 (based on the k2 parameter from the DFOP fit)	20	0.237	20	0.522	0.5757	66.2
Primary Reviewer geomean							69	



IN-QKV54 best fit – for use against regulatory triggers and in PECsoil calculations (non-normalised)

Study	Soil DegT ₅₀		DegT ₉₀	Optimized parameters ± standard error	χ² error	Model
DuPont-17602 (Primary Rev. selection)	Gross Umstadt at 20°C	1186.8	>1000	M0 (%)= 98.29 ± 1.45 α = 0.124 ± 0.016 β = 4.41 ± 1.752	1.6	FOMC
	Nambsheim at 20°C	138.7	651.2	M0 (%) = 101.77 ± 1.29 g = 0.227 k_1 (d ⁻¹) = 0.127 ± 0.029 k_2 (d ⁻¹) = 0.003 ± 0.0003	1.8	DFOP
	Sassafras at 20°C	461.7	>1000	M0 (%)= 100.01 ± 2.8 α = 0.162 ± 0.037 β = 6.438 ± 4.18	3.4	FOMC
	Lleida at 20°C	57.5	1595.4	M0 (%)= 101.51 ± 1.3 α = 0.533 ± 0.055 β = 21.539 ± 4.354	2.18	FOMC
	Tama at 20°C	184.3	884.1	M0 (%) = 99.17 ± 1.96 g = 0.236 k_1 (d ⁻¹) = 0.117 ± 0.039 k_2 (d ⁻¹) = 0.002 ± 0.001	2.8	DFOP

All rate constants (i.e. SFO and DFOP k_1 and k_2) were significantly different from zero on the basis of the t-test (p<0.05). Similarly all FOMC alpha and beta values were considered significantly different from zero on the basis of the reported confidence intervals.



IN-QKV54 DegT50 – for use in PECgw and PWCsw calculations (normalised values)

	Soil	Experimenta	Reference values					
Study		DegT_{50}	T (°C)	M (cc/cc)	T _{REF} (°C)	M _{REF} at 10kPa (cc/cc) ^a	Correction factor	Normalised Deg T ₅₀
DuPont-29555 (Primary Reviewer selection)	Gross- U	215 (SFO)	20	0.240	20	0.295	0.8653	186
	Lleida	231ª	20	0.237	20	0.393	0.7023	162
	Namb.	231ª	20	0.266	20	0.261	1.0000	231
	Sass.	1000 ^b	20	0.157	20	0.191	0.8722	872
	Tama	347 ^a	20	0.336	20	0.522	0.7345	255
Primary Reviewer geomean							274	

^abased on the k₂ parameter from the DFOP fit

IN-M2G98 for use in PECsw and PECgw calculations (Normalised values, SFO)

		EXPERIMENTAL VALUES			FERENCE /ALUES		FORM. FRACTIO		
STUDY	Soil	DEGT 50 (DAYS)	T (°C	SOIL MOISTUR E (CC/CC)	T _{RE} (°C	SOIL MOISTUR E AT 10KPA (CC/CC)	CORRECTI ON FACTOR*	N (FROM IN- K5A79)	NORMALIZ ED DEGT ₅₀ (DAYS)
DuPont- 18868	Tama	118.6	24	0.188	20	0.343	0.9591	0.54	113.7
DuPont- 18868	Sassafr as	250.2	19	0.284	20	0.205	0.9096	0.60	227.6
Applicant Geomean for DT50 (arithmetic mean for formation fraction)									160.9

^bbased on the default k₂ parameter from the DFOP fit



Summary of worst-case best-fit DegT50 values and formation fractions for use in PECsoil calculations

Analytes	Soil	Worst- case DegT ₅₀ ^a	Worst- case DegT ₉₀ ^b	Model	Highest formation fraction
Cyantraniliprole	Sassafras	91.9	376	DFOP	-
	(Primary Reviewer selection)				
IN-JCZ38	Gross Umstadt	133	442	DFOP-SFO	0.60
IN-JSE76	Sassafras	343	1319	DFOP	0.93
IN-K5A79	Tama	130	432	SFO	0.80
IN-J9Z38	Tama	610 ^c	2027 ^c	FOMC-SFO	0.66 ^f
IN-K5A77	Sassafras	328	1680	DFOP	0.89
IN-K5A78	Nambsheim	977°	3244 ^c	SFO	0.93
IN-PLT97	Nambsheim	711 ^c	2363°	SFO	1.00
IN-RNU71	Sassafras	400	2437	DFOP	1.00 ^d
	(Primary Reviewer selection)				
IN-QKV54	Gross-Umstadt (Primary	1000	3322	SFO	1.00 ^e
	Reviewer selection)			default	
IN-M2G98	Sassafras (Applicant selection)	250.2	831	SFO	0.60

 $DegT_{50}$ is from soil with the longest DT_{90} .

Longest DegT₉₀ from the tested soils

These DegT₅₀ and DegT₉₀ values are more than 5X longer than the experimental study duration of 120 days, resulting in relatively little degradation following formation from a precursor and potentially lower accuracy than the more rapidly degrading analytes. However, for each of these slowly degrading chemicals, the cited worst-case $DegT_{50}$ and $DegT_{90}$ values are reasonably similar to values obtained for the other tested soils.

Fornation fraction from IN-J9Z38 to IN-RNU71 in moist soil photolysis.

Fornation fraction from IN-NXX70 to IN-QKV54 in moist soil photolysis.

f Fornation fraction from cyantraniliprole in moist soil photolysis.



Summary of geomean SFO-SFO Deg T_{50} values and average formation fractions for use in PEC_{gw} , PEC_{sw} and PEC_{sed} calculations

Reference ^a	Analytes	Normalized geomean DegT ₅₀ ^b	Average formation fraction
DuPont-15775 and DuPont-17055	Cyantraniliprole	13.3 and 87.0° (Primary Reviewer)	_
DuPont-15775, DuPont- 17055 and DuPont-17597	IN-JCZ38	15.7 (Primary Reviewer) 12.8 d (Applicant) ^d	0.51 0.67 (Applicant) ^d
DuPont-17597 and DuPont- 17598	IN-JSE76	109	0.92
DuPont-17598 and DuPont 18868	IN-K5A79	39	0.62
DuPont-15775, DuPont- 17055 and DuPont-17596	IN-J9Z38	101 (Primary Reviewer) 90 (Applicant) ^d	0.27 0.29 (Applicant) ^d
DuPont-17596 and DuPont- 17602	IN-K5A77	58.6 (Applicant)	0.90
DuPont-17602 and DuPont- 17599	IN-K5A78	173.6	0.96 (IN- K5A77→IN- K5A78) 0.51 (IN- JSE76→IN-K5A78)
DuPont-18868 and DuPont- 19077	IN-PLT97	323	0.68
DuPont-29809	IN-RNU71	69	1.0
DuPont-29555	IN-QKV54	274 (Primary Reviewer)	1.0
DuPont-35754	IN-M2G98	160.9	0.57

^a Summarized in Cyantraniliprole Dossier, Annex II, Document M-II, Section 5, DuPont-27750

^b Geomean DegT₅₀ values include data for chemical applied as parent and as well as chemical formed from immediate precursor in degradation pathway.

 $^{^{\}circ}$ The Secondary Review agreed to the proposal to run two simulations for parent cyantraniliprole using a worst case longest SFO DT₅₀ of 87.0 days to conservatively assess parent behaviour and a second simulation using the shortest SFO DT₅₀ of 13.3 d for use in the metabolite exposure.

^dThe Applicant proposed DT50 and formation fractions for IN-JCZ38 and IN-J9Z38 were based on SFO-SFO fitting of parent dosed soils that was not accepted by the UK RMS in the case of Tama and Lleida soils. However this combination of parameters resulted in a more conservative leaching assessment for the metabolites and were therefore accepted for the purposes of the groundwater exposure assessment.



 $Field\ studies\ -\ best\ fit\ for\ comparison\ against\ regulatory\ triggers\ and\ normalised\ DT50\ values\ for\ modelling$

modelling								
Parent: Cyantraniliprole			(Report		ssipation St nt-28155 and	t udies d DuPont-31	455)	
Location (study number)	Soil type	pH (water)	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	Kinetics Model ^a	DT ₅₀ (d) at 20°C pF2 / 10kPa	Kinetics Model ^b
Grant County, Washington, USA (DuPont-17065, Revision No. 1)	Sandy loam	7.44	90 cm	31.9 9.7	105.9 174	FOMC DFOP ^c	31.4	FOMC
Porterville California, USA (DuPont-17066)	Sandy Loam	7.81	90 cm	22.4 10.2	74.3 89.8	FOMC DFOP ^c	20.9	FOMC
Shelby County, Missouri, USA (DuPont-17067)	Silt loam	6.2	90 cm	44	333	DFOP	50.8	SFO
Raymondville, Texas, USA (DuPont-17457, Revision No. 1)	Sandy clay loam	7.9	90 cm	16.7	55.5	SFO	22.9	FOMC
Portage La Prairie, Manitoba, Canada (DuPont-17068)	Clay loam	7.8	90 cm	13.5	246	FOMC	38.5	FOMC
Nambsheim, France (DuPont-17062, Revision No. 1)	Clay loam	7.93	90 cm	27.9	92.8	SFO	16.9	SFO
Sevilla, Spain (DuPont-17061, Revision No. 1)	Loamy sand	8.22	90 cm	18.4	130.5	DFOP	31.5	FOMC
Goch, Germany (DuPont-17063, Revision No. 1)	Silt loam	6.3	90 cm	14.1	299	FOMC	46.7	FOMC
Milan, (Lodi) Italy (DuPont-17058)	Loam	6	90 cm	14.8	137.4	FOMC	33.8	FOMC
North Rose, New York, USA (DuPont-17064)	Loamy sand	6.5	90 cm	21.6	257.4	FOMC	51.3	FOMC
Geomean							32.4	
pH dependence (yes/no) (if yes, typ	e of depend	lence)		Yes	s – based on	lab and field	data sets comb	ined
Soil accumulation	on and platea	u concentra	tion:			yantraniliprole ot conducted.	e, accumulation st	tudies are

Actual DT₅₀/DT₉₀ from non-normalized best fit, based on kinetic model.

b Kinetic model for normalized DT₅₀.

Primary Reviewer actually selected the DFOP kinetic as best fit for the Washington and California field trial sites on the basis of the improved visual and statistical fit in comparison with the SFO or FOMC



Summary of combined laboratory and field modelling DT_{50} values (pF2 and $20^{\circ}C$) used to select refined input parameters for acid (pH < 7) and alkali (pH > 7) soil scenarios

Soil	Soil pH (H ₂ O)	Modelling DT ₅₀ at pF2 and 20°C				
	Laborato	ry soils				
Sassafras ^a	4.62	SFO	87			
Tama ^a	6.2	SFO	56.3			
Gross Umstadt	7.04	SFO	38.9			
Nambsheim	7.9	SFO	13.3			
Lleida	8.05	SFO	18.9			
	Field s	soils				
Italy	6	FOMC DT ₉₀ /3.32	33.8			
Missouri	6.2	SFO	50.8			
Germany	6.3	FOMC DT ₉₀ /3.32	46.7			
New York	6.5	FOMC DT ₉₀ /3.32	51.3			
Washington	7.44	FOMC DT ₉₀ /3.32	31.4			
Canada	7.8	FOMC DT ₉₀ /3.32	38.5			
California	7.81	FOMC DT ₉₀ /3.32	20.9			
Texas	7.9	FOMC DT ₉₀ /3.32	22.9			
France	7.93	SFO	16.9			
Spain	8.22	FOMC DT ₉₀ /3.32	31.5			
	Soils with	pH <7				
Sassafras (lab)	4.62	SFO	87			
Italy (field)	6	FOMC DT ₉₀ /3.32	33.8			
Tama (lab)	6.2	SFO	56.3			
Missouri (field)	6.2	SFO	50.8			
Germany (field)	6.3	FOMC DT ₉₀ /3.32	46.7			
New York (field)	6.5	FOMC DT ₉₀ /3.32	51.3			
		Geometric mean (n=6)	52.2			
	Soils with	nH >7				
Gross Umstadt (lab)	7.04	SFO	38.9			
Washington (field)	7.44	FOMC DT ₉₀ /3.32	31.4			
Canada (field)	7.8	FOMC DT ₉₀ /3.32	38.5			
California (field)	7.81	FOMC DT ₉₀ /3.32	20.9			
Texas (field)	7.9	FOMC DT ₉₀ /3.32	22.9			
Nambsheim (lab)	7.9	SFO	13.3			
France (field)	7.93	SFO	16.9			
Lleida (lab)	8.05	SFO	18.9			
Spain (field)	8.22	FOMC DT ₉₀ /3.32	31.5			
		Geometric mean	24.4			
		Median (n = 9)	22.9			



Laboratory studies

Parent: Cyantraniliprole	Anaerobic conditions (Report No. DuPont-17057)									
Soil type	Redox potential (mV) ^a	рН	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d) ^b	SFO DT ₅₀ (d) 20°C pF2 / 10kPa	ST. (χ², %)	Method of calculation			
Nambsheim (Sandy loam), Nambsheim, France	Water: 58 to -238 Soil: -256 to - 556	Water: 8.17-9.31 Soil: 7.73-9.32	20°C / flooded soil	4.36/28.5	8.6 (based on FOMC DT90/3.32)	1.19	FOMC			

Range of values measured over 120 days duration of the study. Best fit values *via* FOMC kinetics.

Parent: Cyantraniliprole	Irradiated soil (Report Nos. DuPont-17056 and DuPont-28730)								
Soil type	Light conditions	pH (water)	t. °C / % MWHC	DT_{50} / DT_{90} $(d)^{a}$	DT ₅₀ (d) 20°C pF2 / 10kPa	ST. (χ ² , %)	Method of calculation		
Nambsheim (Sandy loam),	Xenon arc (300-800 nm, 456 W.m ²)	7.51	20°C / air dried	84/278	Not required		SFO		
Nambsheim, France	Dark Control		aried	115/381	Not required				
Nambsheim (Sandy loam), Nambsheim,	Xenon arc (300-800 nm, 456 W.m2)	8.0	20°C / 50	6.8/23	Not required	12	SFO		
France	Dark Control			15.5/51	Not required	8.8			



Soil adsorption/desorption (Annex IIA, OECD Points IIA 7.4.1 and IIA 7.4.2)

Parent: Cyantraniliprole (Report No. DuPont-18871)										
Soil type	OC%	Soil pH	K _d (mL/mg)	K _{oc} (mL/mg)	K _f (mL/mg)	K _{foc} (mL/mg)	1/n			
Gross Umstadt (Silt loam), Darmstadt Hessen, Germany	1.1	6.63	2.77	251	2.472	225	0.958			
Lleida (Silty clay loam), Lleida, Cateylunya, Spain	1.6	7.56	2.81	176	2.479	155	0.954			
Nambsheim (Loam), Nambsheim, France	1.6	7.39	2.51	157	2.054	128	0.925			
Sassafras (Sandy loam), Chestertown, Kent County, Maryland, USA	1.4	5.17	3.40	243	2.695	193	0.918			
Tama (Silty clay loam), Toulan, Stark County, Illinois, USA	1.9	5.63	7.14	376	5.049	266	0.895			
Arithmetic mean			3.73	241	2.95	193	0.93			
pH dependence (yes or	no)		No							

			tabolite: IN- rt No. DuPor					
Soil type	OC%	Soil pH	K _d (mL/mg)	K _{oc} (mL/mg)	K _f (mL/mg)	K_{foc} (mL/mg)	1/n	
Gross Umstadt (Silt loam), Darmstadt Hessen, Germany	1.1	6.63	82	7475	77.09	7008	0.988	
Lleida (Silty clay loam), Lleida, Cateylunya, Spain	1.6	7.56	83	5158	76.38	4774	0.985	
Nambsheim (Loam), Nambsheim, France	1.6	7.39	72	4528	44.20	2762	0.904	
Sassafras (Sandy loam), Chestertown, Kent County, Maryland, USA	1.4	5.17	110	7887	58.08	4148	0.889	
Tama (Silty clay loam), Toulan, Stark County, Illinois, USA	1.9	5.63	352	18537	341.59	17978	0.995	
Arithmetic mean			140	8717	119.47	7334	0.952	
pH dependence (yes or	no)		No					
Metabolite: IN-JCZ38 (Report No. DuPont-17604)								
Soil type	OC%	Soil pH	K _d (mL/mg)	K _{oc} (mL/mg)	$\frac{K_{\rm f}}{(\text{mL/mg})}$	K_{foc} (mL/mg)	1/n	
Gross Umstadt (Silt loam), Darmstadt Hessen, Germany	1.1	6.63	2.40	218	1.76	160	0.89	



Lleida (Silty clay loam), Lleida, Cateylunya, Spain	1.6	7.56	2.58	161	2.01	126	0.91	
Nambsheim (Loam), Nambsheim, France	1.6	7.39	1.99	124	1.52	95	0.90	
Sassafras (Sandy loam), Chestertown, Kent County, Maryland, USA	1.4	5.17	2.92	209	2.27	162	0.91	
Tama (Silty clay loam), Toulan, Stark County, Illinois, USA	1.9	5.63	9.15	482	6.26	329	0.89	
Arithmetic mean			3.81	239	2.76	174	0.90	
pH dependence (yes or no)			No					

Metabolite: IN-JSE76 (Report No. DuPont-17605)										
Soil type	OC%	Soil pH	K _d (mL/mg)	K _{oc} (mL/mg)	$K_{\rm f}$ (mL/mg)	K_{foc} (mL/mg)	1/n			
Gross Umstadt (Silt loam), Darmstadt Hessen, Germany	1.1	6.63	0.27	25	0.27	25	1.02			
Lleida (Silty clay loam), Lleida, Cateylunya, Spain	1.6	7.56	0.25	16	0.26	16	1.02			
Nambsheim (Loam), Nambsheim, France	1.6	7.39	0.21	14	0.20	13	0.98			
Sassafras (Sandy loam), Chestertown, Kent County, Maryland, USA	1.4	5.17	0.39	28	0.38	27	0.99			
Tama (Silty clay loam), Toulan, Stark County, Illinois, USA	1.9	5.63	1.24	65	1.00	52	0.93			
Arithmetic mean			0.47	30	0.42	27	0.99			
pH dependence (yes or	no)		No							

Metabolite: IN-K5A77 (Report No. DuPont-17607)										
			K _d	K _{oc}	$K_{\rm f}$	K_{foc}				
Soil type	OC%	Soil pH	(mL/mg)	(mL/mg)	(mL/mg)	(mL/mg)	1/n			
Gross Umstadt (Silt loam), Darmstadt Hessen, Germany	1.1	6.63	75.91	6901	38.73	3521	0.87			
Lleida (Silty clay loam), Lleida, Cateylunya, Spain	1.6	7.56	93.51	5845	45.59	2850	0.87			
Nambsheim (Loam), Nambsheim, France	1.6	7.39	59.32	3707	31.25	1953	0.87			
Sassafras (Sandy loam), Chestertown, Kent County, Maryland, USA	1.4	5.17	88.11	6294	48.97	3498	0.89			



Tama (Silty clay loam), Toulan, Stark County, Illinois, USA	1.9	5.63	480.82	25306	278.87	14677	0.92	
Arithmetic mean			159.53	9611	88.68	5300	0.88	
pH dependence (yes or no)			No					

Metabolite: IN-K5A78 (Report No. DuPont-17606, Revision No. 1)							
Soil type	OC%	Soil pH	K _d (mL/mg)	K _{oc} (mL/mg)	$K_{\rm f}$ (mL/mg)	K _{foc} (mL/mg)	1/n
Gross Umstadt (Silt loam), Darmstadt Hessen, Germany	1.1	6.63	9.56	869	6.08	552	0.873
Lleida (Silty clay loam), Lleida, Cateylunya, Spain	1.6	7.56	7.96	497	5.35	335	0.884
Nambsheim (Loam), Nambsheim, France	1.6	7.39	6.60	412	4.30	269	0.871
Sassafras (Sandy loam), Chestertown, Kent County, Maryland, USA	1.4	5.17	12.82	916	8.26	590	0.862
Tama (Silty clay loam), Toulan, Stark County, Illinois, USA	1.9	5.63	48.35	2545	24.63	1296	0.837
Arithmetic mean			16.94	1042	9.67	608	0.865
pH dependence (yes or	no)		No				

Metabolite: IN-K5A79 (Report No. DuPont-18870, Revision No. 2)							
Soil type	OC%	Soil pH	K _d (mL/mg)	K _{oc} (mL/mg)	K _f (mL/mg)	K _{foc} (mL/mg)	1/n
Soil type Gross Umstadt (Silt	OC%	зоп рп	(IIIL/IIIg)	(IIIL/IIIg)	(IIIL/IIIg)	(IIIL/IIIg)	1/11
loam), Darmstadt	1.1	7.89	0.46	42	0.39	36	0.93
Hessen, Germany	1.1	7.09	0.40	42	0.39	30	0.93
Lleida (Silty clay							
loam), Lleida,	2.0	7.7	0.49	24	0.43	21	0.95
Cateylunya, Spain	2.0	7.7	0.49	24	0.43	21	0.93
Nambsheim (Loam),							
Nambsheim, France	1.6	7.55	0.43	26	0.34	21	0.90
Sassafras (Sandy							
loam), Chestertown,							
Kent County,	1.2	5.67	0.98	85	0.86	72	0.94
Maryland, USA							
Tama (Silty clay							
loam), Toulan, Stark	2.7	6.45	1.47	55	1.19	44	0.91
County, Illinois, USA	2.,	0.15	1.17	33	1.17		0.71
Arithmetic mean			0.77	46	0.64	39	0.93
Arithmetic mean of soils with pH > 6.5 (n=3)		0.46	30.7	0.39	26	0.93	
pH dependence (yes or	no)		Yes	•			



Metabolite: IN-PLT97 (Report No. DuPont-19078)							
Soil type	OC%	Soil pH	K _d (mL/mg)	K _{oc} (mL/mg)	$K_{\rm f}$ (mL/mg)	$\frac{K_{foc}}{(mL/mg)}$	1/n
Gross Umstadt (Silt loam), Darmstadt Hessen, Germany	1.1	6.63	18.42	1675	11.46	1042	0.86
Lleida (Silty clay loam), Lleida, Cateylunya, Spain	1.6	7.56	15.65	978	8.57	536	0.82
Nambsheim (Loam), Nambsheim, France	1.6	7.39	11.21	701	6.77	423	0.84
Sassafras (Sandy loam), Chestertown, Kent County, Maryland, USA	1.4	5.17	25.69	1835	13.04	932	0.81
Tama (Silty clay loam), Toulan, Stark County, Illinois, USA	1.9	5.63	95.54	5029	59.07	3109	0.90
Arithmetic mean			33.30	2044	19.78	1208	0.85
pH dependence (yes or	no)		No				

Metabolite: IN-QKV54 (Report No. DuPont-29558)							
Soil type	OC%	Soil pH	K _d (mL/mg)	K_{oc} (mL/mg)	$K_{\rm f}$ (mL/mg)	$\begin{array}{c} K_{foc} \\ (mL/mg) \end{array}$	1/n
Gross Umstadt (Silt loam), Darmstadt Hessen, Germany	1.4	6.9	154.88	11063	57.68	4120	0.805
Lleida (Silty clay loam), Lleida, Cateylunya, Spain	1.7	7.8	191.67	11275	76.02	4471	0.824
Nambsheim (Loam), Nambsheim, France	2.0	7.6	186.89	9345	69.65	3482	0.811
Sassafras (Sandy loam), Chestertown, Kent County, Maryland, USA	0.8	5.3	68.57	8571	31.40	3925	0.822
Tama (Silty clay loam), Toulan, Stark County, Illinois, USA	3.3	6.7	1061	32152	489.33	14828	0.887
Arithmetic mean			332.6	14481	144.82	6165	0.83
pH dependence (yes or	no)		No				



Metabolite: IN-RNU71 (Report No. DuPont-29989)							
G 11.	0.00/	G '1 II	K _d	K _{oc}	K _f	K _{foc}	1 /
Soil type	OC%	Soil pH	(mL/mg)	(mL/mg)	(mL/mg)	(mL/mg)	1/n
Gross Umstadt (Silt loam), Darmstadt Hessen, Germany	1.4	6.9	2.12	152	2.055	147	0.987
Lleida (Silty clay loam), Lleida, Cateylunya, Spain	1.7	7.8	1.77	104	1.779	105	1.002
Nambsheim (Loam), Nambsheim, France	2.0	7.6	2.47	124	2.167	108	0.946
Sassafras (Sandy loam), Chestertown, Kent County, Maryland, USA	0.8	5.3	1.45	181	1.585	198	1.043
Tama (Silty clay loam), Toulan, Stark County, Illinois, USA	3.3	6.7	5.65	171	4.569	138	0.925
Arithmetic mean			2.69	146	2.431	139	0.981
pH dependence (yes or no)			No				

Mobility in soil (Annex IIA, OECD Points IIA 7.4.3 to IIA 7.4.8; Annex IIIA, OECD Point IIIA 9.3)

Column leaching	Not required since batch equilibrium sorption studies were performed with parent material and all metabolites >5% of applied.
Aged residues leaching	Not performed.
Lysimeter/field leaching studies	Not performed as groundwater modelling shows low potential for movement into groundwater.



PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation

Application data

 DT_{50} (d): 91.9 d DT_{90} (d): 376 d (g = 0.15859; K_1 =

 0.13056 d^{-1} ; $K_2 = 0.00567 \text{ d}^{-1}$)

Kinetics: DFOP

Representative worst case from laboratory studies.

Glasshouse uses

Crop: aubergine, tomato, cucurbits and peppers

Depth of soil layer: 5cm Soil bulk density: 1.5g/cm³

% plant interception: 0 % assumed as a conservative first

tier

Number of applications: 1

Interval (d): -

Application rate(s): 480 g as/ha (proposed GAP of 4 x 120 g a.s./ha modelled as a single application event)

Field uses

Crop: nectarines, citrus and olives

Depth of soil layer: 5cm Soil bulk density: 1.5g/cm³

% plant interception: 0 % assumed as a conservative first

tier

Number of applications: 1

Interval (d): -

Application rate(s): 300 g as/ha (proposed GAP of 2 x 150 g a.s./ha modelled as a single application event)

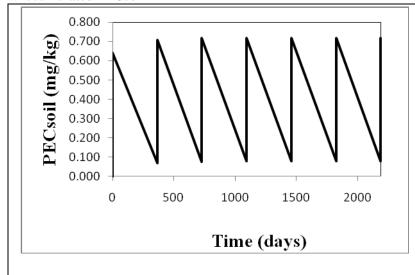
Glasshouse uses (1 x 480 g a.s./ha)

Single annual application

Days after appl. (days)	Actual PEC _{soil}	TWA PEC _{soil}			
(uays)	(mg kg ⁻¹)				
0	0.640	-			
1	0.625	0.632			
2	0.611	0.625			
4	0.587	0.612			
7	0.558	0.595			
14	0.514	0.564			
21	0.485	0.542			
28	0.462	0.525			
42	0.425	0.498			
50	0.406	0.484			
100	0.305	0.419			



Accumulated PECsoil



Days after	Actual PEC _{soil}	TWA PEC _{soil}			
appl. (days)	(mg kg ⁻¹)				
0	0.718	-			
1	0.700	0.709			
2	0.685	0.701			
4	0.658	0.686			
7	0.626	0.667			
14	0.576	0.633			
21	0.544	0.608			
28	0.518	0.589			
42	0.476	0.558			
50	0.455	0.543			
100	0.343	0.470			

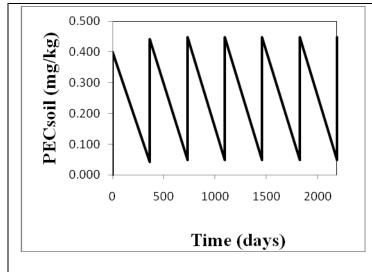
Field uses (1 x 300 g a.s./ha)

Single annual application

Days after appl. (days)	Actual PEC _{soil}	TWA PEC _{soil}			
(uays)	(mg kg ⁻¹)				
0	0.400	-			
1	0.390	0.395			
2	0.382	0.391			
4	0.367	0.383			
7	0.349	0.372			
14	0.321	0.353			
21	0.303	0.339			
28	0.289	0.328			
42	0.266	0.311			
50	0.254	0.303			
100	0.191	0.262			



Accumulated PECsoil



Days after	Actual PEC _{soil}	TWA PEC _{soil}			
appl. (days)	(mg kg ⁻¹)				
0	0.449	-			
1	0.438	0.443			
2	0.428	0.438			
4	0.411	0.429			
7	0.391	0.417			
14	0.360	0.396			
21	0.340	0.380			
28	0.324	0.368			
42	0.298	0.349			
50	0.284	0.339			
100	0.214	0.294			

Metabolites

Key input parameters used in simulation of PEC_{soil} for cyantraniliprole and its soil metabolites



Parameters	Value	Units	Notes
Soil dry bulk density	1.5	g/cm ³	default assumption
Soil mixing depth	5	cm	default assumption
Interception	0	%	Conservative 1 st tier assumption
Cyantraniliprole			-
Molecular weight	473.7	g/mole	
Worst-case DFOP DT _{50/90}	91.9/376	days	Sassafras laboratory soil
IN-JCZ38		•	· ·
Molecular weight	491.7	g/mole	
Worst-case SFO DT _{50/90}	133/442	days	Gross Umstadt laboratory soil
Peak occurrence	39.6	% AR	Sassafras laboratory soil
IN-JSE76			· ·
Molecular weight	492.7	g/mole	
Worst-case DFOP DT _{50/90}	343/1319	days	Sassafras laboratory soil
Peak occurrence	42.9	% AR	Tama laboratory soil
IN-K5A79			, and the second
Molecular weight	478.7	g/mole	
Worst-case SFO DT _{50/90}	130/432	days	Tama laboratory soil
Peak occurrence	9.34	% AR	Nambsheim laboratory soil
IN-PLT97			,
Molecular weight	460.7	g/mole	
Worst-case SFO DT _{50/90}	711/2363	days	Nambsheim laboratory soil
Peak occurrence	26.3	% AR	Nambsheim laboratory soil
IN-J9Z38			,
Molecular weight	455.7	g/mole	
Worst-case SFO DT _{50/90}	610/2027	days	Tama laboratory soil
Peak occurrence	71.9	% AR	Anaerobic degradation in Nambsheim soil
IN-K5A77			
Molecular weight	473.7	g/mole	
Worst-case DFOP DT _{50/90}	328/1680	days	Sassafras laboratory soil
Peak occurrence	8.93	% AR	Nambsheim laboratory soil
IN-K5A78			,
Molecular weight	474.7	g/mole	
Worst-case SFO DT _{50/90}	977/3244	days	Nambsheim laboratory soil
Peak occurrence	28.8	% AR	Nambsheim laboratory soil
IN-QKV54			
Molecular weight	344.2	g/mole	
Worst-case SFO DT _{50/90}	1000/3322	days	Default value for Gross Umstadt laboratory soil
Peak occurrence	14	% AR	Nambsheim moist soil photolysis
IN-RNU71			• •
Molecular weight	437.3	g/mole	
Worst-case DFOP DT _{50/90}	400/2437	days	Sassafras laboratory soil
Peak occurrence	13.1	% AR	Nambsheim moist soil photolysis



Summary of <u>accumulated</u> PEC $_{soil}$ values for cyantraniliprole metabolites (worst-case lab DegT $_{50}$, 0% canopy interception, 5 cm soil depth; single total parent application of 480 g a.s./ha for glasshouse uses)

Metabolite	Peak accumulated PEC _{soil} (mg kg ⁻¹)
IN-JCZ38	0.347
IN-JSE76	0.662
IN-K5A79	0.079
IN-PLT97	0.613
IN-J9Z38	1.462
IN-K5A77	0.151
IN-K5A78	0.908
IN-QKV54	0.327
IN-RNU71	0.222

Summary of <u>accumulated</u> PEC_{soil} values for cyantraniliprole metabolites (worst-case lab $DegT_{50}$, 0% canopy interception, 5 cm soil depth; single total parent application of 300 g a.s./ha for field uses)

Metabolite	Peak accumulated PEC _{soil} (mg kg ⁻¹)
IN-JCZ38	0.217
IN-JSE76	0.414
IN-K5A79	0.049
IN-PLT97	0.383
IN-J9Z38	0.914
IN-K5A77	0.094
IN-K5A78	0.567
IN-QKV54	0.204
IN-RNU71	0.139



Route and rate of degradation in water (Annex IIA, OECD Points IIA 2.9 and IIA 7.5 to IIA 7.9)

Hydrolytic degradation of the active ingredient and metabolites >10%. Study conducted at 15, 25 and 35°C, DT_{50's} at 20°C calculated using Arrhenius equation.

pH 4: 261 days at 20°C (1st order)

Met IN-J9Z38: Maximum 2-26% AR at pH 4

Report No. DuPont-17058

pH 7: 61 days at 20°C (1st order)

Met IN-J9Z38: Maximum 14.5-88.4% AR at pH 7

Report No. DuPont-17058

pH 9: 1.8 days at 20°C (1st order)

Met IN-J9Z38: 97% AR at pH 9 and at 35°C

Report No. DuPont-17058

Photolytic degradation of active ingredient and metabolites >10%

DT₅₀: 0.22 days in Natural water

Met I: IN-NXX70: Maximum 53% of AR ($DT_{50} = 0.63$

d)

Met II: IN-QKV54: Maximum 85% of AR ($DT_{50} = 28$

d)

Report No. DuPont-17060

Estimated DT_{50} at $40^{\circ}N = 0.23$ days and at $60^{\circ}N = 4.12$

days

Report No. DuPont-21506

Quantum yield of direct phototransformation in water at Σ >290 nm

Quantum efficiency for cyantraniliprole

 $\Phi = 1.195 \times 10^{-4}$ molecules/photon

Report No. DuPont-17060

Quantum efficiency for metabolites:

IN-RNU71 = 9.0×10^{-06} ,

IN-QKV54 = 2.003×10^{-07}

IN-NXX70 = 2.3×10^{-04}

Report No. DuPont-20286

Readily biodegradable (yes/no)

No

Report No. DuPont-21504

Degradation in water/sediment in dark

Parent Cyantraniliprole	Report	Distribution (max 2% in water after 100 days. Max.8.6% in sediment after 100 days) Report Nos. DuPont-17059 and DuPont-24742, Revision No. 1 [Report Nos. DuPont-18869, Revision No. 1 and DuPont-28191] ^a								
Water / sediment system	pH water phase	pH sed	t. °C	DT ₅₀ -DT ₉₀ whole system	St. (r ²)	DT ₅₀ -DT ₉₀ water	St. (r ²)	DT ₅₀ -DT ₉₀ sed	St. (r ²)	Method of calculation
Loamy sand	6.1	5.6	20	25.1/83.4	0.99	-	-	-	-	SFO
Silt loam	7.6	7.7	20	3.9/12.8	0.99	-	-	-	_	SFO
Paddy soil, Japan	b	5.9	25	50/166.5	b	-	-	-	-	SFO-water FOMC-soil
Sandy Loam (anaerobic) ^a	7.8	6.9	20	2.1/11.2	0.99	1.7/5.8	0.99	12.1/78	0.99	SFO-water FOMC-sed
Loamy sand (anaerobic) ^a	6.6	5.9	20	11.9/39.6	0.98	10.3/34.2	0.99	23/76	0.78	SFO
Geometric mean I	OT ₅₀ ^c	_		7.03		-		-		



^a Anaerobic water sediment systems.

Japanese paddy soil excluded from geo-mean calculation

Metabolite IN-J9Z38		Distribution (Max 41.8% in water after 9 days; and Max. 77% in sed at 56 days) Report No. DuPont-17059								
Water/sediment system	pH water phase	water $ pH $ whole $ St. DT_{50}-DT_{90} St. DT_{50}-DT_{90} St. Method of $								
Loamy sand	6.1	5.6	20	155/515	0.97	-	-	-	-	SFO
Silt loam	7.6	7.7	20	272/905	0.98	-	_	-	_	SFO
Sandy loam (anaerobic) ^a	7.8	6.9	20	580/1926	0.72	-	_	-	_	SFO

from anaerobic water sediment study, all others from aerobic studies

Mineralization a	Mineralization and non extractable residues									
Water/sediment system	pH water phase	pH sed	Mineralization x% after n d (end of the study)	Non-extractable residues in sed. Max x% after n d	Non-extractable residues in sed. Max% after n d (end of the study					
Loamy sand	6.1	5.6	<loq< td=""><td>Max 13.5% after 70 days</td><td>Max 12.7% after 100 days</td></loq<>	Max 13.5% after 70 days	Max 12.7% after 100 days					
Silt loam	7.6	7.7	<loq< td=""><td>Max 6.3% after 100 days</td><td>Max 6.3% after 100 days</td></loq<>	Max 6.3% after 100 days	Max 6.3% after 100 days					
Paddy soil, Japan	_a	5.9	25	Max 34.8% after 180 days	Max 34.8% after 180 days					

pH not measured.

Degradation in water/sediment in natural sunlight

Parent: Cyantraniliprole	Report	Report No. DuPont-24798, Revision No. 1								
Water / sediment system	pH water phase	pH sed	t. °C	DT ₅₀ /DT ₉₀ whole system	St. (r ²)	DT ₅₀ /DT ₉₀ water	St. (r ²)	DT ₅₀ /DT ₉₀ sed	St. (r ²)	Method of calculation
Sand	7.2	6.8	20	4.5/14.9	0.98	-	-	-	-	SFO
Silt loam	7.9	7.9	20	3.6/11.9	0.99	-	-	-	-	SFO

Not reported.



A summary of all the aquatic input parameters for cyantraniloprole and its metabolites considered valid by the Primary Reviewer is detailed below:

	Compartment	DT ₅₀	Comment
	System	25.1	Worst case from dark aerobic water/sediment study.
Cyantraniliprole	Water	25.1	FOCUS default, use total system value.
	Sediment	1000	FOCUS default to be used with total system DT50 value
	System	272	Worst case from dark aerobic water/sediment study.
IN-J9Z38	Water	272	FOCUS default, use total system value.
	Sediment	272	FOCUS default, use total system value.
	System	1000	FOCUS worst case default as no valid degradation rate.
IN-K5A77	Water	1000	FOCUS worst case default as no valid degradation rate.
	Sediment	1000	FOCUS worst case default as no valid degradation rate.
	System	1000	FOCUS worst case default as no valid degradation rate.
IN-RNU71	Water	1000	FOCUS worst case default as no valid degradation rate.
	Sediment	1000	FOCUS worst case default as no valid degradation rate.
	System	28.4	Worst case from aqueous photolysis study
IN-QKV54	Water	28.4	FOCUS default, use total system value.
	Sediment	28.4	FOCUS default, use total system value.
	System	36.2	Worst case from aquous photolysis study
IN-NXX70	Water	36.2	FOCUS default, use total system value.
	Sediment	36.2	FOCUS default, use total system value.

Note that other major soil metabolties included in the surface water assessment (e.g. IN-JCZ38, IN-K5A79, IN-PLT97 etc) all utilised a simple worst case default of 1000 d.



PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Parent

Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: Step 1-2 v 2.1;

Substance specific input parameters: see larger summary

table below

All Step 2 assessments assumed minimal crop cover (i.e. for the OD and SE formulations). The only exception was the drip irrigation applications of the SC formulation where no interception was assumed for the Step 2

simulations.

Parameters used in FOCUSsw step 3 (if performed)

Version control no.'s of FOCUS software: Step 3 SWASH v 3.1; MACRO v 4.4.2; PRZM v 1.5.6;

TOXSWA v 3.3.1, and Drift Calculator vers. 1.1; Step 4

SWAN v 1.1.4

Substance specific input parameters: see larger summary

table below

Application rate

See below for each formulation



Parameter Unit	Value Remarks
----------------	---------------



	Molecular weight	g mol ⁻¹	473.7	
	Solubility in water	mg L ⁻¹	14.2	
	Vapour Pressure	Pa	5.1×10^{-15}	20°C
	K _{FOC}	L kg ⁻¹	193	Arithmetic mean
	Freundlich exponent	1/n	0.93	Arithmetic mean
C	DegT ₅₀ lab. (20°C/pF 2)	d	87.0	Maximum DT ₅₀ , Step 1 to 3, Tier 1
Cyantraniliprole	DT ₅₀ total sys. (20°C)	d	25.1	Step 1, worst-case from two dark w/s studies
	DT ₅₀ water (20°C)	d	25.1	Step 2 and 3 (equal to total system)
	DT ₅₀ sed. (20°C)	d	1000	Step 2 and 3, default
	Plant uptake	(-)	0.5	Default for systemic substance
	Molecular weight	g mol ⁻¹	455.7	
	K _{FOC}	L kg ⁻¹	7334	Arithmetic mean
	Freundlich exponent	1/n	0.95	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	d	101	Geomean
	DT ₅₀ total sys. (20°C)	d	272	Step 1, worst-case from two dark w/s
	D150 total sys. (20 C)	u		studies
	DT ₅₀ water (20°C)	d	272	Step 2 (equal to total system)
	DT ₅₀ sed. (20°C)	d	272	Step 2 (equal to total system)
IN-J9Z38	Max formation in soil	%AR	18.3	Step 1 and 2 (note a significantly higher maximum formation level of 41.7% was observed in the bare soil field dissipation trial conducted in France. To account for this difference the PECsw and sed values calculated on the lower laboratory formation level have
	Kinetic formation fraction in soil	-	0.66	been factored up by 41.7/18.3 = 2.28) Photolysis from parent (lab moist soil) (Step 3)
	Max formation w/ sed.	%AR	89.09	Step 1 and 2, dark w/s study
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g mol ⁻¹	473.7	
	K _{FOC}	L kg ⁻¹	5300	Arithmetic mean
	Freundlich exponent	1/n	0.88	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	d	58.6	Geo-mean
	DT ₅₀ total sys. (20°C)	d	1000	FOCUS default
IN-K5A77	DT ₅₀ water (20°C)	d	1000	FOCUS default
	DT ₅₀ sed. (20°C)	d	1000	FOCUS default
	Max formation in soil	%AR	8.93	Step 1 and 2
	Max formation w/ sed.	%AR	12.85	Step 1 and 2, dark w/s study
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g mol ⁻¹	491.7	
	K _{FOC}	L kg ⁻¹	174	Arithmetic mean
	Freundlich exponent	1/n	0.90	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	d	15.7	Geomean
D. 10720	DT ₅₀ total sys. (20°C)	d	1000	FOCUS default
IN-JCZ38	DT ₅₀ water (20°C)	d	1000	FOCUS default
	DT ₅₀ sed. (20°C)	d	1000	FOCUS default
	Max formation in soil	%AR	39.6	STEP 1 and 2
	Max formation w/ sed.	%AR		Not found in w/s studies
	Plant uptake	(-)	0.0	Worst-case



	Parameter	Unit	Value	Remarks
	Molecular weight	g mol ⁻¹	492.7	
	K_{FOC}	L kg ⁻¹	27	Arithmetic mean
	Freundlich exponent	1/n	0.99	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	d	109	Geo-mean
	DT ₅₀ total sys. (20°C)	d	1000	FOCUS default
	DT ₅₀ water (20°C)	d	1000	FOCUS default
IN-JSE76	DT ₅₀ sed. (20°C)	d	1000	FOCUS default
11,002,0	Formation fraction	(-)	0.51	Formation fraction for DPX-HGW86 → IN-JCZ38 = 0.51; Assumption that 100% IN-JCZ38 quickly converts to IN-JSE76
	Max formation in soil	%AR	42.9	Step 1 and 2
	Max formation w/ sed.	%AR		Not found in w/s studies
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g mol ⁻¹	478.7	
	K_{FOC}	L kg ⁻¹	26	Arithmetic mean (n = 3, soils with $pH>5.6$)
	Freundlich exponent	1/n	0.93	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	d	39	Geomean
IN-K5A79	DT ₅₀ total sys. (20°C)	d	1000	FOCUS default
	DT ₅₀ water (20°C)	d	1000	FOCUS default
	DT ₅₀ sed. (20°C)	d	1000	FOCUS default
	Max formation in soil	%AR	9.34	Step 1 and 2
	Max formation w/ sed.	%AR		Not found in w/s studies
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g mol ⁻¹	474.7	
	K_{FOC}	L kg ⁻¹	608	Arithmetic mean
	Freundlich exponent	1/n	0.86	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	d	173.6	Geomean
DI 175 A 70	DT ₅₀ total sys. (20°C)	d	1000	FOCUS default
IN-K5A78	DT ₅₀ water (20°C)	d	1000	FOCUS default
	DT ₅₀ sed. (20°C)	d	1000	FOCUS default
	Max formation in soil	%AR	28.69	Step 1 and 2
	Max formation w/ sed.	%AR		Not found in w/s studies
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g mol ⁻¹	460.7	
	K_{FOC}	L kg ⁻¹	1208	Arithmetic mean
	Freundlich exponent	1/n	0.85	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	d	323	Geo-mean
	DT ₅₀ total sys. (20°C)	d	1000	FOCUS default
IN-PLT97	DT ₅₀ water (20°C)	d	1000	FOCUS default
	DT ₅₀ sed. (20°C)	d	1000	FOCUS default
	Max formation in soil	%AR	26.27	Step 1 and 2
	Max formation w/ sed.	%AR	20.27	Not found in w/s studies
	Plant uptake	(-)	0.0	Worst-case
	1 faint uptake	(-)	0.0	11 015t-casc



	Parameter	Unit	Value	Remarks
	Molecular weight	g mol ⁻¹	437.3	
	K _{FOC}	L kg ⁻¹	139	Arithmetic mean
	Freundlich exponent	1/n	0.98	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	d	69	Rate of deg study, SFO DT ₅₀
IN-RNU71	DT ₅₀ total sys. (20°C)	d	1000	FOCUS Default
IN-KNU/I	DT ₅₀ water (20°C)	d	1000	FOCUS Default
	DT ₅₀ sed. (20°C)	d	1000	FOCUS Default
	Max formation in soil	%AR	13.10	Step 1 and 2, moist soil photolysis study
	Max formation w/ sed.	%AR	15.06	Step 1 and 2, outdoor w/s study
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g mol ⁻¹	344.2	
	K_{FOC}	L kg ⁻¹	6165	Arithmetic mean
	Freundlich exponent	1/n	0.83	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	d	274	Geomean
IN OVV54	DT ₅₀ total sys. (20°C)	d	28.4	Worst-case from aqueous photolysis study, SFO DT ₅₀ , Recommended by UK CRD (2012a)
IN-QKV54	DT ₅₀ water (20°C)	d	28.4	Step 2 (equal to total system),
	DT ₅₀ sed. (20°C)	d	28.4	Step 2 (equal to total system),
	Max formation in soil	%AR	14.0	Step 1 and 2, from moist soil photolysis study
	Max formation w/ sed.	%AR	84.7	Step 1 and 2, from aqueous photolysis study
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g mol ⁻¹	437.3	
	K _{FOC}	L kg ⁻¹	7334	Assumed same as IN-J9Z38
	Freundlich exponent	1/n	0.95	Assumed same as IN-J9Z38
	DegT ₅₀ lab. (20°C/pF 2)	d	1.5	From moist soil photolysis study, SFO DegT ₅₀
IN-NXX70	DT ₅₀ total sys. (20°C)	d	36.2	Worst-case from aqueous photolysis study, SFO DT ₅₀
	DT ₅₀ water (20°C)	d	36.2	Step 2 (equal to total system),
	DT ₅₀ sed. (20°C)	d	36.2	Step 2 (equal to total system),
	Max formation in soil	%AR	3.8	Step 1 and 2, moist soil photolysis study
	Max formation w/ sed.	%AR	53.1	Step 1 and 2, aqueous photolysis study
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g mol ⁻¹ L kg ⁻¹	301.53 111.8	K_{oc} as calculated based on its structure
	K _{FOC} Freundlich exponent	1/n	1.0	Default for K _d
	DegT ₅₀ lab. (20°C/pF 2)	d	160.9	Geomean of two soils
	DT ₅₀ total sys. (20°C)	d	1000	FOCUS default
	DT ₅₀ total sys. (20°C) DT ₅₀ water (20°C)	d	1000	FOCUS default
IN-M2G98	DT ₅₀ water (20°C)	d	1000	FOCUS default
	D 150 300. (20 C)		1000	9.34 %AR (IN-K5A79) × 32.91%AR
	Max formation in soil	%AR	3.1	(IN-M2G98) / 100% = 3.1% AR used at Step 1 and 2.
	Max formation w/ sed.	%AR		Not found in w/s studies
	Plant uptake	(-)	0.0	Worst-case



Application rates used in Step 1 to 4 and application windows used in Steps 3 and 4 for the 100~g/l OD formulation

Scenario	Date of emergence	Application window	Julian days
Crop -	- Lettuce 1 x 90 g a.s./ha ear	ly (Surrogate crop – Leafy Vegetab	les)
D3 (1st)	25-Apr	5-May - 4-Jun	125-155
D3 (2nd)	05-Aug	15-Aug - 14-Sep	227-257
D4	10-May	20-May - 19-Jun	140-170
D6	15-Aug	25-Aug - 24-Sep	237-267
R1 (1st)	20-Apr	30-Apr - 30-May	120-150
R1 (2nd)	31-Jul	10-Aug - 9-Sep	222-252
R2 (1st)	28-Feb	10-Mar - 9-Apr	69-99
R2 (2nd)	31-Jul	10-Aug - 9-Sep	222-252
R3 (1st)	01-Mar	11-Mar - 10-Apr	70-100
R3 (2nd)	15-Jun	25-Jun - 25-Jul	176-206
R4 (1st)	01-Mar	11-Mar - 10-Apr	70-100
R4 (2nd)	15-Jun	25-Jun - 25-Jul	176-206
	2 x 90 g a.s./ha early with a	7 d interval (Surrogate crop – Leaf	y Vegetables)
D3 (Vreedepeel) 1 st	April 25	May 05 – June 11	125 – 162
D3 (Vreedepeel) 2 nd	August 05	August 15 – September 21	227 – 264
D4 (Skousbo)	May 10	May 20 – June 26	140 – 177
D6 (Thiva)	August 15	August 25 – October 01	237 - 274
R1 (Weiherbach) 1 st	April 20	April 30 – June 06	120 – 157
R1 (Weiherbach) 2 nd	July 31	August 10 – September 16	222 – 259
R2 (Porto) 1 st	February 28	March 10 – April 16	69 – 106
R2 (Porto) 2 nd	July 31	August 10 – September 16	222 – 259
R3 (Bologna) 1 st	March 01	March 11 – April 17	70 – 107
R3 (Bologna) 2 nd	June 15	June 25 – August 01	176 – 213
R4 (Roujan) 1 st	March 01	March 11 – April 17	70 – 107
R4 (Roujan) 2 nd	June 15	June 25 – August 01	176 – 213
	– Lettuce 1 x 90 g a.s./ha lat	te (Surrogate crop – Leafy Vegetabl	es)
D3 (1st)	25-Apr	12-Jun - 12-Jul	163-193
D3 (2nd)	05-Aug	12-Sep - 12-Oct	255-285
D4	10-May	19-Aug - 18-Sep	231-261
D6	15-Aug	23-Oct - 22-Nov	296-326
R1 (1st)	20-Apr	7-Jun - 7-Jul	158-188
R1 (2nd)	31-Jul	7-Sep - 7-Oct	250-280
R2 (1st)	28-Feb	24-May - 23-Jun	144-174
R2 (2nd)	31-Jul	8-Oct - 7-Nov	281-311
R3 (1st)	01-Mar	24-Apr - 24-May	114-144
R3 (2nd)	15-Jun	8-Aug - 7-Sep	220-250
R4 (1st)	01-Mar	24-Apr - 24-May	114-144
R4 (2nd)	15-Jun	8-Aug - 7-Sep	220-250
Crop – Lettuce	2 x 90 g a.s./ha late with a 7	d interval (Surrogate crop – Leafy	Vegetables)
D3 (1st)	25-Apr	12-Jun - 19-Jul	163-200
D3 (2nd)	05-Aug	12-Sep - 19-Oct	255-292
D4	10-May	19-Aug - 25-Sep	231-268
D6	15-Aug	23-Oct - 29-Nov	296-333
R1 (1st)	20-Apr	7-Jun - 14-Jul	158-195
R1 (2nd)	31-Jul	7-Sep - 14-Oct	250-287
R2 (1st)	28-Feb	24-May - 30-Jun	144-181
R2 (2nd)	31-Jul	8-Oct - 14-Nov	281-318



Application rates used in Step 1 to 4 and application windows used in Steps 3 and 4 for the 100~g/l OD formulation

Scenario	Date of emergence	Application window	Julian days
R3 (1st)	01-Mar	24-Apr - 31-May	114-151
R3 (2nd)	15-Jun	8-Aug - 14-Sep	220-257
R4 (1st)	01-Mar	24-Apr - 31-May	114-151
R4 (2nd)	15-Jun	8-Aug - 14-Sep	220-257
(Crop – Melons 1 x 90 g a.s./ha	a early (Surrogate crop - Potatoes)	
D3	10-May	20-May - 19-Jun	140-170
D4	22-May	1-Jun - 1-Jul	152-182
D6 (1st)	10-Apr	20-Apr - 20-May	110-140
D6 (2nd)	05-Aug	15-Aug - 14-Sep	227-257
R1	05-May	15-May - 14-Jun	135-165
R2	15-Mar	25-Mar - 24-Apr	84-114
R3	10-Apr	20-Apr - 20-May	110-140
D3	10-May	20-May - 19-Jun	140-170
D4	22-May	1-Jun - 1-Jul	152-182
D6 (1st)	10-Apr	20-Apr - 20-May	110-140
D6 (2nd)	05-Aug	15-Aug - 14-Sep	227-257
R1	05-May	15-May - 14-Jun	135-165
R2	15-Mar	25-Mar - 24-Apr	84-114
R3	10-Apr	20-Apr - 20-May	110-140
		th a 7 d interval (Surrogate crop - F	•
D3 (Vreedepeel)	May 10	May 20 – June 26	140 – 177
D4 (Skousbo)	May 22	June 01 – July 08	152 – 189
D6 (Thiva) 1 st	April 10	April 20 – May 27	110 – 147
O6 (Thiva) 2 nd	August 05	August 15 – September 21	227 – 264
R1 (Weiherbach)	May 05	May 15 – June 21	135 – 172
R2 (Porto)	May 05	May 15 – June 21	135 – 172
R3 (Bologna)	March 15	March 25 – May 01	84 – 121
R4 (Roujan)	April 10	April 20 – May 27	110 – 147
	Crop – Melons 1 x 90 g a.s./h	a late (Surrogate crop - Potatoes)	
D3	10-May	10-Jul - 9-Aug	191-221
D4	22-May	18-Jul - 17-Aug	199-229
D6 (1st)	10-Apr	9-May - 8-Jun	129-159
D6 (2nd)	05-Aug	19-Sep - 19-Oct	262-292
R1	05-May	3-Jul - 2-Aug	184-214
R2	15-Mar	9-Apr - 9-May	99-129
R3	10-Apr	26-Jun - 26-Jul	177-207
Crop – M	<u> </u>	h a 7 d interval (Surrogate crop - Po	
D3	10-May	10-Jul - 16-Aug	191-228
D4	22-May	18-Jul - 24-Aug	199-236
D6 (1st)	10-Apr	9-May - 15-Jun	129-166
D6 (2nd)	05-Aug	19-Sep - 26-Oct	262-299
R1	05-May	3-Jul - 9-Aug	184-221
R2	15-Mar	9-Apr - 16-May	99-136
R3	10-Apr	26-Jun - 2-Aug	177-214
(5)	Crop - Tomato	1 x 90 g a.s./ha early also covering field peppers and gree	1
(Niirrogata	cron — Friinno Vegetanies (aiso covering nein nennere ann oree	n neans)



Application rates used in Step 1 to 4 and application windows used in Steps 3 and 4 for the 100~g/l OD formulation

Scenario	Date of emergence	e of emergence Application window				
R2	15-March	25-Mar - 24-Apr	84-114			
R3	10-May	20-May - 19-Jun	140-170			
R4	20-April	30-Apr - 30-May	120-150			
(G		./ha early with a 7 d interval				
(Surrogat	te crop – Fruiting Vegetables als	so covering field peppers and gr	een beans)			
D6 (Thiva)	April 10	April 20 – May 27	110 – 147			
R2 (Porto)	March 15	March 25 – May 01	84 – 121			
R3 (Bologna)	May 10	May 20 – June 26	140 - 177			
R4 (Roujan)	April 20	April 30 – June 06	120 – 157			
		x 90 g a.s./ha late				
(Surrogat	te crop – Fruiting Vegetables als	so covering field peppers and gr	een beans)			
D6	10-April	3-Jul - 2-Aug	184-214			
R2	15-March	24-Jul - 23-Aug	205-235			
R3	10-May	18-Jul - 17-Aug	199-229			
R4	20-April	7-Jun - 7-Jul	158-188			
	Crop – Tomato 2 x 90 g a.	s./ha late with a 7 d interval				
(Surrogate crop – Fruiting Vegetables also covering field peppers and green beans)						
D6	10-April	3-Jul - 9-Aug	184-221			
R2	15-March	24-Jul - 30-Aug	205-242			
R3	10-May	18-Jul - 24-Aug	199-236			
R4	20-April	7-Jun - 14-Jul 158-195				

Note the melon simulation also covers the proposed potato use at only 2 x 12.5 g a.s./ha



Application rates used in Step 1 to 4 and application windows used in Steps 3 and 4 for the 100 g/l SE formulation

Crop - Nectarines (Representative crop - Pome Fruits, Late application) (1 x 150 g a.s./ha)	-165 -165 -165 -151 -151 -151 -172 -172 -172 -172 -172
D3 15-Apr 15-May - 14-Jun 135-D4 D4 20-Apr 15-May - 14-Jun 135-D5 D5 1-Apr 15-May - 14-Jun 135-D1 R1 15-Apr 15-May - 14-Jun 135-D1 R2 15-Mar 1-May - 31-May 121-D1 R3 1-Apr 1-May - 31-May 121-D1 R4 15-Mar 1-May - 31-May 121-D1 Crop - Nectarines (Representative crop - Pome Fruits, Late application) 121-D1 121-D1 D3 15-Apr 15-May - 21-Jun 135-D1 D4 20-Apr 15-May - 21-Jun 135-D1 D5 1-Apr 15-May - 21-Jun 135-D1 R1 15-Apr 15-May - 21-Jun 135-D1 R2 15-Mar 1-May - 7-Jun 121-D1 R3 1-Apr 1-May - 7-Jun 121-D1 R4 15-Mar 1-May - 7-Jun 121-D1	-165 -165 -165 -151 -151 -151 -172 -172 -172 -172 -172
D5 1-Apr 15-May - 14-Jun 135-R1 R1 15-Apr 15-May - 14-Jun 135-R2 R2 15-Mar 1-May - 31-May 121-R3 R3 1-Apr 1-May - 31-May 121-R4 R4 15-Mar 1-May - 31-May 121-R4 Crop - Nectarines (Representative crop - Pome Fruits, Late application) ^a (2 x 150 g a.s./ha with a 7 d interval) 135-R4 D3 15-Apr 15-May - 21-Jun 135-R4 D4 20-Apr 15-May - 21-Jun 135-R4 D5 1-Apr 15-May - 21-Jun 135-R4 R1 15-Apr 15-May - 21-Jun 135-R4 R2 15-Mar 1-May - 7-Jun 121-R4 R3 1-Apr 1-May - 7-Jun 121-R4 R4 15-Mar 1-May - 7-Jun 121-R4	-165 -165 -151 -151 -151 -172 -172 -172 -172 -172
R1 15-Apr 15-May - 14-Jun 135-R2 R2 15-Mar 1-May - 31-May 121-R3 R3 1-Apr 1-May - 31-May 121-R4 R4 15-Mar 1-May - 31-May 121-R4 Crop - Nectarines (Representative crop - Pome Fruits, Late application) ^a (2 x 150 g a.s./ha with a 7 d interval) D3 15-Apr 15-May - 21-Jun 135-D4 D4 20-Apr 15-May - 21-Jun 135-D5 D5 1-Apr 15-May - 21-Jun 135-R1 R1 15-Apr 15-May - 21-Jun 135-R2 R2 15-Mar 1-May - 7-Jun 121-R3 R3 1-Apr 1-May - 7-Jun 121-R3 R4 15-Mar 1-May - 7-Jun 121-R3	-165 -151 -151 -151 -172 -172 -172 -172 -158
R2 15-Mar 1-May - 31-May 121- R3 1-Apr 1-May - 31-May 121- R4 15-Mar 1-May - 31-May 121- Crop – Nectarines (Representative crop – Pome Fruits, Late application) ^a (2 x 150 g a.s./ha with a 7 d interval) D3 15-Apr 15-May - 21-Jun 135- D4 20-Apr 15-May - 21-Jun 135- D5 1-Apr 15-May - 21-Jun 135- R1 15-Apr 15-May - 21-Jun 135- R2 15-Mar 1-May - 7-Jun 121- R3 1-Apr 1-May - 7-Jun 121- R4 15-Mar 1-May - 7-Jun 121-	-151 -151 -151 -172 -172 -172 -172 -158
R3 1-Apr 1-May - 31-May 121- R4 15-Mar 1-May - 31-May 121- Crop – Nectarines (Representative crop – Pome Fruits, Late application) ^a (2 x 150 g a.s./ha with a 7 d interval) D3 15-Apr 15-May - 21-Jun 135- D4 20-Apr 15-May - 21-Jun 135- D5 1-Apr 15-May - 21-Jun 135- R1 15-Apr 15-May - 21-Jun 135- R2 15-Mar 1-May - 7-Jun 121- R3 1-Apr 1-May - 7-Jun 121- R4 15-Mar 1-May - 7-Jun 121-	-151 -151 -172 -172 -172 -172 -158
R3 1-Apr 1-May - 31-May 121- R4 15-Mar 1-May - 31-May 121- Crop – Nectarines (Representative crop – Pome Fruits, Late application) ^a (2 x 150 g a.s./ha with a 7 d interval) D3 15-Apr 15-May - 21-Jun 135- D4 20-Apr 15-May - 21-Jun 135- D5 1-Apr 15-May - 21-Jun 135- R1 15-Apr 15-May - 21-Jun 135- R2 15-Mar 1-May - 7-Jun 121- R3 1-Apr 1-May - 7-Jun 121- R4 15-Mar 1-May - 7-Jun 121-	-151 -151 -172 -172 -172 -172 -175
R4 15-Mar 1-May - 31-May 121- Crop – Nectarines (Representative crop – Pome Fruits, Late application) ^a (2 x 150 g a.s./ha with a 7 d interval) D3 15-Apr 15-May - 21-Jun 135- D4 20-Apr 15-May - 21-Jun 135- D5 1-Apr 15-May - 21-Jun 135- R1 15-Apr 15-May - 21-Jun 135- R2 15-Mar 1-May - 7-Jun 121- R3 1-Apr 1-May - 7-Jun 121- R4 15-Mar 1-May - 7-Jun 121-	-172 -172 -172 -172 -172
Crop – Nectarines (Representative crop – Pome Fruits, Late application) ^a	-172 -172 -172 -158
D3 15-Apr 15-May - 21-Jun 135- D4 20-Apr 15-May - 21-Jun 135- D5 1-Apr 15-May - 21-Jun 135- R1 15-Apr 15-May - 21-Jun 135- R2 15-Mar 1-May - 7-Jun 121- R3 1-Apr 1-May - 7-Jun 121- R4 15-Mar 1-May - 7-Jun 121-	-172 -172 -172 -158
D4 20-Apr 15-May - 21-Jun 135- D5 1-Apr 15-May - 21-Jun 135- R1 15-Apr 15-May - 21-Jun 135- R2 15-Mar 1-May - 7-Jun 121- R3 1-Apr 1-May - 7-Jun 121- R4 15-Mar 1-May - 7-Jun 121-	-172 -172 -158
D5 1-Apr 15-May - 21-Jun 135- R1 15-Apr 15-May - 21-Jun 135- R2 15-Mar 1-May - 7-Jun 121- R3 1-Apr 1-May - 7-Jun 121- R4 15-Mar 1-May - 7-Jun 121-	-172 -172 -158
R1 15-Apr 15-May - 21-Jun 135-R2 R2 15-Mar 1-May - 7-Jun 121-R3 R3 1-Apr 1-May - 7-Jun 121-R4 R4 15-Mar 1-May - 7-Jun 121-R4	-158
R2 15-Mar 1-May - 7-Jun 121- R3 1-Apr 1-May - 7-Jun 121- R4 15-Mar 1-May - 7-Jun 121-	-158
R3 1-Apr 1-May - 7-Jun 121- R4 15-Mar 1-May - 7-Jun 121-	
R4 15-Mar 1-May - 7-Jun 121-	
	-158
Crop – Pome and stone fruits (Representative crop – Pome Fruits, Early application, BBCF (1 x 90 g a.s./ha)	
D3 15-Apr 25-May 115-	-145
1 1	-150
D5 1-Apr 11-Apr - 11-May 101-	
R1 15-Apr 25-May 115-	
R2 15-Mar 25-Mar - 24-Apr 84-1	
R3 1-Apr 11-Apr - 11-May 101-	
R4 15-Mar 25-Mar - 24-Apr 84-1	
Crop – Pome and stone fruits (Representative crop – Pome Fruits, Early application, BBCF (2 x 90 g a.s./ha with a 7 d interval)	I 31-60)
D3 15-Apr 25-Apr - 1-Jun 115-	-152
D4 20-Apr 30-Apr - 6-Jun 120-	
D5 1-Apr 11-Apr - 18-May 101-	
R1 15-Apr 25-Apr - 1-Jun 115-	-152
R2 15-Mar 25-Mar - 1-May 84-1	21
R3 1-Apr 11-Apr - 18-May 101-	-138
R4 15-Mar 25-Mar - 1-May 84-1	21
Crop – Pome and stone fruits (Representative crop – Pome Fruits, Late application, BBCH 70-87) (1 x 90 g a.s./ha)	
D3 15-Apr 16-Sep - 16-Oct 259-	-289
D4 20-Apr 16-Sep - 16-Oct 259-	
D5 1-Apr 27-Aug - 26-Sep 239-	
R1 15-Apr 16-Sep - 16-Oct 259-	
R2 15-Mar 17-Aug - 16-Sep 229-	
R3 1-Apr 1-Sep - 1-Oct 244-	
R4 15-Mar 1-Sep - 1-Oct 244-	
Crop – Pome and stone fruits (Representative crop – Pome Fruits, Late application, BBCH (2 x 90 g a.s./ha with a 7 d interval)	
D3 15-Apr 16-Sep - 23-Oct 259-	-296
D4 20-Apr 16-Sep - 23-Oct 259-	
D5 1-Apr 27-Aug - 3-Oct 239-	
R1 15-Apr 16-Sep - 23-Oct 259-	



	The state of the s		
R2	15-Mar	17-Aug - 23-Sep	229-266
R3	1-Apr	1-Sep - 8-Oct	244-281
R4	15-Mar	1-Sep - 8-Oct	244-281
	Crop – Citrus (Rej	presentative crop - Citrus) ^b	
	1 x	150 g a.s./ha	
D6	constant flush of leaves	1-Apr - 1-May	91-121
R4	constant flush of leaves	1-Apr - 1-May	91-121
	Crop – Citrus (Re	presentative crop - Citrus) ^b	
		ha with a 7 d interval	
D6 (Thiva)	Constant flush of leaves	April 01 – May 08	91 – 128
R4 (Roujan)	Constant flush of leaves	April 01 – May 08	91 – 128
		ive crop – Vines, Late application) ^c	
		12.5 g a.s./ha	
D6	1-Feb	1-Jun - 1-Jul	152-182
R1	15-Apr	15-Jun - 15-Jul	166-196
R2	15-Mar	15-Jun - 15-Jul	166-196
R3	1-Apr	15-Jun - 15-Jul	166-196
R4	10-Mar	15-Jun - 15-Jul	166-196
		ive crop – Vines, Late application /ha with a 14 d interval)) ^c
D6 (Thiva)	February 01	June 01 – July 15	152 – 196
R1 (Weiherbach)	April 15	June 15 – July 29	166 – 210
R2 (Porto)	March 15	June 15 – July 29	166 – 210
R3 (Bologna)	April 01	June 15 – July 29	166 – 210
R4 (Roujan)	March 10	June 15 – July 29	166 – 210
		presentative crop - Olives) ^d	
D6	1 X	150 g a.s./na	
D0	constant flush of leaves	150 g a.s./ha 1-Apr - 1-May	91-121
R4		1-Apr - 1-May 1-Apr - 1-May	91-121 91-121
	constant flush of leaves constant flush of leaves Crop – Olives (Rep	1-Apr - 1-May	ı
	constant flush of leaves constant flush of leaves Crop – Olives (Rep	1-Apr - 1-May 1-Apr - 1-May presentative crop - Olives) ^d	

Note the apple simulation also covers the proposed pear, nectarine, peach and apricot use at up to $2 \times 150 \text{ g}$ a.s./ha

Application Window = 30 + (number of applications-1) * interval

Pome fruits are sprayed after flowering. The typical spraying window is mid to end May in northern Europe and beginning of May in warmer climate zones. The application window starts after flowering therefore drift rates for 'pome fruits, late application' were chosen in the simulations.

Citrus is defined as a perennial crop in FOCUS scenarios. The application window of 1st April to 8th May is selected corresponding to the BBCH stage of 09-71.

Vines are treated during or after flowering. This means that all leaves are developed and the crop exhibits full leaf area. FOCUS run-off scenarios assume that maturity is reached between beginning to end of July, which seems to be too late. The practical impact of this definition is that crop interception will be conservatively underestimated when using a more realistic application date in June. The maturation date in the drain flow scenario (D6, Thiva) seems to be more realistic (1 May). All drift rates relate to 'vines, late application' because all applications are done when leaves are developed.

Olives; the same application window as for citrus was selected



Application rates used in Step 1 to 4 and application windows used in Steps 3 and 4 for the 200 g/l SC formulation

Scenario	Date of emergence Application window		Julian days			
Crop – Tomato and Pepper early applications (Surrogate crop – Fruiting Vegetables) 1 x 75 g a.s./ha						
D6	10-April	20-Apr - 20-May	110-140			
R2	15-March	25-Mar - 24-Apr	84-114			
R3	10-May	20-May - 19-Jun	140-170			
R4	20-April	30-Apr - 30-May	120-150			
Crop – To	mato and Pepper early applicat	tions (Surrogate crop – Fruiting	Vegetables)			
	2 x 75 g a.s./ha	with a 7 d interval				
D6 (Thiva)	April 10	April 20 – May 27	110–147			
R2 (Porto)	March 15	March 25 – May 01	84–121			
R3 (Bologna)	May 10	May 20 – June 26	140–177			
R4 (Roujan)	April 20	April 30 – June 06	120–157			
Crop – To		ions (Surrogate crop – Fruiting V g a.s./ha	Vegetables)			
D6	10-April	3-Jul - 2-Aug	184-214			
R2	15-March	24-Jul - 23-Aug	205-235			
R3	10-May	18-Jul - 17-Aug	199-229			
R4	20-April	7-Jun - 7-Jul	158-188			
Crop – To		ions (Surrogate crop – Fruiting V with a 7 d interval	/egetables)			
D6	10-April	3-Jul - 9-Aug	184-221			
R2	15-March	24-Jul - 30-Aug	205-242			
R3	10-May	18-Jul - 24-Aug	199-236			
R4	20-April	7-Jun - 14-Jul	158-195			

Application windows used in Steps 3 and 4 for the 400 g/kg formulation

Crop	Scenario	Window Start	Julian	Window End	Julian Day
	D3	1st June	152	21st July	202
	D4	1st June	152	21st July	202
	D5	1st June	152	21st July	202
Pome fruit	R1	1st June	152	21st July	202
	R2	15th May	135	4th July	185
	R3	15th May	135	4th July	185
	R4	15th May	135	4th July	185

Application rate simulated was 2 x 125 g a.s./ha with a 7 d interval



Step 1 to 4 results: 100 g/l OD formulation

Step 1: Actual and time-weighted average PEC_{sw} and PEC_{sed} values for cyantraniliprole in Europe for the 100 g/l OD formulation

	P	PEC _{sw}	PEC _{sed}		
Time after application (days)	Actual PEC _{sw} (μg/L)	Time weighted PEC _{sw} (μg/L)	Actual PEC _{sed} (μg/kg)	Time weighted PEC _{sed} (µg/kg)	
Crop – Lettuce, M			eld peppers, potatoes a	and green beans)	
	(2 x 9	0 g a.s./ha with a 7 d i	interval)		
0	49.375	-	92.100	-	
1	47.701	48.538	92.063	92.081	
2	46.402	47.793	89.555	91.442	
4	43.908	46.469	84.743	89.285	
7	40.417	44.613	78.006	85.875	
14	33.313	40.682	64.294	78.402	
21	27.458	37.218	52.993	71.755	
28	22.631	34.155	43.679	65.863	
42	15.375	29.027	29.673	55.984	
50	12.327	26.590	23.791	51.286	
100	3.099	16.637	5.981	32.093	



Step 2: Actual and time-weighted average PEC_{sw} and PEC_{sed} values for cyantraniliprole in Europe (northern and southern Europe) for the ${\bf 100~g/l~OD}$ formulation

	Northern Europe, March - May			Southern Europe, March - May				
	PE	$\mathrm{CC}_{\mathrm{sw}}$	PI	$\mathrm{EC}_{\mathrm{sed}}$	PI	$\mathrm{EC}_{\mathrm{sw}}$	PEC _{sed}	
Time after application (days)	Actual PEC _{sw} (μg/L)	Time weighted PEC _{sw} (µg/L)	Actual PEC _{sed} (μg/kg)	Time weighted PEC _{sed} (µg/kg)	Actual PEC _{sw} (μg/L)	Time weighted PEC _{sw} (µg/L)	Actual PEC _{sed} (μg/kg)	Time weighted PEC _{sed} (µg/kg)
	Crop	– Lettuce an	d Tomato (also coverin	g peppers a	nd green bea	ns)	•
		(2	2 x 90 g a.s.	/ha with a 7	d interval)			
0	7.790	-	14.895	-	14.536	-	27.905	-
1	7.513	7.651	14.570	14.733	14.074	14.305	27.296	27.601
2	7.349	7.541	14.253	14.572	13.768	14.113	26.701	27.300
4	7.032	7.365	13.638	14.258	13.174	13.791	25.549	26.711
7	6.582	7.125	12.765	13.803	12.331	13.344	23.914	25.859
14	5.641	6.612	10.940	12.816	10.567	12.385	20.494	24.010
21	4.834	6.151	9.375	11.923	9.056	11.521	17.564	22.338
28	4.143	5.733	8.035	11.115	7.761	10.739	15.052	20.822
42	3.043	5.010	5.901	9.714	5.700	9.385	11.055	18.199
50	2.551	4.655	4.947	9.025	4.778	8.720	9.267	16.908
100	0.847	3.100	1.643	6.011	1.587	5.808	3.078	11.262
		Cro	p – Melon	s (also coveri	ng potatoe	s)		
		(2	x 90 g a.s.	/ha with a 7	d interval)			
0	8.690	-	16.630	=	16.334	=	31.374	=
1	8.388	8.539	16.267	16.448	15.824	16.079	30.690	31.032
2	8.205	8.417	15.912	16.269	15.479	15.865	30.021	30.694
4	7.851	8.222	15.23	15.918	14.811	15.504	28.726	30.032
7	7.348	7.954	14.252	15.411	13.864	15.002	26.887	29.074
14	6.298	7.382	12.214	14.309	11.881	13.925	23.042	26.995
21	5.397	6.867	10.467	13.312	10.182	12.953	19.747	25.115
28	4.625	6.400	8.970	12.409	8.726	12.074	16.923	23.411
42	3.397	5.593	6.588	10.845	6.409	10.552	12.429	20.461
50	2.848	5.197	5.523	10.077	5.372	9.804	10.420	19.011
100	0.946	3.461	1.834	6.712	1.784	6.530	3.460	12.662



Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC $_{sw}$ value below the RAC of 1 μ g/l for each crop, scenario and water body combination for the **100** g/l **OD formulation**

Samoria	Lettuce (2 x 90 g a.s./ha)			o (2 x 90 g ./ha)	Melon (2 x 90 g a.s./ha)	
Scenario	PECsw	Assessment tier and	PECsw	Assessment tier and	PECsw	Assessment tier and
	(µg/l)	mitigation	(µg/l)	mitigation	(µg/l)	mitigation



D3 Ditch 1 st early	0.575 (single)	Step 3			0.477 (single)	Step 3
D3 Ditch 2 nd early	0.577 (single)	Step 3	-	-	-	-
D3 Ditch 1 st late	0.573 (single)	Step 3			0.475 (single)	Step 3
D3 Ditch 2 nd late	0.572 (single)	Step 3			-	-
D4 Pond early	0.796 (multiple)	Step 3	-	-	0.903 (multiple)	Step 3
D4 Stream early	0.814 (multiple)	Step 3	-	-	0.916 (multiple)	Step 3
D4 Pond late	1.132 (multiple)	Step 3 (no mitigation possible)			1.154 (multiple)	Step 3 (no mitigation possible)
D4 Stream late	1.399 (multiple)	Step 3 (no mitigation possible)			1.340 (multiple)	Step 3 (no mitigation possible)
D6 Ditch 1 st early	2.330 ^b (multiple)	Step 3 (no mitigation possible)	0.585 (single)	Step 3-	0.558 (multiple)	Step 3
D6 Ditch 2nd early	-	-	-	-	2.465 ^b (multiple)	Step 3 (no mitigation possible)
D6 Ditch 1 st late	5.950 (multiple)	Step 3 (no mitigation possible)	1.727 (multiple)	Step 3 (no mitigation possible)	0.495 (single)	Step 3
D6 Ditch 2nd late	-	-			4.539 ^b (multiple)	Step 3 (no mitigation possible)
R1 Pond 1 st early	0.155 (multiple)	Step 3	-	-	0.178 (multiple)	Step 3
R1 Pond 2 nd early	0.166 (multiple)	Step 3	-	-	-	-
R1 Pond 1 st late	0.388 (multiple)	Step 3			0.087 (single)	Step 3
R1 Pond 2 nd late	0.141 (multiple)	Step 3			-	-
R1 Stream 1st early	0.590 (multiple)	Step 4 (20m VFS)	-	-	1.000	Step 4 (10m VFS)



R1 Stream 2 nd early	0.541 (multiple)	Step 4 (20m VFS)	-	-	-	-
R1 Stream 1st late	0.460 (multiple)	Step 4 (20m VFS)			0.756 (multiple)	Step 4 (10m VFS)
R1 Stream 2 nd late	0.878 (multiple)	Step 4 (10m VFS)			-	-
R2 Stream 1 st early	0.892 (multiple)	Step 4 (10m VFS)	0.797 (multiple)	Step 4 (10m VFS)	0.772 (multiple)	Step 4 (10m VFS)
R2 Stream 2 nd early	0.703 (multiple)	Step 3	-	-	-	-
R2 Stream 1 st late	0.604 (multiple)	Step 4 (10m VFS)	0.755 (multiple)	Step 3	0.772 (multiple)	Step 4 (10m VFS)
R2 Stream 2 nd late	0.996 (multiple)	Step 3	-	-	-	-
R3 Stream 1 st early	0.686 (multiple)	Step 4 (20m VFS)	0.777 (multiple)	Step 4 (20m VFS)	0.635 (multiple)	Step 4 (20m VFS)
R3 Stream 2 nd early	0.733 (multiple)	Step 4 (20m VFS)	-	-	-	-
R3 Stream 1 st late	0.576 (multiple)	Step 4 (20m VFS)	0.585 (multiple)	Step 4 (20m VFS)	0.667 (multiple)	Step 4 (20m VFS)
R3 Stream 2 nd late	0.674 (multiple)	Step 4 (20m VFS)	-	-	-	-
R4 Stream 1 st early	0.652 (multiple)	Step 4 (20m VFS)	0.986 (multiple)	Step 4 (20m VFS)	-	-
R4 Stream 2 nd early	0.691 (multiple)	Step 4 (20m VFS)	-	-	-	-
R4 Stream 1 st late	0.760 (multiple)	Step 4 (20m VFS)	0.715 (multiple)	Step 4 (20m VFS		
R4 Stream 2 nd late	0.769 (multiple)	Step 4 (20m VFS)				

bthe peak PEC_{sw} value for the D4 pond late and D6 ditch scenario was due to drainflow which was not mitigated by the introduction of either no spray buffer zones or vegetated filter strips
"-" represents a non-relevant FOCUS_{sw} scenario for that specific crop
VFS = vegetated filter strip
Note the melon simulation also covers the proposed potato use at only 2 x 12.5 g a.s./ha



Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC $_{sed}$ value below the RAC of 2.41 μ g/kg for each crop, scenario and water body combination for the **100 g/l OD formulation**

Securation		e (2 x 90 g ./ha)	Melon (2 x 90 g a.s./ha)		
Scenario	PECsed (μg/kg)	Assessment tier and mitigation	PECsed (μg/kg)	Assessment tier and mitigation	



	0.220	C4 2	0.210	C+ 2
D3 Ditch 1 st early	0.238	Step 3	0.210	Step 3
D3 Ditch 2 nd early	0.229	Step 3	-	-
D3 Ditch 1 st late	0.227	Step 3	0.207	Step 3
D3 Ditch 2 nd late	0.226	Step 3	-	-
D4 Pond early	2.987	Step 4 (20m BZ)	3.513	Step 4 (20m BZ)
D4 Stream early	1.647	Step 3	1.911	Step 3
D4 Pond late	3.420	Step 4 (10m BZ)	3.837	Step 4 (10m BZ)
D4 Stream late	1.862	Step 3	2.023	Step 3
D6 Ditch 1 st early	1.967	Step 3	0.683	Step 3
D6 Ditch 2nd early	-	-	1.912	Step 3
D6 Ditch 1 st late	4.475	Step 4 (10m BZ)	0.609	Step 3
D6 Ditch 2nd late	-	-	2.832	Step 4 (10m BZ)
R1 Pond 1 st early	0.304	Step 3	0.383	Step 3
R1 Pond 2 nd early	0.330	Step 3	-	-
R1 Stream 1st early	0.615	Step 3	0.575	Step 3
R1 Stream 2 nd early	0.703	Step 3	-	-
R1 Pond 1 st late	0.656	Step 3	0.147	Step 3
R1 Pond 2 nd late	0.428	Step 3	-	-
R1 Stream 1st late	0.952	Step 3	0.453	Step 3
R1 Stream 2 nd late	0.434	Step 3	-	-
R2 Stream 1 st early	1.105	Step 3	0.478	Step 3
R2 Stream 2 nd early	0.413	Step 3	-	-
R2 Stream 1 st late	1.025	Step 3	0.478	Step 3
R2 Stream 2 nd late	0.366	Step 3	-	-
R3 Stream 1 st early	0.992	Step 3	0.679	Step 3
R3 Stream 2 nd early	1.268	Step 3	-	-
R3 Stream 1 st late	0.671	Step 3	1.195	Step 3
	I	I		1



R3 Stream 2 nd late	1.491	Step 3	-	-
R4 Stream 1 st early	0.847	Step 3	-	-
K4 Stream 1 earry	1.007	C4 2		
R4 Stream 2 nd early	1.097	Step 3	-	-
R4 Stream 1 st late	1.119	Step 3	-	-
R4 Stream 2 nd late	1.316	Step 3	-	-

[&]quot;-" represents a non-relevant FOCUS_{sw} scenario for that specific crop

VFS = vegetated filter strip
BZ = spray drifty buffer zone
Note no mitigation was required for tomatoes as the maximum Step 3 PECsed values was already below the RAC for this crop; Note values in **bold** exceed the RAC irrespective of risk mitigation applied



Summary of maximum PECsw values for the metabolites of cyantraniliprole (Steps 1 and 2) for the 100 g/l OD formulation

Substance	Step 1 (same PECsw for all crops) (µg/l)	Step 2 Lettuce AND Tomato (and surrogate for field peppers and green beans) (µg/l)	Step 2 Melon (surrogate for potatoes) (µg/l)
IN-J9Z38 ^a	5.470	1.617	1.617
IN-K5A77	0.877	0.216	0.240
IN-JCZ38	20.019	4.364	4.946
IN-JSE76	25.842	7.393	8.379
IN-K5A79	5.473	1.440	1.632
IN-K5A78	9.527	2.774	3.144
IN-PLT97	5.872	1.734	1.965
IN-RNU71	6.352	1.884	2.112
IN-QKV54	1.681	0.509	0.509
IN-NXX70	1.007	0.400	0.400
IN-M2G98	1.030	0.299	0.339

NB: at Step 2, the early season Southern Europe simulations for multiple application GAPs always gave the higher PECsw values compared with the Northern Europe simulations

100 g/l OD formulation: Glasshouse uses (simple drift losses to a 30cm deep static water body only)

Maximum initial PEC_{sw} and PEC_{sed} values of cyantraniliprole and its metabolites following application of cyantraniliprole to fruiting vegetables (4 x 120 g a.s./ha)

	Initial PE	C _{sw} (μg/L)	Initial PEC _{sed} (µg/kg)			
Compound	Drift (acc. to FOCUS SW Step3 at 5 m – 0.3808% for 4 applications)	Drift ^a (Ultra-low Volume Application, 0.2%)	Drift (acc. to FOCUS SW Step3 at 5 m)	Drift ^a (Ultra-low Volume Application)		
Cyantraniliprole	0.467	0.245	0.766	0.402		
IN-J9Z38	0.331	0.174	3.371	1.771		
IN-K5A77	0.078	0.041	4.537	2.383		
IN-RNU71	0.061	0.032	0.215	0.113		
IN-QKV54	0.296	0.155	2.617	1.374		
IN-NXX70	0.247	0.130	3.489	1.832		

Worst case drift assumptions resulting from indoor ultra-low volume applications (FOCUS, 2008).

^aAll PECsw values for IN-J9Z38 have been increased by a factor of 2.28 to cover the higher formation observed under field conditions of 41.7% compared to lab formation of 18.3% (i.e. 18.3/41.7 = 2.28)



Maximum initial PEC_{sw} and PEC_{sed} values of cyantraniliprole and its metabolites following application of cyantraniliprole to leafy vegetables (2 x 75 g a.s./ha)

	Initial PE	С _{sw} (µg/L)	Initial PEC _{sed} (μg/kg)			
Compound	Drift (acc. to FOCUS SW Step3 at 5 m – 0.4797% for 2 applications)	Drift ^a (Ultra-low Volume Application, 0.2%)	Drift (acc. to FOCUS SW Step3 at 5 m)	Drift ^a (Ultra-low Volume Application)		
Cyantraniliprole	0.219	0.091	0.303	0.126		
IN-J9Z38	0.133	0.055	1.334	0.556		
IN-K5A77	0.031	0.013	1.795	0.748		
IN-RNU71	0.024	0.010	0.085	0.036		
IN-QKV54	0.136	0.057	1.204	0.502		
IN-NXX70	0.110	0.046	1.556	0.649		

^a Worst case drift assumptions resulting from indoor ultra-low volume applications (FOCUS, 2008).



Step 1 to 4 results: 100 g/l SE formulation

Step 1: Actual and time-weighted average PEC_{sw} and PEC_{sed} values for cyantraniliprole in Europe for the ${\bf 100g/l~SE}$ formulation



	PE	CC_{sw}	PE	C_{sed}								
Time after application (days)	Actual PEC _{sw} (μg/L)	Time weighted PEC _{sw} (µg/L)	Actual PEC _{sed} (μg/kg)	Time weighted PEC _{sed} (µg/kg)								
	Crop – Apples 2 x 90 g a.s./ha (early application)											
0	65.238	na	92.100	na								
1	59.974	62.606	115.749	103.924								
2	58.340	60.880	112.596	109.045								
4	55.205	58.819	106.546	109.294								
7	50.816	56.317	98.075	106.276								
14	41.884	51.261	80.836	97.727								
21	34.522	46.869	66.627	89.652								
28	28.454	42.999	54.916	82.385								
42	19.330	36.533	37.307	70.105								
50	15.499	33.462	29.912	64.244								
100	3.896	20.933	7.520	40.231								
	<u>.</u>	Crop – Apples										
	2 x	90 g a.s./ha (late appl	lication)									
0	57.155	na	92.100	na								
1	53.720	55.437	103.679	97.890								
2	52.257	54.211	100.855	100.075								
4	49.449	52.526	95.436	99.098								
7	45.517	50.353	87.848	95.880								
14	37.517	45.870	72.407	87.880								
21	30.922	41.951	59.680	80.533								
28	25.487	38.493	49.190	73.966								
42	17.315	32.708	33.417	62.909								
50	13.883	29.960	26.793	57.641								
100	3.490	18.744	6.735	36.084								
	Crop – App	les, Citrus, and Olives	(2 x 150 g a.s./ha)									
0	95.258	-	153.500	-								
1	89.533	92.396	172.799	163.149								
2	87.094	90.352	168.092	166.792								
4	82.415	87.542	159.060	165.163								
7	75.862	83.921	146.414	159.800								
14	62.528	76.451	120.678	146.466								
21	51.537	69.919	99.466	134.221								
28	42.478	64.155	81.983	123.277								
42	28.858	54.513	55.695	104.849								
50	23.137	49.934	44.655	96.069								
100	5.816	31.239	11.226	60.140								
	Crop – Vir	nes (late applications, 2	x 112.5 g a.s./ha)									
0	65.671	-	115.125	-								
1	62.684	64.177	120.979	118.052								
2	60.976	63.002	117.684	118.688								
4	57.700	61.162	111.361	116.591								
7	53.112	58.682	102.507	112.426								
14	43.777	53.488	84.489	102.817								
21	36.082	48.927	69.638	94.153								
28	29.740	44.898	57.398	86.445								
42	20.204	38.153	38.993	73.498								

Peer review of the pesticide risk assessment of the active substance cyantraniliprole

50	16.199	34.949	31.264	67.336
100	4.072	21.866	7.859	42.143



Step 2: Actual and time-weighted average PEC_{sw} and PEC_{sed} values for cyantraniliprole in Europe (northern and southern Europe) for the ${\bf 100~g/g~SE}$ formulation



	Nort	thern Europ	e, March	- May	Sou	thern Euro	pe, March	- May			
	PI	EC _{sw}	PF	$\mathrm{EC}_{\mathrm{sed}}$	Pl	$\mathrm{EC}_{\mathrm{sw}}$	PE	CC_{sed}			
Time after application (days)	Actual PEC _{sw} (μg/L)	Time weighted PEC _{sw} (µg/L)	Actual PEC _{sed} (µg/kg)	Time weighted PEC _{sed} (µg/kg)	Actual PEC _{sw} (μg/L)	Time weighted PEC _{sw} (µg/L)	Actual PEC _{sed} (µg/kg)	Time weighted PEC _{sed} (µg/kg)			
		2 x 90 g a.s.,		op – Apples 7 d interva		oplication)					
0	18.135	na	33.621	na	25.330	na	47.498	na			
1	16.958	17.546	32.888	33.255	23.957	24.643	46.463	46.980			
2	16.588	17.160	32.171	32.892	23.434	24.170	45.449	46.468			
4	15.872	16.694	30.783	32.183	22.424	23.548	43.489	45.466			
7	14.857	16.122	28.813	31.157	20.989	22.756	40.706	44.016			
14	12.732	14.945	24.693	28.929	17.987	21.103	34.885	40.869			
21	10.911	13.896	21.162	26.914	15.415	19.625	29.896	38.022			
28	9.351	12.950	18.135	25.088	13.210	18.290	25.621	35.443			
42	6.868	11.315	13.319	21.927	9.702	15.982	18.817	30.977			
50	5.757	10.512	11.166	20.372	8.134	14.848	15.774	28.781			
100	1.912	7.000	3.708	13.569	2.701	9.888	5.239	19.170			
$Crop-Apples \\ 2 \ x \ 90 \ g \ a.s./ha \ with \ a \ 7 \ d \ interval \ (late \ application, June \ to \ September)$											
0	7.895	na	14.584	na	9.244	na	17.186	na			
1	7.356	7.626	14.266	14.425	8.668	8.956	16.811	16.998			
2	7.195	7.451	13.955	14.268	8.479	8.765	16.444	16.813			
4	6.885	7.245	13.353	13.960	8.113	8.530	15.735	16.450			
7	6.444	6.995	12.498	13.515	7.594	8.239	14.728	15.926			
14 21	5.523	6.484	10.711	12.548	6.508	7.638	12.622	14.787			
28	4.733 4.056	6.028 5.618	9.179 7.867	11.674 10.882	5.577 4.780	7.102 6.619	10.817 9.270	13.757 12.824			
42	2.979	4.909	5.778	9.511	3.511	5.784	6.808	11.208			
50	2.497	4.560	4.843	8.837	2.943	5.764	5.708	10.413			
100	0.829	3.037	1.609	5.886	0.977	3.578	1.896	6.936			
	I	ples (and a s					I	0.730			
	010P 11P			/ha with a 7							
0	20.654	na	38.761	na	32.646	na	61.890	na			
1	19.550	20.102	37.916	38.339	31.215	31.931	60.540	61.215			
2	19.124	19.720	37.090	37.921	30.535	31.403	59.220	60.548			
4	18.299	19.214	35.490	37.103	29.218	30.638	56.666	59.242			
7	17.128	18.569	33.218	35.920	27.348	29.625	53.039	57.353			
14	14.679	17.221	28.468	33.352	23.437	27.484	45.454	53.252			
21	12.579	16.015	24.397	31.028	20.085	25.562	38.954	49.542			
28	10.781	14.925	20.908	28.923	17.213	23.825	33.384	46.181			
42	7.918	13.042	15.356	25.279	12.642	20.820	24.518	40.362			
50	6.637	12.117	12.873	23.487	10.598	19.343	20.554	37.501			
100	2.204	8.069 2 x		15.644 cop – Citrus /ha with a 7		12.883 	6.826	24.978			
0	13.159	-	24.306	-	17.656	-	32.979	-			
1	12.259	12.709	23.776	24.041	16.634	17.145	32.260	32.620			
2	11.992	12.417	23.258	23.779	16.271	16.799	31.557	32.264			
4	11.475	12.075	22.255	23.266	15.569	16.359	30.196	31.568			



	Nort	thern Europ	e, March	- May	Sou	thern Euroj	pe, March	- May
	$\mathbf{PEC}_{\mathbf{sw}}$		PE	$\mathrm{EC}_{\mathrm{sed}}$	Pl	$\mathbf{PEC_{sw}}$		C_{sed}
Time after application (days)	Actual weighted PEC _{sw} (μg/L) (μg/L)		Actual PEC _{sed} (μg/kg)	Time weighted PEC _{sed} (µg/kg)	Actual PEC _{sw} (μg/L)	Time weighted PEC _{sw} (µg/L)	Actual PEC _{sed} (µg/kg)	Time weighted PEC _{sed} (µg/kg)
7	10.740	11.659	20.830	22.525	14.573	15.805	28.263	30.562
14	9.205	10.806	17.852	20.914	12.489	14.655	24.221	28.377
21	7.888	10.047	15.299	19.457	10.703	13.628	20.758	26.400
28	6.760	9.363	13.111	18.137	9.172	12.700	17.789	24.609
42	4.965	8.181	9.629	15.852	6.737	11.098	13.065	21.508
50	4.162	7.600	8.072	14.728	5.647	10.310	10.953	19.983
100	1.382	5.061	2.681	9.810	1.876	6.866	3.637	13.310
		2 x 1		rop – Vines ./ha with a 1	4 d interv	val		
0	10.114	-	19.067	-	16.682	-	31.734	-
1	9.617	9.866	18.652	18.859	16.006	16.344	31.042	31.388
2	9.407	9.689	18.245	18.654	15.657	16.087	30.365	31.046
4	9.002	9.446	17.458	18.252	14.981	15.702	29.055	30.376
7	8.425	9.131	16.341	17.670	14.023	15.186	27.196	29.408
14	7.221	8.469	14.004	16.406	12.017	14.090	23.307	27.305
21	6.188	7.877	12.001	15.263	10.299	13.106	19.974	25.403
28	5.303	7.341	10.29	14.228	8.826	12.215	17.118	23.680
42	3.895	6.415	7.554	12.435	6.482	10.675	12.572	20.696
50	3.265	5.960	6.332	11.554	5.434	9.918	10.539	19.229
100	1.084	3.969	2.103	7.695	1.805	6.605	3.500	12.807



Step 2: Actual and time-weighted average PEC_{sw} and PEC_{sed} values for cyantraniliprole in Europe (northern and southern Europe) for the ${\bf 100~g/g~SE}$ formulation

	Nor	thern Europ	e, March -	May	Southern Europe, March - May				
	PE	EC _{sw}	PF	PEC _{sed}		PEC _{sw}		\mathbf{C}_{sed}	
Time after application (days)	Actual PEC _{sw} (μg/L) Time weighted PEC _{sw} (μg/L)		$ \begin{array}{c cccc} weighted & Actual & weighted \\ PEC_{sw} & PEC_{sed} & PEC_{sed} \\ \end{array} $		Actual PEC _{sw} (μg/L)	Time weighted PEC _{sw} (µg/L)	Actual PEC _{sed} (µg/kg)	Time weighted PEC _{sed} (µg/kg)	
			Crop - Ol	ives (2 x 150	g a.s./ha)				
0	12.836	-	23.716	-	17.281	-	32.290	_	
1	11.962	12.399	23.199	23.458	16.286	16.783	31.586	31.938	
2	11.701	12.115	22.693	23.202	15.931	16.446	30.897	31.589	
4	11.196	11.781	21.714	22.701	15.244	16.016	29.564	30.908	
7	10.480	11.375	20.325	21.978	14.268	15.474	27.672	29.923	
14	8.981	10.543	17.418	20.406	12.228	14.348	23.715	27.783	
21	7.697	9.803	14.927	18.985	10.479	13.342	20.324	25.848	
28	6.596	9.136	12.793	17.697	8.981	12.435	17.417	24.094	
42	4.844	7.982	9.395	15.467	6.596	10.865	12.792	21.058	
50	4.061	7.416	7.876	14.370	5.529	10.095	10.724	19.565	
100	1.349	4.938	2.616	9.571	1.836	6.722	3.561	13.032	



Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC $_{sw}$ value below the RAC of 1 $\mu g/l$ for each crop, scenario and water body combination for the 100 g/l SE formulation

Saamaria	early	(Pome fruit r, 2 x 90 g ss./ha)		(Pome fruit 90 g a.s./ha)	late,	(Pome fruit 2 x 150 g s./ha)		(2 x 150 g .s./ha)	Olives (2 x 150 g a.s./ha)		Vines, late (2 x 112.5 g a.s./ha)	
Scenario	PEC _{sw} (μg/l)	Assessment tier and mitigation	PEC _{sw} (μg/l)	Assessment tier and mitigation	PEC _{sw} (μg/l)	Assessment tier and mitigation	PEC _{sw} (μg/l)	Assessment tier and mitigation	PEC _{sw} (μg/l)	Assessment tier and mitigation	PEC _{sw} (μg/l)	Assessment tier and mitigation
D3 Ditch	0.773	20m BZ	0.999	10m BZ	0.723	Step 4 (15m BZ)	-	-	-	-	-	-
D4 Pond	0.716	Step 3	1.864	20m BZ	0.990	Step 3	-	-	1	-	1	-
D4 Stream	0.868	20m BZ	2.502	20m BZ	0.996	Step 4 (15m BZ)	-	-	-	-	-	-
D5 Pond	0.803	Step 3	0.546	Step 3	0.580	Step 3	-	-	-	-	-	-
D5 Stream	0.899	20m BZ	0.588	20m BZ	0.976	Step 4 (15m BZ)	-	-	-	-	-	-
D6 Ditch	-	-	-	-	-	-	0.521	Step 4 (20m BZ)	0.521	Step 4 (20 m BZ)	0.423	Step 4 (10 m BZ)
R1 Pond	0.687	Step 3	0.202	Step 3	0.357	Step 3	-	-	-	-	0.163	Step 3
R1 Stream	0.682	20m BZ + VFS	0.886	10m BZ + VFS	0.455	Step 4 (20m BZ + VFS)	-	-	-	-	0.558	Step 4 (10 m BZ + VFS)
R2 Stream	0.904	20m BZ + VFS	0.366	20m BZ + VFS	0.609	Step 4 (20m BZ + VFS)	-	-	-	-	0.827	Step 4 (10 m BZ)
R3 Stream	0.964	20m BZ + VFS	0.603	20m BZ + VFS	0.638	Step 4 (20m BZ + VFS)	-	-	-	-	0.524	Step 4 (10 m BZ + VFS)
R4 Stream	0.686	20m BZ + VFS	0.886	10m BZ + VFS	0.553	Step 4 (20m BZ + VFS)	0.705	Step 4 (20m BZ + VFS)	0.730	Step 4 (20 m BZ + VFS)	0.462	Step 4 (10 m BZ + VFS)

[&]quot;-" represents a non-relevant FOCUSsw scenario for that specific crop

BZ = no spray buffer zone

Values in bold exceed the RAC irrespective of the level of risk mitigation applied.



Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC $_{sed}$ value below the RAC of 2.41 μ g/kg for each crop, scenario and water body combination for the **100** g/l SE formulation

	Apples (Pome fruit early, 2 x 90 g a.s./ha)		fruit la	Apples (Pome fruit late, 2 x 90 g a.s./ha)		Apples (Pome fruit late, 2 x 150 g a.s./ha)		(2 x 150 g s./ha)	Olives (2 x 150 g a.s./ha)	
Scenar io	PEC _{se}	Assessm ent tier and	PEC _{se}	Assessm ent tier and	PEC _{se}	Assessm ent tier and	PEC _{se}	Assessm ent tier and	PEC _{se}	Assessm ent tier and
	(μg/k g)	mitigatio n	(μg/k g)	mitigatio n	(μg/k g)	mitigatio n	(μg/k g)	mitigatio n	(μg/k g)	mitigatio n
D3 Ditch	2.269	Step 3	1.364	Step 3	1.919	Step 3	-	-	-	-
D4 Pond	2.039	Step 3	4.961	20m BZ	2.994	Step 4 (20m BZ + VFS)	-	-	-	-
D4 Stream	0.766	Step 3	2.442	20m BZ	1.402	Step 3	-	-	-	-
D5 Pond	1.733	Step 3	2.051	Step 3	2.255	Step 3	-	-	-	-
D5 Stream	0.594	Step 3	0.901	Step 3	1.556	Step 3	-	-	-	-
D6 Ditch		•	-	-	-	-	0.494	Step 4 (20m BZ)	0.521	Step 4 (20 m BZ)
R1 Pond	1.149	Step 3	0.425	Step 3	0.629	Step 3	-	-	-	-
R1 Stream	0.541	Step 3	0.290	Step 3	0.673	Step 3	-	-	-	-
R2 Stream	0.395	Step 3	0.292	Step 3	0.719	Step 3	-	-	-	-
R3 Stream	1.446	Step 3	1.017	Step 3	0.857	Step 3	-	-	-	-
R4 Stream	0.764	Step 3	0.665	Step 3	0.824	Step 3	1.121	Step 4 (10m BZ + VFS)	0.950	Step 3

[&]quot;-" represents a non-relevant FOCUSsw scenario for that specific crop

BZ =no spray buffer zone

Vines not included because the maximum Step 3 PECsed value was already below the RAC

Values in bold exceed the RAC irrespective of the level of risk mitigation applied.



Summary of maximum PECsw values for the metabolites of cyantraniliprole (Steps 1 and 2) for the 100 g/l SE formulation

Substance	Step 1 Apples, Citrus and Olives (µg/l) (2 x 150 g a.s./ha)	Step 1 Vines (μg/l) (2 x 112.5 g a.s./ha)	Step 2 Apples (µg/l) (2 x 150 g a.s./ha with a 14 d interval)	Step 2 Citrus (µg/l) (2 x 150 g a.s./ha with a 7 d interval)	Step 2 Olives (µg/l) (2 x 150 g a.s./ha with a 10 d interval)	Step 2 Vines (µg/l) (2 x 112.5 g a.s./ha with a 14 d interval)
IN-J9Z38 ^a	34.451	14.558	13.372	13.4017	13.386	5.887
IN-K5A77	3.128	1.604				
IN-JCZ38	33.364	25.023	6.886	2.910	2.757	3.873
IN-JSE76	43.070	32.303				
IN-K5A79	9.122	6.842				
IN-K5A78	15.878	11.909				
IN-PLT97	9.786	7.340	3.059	1.156	1.152	1.721
IN-RNU71	12.389	8.489				
IN-QKV54	10.781	4.533				
IN-NXX70	8.034	3.196				
IN-M2G98	1.717	1.288				

NB: at Step 2, the Southern Europe simulations always gave the higher PEC_{sw} values compared with the Northern Europe simulations

 $^{^{}a}$ All PEC_{sw} values for IN-J9Z38 have been increased by a factor of 2.28 to cover the higher formation observed under field conditions of 41.7% compared to lab formation of 18.3% (i.e. 18.3/41.7 = 2.28)



Step 1 to 4 results: 200 g/l SC formulation

Step 1: Actual and time-weighted average PEC_{sw} and PEC_{sed} values for cyantraniliprole in Europe for the **200** g/l SC formulation (Tomatoes and field peppers (2 x 75 g a.s./ha))

	P	EC _{sw}	PEC _{sed}		
Time after application (days)	Actual PEC _{sw} (μg/L)	Time weighted PEC _{sw} (µg/L)	Actual PEC _{sed} (μg/kg)	Time weighted PEC _{sed} (µg/kg)	
0	39.767	-	76.750	-	
1	38.684	39.225	74.659	75.705	
2	37.630	38.690	72.626	74.671	
4	35.608	37.650	68.723	72.664	
7	32.777	36.160	63.259	69.788	
14	27.016	32.982	52.140	63.654	
21	22.267	30.176	42.975	58.240	
28	18.353	27.694	35.422	53.449	
42	12.468	23.536	24.064	45.425	
50	9.997	21.560	19.294	41.612	
100	2.513	13.490	4.850	26.036	

Step 2: Actual and time-weighted average PEC_{sw} and PEC_{sed} values for cyantraniliprole in Europe (northern and southern Europe) for the **200 g/l SC** formulation (Tomatoes and field peppers (2 x 75 g a.s./ha))

	Nor	thern Europ	e, March -	May	Southern Europe, March - May			
	PE	$\mathbf{CC_{sw}}$	PEC _{sed}		PEC_{sw}		PEC _{sed}	
Time after application (days)	Actual PEC _{sw} (μg/L)	Time weighted PEC _{sw} (µg/L)	Actual PEC _{sed} (µg/kg)	Time weighted PEC _{sed} (µg/kg)	Actual PEC _{sw} (µg/L)	Time weighted PEC _{sw} (µg/L)	Actual PEC _{sed} (μg/kg)	Time weighted PEC _{sed} (µg/kg)
0	7.495	-	14.465	-	14.990	-	28.930	-
1	7.291	7.393	14.455	14.460	14.582	14.786	28.910	28.920
2	7.132	7.302	14.140	14.379	14.264	14.604	28.280	28.758
4	6.824	7.140	13.530	14.106	13.648	14.279	27.060	28.212
7	6.387	6.910	12.664	13.672	12.775	13.820	25.328	27.344
14	5.474	6.415	10.853	12.704	10.948	12.829	21.706	25.408
21	4.691	5.967	9.301	11.822	9.382	11.935	18.602	23.644
28	4.020	5.562	7.971	11.021	8.041	11.125	15.942	22.042
42	2.953	4.861	5.854	9.634	5.905	9.723	11.709	19.267
50	2.475	4.517	4.908	8.951	4.951	9.033	9.815	17.902
100	0.822	3.008	1.630	5.962	1.644	6.017	3.260	11.925



Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC_{sw} value below the RAC of 1 μ g/l for each scenario and water body combination for the **200** g/l SC formulation

	Tomatoes and field peppers (2 x 75 g a.s./ha)					
Scenario	PEC _{sw}	Assessment tier and mitigation				
	(µg/l)	Assessment der and midgadon				
D6 Ditch	0.291	Step 3				
R2 Stream	0.779	Step 4 (10 m VFS)				
R3 Stream	0.838	Step 4 (20 m VFS)				
R4 Stream	0.904	Step 4 (20 m VFS)				

Summary of maximum PEC_{sw} values for the metabolites of cyantraniliprole for the **200 g/l SC formulation** (Steps 1 and 2) (Tomatoes and field peppers (2 x 75 g a.s./ha))

Substance	Step 1	Step 2
	(µg/l)	(μg/l)
IN-J9Z38 ^a	1.863	
IN-K5A77	0.554	
IN-JCZ38	16.682	
IN-JSE76	21.535	
IN-K5A79	4.561	
IN-K5A78	7.939	
IN-PLT97	4.893	1.926
IN-RNU71	5.101	
IN-QKV54	0.552	
IN-NXX70	0.163	
IN-M2G98	0.859	

 $[\]overline{\text{NB}}$: at Step 2, the Southern Europe simulations always gave the higher $\overline{\text{PEC}}_{\text{sw}}$ values compared with the Northern Europe simulations

 $^{^{}a}$ All PEC_{sw} values for IN-J9Z38 have been increased by a factor of 2.28 to cover the higher formation observed under field conditions of 41.7% compared to lab formation of 18.3% (i.e. 18.3/41.7 = 2.28)



200 g/l SC formulation: Glasshouse uses (simple drift losses to a 30cm deep static water body only)

Maximum initial PEC_{sw} and PEC_{sed} values of cyantraniliprole and its metabolites following application of cyantraniliprole to fruiting vegetables (4 x 100 g a.s./ha)

	Initial PE	C _{sw} (μg/L)	Initial PEC _{sed} (μ g/kg)		
Compound	Drift (acc. to FOCUS SW Step 3 at 5 m - 0.3808% for 4 applications)	Drift ^a (Ultra-low Volume Application, 0.2%)	Drift (acc. to FOCUS SW Step 3 at 5 m)	Drift ^a (Ultra-low Volume Application)	
Cyantraniliprole	0.389	0.204	0.639	0.335	
IN-J9Z38	0.276	0.145	2.809	1.476	
IN-K5A77	0.065	0.034	3.780	1.986	
IN-RNU71	0.050	0.026	0.179	0.094	
IN-QKV54	0.246	0.129	2.181	1.145	
IN-NXX70	0.206	0.108	2.908	1.527	

Worst case emission assumptions resulting from indoor ultra-low volume applications (FOCUS, 2008).

Maximum initial PEC_{sw} and PEC_{sed} values of cyantraniliprole and its metabolites following application of cyantraniliprole to leafy vegetables (3 x 100 g a.s./ha)

	Initial PE	C _{sw} (µg/L)	Initial PEC _{sed} (μg/kg)		
Compound	Drift (acc. to FOCUS SW Step 3 at 5 m- 0.4078% for 3 applications)	Drift ^a (Ultra-low Volume Application, 0.2%)	Drift (acc. to FOCUS SW Step 3 at 5 m)	Drift ^a (Ultra-low Volume Application)	
Cyantraniliprole	0.340	0.167	0.514	0.252	
IN-J9Z38	0.223	0.110	2.262	1.109	
IN-K5A77	0.052	0.026	3.044	1.493	
IN-RNU71	0.041	0.020	0.144	0.071	
IN-QKV54	0.214	0.105	1.892	0.928	
IN-NXX70	0.176	0.086	2.484	1.218	

Worst case emission assumptions resulting from indoor ultra-low volume applications (FOCUS, 2008).



Step 3 and 4 results: 400 g/kg WG formulation

Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC $_{sw}$ value below the RAC of 1 μ g/l for each scenario and water body combination for the **400 g/kg WG** formulation

	App	lles (Pome fruit late, 2 x 125 g a.s./ha)
Scenario	PECsw (μg/l)	Assessment tier and mitigation
D3 Ditch	0.431	Step 4 (20 m BZ; single application GAP)
D4 Pond	1.799	Step 4 (20 m BZ, multiple application GAP)
D4 Stream	2,294	Step 4 (20 m BZ, multiple application GAP)
D5 Pond	0.675	Step 3 (multiple application GAP)
D5 Stream	0.850	Step 4 (20 m BZ, multiple application GAP)
R1 Pond	0.318	Step 3 (multiple application GAP)
R1 Stream	1.109	Step 4 (20 m BZ and VFS, multiple application GAP)
R2 Stream	0.549	Step 4 (20 m BZ and VFS, multiple application GAP)
R3 Stream	0.531	Step 4 (20 m BZ and VFS, single application GAP)
R4 Stream	0.918	Step 4 (20 m BZ and VFS, multiple application GAP)

BZ = no spray buffer zone VFS = vegetated filter strip

values in bold exceed the RAC irrespective of the level of risk mitigation currently applied



Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC $_{sed}$ value below the RAC of 2.41 $\mu g/kg$ for each scenario and water body combination for the **400 g/kg WG** formulation

	App	les (Pome fruit late, 2 x 125 g a.s./ha)
Scenario	PECsed (μg/kg) 1.707 5.275 2.471 2.432 1.442 0.597 1.569 1.006 0.720	Assessment tier and mitigation
D3 Ditch	1.707	Step 3 (multiple application GAP)
D4 Pond	5.275	Step 4 (20 m BZ and VFS, multiple application GAP)
D4 Stream	2.471	Step 4 (20 m BZ and VFS, multiple application GAP)
D5 Pond	2.432	Step 4 (20 m BZ and VFS, multiple application GAP)
D5 Stream	1.442	Step 3 (multiple application GAP)
R1 Pond	0.597	Step 3 (multiple application GAP)
R1 Stream	1.569	Step 3 (multiple application GAP)
R2 Stream	1.006	Step 3 (multiple application GAP)
R3 Stream	0.720	Step 3 (multiple application GAP)
R4 Stream	1.274	Step 3 (multiple application GAP)

BZ = no spray buffer zone VFS = vegetated filter strip

values in bold exceed the RAC irrespective of the level of risk mitigation currently applied



Metabolites IN-J9Z38, IN-RNU71 and IN-NXX70: Maximum Step 3calculated PEC Following Applications of **400 g/kg WG** formulation (Pome fruit late, 2 x 125 g a.s./ha) at FOCUS step 3

Application scheme	10 70 Television (10	Maximum ated PEC		Maximum ited PEC	IN-NXX70 Maximum Calculated PEC		
(g a.s. ha ⁻¹)	PEC _{sw} (μg L ⁻¹)	PEC _{SED} (μg kg ⁻¹)	PEC _{sw} (μg L ⁻¹)	PEC _{SED} (μg kg ⁻¹)	PEC _{sw} (μg L ⁻¹)	PEC _{SED} (μg kg ⁻¹)	
1 x 125	0.176	1.773	0.100	0.286	0.179	0.624	
2 x 125	0.259	2.826	0.143	0.616	0.258	0.916	



PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study – FOCUS modelling

For FOCUS gw modelling, values used -

Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.

Model(s) used: (with version control no.(s)) FOCUS PELMO 4.4.3 and FOCUS PEARL 4.4.4

Crop and scenarios:-

100 g/l OD

Lettuce: Châteaudun, Hamburg, Jokioinen, Kremsmünster, Porto, Sevilla, Thiva

Melons: Châteaudun, Hamburg, Jokioinen,

Kremsmünster, Okehampton, Piacenza, Porto, Sevilla,

Tomatoes: Châteaudun, Piacenza, Porto, Sevilla, Thiva

Beans: Porto, Thiva

Note the melon assessment is considered sufficient to address the proposed use on potatoes at a lower application rate of only 2 x 12.5 g a.s./ha. The tomato assessment is considered sufficient to address the proposed use on peppers at the same rate and timings.

100 g/l SE

Apples: Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiya

Citrus: Piacenza, Porto, Sevilla, Thiva

Vines: Châteaudun, Hamburg, Kremsmünster, Piacenza, Porto, Sevilla, Thiva

Note the apple assessment is considered sufficient to address the proposed uses on pears, nectarines, peaches, apricots and olives as the highest proposed application rate of $2 \times 150 \, \mathrm{g}$ a.s./ha was used in the simulation.

200 g/l SC

Field tomato and field pepper: Châteaudun, Piacenza, Porto, Sevilla, Thiva

400 g/kg WG

The proposed uses of the 400 g/kg WG formulation fall within the GAP modelled for the 100 g/l SE formulation.

Geometric mean or median parent $DT_{50lab/field}$ and K_{OC} : parent and metabolites – see larger summary table below

See below for each formulation

Application rate



Maximum application scenarios for the $100 \ g/l \ OD$ formulation

GAP Crop	FOCUS Crop	Appl. rate (g a.s./ha)		BBCH Stage	Growth description	First application (days after emergence)	Worst-case FOCUS interception (%)	Max soil deposit (g a.s./ha)
Lettuce	Cabbage	2 × 90	7	10-89	Leaf dev to ripe fruit	10	25 + 40	67.5 + 54
Melons	Potato	2 × 90	7	10-89	Leaf dev to ripe fruit	10	15 + 50	76.5 + 45
Tomatoes	Tomato	2 × 90	7	10-89	Leaf dev to ripe fruit	10	50 + 70	45 + 27
Beans	Beans (vegetable)	2 × 90	7	10-89	leaf dev – ripe fruit	10 ^a	25+40	67.5+54

The Thiva scenario covers two growth periods for beans (vegetables) (FOCUS, 2009), which are named Thiva (early) (emergence April 1) and Thiva (late) (emergence July 8)

Maximum application scenarios for the 100 g/L SE formulation

GAP crop	FOCUS crop	Appl. rate (g ai/ha)	Interval (d)	BBCH Stage	Growth description	First application (days after emergence)	Worst-case FOCUS Interception (%)	Max soil deposit (g ai/ha)
Nectarines	Apples	2 × 150	14	11-79	Leaf development to fruit development	10	65 + 70	52.5 + 45.0
Nectarines	Apples	2 × 150	7	11-79	Leaf development to fruit development	10	65 + 70	52.5 + 45.0
Apples, peaches, apricots, pears and olives	Apples	2 × 90	7	11-79	Leaf development to fruit development	10	65 + 70	31.5 + 27.0
Citrus	Citrus	2 × 150	7	09-71	Leaf development to fruit development	10	70	2 × 45.0
Vines	Vines	2 × 112.5	14	55-85	Flowering to fruit development	10	70	2 × 33.75



Maximum application scenarios for the $200\ g/L\ SC$ formulation

GAP Crop	FOCUS Crop	Appl. rate (g a.s./ha)	Interval (d)	BBCH Stage	Growth description	First application (days after emergence)	Worst-case FOCUS interception (%)	Max soil deposit (g a.s./ha)
Field Tomato/ Field Pepper	Tomato	2 × 75	7	10-89	Leaf dev to ripe fruit	10	0	75 + 75



Compound	Parameter	Unit	Value	Remarks
	Molecular weight	g/mol	473.7	
	Solubility in water	mg/L	14.2	
	Vapour pressure (20°C)	Pa	5.1×10^{-15}	
	K _{FOC}	L/kg	193	Arithmetic mean
Cyantraniliprole	K _{FOM}	L/kg	112	Arithmetic mean
Cyantranniprofe	Freundlich exponent	1/n	0.93	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	Days	87 ^a /13.3 ^b	Longest /Shortest (Tier-1)
	Calculated DT ₅₀	Days	60.9°/73.6°/58.74°	At pH 5.9/pH 5.3/pH 6.0 (Tier 2)
			54.5 ^f /63 ^g /67.2 ^h	At pH 6.2/pH5.8/pH5.6 (Tier 2)
	Plant uptake	(-)	0.5	Default
	Molecular weight	g/mol	455.7	
	Solubility in water	mg/L	14.2	Parent data
	Vapour pressure (20°C)	Pa	5.1×10^{-15}	Parent data
	K _{FOC}	L/kg	7334	Arithmetic mean
	K _{FOM}	L/kg	4254	Arithmetic mean
	Freundlich exponent	1/n	0.95	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	Days	90.0	Geomean (Tier-1)
IN-J9Z38	Kinetic conversion	(-)	0.29	Average, Lab (Tier-1)
	Vinatia annuanian fan	(-)	0.66	Photolysis from parent (lab moist soil) (Tier-1)
	Kinetic conversion for	(-)	0.05	Field study from parent (Tier-2)
	photo degradation			Peak conc. observed for IN-RNU71 in
		(-)	0.01	field study is used for SE formulation on
				Apples only (Tier-3)
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g/mol	491.7	
	Solubility in water	mg/L	14.2	Parent data
	Vapour pressure (20°C)	Pa	5.1×10^{-15}	Parent data
	K _{FOC}	L/kg	174	Arithmetic mean
	K _{FOM}	L/kg	101	Arithmetic mean
IN-JCZ38	Freundlich exponent	1/n	0.90	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	Days	12.8	Geomean (Tier -1)
	Kinetic conversion	(-)	0.67	Average, Lab (Tier -1)
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g/mol	492.7	
	Solubility in water	mg/L	14.2	Parent data
	Vapour pressure (20°C)	Pa	5.1×10^{-15}	Parent data
	K _{FOC}	L/kg	27	Arithmetic mean
	K _{FOM}	L/kg	16	Arithmetic mean
IN-JSE76	Freundlich exponent	1/n	0.99	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	Days	109	Geomean (Tier-1)
	Kinetic conversion	(-)	0.92	Average, Lab (Tier-1)
	Plant uptake	(-)	0.0	Worst-case



Compound	Parameter	Unit	Value	Remarks
	Molecular weight	g/mol	473.7	
	Solubility in water	mg/L	14.2	Parent data
	Vapour pressure (20°C)	Pa	5.1×10^{-15}	Parent data
	K _{FOC}	L/kg	5300	Arithmetic mean
	K_{FOM}	L/kg	3074	Arithmetic mean
IN-K5A77	Freundlich exponent	1/n	0.88	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	Days	58.6	Geomean (Tier-1)
	Kinetic conversion	(-)	0.90	Average, Lab (Tier-1)
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g/mol	474.7	
	Solubility in water	mg/L	14.2	Parent data
	Vapour pressure (20°C)	Pa	5.1×10^{-15}	Parent data
	K_{FOC}	L/kg	608	Arithmetic mean
	K _{FOM}	L/kg	353	Arithmetic mean
IN-K5A78	Freundlich exponent	1/n	0.86	Arithmetic mean
IN-KSA76	DegT ₅₀ lab. (20°C/pF 2)	Days	173.6	Geomean (Tier-1)
	Kinetic conversion	(-)	0.96 0.51	Average, Lab (Tier-1) from IN-K5A77 Average, Lab (Tier-1) from IN-JSE76
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g/mol	478.7	
	Solubility in water	mg/L	14.2	Parent data
	Vapour pressure (20°C)	Pa	5.1×10^{-15}	Parent data
	K _{FOC}	L/kg	26	Arithmetic mean (pH >6.5)
	K _{FOM}	L/kg	15.1	Arithmetic mean (pH >6.5)
IN-K5A79	Freundlich exponent	1/n	0.93	Arithmetic mean (pH >6.5)
	DegT ₅₀ lab. (20°C/pF 2)	Days	39	Geomean (Tier-1)
	Kinetic conversion	(-)	0.62	Average, Lab (Tier-1)
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g/mol	301.5	
	Solubility in water	mg/L	14.2	Parent data
	Vapour Pressure (20°C)	Pa	5.1×10^{-15}	Parent data
	K _{FOC}	L/kg	111.8	Calculated based on its structure
IN-M2G98	K _{FOM}	L/kg	64.8	Calculated based on its structure
111-1112030	Freundlich exponent	1/n	1.0	default for K_d
	DegT ₅₀ lab. (20°C/pF 2)	Days	160.9	Geomean (two soils)
	Kinetic conversion	(-)	0.57	Average (Sassafras and Tama soils) from IN-K5A79
	Plant uptake	(-)	0.0	Worst-case



Compound	Parameter	Unit	Value	Remarks
	Molecular weight	g/mol	437.3	
	Solubility in water	mg/L	14.2	Parent data
	Vapour Pressure (20°C)	Pa	5.1×10^{-15}	Parent data
	K_{FOC}	L/kg	7334	Assumed same as IN-J9Z38
	K_{FOM}	L/kg	4254	Assumed same as IN-J9Z38
	Freundlich exponent	1/n	0.95	Assumed same as IN-J9Z38
IN-NXX70	DegT ₅₀ lab. (20°C/pF 2)	Days	1.5	From moist soil photolysis study, SFO DT ₅₀
		(-)	0.34	Photolysis, from cyantraniliprole (Tier-1)
	Kinetic conversion		0.05	Field study, from cyantraniliprole (Tier-2)
		(-)	1.00	Photolysis, from IN-RNU71 (Tier-2)
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g/mol	460.7	
	Solubility in water	mg/L	14.2	Parent data
	Vapour Pressure (20°C)	Pa	5.1×10^{-15}	Parent data
	K_{FOC}	L/kg	1208	Arithmetic mean
	K_{FOM}	L/kg	701	Arithmetic mean
IN-PLT97	Freundlich exponent	1/n	0.85	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	Days	323	Geomean (Tier-1)
	Kinetic conversion	(-)	0.68	Average, Lab, from IN-K5A79 (Tier-1)
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g/mol	437.3	
	Solubility in water	mg/L	14.2	Parent data
	Vapour Pressure (20°C)	Pa	5.1×10^{-15}	Parent data
	K_{FOC}	L/kg	139	Arithmetic mean
IN-RNU71	K_{FOM}	L/kg	80.6	Arithmetic mean
	Freundlich exponent	1/n	0.98	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	Days	69.0	Geomean
	Kinetic conversion	(-)	1.00	Photolysis, from IN-J9Z38
	Plant uptake	(-)	0.0	Worst-case
	Molecular weight	g/mol	344.2	
	Solubility in water	mg/L	14.2	Parent data
	Vapour Pressure (20°C)	Pa	5.1×10^{-15}	Parent data
	K _{FOC}	L/kg	6165	Arithmetic mean
IN-QKV54	K_{FOM}	L/kg	3576	Arithmetic mean
	Freundlich exponent	1/n	0.83	Arithmetic mean
	DegT ₅₀ lab. (20°C/pF 2)	Days	274	Geomean
	Kinetic conversion	(-)	1.00	Photolysis, from IN-NXX70
	Plant uptake	(-)	0.0	Worst-case

^a Maximum DegT₅₀ used in the simulations for parent; ^b Minimum DegT₅₀ used in the simulations for metabolites

^cUsed for lettuce and melons; ^dfor tomatoes and beans; ^efor field tomatoes/peppers for the 200g/l SC; ^ffor apples; ^gfor citrus; ^hfor vines



The Tier-1 maximum 80th percentile PEC_{gw} values of Cyantraniliprole and its metabolites after application of the <u>100 g/l OD</u> formulation on lettuce, melons, tomatoes, and beans, as predicted with <u>FOCUS PELMO 4.4.3</u>

Application scenario	Total soil	Cyantranili	IN-JCZ38	IN-JSE76	IN-	IN-	IN-	IN-	IN-	IN-
	deposition (g/ha)	prole			K5A79	PLT97	J9Z38	K5A77	K5A78	M2G98
			Max	ximum 80 th per	centile PE	Cgw (µg/l)				
Lettuce (2 x 90 g a.s./ha every year)	121.5	0.284	< 0.001	14.526	2.844	0.616	< 0.001	< 0.001	0.436	1.986
Melons (2 x 90 g a.s./ha every year)	121.5	0.349	< 0.001	13.506	2.742	0.659	< 0.001	< 0.001	0.556	2.337
Tomatoes (2 x 90 g a.s./ha every year)	72.0	0.168	< 0.001	7.298	1.720	0.389	< 0.001	< 0.001	0.280	1.603
Beans (2 x 90 g a.s./ha every year)	121.5	0.182	< 0.001	10.216	2.379	0.718	< 0.001	< 0.001	0.476	2.131
		IN-NXX70	IN-RNU71 ^a	IN-QKV54						
Lettuce (2 x 90 g a.s./ha every year)	121.5	0.009	0.956	0.053						
Melons (2 x 90 g a.s./ha every year)	121.5	0.008	0.897	0.045						
Tomatoes (2 x 90 g a.s./ha every year)	72.0	0.004	0.467	0.019						
Beans (2 x 90 g a.s./ha every year)	121.5	< 0.001	0.655	0.008						

The DegT50 of 87 days was used to calculate worst-case PEC_{GW} for cyantraniliprole, while DT50 of 13.3 days was used to calculate worst-case formation of metabolites.

^a all Tier 2 PECgw values for IN-RNU71 were <0.1µg/l



The Tier-1 maximum 80th percentile PEC_{gw} values of Cyantraniliprole and its metabolites after application of the <u>100 g/l OD</u> formulation on lettuce, melons, tomatoes, and beans, as predicted with <u>FOCUS PEARL 4.4.4</u>

Application scenario	Total soil deposition (g/ha)	Cyantranili prole	IN-JCZ38	IN-JSE76	IN- K5A79	IN- PLT97	IN- J9Z38	IN- K5A77	IN- K5A78	IN- M2G98
			Ma	 ximum 80 th per	centile PE	Cgw (μg/l)				
Lettuce (2 x 90 g a.s./ha every year)	121.5	0.357	< 0.001	14.603	3.041	0.741	< 0.001	< 0.001	0.522	1.902
Melons (2 x 90 g a.s./ha every year)	121.5	0.382	< 0.001	15.311	3.160	0.787	< 0.001	< 0.001	0.529	2.978
Tomatoes (2 x 90 g a.s./ha every year)	72.0	0.159	< 0.001	7.891	1.901	0.485	< 0.001	< 0.001	0.328	1.847
Beans (2 x 90 g a.s./ha every year)	121.5	0.163	< 0.001	11.360	2.706	0.932	< 0.001	< 0.001	0.544	2.354
		IN-NXX70	IN-RNU71 ^a	IN-QKV54						
Lettuce (2 x 90 g a.s./ha every year)	121.5	0.012	0.921	0.028						
Melons (2 x 90 g a.s./ha every year)	121.5	0.011	0.914	0.026						
Tomatoes (2 x 90 g a.s./ha every year)	72.0	0.005	0.444	0.015						
Beans (2 x 90 g a.s./ha every year)	121.5	< 0.001	0.559	0.007						

The DegT50 of 87 days was used to calculate worst-case PEC_{GW} for cyantraniliprole, while DT50 of 13.3 days was used to calculate worst-case formation of metabolites.

^a all Tier 2 PECgw values for IN-RNU71 were <0.1μg/l



Additional modelling was performed as a result of discussions at Pesticides peer review 113 to explore the effect of increasing the parent DT_{50} on the PECgw values of the IN-JCZ38 and IN-JSE76 pathway. Results below (simulated with PEARL 4.4.4) are for the lettuce GAP.

Scenario	CyanT	IN- JCZ38	IN- JSE76	CyanT	IN- JCZ38	IN- JSE76
	Parent m	odelling DT	$t_{50} = 13.3 \text{ d}$	Parent m	odelling D	$T_{50} = 87 d$
Châteaudun	< 0.001	< 0.001	11.040	0.143	0.011	11.894
Hamburg	< 0.001	< 0.001	14.603	0.357	0.032	15.559
Jokioinen	< 0.001	< 0.001	13.338	0.098	0.007	13.846
Kremsmünster	< 0.001	< 0.001	9.291	0.265	0.022	10.103
Porto	< 0.001	< 0.001	5.405	0.160	0.012	6.355
Sevilla	< 0.001	< 0.001	5.877	0.004	< 0.001	6.935
Thiva	< 0.001	< 0.001	10.030	0.084	0.006	8.386

The Tier-1 maximum 80th percentile PEC_{gw} values of Cyantraniliprole and its metabolites after application of the <u>100 g/l SE</u> formulation on apples, citrus and vines as predicted with <u>FOCUS PELMO 4.4.3</u>

Application scenario	Total soil deposition	Cyantra	IN-	IN-	IN-	IN-	IN-	IN-	IN-	IN-
	(g/ha)	niliprole	JCZ38	JSE76	K5A79	PLT97	J9Z38	K5A77	K5A78	M2G98
		Maximum 80 ^t				^h percentile PECgw (μg/l)				
Apples (2 x 150 g a.s./ha every year, 14 d interval)	97.5	0.428	< 0.001	18.903	4.768	1.277	< 0.001	<0.001	0.874	4.092
Apples (2 x 150 g a.s./ha every year, 7 d interval)	97.5	0.428	< 0.001	19.033	4.807	1.282	< 0.001	<0.001	0.876	4.104
Apples (2 x 90 g a.s./ha every year, 7 d interval)	58.5	0.229	< 0.001	11.362	2.807	0.701	< 0.001	<0.001	0.486	2.460
Citrus (2 x 150 g a.s./ha every year)	90.0	0.300	< 0.001	6.056	1.485	0.348	< 0.001	< 0.001	0.246	1.360
Vines (2 x 112.5 g a.s./ha every year)	67.5	0.223	< 0.001	8.238	2.098	0.608	< 0.001	< 0.001	0.413	2.333
		IN- NXX70	IN- RNU71 a	IN- QKV54						
Apples (2 x 150 g a.s./ha every year)	97.5	0.011	1.128	0.053						
Citrus (2 x 150 g a.s./ha every year)	90.0	0.006	0.680	0.023						
Vines (2 x 112.5 g a.s./ha every year)	67.5	0.006	0.637	0.028						

The DegT₅₀ of 87 days was used to calculate worst-case PEC_{gw} for cyantraniliprole, while DT₅₀ of 13.3 days was used to calculate worst-case formation of metabolites.

 $^{^{}a}$ all Tier 2 PECgw values for IN-RNU71 were $<\!0.1\mu g/l$



The Tier-1 maximum 80th percentile PEC_{gw} values of Cyantraniliprole and its metabolites after application of the <u>100 g/l SE</u> formulation on apples, citrus and vines as predicted with <u>FOCUS PEARL 4.4.4</u>

Application scenario	Total soil deposition	Cyantra	IN-	IN-	IN-	IN-	IN-	IN-	IN-	IN-
	(g/ha)	niliprole	JCZ38	JSE76	K5A79	PLT97	J9Z38	K5A77	K5A78	M2G98
			Ma	ximum 80 th	percentile	PECgw (µ	ıg/l)			
Apples (2 x 150 g a.s./ha every year, 14 d interval)	97.5	0.572	< 0.001	24.434	5.219	1.174	< 0.001	<0.001	0.992	3.842
Apples (2 x 150 g a.s./ha every year, 7 d interval)	97.5	0.568	<0.001	24.394	5.224	1.172	< 0.001	<0.001	0.989	3.845
Apples (2 x 90 g a.s./ha every year, 7 d interval)	58.5	0.304	<0.001	14.589	3.079	0.653	< 0.001	<0.001	0.565	2.306
Citrus (2 x 150 g a.s./ha every year)	90.0	0.266	< 0.001	9.488	2.451	0.489	< 0.001	<0.001	0.364	2.265
Vines (2 x 112.5 g a.s./ha every year)	67.5	0.215	< 0.001	7.501	1.875	0.478	< 0.001	<0.001	0.342	1.914
		IN- NXX70	IN- RNU71	IN- QKV54						
Apples (2 x 150 g a.s./ha every year)	97.5	0.019	1.610	0.058		_				
Citrus (2 x 150 g a.s./ha every year)	90.0	0.008	0.701	0.025						_
Vines (2 x 112.5 g a.s./ha every year)	67.5	0.008	0.549	0.019					•	

The $DegT_{50}$ of 87 days was used to calculate worst-case PEC_{GW} for cyantraniliprole, while DT_{50} of 13.3 days was used to calculate worst-case formation of metabolites.

Additional modelling was performed as a result of discussions at Pesticides peer review 113 to explore the effect of increasing the parent DT_{50} on the PECgw values of the IN-JCZ38 and IN-JSE76 pathway. Results below (simulated with PEARL 4.4.4) are for the 2 x 150 g a.s./ha GAP with 7 d intervals.

a all Tier 2 PECgw values for IN-RNU71 were <0.1 µg/l, except for apples at one scenario which was reduced to <0.1 µg/l at Tier 3 based on maximum peak concentration of IN-RNU71 in the field.



Scenario	CyanT	IN- JCZ38	IN- JSE76	CyanT	IN- JCZ38	IN- JSE76	CyanT	IN- JCZ38	IN- JSE76	CyanT	IN- JCZ38	IN- JSE76
	Parent mo	delling DT ₅₀	$_{0} = 13.3 d$	Parent m	odelling DT	$T_{50} = 22.9 \text{ d}$	Parent m	nodelling I	$OT_{50} = 52.2 d$	Parent	modelling	$DT_{50} = 87 d$
Châteaudun	< 0.001	< 0.001	14.173	< 0.001	< 0.001	14.296	0.028	0.004	14.559	0.320	0.028	15.035
Hamburg	< 0.001	< 0.001	24.394	< 0.001	< 0.001	24.669	0.073	0.013	25.097	0.568	0.055	25.548
Jokioinen	< 0.001	< 0.001	19.314	< 0.001	< 0.001	19.371	0.006	0.001	19.682	0.127	0.010	19.879
Kremsmünster	< 0.001	< 0.001	10.426	< 0.001	< 0.001	10.710	0.031	0.005	11.253	0.304	0.026	11.609
Okehampton	< 0.001	< 0.001	8.471	< 0.001	< 0.001	8.699	0.042	0.006	9.240	0.372	0.032	9.504
Piacenza	< 0.001	< 0.001	12.203	< 0.001	< 0.001	12.333	0.028	0.005	12.683	0.286	0.027	12.876
Porto	< 0.001	< 0.001	5.778	< 0.001	< 0.001	5.955	0.014	0.002	6.246	0.172	0.013	6.432
Sevilla	< 0.001	< 0.001	16.734	< 0.001	< 0.001	16.553	0.018	0.002	16.246	0.211	0.018	16.132
Thiva	< 0.001	< 0.001	20.435	< 0.001	< 0.001	20.664	0.017	0.002	20.879	0.232	0.020	21.081



The Tier-1 maximum 80th percentile PEC_{gw} values of Cyantraniliprole and its metabolites after application of the $\underline{200 \text{ g/l SC}}$ formulation on tomatoes (and as a surrogate crop for peppers) as predicted with $\underline{FOCUS \text{ PELMO 4.4.3}}$

Application scenario	Total soil deposition (g/ha)	Cyantra niliprole	IN- JCZ38	IN- JSE76	IN- K5A79	IN- PLT97	IN- J9Z38	IN- K5A77	IN- K5A78	IN- M2G98
	Maximum 80 th percentile PECgw (μg/l)									
Tomato (2 x 75 g a.s./ha every year)	150	0.415	< 0.001	15.291	3.687	0.916	< 0.001	< 0.001	0.641	3.348
		IN- NXX70	IN- RNU71	IN- QKV54						
Tomato (2 x 75 g a.s./ha every year)	150	0.009	1.011	0.042						

The Deg T_{50} of 87 days was used to calculate worst-case PEC_{sw} for cyantraniliprole, while DT_{50} of 13.3 days was used to calculate worst-case formation of metabolites. ^a all Tier 2 PECgw values for IN-RNU71 were <0.1 μ g/l



The Tier-1 maximum 80th percentile PEC_{gw} values of Cyantraniliprole and its metabolites after application of the $\underline{200 \text{ g/l SC}}$ formulation on tomatoes (and as a surrogate crop for peppers) as predicted with $\underline{FOCUS \ PEARL \ 4.4.4}$

Application scenario	Total soil deposition (g/ha)	Cyantra niliprole	IN- JCZ38	IN- JSE76	IN- K5A79	IN- PLT97	IN- J9Z38	IN- K5A77	IN- K5A78	IN- M2G98
	Maximum 80 th percentile PECgw (μg/l)									
Tomato (2 x 75 g a.s./ha every year)	150	0.394	< 0.001	16.540	4.068	1.141	< 0.001	< 0.001	0.749	3.850
		IN- NXX70	IN- RNU71	IN- QKV54						
Tomato (2 x 75 g a.s./ha every year)	150	0.011	0.957	0.034						

The $DegT_{50}$ of 87 days was used to calculate worst-case PEC_{GW} for cyantraniliprole, while DT_{50} of 13.3 days was used to calculate worst-case formation of metabolites. ^a all Tier 2 PECgw values for IN-RNU71 were <0.1 μ g/l



Tier 2 80^{th} Percentile PEC_{gw} of cyantraniliprole from application of the **100 g/L OD** formulation to lettuce, melons, tomatoes, and beans

int	Crops	Lettuce	Melon	Tomatoes	Beans
End point	рН	5.9	5.9	5.3	5.3
Enc	Calculated DT ₅₀ (days)	60.9	60.9	73.6	73.6
	PEC _{gw} (μg/	L) - FOCUS P	ELMO 4.4.3		
	Châteaudun	0.013	0.011	0.019	
	Hamburg	0.059	0.058	-	
0	Jokioinen	0.011	0.009	-	
nario	Kremsmünster	0.049	0.049	-	
FOCUS Scenario	Okehampton	-	0.083	-	
ns:	Piacenza	-	0.065	0.089	
,0C	Porto	0.049	0.043	0.043	0.092
<u> </u>	Sevilla	< 0.001	< 0.001	< 0.001	-
	Thiva (Early)	0.009	0.002	0.004	0.010
	Thiva (late)	=	=	-	0.017
	PEC _{gw} (μg/	L) – FOCUS P	EARL 4.4.4		
	Châteaudun	0.019	0.018	0.041	-
	Hamburg	0.082	0.087	-	=
0	Jokioinen	0.013	0.011	-	-
ıari	Kremsmünster	0.054	0.056	-	=
Scer	Okehampton	-	0.088	-	-
FOCUS Scenario	Piacenza	-	0.062	0.082	-
,oc	Porto	0.029	0.019	0.038	0.078
	Sevilla	< 0.001	< 0.001	< 0.001	-
	Thiva (early)	0.012	0.003	0.009	0.021
	Thiva (late)	-	- "	-	0.034

Tier 2 groundwater assessments used the following regression to estimate soil specific degradation rates: $DT_{50} = -21.268*pH_{(water)} + 186.36$



Tier-2 80^{th} percentile PEC_{gw} of cyantraniliprole from application of the ${f 100~g/L~SE}$ formulation to apples, citrus and vines

11 17 17 17 17 17 17 17 17 17 17 17 17 1							
End point	Crops	Nectarine (2 x 150 g a.s./ha, 14 d int.)	Nectarine (2 x 150 g a.s./ha, 7 d int.)	Apples (2 x 90 g a.s./ha, 7 d int.)	Citrus	Vines	
	pН	6.2	6.2	6.2	5.8	5.6	
	Calculated DT ₅₀ (days)	54.5	54.5	54.5	63.0	67.2	
PEC _{gw} (μg/L) - PELMO 4.4.3							
	Châteaudun	0.039	0.040	0.042	-	0.049	
0	Hamburg	0.047	0.047	0.047	-	0.080	
ari	Jokioinen	0.010	0.010	0.011	-	-	
cen	Kremsmünster	0.040	0.041	0.043	-	0.074	
FOCUS Scenario	Okehampton	0.068	0.068	0.067	-	-	
	Piacenza	0.077	0.077	0.074	0.096	0.090	
0.0	Porto	0.034	0.034	0.035	0.054	0.043	
Ξ.	Sevilla	0.003	0.004	0.004	0.009	0.004	
	Thiva	0.010	0.011	0.013	0.022	0.010	
PEC _{gw} (μg/L) - PEARL 4.4.4							
	Châteaudun	0.036	0.036	0.040	-	0.053	
0	Hamburg	0.091	0.090	0.089	-	0.079	
FOCUS Scenario	Jokioinen	0.008	0.008	0.010	-	-	
cen	Kremsmünster	0.038	0.039	0.042	-	0.060	
Š	Okehampton	0.052	0.052	0.053	-	-	
). U	Piacenza	0.036	0.035	0.039	0.076	0.059	
00	Porto	0.018	0.018	0.021	0.043	0.026	
Ŧ	Sevilla	0.023	0.023	0.024	0.029	0.020	
	Thiva	0.022	0.022	0.025	0.019	0.013	

Tier 2 groundwater assessments used the following regression to estimate soil specific degradation rates: $DT_{50} = -21.268*pH_{(water)} + 186.36$



Tier 2 80^{th} Percentile PEC_{gw} of cyantraniliprole from application of the **200 g/L SC** formulation to tomatoes and field peppers $(2 \times 75 \text{ g a.s./ha})$

int	Стор	Tomatoes
Endpoint	рН	6.0
En	Calculated DT ₅₀ (days)	58.74
	PEC_{gw} (µg/L) - PELMO 4.4.3	
rio	Châteaudun	0.013
FOCUS Scenario	Piacenza	0.087
SS	Porto	0.037
	Sevilla	< 0.001
FO	Thiva	0.003
	$PEC_{gw}\left(\mu g/L\right)-PEARL~4.4.4$	
rj.	Châteaudun	0.031
ena	Piacenza	0.075
FOCUS Scenario	Porto	0.031
	Sevilla	< 0.001
FO FO	Thiva	0.006

Tier 2 groundwater assessments used the following regression to estimate soil specific degradation rates: $DT_{50} = -21.268*pH_{(water)} + 186.36$



Fate and behaviour in air (Annex IIA, OECD Points IIA 7.10; Annex IIIA, OECD Point IIIA 9.9)

Latitude: 40 Season: summer DT₅₀: 0.23 days Direct photolysis in top layer of aqueous system Latitude: 40 Season: winter DT₅₀: 0.76 days Report No. DuPont-21506 [GC Solar method] Air concentration expected to be negligible due to low vapour pressure Quantum yield of direct Phototransformation Cyantraniliprole: Quantum yield calculated to be $\Phi = 1.195 \times 10^{-4}$ molecules degraded/photon Air concentration expected to be negligible Report No. DuPont-17060 due to low vapour pressure. If volatilized, photodegradation in air could be similar to The quantum efficiency for metabolites, for the water degradation. photolysis of IN-RNU71, IN-QKV54 and IN-NXX70 in water (pH 7) is: 9.0×10^{-06} , 2.003×10^{-07} and 2.3×10^{-04} , mol degraded/photon, respectively Report No. DuPont-20286 Photochemical oxidative degradation in air DT₅₀ of 8 hours derived by the Atkinson model (version (DT_{50}) 1988). OH (12 h) concentration assumed = 1.5×10^6 Report No. DuPont-21505 Volatilisation From plant surfaces: <0.001% after 24 hours Lyman method Report No. DuPont-27763 From soil: <0.001% after 24 hours Report No. DuPont-27763 PEC (air) Method of calculation Expected to be insignificant PEC(a) Maximum concentration Not studied



Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure Soil: Cyantraniliprole, IN-J9Z38, IN-JCZ38, IN-JSE76, IN-K5A78, IN-PLT97, IN-QKV54, IN-RNU71

Surface water: Cyantraniliprole, IN-J9Z38, IN-JCZ38, IN-JSE76, IN-K5A77, IN-K5A78, IN-PLT97, IN-QKV54, IN-RNU71 and IN-NXX70

Sediment: Cyantraniliprole, IN-J9Z38, IN-JCZ38, IN-JSE76, IN-K5A77, IN-K5A78, IN-PLT97, IN-QKV54, IN-RNU71 and IN-NXX70

Groundwater:- Cyantraniliprole, IN-J9Z38, IN-JCZ38, IN-JSE76, IN-K5A77, IN-K5A78, IN-K5A79, IN-PLT97, IN-QKV54, IN-RNU71 IN-NXX70 and IN-M2G98

Air: Cyantranilprole by default

Monitoring data, if available (Annex IIA, OECD Point IIA 7.12)

Soil (indicate location and type of study)	None.
Surface water (indicate location and type of study)	None.
Ground water (indicate location and type of study)	None.
Air (indicate location and type of study)	None.

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data Candidate for R53 in the EU



Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point	End point (mg/kg feed)
Birds ‡				
Bobwhite quail	a.s.	Acute	>2250 mg/kg bw	-
Zebra finch	a.s.	Acute	>2250 mg/kg bw	-
Bobwhite quail	Cyantraniliprole 100 g/L OD	Acute	>2250 mg/kg bw	-
Bobwhite quail	Cyantraniliprole 200 g/L SC	Acute	>2020 mg /kg bw	-
Bobwhite quail	a.s.	Short-term	>1343	>5620
Mallard duck	a.s.	Short-term	>2583	>5620
Bobwhite quail	a.s.	Long-term	93.2	1000
Mallard duck	a.s.	Long-term	139.6	1000
Mammals ‡				
Rat	a.s.	Acute	>5000 mg a.s. /kg bw	-
Rat	100 g/L OD	Acute	>5000 mg form/kg bw	-
Rat/Mouse	100 g/L SE	Acute	>5000 mg form/kg bw	-
Rat/Mouse	200 g/L SC	Acute	>5000 mg form/kg bw	-
Rat	400 g/kg WG 'A16971B'	Acute	>5000 mg form/kg bw	-
Rat	IN-JSE76	Acute	>5000 mg/kg bw	-
Mouse	IN-PLT97	Acute	>5000 mg/kg bw	-
Mouse	IN-F6L99	Acute	>2000 mg/kg bw	-
Mouse	IN-N5M09	Acute	>5000 mg/kg bw	-
Dog (1-year dietary)	a.s.	Long term	1 mg a.s./kg bw per day	40
Rabbit (developmental)	a.s.	Long-term	25 mg a.s./kg bw per day	-



Rat (2-generation)	a.s.	Long term	1.2 mg a.s./kg	20
			bw per day (adult)	200
			13.9 mg	200
			a.s./kg bw per day (offspring)	
			135.2 mg a.s./kg bw per	2000
			day (pup bodyweight)	

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Indicator species/Category	Time scale	DDD	TER	Trigger		
	Screeni	ng step – bir	ds			
Field uses (as ground directed spray) in melon, tomato, green bean, and pepper, lettuce, potatoes, (worst case: application rate 120 g a.s./ha, 4 application interval 7 day)						
Cyantraniliprole	Acute	20.0	>112	10		
IN-J9Z38 (27.9% TRR)	Acute	5.58 ^b	>40.3	10		
IN-NXX70 (21.7% TRR)	Acute	4.34 ^b	>51.8	10		
IN-QKV54 (10.3% TRR)	Acute	2.06 ^b	>109	10		
Cyantraniliprole	Reproductive	4.95	18.8	5		
IN-J9Z38 (27.9% TRR)	Reproductive	1.38	6.75	5		
IN-NXX70 (21.7% TRR)	Reproductive	1.07	8.68	5		
IN-QKV54 (10.3% TRR)	Reproductive	0.50	18.3	5		
	Screening	step – mamı	mals			
Field uses (as ground directed scase: appli	spray) in melon, to cation rate 120 g a					
Cyantraniliprole	Acute	17.2	291	10		
Cyantraniliprole	Reproductive	5.52	0.181	5		
	First ti	er – mamma	ls			
Tomato, pepper (2 x 90 g a.s./h	a with 7 d interval	on fruiting	vegetables, B	BCH 10-89)		
Frugivorous mammal "rat"	Reproductive	1.92	0.62	5		
Small insectivorous mammal "shrew"	Reproductive	0.32	3.74	5		
Small herbivorous mammal "vole"	Reproductive	5.52	0.22	5		
Small omnivorous mammal "mouse"	Reproductive	0.6	2.02	5		
Green bean (2 x 90 g a.s/ha with	7 d interval on puls	ses, BBCH 10)-89)			
Small insectivorous mammal "shrew"	Reproductive	0.32	3.74	5		
Small herbivorous mammal "vole"	Reproductive	5.52	0.22	5		
Large herbivorous mammal "lagomorph"	Reproductive	1.09	1.10	5		



Time scale	DDD	TER	Trigger
Reproductive	0.6	2.02	5
d interval on leafy	vegetables)		
Reproductive	0.28	4.32	5
Reproductive	4.78	0.25	5
Reproductive	0.95	1.27	5
Reproductive	0.52	2.33	5
4 d interval on po	tatoes, BBCI	H 31-60)	
Reproductive	0.04	30.8	5
Reproductive	0.20	5.96	5
Reproductive	0.13	9.05	5
Reproductive	0.07	16.59	5
Higher	tier - mamm	als	
a with 7 d interval	on fruiting	vegetables, B	BCH 10-89)
Reproductive	1.92	13	5
Reproductive	0.32	78.1	5
Reproductive	5.52	4.53	5
Reproductive	0.6	41.7	5
th 7 d interval on p	oulses, BBCH	I 10-89)	
Reproductive	0.32	78.1	5
Reproductive	5.52	4.53	5
Reproductive	1.09	22.9	5
Reproductive	0.6	41.7	5
d interval on leafy	vegetables)		
Reproductive	0.28	89.3	5
Reproductive	4.78	5.23	5
	ì	i	
Reproductive	0.95	26.3	5
	Reproductive Reproductive	Reproductive 0.6 d interval on leafy vegetables) Reproductive 0.28 Reproductive 4.78 Reproductive 0.95 Reproductive 0.52 d d interval on potatoes, BBCI Reproductive 0.20 Reproductive 0.13 Reproductive 0.07 Higher tier - mamma a with 7 d interval on fruiting Reproductive 0.32 Reproductive 0.32 Reproductive 0.6 th 7 d interval on pulses, BBCI Reproductive 0.32 Reproductive 0.6 th 7 d interval on pulses, BBCI Reproductive 0.32 Reproductive 0.6 d interval on leafy vegetables) Reproductive 0.6 d interval on leafy vegetables) Reproductive 0.28	Reproductive 0.6 2.02 d interval on leafy vegetables) Reproductive 0.28 4.32 Reproductive 4.78 0.25 Reproductive 0.95 1.27 Reproductive 0.52 2.33 4 d interval on potatoes, BBCH 31-60) Reproductive 0.04 30.8 Reproductive 0.20 5.96 Reproductive 0.13 9.05 Reproductive 0.07 16.59 Higher tier - mammals a with 7 d interval on fruiting vegetables, B Reproductive 1.92 13 Reproductive 0.32 78.1 Reproductive 0.6 41.7 th 7 d interval on pulses, BBCH 10-89) Reproductive 5.52 4.53 Reproductive 5.52 4.53 Reproductive 0.6 41.7 d interval on leafy vegetables) Reproductive 0.28 89.3

^a There are no toxicity data available for the metabolites, therefore the RMS has assumed them to be 10 times more toxic than the parent.

^b The DDD was calculated by taking account for the formation fraction, i.e. the maximum TRR percentage found in the plant metabolism studies



Indicator species/Category	Time scale	DDD	TER	Trigger
	Screenii	ng step – bir	ds	
Use in apples, pears, peaches,				
applications at 150 g a.s./ha); u	se in grapes (wors	t case: 2 app	lications at 1	12.5 g a.s./ha)
Cyantraniliprole		9.83	229	10
• •	Acute (orchard)			
IN-J9Z38 (27.9% TRR)	Acute (orchard)	2.74	82.1	10
IN-NXX70 (21.7% TRR)	Acute (orchard)	2.13	106	10
IN-QKV54 (10.3% TRR)	Acute (orchard)	1.01	222	10
Cyantraniliprole	Acute (vineyard)	13.94	161	10
IN-J9Z38 (27.9% TRR)	Acute (vineyard)	3.89	57.9	10
IN-NXX70 (21.7% TRR)	Acute (vineyard)	3.02	74.4	10
IN-QKV54 (10.3% TRR)	Acute (vineyard)	1.44	157	10
Cyantraniliprole	Reproductive (orchard)	2.32	40.3	5
IN-J9Z38 (27.9% TRR)	Reproductive (orchard)	0.65	14.4	5
IN-NXX70 (21.7% TRR)	Reproductive (orchard)	0.50	18.6	5
IN-QKV54 (10.3% TRR)	Reproductive (orchard)	0.24	39.1	5
Cyantraniliprole	Reproductive (vineyard)	3.25	28.7	5
IN-J9Z38 (27.9% TRR)	Reproductive (vineyard)	0.91	10.3	5
IN-NXX70 (21.7% TRR)	Reproductive (vineyard)	0.70	13.2	5
IN-QKV54 (10.3% TRR)	Reproductive (vineyard)	0.33	27.9	5
	Screening	step – mami	mals	
Use in apples, pears, peaches,				
applications at 150 g a.s./ha); u	se in grapes (wors	t case: 2 app	lications at 1	12.5 g a.s./ha)
Cyantraniliprole	Acute	28.6	175	10
Cyantraniliprole	Reproductive	10.1	0.109	5
	First tie	er - mamma	ls	
Citrus, mandarins, olives (2 x	150 g a.s./ha with 7	d interval o	on orchards, l	BBCH 9-89)
Small insectivorous mammal "shrew"	Reproductive	0.24	4.97	5
Small herbivorous mammal "vole"	Reproductive	9.20	0.13	5
Large herbivorous mammal "lagomorphs"	Reproductive	1.82	0.66	5
Small omnivorous mammal "mouse"	Reproductive	0.99	1.21	5
Frugivorous mammal "dormouse"	Reproductive	2.89	0.42	5



Indicator species/C	ategory	Time scale	DDD	TER	Trigger		
Grapes (2 x 112.5 g a					1115501		
Large herbivorous		Reproductive	0.30	4.07	5		
"lagomorphs"		Reproductive	0.30	4.07	3		
Small insectivorous "shrew"		Reproductive	0.17	7.06	5		
Small herbivorous "vole"	mammal	Reproductive	1.94	0.62	5		
Small omnivorous "mouse"	mammal	Reproductive	0.21	5.84	5		
Nectarines etc. (2 x 150 g a.s./ha with 7 d interval on orchards, BBCH 59-87)							
Small herbivorous "vole"	mammal	Reproductive	2.76	0.43	5		
Large herbivorous "lagomorphs"	mammal	Reproductive	0.55	2.19	5		
Small omnivorous "mouse"	mammal	Reproductive	0.29	4.10	5		
Frugivorous "dormouse"	mammal	Reproductive	2.89	0.42	5		
Apples, pears (2 x 90	g a.s./ha v	vith 7 d interval, F	BBCH 31-87)				
Small herbivorous "vole"	mammal	Reproductive	3.31	0.36	5		
Large herbivorous "lagomorphs"	mammal	Reproductive	0.66	1.83	5		
Small omnivorous "mouse"	mammal	Reproductive	0.36	3.35	5		
Frugivorous "dormouse"	mammal	Reproductive	1.73	0.69	5		
		Higher	tier - mamm	als			
Citrus,mandarins, ol	lives (2 x 1:	50 g a.s./ha with 7	d interval or	orchards, B	BCH 9-89)		
Small insectivorous "shrew"		Reproductive	0.24	104	5		
Small herbivorous "vole"	mammal	Reproductive	9.20	2.72	5		
Large herbivorous "lagomorphs"	mammal	Reproductive	1.82	13.7	5		
Small omnivorous "mouse"	mammal	Reproductive	0.99	25.3	5		
Frugivorous "dormouse"	mammal	Reproductive	2.89	8.65	5		
Grapes (2 x 112.5 g a	a.s./ha with	14 d interval on v	vinevard. BB	CH 55-85)			
Large herbivorous	mammal	Reproductive	0.30	84.7	5		
"lagomorphs" Small herbivorous	mammal	Reproductive	1.94	12.9	5		
"vole"	150 ~	-					
Nectarines etc. (2 x 1				1			
Small herbivorous "vole"	mammal	Reproductive	2.76	9.06	5		
Large herbivorous "lagomorphs"	mammal	Reproductive	0.55	45.5	5		
Small omnivorous "mouse"	mammal	Reproductive	0.29	86.2	5		
Frugivorous "dormouse"	mammal	Reproductive	2.89	8.65	5		



Indicator species/Category	Time scale	DDD	TER	Trigger
Apples, pears (2 x 90 g a.s./ha				
Small herbivorous mammal "vole"	Reproductive	3.31	7.55	5
Large herbivorous mammal "lagomorphs"	Reproductive	0.66	37.9	5
Small omnivorous mammal "mouse"	Reproductive	0.36	69.4	5
Frugivorous mammal "dormouse"	Reproductive	1.73	14.5	5

^a There are no toxicity data available for the metabolites, therefore the RMS has assumed them to be 10 times more toxic than the parent.

^b The DDD was calculated by taking account for the formation fraction, i.e. the maximum TRR percentage found in the plant metabolism studies

Indicator species/Category	Time scale	DDD	TER	Trigger
	Screenin	ıg step – biı	ds	
Outdoor drip irrigation uses	in tomato, pepper a	and lettuce	(worst case: 2 ap	oplications at 100 g a.s./ha)
Cyantraniliprole	Acute (Bare soil)	2.66	846	10
Cyantraniliprole	Acute (Fruiting veg)	14.3	157	10
IN-J9Z38 (27.9% TRR)	Acute (Fruiting veg)	4.00	56.3	10
IN-NXX70 (21.7% TRR)	Acute (Fruiting veg)	3.11	72.4	10
IN-QKV54 (10.3% TRR)	Acute (Fruiting veg)	1.48	153	10
Cyantraniliprole	Reproductive (Bare soil)	0.73	93.2	5
Cyantraniliprole	Reproductive (Fruiting veg)	4.12	22.6	5
IN-J9Z38 (27.9% TRR)	Reproductive (Fruiting veg)	1.15	8.11	5
IN-NXX70 (21.7% TRR)	Reproductive (Fruiting veg)	0.89	10.4	5
IN-QKV54 (10.3% TRR)	Reproductive (Fruiting veg)	0.42	22.0	5
	Screening	step – mam	mals	
Outdoor drip irrigatio	n uses in tomato, pe	pper (wors	case: 2 applicat	tions at 100 g a.s./ha)
Cyantraniliprole	Acute (Fruiting veg)	14.3	349	10
Cyantraniliprole	Acute (Bare soil)	1.51	3307	10
Cyantraniliprole	Reproductive (Fruiting veg)	4.6	0.217	5
Cyantraniliprole	Reproductive (Bare soil)	0.42	2.38	5



I 1'	TT: 1	DDD	TED	m :
Indicator species/Category	Time scale	DDD	TER	Trigger
	First ti	er - mamma	als	
Tomato and pepper (2 x 75 g a.	s./ha on bare soil	with 7 d inte	erval, BBCH <1	0)
Small omnivorous mammal "vole"	Reproductive	0.36	3.31	5
Tomato and pepper (2 x 75 g a.	s./ha on bare soi v	vith 7 d inte	rval, BBCH 10-	89)
Small insectivorous mammal "shrew"	Reproductive	0.27	4.49	5
Small herbivorous mammal "vole"	Reproductive	4.60	0.26	5
Small omnivorous mammal "mouse"	Reproductive	0.50	2.42	5
Frugivorous mammal "rat"	Reproductive	1.60	0.75	5
	Higher t	ier – mamn	nals	
Tomato and pepper (2 x 75 g a.	s./ha on bare soil	with 7 d inte	erval, BBCH <1	0)
Small omnivorous mammal "vole"	Reproductive	0.36	69.4	5
Tomato and pepper (2 x 75 g a.	s./ha on bare soi v	vith 7 d inte	rval, BBCH 10-	89)
Small insectivorous mammal "shrew"	Reproductive	0.27	92.6	5
Small herbivorous mammal "vole"	Reproductive	4.60	5.43	5
Small omnivorous mammal "mouse"	Reproductive	0.50	50	5
Frugivorous mammal "rat"	Reproductive	1.60	15.6	5

^a There are no toxicity data available for the metabolites, therefore the RMS has assumed them to be 10 times more toxic than the parent.

^b The DDD was calculated by taking account for the formation fraction, i.e. the maximum TRR percentage found in the plant metabolism studies



Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Laboratory tests ‡	•			
Fish				
Rainbow trout	a.s.	Static (96 h)	Mortality, LC ₅₀	>12.6 (m.m)
Bluegill sunfish	a.s.	Static renewal (96 h)	Mortality, LC ₅₀	>13.0 (m.m)
Channel catfish	a.s.	Flow- through (96 h)	Mortality, LC ₅₀	>10.0 (m.m)
Sheepshead minnow	a.s.	Flow- through (96 h)	Mortality, LC ₅₀	>12.0 (m.m)
Rainbow trout	a.s.	Flow- through (90 d)	NOEC, Growth and reproduction	10.7 (m.m)
Sheepshead minnow	a.s.	Flow- through (33 d)	NOEC, Growth	2.9 (m.m)
Bluegill sunfish	a.s.	Flow- through	BCF	<1
Lepomis macrochirus	Cyantraniliprole 200 g/L SC	Static (96 h)	Mortality, LC ₅₀	7.77 mg a.s./L (m.m)
Lepomis macrochirus	Cyantraniliprole 100 g/L OD	Static (96 h)	Mortality, LC ₅₀	2.4 mg a.s./L (m.m)
Oncorhynchus mykiss	Cyantraniliprole WG (A16971B)	(96 h)	Mortality, LC ₅₀	> 100 mg form/L (>40.7 mg a.s./L)(nom)
	Aqua	atic crustaceans	S	
Daphnia magna	a.s.	48 h (static)	Mortality, EC ₅₀	0.0204 (m.m)
Gammarus pseudolimnaeus	a.s.	48 h (static)	Mortality, EC ₅₀	0.172 (m.m)
Hyalella azteca	a.s.	48 h (static)	Mortality, EC ₅₀	>1.37 (m.m)
Procambarus clarkii	a.s.	Static renewal (48 h)	Mortality, EC ₅₀	4.0 (m.m)
Americamysis bahia	a.s.	Flow- through (96 h)	Mortality, EC ₅₀	1.2 (m.m)
Daphnia magna	a.s.	Static renewal (21 d)	NOEC	0.00969 (m.m)
Ceriodaphnia dubia	a.s.	Static renewal (48 h)	Mortality, EC ₅₀	0.040 (nom)
Ceriodaphnia dubia	a.s.	Static	NOEC	0.005 (nom)



Group	Test substance	Time-scale	End point	Toxicity
		(Test type)		(mg/L)
		renewal (7 d)		
Americamysis bahia	a.s.	Flow- through (5 d)	NOEC	0.72 (m.m)
Daphnia magna	Cyantraniliprole 100 g/L OD	48 h (static)	Mortality, EC ₅₀	0.126 mg form/L 0.00947 mg a.s./L (nom)
Daphnia magna	Cyantraniliprole 100 g/L OD plus codacide oil	48 h (static)	Mortality, EC ₅₀	0.215 mg form/L 0.018 mg a.s./L (nom)
Daphnia magna	Cyantraniliprole 100 g/L SE	48 h (static)	Mortality, EC ₅₀	0.232 mg form/L 0.0185 mg a.s./L (nom)
Daphnia magna	Cyantraniliprole 200 g/L SC	48 h (static)	Mortality, EC ₅₀	0.0724 mg form/L 0.0145 mg a.s./L (nom)
Daphnia magna	Cyantraniliprole WG	48 h (static)	Mortality, EC ₅₀	0.027 mg form/L ^a
Daphnia magna	IN-J9Z38	48 h (static)	Mortality, EC ₅₀	>0.22
Daphnia magna	IN-JCZ38	48 h (static renewal)	Mortality, EC ₅₀	1.85
Daphnia magna	IN-JSE76	48 h (static)	Mortality, EC ₅₀	22.46
Daphnia magna	IN-K5A77	48 h (static)	Mortality, EC ₅₀	>0.85
Daphnia magna	IN-K5A78	48 h (static renewal)	Mortality, EC ₅₀	>31.39
Daphnia magna	IN-K5A79	48 h (static)	Mortality, EC ₅₀	>31.57
Daphnia magna	IN-NXX70	48 h (static)	Mortality, EC ₅₀	>0.184
Daphnia magna	IN-PLT97	48 h (static renewal)	Mortality, EC ₅₀	0.40
Daphnia magna	IN-QKV54	48 h (static)	Mortality, EC ₅₀	>0.287
Daphnia magna	IN-RNU71	48 h (static)	Mortality, EC ₅₀	>2.7
Daphnia magna	IN-J9Z38	21 d (static renewal)	NOEC, Growth and reproduction	0.24 (mm)
Daphnia magna	IN-K5A77	21 d (static renewal)	NOEC, growth	0.117 (mm)
	Aq	uatic insects	T	1
Centroptillium triangulifer	a.s.	Static (48 h)	Mortality, EC ₅₀	0.0715 (m.m)
Lepidostoma ontario	a.s.	Static (48 h)	Mortality, EC ₅₀	0.0748 (m.m)
Soyedina carolinensis	a.s.	Static (48 h)	Mortality, EC ₅₀	14.0 (m.m)
Chironomus riparius	a.s.	Static (48 h)	Mortality, EC ₅₀	0.719 (m.m)
Chironomus riparius	a.s.	Static,	NOEC	0.0241 mg/kg (nom)



Group	Test substance	Time-scale	End point	Toxicity
		(Test type)		(mg/L)
		spiked sediment (28 d)		
Chironomus riparius	a.s.	Static, spiked water (28 d)	NOEC	0.01 (nom)
	Other ag	uatic invertebr	rates	
Crassostrea virginica	a.s.	Flow- through (96 h)	Mortality, EC ₅₀	0.45 (m.m)
Lumbriculus variegates	a.s.	48 h (static)	Mortality, EC ₅₀	>13.7 (m.m)
Re	efined acute toxicity e	endpoint for aqu	uatic invertebrates	•
Aquatic invertebrates	a.s.	Acute	HC ₅ (from SSD curve)	0.0118
		Algae		
Pseudokirchneriella subcapitata	a.s.	72 h	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>13 (m.m) >13 (m.m)
Anabaena flos-aquae	a.s.	72 h 96 h	Biomass: E_bC_{50} Growth rate: E_rC_{50} Biomass: E_bC_{50}	>15 (m.m) >15 (m.m) >15 (m.m) >15 (m.m)
Navicula pelliculosa			Growth rate: E _r C ₅₀	>14 (m.m)
Turrenta pententosa	a.s.	72 h 96 h	Biomass: E_bC_{50} Growth rate: E_rC_{50} Biomass: E_bC_{50}	>14 (m.m) >14 (m.m) >14 (m.m) >14 (m.m)
			Growth rate: E _r C ₅₀	
Skeletonema costatum	a.s.	72 h	Biomass: E_bC_{50} Growth rate: E_rC_{50}	3.2 (m.m) >10 (m.m)
		96 h	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>10 (m.m) >10 (m.m)
Pseudokirchneriella subcapitata	Cyantraniliprole 100 g/L OD	72 h	$E_{r}C_{50}$ $E_{b}C_{50}$	6.62 mg a.s./L 1.18 mg a.s./L
Pseudokirchneriella subcapitata	Cyantraniliprole 100 g/L SE	72 h	E_rC_{50}	3.39 mg a.s./L 0.825 mg a.s./L
Pseudokirchneriella subcapitata	Cyantraniliprole 200 g/L SC	72 h	$\begin{array}{c} E_bC_{50} \\ E_rC_{50} \end{array}$	>12.4 mg a.s./L 7.37 mg a.s./L
Pseudokirchneriella subcapitata	Cyantraniliprole WG	72 h	$\begin{array}{c} E_bC_{50} \\ E_rC_{50} \end{array}$	>100 mg form/L
			E_bC_{50} E_yC_{50}	16 mg form/L 17 mg form/L (nom)
	I	Higher plant		



Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Lemna gibba G3	a.s.	7 d (static renewal)	$E_{r}C_{50}$ $E_{b}C_{50}$ $E_{y}C_{50}$	>12.1 (m.m) >12.1 (m.m) >12.1 (m.m)
Microcosm or mesocosm tests	S			
Indicate if not required				

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

FOCUS Step 1 -Worst-case PECsw and/or PECsed- uses in lettuce, tomato, green bean, and pepper, potatoes (critical GAP, 2 applications at 90 g a.s./ha). (For melon with 4 applications at 90 g a.s./ha, data gap)

Test substance	Organism	Toxicity end point [μg/ L]	Time scale	PECsw, max [μg/ L]	TER	Trigger
Fish	,					1
a.s.	Channel catfish	10000	Acute	49.375	203	100
Cyantraniliprol e 100 g/L OD	Lepomis macrochirus	2400	Acute	49.375	48.6	100
a.s.	Sheepshead minnow	2900	Chronic	49.375	58.7	10
Aquatic invertel	orates		•	•		
a.s.	Refined invertebrate toxicity endpoint (HC ₅)	11.8	Acute	49.375	0.24	3
a.s.	Chironomus riparius (to cover chronic risk to all invertebrates)	10	Chronic	49.375	0.2	10
a.s.	Chironomus riparius	24.1*	Chronic	92.1*	0.26	10
Cyantraniliprol e 100 g/L OD	Daphnia magna	9.47	Acute	49.375	0.19	100
IN-J9Z38	Daphnia magna	220	Acute	5.47	>40.2	100
IN-JCZ38	Daphnia magna	1850	Acute	20.019	92.4	100
IN-JSE76	Daphnia magna	22460	Acute	25.842	869	100
IN-K5A77	Daphnia magna	850	Acute	0.877	>969	100
IN-K5A78	Daphnia magna	31390	Acute	9.527	>329	100
IN-K5A79	Daphnia magna	31570	Acute	5.473	>576 8	100
IN-NXX70	Daphnia magna	184	Acute	1.007	>183	100
IN-PLT97	Daphnia magna	400	Acute	5.872	68.1	100
IN-QKV54	Daphnia magna	287	Acute	1.681	>171	100
IN-RNU71	Daphnia magna	2700	Acute	6.352	>425	100
IN-M2G98 [^]	Daphnia magna	120000	Acute	1.03	>116 500	100
IN-J9Z38	Daphnia magna	240	Chronic	5.47	43.9	10
IN-K5A77	Daphnia magna	117	Chronic	0.877	133	10



Algae								
a.s.	Skeletonema costatum	3200	EbC50	49.375	64.8	10		
Cyantraniliprol e 100 g/L OD	Pseudokirchneriella subcapitata	1180	EbC50	49.375	23.9	10		
Aquatic macrophytes								
a.s.	Lemna gibba	12100	EC50	49.375	>245	10		

FOCUS Step 1 -Worst-case PECsw and/or PECsed - uses in apples, citrus, and olives (2 x 150 g a.s./ha) (also covering the representative uses in pears, peaches and apricots, plums, nectarines).

Test substance	Organism	Toxicity end point [µg/ L]	Time scale	PECsw , max [µg/ L]	TER	Trigger
Fish	_					
a.s.	Channel catfish	10000	Acute	95.258	104.98	100
a.s.	Sheepshead minnow	2900	Chronic	95.258	30.44	10
Aquatic inverteb						
	Refined invertebrate					
a.s.	toxicity endpoint (HC ₅)	11.8	Acute	95.258	0.12	3
a.s.	Chironomus riparius	10	Chronic	95.258	0.10	10
a.s.	Chironomus riparius	24.1	Chronic	153.5	0.16	10
Cyantraniliprole 100 g/L SE	Daphnia magna	18.5	Acute	95.258	0.19	100
IN-J9Z38	Daphnia magna	220	Acute	15.11	>14.56	100
IN-JCZ38	Daphnia magna	1850	Acute	33.364	55.45	100
IN-JSE76	Daphnia magna	22460	Acute	43.07	521	100
IN-K5A77	Daphnia magna	850	Acute	3.128	>272	100
IN-K5A78	Daphnia magna	31390	Acute	15.878	>1977	100
IN-K5A79	Daphnia magna	31570	Acute	9.122	>3461	100
IN-NXX70	Daphnia magna	184	Acute	8.034	>22.9	100
IN-PLT97	Daphnia magna	400	Acute	9.786	40.87	100
IN-QKV54	Daphnia magna	287	Acute	10.781	>26.62	100
IN-RNU71	Daphnia magna	2700	Acute	12.389	>218	100
IN-M2G98 [^]	Daphnia magna	120000	Acute	1.717	>69900	100
IN-J9Z38	Daphnia magna	240	Chronic	15.11	15.88	10
IN-K5A77	Daphnia magna	117	Chronic	3.128	37.40	10
Algae						
a.s.	Skeletonema costatum	3200	EbC50	95.258	33.59	10
Cyantraniliprole 100 g/L SE	Pseudokirchneriella subcapitata	825	EbC50	95.258	8.66	10
Aquatic macroph	•	<u>'</u>	1	I.		
a.s.	Lemna gibba	12100	EC50	95.258	>127	10

^{*} μg a.s./kg sediment ^ Toxicity endpoint derived from study carried out with surrogate compound IN-DBC80; PEC calculated for IN-M2G98

^{*} μg a.s./kg sediment

^ Toxicity endpoint derived from study carried out with surrogate compound IN-DBC80; PEC calculated for IN-M2G98.



FOCUS Step 1 -Worst-case PECsw and/or PECsed - Use in grapes (2 x 112.5 g a s /ha)

Test substance	Organism	Toxicity end point [µg/ L]	Time scale	PECsw, max [μg/ L]	TER	Annex VI Trigger
Fish						
a.s.	Channel catfish	10000	Acute	65.671	152.27	100
a.s.	Sheepshead minnow	2900	Chronic	65.671	44.16	10
Aquatic invertebr	ates					
	Refined invertebrate toxicity endpoint (HC ₅)	11.0	Aguta	65 671	0.10	2
a.s.		11.8	Acute	65.671	0.18	3
a.s.	Chironomus riparius	10	Chronic	65.671	0.15	10
a.s.	Chironomus riparius	24.1	Chronic	115.125	0.21	10
Cyantraniliprole 100 g/L SE	Daphnia magna	18.5	Acute	65.671	0.28	100
IN-J9Z38	Daphnia magna	220	Acute	6.385	>34.46	100
IN-JCZ38	Daphnia magna	1850	Acute	25.023	73.93	100
IN-JSE76	Daphnia magna	22460	Acute	32.303	695	100
IN-K5A77	Daphnia magna	850	Acute	1.604	>530	100
IN-K5A78	Daphnia magna	31390	Acute	11.909	>2636	100
IN-K5A79	Daphnia magna	31570	Acute	6.842	>4614	100
IN-NXX70	Daphnia magna	184	Acute	3.196	>57.57	100
IN-PLT97	Daphnia magna	400	Acute	7.34	54.50	100
IN-QKV54	Daphnia magna	287	Acute	4.533	>63.31	100
IN-RNU71	Daphnia magna	2700	Acute	8.489	>318	100
IN-M2G98 [^]	Daphnia magna	120000	Acute	1.288	>93168	100
IN-J9Z38	Daphnia magna	240	Chronic	6.385	37.59	10
IN-K5A77	Daphnia magna	117	Chronic	1.604	72.94	10
Algae						
a.s.	Skeletonema costatum	3200	EbC50	65.671	48.73	10
Cyantraniliprole 100 g/L SE	Pseudokirchneriella subcapitata	825	EbC50	65.671	12.56	10
Aquatic macrophy			<u>'</u>			
a.s.	Lemna gibba	12100	EC50	65.671	>184	10

FOCUS Step 1 -Worst-case PECsw and/or PECsed - uses in outdoor drip irrigation tomatoes and field peppers (2 x 75 g a.s./ha) (Cyantraniliprole 200 g/L S).

Test substance	Organism	Toxicity end point [µg/ L]	Time scale	PECsw,max [μg/ L]	TER	Trigger
Fish						

^{*} µg a.s./kg sediment ^ Toxicity endpoint derived from study carried out with surrogate compound IN-DBC80; PEC calculated for IN-M2G98.



a.s.	Channel catfish	>10000	Acute	39.767	>251	100
Cyantraniliprole 200 g/L SC	Lepomis macrochirus	7770	Acute	39.767	195	100
a.s.	Sheepshead minnow	2900	Chronic	39.767	72.9	10
Aquatic inverts			<u> </u>	<u> </u>		
a.s.	Refined invertebrate toxicity endpoint (HC ₅)	11.8	Acute	39.767	0.30	3
a.s.	Chironomus riparius	10	Chronic	39.767	0.251	10
a.s.	Chironomus riparius	24.1	Chronic	76.75*	0.314	10
Cyantraniliprole 200 g/L SC	Daphnia magna	14.5	Acute	39.767	0.365	100
IN-J9Z38	Daphnia magna	>220	Acute	0.817	269	100
IN-JCZ38	Daphnia magna	1850	Acute	16.682	111	100
IN-JSE76	Daphnia magna	22460	Acute	21.535	1043	100
IN-K5A77	Daphnia magna	>850	Acute	0.554	1534	100
IN-K5A78	Daphnia magna	31390	Acute	7.939	3953	100
IN-K5A79	Daphnia magna	31570	Acute	4.561	6921	100
IN-NXX70	Daphnia magna	184	Acute	0.163	1129	100
IN-PLT97	Daphnia magna	400	Acute	4.893	81.7	100
IN-QKV54	Daphnia magna	287	Acute	0.552	520	100
IN-RNU71	Daphnia magna	>2700	Acute	5.101	529	100
IN-M2G98 [^]	Daphnia magna	120000	Acute	0.859	139697	100
IN-J9Z38	Daphnia magna	240	Chronic	0.817	294	10
IN-K5A77	Daphnia magna	117	Chronic	0.554	212	10
Algae			<u>'</u>		'	
a.s.	Skeletonema costatum	3200	EbC50	39.767	80.5	10
Cyantraniliprole 200 g/L SC	Pseudokirchneriella subcapitata	7370	EbC50	39.767	185	10
Aquatic macrophyte			<u>l</u>	l .		
a.s.	Lemna gibba	12100	EC50	39.767	304	10

FOCUS Step 2 - Worst-case PECsw and/or PECsed - uses in lettuce, tomato, green bean, and pepper (also covering potatoes) (critical GAP, 2 applications at 90 g a.s./ha). (For melon with 4 applications at 90 g a.s./ha, data gap)

Test substance	Organism	Toxicity end point [µg/ L]	Time scale	North/ South	PECsw, max [μg/ L]	TER	Trigger
Fish							
Cyantraniliprole 100 g/L OD	Lepomis macrochirus	2400	Acute	N	7.79	308	100
Cyantraniliprole 100 g/L OD	Lepomis macrochirus	2400	Acute	S	14.536	165	100

^{*} μg a.s./kg sediment ^ Toxicity endpoint derived from study carried out with surrogate compound IN-DBC80; PEC calculated for IN-M2G98.



Test substance	Organism	Toxicity end point [µg/ L]	Time scale	North/ South	PECsw, max [µg/ L]	TER	Trigger
a.s.	Sheepshead minnow	2900	Chronic	N	7.79	372	10
a.s.	Sheepshead minnow	2900	Chronic	S	14.536	200	10
Aquatic invertebr	ates						
a.s.	Refined invertebrate toxicity endpoint (HC ₅) Refined invertebrate	11.8	Acute	N	7.79	1.51	3
	toxicity endpoint	11 0	Aguta	C	14.526	0.01	2
a.s.	(HC ₅) Chironomus riparius (to cover chronic risk to all invertebrates)	11.8	Acute Chronic	S N	7.79	1.28	10
a.s.	Chironomus riparius (to cover chronic risk to all invertebrates)	10	Chronic	S	14.536	0.69	10
a.s.	Chironomus riparius	24.1	Chronic	N	14.895*	1.62	10
a.s.	Chironomus riparius	24.1	Chronic	S	27.905*	0.86	10
Cyantraniliprole 100 g/L OD	Daphnia magna	9.47	Acute	N	7.79	1.22	100
Cyantraniliprole 100 g/L OD	Daphnia magna	9.47	Acute	S	14.536	0.65	100
IN-J9Z38	Daphnia magna	220	Acute	N [^]	1.617	>136	100
IN-J9Z38	Daphnia magna	220	Acute	S [^]	1.617	>136	100
IN-J9Z38	Daphnia magna	220	Acute	N ^{\$}	1.617	>136	100
IN-J9Z38	Daphnia magna	220	Acute	S ^{\$}	1.617	>136	100
IN-JCZ38	Daphnia magna	1850	Acute	S^	4.364	424	100
IN-JCZ38	Daphnia magna	1850	Acute	N^	2.182	848	100
IN-JCZ38	Daphnia magna	1850	Acute	N ^{\$}	2.473	748	100
IN-JCZ38	Daphnia magna	1850	Acute	S ^{\$}	4.946	374	100
IN-PLT97	Daphnia magna	400	Acute	N^	0.867	461	100
IN-PLT97	Daphnia magna	400	Acute	S^	1.734	231	100
IN-PLT97	Daphnia magna	400	Acute	N ^{\$}	0.982	407	100
IN-PLT97	Daphnia magna	400	Acute	S ^{\$}	1.965	204	100

^{*} μg a.s./kg sediment

FOCUS Step 2 -Worst-case PECsw and/or PECsed-apples (and a surrogate crop for nectarines, peaches and apricots) 2×150 g a.s./ha with a 7 d interval. To be considered covering also for plums



Test substance	Organism	Toxicity end point [µg/ L]	Time scale	North/ South	PECsw, max [µg/ L]	TER	Trigger
Fish	<u> </u>			I			
a.s.	Sheepshead minnow	2900	Chronic	N	20.654	140.41	10
a.s.	Sheepshead minnow	2900	Chronic	S	32.646	88.33	10
Aquatic invertebrate	es	•	•	•	•		
a.s.	Refined invertebrate toxicity endpoint (HC ₅)	11.8	Acute	N	20.654	0.57	3
a.s.	Refined invertebrate toxicity endpoint (HC ₅)	11.8	Acute	S	32.646	0.36	3
a.s.	Chironomus riparius	10	Chronic	N	20.654	0.48	10
a.s.	Chironomus riparius	10	Chronic	S	32.646	0.31	10
a.s.	Chironomus riparius	24.1	Chronic	N	37.059*	0.65	10
a.s.	Chironomus riparius	24.1	Chronic	S	59.577*	0.40	10
Cyantraniliprole 100 g/L SE	Daphnia magna	18.5	Chronic	N	20.654	0.90	10
Cyantraniliprole 100 g/L SE	Daphnia magna	18.5	Chronic	S	32.646	0.57	10
IN-J9Z38	Daphnia magna	>220	Acute	N	5.865	>37.51	100
IN-J9Z38	Daphnia magna	>220	Acute	S	5.865	>37.51	100
IN-JCZ38	Daphnia magna	1850	Acute	N	3.443	537.32	100
IN-JCZ38	Daphnia magna	1850	Acute	S	6.886	268.66	100
IN-PLT97	Daphnia magna	400	Acute	N	1.53	261.44	100
IN-PLT97	Daphnia magna	400	Acute	S	3.059	130.76	100

^{*} µg a.s./kg sediment



FOCUS Step 2 -Worst-case PECsw and/or PECsed - Use in grapes (2 x 112.5 g a.s./ha)

Test substance	Organism	Toxicity end point [µg/ L]	Time scale	North/ South	PECsw, max [µg/ L]	TER	Trigger
Fish							
a.s.	Sheepshead minnow	2900	Chronic	N	10.114	286.73	10
a.s.	Sheepshead minnow	2900	Chronic	S	16.682	173.84	10
Aquatic invertebrate	es						
a.s.	Refined invertebrate toxicity endpoint (HC ₅)	11.8	Acute	N	10.114	1.17	3
a.s.	Refined invertebrate toxicity endpoint (HC ₅)	11.8	Acute	S	16.682	0.71	3
a.s.	Chironomus riparius	10	Chronic	N	10.114	0.99	10
a.s.	Chironomus riparius	10	Chronic	S	16.682	0.60	10
a.s.	Chironomus riparius	24.1	Chronic	N	19.067*	1.26	10
a.s.	Chironomus riparius	24.1	Chronic	S	31.734*	0.76	10
Cyantraniliprole 100 g/L SE	Daphnia magna	18.5	Chronic	N	10.114	1.83	100
Cyantraniliprole 100 g/L SE	Daphnia magna	18.5	Chronic	S	16.682	1.11	10
IN-J9Z38	Daphnia magna	220	Acute	N	2.582	85.21	100
IN-J9Z38	Daphnia magna	220	Acute	S	2.582	85.21	100
IN-JCZ38	Daphnia magna	1850	Acute	N	1.937	955.09	100
IN-JCZ38	Daphnia magna	1850	Acute	S	3.873	477.67	10
IN-PLT97	Daphnia magna	400	Acute	N	0.86	465.12	100
IN-PLT97	Daphnia magna	400	Acute	S	1.721	232.42	10

FOCUS Step 2 -Worst-case PECsw and/or PECsed- uses in outdoor drip irrigation tomatoes and field peppers (2 x 75 g a.s./ha)

Test substance	Organism	Toxicity end point [µg/ L]	Time scale	North/ South	PECsw, max [µg/ L]	TER	Trigger
Fish					1		
a.s.	Sheepshead minnow	2900	Chronic	N	7.495	387	10
a.s.	Sheepshead minnow	2900	Chronic	S	14.99	193	10
Aquatic invertebra	tess						
a.s.	Refined invertebrate toxicity endpoint		Acute	N	7.495	1.57	3



	(HC ₅)						
a.s.	Refined invertebrate toxicity endpoint (HC ₅)	11.8	Acute	S	14.99	0.79	3
a.s.	Chironomus riparius	10	Chronic	N	7.495	1.33	10
a.s.	Chironomus riparius	10	Chronic	S	14.99	0.667	10
a.s.	Chironomus riparius	24.1	Chronic	N	14.465	1.666	10
a.s.	Chironomus riparius	24.1	Chronic	S	28.93	0.833	10
Cyantraniliprole 200 g/L SC	Daphnia magna	14.5	Acute	N	7.495	1.93	100
Cyantraniliprole 200 g/L SC	Daphnia magna	14.5	Acute	S	14.99	0.967	100
IN-PLT97	Daphnia magna	400	Acute	N	0.963	415	100
IN-PLT97	Daphnia magna	400	Acute	S	1.926	208	100



Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Steps 3 and 4

Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC_{sw} value below the RAC of 1 $\mu g/l$ for each crop, scenario and water body combination (values in bold exceed the RAC irrespective of the level of risk mitigation currently applied)

	Lettuce (2	x 90 g a.s./ha)	Tomato (2	x 90 g a.s./ha)	Melon (2 x 90 g a.s./ha)		
Scenario	PECsw (µg/l)	Assessment tier and mitigation	PECsw (μg/l)	Assessment tier and mitigation	PECsw (μg/l)	Assessment tier and mitigation	
D3 Ditch 1 st early	0.575 (single)	Step 3	_	-	0.477 (single)	Step 3	
D3 Ditch 2 nd early	0.577 (single)	Step 3	-	-	-	-	
D3 Ditch 1 st late	0.573 (single)	Step 3	-	-	0.475 (single)	Step 3	
D3 Ditch 2 nd late	0.572 (single)	Step 3	-	-	-	-	
D4 Pond early	0.796 (multiple)	Step 3	-	-	0.903 (multiple)	Step 3	
D4 Stream early	0.814 (multiple)	Step 3	-	-	0.916 (multiple)	Step 3	
D4 Pond late	1.132 (multiple)	Step 3 (no mitigation possible as peak PEC is from drainage event)	-	-	1.154 (multiple)	Step 3 (no mitigation possible)	
D4 Stream late	1.399 (multiple)	Step 3 (no mitigation possible as peak PEC is from drainage event)	-	-	1.340 (multiple)	Step 3 (no mitigation possible)	
D6 Ditch 1 st early	2.330 ^b (multiple)	Step 3 (no mitigation possible, as peak PEC is from drainage event)	0.585 (single)	Step 3-	0.558 (multiple)	Step 3	
D6 Ditch 2nd early	-	-	-	-	2.465 ^b (multiple)	Step 3 (no mitigation possible)	



D6 Ditch 1 st late	5.950 (multiple)	Step 3 (no mitigation possible as peak PEC is from drainage event)	1.727 (multiple)	Step 3 (no mitigation possible)	0.495 (single)	Step 3
D6 Ditch 2nd late	-	-			4.539 ^b (multiple)	Step 3 (no mitigation possible)
R1 Pond 1st early	0.155 (multiple)	Step 3	-	-	0.178 (multiple)	Step 3
R1 Pond 2 nd early	0.166 (multiple)	Step 3	-	-	-	-
R1 Pond 1 st late	0.388 (multiple)	Step 3			0.087 (single)	Step 3
R1 Pond 2 nd late	0.141 (multiple)	Step 3			-	-
R1 Stream 1st early	0.590 (multiple)	Step 4 (20m VFS)	-	-	1.000	Step 4 (10m VFS)
R1 Stream 2 nd early	0.541 (multiple)	Step 4 (20m VFS)	-	-	-	-
R1 Stream 1st late	0.460 (multiple)	Step 4 (20m VFS)			0.756 (multiple)	Step 4 (10m VFS)
R1 Stream 2 nd late	0.878 (multiple)	Step 4 (10m VFS)			-	-
R2 Stream 1 st early	0.892 (multiple)	Step 4 (10m VFS)	0.797 (multiple)	Step 4 (10m VFS)	0.772 (multiple)	Step 4 (10m VFS)
R2 Stream 2 nd early	0.703 (multiple)	Step 3	-	-	-	-
R2 Stream 1 st late	0.604 (multiple)	Step 4 (10m VFS)	0.755 (multiple)	Step 3	0.772 (multiple)	Step 4 (10m VFS)
R2 Stream 2 nd late	0.996 (multiple)	Step 3	-	-	-	-
R3 Stream 1 st early	0.686 (multiple)	Step 4 (20m VFS)	0.777 (multiple)	Step 4 (20m VFS)	0.635 (multiple)	Step 4 (20m VFS)
R3 Stream 2 nd early	0.733 (multiple)	Step 4 (20m VFS)	-	-	-	-
R3 Stream 1 st late	0.576 (multiple)	Step 4 (20m VFS)	0.585 (multiple)	Step 4 (20m VFS)	0.667 (multiple)	Step 4 (20m VFS)



R3 Stream 2 nd late	0.674 (multiple)	Step 4 (20m VFS)	-	-	-	-
R4 Stream 1 st early	0.652 (multiple)	Step 4 (20m VFS)	0.986 (multiple)	Step 4 (20m VFS)	-	-
R4 Stream 2 nd early	0.691 (multiple)	Step 4 (20m VFS)	-	-	-	-
R4 Stream 1 st late	0.760 (multiple)	Step 4 (20m VFS)	0.715 (multiple)	Step 4 (20m VFS		
R4 Stream 2 nd late	0.769 (multiple)	Step 4 (20m VFS)				
	Leafy vegeta a.s./ha)	ables (2 x 75 g	Fruiting veg	getables (4 x 120	g a.s./ha)	
Glasshouse 0.2 % drift value	PECsw (μg/l)	Assessment tier and mitigation	PECsw (μg/l)		Assessment mitigation	tier and
driit value	0.091	Step 3	0.	245	Ste	ep 3



Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC_{sed} value below the RAC of $2.41~\mu g/kg$ for each crop, scenario and water body combination (values in bold exceed the RAC irrespective of the level of risk mitigation currently applied)

	Lettuce (2 x 90 g a.s./ha)	Melon (2	2 x 90 g a.s./ha)
Scenario	PECsed (μg/kg)	Assessment tier and mitigation	PECsed (μg/kg)	Assessment tier and mitigation
D3 Ditch 1 st early	0.238	Step 3	0.210	Step 3
D3 Ditch 2 nd early	0.229	Step 3	-	-
D3 Ditch 1 st late	0.227	Step 3	0.207	Step 3
D3 Ditch 2 nd late	0.226	Step 3	-	-
D4 Pond early	2.987	Step 4 (20m BZ)	3.513	Step 4 (20m BZ)
D4 Stream early	1.647	Step 3	1.911	Step 3
D4 Pond late	3.420	Step 4 (10m BZ)	3.837	Step 4 (10m BZ)
D4 Stream late	1.862	Step 3	2.023	Step 3
D6 Ditch 1 st early	1.967	Step 3	0.683	Step 3
D6 Ditch 2nd early	-	-	1.912	Step 3
D6 Ditch 1 st late	4.475	Step 4 (10m BZ)	0.609	Step 3
D6 Ditch 2nd late	-	-	2.832	Step 4 (10m BZ)
R1 Pond 1 st early	0.304	Step 3	0.383	Step 3
R1 Pond 2 nd early	0.330	Step 3	-	-
R1 Stream 1st early	0.615	Step 3	0.575	Step 3
R1 Stream 2 nd early	0.703	Step 3	-	-
R1 Pond 1 st late	0.656	Step 3	0.147	Step 3
R1 Pond 2 nd late	0.428	Step 3	-	-
R1 Stream 1st late	0.952	Step 3	0.453	Step 3
R1 Stream 2 nd late	0.434	Step 3	-	-
R2 Stream 1 st early	1.105	Step 3	0.478	Step 3
R2 Stream 2 nd early	0.413	Step 3	-	-
R2 Stream 1 st late	1.025	Step 3	0.478	Step 3



Glasshouse 0.2 % drift value	(μg/kg)	Assessment tier and mitigation Step 3	(μg/kg)	Assessment tier and mitigation Step 3
	Leafy vegetab PECsw	les (2 x 75 g a.s./ha)		getables (4 x 120 g s./ha)
R4 Stream 2 nd late	1.316	Step 3	-	-
R4 Stream 1 st late	1.119	Step 3	-	-
R4 Stream 2 nd early	1.097	Step 3	-	-
R4 Stream 1 st early	0.847	Step 3	-	-
R3 Stream 2 nd late	1.491	Step 3	-	-
R3 Stream 1 st late	0.671	Step 3	1.195	Step 3
R3 Stream 2 nd early	1.268	Step 3	-	-
R3 Stream 1 st early	0.992	Step 3	0.679	Step 3
R2 Stream 2 nd late	0.366	Step 3	-	-

 $Metabolites, worst-case\ PECsw\ (glassohouse\ uses\ -\ fruiting\ vegetables\ (4\ x\ 120\ g\ a.s./ha)$

Metabolite	PECsw (μg/L)	Organism	Toxicity end point [µg/ L]	Time scale	TER	Trigger
IN-J9Z38	0.174	Daphnia magna	220	Acute	1264	100
IN-K5A77	0.041	Daphnia magna	850	Acute	20732	100
IN-RNU71	0.032	Daphnia magna	2700	Acute	84375	100
IN-QKV54	0.155	Daphnia magna	287	Acute	1852	100
IN-NXX70	0.13	Daphnia magna	184	Acute	1415	100
IN-J9Z38	0.174	Daphnia magna	240	Chronic	1379	10
IN-K5A77	0.041	Daphnia magna	117	Chronic	2854	10



Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC_{sw} value below the RAC of 1 $\mu g/l$ for each crop, scenario and water body combination (values in bold exceed the RAC irrespective of the level of risk mitigation currently applied)

	Apples (Pome fruit early, 2 x 90 g a.s./ha)		Apples (Pome fruit late, 2 x 90 g a.s./ha)			Apples (Pome fruit late, 2 x 150 g a.s./ha)		Citrus (2 x 150 g a.s./ha)		(2 x 150 g s./ha)	Vines, late (2 x 112.5 g a.s./ha)	
Scenario	PEC _{sw} (μg/l)	Assessment tier and mitigation	PEC _{sw} (µg/l)	Assessment tier and mitigation	PEC _{sw} (μg/l)	Assessment tier and mitigation	PEC _{sw} (µg/l)	Assessment tier and mitigation	PEC _{sw} (μg/l)	Assessment tier and mitigation	PEC _{sw} (μg/l)	Assessment tier and mitigation
D3 Ditch	0.773	20m BZ	0.999	10m BZ	0.723	Step 4 (15m BZ)	-	-	-	-	-	-
D4 Pond	0.716	Step 3	1.864	20m BZ	0.990	Step 3	-	-	_	-	-	-
D4 Stream	0.868	20m BZ	2.502	20m BZ	0.996	Step 4 (15m BZ)	-	-	-	-	-	-
D5 Pond	0.803	Step 3	0.546	Step 3	0.580	Step 3	-	-	-	-	-	-
D5 Stream	0.899	20m BZ	0.588	20m BZ	0.976	Step 4 (15m BZ)	-	-	-	-	-	-
D6 Ditch	-	-	-	-	-	-	0.521	Step 4 (20m BZ)	0.521	Step 4 (20 m BZ)	0.423	Step 4 (10 m BZ)
R1 Pond	0.687	Step 3	0.202	Step 3	0.357	Step 3	-	-	-	-	0.163	Step 3
R1 Stream	0.682	20m BZ + VFS	0.886	10m BZ + VFS	0.455	Step 4 (20m BZ + VFS)	-	-	-	-	0.558	Step 4 (10 m BZ + VFS)
R2 Stream	0.904	20m BZ + VFS	0.366	20m BZ + VFS	0.609	Step 4 (20m BZ + VFS)	-	-	-	-	0.827	Step 4 (10 m BZ)



R3 Stream	0.964	20m BZ + VFS	0.603	20m BZ + VFS	0.638	Step 4 (20m BZ + VFS)	-	-	-	-	0.524	Step 4 (10 m BZ + VFS)
R4 Stream	0.686	20m BZ + VFS	0.886	10m BZ + VFS	0.553	Step 4 (20m BZ + VFS)	0.705	Step 4 (20m BZ + VFS)	0.730	Step 4 (20 m BZ + VFS)	0.462	Step 4 (10 m BZ + VFS)



Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC_{sed} value below the RAC of 2.41 $\mu g/kg$ for each crop, scenario and water body combination (values in bold exceed the RAC irrespective of the level of risk mitigation currently applied)

Scenario			Apples (Pome fruit late, 2 x 90 g a.s./ha)		late,	Apples (Pome fruit late, 2 x 150 g a.s./ha)		Citrus (2 x 150 g a.s./ha)		Olives (2 x 150 g a.s./ha)	
Scenario	PEC _{sed} (μg/kg)	Assessment tier and mitigation	PEC _{sed} (μg/kg)	Assessment tier and mitigation	PEC _{sed} (μg/kg)	Assessment tier and mitigation	PEC _{sed} (μg/kg)	Assessment tier and mitigation	PEC _{sed} (μg/kg)	Assessment tier and mitigation	
D3 Ditch	2.269	Step 3	1.364	Step 3	1.919	Step 3	-	-	-	-	
D4 Pond	2.039	Step 3	4.961	20m BZ	2.994	Step 4 (20m BZ + VFS)	-	-	-	-	
D4 Stream	0.766	Step 3	2.442	20m BZ	1.402	Step 3	-	-	-	-	
D5 Pond	1.733	Step 3	2.051	Step 3	2.255	Step 3	-	-	-	-	
D5 Stream	0.594	Step 3	0.901	Step 3	1.556	Step 3	-	-	-	-	
D6 Ditch	-	-	-	-	-	-	0.494	Step 4 (20m BZ)	0.521	Step 4 (20 m BZ)	
R1 Pond	1.149	Step 3	0.425	Step 3	0.629	Step 3	-	-	-	-	
R1 Stream	0.541	Step 3	0.290	Step 3	0.673	Step 3	-	-	-	-	
R2 Stream	0.395	Step 3	0.292	Step 3	0.719	Step 3	-	-	-	-	
R3 Stream	1.446	Step 3	1.017	Step 3	0.857	Step 3	-	-	-	-	
R4 Stream	0.764	Step 3	0.665	Step 3	0.824	Step 3	1.121	Step 4 (10m BZ + VFS)	0.950	Step 3	

Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC_{sw} value below the RAC of 1 $\mu g/l$ for each crop, scenario and water body combination (values in bold exceed the RAC irrespective of the level of risk mitigation currently applied)

	Tomatoes ar	nd field peppers (2 x 75 g a.s./ha)
Scenario	PEC _{sw} (μg/l)	Assessment tier and mitigation



D6 Ditch		0.291	Step 3		
R2 Stream		0.779	Step 4 (1	0 m VFS)	
R3 Stream		0.838	Step 4 (2	20 m VFS)	
R4 Stream		0.904	Step 4 (20 m VFS)		
		egetables (4 x 100 a.s./ha)	Leafy vegetables	s (3 x 100 g a.s./ha)	
	PECsw	Assessment tier	PECsw	Assessment tier and	
Glasshouse 0.2 % drift value	(µg/l)	and mitigation	$(\mu g/l)$	mitigation	
	0.204 Step 3		0.167	Step 3	

Metabolites, worst-case PECsw (glasshouse uses (Fruiting vegetables (4 x 100 g a.s./ha))

Metabolite	PECsw (μg/L)	Organism	Toxicity end point [µg/L]	Time scale	TER	Trigger
IN-J9Z38	0.145	Daphnia magna	220	Acute	1517	100
IN-K5A77	0.034	Daphnia magna	850	Acute	25000	100
IN-RNU71	0.026	Daphnia magna	2700	Acute	103846	100
IN-QKV54	0.129	Daphnia magna	287	Acute	2225	100
IN-NXX70	0.108	Daphnia magna	184	Acute	1704	100
IN-J9Z38	0.145	Daphnia magna	240	Chronic	1655	10
IN-K5A77	0.034	Daphnia magna	117	Chronic	3441	10

Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC_{sw} value below the RAC of 1 $\mu g/l$ for each crop, scenario and water body combination (values in bold exceed the RAC irrespective of the level of risk mitigation currently applied)

	For plums as a s	surrogate apples (Pome fruit late, 2 x 125 g a.s./ha)
Scenario	PECsw	Assessment tier and mitigation
	(μg/l)	Ç



D3 Ditch	0.431	Step 4 (20 m BZ; single application GAP)
D4 Pond	1.799	Step 4 (20 m BZ, multiple application GAP)
D4 Stream	2.294	Step 4 (20 m BZ, multiple application GAP)
D5 Pond	0.675	Step 3 (multiple application GAP)
D5 Stream	0.850	Step 4 (20 m BZ, multiple application GAP)
R1 Pond	0.318	Step 3 (multiple application GAP)
R1 Stream	1.109	Step 4 (20 m BZ and VFS, multiple application GAP)
R2 Stream	0.549	Step 4 (20 m BZ and VFS, multiple application GAP)
R3 Stream	0.531	Step 4 (20 m BZ and VFS, single application GAP)
R4 Stream	0.918	Step 4 (20 m BZ and VFS, multiple application GAP)

Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC_{sed} value below the RAC of 2.41 μ g/kg for each crop, scenario and water body combination (values in bold exceed the RAC irrespective of the level of risk mitigation currently applied)

	For plums as a surrogate apples (Pome fruit late, 2 x 125 g a.s./ha)					
Scenario	PECsed (μg/kg)	Assessment tier and mitigation				
D3 Ditch	1.707	Step 3 (multiple application GAP)				
D4 Pond	5.275	Step 4 (20 m BZ and VFS, multiple application GAP)				
D4 Stream	2.471	Step 4 (20 m BZ and VFS, multiple application GAP)				
D5 Pond	2.432	Step 4 (20 m BZ and VFS, multiple application GAP)				
D5 Stream	1.442	Step 3 (multiple application GAP)				
R1 Pond	0.597	Step 3 (multiple application GAP)				
R1 Stream	1.569	Step 3 (multiple application GAP)				
R2 Stream	1.006	Step 3 (multiple application GAP)				
R3 Stream	0.720	Step 3 (multiple application GAP)				
R4 Stream	1.274	Step 3 (multiple application GAP)				



Bioconcentration									
	Active substance	IN- J9Z38	IN- JCZ38	IN- JSE76	IN- K5A77	IN- K5A78	IN- K5A79	IN- K7H19	IN- PLT97
$logP_{O/W}$	1.74- 2.02 (mean 1.94)	2.8	1.3	1.7	2.1	2.6	1.5	1.1	2.6
Bioconcentration factor (BCF) ¹ ‡	<1	n.d.							
Annex VI Trigger for the bioconcentration factor									
Clearance time (days) (CT ₅₀)									
(CT ₉₀)									
Level and nature of residues (%) in organisms after the 14 day depuration phase									

 $^{^{1}}$ only required if log $P_{O/W} > 3$.

* based on total ^{14}C or on specific compounds



Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD ₅₀ µg/bee)	Acute contact toxicity (LD ₅₀ μg/bee)
a.s. ‡	>0.1055 ^{a^}	>0.0934\$
Cyantraniliprole 100 g/L OD	0.39 (3.79 µg form/bee)	0.65 (6.31 μg form/bee) ^b
Cyantraniliprole 100 g/L SE	0.92 (8.76 μg form/bee)	2.78 (26.47 μg form/bee)
Cyantraniliprole 200 g/L SC	0.404 (2.181 μg form/bee)	0.659 (3.558 μg form/bee)
'A16971 B'	0.24 (0.58 4 μg form/bee)	0.98 (2.4 µg form/bee)
IN-HGW87	0.298 μg IN- HGW87/bee	-
IN-HGW87	>0.030° µg IN- HGW87/bee	-
IN-J9Z38	>8.34 ng IN-J9Z38/bee	-
IN-K5A78	>45.61 μg IN- K5A78/bee	-
IN-DBC80	>49.29 μg IN-DBC80/bee	-
Field or semi-field tests- see tables below.	<u>.</u>	

Highest dose/concentration tested.

Endpoint based on effects after 96 hour exposure. 2% mortality at this rate. 34% mortality at this rate.



Semi-field and field tests

Test item and no. applications (interval)	Rate(s) tested, timing and application method	Study type/ crop/species	Mortality	Flight activity and Behavioural effects	Impact on colonies	Exposure confirmed?	Reference
Higher tier risk as							
Cyantraniliprole 100 g/L OD Two applications (14 d)	100 g a.s./ha once before flowering and once during flowering during bee flight	Semi- field/tunnel test/ Phacelia tanacetifolia/ A. m. carnica	application: No effect 2 nd application: Increased mortality observed for two days.	1 st application: No effect on flight activity or behaviour 2 nd application: Reduced flight activity for 2 days. Intoxication symptoms for 2 days.	No impact on brood development. Slight impact on colony size but not considered to be treatment related.	Semi field study. Reference item included.	DuPont- 21984
Cyantraniliprole 100 g/L OD One application	100 g a.s./ha applied once during bee flight to the flowering crop	Semi- field/tunnel test/ Phacelia tanacetifolia/ A. m. mellifera	Increased mortality observed for two days.	Reduced flight activity for 2 days. Behavioural abnormalities for one day.	Results indicate that no impact on brood development or colony strength, but measurements were indicative only.	Semi field study. Reference item included.	DuPont- 21706
Cyantraniliprole 100 g/L OD One application	100 g a.s./ha applied once during bee flight to the flowering crop	Semi- field/tunnel test/ Wheat treated with sugar solution to simulate honeydew/ A. m. mellifera	Increased mortality observed for three days.	Results indicate that flight activity reduced for at least 6 days, but control flight very low on day of application and fairly low for remainder of study. Intoxication symptoms observed for two days after application.	Slight decrease in the number of brood combs and adult bee populations observed, but measurements were indicative only. ^a	Semi field study. Reference item included.	DuPont- 21705



Higher tier risk as	ssessment- no ris	k mitigation: Field					
Cyantraniliprole	90 g a.s./ha	Field/ Brassica	1 st	1 st application:	No effect on colony	Residue	DuPont-
100 g/L OD	applied once	napus/ Apis	application:		strength or brood	analysis of	29572
_	before	mellifera		No effect on flight	development, including	nectar, pollen	
Two applications	flowering and	carnica	No effect	activity. One day	after over-wintering.	and wax from	
	once during		2 nd	effect on behaviour		the hives.	
	flowering		_	indicated			
	during bee		application:	2nd 1: 4:			
	flight.		Increased	2 nd application:			
			mortality for	Control flight activity			
			five days.	too low to conclude			
			live days.	decisively whether			
				test item affected			
				flight activity.			
				Indication that if			
				flight activity were			
				affected, this effect			
				was not maintained.			
				Intoxication			
				symptoms observed			
				for 2 days.			
Cyantraniliprole	90 g a.s./ha	Field/ Brassica	1 st	1 st application:	No effect on colony	Residue	DuPont-
100 g/L OD	plus 2.5 L	napus/ Apis	application:		strength or brood	analysis of	29571
	codacide oil	mellifera		No effect on flight	development, including	nectar, pollen	
Two applications	applied once before	carnica	No effect	activity or behaviour	after over-wintering.	and wax from the hives.	
	flowering and		$2^{\rm nd}$	2 nd application:		die in ves.	
	once during		application:	11			
	flowering		* *	Control flight activity			
	during bee		Slight	too low to conclude			
	flight.		increase in	decisively whether			
	9		mortality for	test item affected			



			one day two days after application.	flight activity. Slight effect on behaviour for 2 days.			
Higher tier risk as			eld studies 1 st	1 St application	No impact on broad	Comi field	DuDont
Cyantraniliprole 100 g/L OD and OD plus codacide oil Two applications	90 g a.s./ha once before flowering and once during flowering after bee flight 90 g a.s./ha plus 2.5 L codacide oil once before flowering and once during flowering after bee flight	Semi- field/tunnel test/ Phacelia tanacetifolia/ Apis mellifera	application: No effect 2 nd application: Increase in mortality for one day.	1st application: No effect on flight activity or behaviour 2nd application: Reduced flight activity for one day without adjuvant and two days with adjuvant. Behavioural abnormalities for one day.	No impact on brood development or colony strength.	Semi field study. Reference item included.	DuPont- 30550
Cyantraniliprole 100 g/L OD	100 g a.s./ha applied once during	Semi- field/tunnel test/ <i>Phacelia</i>	Increase in mortality for two days.	Reduced flight activity for one day. Behavioural	Results indicate that no impact on brood development or colony	Semi field study. Reference item	DuPont- 21706
One application	flowering after bee flight	tanacetifolia/ A. m. mellifera		abnormalities for one day.	strength, but measurements were indicative only. ^c	included.	
Cyantraniliprole 100 g/L OD	100 g a.s./ha applied once during	Semi- field/tunnel test/ Wheat	Increase in mortality for two days.	Results indicate that flight activity reduced for at least 6 days, but	Slight decrease in the number of brood combs and adult bee	Semi field study. Reference item	DuPont- 21705
One application	flowering after bee flight	treated with sugar solution to simulate honeydew/ A. m. mellifera		control flight very low on day of application and fairly low for remainder of study. Intoxication	populations observed, but results limited due to method of recording ^a	included.	



Higher tier risk assessment- risk mitigation: Field studies Cyantraniliprole 100 g/L OD applications Two applications Two applications Once during flowering after bee flight. Duplication: No impact on mortality. No impact on mortality. Control flight activity too low to conclude decisively whether test item affected flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 100 g/L OD plus 2.5 L Cyantraniliprole 100 g/L OD plus 2.5 L Pield/ Brassica napus/ Apis malplication: No impact on mortality. Indication: Intoxication symptoms observed for 1 day. In application: No effect on colony strength or brood development, including after over-wintering. Residue analysis of nectar, pollen and wax from the hives. Control flight activity too low to conclude decisively whether test item affected flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 100 g/L OD plus 2.5 L Residue nactar, pollen and wax from the hives. Dup strength or brood analysis of nectar, pollen and wax from the hives.					symptoms observed			
Migher tier risk assessment- risk mitigation: Field brassica 1st application: 1st application: 290 g a.s./ha application: 600 g/L OD 100								
Programmiliprole 100 g/L OD					_			
Cyantraniliprole 100 g/L OD	Higher tion right of	ggoggmant miglzn	itigation: Field at	udios	аррисанон.			
Two applications Two applicat					1 St applications	No offect on colony	Dagidua	DuPont-
Two applications before flowering and once during flowering after bee flight. No effect on flight activity. One day effect on behaviour indicated application: No impact on mortality. No impact on mortality. No impact on mortality. No impact on mortality. Indication that flight activity. Indication that flight activity was not affected. Lintoxication symptoms observed for 1 day. Cyantraniliprole 100 g/L OD plus 2.5 L Possible rationary application: No effect on flight activity. One day effect on behaviour indicated activity. One day effect on behaviour indicated activity. One day effect on behaviour indicated application: Control flight activity. Indication that flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 100 g/L OD plus 2.5 L Possible rationary application: No effect on flight activity. One day effect on behaviour indicated activity. One day effect on behaviour indicated activity. One day effect on behaviour indicated application: 1 Intoxication symptoms observed for 1 day. No effect on flight activity. One day effect on behaviour indicated application: No impact on mortality. 1 Intoxication symptoms observed for 1 day. No effect on flight activity. One day effect on behaviour indicated application: 2 Intoxication symptoms observed for 1 day. No effect on flight activity. One day effect on behaviour indicated application: No impact on behaviour indicated application: No impact on behaviour indicated application: No effect on colony strength or brood analysis of 295		•		_	application:	1		
Two applications flowering and once during flowering after bee flight. No effect 2nd application: No impact on mortality. No impact on mortality. Control flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 100 g/L OD plus 2.5 L napus/Apis application: Ro impact on mortality. No effect activity. One day effect on behaviour indicated activity. One day effect on behaviour indicated activity. Control flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. No effect on colony strength or brood analysis of 295	100 g/L OD	* *	1 1	application:	No official on flight	C	•	29572
once during flowering after bee flight. No impact on mortality. No impact on mortality. Control flight activity too low to conclude decisively whether test item affected flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 100 g/L OD plus 2.5 L napus/Apis application: once during flowering after bee flight. 2nd application: Control flight activity too low to conclude decisively whether test item affected flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole plus 2.5 L napus/Apis application: Selfect on behaviour indicated 2nd application: No effect on colony strength or brood analysis of 295	TD 1' 4'		· ·	NI CC 4	_			
flowering after bee flight. Positive content of the properties	I wo applications		carnica	No effect		after over-wintering.		
howeing after bee flight. application: No impact on mortality. Control flight activity too low to conclude decisively whether test item affected flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 90 g a.s./ha plus 2.5 L Pield/ Brassica napus/Apis application: No impact on mortality. Control flight activity too low to conclude decisively whether test item affected flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 90 g a.s./ha plus 2.5 L plus 2.5 L page 3 application: No effect on colony strength or brood analysis of 295		_		and			the hives.	
Control flight activity too low to conclude decisively whether test item affected flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day.		•		<u> </u>	indicated			
No impact on mortality. No impact on mortality. Control flight activity too low to conclude decisively whether test item affected flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day.		bee flight.		application:	and			
Control flight activity too low to conclude decisively whether test item affected flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 90 g a.s./ha plus 2.5 L napus/ Apis application: To strong flight activity too low to conclude decisively whether test item affected. Intoxication symptoms observed for 1 day. No effect on colony strength or brood analysis of 295				NY .	2 nd application:			
too low to conclude decisively whether test item affected flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 100 g/L OD plus 2.5 L napus/Apis application: 1st applicat				•				
decisively whether test item affected flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 100 g/L OD plus 2.5 L napus/Apis application: DuPatient DuPatie				mortality.				
test item affected flight activity. Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 100 g/L OD plus 2.5 L napus/Apis application: 1st application: 295								
Cyantraniliprole 90 g a.s./ha plus 2.5 L Field/ Brassica napus/ Apis application: Tit application: No effect on colony strength or brood analysis of 295 2								
Indication that flight activity was not affected. Intoxication symptoms observed for 1 day. Cyantraniliprole 100 g/L OD 90 g a.s./ha plus 2.5 L Field/ Brassica napus/Apis 1st application: 1st application: No effect on colony strength or brood 295 2								
Cyantraniliprole 100 g/L OD Plus 2.5 L napus/Apis activity was not affected. Intoxication symptoms observed for 1 day. Ist application: No effect on colony strength or brood analysis of 295								
Cyantraniliprole 100 g/L OD Plus 2.5 L Pield/ Brassica napus/ Apis application: affected. Intoxication symptoms observed for 1 day.								
Cyantraniliprole 100 g/L OD Plus 2.5 L Pield/ Brassica napus/ Apis application: Intoxication symptoms observed for 1 day. Intoxication symptoms observed for 1 day. 1st application: No effect on colony strength or brood analysis of 295					activity was not			
Symptoms observed for 1 day. Cyantraniliprole 100 g/L OD plus 2.5 L napus/Apis application: symptoms observed for 1 day. Symptoms observed for 1 day. 1st application: No effect on colony strength or brood analysis of 295					affected.			
Symptoms observed for 1 day. Cyantraniliprole 100 g/L OD plus 2.5 L					Intoxication			
Cyantraniliprole 90 g a.s./ha Field/ Brassica 1st 1st application: No effect on colony Residue DuPled 100 g/L OD plus 2.5 L napus/ Apis application: strength or brood analysis of 295								
Cyantraniliprole 90 g a.s./ha Field/ Brassica 1st 1st application: No effect on colony Residue DuP 100 g/L OD plus 2.5 L napus/ Apis application: strength or brood analysis of 295								
100 g/L OD plus 2.5 L napus/Apis application: strength or brood analysis of 295					ioi i duj.			
100 g/L OD plus 2.5 L napus/ Apis application: strength or brood analysis of 295	Cyantraniliprole	90 g a.s./ha	Field/ Brassica	1 st	1 st application:	No effect on colony	Residue	DuPont-
	•	•	napus/ Apis	application:			analysis of	29571
codacide oil <i>mellifera</i> No effect on flight development, including nectar. pollen	C	codacide oil	mellifera		No effect on flight	development, including	nectar, pollen	
Two applications applied once carnica No effect activity or behaviour after over-wintering. and wax from	Two applications		U	No effect	_	1	· •	
before the hives.	11	* *						
flowering and 2 nd application:				2 nd	2 nd application:			
once during application: Control flight activity		_		application:				
flowering after No impact on too low to conclude		_						
decisively whether		110 Worling after		,				



bee flight.	mortality.	test item affected flight activity. Indication that flight activity was affected.		
		Slight effect on behaviour for 1 day.		



Test item and no. applications (interval)	Rate(s) tested, timing and application method	Study type/ crop/species	Mortality	Flight activity and Behavioural effects	Impact on colonies	Reference
Studies with one	application before flowering and on	e application during	flowering			
Cyantraniliprole 100 g/L SE plus codacide oil Two applications (19 d) (5 d aging interval)	150 g a.s./ha plus 2.5 L codacide oil once before flowering and once during flowering after bee flight	Semi-field/tunnel test/ Apple/ Apis mellifera	1 st application: No effect on mortality 2 nd application: Mortality affected for one day	1st and 2nd application: Control flight activity too low to conclude decisively whether test item affected flight activity. Indication that flight activity not affected. No effects on behaviour.	No effect on colony strength or brood development.	DuPont-27904
Cyantraniliprole 100 g/L SE plus codacide oil Two applications (7 d) (3 day aging interval)	100 g a.s./ha plus 2.5 L codacide oil once before flowering and once during flowering after bee flight applications before flowering	Semi-field/Tunnel test/ Nectarine/ Apis mellifera	1 st application: Mortality affected for 2-3 days. 2 nd application: Effect on mortality but extent of this is unknown, due to lack of stable mortality in control.	1 st application: No effect on flight activity. No effects on behaviour. 2 nd application: No effect on flight activity. No effects on behaviour.	No effect on colony strength or brood development.	DuPont-29812

EFSA Journal 2014;12(9):3814



Cyantraniliprole 100 g/L SE Two applications (7 d) (7 d aging interval)	150 g a.s./ha plus 2.5 L codacide oil applied twice before flowering seven days before hives set up	Semi-field/tunnel test/ Brassica napus/ Apis mellifera carnica	No effect on mortality.	Flight activity in control very low, but results indicate not affected by treatment. No treatment related behavioural abnormalities	No effect on colony strength or brood development.	DuPont-21317
Cyantraniliprole 100 g/L SE Two	150 g a.s./ha plus 2.5 L codacide oil applied twice before flowering and twelve days before hives set up	Semi-field/tunnel test/ Brassica napus/	No effect on mortality.	observed. No impact on flight activity. No treatment related behavioural	No effect on colony strength or brood development.	DuPont-21318
applications (8 d) (8 d aging interval)		Apis mellifera carnica		abnormalities observed.	development.	

EFSA Journal 2014;12(9):3814



Test item and no. applications (interval)	Rate(s) tested, timing and application method	Study type/ crop/species	Mortality	Flight activity and Behavioural effects	Impact on colonies	Exposure demonstrated	Reference
Cyantraniliprole 200 g/L SC Two applications (7 d)	100 g a.s./ha applied via drip irrigation twice during flowering. Once before hives moved into tunnels. The test item applications were carried out <i>via</i> drip irrigation. The controls were applied as spray applications.	Semi- field/tunnel test/Melon/ Apis mellifera	1 st and 2 nd applications: No effect on mortality.	1 st and 2 nd applications: No behavioural impacts. Flight activity did not appear to be affected.	No impact on colony strength or brood development.	No.	DuPont- 29970 ^b
Cyantraniliprole 200 g/L SC Three applications (7 d)	100 g a.s./ha applied <i>via</i> drip irrigation three times during flowering. Twice before hives moved into tunnels. The test item applications were carried out <i>via</i> drip irrigation. The control was applied as a spray.	Semi-field residue trial/ tunnel test/Melon/ Apis mellifera	1 st , 2 nd and 3 rd applications: No effect on mortality.	1 st , 2 nd and 3 rd applications: No impact on flight activity. 1 st , 2 nd and 3 rd applications: Behavioural effects observed but duration unknown due to lack of observations.	No impact on colony strength or brood development indicated, but one colony in the control group, thus results include some uncertainty.	Results of residue analysis.	DuPont- 27903, Revision No. 2 ^b

^a Brood assessments only carried out once before and once after application (approximately a week after application), which was not considered a sufficiently long enough period for deriving endpoints regarding colony strength and brood development.

EFSA Journal 2014;12(9):3814

b Study provisionally denoted to be 'Reliable with restrictions' based on Primary Review.

Study provisionally denoted to be 'Not reliable' based on Primary Review.

d Study not complaint with GLP.

Brood assessments only carried out once before and twice after application (approximately one and three weeks after application), which was not considered a sufficiently long enough period for deriving endpoints regarding colony strength and brood development.



Hazard quotients for honey bees (Annex IIIA, point 10.4)

Uses as ground spray in field melon, tomato, green bean, and field pepper, lettuce

Test substance	Route	Toxicity endpoint	Hazard quotient 12.5 g a.s.//ha	Hazard quotient 78 g a.s.//ha	Hazard quotient 90 g a.s.//ha	Trigger
Cyantraniliprole	Contact	>0.0934 µg a.s./bee	<134	<835	<964	50
Cyantraniliprole	Oral	>0.1055 μg a.s./bee	<118	<739	<853	50
'Cyantraniliprole 100 g/L OD'	Contact	0.65 μg a.s./bee	19.2	120	138	50
'Cyantraniliprole 100 g/L OD'	Oral	0.39 μg a.s./bee	32.1	200	231	50

Uses as spray application on apples, pears, nectarines peaches and apricots, citrus, mandarins, olives, grapes

Test substance	Rout e	Toxicity endpoint	Hazard quotient 40 g a.s./ha	Hazard quotient 100 g a.s./ha	Hazard quotient 112.5 g a.s./ha	Hazard quotient 150 g a.s./ha	Trigger
Cyantranilip role	Conta ct	>0.0934 µg a.s./bee	<428	<1071	<1204	<1606	50
Cyantranilip role	Oral	>0.1055 μg a.s./bee	<379	<948	<1066	<1422	50
Cyantranilip role 100 g/L SE	Conta ct	2.78 µg a.s./bee	14.4	36.0	40.5	54.0	50
Cyantranilip role 100 g/L SE	Oral	0.92 μg a.s./bee	43.5	109	122	163	50

Uses as spray application on apples, pears, nectarines peaches plums citrus

		Toxicity endpoint		Hazard quotient 125 g a.s./ha	
Test substance	Route		Hazard quotient 75 g a.s./ha		Trigger
Cyantraniliprole	Contact	>0.0934 µg a.s./bee	<803	<1338	50
Cyantraniliprole	Oral	>0.1055 μg a.s./bee	<711	<1184	50
'A16971 B'	Contact	0.98 μg a.s./bee	76.5	128	50
'A16971 B'	Oral	0.24 μg a.s./bee	313	521	50



Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Effects on other non-target arthropods tested with artificial (glass) substrates (Tier 1)

Species	Test material	Nominal rate (g product/ha)	Nominal application rates (g ai/ha)	Effects	Effects (g ai/ha)	Reference
Aphidius rhopalosiphi	Cyantraniliprole 100 g/L OD	0.039, 0.156, 0.625, 2.5, 10.0	0.0039, 0.0156, 0.0625, 0.2500, 1.000	Mortality	LR ₅₀ =0.1019	DuPont- 21472
Aphidius rhopalosiphi	Cyantraniliprole 100 g/L SE	0.123, 0.37, 1.11, 3.33, 10.0	0.0123, 0.037, 0.111, 0.333, 1.00	Mortality reproduction	$LR_{50} = 0.095$ $ER_{50} > 0.0111$	DuPont- 25994
Aphidius rhopalosiphi	Cyantraniliprole 200 g/L SC	0.24, 0.70, 2.01, 5.79, 16.71, 48.22	0.05, 0.14, 0.42, 1.20, 3.47, 10.0	Mortality reproduction	LR ₅₀ =0.36 ER ₅₀ =0.30	DuPont- 24250
Typhlodromus pyri	Cyantraniliprole 100 g/L OD	143.8, 287.5, 575.0, 1150.0, 2300.0	14.38, 28.75, 57.50, 115.0, 230.0	Mortality	LR ₅₀ >230	DuPont- 21471
Typhlodromus pyri	Cyantraniliprole 100 g/L SE	187.5, 375, 750, 1500, 3000	18.75, 37.5, 75.0, 150.0, 300.0	Mortality reproduction	LR ₅₀ >300 ER ₅₀ >300	DuPont- 25993
Typhlodromus pyri	Cyantraniliprole 200 g/L SC	69.33, 138.6, 277.2, 554.5, 1109	14.38, 28.75, 57.50, 115.0, 230.0	Mortality reproduction	LR ₅₀ >230 ER ₅₀ >230	DuPont- 24249

Tier 1 non-target arthropod in-field and off-field hazard quotients (HQ) for Cyantraniliprole 100 g/L OD used in field-grown melons at 4×90 g cyantraniliprole/ha

Species	LR ₅₀ (g a.s./ha)	In-field HQ	Off-field HQ	Trigger
T. pyri	>230	<1.06	< 0.02	2
A. rhopalosiphi	0.1019	2385	44.1	2

Tier 1 non-target arthropod in-field and off-field hazard quotients (HQ) for Cyantraniliprole 100 g/L OD used in field-grown 'fruiting vegetables' at 2×90 g cyantraniliprole/ha

Species	LR ₅₀ (g a.s./ha)	In-field HQ	Off-field HQ	Trigger
T. pyri	>230	< 0.665	< 0.048	2
A. rhopalosiphi	0.1019	1502	109	2

Tier 1 non-target arthropod in-field and off-field hazard quotients (HQ) for Cyantraniliprole 100 g/L OD used in field-grown potatoes at 2×12.5 g cyantraniliprole/ha

Species	LR ₅₀ (g a.s./ha)	In-field HQ	Off-field HQ	Trigger
T. pyri	>230	<0.665	<0.048	2
A. rhopalosiphi	0.1019	208	15	2



Tier 1 non-target arthropod in-field and off-field hazard quotients (HQ) for Cyantraniliprole 100 g/L SE used in citrus at 2×150 g cyantraniliprole/ha

Citrus (2 applications, earl	y)			
	LR ₅₀			
Species	(g cyantraniliprole/ha)	In-field HQ	Off-field HQ	Trigger
T. pyri	>300	< 0.85	< 0.217	2
A. rhopalosiphi	0.095	2684	685	2
Citrus (2 applicati	ons, late)			
	LR ₅₀			
Species	(g cyantraniliprole/ha)	In-field HQ	Off-field HQ	Trigger
T. pyri	>300	< 0.85	< 0.103	2
A. rhopalosiphi	0.095	2684	326	2

Tier 1 non-target arthropod in-field hazard quotients (HQ) for Cyantraniliprole 200 g/L SC used in outdoor tomatoes and peppers at 2×75 g cyantraniliprole/ha

Species	LR ₅₀ (g cyantraniliprole/ha)	In-field HQ	Trigger
T. pyri	>230	< 0.554	2
A. rhopalosiphi	0.36	354	2



Summary of extended laboratory and semi-field studies with the parasitoid, Aphidius rhopalosiphi

		Г	Г		
Species and test material	Test type	Nominal application rate (mL or g product/ha)	Nominal rate (g ai /ha)	Effects (g ai /ha)	Reference
Aphidius rhopalosiphi Cyantraniliprole 100 g/L OD	Extended lab test; exposure to fresh dried residues on natural substrate (barley seedlings)	1.23, 3.70, 11.1, 33.3, 100 mL/ha using a spray volume of 400 L water/ha	0.123, 0.370, 1.11, 3.33, 10.0	$LR_{50} = 0.822$ $ER_{50} > 0.123, \text{ (only lowest dose was tested)}$	DuPont- 25528
Aphidius rhopalosiphi Cyantraniliprole 100 g/L OD plus codacide oil	Extended lab test with foliar residue (barley seedlings) aged for 0, 13 and 27 days after 2 nd applic.n	2 x 1 L plus 2.5 L codacide oil/ha using a spray volume of 400 L water/ha and 7- day spray interval	2 x 100	Corrected mortality in each bioassay: 1 st : 87.2%; 2 nd : 28.2%; 3 rd : 5.30% reproductive effect <50% in 2 nd and 3 rd bioassay	DuPont- 27694
Aphidius rhopalosiphi Cyantraniliprole 100 g/L OD plus codacide oil	Modified extended lab with directly sprayed aphid mummies	250, 500, 1000, and 1500 mL/ha plus 417, 834, 1667, and 2500 mL/ha codacide oil	25, 50, 100, and 150	No effect >50% on aphid mummy hatching rate or reproduction up to and including 150 g ai/L	DuPont- 29294*
Aphidius rhopalosiphi Cyantraniliprole 100 g/L OD plus codacide oil	Extended lab test; exposure to fresh dried residues on natural substrate (barley seedlings)	22, 44, and 66 plus 36.7, 73.3, 110 mL codacide oil/ha, respectively, using a spray volume of 400 L water/ha	2.2, 4.4, and 6.6	Corrected mortality: 25, 46, 63%, respectively LR ₅₀ subsequently calculated by Canadian PMRA to be 47.1 ml/ha (≈ 4.7 g a.i./ha) No repellent effect No effect >50% on reproduction up to 6.6 g ai/ha	DuPont- 28801, Revision, No.1
Aphidius rhopalosiphi Cyantraniliprole 100 g/L SE plus codacide oil	Extended lab test; exposure to fresh dried residues on natural substrate (barley seedlings)	0.32, 1.6, 8.0, 40.0, 200.0 + 0.534, 2.67, 13.4, 66.8, 334 mL codacide oil/ha, respectively using a spray volume of 400 L water/ha	0.032, 0.16, 0.8, 4.0, 20.0	$LR_{50} = 2.06$ $ER_{50} > 0.8, \text{ the highest dose rate}$ where reproduction was tested.	DuPont- 26915



${\bf Summary\ of\ extended\ laboratory\ and\ semi-field\ studies\ with\ the\ parasitoid,} \ {\it Aphidius\ rhopalosiphi}\ (continued)$

Species and test material	Test type	Nominal application rate (mL or g product/ha)	Nominal rate (g ai /ha)	Effects (g ai /ha)	Reference
Aphidius rhopalosiphi Cyantraniliprole 100 g/L SE plus codacide oil	Extended lab test; exposure to fresh dried residues on natural substrate (barley seedlings)	22, 44, and 66 plus 36.7, 73.3, 110 mL codacide oil/ha, respectively, using a spray volume of 400 L water/ha	2.2, 4.4, and 6.6 plus 3.67, 7.33, 11.0	Corrected Mortality: 42.1%, 63.6%, 56.1% Reproduction was affected at all rates above the trigger value of 50%	DuPont- 28802
Aphidius rhopalosiphi Cyantraniliprole 100 g/L SE plus codacide oil	Extended lab, foliar residue on apple leaves aged for 0, 14 and 28 days after 2 nd applic.n, reproduction on untreated barley seedlings	2 × 1485 plus 2500 mL codacide oil/ha, using a spray volume of 1100 L water/ha and 7- day spray interval	2 × 150	Corrected mortality in each bioassay: 1st: 92.1%; 2nd: 7.5%; 3rd: 7.9% No effect >50% on reproduction where tested in 2 nd and 3 rd bioassays	DuPont- 27934
Aphidius rhopalosiphi 100 g/L SE plus Codacide oil	Extended lab, foliar residue on apple leaves aged for 0, 2 and 7 days after applic.n, reproduction on untreated barley seedlings	-	≡ 7.0, 13.0, 19.5, 26.0, and 32.6 g cyantraniliprole plus 116.7, 216.7, 325.0, 433.3, and 543.3 mL Codacide oil/ha	Bioassay 1 (fresh residue) $LR_{50} = 19.8$ reproductive $ER_{50} > 19.5$. Bioassays 2 and 3 (2 and 7 days aging): variable reductions in mortality and/or reproduction seen but overall ER_{50} still >19.5 but <26.0 .	DuPont- 32636
Aphidius rhopalosiphi 100 g/L OD plus codacide oil	Semi-field exposure to fresh dried residues on natural substrate (barley seedlings)	22 plus 36.7 mL codacide oil per ha	2.2	Only reproductive effect assessed:- at 22.4% after 11 days exposure (i.e. <50%)	DuPont- 28127
Aphidius rhopalosiphi 100 g/L OD plus codacide oil or without codacide oil	Semi-field exposure to fresh dried residues on natural substrate (barley seedlings)	60 and 120 without, and 60, 120, and 180 plus 166.7, 333, and 500 g/L codacide oil	6, 12, and 18	No effect on reproduction or parasitism capacity >50% at 6 g without oil. At 12 g without oil and all dosages with oil, effects on reproductive capacity were above 50%	DuPont- 29957



Aphidius rhopalosiphi 100 g/L SE plus codacide oil	Semi-field exposure to fresh dried residues on natural substrate (barley seedlings)	30, 60, 90, 120, and 180 mL plus 50, 100, 150, 200, and 300 mL codacide oil/ha	3, 6, 9, 12, and 18	Parasitism rate was affected (>50%) at all dose rates	DuPont- 29958*
Aphidius rhopalosiphi 400 g/kg WG A16971B	Extended lab test exposure to fresh dried residues on natural substrate (barley seedlings)	0.4, 2, 10, 50 and 250 g/ha	0.163, 0.814, 4.07, 20.35 and 101.75	LR50 = 4.11 No adverse reproductive effect >50% up to and including 4.07 g ai./ha)	SYN-10- 12
Aphidius rhopalosiphi 400 g/kg WG A16971B	Semi-field exposure to fresh dried residues on natural substrate (apple leaves)	10.4 and 109.5 g/ha	4.23 and 44.6	Corrected mortality: 25.6 and 87.2%, respectively; 38.8% effect on reproduction at 4.23 g ai/ha (i.e. <50%)	SYN-09- 22

^{*} Study provisionally denoted to be 'Reliable with restrictions' based on Primary Review.



Summary of extended laboratory semi-field and field studies with predatory mites

Species and test material	Test type	Nominal application rate (mL or g product/ha)	Nominal rate (g cyantraniliprole ai /ha)	Effects (g cyantraniliprole ai/ha)	Reference
Typhlodromus pyri 400 g/kg WG A16971B	Extended lab test; exposure to fresh dried residues on natural substrate (bean leaves)	15.6, 31.25, 62.5, 125 and 250 g /ha	6.35, 12.72, 25.44, 50.88 and 101.75 g ai/ha	LR ₅₀ > 101.75 No adverse reproductive effect >50% up to and including 101.75 g ai./ha)	SYN-10- 11
Predatory mites (99.6% Typhlodromus pyri, 0.4% Euseius finlandicus); Cyantraniliprole 100 g/L SE plus codacide oil	Field test on apple trees in Germany	2 x 1485 mL plus 2500 mL codacide oil/ha using a spray volume of 1100 L water/ha and 7-day interval	ray D		DuPont- 27849
Predatory mites 98.2% (Kampimodromus aberrans, 0.5% Amblyseius andersonii, 1.4% Typhlodromus phialatus) Cyantraniliprole 100 g/L SE plus Codacide oil	Field test on grapes vines in Italy	2 x 1485 mL plus 2500 mL codacide oil/ha using a spray volume of 1100 L water/ha and 14- day interval	2 x 150	Did not cause significant reduction in predatory mite population. Corrected mortality did not exceed 19% compared to control	DuPont- 27850



$Summary\ of\ extended\ laboratory\ tests\ for\ foliage\ dwelling\ predatory\ species,\ \textit{Coccinella\ septempunctata}\ and\ \textit{Chrysoperla\ carnea}$

Species and test material	Test type	Nominal application rate (mL product/ha)	Nominal rate (g ai/ha)	Effects (g ai/ha)	Reference
Coccinella septempunctata Cyantraniliprole 100 g/L OD	Extended lab test; exposed to fresh dried residues on natural substrate (bean leaves)	75, 150, 300, 600, and 1200 using a spray volume of 200 L water/ha	7.5, 15.0, 30.0, 60.0, and 120.0	LR ₅₀ = 61.5 ER ₅₀ not determined but reproduction was not affected >50% at up to and including 60.0 g ai/ha	DuPont- 25526
C.septempunctata Cyantraniliprole 100 g/L OD	Extended lab test with foliar residue (bean leaves) aged for 0, 14 and 28 days after 2 nd applic.n	2 x 1 L plus 2.5 L/ha codacide oil using a spray volume of 400 L water/ha and 7- day interval	2 x 100	Corrected mortality in each bioassay: 1st: 66.7%; 2nd: 2.6%; 3rd: -2.8% Where tested in 2nd and 3rd bioassays, reproduction was greater than the 2 fertile eggs/female/day validity criterion and not affected by >50%	DuPont- 28014, Revision No.1
Chrysoperla carnea Cyantraniliprole 100 g/L OD	Extended lab test; exposed to fresh dried residues on natural substrate (bean leaves)	82.9, 207, 518, 1296, and 3240 using a spray volume of 200 L water/ha	8.29, 20.7, 51.8, 129.6, and 324.0	$LR_{50} = 260.9$ Reproduction was not affected >50% up to and including 129.6 g ai/ha, the highest dose where this was tested	DuPont- 25525
C.carnea Cyantraniliprole 100 g/L OD plus codacide oil	Extended lab test with foliar residue (bean leaves) aged for 0 and 14 days after 2 nd applic.n	2 x 1 + 2.5 L/ha codacide oil, using a spray volume of 400 L water/ha and 7- day interval	2 x 100	Corrected mortality in each bioassay: 1 st : 0%; 2 nd : -2.8% Reproduction assessment was not entirely valid	DuPont- 28013*



Summary of extended laboratory tests for foliage dwelling predatory species, *Coccinella septempunctata*, and *Chrysoperla carnea* (continued)

Species and test material	Test type	Nominal application rate (mL product/ha)	Nominal rate (g ai/ha)	Effects (g ai/ha)	Reference
C.septempunctata Cyantraniliprole 100 g/L SE	Extended lab test; exposed to fresh dried residues on natural substrate (bean leaves)	62.5, 125, 250, 500, and 1000 using a spray volume of 200 L water/ha	6.25, 12.5, 25.0, 50.0, and 100.0	LR ₅₀ = 43.3 Reproduction was not affected >50% up to and including 25.0 g ai/ha, the highest dose where this was tested	DuPont- 26928
C.septempunctata Cyantraniliprole 100 g/L SE plus codacide oil	Extended lab test with foliar residue (apple leaves) aged for 0, 14 and 28 days after 2 nd applic.n	2 x 1485 plus 2500 mL codacide oil, using a spray volume of 1100 L/ha and 7-day interval	2 x 150	Corrected mortality in each bioassay: 1st: -35.3% (invalid); 2nd: 11.5%; 3rd: -3.5% Reproduction was greater than the 2 fertile eggs/ female/day validity criterion and not significantly different from the control (or by >50%) in the valid 2nd and 3rd bioassays	DuPont- 27852*
C.carnea Cyantraniliprole 100 g/L SE	Extended lab test; exposed to fresh dried residues on natural substrate (bean leaves)	789, 1025, 1332, 1731, and 2250 using a spray volume of 200 L water/ha	78.9, 102.5, 133.2, 173.1, and 225.0	$LR_{50} = 212.6$ Reproduction was not affected (>50%) up to and including 225.0 g ai/ha. Hatching rate was affected by 19.7% at 225.0 g ai/ha but the overall ER_{50} is the same as the LR_{50} due to mortality	DuPont- 26927
C.carnea Cyantraniliprole 100 g/L SE plus codacide oil	Extended lab test with foliar residue (apple leaves) aged for 0, 14 and 28 days after 2 nd applic.n	2 x 1485 plus 2500 mL codacide oil using a spray volume of 1100 L water/ha and 7-day interval	2 x 150	Corrected mortality in each bioassay: 1st. 14.3%; 2nd. 10.3%; 3rd. 8.1% Reproduction was greater than the 2 fertile eggs/ female/day and not significantly reduced from the control (or by >50%) in each bioassay	DuPont- 27851

^{*} Study provisionally denoted to be 'Reliable with restrictions' based on Primary Review.



Summary of extended laboratory tests for ground/surface-dwelling species - the rove beetle, $Aleochara\ bilineata$ and $Pardosa\ spp.$ spiders

Species and test material	Test type	Nominal formulation application rate/ha	Nominal rate (g ai/ha)	Effects (g ai/ha)	Reference
Aleochara bilineata Cyantraniliprole 200 g/L SC	Extended lab test; exposed on natural substrate (Lufa 2.1 soil)	13.4, 46.8, 164, 572, and 2005 mL/ha using a spray volume of 400 L water/ha	2.5, 8.75, 30.6, 107, and 375	Reproduction $ER_{50} = 56.4$ LR_{50} was not determined but would be > 30.6	DuPont- 26172
Aleochara bilineata Cyantraniliprole 200 g/L SC	Extended lab test with treated Lufa 2.1 soil residue aged for 2, 30 and 86 days after 2 nd applic.n	1 x 6.846 L/ha plus 1 x 4.89 L/ha using a spray volume of 400 L water/ha and 7-day interval, followed by irrigation with 4 x 5000 L water/ha	1400 + 1000	Effect on reproduction in each bioassay: 1 st : 100%; 2 nd : -9.1%; 3 rd : 13.5%	DuPont- 29908
Pardosa spiders Cyantraniliprole 200 g/L SC	Extended lab test; exposed on natural substrate (Lufa 2.1 soil)	0.130, 0.261, 0.521, 1.043, and 2.086 kg/ha using a spray volume of 400 L water/ha	25, 50, 100, 200, and 400	Mortality and feeding was not not significantly different from the control (or affected by >50%) up to and including 400 g ai/ha.	DuPont- 26173

Higher tier assessment for non-target arthropods exposed to Cyantraniliprole 100 g/L OD with predicted exposure rates in-field and off-field



Crop	Species	Situation and test type	Higher tier exposure (g a.s./ha)	Lowest Tier 2 ER ₅₀ (g a.s./ha)	Risk low?
Field-grown	A. rhopalosiphi	In-field	243	0.822	No
melons		Off-field 3D	24.4		No
(S EU)	C. carnea	In-field	243	129.6	No
		Off-field 2D	2.44		Yes
	C. septempunctata	In-field	243	61.5	No
		Off-field 2D	2.44		Yes
Field-grown	A. rhopalosiphi	In-field	153	0.822	No
fruiting vegetables		Off-field 3D	55.3		No
(S EU)	C. carnea	In-field	153	129.6	No
2x90g a.s./ha		Off-field 2D	5.53		Yes
	C. septempunctata	In-field	153	61.5	No
		Off-field 2D	5.53		Yes
Field-grown	A. rhopalosiphi	In-field	21.25	0.822	No
potatoes		Off-field 3D	0.77		Yes
(N EU/ N EU) 2x12.5g a.s./ha	C. carnea	In-field	21.25	129.6	Yes
		Off-field 2D	0.77		Yes
	C. septempuctata	In-field	21.25	61.5	Yes
		Off-field 2D	0.77		Yes

Higher tier assessment for non-target arthropods exposed to Cyantraniliprole 100~g/L SE with predicted exposure rates in-field and off-field (worst-case use on citrus)

Crop and growth stage	Species	Situation and test type	Higher tier exposure rate	Lowest Tier 2 ER ₅₀	Risk low?
			(g a.s./ha)	(g a.s./ha)	
Citrus (S EU)	A. rhopalosiphi	In-field	127.5	>0.8	No
BBCH 9-59		Off-field 3D	325.5		No
(early)	C. carnea	In-field	127.5	212.6	Yes
		Off-field 2D	32.6]	Yes
	C. septempunctata	In-field	127.5	>25	No
		Off-field 2D	32.6		No
Citrus (S EU)	A. rhopalosiphi	In-field	204	>0.8	No
BBCH 69-89		Off-field 3D	154.9		No
(late)	C. carnea	In-field	204	212.6	Yes
		Off-field 2D	15.5		Yes
	C. septempunctata	In-field	204	>25	No
		Off-field 2D	15.5		Yes

Higher tier test assessment for A. rhopalosiphi, exposed to Cyantraniliprole 400 g/kg WG with predicted exposure rates in-field and off-field (worst-case use on orchard fruit)



Crop and growth stage	Species and test type	Situation and test type	Higher tier exposure rate (g a.s./ha)	Lowest Tier 2 ER ₅₀ (g a.s./ha)	Risk low?
Orchard fruit	A. rhopalosiphi	In-field	170	4.11	No
(late)	extended lab	Off-field 3D	129		No
	A. rhopalosiphi	In-field	170	>4.23	No
	semi-field	Off-field 3D	129		No



Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Toxicity endpoint values for earthworms

Test item	Test/ duration	Endpoint ^b	Nominal endpoint value not adjusted for purity (mg/kg dry wt soil) ^a	Nominal endpoint value adjusted for technical purity (mg/kg dry wt soil) ^a	Reference
			Acute studies		
Cyantraniliprole	Acute, 14 d	LC ₅₀ b	> 1000	> 945	DuPont- 24880
IN-J9Z38	Acute, 14 d	LC ₅₀	> 1000	> 964	DuPont- 21324
IN-JCZ38	Acute, 14 d	LC ₅₀	> 1000	> 921	DuPont- 21325
IN-JSE76	Acute, 14 d	LC ₅₀	> 1000	> 938	DuPont- 24239
IN-K5A77	Acute, 14 d	LC ₅₀	> 1000	> 953	DuPont- 21393
IN-K5A78	Acute, 14 d	LC ₅₀	> 1000	> 949	DuPont- 24236
IN-K5A79	Acute, 14 d	LC ₅₀	> 1000	> 844	DuPont- 24245
IN-PLT97	Acute, 14 d	LC ₅₀	> 1000	> 870	DuPont- 24244
IN-QKV54	Sub-lethal, 28 d	LC ₅₀	> 100	> 98.3	DuPont- 29960
IN-RNU71	Sub-lethal, 28 d	LC ₅₀	> 100	> 92.4	DuPont- 30092
200 g/L SC	Acute, 14 d	LC ₅₀ b	> 1000	≡>207.4 mg ai/kg	DuPont- 26583
100 g/L OD	Acute, 14 d	LC ₅₀	> 1000	≡>104.8 mg ai/kg	DuPont- 24879
400 g/kg WG A16971B	Acute, 14 d	LC ₅₀	> 2500	≡ >1017.5 mg ai/kg	10 10 48 024 S
A16901B WG 20 g/kg cyantraniliprole + 20 g/kg thiamethoxam	Acute, 14 d	LC ₅₀	> 5000	≡>1030 mg cyantraniliprole/kg + >1030 mg thiamethoxam/kg	10 10 48 025 S



Toxicity endpoint values for earthworms (continued)

Chronic studies								
Cyantraniliprole	Sub-lethal, 56 d	NOEC ^b	1000	945	DuPont- 26883			
IN-J9Z38	Sub-lethal, 56 d	NOEC ^b	1028.8	1000	DuPont- 27347			
IN-JCZ38	Sub-lethal, 56 d	NOEC ^b	1059	1000	DuPont- 27351			
IN-JSE76	Sub-lethal, 56 d	NOEC ^b	1000	938	DuPont- 27352			
IN-K5A77	Sub-lethal, 56 d	NOEC ^b	1000	923	DuPont- 27353			
IN-K5A78	Sub-lethal, 56 d	NOEC ^b	1036	1000	DuPont- 27350			
IN-K5A79	Sub-lethal, 56 d	NOEC b	1185	1000	DuPont- 27349			
IN-PLT97	Sub-lethal, 56 d	NOEC b	1149	1000	DuPont- 27348			
IN-QKV54	Sub-lethal, 56 d	NOEC b	100	98.3	DuPont- 29960			
IN-RNU71	Sub-lethal, 56 d	NOEC b	100	92.4	DuPont- 30092			
100 g/L OD + codacide oil	Sub-lethal, 56 d	NOEC ^b	1000 (+ 1578 codacide oil)	≡ 104.8 mg ai/kg	DuPont- 29052			

Represents the highest concentration tested.

Summary of toxicity endpoints for cyantraniliprole and soil metabolites on Collembola

Test material	Measurement endpoint ^a	Endpoint value (mg ai/kg dry wt. soil) ^a	Reference
Cyantraniliprole technical	28-day NOEC	0.080	DuPont-27444
IN-J9Z38	28-day NOEC	250 ^b	DuPont-28208
IN-JCZ38	28-day NOEC	12.0	DuPont-28199
IN-JSE76	28-day NOEC	250	DuPont-28209
IN-K5A77	28-day NOEC	< 31.3 ^b	DuPont-27975
IN-K5A78	28-day NOEC	500 ^b	DuPont-28205
IN-K5A79	28-day NOEC	125	DuPont-28204
IN-PLT97	28-day NOEC	500 ^b	DuPont-27976
IN-QKV54	28-day NOEC	98.3	DuPont-29990
IN-RNU71	28-day NOEC	12.5	DuPont-30093

The organic matter content of the test soil was 5% in each case The NOEC has been divided by 2 since the log Pow is >2

Endpoint based on test conducted with artificial soil containing 5% peat rather than standard 10%



Summary of toxicity endpoints for cyantraniliprole and soil metabolites on predatory soil mites, Hypoaspis aculeifer

Test material	Measurement endpoint ^a	Endpoint value (mg/kg soil) ^a	Reference
Cyantraniliprole technical	14-day NOEC	1000	DuPont-27445
IN-J9Z38	14-day NOEC	$500^{\rm b}$	DuPont-28207
IN-JCZ38	14-day NOEC	1000	DuPont-28198
IN-JSE76	14-day NOEC	1000	DuPont-28206
IN-K5A77	14-day NOEC	500 ^b	DuPont-27979
IN-K5A78	14-day NOEC	500 ^b	DuPont-28203
IN-K5A79	14-day NOEC	1000	DuPont-28202
IN-PLT97	14-day NOEC	$250^{\rm b}$	DuPont-27978
IN-QKV54	14-day NOEC	100	DuPont-31375
IN-RNU71	14-day NOEC	100	DuPont-31374

The organic matter content of the test soil was 5% in each case The NOEC has been divided by 2 since the $\log Pow$ is >2

Summary of endpoints for cyantraniliprole and metabolites on leaf litter decomposition

Test material	Test exposure regime	Exposure duration	Findings	Reference
Cyantraniliprole	Plateau concentration in top 10 cm 0.035 mg ai/kg plus overspray of 300 mg cyantraniliprole/ha	6 months		DuPont-28194, Revision No. 1
IN-J9Z38	Plateau concentration in top 10 cm 0.009 mg/kg plus overspray of 300 mg cyantraniliprole /ha	6 months		DuPont-27647
IN-JSE76	Plateau concentration in top 10 cm 0.051 mg/kg plus overspray of 300 mg cyantraniliprole /ha	6 month	No significant effects in	DuPont-28195, Revision No. 1
IN-K5A77	Plateau concentration in top 10 cm 0.038 mg/kg plus overspray of 300 mg cyantraniliprole /ha	6 months	straw decomposition compared to controls after exposure to treated soil for 6 months in all	DuPont-29959
In-K5A78	Plateau concentration in top 10 cm 0.068 mg/kg plus overspray of 300 mg cyantraniliprole /ha	6 months	studies	DuPont-27319
IN-K5A79	Plateau concentration in top 10 cm 0.005 mg/kg plus overspray of 300 mg cyantraniliprole /ha	6 months		DuPont-27322
IN-PLT97	Plateau concentration in top 10 cm 0.075 mg/kg plus overspray of 300 mg cyantraniliprole /ha	6 months		DuPont-28196, Revision No. 1

Effects of cyantraniliprole on non-target soil macro-organisms: field studies

Test material	Test exposure regime	Exposure duration	Findings	Reference
Treatments T1	First application: 17.9	Microarthropods	Reductions 27 days and	DuPont-29454
(DPX-HGW86-	g a.i./ha (T1), 142.2 g	were sampled 10	88 days after the second	DuPont-29434



499 OD), T2 (DPX- HGW86- 499 OD + Codacide Oil, T3 (DPX- HGW86- 547 SE + Codacide Oil), T4 (DPX- HGW86- 547 SE/ DPX- HGW86-500 SC)	a.i./ha (T2), 293.6 g a.i./ha (T3) and 1502.2 g a.i./ha (T4) Second application: 13.2 g a.i./ha (T1), 100.8 g a.i./ha (T2), 201.8 g a.i./ha (T3) and 958.8 g a.i./ha (T4)	days before 2 nd application, 27 days after 2 nd application, 88 days after 2 nd application, 159 days after 2 nd application and 368 days after 2 nd application.	application for individual taxa in T2 and T4 treatments. By 159 days and 368 days after the second application there were no significant reductions but there was a significant increase for total undetermined Entomobryidae with treatment T3 and for <i>Isotomiella minor</i> with treatment T1.	
Cyantraniliprole	First application: 53 g a.s./ha cyantraniliprole technical Second application: 300 g a.s./ha Cyantraniliprole 100 g/L OD	GLP sampling 143 days after 2 nd application (earlier non-GLP sampling 92 days after 2 nd application)	No significant effects on soil microarthropods	DuPont-29708

Effects of cyantraniliprole, its soil metabolites and formulations on non-target soil micro-organisms

Test item	Test	Test concentrations (mg/kg)	Parameter	% effect ^a	Reference
Cyantraniliprole technical	28-day laboratory 28-day laboratory	0.14 and 1.14	Respiration Nitrate formation	<25% <25%	DuPont-24874
IN-J9Z38	28-day laboratory 42-day laboratory	0.138 and 1.38	Respiration Nitrate formation	<25% <25%	DuPont-21320
IN-JCZ38	28-day laboratory 42-day laboratory	0.145 and 1.45	Respiration Nitrate formation	<25% <25%	DuPont-21319
IN-JSE76	28-day laboratory 42-day laboratory	0.15 and 1.48	Respiration Nitrate formation	<25% <25%	DuPont-24243
IN-K5A77	28-day laboratory 28-day laboratory	0.140 and 1.40	Respiration Nitrate formation	<25% <25%	DuPont-21391
IN-K5A78	28-day laboratory 28-day laboratory	0.14 and 1.41	Respiration Nitrate formation	<25% <25%	DuPont-24238
IN-K5A79	28-day laboratory 28-day laboratory	0.16 and 1.60	Respiration Nitrate formation	<25% <25%	DuPont-24242
IN-PLT97	28-day laboratory 28-day laboratory	0.15 and 1.49	Respiration Nitrate formation	<25% <25%	DuPont-24241
IN-QKV54	28-day laboratory 43-day laboratory	0.20, 1.02, 2.03	Respiration Nitrate formation	<25% <25%	DuPont-29559
IN-RNU71	28-day laboratory 28-day laboratory	0.22 and 2.16	Respiration Nitrate formation	<25% <25%	DuPont-30090
200 g/L SC	28-day laboratory 44-day laboratory	0.133 and 1.33 ^b	Respiration Nitrate formation	<25% <25%	DuPont-26569
100 g/L OD	28-day laboratory 56-day laboratory	0.124 and 1.24 ^b	Respiration Nitrate formation	<25% <25%	DuPont-24875, Revision No. 1
400 g/kg WG A16971B	28-day laboratory 28-day laboratory	0.34 and 1.7 ^b	Respiration Nitrate formation	<25% <25%	10 10 48 018 C/N



A16901B WG 20 g/kg cyantraniliprole + 20 g/kg thiamethoxam	28-day laboratory 28-day laboratory	0.93 and 4.67 mg product/kg ≡ 0.192 and 0.962 mg of each ai/kg ^b	Respiration Nitrate formation	<25% <25%	10 10 48 019 C/N
--	--	--	----------------------------------	--------------	---------------------

^a % deviation from the control

Toxicity/exposure ratios for soil organisms

Acute TERs for earthworms exposed to maximum accumulated predicted environmental concentrations of cyantraniliprole and its metabolites in soil

Test substance	Duration of test (days)	LC ₅₀ (mg/kg soil)	Maximum PEC _{soil} (mg/kg soil)	TER _a
Cyantraniliprole	14	>945	0.718	>1316
Cyantraniliprole 100 g/L OD	14	≡>104.8 a.s.	0.718	>146
Cyantraniliprole 200 g/L SC	14	≡>207.4 a.s.	0.718	>289
Cyantraniliprole 400 g/kg WG	14	$\equiv > 1017.5 \text{ a.s.}$	0.718	>1417
IN-J9Z38	14	>482ª	1.462	>330
IN-JCZ38	14	>921	0.347	>2654
IN-JSE76	14	>938	0.662	>1417
IN-K5A77	14	>477ª	0.151	>3159
IN-K5A78	14	>475 ^a	0.908	>523
IN-K5A79	14	>844	0.079	>10684
IN-PLT97	14	>435 ^a	0.613	>710
IN-QKV54	28	>98.3	0.327	>301
IN-RNU71	28	>92.4	0.222	>416

The LC_{50} has been divided by 2 since the log Pow is >2 and the test soil organic matter content was 10% (note: the log Pow for cyantraniliprole itself is 1.97 (ref. Vol 3, Section B.2.8) and so the correction has not been made for a.s. and formulation endpoints)

Chronic TERs for earthworms exposed to maximum accumulated predicted environmental concentrations of cyantraniliprole and its metabolites in soil

Test substance	Duration of test (days)	NOEC a (mg/kg soil)	Maximum PEC _{soil} (mg/kg soil)	TER _{lt}
Cyantraniliprole	56	945	0.718	1316
Cyantraniliprole 100 g/L OD	56	$\equiv 104.8 \text{ a.s.}$	0.718	146
IN-J9Z38	56	500 ^b	1.462	342
IN-JCZ38	56	1000	0.347	2882
IN-JSE76	56	938	0.662	1417
IN-K5A77	56	462 ^b	0.151	3060
IN-K5A78	56	500 ^b	0.908	551
IN-K5A79	56	1000	0.079	12658
IN-PLT97	56	500 ^b	0.613	816
IN-QKV54	56	98.3	0.327	301
IN-RNU71	56	92.4	0.222	416

The organic matter content of the test soil was 5% in each case

Based on equivalent concentration of active substance

The LC₅₀ has been divided by 2 since the log Pow is >2



Chronic TERs for collembola and soil mites exposed to maximum predicted environmental concentrations of cyantraniliprole and major metabolites in soil (covering all proposed uses).

Test item	Test organism	NOEC (mg/kg soil)	Maximum PEC _{soil} (mg/kg soil)	TER _{lt}
Cyantraniliprole technical	Folsomia candida	0.0800		0.11
	Hypoaspis aculeifer	1000	0.718	1393
IN-J9Z38	F. candida	250	1.462	171
	H. aculeifer	500	1.462	342
IN-JCZ38	F. candida	12.0	0.347	34.6
	H. aculeifer	1000	0.347	2882
IN-JSE76	F. candida	250	0.662	378
	H. aculeifer	1000	0.002	1511
IN-K5A77	F. candida	<31.3	0.151	<207
	H. aculeifer	500	0.131	6623
IN-K5A78	F. candida	500	0.908	551
	H. aculeifer	500	0.908	551
IN-K5A79	F. candida	125	0.079	1582
	H. aculeifer	1000	0.079	12658
IN-PLT97	F. candida	500	0.613	816
	H. aculeifer	250	0.013	408
IN-QKV54	F. candida	98.3	0.327	301
	H. aculeifer	100	0.327	306
IN-RNU71	F. candida	12.5	0.222	56.3
	H. aculeifer	100	0.222	450



Risk assessment for technical and formulated cyantraniliprole and metabolites on soil micro-organisms

Test item	Test concentrations (mg/kg)	Parameter	PECsoil (mg/kg)	< 25 % effect at PECsoil
Cyantraniliprole technical	0.14 and 1.14	Respiration Nitrate formation	0.718	Yes Yes
IN 10729	0.120 and 1.20	Respiration Nitrate formation	All uses = 1.462	No No
IN-J9Z38	0.138 and 1.38	Respiration Nitrate formation	Field uses only = 0.914	Yes Yes
IN-JCZ38	0.145 and 1.45	Respiration Nitrate formation	0.347	Yes Yes
IN-JSE76	0.15 and 1.48	Respiration Nitrate formation	0.662	Yes Yes
IN-K5A77	0.140 and 1.40	Respiration Nitrate formation	0.151	Yes Yes
IN-K5A78	0.14 and 1.41	Respiration Nitrate formation	0.908	Yes Yes
IN-K5A79	0.16 and 1.60	Respiration Nitrate formation	0.079	Yes Yes
IN-PLT97	0.15 and 1.49	Respiration Nitrate formation	0.613	Yes Yes
IN-QKV54	0.20, 1.02, 2.03	Respiration Nitrate formation	0.327	Yes Yes
IN-RNU71	0.22 and 2.16	Respiration Nitrate formation	0.222	Yes Yes
200 g/L SC	0.133 and 1.33 ^a	Respiration Nitrate formation	0.718	Yes Yes
100 g/L OD	0.124 and 1.24 ^a	Respiration Nitrate formation	0.718	Yes Yes
400 g/kg WG A16971B	0.34 and 1.7 ^a	Respiration Nitrate formation	0.718	Yes Yes
A16901B WG 20 g/kg cyantraniliprole + 20 g/kg thiamethoxam	0.93 and 4.67 mg product/kg \equiv 0.192 and 0.962 mg of each a.s./kg ^a	Respiration Nitrate formation	0.718	Yes Yes

Based on equivalent concentration of active substance



Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8) Preliminary screening data

Summary of studies investigating the effects of cyantraniliprole on terrestrial non-target plants

Test substance	Study type	Number of species	Lowest	Reference
		satisfying validity	overall ER ₅₀	
		criteria		
Cyantraniliprole (DPX-	21 d Seedling	7 (corn, oat, onion,	> 1.43 L	Porch &
HGW86) 100 g/L OD	emergence, OECD	ryegrass, cucumber, pea	form/ha (>	Martin
	208, GLP	and sugar beet)	150 g a.s./ha)	(2009b)
Cyantraniliprole (DPX-	21 d Seedling	7 (corn, cucumber, oilseed	> 1.5 L	Porch &
HGW86) 100 g/L OD +	emergence, OECD	rape, soybean, sugar beet,	form/ha (>	Kendall
Codacide oil	208, GLP	ryegrass and tomato)	150 g a.s./ha)	(2010a)
Cyantraniliprole (DPX-	21 d Vegetative	6 (corn, oat, ryegrass,	> 1.43 L	Porch &
HGW86) 100 g/L OD	vigour, OECD	oilseed rape, pea and	form/ha (>	Martin
	227, GLP	soybean)	150 g a.s./ha)	(2009a)
Cyantraniliprole (DPX-	21 d Vegetative	10 (all species tested)	> 1.5 L	Porch &
HGW86) 100 g/L OD +	vigour, OECD		form/ha (>	Martin
Codacide oil	227, GLP		150 g a.s./ha)	(2010b)



Risk to terrestrial non-target plants from the proposed use of Cyantraniliprole 100 g/L OD

Crop	Field or	Maximum single	Effect	Endpoint	Less than 50%
	glasshouse?	application rate (g			effects at
		a.s./ha)			maximum rate?
Melons (melon	F/G	90	Seedling	$ER_{50} > 150$	Yes
& water melon)			emergence/	g a.s./ha	
Tomato	F	90	vegetative vigour		Yes
Pepper	F	90			Yes
Green bean	F	90			Yes
Lettuce	F/G	78			Yes
Potatoes	F	12.5			Yes
Aubergine,	G	120			Yes
tomato					
Cucurbits edible	G	120			Yes
and inedible					
peel					
Pepper	G	120			Yes
Green bean	G	90			Yes

Risk to terrestrial non-target plants from the proposed use of Cyantraniliprole 100 g/L SE

Crop	Field or	Maximum single	Effect	Endpoint	Less than 50%
	glasshouse?	application rate (g			effects at
		a.s./ha)			maximum rate?
Citrus	F	150	Seedling	$ER_{50} > 150$	Yes
Citrus,	F	32	emergence/	g a.s./ha	Yes
mandarins			vegetative vigour		
Nectarine	F	150			Yes
Nectarine,	F	90			Yes
peaches and					
apricots					
Olives	F	150			Yes
Grapes	F	112.5			Yes
Apples, pears	F	90			Yes

Risk to terrestrial non-target plants from the proposed use of Cyantraniliprole 100 g/L SC

Crop	Field or glasshouse?	Maximum single application rate (g a.s./ha)	Effect	Endpoint	Less than 50% effects at maximum rate?
Field tomato and pepper	F	75	Seedling emergence/	ER ₅₀ > 150 g a.s./ha	Yes
Aubergine and tomato	G	100	vegetative vigour		Yes
Cucurbits edible and inedible peel	G	100			Yes
Pepper	G	100			Yes
Lettuce	G	100			Yes
Melons (melon and water melon)	G	75			Yes

Risk to terrestrial non-target plants from the proposed use of Cyantraniliprole 400 g/kg WG

Crop	Field or	Maximum single	Effect	Endpoint	Less than	50%
	glasshouse?	application rate (g			effects	at



		a.s./ha)			maximum rate?
Peach/nectarine	F	125	Seedling	$ER_{50} > 150$	Yes
Plums	F	125	emergence/	g a.s./ha	Yes
Apples	F	75	vegetative vigour		Yes
Pears	F	75			Yes

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	EC ₅₀ >100 mg a.s./L

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Cyantraniliprole
water	Cyantraniliprole
sediment	Cyantraniliprole
groundwater	Cyantraniliprole

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)*

Active substance

RMS/peer review proposal				
Cyantraniliprole				
Regulation (EC) 1272/2008				
Category: Aquatic Acute 1, H400; Aquatic Chronic 1, H410: Very Toxic to aquatic life with long lasting effects				
M-factor: 10 (acute); 10 (chronic) Pictogram Code: GHS09				
Signal word: Warning				
The classification is based on the acute EC_{50} in the range 0.1-0.01 mg/l and NOEC in the range of 0.01-0.001 mg/L for aquatic invertebrates.				

^{*} It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.



$\ \, \textbf{APPENDIX B} - \textbf{USED COMPOUND CODE}(S)$

Code/Trivial name*	Chemical name/SMILES notation**	Structural formula
IN-F6L99	3-bromo-N-methyl-1H-pyrazole-5-carboxamide Brc1cc(nn1)C(=O)NC	O Br
	Bicicc(iiii)c(=0)ivc	CH ₃ H
IN-J9Z38	2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carbonitrile	CH ₃ N N N Br
	Cc4cc(C#N)cc3c4N=C(c2cc(Br)nn2c1ncccc1Cl) N(C)C3=O	N CH ₃
IN-JCZ38	4-({[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]carbonyl}amino)-N3,5-dimethylisophthalamide	O CH ₃ N CI
	NC(=O)c3cc(C)c(NC(=O)c2cc(Br)nn2c1ncccc1C 1)c(c3)C(=O)NC	HN O Br
IN-JSE76	4-({[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]carbonyl}amino)-3-methyl-5-(methylcarbamoyl)benzoic acid	OH CH ₃ N CI
	O=C(O)c3cc(C)c(NC(=O)c2cc(Br)nn2c1ncccc1C 1)c(c3)C(=O)NC	HN O Br
IN-K5A77	2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carboxamide	CH ₃ N N N Br
	NC(=O)c3cc(C)c4N=C(c2cc(Br)nn2c1ncccc1Cl) N(C)C(=O)c4c3	O NH ₂ O CH ₃
IN-K5A78	2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carboxylic acid	CH ₃ N-N
	O=C(O)c3cc(C)c4N=C(c2cc(Br)nn2c1ncccc1Cl) N(C)C(=O)c4c3	O N CH ₃



IN-K5A79	4-({[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]carbonyl}amino)-3-carbamoyl-5-methylbenzoic acid O=C(O)c3cc(C)c(NC(=O)c2cc(Br)nn2c1ncccc1C l)c(c3)C(N)=O	HO CI CH ₃ O N N N Br NH ₂
IN-K7H19	4-({[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]carbonyl}amino)-5-methylisophthalamide NC(=O)c3cc(C)c(NC(=O)c2cc(Br)nn2c1ncccc1C l)c(c3)C(N)=O	O H ₂ N CI N N N N N Br
IN-M2G98	3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide NC(=O)c2cc(Br)nn2c1ncccc1Cl	O Br H ₂ N N CI
IN-MLA84	2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-8-methyl-4-oxo-1,4-dihydroquinazoline-6-carbonitrile Cc4cc(C#N)cc1c4N=C(NC1=O)c3cc(Br)nn3c2nc ccc2Cl	N CI N N N N Br
IN-MYX98	3-bromo-1-(3-chloropyridin-2-yl)-N-{4-cyano-2-[(hydroxymethyl)carbamoyl]-6-methylphenyl}-1H-pyrazole-5-carboxamide OCNC(=O)c3cc(C#N)cc(C)c3NC(=O)c2cc(Br)nn 2c1nccc1Cl	HO NH N CI CI NH N CI



IN-NXX70	2-[3-bromo-1-(3-hydroxypyridin-2-yl)-1H-pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carbonitrile Cc4cc(C#N)cc3c4N=C(c2cc(Br)nn2c1ncccc1O)N (C)C3=O	CH ₃ N N Br
IN-N5M09	6-chloro-4-methyl-11-oxo-11H-pyrido[2,1-b]quinazoline-2-carbonitrile Cc3cc(C#N)cc2c3N=C1C(Cl)=CC=CN1C2=O	CI CH ₃
IN-N7B69	3-bromo-1-(3-chloropyridin-2-yl)-N-[4-cyano-2-(hydroxymethyl)-6-(methylcarbamoyl)phenyl]- 1H-pyrazole-5-carboxamide CNC(=O)c3cc(C#N)cc(CO)c3NC(=O)c2cc(Br)nn 2c1ncccc1Cl	OH O
IN-PLT97	2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-8-methyl-4-oxo-1,4-dihydroquinazoline-6-carboxylic acid O=C(O)c1cc2C(=O)N=C(Nc2c(C)c1)c4cc(Br)nn 4c3ncccc3Cl	HO O O O CI
IN-QKV54	2-(5-bromo-1H-pyrazol-3-yl)-3,8-dimethyl-4-oxo-1,2,3,4-tetrahydroquinazoline-6-carbonitrile Cc2cc(C#N)cc1C(=O)N(C)C(Nc12)c3cc(Br)nn3	CH ₃ H N Br
IN-RNU71	2-(2-bromo-4-oxopyrazolo[1,5-a]pyrido[3,2-e]pyrazin-5(4H)-yl)-5-cyano-N,3-dimethylbenzamide CNC(=O)c4cc(C#N)cc(C)c4N2c1cccnc1n3nc(Br) cc3C2=O	N N N N N N N N N N N N N N N N N N N



IN-DBC80	3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxylic acid O=C(O)c2cc(Br)nn2c1ncccc1Cl	O OH
IN-Q6S09	1,6,10-trimethyl-5-oxo-5,6-dihydroindazolo[2,3-a]quinazoline-3,8-dicarbonitrile N#Cc3cc2c4N(C)C(=O)c1cc(C#N)cc(C)c1n4nc2 c(C)c3	N CH ₃ CH ₃
IN-RYA13	3-bromo-1-(3-chloropyridin-2-yl)-N-[4-formamido-2-methyl-6-(methylcarbamoyl)phenyl]-1H-pyrazole-5-carboxamide CNC(=O)c3cc(NC=O)cc(C)c3NC(=O)c2cc(Br)nn 2c1ncccc1Cl	O CH ₃ O CI NH N N Br
methanesulfonic acid	methanesulfonic acid $CS(=O)(=O)O$	O HO-S-CH ₃ O
acetonitrile	acetonitrile CC#N	H ₃ C
heptane	heptane CCCCCC	H ₃ C CH ₃
3-picoline	3-methylpyridine	CH ₃

^{*} The metabolite name in bold is the name used in the conclusion.

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



ABBREVIATIONS

1/n slope of Freundlich isotherm

 λ wavelength

ε decadic molar extinction coefficient

°C degree Celsius (centigrade)

μg microgram

μm micrometer (micron)
a.s. active substance
AChE acetylcholinesterase
ADE actual dermal exposure
ADI acceptable daily intake
AF assessment factor

AOEL acceptable operator exposure level

AP alkaline phosphatase AR applied radioactivity ARfD acute reference dose

AST aspartate aminotransferase (SGOT)

AV avoidance factor
BCF bioconcentration factor
BUN blood urea nitrogen
bw body weight

CAS Chemical Abstracts Service CFU colony forming units

ChE cholinesterase
CI confidence interval

CIPAC Collaborative International Pesticides Analytical Council Limited

CL confidence limits cm centimetre d day

DAA days after application
DAR draft assessment report
DAT days after treatment
DDD daily dietary dose
DM dry matter

 DT_{50} period required for 50 percent disappearance (define method of estimation) DT_{90} period required for 90 percent disappearance (define method of estimation)

dw dry weight

EbC₅₀ effective concentration (biomass)

EC₅₀ effective concentration ECHA European Chemicals Agency EEC European Economic Community

EINECS European Inventory of Existing Commercial Chemical Substances

ELINCS European List of New Chemical Substances

EMDI estimated maximum daily intake ER₅₀ emergence rate/effective rate, median ErC₅₀ effective concentration (growth rate)

EU European Union

EUROPOEM European Predictive Operator Exposure Model

f(twa) time weighted average factor

FAO Food and Agriculture Organization of the United Nations

FID flame ionisation detector

FIR Food intake rate

FOB functional observation battery

FOCUS Forum for the Co-ordination of Pesticide Fate Models and their Use



g gram

GAP good agricultural practice GC gas chromatography

GC-FID gas chromatography with flame ionisation detector

GCPF Global Crop Protection Federation (formerly known as GIFAP)

GGT gamma glutamyl transferase

GM geometric mean
GS growth stage
GSH glutathion
h hour(s)
ha hectare
Hb haemoglobin

HC hazard concentration

Hct haematocrit hL hectolitre

HPLC high pressure liquid or high performance liquid chromatography
HPLC-UV high performance liquid chromatography with ultra violet detector

HQ hazard quotient
IC ion chromatography
ICP inductively coupled plasma

IEDI international estimated daily intake
IESTI international estimated short-term intake
ISO International Organization for Standardization
IUPAC International Union of Pure and Applied Chemistry

JMPR Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and

the Environment and the WHO Expert Group on Pesticide Residues (Joint

Meeting on Pesticide Residues)

K_{doc} organic carbon linear adsorption coefficient

kg kilogram

K_{Foc} Freundlich organic carbon adsorption coefficient

KFT Karl Fischer titration

L litre

LC liquid chromatography LC₅₀ lethal concentration, median

LC-MS liquid chromatography-mass spectrometry

LC-MS/MS liquid chromatography with tandem mass spectrometry

LD₅₀ lethal dose, median; dosis letalis media

LDH lactate dehydrogenase

LOAEL lowest observable adverse effect level

LOD limit of detection

LOO limit of quantification (determination)

m metre

M/L mixing and loading
MAF multiple application factor
MCH mean corpuscular haemoglobin

MCHC mean corpuscular haemoglobin concentration

MCV mean corpuscular volume

mg milligram mL millilitre

mm millimetre (also used for mean measured concentrations)

mN milli-newton

MRL maximum residue limit or level

MS mass spectrometry
MSDS material safety data sheet
MTD maximum tolerated dose



MWHC maximum water holding capacity
NESTI national estimated short-term intake

ng nanogram

NOAEC no observed adverse effect concentration

NOAEL no observed adverse effect level NOEC no observed effect concentration

NOEL no observed effect level NPD nitrogen phosphorous detector

OD oil dispersion

OECD Organisation for Economic Co-operation and Development

OM organic matter content

Pa pascal

PAI pure active ingredient

PD proportion of different food types
PEC predicted environmental concentration
PEC_{air} predicted environmental concentration in air

PEC_{gw} predicted environmental concentration in ground water PEC_{sed} predicted environmental concentration in sediment PEC_{soil} predicted environmental concentration in soil

PEC_{sw} predicted environmental concentration in surface water

pH pH-value

PHED pesticide handler's exposure data

PHI pre-harvest interval

PIE potential inhalation exposure

pK_a negative logarithm (to the base 10) of the dissociation constant

P_{ow} partition coefficient between *n*-octanol and water

PPE personal protective equipment

ppm parts per million (10⁻⁶)

PT proportion of diet obtained in the treated area

PTT partial thromboplastin time

QSAR quantitative structure-activity relationship

coefficient of determination

RAC Regulatory acceptable concentration

REACH Registration, Evaluation, Authorisation of Chemicals Regulation

RPE respiratory protective equipment

RPLC-MS/MS reversed phase liquid chromatography with tandem mass spectrometry

RPLC-UV reversed phase liquid chromatography with ultra violet detector

RUD residue per unit dose
SC suspension concentrate
SD standard deviation
SE suspo-emulsion
SFO single first-order

SMILES simplified molecular-input line-entry system

 $\begin{array}{ll} SSD & species sensitivity distribution \\ STMR & supervised trials median residue \\ t_{1/2} & half-life (define method of estimation) \end{array}$

TER toxicity exposure ratio

TER_A toxicity exposure ratio for acute exposure

TER_{LT} toxicity exposure ratio following chronic exposure TER_{ST} toxicity exposure ratio following repeated exposure

TGAI technical grade active ingredient

TK technical concentrate TLV threshold limit value

TMDI theoretical maximum daily intake

TRR total radioactive residue



TSH thyroid stimulating hormone (thyrotropin)

TWA time weighted average UDS unscheduled DNA synthesis

UV ultraviolet
W/S water/sediment
w/v weight per volume
w/w weight per weight
WBC white blood cell

WG water dispersible granule WHO World Health Organization

wk week yr year