CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance chlorantraniliprole[1]

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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 Ireland, for the pesticide active substance chlorantraniliprole are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative uses of chlorantraniliprole as an insecticide on tree fruit, grapes, citrus, potatoes, aubergine, tomato, pepper, lettuce and cucurbits. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, 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.

KEY WORDS

Chlorantraniliprole, peer review, risk assessment, pesticide, insecticide

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SUMMARY

Chlorantraniliprole is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC Ireland (hereinafter referred to as the 'RMS') received an application from DuPont de Nemours for approval Complying with Article 6(3) of Directive 91/414/EEC the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2007/560/EC.

The RMS provided its initial evaluation of the dossier on chlorantraniliprole in the Draft Assessment Report (DAR), which was received by the EFSA on 17 February 2010. In accordance with Commission Regulation No 188/2011 Article 11(6) additional information was requested. The RMS's evaluation of the additional information was submitted to the EFSA in the format of addenda to the DAR. The peer review was initiated on 1 February 2012 by dispatching the DAR and the Addenda for consultation of the Member States and the applicant (DuPont de Nemours).

Following consideration of the comments received on the DAR and the addenda, it was concluded that EFSA should conduct an expert consultation in the areas of mammalian toxicology and ecotoxicology and EFSA should adopt a conclusion on whether chlorantraniliprole can be expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC, in accordance with Article 8 of Commission Regulation (EU) No 188/2011.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of chlorantraniliprole as an insecticide on tree fruit, grapes, citrus, potatoes, aubergine, tomato, pepper, and lettuce (field uses) and cucurbits, aubergine, tomato, pepper, and lettuce (glasshouse uses) as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

No data gaps or areas of concern were identified for the sections identity, physical and chemical properties and analytical methods.

No data gap or critical area of concern was identified in the mammalian toxicology section.

Based on the available studies, the plant residue definition for monitoring and risk assessment was limited to the parent chlorantraniliprole. MRLs were proposed for several crops, considering the trials conducted according to the GAPs supported in the northern and southern EU. No chronic risk was identified for consumers, the highest TMDI being only 0.3% of the ADI.

The assessments available were only sufficient to complete the environmental exposure assessment to surface water and sediment at a rudimentary level of sophistication (FOCUS Step 2). The groundwater exposure assessment was not finalised for chlorantraniliprole and its soil metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-GAZ70 and IN-F9N04.

A low risk to birds, mammals, fish, non-target arthropods, soil microorganisms, earthworms, non-target plants and sewage treatment organisms was concluded. A high risk to soil macro-organisms was identified for all representative uses other than those in citrus and potatoes. A high acute and chronic risk to aquatic invertebrates and chronic risk to sediment dwelling organisms was identified for all of the representative outdoor uses while the aquatic risk assessment for aqueous photolysis metabolites IN-LBA22, IN-LBA23 and IN-LBA24 could not be finalised with the available data and therefore a data gap was identified, relevant to all of the representative uses The risk assessment for honey bees could not be finalised for the representative outdoor uses. A low risk to honey bees was concluded for the representative glasshouse uses.

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BACKGROUND

In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009,[3] Council Directive 91/414/EEC[4] continues to apply with respect to the procedure and conditions for approval for active substances for which a decision recognising in principle the completeness of the dossier was adopted in accordance with Article 6(3) of that Directive before 14 June 2011.

Commission Regulation (EU) No 188/2011[5] (hereinafter referred to as 'the Regulation') lays down the detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market on 26 July 1993. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant 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 8 of the Regulation, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC within 4 months from the end of the period provided for the submission of written comments, subject to an extension of 2 months where an expert consultation is necessary, and a further extension of upto 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 8(3).

In accordance with Article 6(2) of Council Directive 91/414/EEC Ireland (hereinafter referred to as the 'RMS') received an application from DuPont de Nemours for approval of the active substance chlorantraniliprole. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2007/560/EC of 2 August 2007.[6]

The RMS provided its initial evaluation of the dossier on chlorantraniliprole in the DAR, which was received by the EFSA on 17 February 2010 (Ireland, 2010). In accordance with Commission Regulation No 188/2011 Article 11(6) additional information was requested. The RMS's evaluation of the additional information was submitted to the EFSA in the format of addenda to the DAR. The peer review was initiated on 1 February 2012 by dispatching the DAR and the addenda to Member States and the applicant DuPont de Nemours for consultation and 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 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 comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 8(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 24 May 2012. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was

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

[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.

[5] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.

[6] Commission Decision 2007/560/EC of 2 August 2007, recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of chlorantraniliprole, heptamaloxyglucan, spirotetramat and *Helicoverpa armigera* nucleopolyhedrovirus in Annex I to Council Directive 91/414/EEC. OJ No L 231, 15.8.2007, p. 29-31

concluded that additional information should be requested from the applicant and the EFSA should organise an expert consultation in the areas of mammalian toxicology and ecotoxicology.

The outcome of the telephone conference, together with 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 consideration, including those issues to be considered in an expert consultation and the additional information to be submitted by the applicant 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.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in February 2013.

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 chlorantraniliprole as an insecticide on tree fruit, grapes, citrus, potatoes, aubergine, tomato, pepper, and lettuce (field uses) and cucurbits, aubergine, tomato, pepper, and lettuce (glasshouse uses) as proposed by the applicant A list of the relevant end points for the active substance as well as the formulation 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, 2013) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (24 May 2012)
- the Evaluation Table (15 February 2013),
- 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 addendum (compiled version of February 2013 containing all individually submitted addenda (Ireland, 2013)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Chlorantraniliprole is the ISO common name for 3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide (IUPAC).

The representative formulated products for the evaluation were ‘Coragen (Chlorantraniliprole (DPX-E2Y45) 20SC)’, a suspension concentrate (SC) containing 200 g/L chlorantraniliprole and ‘Altacor (Chlorantraniliprole (DPX-E2Y45) 35WG)’, a water dispersible granule (WG) containing 350 g/kg chlorantraniliprole.

The representative uses evaluated comprise field spray applications for control of lepidopteran pests on apples, pears, peaches, apricots, citrus, grapes, tomato, aubergine, potatoes, pepper and lettuce and glasshouse spray applications on tomato, aubergine, pepper, cucurbits and lettuce. Full details of the GAPs can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000) and SANCO/825/00 rev. 8.1 (European Commission, 2010).

The minimum purity of the active substance is 950 g/kg. No FAO specification exists.

The specification is based on industrial scale production. The impurities acetonitrile, 3-picoline and methanesulfonic acid are relevant impurities from the toxicological point of view, although at the level found in the technical specification they are considered to be of no concern.
The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of chlorantraniliprole or the representative formulation. The main data regarding the identity of chlorantraniliprole and its physical and chemical properties are given in appendix A.

Adequate analytical methods are available for the determination of chlorantraniliprole in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. Appropriate LC-MS/MS methods are available for the post-registration monitoring of chlorantraniliprole in food of plant and animal origin with LOQs of 0.01 mg/kg.

Validated analytical methods based on HPLC-MS/MS or GC-ECD exist for the determination of chlorantraniliprole in soil with LOQs of 0.5 µg/kg or 0.01 mg/kg respectively. Residues of chlorantraniliprole in ground water and surface water can be monitored by HPLC-MS/MS method with LOQ of 0.1 µg/L. Pending on the final residue definition for monitoring, additional information might be required. LC-MS/MS method is available for the determination of chlorantraniliprole in air with LOQ of 0.5 µg/m^3. A method for residues in body fluids and tissues is not required as the active substance is not classified 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/222/2000 rev. 7 (European Commission, 2004) and SANCO/10597/2003 – rev. 10.1 (European Commission, 2012).

Chlorantraniliprole was discussed at the Pesticides Peer Review Meeting 95 in September 2012.

The batches used in the toxicological studies support the technical specification as presented for the full scale commercial production. The impurities acetonitrile, 3-picoline and methanesulfonic acid are relevant from the toxicological point of view, however they do not raise concern at the levels specified in the technical specification.

Low acute toxicity has been observed when chlorantraniliprole was administered by the oral, dermal and inhalation routes. No skin or eye irritation was observed and no potential for skin sensitisation was reported in either a Maximisation test of Magnusson & Kligman (M&K) or a Local Lymph Node Assay (LLNA).

Low toxicity was also observed upon repeated dosing of chlorantraniliprole. In rats treated dermally or orally for 28 days to 2 years, treatment-related increased incidences of adrenal cortical microvesiculation were noted which were not considered adverse as they did not impair the functional response of the adrenals, and no signs of adrenal cellular degeneration or toxicity were observed. Increased liver weight was consistently observed in rats, mice and dogs treated with the highest dose tested of ca. 1000 mg/kg bw per day as a pharmacological response to liver metabolism and cytochrome P450 liver enzyme induction. These findings were regarded as adaptive and as a non-adverse reaction in rats and mice, however, considering the high increase in absolute and relative liver weights observed in dogs (more than 30% absolute increase compared to respective controls in the 1-year dog study), the adversity of the effect could not be excluded. The NOAELs were decreased accordingly to the next lower dose level of 278 mg/kg bw per day in the 1-year dog and 303 mg/kg bw per day in the 90-day dog studies.

Upon long term exposure, the NOAEL in rats was 156 mg/kg bw per day based on increased liver weight and thyroid adenomas seen in females and 158 mg/kg bw per day in mice based on liver eosinophilic foci in males, accompanied by hepatocellular hypertrophy and increased liver weight.

No genotoxic potential was found and chlorantraniliprole is unlikely to pose a carcinogenic risk to humans. No adverse effects were observed in reproduction and developmental studies in rats and rabbits, in acute and subchronic neurotoxicity, and in immunotoxicity studies in rats and mice.

Acute toxicity by the oral route and *in vitro* bacterial mutagenicity tests were performed on four metabolites: IN-EQW78, IN-LBA24, IN-ECD73 and IN-F6L99; all metabolites presented an oral median lethal dose (LD_{50}) in excess of 2000 mg/kg bw in females and did not present mutagenic potential.

It was agreed that the toxicity of the metabolites IN-HXH44 and IN-K9T00 present in significant proportions in milk, is covered by the toxicological studies presented for the parent compound and the reference values of chlorantraniliprole apply to these two metabolites.

No toxicological data have been provided for the groundwater metabolites IN-GAZ70 and IN-F9N04; pending on the exposure assessment in groundwater (see section 4), toxicological data and studies may be required to demonstrate that they are not toxicologically relevant according to the guidance document on groundwater metabolites (European Commission, 2003). Regarding metabolites IN-EQW78, IN-ECD73 and IN-F6L99, pending on the exposure assessment in groundwater, further toxicological studies may be necessary according to the same guidance document.

The acceptable daily intake (ADI) of chlorantraniliprole is 1.56 mg/kg bw per day, based on the rat, 2-year study, supported by the mouse 18-month study, and applying the standard uncertainty factor (UF) of 100. The acceptable operator exposure level (AOEL) is 0.36 mg/kg bw per day, based on the NOAEL of 278 mg/kg bw per day from the 1-year dog study, 100 UF applied, and corrected by 13% for the limited oral absorption observed at the high dose level of 200 mg/kg bw in the toxicokinetic studies. No acute reference dose (ARfD) is allocated as it was considered not necessary.

The estimated operator and worker exposure levels were below the AOEL when no personal protective equipment (PPE) was considered. Estimated bystander exposure levels were considered negligible, being below 1% of the AOEL.

3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999), and the recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004, 2007).

Metabolism in plants was investigated in 4 different plant groups following foliar applications on fruiting crops (apple, tomato), leafy crops (lettuce) and pulses/oilseeds (cotton) and using soil application on cereals (rice). Studies were conducted with ^{14}C-chlorantraniliprole either labelled on the benzamide carbonyl or pyrazol carbonyl moiety or with a mixture containing both radiolabelled forms in a ratio 1:1. Experimental designs were in compliance with the representative uses, the total dose rates representing a 1.4N rate when compared to the US/Canadian GAPs and a 2.5N to 3.6N rates when compared to the EU GAPs.

Following foliar applications, chlorantraniliprole was metabolised to a very limited extent, accounting for more than 80% TRR in all plant samples collected up to 30 days after the last application and 57% TRR in the mature cotton seeds harvested 126 days after the last treatment. The metabolism was more extensive in rice after soil application with a total of 14 metabolites identified, each accounting for less than 6% TRR, but chlorantraniliprole still remained the major component of the residues, representing more than 50% TRR in all rice matrices at harvest (0.08 mg/kg in grain). A similar profile was observed in the confined rotational crop studies conducted at a total dose rate of 126 g a.s./ha, where chlorantraniliprole was identified as the major component of the residues, accounting for more than 50% TRR, with the exception of the red beet foliage. Minor additional components were identified, all individually present at less than 6% TRR (maximum 0.002 mg/kg in food items). Considering that following foliar applications, chlorantraniliprole is not metabolised to a great extent and since chlorantraniliprole is also the major component of the residues after soil application and in rotational crops, the plant residue definition for monitoring and risk assessment was limited to chlorantraniliprole.

Numerous residue trials performed according to the different GAPs supported in the EU, North America (USA, Canada), South America (Argentina) and Australia were submitted for a large number of crops. However, EFSA limited the assessment to the crops and to the trials conducted according to the cGAPs defined for the northern and southern EU and therefore, MRLs were only proposed for apple, pear, peach, apricot, grapes, potato, tomato, pepper, cucumber, courgette, melon, lettuce and lamb’s lettuce. No MRLs are proposed for citrus as the use in EU is proposed on young citrus trees during early establishment of the citrus orchards, prior to commercial fruit bearing years. Field rotational crop studies conducted in the EU and in the USA were submitted. The US studies were considered more appropriate to investigate the residues in rotational crops, as they were conducted using dose levels more representative of the expected plateau level reached in soil following 20 years of consecutive applications (0.11 mg/kg, 20 cm soil, see section 4). No residues were detected above 0.006 mg/kg in the edible parts of the plants in the US trials conducted at a dose rate of 200/225 g/ha (*ca.* 0.8N plateau level) and it was therefore concluded that no significant residues of chlorantraniliprole are expected to be present in rotational crops when the active substance is applied according to the GAPs proposed in EU. These residue data are supported by the storage stability studies showing chlorantraniliprole residues to be stable up to 24 months in water-, oil-, protein- and starch-containing matrices, when stored frozen at -20°C.

Chlorantraniliprole was slightly degraded to the metabolites IN-ECD73, IN-EQW78 and IN-F6L99 (11%-14% TRR) under standard hydrolysis conditions simulating boiling/baking. However, since these metabolites were only detected at low levels (0.016 mg/kg) in some processed tomato fractions in the processing studies conducted on apple, grape and tomato, it was concluded that chlorantraniliprole alone remains a sufficient marker for the residues in processed commodities.

The metabolic fate of chlorantraniliprole in livestock was investigated in hen and goat. Animals were dosed at 10 mg/kg DM with a mixture (1:1) of ^{14}C-pyrazol-carbonyl and ^{14}C-benzamide-carbonyl-chlorantraniliprole over 7 (goat) and 14 (poultry) consecutive days. Chlorantraniliprole was extensively eliminated and less than 4% (poultry) and 1% (goat) of the administered radioactivity was recovered eggs, milk and animals products. Contrary to plants, the metabolism was more extensive, chlorantraniliprole accounting for less than 40% TRR in all animal matrices with the exception of the goat fat where it represented up to 75% TRR. In addition to the parent, metabolites IN-HXH44 and IN-K9T00 were identified in significant proportions and levels in milk (26% TRR, 0.02 mg/kg) and metabolites IN-H2H20 and IN-K7H29 in egg yolk and egg white (11-24% TRR, 0.05-0.08 mg/kg). Based on these studies the residue definition for monitoring was limited to chlorantraniliprole. For risk assessment, considering that IN-HXH44 and IN-K9T00 represent a significant part of the residue in milk and they are covered with the studies of the parent (see section 2), the residue definition was proposed as "sum of chlorantraniliprole, HXH44, IN-K9T00 expressed as chlorantraniliprole". Conversion factors derived from the feeding study were proposed for ruminant products. Chlorantraniliprole residues should be designated "fat soluble" as the concentrations in fat and cream were approximately 6 times higher than in muscle and whole milk. Based on the representative uses and the expected animal intakes, the setting of MRLs for products of animal origin was considered unnecessary.

No chronic risk was identified for consumers. Using the EFSA PRIMo model and the proposed MRL values, the highest TMDI was calculated to be 0.3% of the ADI (DE, child). No acute risk assessment was performed as it was concluded that the setting of an ARfD was not necessary for chlorantraniliprole.

4. Environmental fate and behaviour

The following evaluation of section 4 has been completed having consideration of the following guidance: EFSA (2004), EFSA (2007), European Commission (2002b), FOCUS (2000, 2001, 2006, 2007, 2008 and 2009).

In soil laboratory incubations under aerobic conditions in the dark, chlorantraniliprole exhibited high to very high persistence, forming the major (>10% applied radioactivity (AR)) metabolite IN-EQW78 (max. 33.3 % AR) which exhibited very high persistence. IN-GAZ70 (max. 7.4 % AR), IN-ECD73 (max. 8.2 % AR) and IN-F6L99 (max. 5.2 % AR) reached levels that trigger consideration for groundwater exposure. In addition the applicant and RMS completed environmental exposure assessments for the soil metabolite IN-F9N04 (max. 4.75 % AR) due to its structural similarity to chlorantraniliprole. These metabolites all exhibited very high persistence except IN-F6L99 which exhibited moderate persistence and IN-F9N04 for which data were not available, but assessments were completed assuming comparable persistence to the active substance. Mineralisation of the benzamide carbonyl and pyrazole carbonyl ^{14}C radiolabels to carbon dioxide was limited being either below the level that could be measured, or when measureable, in the range 0.47 – 2.32 % AR after 120 days. The formation of unextractable residues (not extracted by acetonitrile / water) for these radiolabels accounted for 5.73 – 8.83 % AR after 120 days. In anaerobic soil incubations chlorantraniliprole was again very persistent with IN-EQW78 also being formed (max. 26.7% at study end). In laboratory experiments, photolysis at the soil surface was shown to have the potential to enhance the rate of transformation of chlorantraniliprole, but no novel photolysis products were identified. Chlorantraniliprole exhibited high to low mobility in soil. IN-EQW78 and IN-GAZ70 exhibited slight mobility or can be considered immobile. IN-ECD73 is immobile and IN-F6L99 exhibits very high to medium mobility. IN-F9N04 was assessed as exhibiting high to low mobility on the basis of its structural similarity to parent chlorantraniliprole. It was concluded that the adsorption to soil of all these compounds was not pH dependent.

Satisfactory finalised field soil dissipation studies were carried out at 16 sites (8 in Europe (2 each in Spain, Italy and France, 1 each in Poland and Germany) and 8 in the USA (3 in California 1 each in Texas, , Ohio, Washington, Georgia and New Jersey). Spray applications were in late spring to the soil surface on plots maintained bare and at 5 of the US trial sites, additional test plots were cropped (1 with peppers, 2 with established turf, 1 to bare soil pre-seeded with grass that subsequently germinated and 1 with a leafy vegetable). At the European trial sites parent chlorantraniliprole exhibited high to very high persistence. In addition to chlorantraniliprole, sample analyses were carried out for IN-EQW78 and IN-ECD73 and at some sites IN-GAZ70, which accounted for up to 29.3%, 10.3% and 7.9 % of day 0 residues respectively. Declines in metabolite levels were not observed (degradation rates were not faster than formation rates). Field dissipation information was also available in reports of soil dissipation trials located in Minnesota USA and Prince Edward Island Canada that have been indicated to be not finalised. The applicant normalised the EU field studies to FOCUS reference conditions (20° and PF2 soil moisture content) following FOCUS (2006) guidance and using an obsolete (since March 2009) Q10 of 2.2. They subsequently used an average of these normalised values as input in FOCUS simulation modelling to estimate predicted environmental concentrations (PEC) in surface water, sediment and groundwater. For this approach to be accepted it is necessary (following FOCUS, 2006 guidance) to exclude that in the field studies, photolysis at the soil surface is not contributing significantly to degradation in the field. In this case, the evidence obtained by comparing DT_{50} estimates from North American trial sites, where there were both cropped (soil shaded) and bare plots was accepted as sufficient evidence, that photolysis would not be expected to be an important process affecting DT_{50}. However as the available normalised field DT_{50} had not used the Q10 of 2.58 (EFSA, 2007) and the results from the North American field dissipation trials have not been assessed for their utility to be normalised to FOCUS reference conditions, a data gap for this to be done has been identified, (see section 7)[7].

Information on the behaviour of chlorantraniliprole and its metabolites in soil following multiple seasons of application was collected from soil accumulation trials conducted at 4 sites in Europe (2 sites in Spain, 1 in France and 1 in Germany). In these trials, chlorantraniliprole was applied to a variety of crops in consecutive years to simulate actual agricultural practices (generally 1 x 100 g a.s./ha/yr for six years). At the end of the accumulation trials significant residues of chlorantraniliprole remained in soil ranging from 24-52 % of applied. Overall the accumulation studies are considered to provide tentative evidence that a plateau level may be being approached for chlorantraniliprole after 6 years, since the accumulation factor that can be estimated is decreasing. The decline in residues of chlorantraniliprole was followed by a rise in the concentrations of the measured degradation products, IN-EQW78, IN-ECD73, and IN-GAZ70. However, there is no evidence that a plateau was being reached for any of these metabolites.

The PEC in soil that were calculated, including accumulation estimates from use over successive years, covering the representative uses assessed, can be found in Appendix A

In laboratory incubations in dark aerobic natural sediment water systems, chlorantraniliprole exhibited high persistence, forming the major metabolite IN-EQW78 (max. 34.7 % AR in sediment, exhibiting high to very high persistence). The unextractable sediment fraction (not extracted by acetonitrile / water followed by acidified (formic acid) acetonitrile and acidified sodium dodecyl sulfate) was a minor sink for the benzamide carbonyl and pyrazole carbonyl ^{14}C radiolabels accounting for ca. 5 % AR at study end (100 days). Mineralisation of these radiolabels accounted for only 0.15 – 0.53 % AR at the end of the study. In laboratory sterile aqueous photolysis experiments chlorantraniliprole exhibited very low persistence forming the major transformation products IN-LBA22 (max 52.8% AR), IN-LBA23 (max 51.4 % AR) and IN-LBA24 (max 94.4% AR). In laboratory incubations in irradiated (light energy in June 39°N41') aerobic natural sediment water systems, chlorantraniliprole exhibited moderate persistence (20°C DT_{50} 10-22 days), forming the major metabolite IN-EQW78 (max. 38.1 % AR in sediment). The unextractable sediment fraction (not extracted by acetonitrile /

[7] Via the provision of article 8, 3 of Commission Regulation (EU) No 188/2011 the applicant was already given the opportunity to provide these missing assessments.

water) was a sink for the benzamide carbonyl and pyrazole carbonyl ^{14}C radiolabels , accounting for 12-14 % AR at study end (14 days). Mineralisation of these radiolabels was not observed over the 14 days of the study.

The necessary surface water and sediment exposure assessments (PEC calculations) were carried out for parent chlorantraniliprole and the metabolites IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23 and IN-LBA24 using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 1.1 of the Steps 1-2 in FOCUS calculator). To cover the representative greenhouse uses, the necessary surface water and sediment PEC were estimated using the FOCUS (2001) step 2 approach (version 2.1 of the steps 1-2 in FOCUS calculator), which was then modified by post processing the spray drift input results (option no runoff or drainage was selected) to obtain a 0.2 % emission of chlorantraniliprole from greenhouses being re-deposited on adjacent surface water bodies. This approach has been accepted by Member State experts as an assumption that can be used in EU level surface water exposure assessments for greenhouse uses and is referred to in FOCUS (2008) guidance as being appropriate. These PEC can be found in Appendix A. For the active substance chlorantraniliprole, appropriate step 3 (FOCUS, 2001) and step 4 calculations were not available. The simulations available in the DAR (Ireland, 2010) did not utilise the complete soil field study data base, used an outdated (since March 2009) Q10 of 2.2 in the DT_{50} normalisation assessment methodology and in subsequent FOCUS simulations. In addition the canopy wash off implementation used in simulations was not sufficiently supported by experimental data and for the pertinent northern European FOCUS scenarios, the potential for accumulation in sediment was not addressed. The provision of satisfactory FOCUS step 3 and step 4 simulations for parent chlorantraniliprole was therefore considered a data gap, (see section 7)[7].

Appropriate groundwater exposure assessments for chlorantraniliprole and its soil metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-GAZ70 and IN-F9N04 were not available. The simulations to calculate PEC in groundwater available in the DAR (Ireland 2010), did not utilise the complete soil field study data base and used an outdated (since March 2009) Q10 of 2.2 in the DT_{50} normalisation assessment methodology and in the subsequent FOCUS simulations. Therefore a data gap was identified, (see section 7)[7].

5. Ecotoxicology

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

A low risk to birds and mammals via, dietary exposure, consumption of contaminated water and from bioaccumulation in earthworms and fish, was concluded for all of the representative uses for chlorantraniliprole. A low risk to birds and mammals was also concluded for relevant soil and aquatic metabolites.

As discussed in section 4 above, only the FOCUS Step 1 and 2 surface water exposure assessment was considered reliable for the representative field uses. A low risk to fish (acute and chronic) and algae from the parent substance, chlorantraniliprole, was concluded. However, a high risk was indicated for the acute and chronic risk to aquatic invertebrates and the chronic risk to sediment dwelling organisms. Due to the data gap identified in section 4, for Step 3 and 4 FOCUS surface water modelling, a consequent data gap was identified to complete the aquatic risk assessment to address the acute and chronic risk to aquatic invertebrates and the chronic risk to sediment dwelling organisms for the representative outdoor uses from exposure to parent chlorantraniliprole. In addressing the risk to sediment dwelling organisms, it should be ensured that the exposure estimate accounts for whether exposure is higher in the sediment in comparison to the aquatic phase. In addition, the exposure estimate should account for the potential for accumulation which was indicated as a data gap in section 4. Chlorantraniliprole is very toxic to aquatic invertebrates and sediment dwelling organisms (both in the acute and chronic term). The risk to aquatic invertebrates was discussed at the Pesticides Peer Review Meeting 99 (November, 2012) and the experts agreed on the suitability of the available data for use in a Species Sensitivity Distribution (SSD). The experts also agreed that the median HC_5 (Hazard Concentration) should be used for risk assessment together with an assessment factor of 5. It was concluded that the available SSD was suitable to address both the acute and chronic risk to aquatic invertebrates given the toxicological profile of chlorantraniliprole to aquatic invertebrates. The RMS included a risk assessment in the final addendum (Ireland, 2013) using the updated median HC_5 value and FOCUS Step 4 exposure estimates available in the DAR (Ireland, 2010). The resulting risk assessment indicated a high risk to aquatic invertebrates for the representative use on stone fruit (2 out of 7 scenarios, with a 20 m no-spray buffer zone) and field lettuce (1^{st} cropping, 4 out of 7 scenarios and 2^{nd} cropping, 2 out of 7 scenarios). However, as discussed above, the available FOCUS Step 4 exposure modelling was considered not reliable and therefore a data gap was identified to further consider the risk to aquatic invertebrates from exposure to parent chlorantraniliprole (for the representative field uses). A high risk to aquatic organisms, from exposure to chlorantraniliprole in surface water, was concluded on the basis of the available reliable assessments for the field uses.

A low risk to aquatic organisms was concluded from exposure to parent chlorantraniliprole for the representative glasshouse uses.

The surface water exposure assessment indicated eight metabolites (IN-EQW78, IN-ECD73, IN-F6L99, IN-GAZ70, IN-F9N04 and photolysis metabolites: IN-LBA22, IN-LBA23, IN-LBA24) were relevant for the aquatic risk assessment. A low risk was concluded on the basis of the available FOCUS Step 2 exposure assessment for metabolites IN-EQW78, IN-ECD73, IN-F6L99, IN-GAZ70, IN-F9N04. Screening data for aquatic invertebrates were available for the photolysis metabolites (IN-LBA22, IN-LBA23 and IN-LBA24); however, the data were not considered sufficiently reliable for risk assessment. Consequently a data gap for all representative uses was identified for further information to address the risk to aquatic organisms from metabolites IN-LBA22, IN-LBA23 and IN-LBA24.

The groundwater exposure assessment for parent chlorantraniliprole and metabolites IN-EQW78, IN-ECD73, IN-F6L99, IN-GAZ70 and IN-F9N04 could not be finalised (see section 4). Consequently the risk to aquatic organisms from exposure to these metabolites should be further considered once the groundwater exposure assessment is finalised.

The risk to honey bees was discussed at the Pesticides Peer Review Meeting 99 (November, 2012). In the acute oral and contact honey bee toxicity studies signs of intoxication were observed (e.g. bees were apathetic, moribund and showing signs of uncoordinated movements). In the contact toxicity study honey bees were initially affected (at 4 hours) at all of the tested doses. At lower doses the bees were no longer affected at the study termination. In the oral toxicity study, only bees at the higher doses were initially affected and all bees had recovered by the end of the study. Several higher tier studies were also available and were also discussed at the Pesticides Peer Review Meeting 99 (November, 2012). The experts noted a slight increase in mortality in a number of the higher tier studies but, overall, a low acute risk to adult honey bees was concluded. The experts also discussed the bee brood results in the higher tier studies and noted a potential transient effect on bee larvae. A bee brood semi-field study performed to the OECD 75 test guideline (OECD, 2007) was also available and a potential effect on brood was indicated by a biologically relevant increase in ‘brood termination-rate’. Overall, the experts did not consider that the risk to bee brood could be regarded as low and therefore a data gap was identified. Signs of intoxication were reported in the semi-field bee brood study, although, no obvious effects were observed on the colony strength. Currently, there are no agreed test guidelines for assessing sub lethal effects in honey bees and it is questionable whether the available higher tier data are sufficient to fully address the potential risk posed by sub lethal effects. Therefore the experts at the meeting agreed a data gap should be indicated to further consider the potential risk to honey bees from sub lethal exposure to chlorantraniliprole. A low risk to honey bees was concluded for the representative glasshouse uses.

The risk assessment using the standard tier 1 test species of non-target arthropods indicated a low risk. Given that the mode of action of chlorantraniliprole indicates that oral uptake is an important exposure route, it was questioned whether the standard risk assessment, which uses contact toxicity studies, was sufficiently protective of leaf-feeding non-target arthropods. Additional data were available for a number of species including those recommended in SETAC (2001). Overall, it was concluded that available data were sufficient to address the risk to leaf-feeding non-target arthropod species according to the current guidance.

A low acute and chronic risk to earthworms and to soil micro-organisms was concluded for chlorantraniliprole and the relevant soil metabolites IN-EQW78, IN-ECD73, IN-F6L99, IN-GAZ70 and IN-F9N04. A low chronic risk to soil macro organisms was concluded for the soil metabolites. The available risk assessment for the parent, chlorantraniliprole indicated a high chronic risk to soil macro-organisms. Higher tier litter bag studies were available and were discussed at the Pesticides Peer Review Meeting 99 (November, 2012). However, the experts considered that the available information was not sufficient to conclude a low risk and therefore a data gap was identified for further information to address the chronic risk to soil macro-organisms for the representative uses in lettuce, pome and stone fruit, table grapes, wine grapes and fruiting vegetables (including, where pertinent, the glasshouse uses). A low risk was concluded for the representative use in citrus and potatoes.

A low risk was concluded for non-target plants and organisms involved in biological methods for sewage treatment.

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
chlorantraniliprole	high to very high persistence Single first-order DT_{50} 223-886 days (25ºC 44-50% MWHC soil moisture) European field dissipation studies single first-order DT_{50} 226-540 days or biphasic DT_{50} 82 and 117 days (DT_{90} 1020 and >1000 days)	High chronic risk to soil macro organisms for the representative uses in lettuce, pome and stone fruit, table grapes, wine grapes and fruiting vegetables. Low risk to earthworms and soil micro organisms.
IN-EQW78	very high persistence Single first-order DT_{50} 673-950 days (20ºC pF 2 soil moisture	Low risk to soil organisms.
IN-ECD73	very high persistence Single first-order DT_{50} 855-18693 days (20ºC pF 2 soil moisture	Low risk to soil organisms.
IN-F6L99	moderate persistence Single first-order DT_{50} 14-48 days (20ºC pF 2 soil moisture)	Low risk to soil organisms.
IN-GAZ70	very high persistence Single first-order DT_{50} 858-3796 days or stable (20ºC pF 2 soil moisture	Low risk to soil organisms.
IN-F9N04	high to very high persistence (based on extrapolating behaviour from chlorantraniliprole) No data available. As this metabolite is structurally similar to the active substance, soil DT endpoints for the active substance were accepted as appropriate for use in environmental exposure assessment.	Low risk to soil 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 activity**	**Toxicological relevance**	**Ecotoxicological activity**
chlorantraniliprole	high to low mobility K_{Foc} 180-539 mL/g	Data gap	Yes	Yes	High risk indicated for aquatic organisms in the surface water risk assessment. The risk via groundwater should be further considered once the groundwater exposure assessment is finalised.
IN-EQW78	slight mobility or immobile K_{Foc} 4499-22265 mL/g	Data gap	No	Rat oral LD_{50} > 2000 mg/kg bw (females) Negative Ames test Further data may be required	Low risk indicated for aquatic organisms in the surface water risk assessment. The risk via groundwater should be further considered once the groundwater exposure assessment is finalised.
IN-ECD73	Immobile K_{Foc} 9966-99044 mL/g	Data gap	No	Mouse oral LD_{50} > 2000 mg/kg bw (females) Negative Ames test Further data may be required	Low risk indicated for aquatic organisms in the surface water risk assessment. The risk via groundwater should be further considered once the groundwater exposure assessment is finalised.

IN-F6L99	Very high to medium mobility K_{Foc} 35-448 mL/g	Data gap	No	Mouse oral LD_{50} > 2000 mg/kg bw (females) Negative Ames test Further data may be required	Low risk indicated for aquatic organisms in the surface water risk assessment. The risk via groundwater should be further considered once the groundwater exposure assessment is finalised.
IN-GAZ70	slight mobility or immobile K_{Foc} 3935-53417 mL/g	Data gap	No	No data, data may be required	Low risk indicated for aquatic organisms in the surface water risk assessment. The risk via groundwater should be further considered once the groundwater exposure assessment is finalised.
IN-F9N04	high to low mobility (based on extrapolating behaviour from chlorantraniliprole) No data available. As this metabolite is structurally similar to the active substance, adsorption endpoints for the active substance were accepted as appropriate for use in environmental exposure assessment.	Data gap	Data not available in the RMS assessment	No data, data may be required	Low risk indicated for aquatic organisms in the surface water risk assessment. The risk via groundwater should be further considered once the groundwater exposure assessment is finalised.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
chlorantraniliprole	High acute and chronic risk to aquatic invertebrates and chronic risk to sediment-dwelling organisms.

IN-EQW78	Low risk to aquatic organisms.
IN-ECD73	Low risk to aquatic organisms.
IN-F6L99	Low risk to aquatic organisms.
IN-GAZ70	Low risk to aquatic organisms.
IN-F9N04	Low risk to aquatic organisms.
IN-LBA22	Data gap.
IN-LBA23	Data gap.
IN-LBA24	Data gap.

6.4. Air

Compound (name and/or code)	**Toxicology**
chlorantraniliprole	Rat LC_{50} inhalation >5.1 mg/L air/4 h (nose-only exposure), no classification required

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the 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 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Pending on the exposure assessment of groundwater metabolites IN-EQW78, IN-ECD73, IN-F6L99, IN-GAZ70 and IN-F9N04, toxicological data and studies may be required to demonstrate the toxicological non-relevance of the metabolites according to the respective guidance document on groundwater metabolites (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2, 4)

- Normalisations of all the reliable field dissipation trials (including US and Canadian studies, at least 10 studies at 8 trial sites with final reports appear to be available), for which it has been demonstrated that DT_{50} represent degradation (a characterisation demonstrating insignificant leaching at the US and Canadian sites is outstanding), to FOCUS reference conditions using a Q10 of 2.58 and Walker equation coefficient of 0.7 were not available. Should in the future a normalisation be provided it should follow appropriate guidance that in January 2013 is FOCUS kinetics (FOCUS, 2006) guidance. Any inverse modelling to derive these normalised values should exclude incorporating increased sorption with time. Any such exercise should derive the necessary geomean or median chlorantraniliprole DT_{50} value appropriate to use in FOCUS simulation modelling. Alternatively should appropriate data be generated (following EFSA, 2007), a substance specific Q10 might be used for normalisation, in this case, again all other pertinent guidance noted here should be followed. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4)

- FOCUS surface water calculations to provide PEC in surface water and sediment at steps 3 and 4 for parent chlorantraniliprole using the FOCUS reference condition normalised soil DT_{50} derived from the data gap identified for normalisation of all the reliable field dissipation trials (including pertinent US and Canadian studies), to FOCUS reference conditions using a Q10 of 2.58 and Walker equation coefficient of 0.7, where the Q10 used in subsequent simulations is 2.58 were not available. Should in the future new simulations be completed FOCUS default values for FEXTRC should be used in simulations unless values derived from measured washoff experiments carried out with the representative formulation with top fruit, citrus, grapes and tomato / potatoes leaves are provided. If measured washoff experiment values are used, then study reports for these experiments must be submitted. The regression equation provided by FOCUS to calculate FEXTRC based on just water solubility should not be used in isolation. In any future simulations except at scenarios D6, R2, and R4, potential for chlorantraniliprole to accumulate in sediment should be addressed. Where appropriate, sediment water DT_{50} for chlorantraniliprole used as input in simulations should be normalised to FOCUS reference conditions using a Q10 of 2.58. Should appropriate data be generated, to demonstrate that it is appropriate, a substance specific Q10 might be used in any future simulations, when this same substance specific Q10 is also used for normalising the DT input values (both soil and sediment/water). (Relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4)

- FOCUS groundwater simulations for the representative uses using the geomean or median DT_{50} value derived from the data gap identified for normalisation of all the reliable field dissipation trials (including pertinent US and Canadian studies), to FOCUS reference conditions using a Q10 of 2.58 and Walker equation coefficient of 0.7, where the Q10 used in simulations for chlorantraniliprole and metabolites is 2.58 were not available. Should appropriate data be generated to demonstrate that it is appropriate, a substance specific Q10 for chlorantraniliprole might be used in any future simulations, when this same substance specific Q10 is also used for normalising the chlorantraniliprole soil DT input value. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4)

- Once appropriate Step 3 and 4 FOCUS surface water modelling is finalised, the aquatic risk assessment should be completed to address the acute and chronic risk to aquatic invertebrates and the chronic risk to sediment dwelling organisms from exposure to parent chlorantraniliprole for the representative outdoor uses. In addressing the risk to sediment dwelling organisms, it should be ensured that the exposure estimate accounts for whether exposure is higher in the sediment in comparison to the aquatic phase. In addition, the exposure estimate should account for the potential for accumulation (relevant for all outdoor representative uses evaluated; submission date proposed by the applicant: unknown; see section 4 and 5).

- Further information to address the risk to aquatic organisms from metabolites IN-LBA22, IN-LBA23 and IN-LBA24 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

- Further information is required to address the potential risk to honey bee brood and sub-lethal effects observed in adult honey bees (relevant for all outdoor representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

- Further information is required to address the chronic risk to soil macro organisms from chlorantraniliprole (relevant for the representative uses in lettuce, pome and stone fruit, table grapes, wine grapes, fruiting vegetables including the requested glasshouse uses; submission date proposed by the applicant: unknown; see section 5).

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

- None.

9. Concerns

9.1. 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 of Annex VI to Directive 91/414/EEC 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).

1. The groundwater exposure assessment for parent chlorantraniliprole and metabolites IN-EQW78, IN-ECD73, IN-F6L99, IN-GAZ70 and IN-F9N04 could not be finalised for all the representative uses.

2. The risk to aquatic organisms from photolysis metabolites IN-LBA22, IN-LBA23 and IN-LBA24 could not be finalised for all of the representative uses.

3. Further information is required to address the risk to honey bee colonies consequent to effects on honey bee brood and sub-lethal effects observed in adult honey bees, for the field uses.

9.2. 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 of Annex VI to Directive 91/414/EEC, 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.

None

9.3. 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		**Apples pears**	**Peaches apricots**	**Citrus**	**wine grapes**	**table grapes**	**Potatoes**	**Tomatoes aubergines** (field)
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							
Risk to wild non target terrestrial vertebrates	Risk identified							
	Assessment not finalised							
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	X	X		X	X		X
	Assessment not finalised	X[3]	X[3]	X[3]	X[3]	X[3]	X[3]	X[3]
Risk to aquatic organisms	Risk identified	X	X	X	X	X	X	X
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]
Groundwater exposure active substance	Legal parametric value breached							
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
Groundwater exposure metabolites	Legal parametric value breached							
	Parametric value of 10µg/L[(a)] breached							

	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
Comments/Remarks								

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 4 and 5 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

Representative use		Tomatoes aubergines (protected)	Peppers (field)	Peppers (protected)	Cucurbits edible peel (protected)	Cucurbits inedible peel (protected)	Lettuce (field)	Lettuce (protected)
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							
Risk to wild non target terrestrial vertebrates	Risk identified							
	Assessment not finalised							
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	X	X	X	X	X	X	X
	Assessment not finalised		X[3]				X[3]	
Risk to aquatic organisms	Risk identified		X				X	
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]
Groundwater exposure active substance	Legal parametric value breached							
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
Groundwater exposure metabolites	Legal parametric value breached							
	Parametric value of 10µg/L[(a)] breached							
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
Comments/Remarks								

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 4 and 5 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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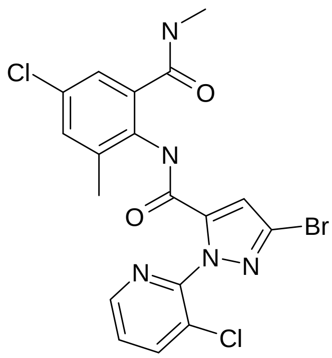
APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Chapter 2.1 Identity, Physical and Chemical Properties, Details of Uses, Further.

Common name (ISO)	Chlorantraniliprole
Function	Insecticide
Rapporteur Member State (EU)	Ireland
Identity (Annex IIA, point 1)	
Chemical name (IUPAC) ‡	3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide
Chemical name (CA) ‡	3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide
CIPAC No ‡	794
CAS No ‡	500008-45-7
EC No (EINECS or ELINCS) ‡	*Not assigned*
FAO Specification (including year of publication) ‡	none
Minimum purity of the active substance as manufactured ‡	950 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	acetonitrile max. 3 g/kg 3-picoline max. 3 g/kg methanesulfonic acid max. 2 g/kg
Molecular formula ‡	$C_{18}H_{14}BrCl_2N_5O_2$
Molecular mass ‡	483.15 g/mole
Structural formula ‡	

- **Physical-chemical properties (Annex IIA, point 2)**

Melting point (state purity) ‡	208–210ºC (PAI, 99.2%) 200–202ºC (TGAI, 95.9%)
Boiling point (state purity) ‡	Not applicable; the test material is a solid which decomposes after melting.
Temperature of decomposition (state purity)	330°C (99.2%)
Appearance (state purity) ‡	Off-white fine crystalline powder (Munsell color N9.5 90%R) (PAI, 99.2%) Brown fine powder (Munsell color 7.5 YR 8/4) (TGAI, 95.9%) commercially produced technical is off white
Vapour pressure (state temperature, state purity) ‡	6.3×10^{-12} Pa at 20°C and 2.1×10^{-11} Pa at 25°C (calculated values)
Henry's law constant ‡	3.2×10^{-9} ·Pa m^3/mole
Solubility in water (state temperature, state purity and pH) ‡	(20°C, 99.2%) pH 4: 0.972 mg/L pH 7: 0.880 mg/L pH 9: 0.971 mg/L
Solubility in organic solvents ‡ (state temperature, state purity)	solvent — (g/L, 20°C, 99.2%) acetone — 3.446 acetonitrile — 0.711 dichloromethane — 2.476 dimethylformamide — 124 ethyl acetate — 1.144 hexane — <0.001 methanol — 1.714 octanol — 0.386 *o*-xylene — 0.162
Surface tension ‡ (state concentration and temperature, state purity)	72.6 ± 0.06 mN/m (90% saturated aqueous solution, 20 ± 0.5°C, 99.2%)
Partition co-efficient ‡ (state temperature, pH and purity)	(20°C, 99.2%) pH 4: 2.77 pH 7: 2.86 pH 9: 2.80
Dissociation constant (state purity) ‡	10.88 (99.2%)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	(99.2%, 25°C) A λ_{max} under basic conditions was ~320 nm. No defined λ_{max}, above 290 nm, under neutral or acidic conditions.
Flammability ‡ (state purity)	Not flammable (94.45%)
Explosive properties ‡ (state purity)	Not sensitive to thermal, friction or impact stimuli. (94.45%)
Oxidising properties ‡ (state purity)	Not an oxidising or reducing agent based on structural assessments.

Good Agricultural Practice (GAP) for DPX-E2Y45 20SC in the European Union

Crop and/or situation (a)	Country	Product name	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment (Normal Volume Sprayers)			PHI (days) (Targeted) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (g/kg) (i)	Method kind (f-h)	Growth Stage & season (j)	Number min-max (k)	Interval between applications (min)	g a.s./hL min-max	water L/ha min-max	g a.s./ha max		
Apples, Pears	NEU SEU	DPX-E2Y45 20SC	F	*Cydia pomonella* Leafminers Leafrollers *Opherophtera brumata*	SC	184 200 g/L)	high pressure mist blower	BBCH70-BBCH87	1-2	14	3.2-4.0 (16-20 mL fp/hL)*	700-1500	60 (300 mL fp/ha)**	14	Minimum recommended application rate is 160 mL fp/ha#
Peaches and Apricots	SEU	DPX-E2Y45 20SC	F	*Cydia molesta Anarsia lineatella*	SC	184 (200 g/L)	high pressure mist blower	BBCH73-BBCH85	1-2	10-14	3.2-4.0 (16-20 mL fp/hL)	800-1500	60 (300 mL fp/ha)	14	Minimum recommended application rate is 160 mL fp/ha
"Citrus"	SEU	DPX-E2Y45 20SC	F	*Ph. citrella*	SC	184 (200 g/L)	mist blower	BBCH31-BBCH50	1-2	10-14	2.0-3.0 (10-15 mL fp/hL)	100-500	15 (75 mL fp/ha)	n.a.	Non bearing crop Minimum recommended application rate is 50 mL fp/ha
Grapes (wine)	NEU SEU	DPX-E2Y45 20SC	F	*L. botrana, E. ambiguella*	SC	184 (200 g/L)	mist blower	BBCH57-BBCH83	1	n.a.	3.0-3.6 (15-18 mL fp/hL)	700-1500	54 (270 mL fp/ha)	30	Minimum recommended application rate is 150 mL fp/ha
Grapes (table)	SEU	DPX-E2Y45 20SC	F	*L. botrana, E. ambiguella*	SC	184 (200 g/L)	mist blower	BBCH57-BBCH85	1-2	10-14	3.0-3.6 (15-18 mL fp/hL)	600-1200	43.2 (216 mL fp/ha)	3	Minimum recommended application rate is 150 mL fp/ha
Field tomato field aubergine	Spain	DPX-E2Y45 20SC	F	*S. littoralis H. armigera S. exigua P. gamma*	SC	184 (200 g/L)	hydraulic ground directed boom	BBCH71-BBCH89	1-2	7-14	2.8-4.0 (14-20 mL fp/hL)	200-1000	40 (140-200 mL fp/ha)	1	Minimum recommended application rate is 140 mL fp/ha
Potatoes	NEU SEU	DPX-E2Y45 20SC	F	*L. decemlineata*	SC	184 (200 g/L)	hydraulic ground directed boom	BBCH31-BBCH60	1-2	10-14	n.a.	300-600	12 (50-60 mL fp/ha)	14	Minimum recommended application rate is 50 mL fp/ha

* fp/hL = formulated product/hectolitre ** fp/ha = formulated product/hectare # Minimum recommended application rate is irrespective of water volume and equipment used

Good Agricultural Practice (GAP) for DPX-E2Y45 35WG in the European Union

Crop and/or situation (a)	Country	Product name	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment (Normal Volume Sprayers)			PHI (days) (Targeted) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (g/kg) (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g a.s./hL min-max	water L/ha min-max	g a.s./ha max		
Grapes (table)	Spain	DPX-E2Y45 35WG	F	*L. botrana, E. ambiguella*	WG	350 g/kg	mist blower	BBCH57-BBCH85	1-2	10-14	2.8-3.5 (8-10 g fp/hL)*	600-1200	42 (120 g fp/ha)**	3	Minimum recommended application rate is 80 g fp/ha[#]
Aubergine, tomato	SEU	DPX-E2Y45 35WG	G	*S. littoralis H. armigera S. exigua P. gamma*	WG	350 g/kg	broadcast mist blower, hydraulic ground directed boom	BBCH15-BBCH89	1-2	7-14	2.8-4.2 (8-12 g fp/hL)	500-1500	63 (180 g fp/ha)	1	Minimum recommended application rate is 80 g fp/ha
Field tomato Field aubergine	SEU	DPX-E2Y45 35WG	F	*S. littoralis H. armigera S. exigua P. gamma*	WG	350 g/kg	hydraulic ground directed boom	BBCH71-BBCH89	1-2	7-14	2.8-4.2 (8-12 g fp/hL)	200-1000	42 (80-120 g fp/ha)	1	Minimum recommended application rate is 80 g fp/ha
Pepper	SEU	DPX-E2Y45 35WG	G	*S. littoralis H. armigera S. exigua O. nubilalis*	WG	350 g/kg	broadcast mist blower	BBCH15-BBCH89	1-2	7-14	2.8-3.5 (8-10 g fp/hL)	300-1250	43.75 (125 g fp/ha)	1	Minimum recommended application rate is 80 g fp/ha
Field pepper	SEU	DPX-E2Y45 35WG	F	*S. littoralis H. armigera S. exigua O. nubilalis*	WG	350 g/kg	hydraulic ground directed boom	BBCH71-BBCH89	1-2	7-14	2.8-4.2 (8-12 g fp/hL)	200-1000	42 (80-120 g fp/ha)	1	Minimum recommended application rate is 80 g fp/ha
Cucurbits edible and inedible peel	SEU	DPX-E2Y45 35WG	G	*H. armigera S. exigua P. gamma S. littoralis*	WG	350 g/kg	broadcast, high pressure mist blower	BBCH15-BBCH89	1-2	7-14	2.8-4.2 (8-12 g fp/hL)	500-1200	50.4 (144 g fp/ha)	1	Minimum recommended application rate is 80 g fp/ha
Lettuce	SEU	DPX-E2Y45 35WG	F + G	*S. exigua S. littoralis H. armigera*	WG	350 g/kg	hydraulic ground directed boom	BBCH12-BBCH49	1-2	7-14	3.1-4.2 (9-12 g fp/hL)	500-1000	42 (90-120 g fp/ha)	1	Minimum recommended application rate is 80 g fp/ha

* fp/hL = formulated product/hectolitre ** fp/ha = formulated product/hectare # Minimum recommended application rate is irrespective of water volume and equipment used

- * For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
- (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)
- (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (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 give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
- (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) Indicate the minimum and maximum number of application possible under practical conditions of use

Crop and/or situation (a)	Country	Product name	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment (Normal Volume Sprayers)			PHI (days) (Targeted) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (g/kg) (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g a.s./hL min-max	water L/ha min-max	g a.s./ha max		

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Chapter 2.2 Methods of Analysis

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

Technical as (analytical technique)	HPLC/UV
Impurities in technical as (analytical technique)	HPLC/UV
Plant protection product (analytical technique)	HPLC/UV

Residue definitions for monitoring purposes

Food of plant origin		The residue definition is the parent molecule chlorantraniliprole.
Food of animal origin		The residue definition is the parent molecule chlorantraniliprole.
Soil		The residue definition for environmental assessment is the parent molecule chlorantraniliprole and its metabolites IN-EQW78, IN-ECD73, IN-F9N04, IN-GAZ70 and IN-F6L99. The proposed residue definition for an enforcement method is the parent molecule chlorantraniliprole.
Water	surface	The residue definition for environmental assessment is the parent molecule chlorantraniliprole and its metabolites IN-EQW78, IN-ECD73, IN-F9N04, IN-GAZ70 IN-F6L99, IN-LBA22, IN-LBA23 and IN-LBA24. The proposed residue definition for an enforcement method is at least the parent molecule chlorantraniliprole, but data gaps need to be filled before IN-LBA22, IN-LBA23 and IN-LBA24 can be excluded from this definition.
	drinking/ground	The residue definition for environmental assessment is the parent molecule chlorantraniliprole and its metabolites IN-EQW78, IN-ECD73, IN-F9N04, IN-GAZ70 and IN-F6L99. The proposed residue definition for an enforcement method is the parent molecule chlorantraniliprole.
Air		The residue definition is the parent molecule chlorantraniliprole.

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	The DGF S 19 (L00.00-34) multi-residue procedure with LC/MS/MS detection is proposed for the analysis of chlorantraniliprole crop residues in regions which accept this multi residue method. The DFG S 19 procedure extracts-chlorantraniliprole from crops using water and acetone. The extracts are purified using gel permeation chromatography and residues are quantified using LC/MS/MS detection. The limit of quantitation for this method is 0.01 mg/kg.

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	The DGF S 19 (L00.00-34) multi-residue procedure with LC/MS/MS detection is proposed for the analysis of chlorantraniliprole animal tissue residues in regions which accept this multi residue method. The DFG S 19 procedure extracts chlorantraniliprole from animal tissue using water and acetone. The extracts are purified using gel permeation chromatography and residues are quantified using LC/MS/MS detection. The limit of quantitation for this method is 0.01 mg/kg.
Soil (analytical technique and LOQ)	HPLC-MS/MS: LOQ = 0.5 µg/kg (chlorantraniliprole) GC-ECD: LOQ = 0.01 mg/kg. (chlorantraniliprole)
Water (analytical technique and LOQ)	Chlorantraniliprole and potential degradation products (IN-F9N04, IN-GAZ70, IN-EQW78, IN-ECD73, and IN-F6L99) were extracted from water samples using a liquid/liquid partition and analyzed using a LC/MS/MS system. The analysis of a polar potential breakdown product (IN-F6L99) was completed using solid phase extraction followed by LC/MS/MS detection. The limit of quantitation for this method is 0.1 µg/L for all analytes.
Air (analytical technique and LOQ)	The analytical method for air consisted of sampling by adsorption in cartridges filled with XAD-2. Chlorantraniliprole was extracted from the XAD-2 cartridges with acetone and the extracts were analyzed using LC-MS/MS. The limit of quantitation for this method is 0.5 µg/m^3.
Body fluids and tissues (analytical technique and LOQ)	No methods of analysis for chlorantraniliprole for body fluids and tissues were submitted by the notifier on the basis that chlorantraniliprole is not classified as toxic or highly toxic.

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

	RMS/peer review proposal & Conclusion by other project partners
Active substance	Chlorantraniliprole and the plant protection products DPX-E2Y45 35 WG and DPX-E2Y45 20 SC will not classify from a physical/chemical viewpoint.

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	73-85% after a single low dose (10 mg/kg bw) and 12-13% after a single high dose (200 mg/kg bw) based on sum in bile, urine, and carcass (except GI contents).
Distribution ‡	Widely distributed
Potential for accumulation ‡	Low potential for accumulation
Rate and extent of excretion ‡	Rapid excretion observed via bile (49-53%) within 48 hours. Extensive excretion (88-97%) within 7 days after single or multiple dose administration. Excretion mainly via faeces (62-92% for the low and high doses) compared with urine (3.7-29% for the high and low doses).
Metabolism in animals ‡	Metabolism of the absorbed dose was extensive and involved sex differences primarily in initial methylphenyl and *N*-methyl carbon hydroxylations. Further metabolism of the hydroxylated metabolites included *N*-demethylation, nitrogen-to-carbon cyclisation with loss of a water molecule, oxidation of alcohols to carboxylic acids, amide bridge cleavage, amine hydrolysis, and O-glucuronidation.
Toxicologically relevant compounds ‡ (animals and plants)	Chlorantraniliprole
Toxicologically relevant compounds ‡ (environment)	Chlorantraniliprole

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5000 mg/kg bw	
Rat LD_{50} dermal ‡	> 5000 mg/kg bw	
Rat LC_{50} inhalation ‡	LC_{50} >5.1 mg/L air/4 h (nose-only exposure)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Non-sensitising (M&K and LLNA)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Dog: Liver / increase in liver weight Rat & mouse: no adverse effects observed	
Relevant oral NOAEL ‡	28-day, rat: 584 mg/kg bw per day * 90-day, rat: 1188 mg/kg bw per day * 90-day, mouse: 1135 mg/kg bw per day * 90-day, dog: 303 mg/kg bw per day 1-year, dog: 278 mg/kg bw per day	

Relevant dermal NOAEL ‡	28-day, rat: 1000 mg/kg bw per day *	
Relevant inhalation NOAEL ‡	No data - not required	

* the highest dose tested

Genotoxicity ‡ (Annex IIA, point 5.4)

	Chlorantraniliprole is unlikely to be genotoxic	

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

Target/critical effect ‡	Rat, females: increased liver weight at the 1-year interim sacrifice and thyroid adenomas Mouse, males: Liver: eosinophilic foci accompanied by hepatocellular hypertrophy and and increased liver weight	
Relevant NOAEL ‡	156 mg/kg bw per day; 2-year, rat 158 mg/kg bw per day; 18-month, mice	
Carcinogenicity ‡	Chlorantraniliprole is unlikely to pose a risk to humans	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No adverse effects on fertility,-reproduction, parental and offspring's generations	
Relevant parental NOAEL ‡	1199 mg/kg bw per day *	
Relevant reproductive NOAEL ‡	1199 mg/kg bw per day *	
Relevant offspring NOAEL ‡	1199 mg/kg bw per day *	

Developmental toxicity

Developmental target / critical effect ‡	Rat & rabbit: None observed	
Relevant maternal NOAEL ‡	Rat / Rabbit: 1000 mg/kg bw per day *	
Relevant developmental NOAEL ‡	Rat / Rabbit: 1000 mg/kg bw per day *	

* the highest dose tested

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Rat: No evidence of neurotoxicity NOAEL = 2000 mg/kg bw	
Repeated neurotoxicity ‡	90-day, rat: No evidence of neurotoxicity NOAEL = 1313 mg/kg bw per day (the highest dose tested)	
Delayed neurotoxicity ‡	No data - not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	14-day, rat gavage study with metabolism and genetic toxicology: No adverse, treatment-related effects were observed, including on the frequency of micronucleated PCEs, or in the ratio of PCEs/NCEs. In females, chlorantraniliprole was a weak inducer of cytochrome P450 isozyme 3A. NOAEL = 1000 mg/kg bw per day (the highest dose tested)
	28-day immunotoxicity feeding study in rats: No evidence of treatment-related toxicity in male or female rats at any dietary concentration tested. NOAEL = 1494 mg/kg bw per day
	28-day immunotoxicity study in mice: No treatment-related effects observed. NOAEL = 1144 mg/kg bw per day
	28-day, rat dermal toxicity study on adrenal function: Chlorantraniliprole had no effect on ACTH-stimulated serum corticosterone concentrations. There was an increased incidence of adrenal cortical microvesiculation in the ACTH-stimulated rats treated with the test substance. However, this did not impair the functional response of the adrenals to ACTH stimulation.
Studies performed on metabolites or impurities ‡	**Metabolite IN-EQW78** Rat oral LD_{50} > 2000 mg/kg bw (females) Negative +/- S9 in *In vitro* bacterial mutagenicity (Ames)
	Metabolite IN-LBA24 Mouse oral LD_{50} > 2000 mg/kg bw (females) Negative +/- S9 in *In vitro* bacterial mutagenicity (Ames)
	Metabolite IN-ECD73 Mouse oral LD_{50} > 2000 mg/kg bw (females) Negative +/- S9 in *In vitro* bacterial mutagenicity (Ames)
	Metabolite IN-F6L99 Mouse oral LD_{50} > 2000 mg/kg bw (females) Negative +/- S9 in *In vitro* bacterial mutagenicity (Ames)

Medical data ‡ (Annex IIA, point 5.9)

	No adverse effects reported from a limited number of workers involved with the synthesis of chlorantraniliprole

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	1.56 mg/kg bw per day	Rat, 2-year study, supported by the mouse, 18-month study	100
AOEL ‡	0.36 mg/kg bw per day	Dog, 1-year study	Overall 769* (100 + 13%)*
ARfD ‡	Not required	-	-

*correction for low oral absorption (13%)

Dermal absorption ‡ (Annex IIIA, point 7.3)

DPX-E2Y45 20SC (Coragen®, 200 g/L SC formulation)	Concentrate: 0.3% rounded to 1% for the risk assessment Spray dilution: 3.6% rounded to 4% for the risk assessment Based on *in vivo* dermal absorption in rats
DPX-E2Y45 35WG (Altacor®, 35% WG formulation)	Concentrate: 1.9% rounded to 2% for the risk assessment Spray dilution: 3.6% rounded to 4% for the risk assessment Based on *in vivo* dermal absorption in rats

Exposure scenarios (Annex IIIA, point 7.2)

Operator	**DPX-E2Y45 20 SC**: Worst case scenario: application rate 60 g a.i./ha in pome fruit: UK POEM — % of AOEL** No PPE — 3 German model No PPE — 2 **DPX-E2Y45 35 WG**: Application rate 42 g a.i./ha: UK POEM — % of AOEL** Field crop, no PPE — 6.84 Grapes, no PPE — 3.37 German model Field crop, no PPE — 1 Grapes, no PPE — 1 Dutch model (greenhouse applications, 63 g a.i./ha) No PPE — 4

Workers	Worst case estimates, max. 2 applications, no PPE:	
	DPX-E2Y45 20 SC	% of AOEL**
	Orchard, EUROPOEM II	3.2
	Orchard, German BBA model	9.6
	DPX-E2Y45 35 WG	% of AOEL**
	Vineyard, EUROPOEM II	2.2
	Vineyard, German BBA model	6.8
	Greenhouse, EUROPOEM II	2.8
	Greenhouse, Dutch model	4.2
Bystanders	Worst case estimates:	
	DPX-E2Y45 20 SC:	< 1% of AOEL**
	DPX-E2Y45 35 WG	< 1% of AOEL**

**Calculations based on the AOEL of 0.2 mg/kg bw per day as proposed by the RMS in the DAR. During the Peer Review the AOEL was changed to a higher value, which would lead to lower exposure estimates than the ones presented.

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

	RMS/peer review proposal
Chlorantraniliprole	No classification required[8]
	Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation): Currently not available

[8] It should be noted that proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals. Classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

Chapter 4: Residues

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

Plant groups covered	Fruit crops (apple, tomato) Leafy crops (lettuce) **foliar applications** Pulses/Oilseeds (cotton) Cereals (rice) **soil application**
Rotational crops	Cereals (wheat), leafy crops (lettuce) and root/tuber crops (red beet)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Standard hydrolytic conditions representative of: pasteurisation (90°C; 20 min; pH 4) baking/brewing/ boiling (100°C; 60 min; pH 5) sterilisation (120°C; 20 min; pH 6)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Chlorantraniliprole stable under pasteurisation and sterilisation conditions but slightly degraded to IN-F6L99, IN-ECD73 and IN-EQW78 under baking/ brewing/boiling conditions (10.9% to 13.6% TRR). However, processing data on apple, grape, tomato, plum and cotton indicate low residues of IN-EQW78, IN-ECD73, and IN-F6L99 (≤0.016 mg/kg) in only few end processed tomato fractions (paste, puree and ketchup), the magnitude of chlorantraniliprole residues being always significantly higher than the magnitude of the degradates.
Plant residue definition for monitoring	chlorantraniliprole
Plant residue definition for risk assessment	chlorantraniliprole
Conversion factor (monitoring to risk assessment)	Not applicable.

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

Animals covered	Goat (ruminant); hen and rat (monogastric)
Time needed to reach a plateau concentration in milk and eggs	Milk: 2 to 3 days Egg white 5 days Egg yolk 8 days
Animal residue definition for monitoring	chlorantraniliprole
Animal residue definition for risk assessment	Sum chlorantraniliprole and metabolites IN-HXH44 and IN-K9T00 expressed as chlorantraniliprole
Conversion factor (monitoring to risk assessment)	Ruminants/pigs: Liver, kidney, muscle: 1.5 Fat: 1 Milk 3 Poultry: not necessary
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes (log P_{ow} <3 [max: 2.86 at pH 7] but residues in milk cream and fat 5 to 6 times higher than in whole milk and muscle)

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

	In the US rotational field studies conducted at a dose rate of 200/225 g/ha (*ca.* 0.8N plateau level in soil), residues of chlorantraniliprole in succeeding crops were ≤0.006 mg/kg in leafy vegetables, roots of root vegetables, cereal grains and soybean seed and mostly ≤0.05 mg/kg in tops of root vegetables, cereal forage, hay and straw for rotational crops grown under realistic field conditions. Chlorantraniliprole residues not expected to be present in significant levels in rotational crops when the active substance is used according to the EU GAPs.

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

	Chlorantraniliprole residues stable at least 24 months when stored frozen at -20 °C in plant matrices with: - high water-content: (apple, grape, tomato, lettuce, cauliflower) - high starch-content: (wheat grain, potato) - high oil content: (cotton seed) - and dry matrices: (straw, alfalfa hay) Chlorantraniliprole and metabolites IN-EQW78, IN-ECD73, IN-F6L99 residues stable for at least 12 months when stored at -20°C in processed fractions (apple juice, tomato ketchup, cottonseed oil and meal and raisins). Chlorantraniliprole and IN-HXH44, IN-K9T00, IN-EQW78, IN-GAZ70 residues stable for at least 12months when stored at –20°C in milk and cattle tissues.

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

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no – if yes , specify the level.)	**Yes**[a] beef cattle (0.18 mg/kg DM) **No,** dairy cattle (0.07 mg/kg DM)	**No**[a] (0.01 mg/kg DM)	**No**[a] (0.04 mg/kg DM)
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	No	No
Based on a feeding level of:	1 mg/kg DM (*ca.* 5N)	Not relevant	Not relevant
Muscle	<0.010 mg/kg		
Liver	<0.010 mg/kg		
Kidney	<0.010 mg/kg		
Fat	<0.010 mg/kg		
Milk	<0.010 mg/kg		
Eggs			

[a]: Animals intakes estimated using the following inputs: STMR apple (0.05 mg/kg), PF apple pomace (0.22) and HR potato (0.01 mg/kg)

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

Crop (Reference report)	**Region** (cGAP)	**Trials results relevant to the critical GAP** (a)	**Recommendations/comments**	**Proposed MRL** (mg/kg)	**HR** (mg/kg) **(c)**	**STMR** (mg/kg) **(b)**
Apple/pear (pome fruits) (DuPont-14141 DuPont-16577)	NEU and SEU (2x 60 g/ha, PHI 14 days)	**NEU:** <0.01, 0.010, 0.046, 0.054, 0.068, 0.069, 0.082, 0.090, 0.091, 0.130 **SEU:** 0.022, 0.024, 0.024, 0.034, 0.039, 0.048, 0.051, 0.053, 0.077, 0.096 (trials on pear underlined)	Residue levels in SEU and SEU not significantly different (U-test, 5%). MRL derived from the merged dataset. R_{ber}: 0.16 R_{max}: 0.13	0.2	0.13	0.05
Peach/Apricot (stone fruit) (DuPont-14144 DuPont-16568 DuPont-18749)	SEU (2x 60 g/ha PHI 14 days)	0.019, 0.022, 0.027, 0.028, 0.030, 0.033, 0.040, 0.043, 0.100, 0.120 (trials on apricot underlined)	Two additional trials on apricot not considered (dose rate of 40 g/ha). R_{ber}: 0.11 R_{max}: 0.15	0.2	0.12	0.03
Grape (Table) (DuPont-16566 DuPont-18751)	SEU (2x 43.2 g/ha PHI 3 days)	4 MoR + 6 decline trials: 0.020, 0.035, 2x 0.07, 0.09, 0.10, 2x 0.12, 0.13, 0.23	Five trials conducted with two different formulations (20SC & 35WG). Highest value taken for MRL calculation. R_{ber}: 0.25 R_{max}: 0.27	0.3	0.23	0.09
Grape (Wine) (DuPont-16567, DuPont 19306)	NEU & SEU (1x 54 g/ha PHI 30 days)	**NEU:** 0.014, 0.021, 0.022, 0.030, 0.036, 0.044, 0.068, 0.074, 0.120 **SEU:** 0.008, 0.031, 0.033, 0.036, 0.039, 0.061, 0.080, 0.130, 0.150	NEU and SEU residue data sets similar (U-test, 5%), MRL derived from the merged data: R_{ber}: 0.15 R_{max}: 0.16 Two additional trials not considered (dose rate 35 g/ha)	0.2	0.15	0.04
Potato (DuPont-14143 DuPont-16565 DuPont 18748)	NEU & SEU (2x 12 g/ha PHI 14 days)	8 MoR trials + 2 decline trials: NEU: 6x <0.01 SEU: 4x <0.01		0.01	0.01	0.01

Crop (Reference report)	Region (cGAP)	Trials results relevant to the critical GAP (a)	Recommendations/comments	Proposed MRL (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
Tomato (incl. cherry) (fruiting vegetables) (DuPont-14153, DuPont-14154, DuPont-16581, DuPont-16582, DuPont-16584 DuPont-18755 DuPont-18756	Indoor (2x 63 g/ha PHI 1 day)	4 MoR trials + 12 decline trials: 2x <0.01, 0.009, 0.012, 2x 0.015, 0.015, 0.018, 0.028, 0.034, 0.037, 0.061, 0.079, 0.079, 0.090, 0.095, 0.110, 0.150 (trials on cherry tomato underlined)	MRL proposal derived from the indoor trials: **Indoor** **Outdoor** R_{ber}: 0.17 0.08 R_{max}: 0.16: 0.08	**0.2**	0.15	0.04
	SEU (field: 2x 42 g/ha PHI: 1 day)	6 MoR trials + 5 decline trials: 0.013, 0.018, 0.023, 0.025, 0.029, 0.030, 0.033, 0.036, 0.041, 0.055, 0.062		(0.1)	0.06	0.03
Pepper (fruiting vegetables) (DuPont-16579, DuPont-16580, DuPont-16585, DuPont-16586) DuPont-18753 DuPont-18754 DuPont-18757 DuPont-18765	SEU (field: 2x 42 g/ha Indoor: 43.75: g/ha PHI: 1 day)	**Peper (bell):** 8 MoR trials + 10 decline trials: 0.018, 0.019, 0.020, 0.022, 0.025, 0.029, 0.036, 0.037, 0.048, 0.049, 0.049, 0.052, 0.058, 0.062, 0.066, 0.072, 0.110, 0.150 (indoor trials underlined)	Residues in hot pepper, significantly higher than in pepper (bell) (U-test, 5%). Both data sets were therefore considered separately. MRL proposal derived from trials on hot peeper. **Pepper (bell)** **Pepper (hot)** R_{ber}: 0.13 0.50 R_{max}: 0.13 0.66 Due to the short PHI (1 day) no significant differences between indoor and outdoor trials. Both data sets considered together for MRL calculation	(0.2)	0.15	0.05
		Pepper (hot): 10 decline trials: 0.064, 0.089, 0.11, 0.13, 0.16, 0.17, 0.18, 0.20, 0.39, 0.57 (indoor trials underlined)		**0.8**	0.57	0.17
Cucumber and courgette (cucurbit) (DuPont-18760)	EU (Indoor: 2x 50.4 g/ha, PHI 1 day)	4 MoR trials + 5 decline trials: <0.01, 0.016, 0.021, 0.039, 0.058, 0.064, 0.083, 0.100, 0.130 (Trials on courgette underlined)	R_{ber}: 0.18 R_{max}: 0.18	0.2	0.13	0.06
Melon (cucurbit) (DuPont-18761)	EU (Indoor: 2x 50.4 g/ha, PHI 1 day)	4 MoR trials + 5 decline trials: **Whole:** 0.010, 2x 0.019, 0.023, 0.030, 2x 0.032, 0.038, 0.068	R_{ber}: 0.07 R_{max}: 0.08	0.1	0.07	0.03
		Pulp: 9x <0.01			0.01	0.01

Crop (Reference report)	**Region** (cGAP)	**Trials results relevant to the critical GAP** (a)	**Recommendations/comments**	**Proposed MRL** (mg/kg)	**HR** (mg/kg) **(c)**	**STMR** (mg/kg) **(b)**
Lettuce (leafy vegetables) (DuPont-18764)	EU (indoor: 2x 42 g/ha, PHI 1 day)	4 MoR trials + 7 decline trials: 0.09, 0.15, 0.38, 1.30, 1.40, 1.60, 1.80, 2.00, 2.30 (Trials on head lettuce underlined)	MRL for lettuce derived from indoor trials: **Indoor** **Outdoor** R_{ber}: 3.8 1.8 R_{max}: 3.7 2.0 Two additional trials in NEU (1.0 and 1.7 mg/kg) not considered for MRL calculation	**4**	2.3	1.4
(DuPont-16573 DuPont -18750)	SEU (field: 2x 42 g/ha PHI 1 day)	4 MoR trials + 5 decline trials: <0.01, 0.01, 0.31, 0.37, 0.45, 0.46, 0.83, 0.86, 0.88 (Trials on head lettuce underlined)		(2)	0.88	0.45
Lamb's lettuce (leafy vegetables) (DuPont-18764)	EU (indoor: 2x 42 g/ha, PHI 1 day)	5 decline trials : 3.2, 4.1, 4.1, 7.8, 8.0	R_{ber}: 15.8 R_{max}: 15.0	15	8.0	4.1

(a) Numbers of trials in which particular residue levels were reported e.g., 3× <0.01, 0.01, 6× 0.02, 0.04, 0.08, 2× 0.1, 2× 0.15, 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP
(c) Highest residue

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

ADI	**1.56 mg/kg bw per day**
TMDI (% ADI) according to EFSA PRIMO model	Highest TMDI: 0.3% ADI (DE child)
IEDI (WHO European Diet) (% ADI)	Not necessary
NEDI (specify diet) (% ADI)	Not necessary
Factors included in IEDI and NEDI	-
ARfD	**not required**
IESTI (% ARfD)	Not applicable
NESTI (% ARfD) according (to be specified)	Not applicable
Factors included in IESTI and NESTI	Not applicable

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

Crop/processed crop (Report No)	**Number of studies**	**Median Processing factors** (individual values)		% Transference
Apple/Wet pomace (DuPont-16587)	4	2.2 (1.8, 2.2, 2.2, 4.2)		
Apple/Dry pomace (DuPont-16587)	4	11.6 (9.3, 11,12, 13)		
Apple/Juice (Pasteurised) (DuPont-16587)	4	0.28 (0.12, 0.18, 0.37, 0.38)		
Apple/Puree (DuPont-16587)	4	0.23 (0.086, 0.091, 0.37, 0.38)		
Apple/Sauce (DuPont-16587)	4	0.32 (0.18, 0.27, 0.37, 0.38)		
Apple/Preserves (Pasteurised) (DuPont-16587)	4	0.28 (0.12, 0.18, 0.37, 0.38)		
Apple/canned (Sterilized) (DuPont-16587)	4	0.28 (0.12, 0.18, 0.37, 0.38)		
Grape/Raisin (DuPont-16590)	4	3.5 (2.7, 2.9, 4.0, 7.1)		
Grape/Juice (Pasteurised) (DuPont-16590)	4	0.72 (0.43, 0.46, 1.0, 1.7)		
Grape/Red wine (DuPont-14572/-16590)	2	1.2 (0.76, 1.6)		
Grape/White wine (DuPont-14572/-16590)	2	0.45 (0.3, 0.59)		
Tomato/Puree (Sterilized) (DuPont-16588)	4	1.5 (1.2, 1.4, 1.5, 1.7)		
Tomato/Paste (Sterilized) (DuPont-16588)	4	1.5 (0.61, 1.1, 2.0, 2.4)		
Tomato/Ketchup (Sterilized) (DuPont-16588)	4	1.0 (0.72, 0.74, 1.2, 1.6)		
Tomato/Washed (DuPont-16588)	2	0.39 (0.38, 0.39)		
Tomato/Canned (Sterilized) (DuPont-16588)	4	0.44 (0.23, 0.33, 0.56, 0.65)		
Tomato/Juice (Pasteurised) (DuPont-16588)	4	0.84 (0.57, 0.78, 0.89, 1.1)		

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

Apple/pear	0.2
Peach	0.2
Apricot	0.2
Grape (table)	0.3
Grape (Wine)	0.2
Potato	0.01*
Tomato	0.2
Pepper	0.8
Cucumber	0.2
Courgette	0.2
Melon	0.1
Lettuce	4
Lamb's lettuce	15

When the MRL is proposed at the LOQ, this should be annotated by an asterisk (*) after the figure.

Chapter 2.5: Fate and Behaviour in the Environment

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

Mineralisation after 100 days	25°C: <LOQ – 1.01% after 120 d, [^{14}C-BC] –label (n = 4) 0.47-2.32% after 120 d, [^{14}C-PC] –label (n = 4) 35°C: <LOQ – 1.76% after 120 d, [^{14}C-BC] –label (n = 4) 1.85-4.37 % after 120 d, [^{14}C-PC] –label (n = 4)
Non-extractable residues after 100 days	25°C: 6.42–8.83% after 120 d, [^{14}C-BC] –label (n = 4) 5.73–7.45% after 120 d, [^{14}C-PC] –label (n = 4) Max 9.24 %AR, day 90 35°C: 3.85–8.11% after 120 d, [^{14}C-BC] –label (n = 4) 2.85-5.72% after 120 d, [^{14}C-PC] –label (n = 4)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	**25°C (n = 4) [^{14}C-BC] & [^{14}C-PC] labels:** IN-EQW78 maximum 9.54% at 365 d IN-GAZ70 maximum 4.35% at 120 d IN-F9N04 maximum 4.75% at 300 d* IN-ECD73 maximum 4.93% at 365 d [^{14}C-BC] label only IN-F6L99 maximum 2.19% at 240 d [^{14}C-PC] label only **35°C (n = 4) [^{14}C-BC] & [^{14}C-PC] labels:** IN-EQW78 maximum 33.27% at 120 d IN-GAZ70 maximum 7.38% at 120 d IN-F9N04 maximum 4.19% at 300 d* IN-ECD73 maximum 8.22% at 180 d [^{14}C-BC] label only IN-F6L99 maximum 5.15% at 240 d [^{14}C-PC] label only n = number of soils * Included for further consideration due to structural similarity to parent substance; present in some samples up to 1.9% at Day 0.

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

Anaerobic degradation

Mineralisation after 100 days	0.17% after 120 d, [14C-BC] –label (n = 1) 0.66% after 120 d, [14C-PC] –label (n = 1)
Non-extractable residues after 100 days	2.83% after 120 d, [^{14}C-BC] –label (n = 1) 4.94% after 120 d, [14C-PC] –label (n = 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	25°C (n = 1) [^{14}C-BC] & [^{14}C-PC] labels: IN-EQW78 maximum 26.68% at 120 d No other metabolite exceeded 4%.

Soil photolysis

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None. No single product exceeded 3% of applied, however at least 17 minor products were detected by 15 days [continuous irradiation]. These accounted for a combined maximum of 14.17 % AR.

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: DPX-E2Y45	**Aerobic conditions**							
				Persistence trigger		Modelling endpoints		
Soil type	X	pH (water)	t. °C / % MWHC	DT_{50} / DT_{90} (d)#	r^2	DT_{50} (d) 20°C pF2 / 10kPa	ST. (χ^2%)	Model
Marietta sandy loam/USA *Study 12779Rev. 1.*		7.0	25/45%	886/2,940	0.87	-	2.2	SFO
			35/45%	443/1,470	0.82	-	3.8	
Geomean						**-**		
Tama silty clay loam/USA *Study 12780*		6.6	25/49%	539/1,790	0.77	-	2.2	
			35/49%	>1,000/>1 000*		-	3.0	
Geomean						**-**		
Sassafras loam/USA *Study 12780*		6.6	25/50%	380/1,260	0.89	-	1.9	
			35/50%	278/925	0.71	-	3.0	
Geomean						**-**		
Lleida clay loam/Spain *Study 12780*		7.9	25/44%	223/773	0.97	-	1.2	
			35/44%	183/1,000*		-	3.4	
Lleida silty clay loam/Spain *Study 14622 Rev. 1.*		6.6	25/50%	323/1,070	0.63	-	2.6	
			34/50%	125/414	0.97	-	2.5	
Geomean						**-**		
Cajon sandy loam/USA *Study 14622 Rev. 1.*		7.7	34/50%	234/777		**-**	2.5	
Geomean (weighted)						**-**		
pH dependence						No.		

Note

\# DT_{90} Values extrapolated beyond duration of Study.

* FOMC kinetics

In Study 12780, with the Lleida soil, the SFO model passed all pertinent statistical and visual criteria and was accepted as a modelling endpoint. However, for the persistence trigger, the best fit model was FOMC.

- Endpoints were derived using total extractable residues.
- Except where otherwise stated, the SFO model passed all pertinent statistical and visual criteria and was accepted as a modelling endpoint as well as a persistence trigger.

Metabolite: IN-EQW78	**Aerobic conditions**						
Soil type	X	pH (water)	t. °C / % MWHC	DT_{50} / DT_{90} (d)#	DT_{50} (d) 20°C pF2 / 10kPa[a)]	ST. (χ^2, %)	Method of calculation
Sassafras sandy loam/ USA		5.0	25/ 40-60%	651/2160	825	1.8	SFO
Speyer 2.2 loamy sand/ Germany		5.7		646/2150	673	2.3	
Lleida silty clay loam/ Spain		8.1		763/2530	868	3.1	
Cajon sandy loam/ USA		8.4		671/2230	783	1.4	
Tama silt loam/ USA		6.3		785/2610	950	1.9	
Geomean					815 d		
pH dependence					No.		

\# Values extrapolated beyond duration of Study.
a) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
The SFO model passed all pertinent statistical and visual criteria and was therefore accepted as a modelling endpoint as well as a persistence trigger.

Metabolite: IN-ECD73	**Aerobic conditions**						
Soil type	X	pH (water)	t. °C / % MWHC	DT_{50} / DT_{90} (d)#	DT_{50} (d) 20°C pF2 / 10kPa[a)]	ST. (χ^2, %)	Method of calculation
Sassafras sandy loam/ USA		5.0	25/ 40-60%	1,070/3,560	1356	1.6	SFO
Speyer 2.2 loamy sand/ Germany		5.7		2,870/9,540	2988	1.6	
Lleida silty clay loam/ Spain		8.1		7,52/2,500	855	1.2	
Cajon sandy loam/ USA		8.4		*16,000/53,100*	18693	1.3	
Tama silt loam/ USA		6.3		2580/8560	3123	1.4	
Geomean					2893		
pH dependence					No.		

\# Values extrapolated beyond duration of Study.
a) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
The SFO model passed all pertinent statistical and visual criteria and was therefore accepted as a modelling endpoint as well as a persistence trigger.

Metabolite: IN-F6L99	**Aerobic conditions**								
			Persistence triggers (d)			**Modelling endpoints (d)**			
Soil type	**pH water**	**t. °C / % MWHC**	**DT_{50}**	**DT_{90}**	**Model**	**$DegT_{50}$**	**$DegT_{50}$ at pF2 / 10kPa[a)]**	**χ^2, %**	**Model**
Sassafras sandy loam/ USA	6.1	25/40-60%	7.6	96	FOMC	29*	35	4.4	*
Speyer 2.2 loamy sand/ Germany	5.9		8.2	73	FOMC	11	14	12.5	SFO
Lleida silty clay loam/ Spain	7.4		10	97	FOMC	14	16	7.3	
Hidalgo sandy clay loam /US	8.3		37	123#	SFO	37	46	8.4	
Tama silt loam/ USA	6.3		29	259#	FOMC	40	48	7.7	
Geomean							27.6		
pH dependence							No		

a) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
\# Values extrapolated beyond duration of Study. * $DegT_{50} = DegT_{90}$ FOMC/3.32

Metabolite: IN-GAZ70	**Aerobic conditions**						
Soil type	X	pH (water)	t. °C / % MWHC	DT_{50} / DT_{90} (d)#	DT_{50} (d) 20°C pF2 / 10kPa[a)]	ST. (χ^2, %)	Method of calculation
Sassafras sandy loam/ USA		5.5	25/ 40-60%	3,690/12200	3796	0.7	SFO
Speyer 2.2 loamy sand/ Germany		6.2		1,050/3500	986	1.0	
Lleida clay loam/ Spain		8.1		741/2460	858	1.7	
Cajon sandy loam/ USA		7.3		Stable	Not calculated	—	
Tama silt loam/ USA		6.0		1,120/3710	1196	0.3	
Geomean					1399		
pH dependence					No.		

\# Values extrapolated beyond duration of Study.
a) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
The SFO model passed all pertinent statistical and visual criteria and was therefore accepted as a modelling endpoint as well as a persistence trigger.

Field studies

Parent: DPX-E2Y45	**Bare Soil Field Dissipation Studies, Application rate 300 g a.s./ha (20 SC/35 WG formulation)**								
							Modelling		
Soil type/Location (Study number)	Residue type[a]	pH (water)	Depth (cm)[b]	DT_{50} (d) actual	DT_{90} (d) actual[c]	St. (χ^2 %)	DT_{50} (d) at 20°C pF2 / 10 kPa	St. (χ^2 %)	Method of calculation
Los Palacios sandy loam/Spain (Study 12787)	Readily Extractable	8.1	90	122 SFO	404	10.5	data gap	9.4	SFO
	Total Extractable			226 SFO	752	10.9			-
Nuits-St-George silt loam/France (Study 12791)	Readily Extractable	7.7		248 SFO	822	10.3	data gap	10.7	SFO
	Total Extractable			362 SFO	1,204	10.7			
Crespelano silt loam/Italy (Study 12793)	Readily Extractable	8.1		77 HS	969	10.5	data gap	14	SFO
	Total Extractable			435 SFO	1,445	15.6	-		
Nambsheim silt loam/France (Study 12792)	Readily Extractable	7.9		49 FOMC	5,628	13.4	data gap	14.1	HS/DFOP#
	Total Extractable			82 HS	1,020	14.8	-		
Goch silt loam/Germany (Study 14444)	Total Extractable	6.4	90	489 SFO	1,624	17.5	data gap	18.3	SFO
Suchozebry sandy loam/Poland (Study 14443)	Total Extractable	5.5		354 SFO	1,175	22.7	data gap	11.9	SFO
Vittoria sandy loam/Italy (Study 14442)	Total Extractable	8.3		540 SFO	1,793		data gap	11.5	SFO
Lleida (Alpicat) silty clay loam/Spain (Study 14441)	Total Extractable	8.0		117 HS	>1,000	7.4	data gap	11.3	SFO
Geomean									

[a] Readily extractable residues are removed by conventional extraction (aqueous, organic), total residues are removed by the exhaustive extraction technique (acid, 60°C). Data from these two extraction techniques are only available for studies initiated in 2003.

[b] Nominal depth of soil core, all residues detected at any depth were summed for use in kinetic calculations.

[c] DT_{90} values extrapolated beyond duration of Study.

$DegT_{50}$ of the 2[nd] phase of the DFOP model. HS/ gave the same value

Field studies ***continued***

pH dependence (yes/no) (if yes, type of dependence)	No
Soil accumulation and plateau concentration:	Information on the behaviour of chlorantraniliprole in soil following multiple seasons of application was collected from soil accumulations conducted at 4 sites in Europe. In theses, chlorantraniliprole was applied to a variety of crops in consecutive years to simulate actual agricultural practices (generally 1 x 100 g a.s./ha/yr for six years). At the end of the accumulations significant residues of chlorantraniliprole remained in soil ranging from 24-52 % of applied. Overall the accumulation studies may provide some tentative evidence that a plateau level is being approached for chlorantraniliprole since the accumulation factor is decreasing. The decline in residues of chlorantraniliprole was followed by a rise in the concentrations of the measured degradation products, IN-EQW78, IN-ECD73, and IN-GAZ70. However, there is no evidence that a plateau is being reached for any of the metabolites.

A summary of the European accumulations with Chlorantraniliprole

Site	App rate (N x g a.s./ha)	Crop	Max observed residue in soil (g peq/ha summed over 0-30 cm depth) Exh /conv	Accum plateau reached
Lleida, Spain	1 x 100 for 6 years	Interrow between pears	189.14/183.15	No
France	1 x 100 for 6 years	Grapes	175.75/152.48	No
Germany	1 x 100 for 6 years	Potatoes/cereals/grass	428.68/320.6	No
Los Palacios, Spain	2 x 100 for 3 years In the 4th year 100 g a.s./ha was applied	Corgette/tomato	259.7/210.3#	No

Exh /conv = residues extracted from the soil via the exhaustive (Exh) / conventional (conv) extraction methods. The main difference between the extractions being that the conventional method extracted all bioavailable residue while the latter retrieved the entire residue including that which was not bioavailable.

Residues may be underestimated in this as significant residues were observed below the 30 cm layer in fields

Laboratory studies

Parent: DPX-E2Y45	**Anaerobic conditions (30 d aerobic, 120 d anaerobic)**						
Soil type	Redox potential (mV)*	pH*	t. °C / % MWHC	DT_{50} / DT_{90} (d)#	DT_{50} (d) 20°C pF2 / 10kPa	ST. (r^2)	Method of calculation
Marietta loam	Water: 167 to 199 Soil: 123 to -481	Water: 6.39-7.70 Soil: 6.52-7.32	25°C / flooded soil	208 / 692	Not required	0.959	SFO

* Range of values measured during Study

\# Values extrapolated beyond duration of Study

The average pH was 6.6 (± 0.6) in the water layer and 6.8 (± 0.6) in the soil during the course of the study, showing that degradation was promoted by reducing conditions and not by changes in pH

Parent	Irradiated Soil						
Soil type	Light conditions	pH (water)	t. °C / % MWHC	DT_{50} / DT_{90} (d)#	DT_{50} (d) 20°C pF2 / 10kPa	ST. (r^2)	Method of calculation
Marietta loam	Xenon arc (300-800 nm, 456 W.m^2)	6.7	25°C / air dried	43 / 144 [15 d cts irradiation]	Not required	0.959	SFO
	Dark control			416 / 1,380	Not required	0.0525	

\# Values extrapolated beyond duration of Study.
The Reviewer notes that equivalent days of natural summer sunlight can be calculated with the following equation:

*d = hr/0.75*12*

where d = days of summer sunlight
h = hours of irradiation by the Xe lamp
r = ratio of intensity (irradiance) of the Xe radiation to that of summer sunlight (1.124)
0.75 = correction for diurnal variation of natural sunlight
12 = conversion factor of hours to days.
Thus under natural sunlight conditions a DT_{50} of 129 days is predicted.

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

Parent: chlorantraniliprole							
Soil type	OC% Ashing method for OM	Soil pH (water)	K_d (mL/g)	K_{OC} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Los Palacios loamy sand/Spain	0.5	7.7	1.22	244	1.2221	244	1.0028
Judson-Nodaway silty clay loam/USA	1.7	5.7	7.88	464	9.158	539	1.0434
Marietta sandy loam/USA	0.6	6.7	2.68	447	1.3602	227	0.8485
Tifton loamy sand/USA	0.2	5.9	0.803	402	0.6334	317	0.937
Crespelano loam/Italy	1.3	7.7	3.31	255	2.341	180	0.9256
Arithmetic mean			3.18	362	2.95	301.4	0.95
pH dependence (yes or no)			No The Reviewer notes K_{foc} decreases with increasing pH. It is not clear if a physical relationship exists for this observation.				

Metabolite: IN-EQW78							
Soil type	OC%	Soil pH (water)	K_d (mL/g)	K_{OC} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Los Palacios loamy sand/Spain	0.8	7.7	59.7	7,468	36.0	4,499	0.8961
Judson-Nodaway silty clay loam/USA	1.8	5.7	345.1	19,170	400.8	22,265	1.0296
Marietta sandy loam/USA	0.5	6.7	111.0	22,196	63.3	12,660	0.8954

Tifton loamy sand/USA	0.3	5.9	38.6	12,860	22.2	7,401	0.8800
Crespelano loam/Italy	1.3	7.7	163.3	12,561	92.4	7,110	0.9004
Arithmetic mean			143.5	14,851	122.9	10,787	0.9203
pH dependence (yes or no)			No				

Metabolite: IN-ECD73							
Soil type	OC%	Soil pH (water)	K_d (mL/g)	K_{OC} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Los Palacios loamy sand/Spain	0.8	7.7	207	25,925	79.7	9,966	0.86
Judson-Nodaway silty clay loam/USA	1.8	5.7	1053	58,495	1782.8	99,044	1.09
Marietta sandy loam/USA	0.5	6.7	289	57,760	67.1	13,410	0.78
Tifton loamy sand/USA	0.3	5.9	152	50,700	39.7	13,221	0.77
Crespelano loam/Italy	1.3	7.7	357	27,485	176.9	13,604	0.89
Arithmetic mean			412	44,073	429.2	29,849	0.88
pH dependence (yes or no)			No				

Metabolite: IN-F6L99							
Soil type	OC%	Soil pH (water)	K_d (mL/g)	K_{OC} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Los Palacios loamy sand/Spain	0.8	7.7	1.30	162	0.80	100	0.8892
Judson-Nodaway silty clay loam/USA	1.8	5.7	2.61	145	1.62	90	0.8995
Marietta sandy loam/USA	0.5	6.7	0.64	128	0.41	82	0.8898
Tifton loamy sand/USA	0.3	5.9	2.09	698	1.34	448	0.9035
Crespelano loam/Italy	1.3	7.7	0.67	51	0.45	35	0.9045
Arithmetic mean			1.46	237	0.93	151	0.8973
pH dependence (yes or no)			No				

Metabolite: IN-GAZ70							
Soil type	OC%	Soil pH (water)	K_d (mL/g)	K_{OC} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Los Palacios loamy sand/Spain	0.8	7.7	51	6,396	31.5	3,935	0.9135
Judson-Nodaway silty clay loam/USA	1.8	5.7	584	32,468	NC*	NC	NC
Marietta sandy loam/USA	0.5	6.7	178	35,583	145.2	29,049	0.9692
Tifton loamy sand/USA	0.3	5.9	82	27,171	160.3	53,417	1.1160
Crespelano loam/Italy	1.3	7.7	185	14,205	103.0	7,922	0.9127
Arithmetic mean			216	23,165	110.0	23,581	0.9779
pH dependence (yes or no)			No				

* Concentration of IN-GAZ70 in the aqueous phase was below the limit of detection and K_f could not be calculated

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 metabolites >5% of applied
Aged residues leaching	^{14}C-DPX-E2Y45 (BC-label) applied to 3 soils: ➢ Goch silt loam (pH 6.1, 1.5% OC), ➢ Lleida silty clay loam (pH 7.9, 1.6% OC) ➢ and Penn silt loam (pH 6.1, 1.2% OC). After one of the following treatments: ➢ immediately after application of chlorantraniliprole to soil (fresh spike), ➢ soil aged for 90 days at approximately 35°C (aged soil) ➢ aged soil after extraction of the readily extractable residues (post-extraction soil). the treated soil was applied to the top of the Myakka sand column (30 cm height, i.d. 5.6 cm) and eluted with 0.01 M $CaCl_2$. The Myakka sand (USA, 0.4% organic matter) represents a worst-case soil for leaching.
	Elution (mm): Volumes greater than 600 mL, equivalent to >324 mm of rainfall. The elution volume used was sufficient to elute at least 95% of the applied radioactivity of a highly mobile compound (saccharin) applied directly to a Myakka sand column

Analysis of soil residue post ageing (soil residues pre-leaching):

Component	Applied Radioactivity[a]		
	Goch Soil	**Lleida Soil**	**Penn Soil**
Extractable Radioactivity			
DPX-E2Y45	66.4	44.3	41.1
IN-EQW78	6.3	21.5	4.1
IN-ECD73	2.1	3.2	1.6
Others[b]	1.7	3.1	1.8

a. Based on combustions of fresh soil spikes for each soil%
b. Sum of unidentified radioactivity

Aged residues leaching

Distribution of radioactivity

% total radioactivity retained in SOIL LAYER applied to soil column			
Soil	**Fresh Spike**	**Aged Soil**	**Post-Extraction Soil**
Goch	60.2	NA*	95.6
Lleida	76.9	80.7	95.9
Penn	27.7	84.2	98.6
% total radioactivity retained in Myakka sand SOIL COLUMN (0-30 cm, excluding applied soil layer)			
Goch	35.1	NA*	0.7
Lleida	18.9	15.4	4.4
Penn	61.5	7.9	4.0
% total radioactivity in LEACHATE			
Goch	4.6	NA*	0.1
Lleida	3.7	1.5	0.7
Penn	9.6	1.8	0.4

Lysimeter/field leaching studies

Not performed.

* Not available, sample lost due to experimental error

PEC (soil) (Annex IIIA, OECD Point IIIA 9.4).

Parent: DPX-E2Y45
Method of calculation

Parameter	Value	Units
Soil depth	5	cm
Soil dry bulk density	1.5	g/cm^3
Molecular weight:	483.15	g/mol
Interception	FOCUS	-
Worst case $DegT_{50}$ in soil at 20°C (Total extractable residues)	1,378*	d

*Degradation studies with chlorantraniliprole were conducted at 25 and 35°C, therefore the DT_{50} values were converted to 20°C and the geometric mean of the two values was taken as the endpoint for each soil. The worst case laboratory value, was used in the risk assessment (DT_{50} = 1,378 d at 20°C (Marietta sandy loam soil).

Application data

Crop	Application rate (g a.s./ha)	Interval (d)	Application period	Crop interception FOCUS (%)	Actual application rate (g a.s./ha)	EU region
DPX-E2Y45 20SC formulation						
Pome fruit	2 × 60	14	BBCH 70-87	70	2 x 18	EU
Stone fruit	2 × 60	10	BBCH 73-85	70	2 x 18	SEU
Potatoes[a]	2 × 12.5	10	BBCH 31-60	50 + 80	6.25 + 2.5	EU
Tomatoes[b]	2 × 42	7	BBCH 71-89	80	2 x 8.4	Spain
Grapes, wine	1 × 54	-	BBCH 57-83	70	1 x 16.2	NEU
Grapes, table	2 × 43.5	10	BBCH 57-85	70	2 x 13.05	SEU
Citrus	2 × 15	10	BBCH 31-50	70	2 x 4.5	SEU
DPX-E2Y45 35WG formulation						
Tomatoes, Pepper	2 × 42	7	BBCH 71-89	80	2 x 8.4	SEU
Lettuce	2 × 42	7	BBCH 12-49	25 + 40	31.5 + 25.2	SEU
Grapes, table	2 × 43.5	10	BBCH 57-85	70	13.05	Spain

Pome fruits = apples, pears   Stone fruits = peaches and apricots.

a. The proposed use rate in potatoes is 2 × 12 g a.s./ha, however all PEC calculations were done at a rate of 12.5 g a.s./ha and are therefore protective for the proposed use rate.

b. The proposed use rate of the 20 SC formulation in the field tomato is 2 × 40 g a.s./ha. The rate that was used in the modelling Study is proposed for the 35 WG formulation and is protective when used in PEC calculations for the 20 SC formulation.

Maximum exposure concentrations of chlorantraniliprole arising in soil as a function of crop type after 20 annual applications [SFO kinetics].

Crop	Application rate (g a.s./ha)	Interval (d)	Crop interception FOCUS (%)	Actual application rate (g a.s./ha)	PEC_{Max} (mg/kg) After 20 annual applications DT_{50lab} 1,378 d
DPX-E2Y45 20SC formulation					
Pome fruit	2 x 60	14	70	2 x 18	0.278
Stone fruit	2 x 60	10	70	2 x 18	0.278
Potatoes[a]	2 x 12.5	10	50 + 80	6.25 + 2.5	0.068
Tomatoes [b]	2 x 42	7	80	2 x 8.4	0.13
Grapes, wine	1 x 54	-	70	1 x 16.2	0.126
Grapes, table	2 x 43.5	10	70	2 x 13.05	0.202
Citrus	2 x 15	10	70	2 x 4.5	0.0695
DPX-E2Y45 35WG formulation					
Lettuce	2 × 42	7	25 + 40	31.5 + 25.2	~0.44
Grapes, table	2 × 43.5	10	70	2 x 13.05	0.202
Tomatoes, Pepper	2 × 42	7	80	2 x 8.4	0.13

Pome fruits = apples, pears. Stone fruits = peaches and apricots.

Predicted exposure concentrations of chlorantraniliprole [20 SC] in soil as a function of time arising after 20 annual applications to stone fruits.

	Stone fruits Short-term and long-term PEC_{soil} for chlorantraniliprole after applications to stone fruits (2 × 60 g a.s./ha, 70 % interception, App. Int. = 10 days)	
PEC(s)	**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial	0.278	---
Short term 24 h	0.278	0.278
2 d	0.278	0.278
4 d	0.278	0.278
Long term 7 d	0.278	0.278
14 d	0.276	0.277
21 d	0.275	0.277
28 d	0.274	0.276
50 d	0.271	0.275
100 d	0.265	0.271
Plateau concentration	Chlorantraniliprole did not reach a plateau concentration after 20 years of consecutive use. The highest exposure concentration of in soil arising from the use of the suspension concentrate formulation occurs from application to pome fruits/stone fruits [0.278 mg/kg]. This is predicted to occur immediately upon application of chlorantraniliprole in the 20th consecutive year. Comparing this value with the maximum chlorantraniliprole concentration calculated for an annual application of chlorantraniliprole gives an accumulation factor of ~6 (0.278/0.048)	

Predicted exposure concentrations of chlorantraniliprole[35 WG] in soil as a function of time arising after 20 annual applications to lettuce crops.

		Lettuce Short-term and long-term PEC_{soil} for chlorantraniliprole after applications to lettuce (2 × 42 g a.s./ha, 25 + 40 % interception, App. Int. = 7 days, SFO)	
PEC(s)		**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial		0.438	---
Short term	24 h	0.438	0.438
	2 d	0.438	0.438
	4 d	0.438	0.438
Long term	7 d	0.437	0.438
	14 d	0.435	0.437
	21 d	0.434	0.436
	28 d	0.432	0.435
	50 d	0.428	0.433
	100 d	0.417	0.423
Plateau concentration		Chlorantraniliprole did not reach a plateau concentration after 20 years of consecutive use. For the 35 WG formulation, the highest exposure concentration occurs from application to lettuce crops [0.438 mg/kg]. This is predicted to occur immediately upon application of chlorantraniliprole in the 20th consecutive year. Comparing this value with the maximum chlorantraniliprole concentration calculated for an annual application of chlorantraniliprole to a lettuce crop gives an accumulation factor of ~6 (0.438/0.075).	

PEC (soil) for chlorantraniliprole soil metabolites

Metabolites

Metabolite	Molecular mass (Mr) (g/mol)	Mr relative to parent	Worst case $DegT_{50lab}$ (days)at 20°C SFO	Comment
IN-EQW78	465.14	0.96	1,164	Tama silt loam/ USA,
IN-ECD73	279.13	0.58	4,257	Speyer 2.2 loamy sand/ Germany,
IN-F6L99	204.03	0.42	159*	Marietta, sandy loam,
IN-F9N04	469.12	0.97	1,378	*
IN-GAZ70	451.11	0.93	5,473	Sassafras sandy loam/ USA,

*IN-F9N04 is structurally similar to the parent compound. For that reason the same degradation endpoints as for chlorantraniliprole were used ($DegT_{50}$ = 1,378 days at 20°C).

Application data

Simulations were conducted for maximum use rates in stone fruits and lettuce which correspond to the maximum use patterns in perennial and field crops.

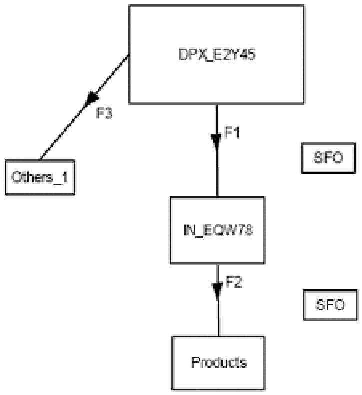
Crop: Lettuce
Depth of soil layer: 5 cm
Soil bulk density: 1.5 g/cm^3
% plant interception: 25 +40 (FOCUS)
Applications: 2
Interval (d): 7
Application rate(s): 42 g a.s./ha

Crop: Stone fruit
Depth of soil layer: 5 cm
Soil bulk density: 1.5 g/cm^3
% plant interception: 70 (FOCUS)
Number of applications: 2
Interval (d): 10
Application rate(s): 60 g a.s./ha

<u>**Metabolite Modelling scheme**</u>

An example of the modelling schemes implemented in ModelMaker™ for metabolite PEC soil calculations are presented hereunder:

Modelling scheme implemented in ModelMaker™ for IN-EQW78 PEC soil calculations.

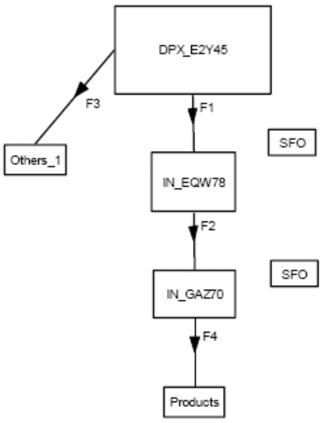


[DPX-E2Y45] = (g x 1 -interception) /750
[IN-EQW78] = $(+F_1 - F_2)$

F_1 = - (0.693/540d) x 0.82 x [DPX_E2Y45]
F_3 = - (0.693/540d) x 0.18 x [DPX_E2Y45]
F_2 = - (0.693/1164d) x [IN-EQW78]

A similar model was used for IN-ECD73, IN-F6L99, IN-F9N04.

Modelling scheme implemented in ModelMaker™ for IN-GAZ70 PEC soil calculations.



[DPX-E2Y45] = (g x 1 -interception) /750
[IN-GAZ70] = (+F2-F4)

F_1 = - (0.693/ 435 d) x 0.68 x [DPX_E2Y45]
F_3 = - (0.693/ 435 d) x 0.32 x [DPX_E2Y45]
F_2 = - (0.693/ 297 d) x [IN-EQW78]
F_4 = - (0.693/5473d) x [IN-GAZ70]

Metabolite formation fractions and degradation rates of metabolite precursor('s) used in PEC soil calculations.

Metabolite	Formation fraction [FF]	DT_{50} of metabolite precursor (days) SFO	Data source	Comment on fit used
IN-EQW78	0.82	DPX-E2Y45 540 [unnormalised]	Vittoria, field Study	FF derived using the scheme in **Figure FB1** [Normalised exhaustive data set] Degradation rate of precursor derived using a Parent → Sink model [SFO], exhaustive extraction data, un-normalised, M_0 constrained.
IN-ECD73	0.35	DPX-E2Y45 435 [unnormalised]	Crespelano, field Study	FF derived using the scheme in **Figure FB1**.[Normalised conventional data set]. Degradation rate of precursor derived using a Parent → Sink model [SFO], exhaustive extraction data, un-normalised.
IN-F6L99	0.60†	DPX-E2Y45 1,378 at 20°C	Marietta lab soil	FF was obtained using residues from the Marietta soil at 35°C Degradation rate of precursor derived using a Parent → Sink model [SFO]
IN-F9N04	0.28†	DPX-E2Y45 1,378 at 20°C	Marietta lab soil	FF was obtained using residues from the Marietta soil at 25°C Degradation rate of precursor derived using a Parent → Sink model [SFO]
IN-GAZ70†	0.68# DPX→IN-EQW78 1.0# IN-EQW78 → IN-GAZ70	DPX-E2Y45* 435 d at 20°C IN-EQW78* 297 d† at 20°C	Lleida Lab soil	$FF_{IN\text{-}EQW78}$ derived using the scheme in **Figure FB1**. [Unnormalised exhaustive data set from Lleida Lab soil at 35 °C $FF_{IN\text{-}GAZ70}$ =1.0 by definition, **Figure FB1**.

† With the available data it was not possible to obtain degradation parameters with statistical certainty.
* IN-GAZ70 was found in the laboratory at a maximum level of 7.4 %AR in Lleida/ Spain clay loam soil at 35°C. Using the residues associated with this soil and the formation fractions for IN-GAZ70# and IN-EQW78#, degradation rates for IN-EQW78 and chlorantraniliprole in this soil were obtained with ModelMaker™.

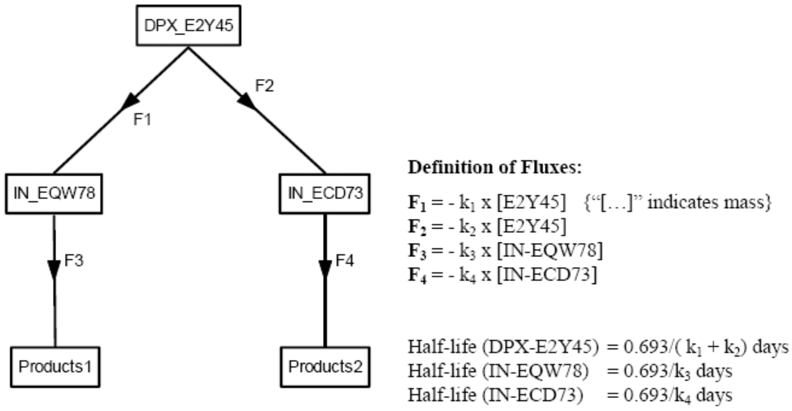


Figure FB1. Conceptual model used to derive formation fractions for IN-EQW78 and IN-ECD73.

Maximum PEC for chlorantraniliprole soil metabolites

	Maximum PECsoil (mg/kg)	
Metabolite	**lettuce 2 x 42 g/ha 25 + 40% interception 35 WG formulation App. Interval = 7 days**	**Stone fruits 2 x 60 g/ha 70 % interception 20 SC formulation App. Interval = 10 days**
IN-EQW78	0.27*	0.171*
IN-ECD73	0.209	0.132
IN-F6L99	0.012*	0.0075*
IN-F9N04	**0.108**	**0.072**
IN-GAZ70	0.74	0.47

* 20 year simulation period. Other metabolites were modelled for a period of 30 years.

SHORT AND LONG TERM PECs FOR THE SOIL METABOLITES

IN-EQW78

Lettuce (2 × 42 g a.s./ha, 25 + 40 % interception, App. Int. = 7 days)			
PEC(s)		**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial		0.270	---
Short term	24 h	0.270	0.270
	2 d	0.270	0.270
	4 d	0.269	0.270
Long term	7 d	0.269	0.270
	14 d	0.268	0.270
	21 d	0.267	0.270
	28 d	0.265	0.270
	50 d	0.262	0.270
	100 d	0.254	0.270

Stone fruits (2 × 60 g a.s./ha, 70 % interception, App. Int. = 10 days)			
PEC(s)		**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial		0.171	---
Short term	24 h	0.171	0.171
	2 d	0.171	0.171
	4 d	0.170	0.171
Long term	7 d	0.170	0.171
	14 d	0.169	0.171
	21 d	0.168	0.171
	28 d	0.168	0.171
	50 d	0.166	0.171
	100 d	0.161	0.171

IN-ECD73

Lettuce (2 × 42 g a.s./ha, 25 + 40 % interception, App. Int. = 7 days)			
PEC(s)		**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial		0.209	---
Short term	24 h	0.209	0.209
	2 d	0.209	0.209
	4 d	0.209	0.209
Long term	7 d	0.209	0.209
	14 d	0.209	0.209
	21 d	0.209	0.209
	28 d	0.208	0.209
	50 d	0.208	0.209
	100 d	0.206	0.209

Stone fruits (2 × 60 g a.s./ha, 70 % interception, App. Int. = 10 days)			
PEC(s)		**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial		0.132	---
Short term	24 h	0.132	0.132
	2 d	0.132	0.132
	4 d	0.132	0.132
Long term	7 d	0.132	0.132
	14 d	0.132	0.132
	21 d	0.132	0.132
	28 d	0.131	0.132
	50 d	0.131	0.132
	100 d	0.130	0.132

IN-F6L99

Lettuce (2 × 42 g a.s./ha, 25 + 40 % interception, App. Int. = 7 days)			
PEC(s)		**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial		0.012	---
Short term	24 h	0.012	0.012
	2 d	0.012	0.012
	4 d	0.012	0.012
Long term	7 d	0.012	0.012
	14 d	0.012	0.012
	21 d	0.012	0.012
	28 d	0.012	0.012
	50 d	0.012	0.012
	100 d	0.012	0.012

Stone fruits (2 × 60 g a.s./ha, 70 % interception, App. Int. = 10 days)			
PEC(s)		**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial		0.0075	---
Short term	24 h	0.0075	0.0075
	2 d	0.0075	0.0075
	4 d	0.0075	0.0075
Long term	7 d	0.0075	0.0075
	14 d	0.0075	0.0075
	21 d	0.0075	0.0075
	28 d	0.0075	0.0075
	50 d	0.0075	0.0075
	100 d	0.0075	0.0075

IN-F9N04

Lettuce (2 × 42 g a.s./ha, 25 + 40 % interception, App. Int. = 7 days)			
PEC(s)		**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial		0.108	---
Short term	24 h	0.108	0.109
	2 d	0.108	0.109
	4 d	0.108	0.109
Long term	7 d	0.108	0.109
	14 d	0.108	0.109
	21 d	0.108	0.109
	28 d	0.108	0.109
	50 d	0.108	0.109
	100 d	0.108	0.109

Stone fruits (2 × 60 g a.s./ha, 70 % interception, App. Int. = 10 days)			
PEC(s)		**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial		0.072	---
Short term	24 h	0.072	0.072
	2 d	0.072	0.072
	4 d	0.072	0.072
Long term	7 d	0.072	0.072
	14 d	0.072	0.072
	21 d	0.072	0.072
	28 d	0.072	0.072
	50 d	0.072	0.072
	100 d	0.072	0.072

IN-GAZ70

Lettuce (2 × 42 g a.s./ha, 25 + 40 % interception, App. Int. = 7 days)			
PEC(s)		**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial		0.74	---
Short term	24 h	0.74	0.74
	2 d	0.74	0.74
	4 d	0.74	0.74
Long term	7 d	0.74	0.74
	14 d	0.74	0.74
	21 d	0.74	0.74
	28 d	0.74	0.74
	50 d	0.74	0.74
	100 d	0.74	0.74

Stone fruits (2 × 60 g a.s./ha, 70 % interception, App. Int. = 10 days)			
PEC(s)		**Actual PEC_{soil} (mg/kg)**	**Time Weighted Average PEC_{soil} (mg/kg)**
Initial		0.47	---
Short term	24 h	0.47	0.47
	2 d	0.47	0.47
	4 d	0.47	0.47
Long term	7 d	0.47	0.47
	14 d	0.47	0.47
	21 d	0.47	0.47
	28 d	0.47	0.47
	50 d	0.47	0.47
	100 d	0.47	0.47

Metabolite accumulation

All soil metabolites exhibit the potential to accumulate in soil. Three of the soil metabolites (IN-EQW78, IN-F6L99, IN-F9N04) appear to approach a plateau concentration after 20/30 years of consecutive use. IN-ECD73 and IN-GAZ70 continued to increase at the end of the 30 year simulation period.

Metabolite accumulation factors after 20/30 years of consecutive chlorantraniliprole use.

	Metabolite accumulation factors in soil [Lettuce crops]		
Metabolite	**PEC max year 1**	**PEC max year 20/30**	**Accumulation factor**
IN-EQW78	0.020	0.27*	~14
IN-ECD73	0.006	0.209	~35
IN-F6L99	0.0016	0.012*	7.5
IN-F9N04	**0.0031**	**0.108**	**~35**
IN-GAZ70	0.0071	0.741	104

* 20 year simulation period. Other metabolites were modelled for a period of 30 years.

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 substance and metabolites >10%

DPX-E2Y45

pH 4: stable at 25°C

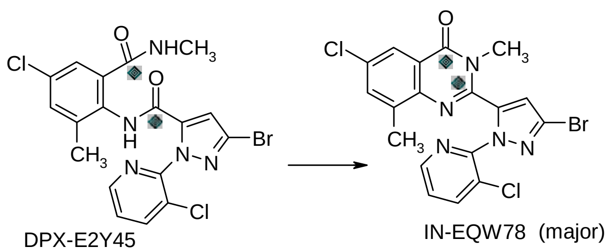
pH 7: stable at 25°C

pH 9: Unstable at 25°C

The degradation rate of chlorantraniliprole as a function of temperature in a *sterile* buffer solution at pH 9 is presented below:

T (°C)	DT_{50} day	r^2	Model	Metabolite Level [IN-EQW78]
15	50	0.924	SFO	32.0%AR (30 d)
25	10	0.957		86.7% [30 d]
50	0.3	0.996		86.6%AR (2 d)

IN-EQW78 did not hydrolyse further at pH 9. In addition, IN-EQW78 was stable in strongly acidic conditions, as demonstrated in the soil extraction procedures used in the field dissipation studies. Therefore, IN-EQW78 can be considered stable to hydrolysis and will not revert back to the parent molecule.



Location of ^{14}C-Labels

Proposed degradation pathway of chlorantraniliprole under hydrolytic conditions (pH 9.0)

Photolytic degradation of active substance and metabolites >10%

DT$_{50}$ DPX-E2Y45

Experimental conditions: Xenon arc lamp (300-800 nm):
DT$_{50}$: 0.37 d in pH 7 buffer (SFO, r^2 = 0.995)
DT$_{50}$: 0.31 d in natural water (SFO, r^2 = 0.986)

Degradation rates expressed in natural sunlight days (55° 57'N, Tranent, Scotland)
DT$_{50}$: 0.7 d in pH 7 buffer
DT$_{50}$: 0.6 d in natural water

% Metabolite formation in an irradiated (Xe arc lamp) pH 7 buffer solution and in sterile natural water.

System	Maximum formation (%AR)		
	IN-LBA22	IN-LBA23	IN-LBA24
pH 7 buffer (BC label)	**52.8**	40.8	88.2
pH 7 buffer (PC label)	49.1	38.6	90.2
Nat. water (BC label)	3.4	**51.4**	89.3
Nat. water (PC label)	2.9	46.8	**94.4**

Degradation times of photolysis metabolites

System	**DT$_{50}$ (d) at 25°C**		
	IN-LBA22	IN-LBA23	IN-LBA24
pH 7 buffer (BC label) pH 7 buffer (PC label)	0.9	1.5	Stable
Nat. water (BC label) Nat. water (PC label)	---	0.5	*

* Unrelaiable parameter (failed the t-test)

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

chlorantraniliprole: 1.246 × 10^{-3} molecules degraded/photon
IN-LBA23: 2.417 × 10^{-4} molecules degraded/photon

Readily biodegradable (yes/no)

No

Degradation in water/sediment (dark)

Parent: DPX-E2Y45	Distribution: Sand sediment: max in water 97.83% at 0 d. Max. sed 56.06% after 75 d Loam sediment: max in water 95.77% at 0 d. Max sed 65.14% after 50 d									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole system (d)	St. (χ^2)	DT_{50}-DT_{90} water (d)	St. (χ^2)	DT_{50}-DT_{90} sed (d)	St. (χ^2)	Method of calculation
Sand (France)	6.7	6.2	25	231-768§	1.67	38-127§	7.35	Not calculated	1.67	SFO
Loam (UK)	7.8	7.5	25	125-414§	2.85	8.5–78.7 (FOMC)	11.8		2.85	SFO
Geomean				170–564§						

Report Nos.: Study 12781, Study 18938

§ Denotes values extrapolated beyond study duration (100 days)

Please note the above are Estimated **persistence** endpoints for chlorantraniliprole from an EU FOCUS Level I analysis
Persistence endpoints for the *whole* system (WC +Sed compartment) represent $DegT_{50}$
Persistence endpoints for the water system represent $DissipT_{50}$

Estimation and use of *persistence endpoints* for parent [EU FOCUS Level P- I analysis].

Approach	Compartment		
	System	Water Column	Sediment
Kinetic Level	Level P-I System DegT50/90	Level P-I Water column DT50/90	Level P-I Sediment DT50/90 **or** Level P-II Sediment DegT50/90
Type of Kinetics	Best-fit model SFO/FOMC/DFOP/HS	Best-fit model SFO/FOMC/DFOP/HS	Best-fit model SFO/FOMC/DFOP/HS **or** SFO

Degradation in water/sediment (dark) ***continued***

Metabolite: IN-EQW78	Distribution: Sand sediment: max in water 0.81% at 10 d. Max. sed 14.68% after 100 d Loam sediment: max in water 1.49% at 3 d. Max sed 34.69% after 75 d									
Water/sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole system§	St. (χ^2)	DT_{50}-DT_{90} water	St. (χ^2)	DT_{50}-DT_{90} sed (d)§	St. (χ^2)	Method of calculation
Sand (France)	6.7	6.2	25	680-2,260^{X}	3.3	Not calculated$^{\#}$	---	680-2,260^{X}	3.3	SFO
Loam (UK)	7.8	7.5	25	121-402^{X}	11.5		---	121-402^{X}	11.5	SFO
Geomean				287-953				287-953		

§ Denotes values extrapolated beyond Study duration (100 days)

X Statistically reliable $DT_{50\ \text{whole system}}$ values for IN-EQW78 could not be determined. IN-EQW78 was observed to increase in three of the four systems.

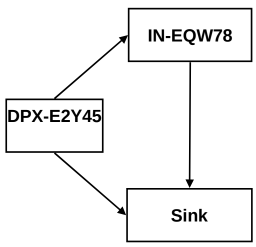
\# No significant amount of IN-EQW78 was present in the water column.

Please note the above are persistence endpoints for IN-EQW78 from an EU FOCUS Level I analysis
Persistence endpoints for the *whole* system [WC +Sed compartment] represent $DegT_{50}$

Estimation and use of ***persistence endpoints*** **for metabolites [EU FOCUS Level M-I analysis].**

Approach	Compartment		
	System	Water Column	Sediment
Kinetic Level	Level M-I System decline DT50/90 **or** Level M-I System DegT50/90	Level M-I Water decline DT50/90 **or** Level M-I System decline DT50/90 **or** Level M-I System DegT50/90 As Justified	Level M-I Sediment decline DT50/90 **or** Level M-I System decline DT50/90 **or** Level M-I System DegT50/90 As Justified
Type of Kinetics	Best-fit model SFO/FOMC/DFOP	Best-fit model SFO/FOMC/DFOP	Best-fit model SFO/FOMC/DFOP

A schematic of the modelling scheme implemented is shown below (whole system):



Degradation level M-1

Degradation in water/sediment (dark) ***continued***

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. at the end of the Study [max value., 100 d]
Sand (France)	6.7	6.2	0.15% at 100 d	7.42% at 75 d	4.65% at 100 d
Loam (UK)	7.8	7.5	0.53% at 100 d	5.06% at 100 d	5.06% at 100 d

Degradation in water/sediment (irradiated)

Parent: DPX-E2Y45	Distribution: Loamy sand sediment [Swiss lake]: max in water 76.9% at 0 d. Max. sed 27.1% after 7 d Sandy loam sediment [Turano pool]: max in water 94.5 % at 0 d. Max sed 38.6% after 5 d *The Reviewer notes the amount of sediment in the Swiss lake [loamy sand] test system is greater than 33 %. This higher mass percentage of sediment may not reflect practice in a field ditch. Thus the results from this test system are of limited value.*									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole system (Level P-I)	St. (χ^2)	DT_{50}-DT_{90} water	St. (χ^2)	DT_{50}-DT_{90} sed*	St. (χ^2)	Method of calculation
Loamy sand (UK)	7.9	5.4	20	22[§]–79[§]	2	9.1–30[§]	8	Not calculated		SFO
Sandy loam (Italy)	8.0	7.9	20	10–33[§]	8	4.1–14[§]	8			SFO
Geomean				15–51		6.1–20				

DuPont Report No.: Study 14438, Revision No. 1; Study 18938

§ Denotes values extrapolated beyond study duration (14 days)

* Whole system values were used for sediment.

The $DegT_{50}$ whole system values ranged from 43 to 91 days in non-irradiated systems

Degradation in water/sediment (irradiated)-*continued*

IN-EQW78	Distribution: Loamy sand sediment: Not detected in water. Max. sed 1.0% after 14 d Sandy loam sediment: max in water 6.4% at 7 d. Max sed 38.1% after 14 d									
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 (UK)	7.9	5.4	20	Not calculated						
Sandy loam (Italy)	8.0	7.9	20	Not calculated						

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 x% after n d (end of the Study)
Loamy sand (UK)	7.9	5.4	Not detected	13.9% at 14 d	13.9% at 14 d
Sandy loam (Italy)	8.0	7.9	Not detected	11.7% at 14 d	11.7% at 14 d

Degradation in water/sediment (anaerobic)

Parent: DPX-E2Y45	Distribution: max in water 94.0% at 0 d. Max. sed 34.03% after 30 d									
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
Loam (UK)	7.1	6.8	25	42-814§	0.958	17-55	0.978	Not calculated	0.958	FOMC

DuPont Report No.: Study 12995, Revision No. 1

§ Denotes values extrapolated beyond Study duration (365 days)

Metabolite: IN-EQW78	Distribution: max in water 19.5% at 21 d. Max. sed ~67.8% after 181 d									
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
Loam (UK)	7.1	6.8	25	701-2,330	0.958	17–55	0.978	Not calculated	0.958	SFO

* Whole system values were used for sediment.

§ Denotes values extrapolated beyond Study duration (365 days)

Parent and metabolite modelled in sequence.

Degradation in water/sediment (anaerobic) ***-continued***

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 x% after n d (end of the Study)
Loam (UK)	7.1	6.8	0.39% at 365 d	4.93% at 181 d	4.81% at 365 d

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

Data Gap for step 3 and step 4 PEC	
Parent:chlorantraniliprole Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Version 1.1 Molecular weight (g/mol): 483.15 Water solubility (mg/L): 0.88 (at pH 7) K_{OC}/K_{OM} (L/kg): 301/175 (arithmetic mean) DT_{50} soil (d): 597 days (SFO, geomean, lab. 20°C/pF2) (note this is estimated using an obsolete Q10 of 2.2) Step 1 DT_{50} water/sediment system (d): 343 d (worst-case at 20°C) Step2 DT_{50} water (d): 1,000 d (default worst-case at 20°C) DT_{50} sediment (d): 343 d (Level P-I-system $DegT_{50}$) (note a geomean whole system half life that has been normalised to 20°C using a Q10 of 2.58 would be shorter at 267 days) Crop: Pome /Stone fruit, late (Step 1 and 2 calculations only) Application rate: 2 × 60 g a.s./ha Number of applications: 2 (Mar-May, Step 1 &2) Interval (d): 10 Crop Interception: 70% (Step 2) Depth of water body: 30 cm Depth of sediment: 5 cm Crop: citrus, (Step 1 and 2 calculations only) Application rate: 2 × 15 g a.s./ha Number of applications: 2 (Jun-Sep, Step 1 &2) Interval (d): 10 Crop Interception: 70% (Step 2) Depth of water body: 30 cm Depth of sediment: 5 cm Crop: protected lettuce, (Step 1 and 2 calculations spray drift entry only then modified to give 0.2% emmission, i.e. PEC multiplied by a factor of 0.082034) Application rate: 2 × 42 g a.s./ha Number of applications: 2 (option no runoff or drainage) Interval (d): 10 Crop Interception: not applicable when no spray drift and runoff is calculated Depth of water body: 30 cm Depth of sediment: 5 cm

PEC surface water

Step 1 and 2 Calculation for applications to pome/stone fruits (2 x 60 g/ha, applications after BBCH 70, App. Int. =10 days)

<u>DPX-E2Y45</u>

Time after application (days)	PEC_{sw} (µg/L)		
	Step 1	Step 2 Northern EU	Step 2 Southern EU
PEC maximum	34.83	5.49	7.19

Note: At Steps 1&2, applications to pome/stone fruits results in the highest loading of DPX-E2Y45 to the surface water body

Step 1 and 2 Calculation for applications to citrus (2 x 15 g/ha, applications after BBCH 70, App. Int. =10 days)

<u>DPX-E2Y45</u>

Time after application (days)	PEC_{sw} (µg/L)		
	Step 1	Step 2 Northern EU	Step 2 Southern EU
PEC maximum	8.71	-	1.79

Note: At Step 2, applications to citrus results in the lowest loading of DPX-E2Y45 to the surface water body of the field crops.

Step 2 type calculation for applications to protected lettuce (2 x 42 g/ha, App. Int. =10 days) but modified to account for 0.2% emmission rather than spray drift. Calculation mode with no runoff or drainage selected

<u>DPX-E2Y45</u>

Time after application (days)	PEC_{sw} (µg/L)		
		Step 2	
PEC maximum		0.04989	

Note: 2, applications to lettuce results in the highest loading of DPX-E2Y45 to the surface water body of the protected crops.

PEC sediment

Step 1 and 2 Calculation for applications to pome/stone fruits (2 x 60 g/ha, applications after BBCH 70, App. Int. =10 days)

DPX-E2Y45

Time after application (days)	PEC_{sed} (µg/kg dry sediment)		
	Step 1	Step 2 Northern EU	Step 2 Southern EU
PEC maximum	99.23	15.40	20.49

Note: At Steps 1&2, applications to pome/stone fruits results in the highest loading of DPX-E2Y45 to the surface water body

Step 2 type calculation for applications to protected lettuce (2 x 42 g/ha, App. Int. =10 days) but modified to account for 0.2% emmission rather than spray drift. Calculation mode with no runoff or drainage selected

DPX-E2Y45

Time after application (days)	PEC_{sw} (µg/ kg dry sediment)		
		Step 2	
PEC maximum		0.08783	

Note: 2, applications to lettuce results in the highest loading of DPX-E2Y45 to the sediment of the protected crops.

Chlorantraniliprole Metabolites Parameters used in $FOCUS_{SW}$ Step 1 and 2	Molecular weight: IN-EQW78: 465.14 g/mol IN-ECD73: 279.13 g/mol IN-F6L99: 204.03 g/mol IN-F9N04: 469.12 g/mol IN-GAZ70: 451.11 g/mol IN-LBA22: 446.69 g/mol IN-LBA23: 446.69 g/mol IN-LBA24: 353.61 g/mol **IN-EQW78**: Water solubility (mg/L): 0.0347 Soil or water metabolite: both K_{FOC} (L/kg): 10,787 $DegT_{50}$ soil (d): 769 (SFO, geomean, lab. 20°C, pF2) DT_{50} water/sediment system (d): 1,000 (FOCUS default) DT_{50} water (d): 1,000 (FOCUS default) DT_{50} sediment (d): 1,000 (FOCUS default) Maximum occurrence observed (% of applied): Water/sediment: 41.0 (irradiated system, worst case) Soil: 31.7 (field) **IN-ECD73**: Water solubility (mg/L): 0.025 Soil or water metabolite: both K_{FOC} (L/kg): 29,849 $DegT_{50}$ soil (d): 2,729 (SFO, geomean, lab. 20°C, pF2) DT_{50} water/sediment system (d): 1,000 d(FOCUS default) DT_{50} water (d): 1,000 (FOCUS default) DT_{50} sediment (d): 1,000 (FOCUS default) Maximum occurrence observed (% of applied): Water/sediment: 4.7 Soil: 11.3 (field) **IN-F6L99:** Water solubility (mg/L): 199 Soil or water metabolite: both K_{FOC} (L/kg): 151 $DegT_{50}$ soil (d): 26 (SFO, geomean, lab. 20°C, pF2) DT_{50} water/sediment system (d): 1,000 (FOCUS default) DT_{50} water (d): 1,000 (FOCUS default) DT_{50} sediment (d): 1,000 (FOCUS default) Maximum occurrence observed (% of applied): Water/sediment: 4.2 Soil: 2.2 (lab 25°C) **IN-F9N04 (* parent data):** Water solubility (mg/L): 1.04 Soil or water metabolite: both K_{FOC} (L/kg): 301* $DegT_{50}$ soil (d): 597* (SFO, geomean, lab. 20°C, pF2) DT_{50} water/sediment system (d): 343 (20°C, Step 1) DT_{50} water (d): 1,000 (FOCUS default) DT_{50} sediment (d): 343* (Step 2, from total system 20°C) *continued on the next page*

Parameters used in $FOCUS_{SW}$ Step 1 and 2	**<u>IN-F9N04-*continued*</u>** <u>Maximum occurrence observed (% of applied):</u> Water/sediment: 2.7 Soil: 4.8 (lab 25°C) ** IN-F9N04 is structurally similar to the parent compound. For that reason data for DPX-E2Y45 was used as a surrogate.* **<u>IN-GAZ70:</u>** Water solubility (mg/L): 0.0098 Soil or water metabolite: both K_{FOC} (L/kg): 23,581 $DegT_{50}$ soil (d): 1,320 (SFO, geomean, lab. 20°C, pF2) DT_{50} water/sediment system (d): 1,000 (FOCUS default) DT_{50} water (d): 1,000 (FOCUS default) DT_{50} sediment (d): 1,000 (FOCUS default) <u>Maximum occurrence observed (% of applied):</u> Water/sediment: 3.1 Soil: 4.4 (lab 25°C) **IN-LBA22:** Water solubility (mg/L): 0.88 (data from chlorantraniliprole) Soil or water metabolite: water only (photolysis product) K_{FOC} (L/kg): 38,800 (calculated value EPI suite) $DegT_{50}$ soil (d): not applicable DT_{50} water/sediment system (d):1.6 (aq. photolysis Study) DT_{50} water (d): 1.6 (aq. photolysis Study) DT_{50} sediment (d): 1.6 (aq. photolysis Study) *DT_{50}s were extrapolated to 20°C* <u>Maximum occurrence observed (% of applied):</u> Water/sediment: 52.8 (aq. photolysis Study) Soil: not present **<u>IN-LBA23:</u>** Water solubility (mg/L): 0.88 (data from chlorantraniliprole) Soil or water metabolite: water only (photolysis product K_{FOC} (L/kg): 112,000 $DegT_{50}$ soil (d): not applicable DT_{50} water/sediment system (d): 2.2 (aq. photolysis) DT_{50} water (d): 2.2 (aq. photolysis, extrap to 20°C) DT_{50} sediment (d): 2.2 (aq. photolysis, extrap to 20°C) <u>Maximum occurrence observed (% of applied):</u> Water/sediment: 51.4 (aq. photolysis Study) Soil: not present **<u>IN-LBA24:</u>** Water solubility (mg/L): 0.88 (data from chlorantraniliprole) Soil or water metabolite: water only (photolysis) K_{FOC} (L/kg): 1,760 (calculated value) $DegT_{50}$ soil (d): not applicable DT_{50} water/sediment system (d): 1,000 (FOCUS default) DT_{50} water (d): 1,000 (FOCUS default) DT_{50} sediment (d): 1,000 (FOCUS default) <u>Maximum occurrence observed (% of applied):</u> Water/sediment: 94.4 (aq. photolysis study) Soil: not present

Parameters used in $FOCUS_{SW}$ Step 1 and 2	Crop: Pome fruit, late app. Application rate: 2 × 60 g a.s./ha (Mar.-May) Number of applications: 2 Interval (d): 10 Crop Interception: 70% (Step 2) IN-LBA23 only Crop: protected lettuce, (Step 1 and 2 calculations spray drift entry only then modified to give 0.2% emmission, i.e. PEC multiplied by a factor of 0.07249) Application rate: 2 × 42 g a.s./ha Number of applications: 2 (option no runoff or drainage) Interval (d): 10 Crop Interception: not applicable when no spray drift and runoff is calculated Depth of water body: 30 cm Depth of sediment: 5 cm

Global maximum predicted environmental concentrations arising in *surface water* for Chlorantraniliprole metabolites at Steps 1&2 from applications to pome fruits/stone fruits

Compound	PEC_{sw} (µg/L)		
	Step 1	Step 2 Northern Europe	Step 2 Southern Europe
IN-EQW78	3.28	1.24(1.05)	1.24(1.05)
IN-ECD73	0.23	0.09(0.07)	0.09(0.07)
IN-GAZ70	0.23	0.09(0.07)	0.09(0.07)
IN-F6L99	0.42	Not required	Not required
IN-F9N04	1.50	0.18	0.26
IN-LBA22	1.54	Not required	Not required
IN-LBA23	1.49	1.49(1.15)	1.49(1.15)
IN-LBA24	4.35	Not required	Not required

Note:
Values in brackets indicate the results for drift calculations with multiple applications when the single application results in a higher PEC.

Global maximum predicted environmental concentrations arising in *sediment* for Chlorantraniliprole metabolites at Steps 1&2 from applications to pome fruits/stone fruits

Compound	PEC_{sed} (µg/kg dry sediment)		
	Step 1	Step 2 Northern Europe	Step 2 Southern Europe
IN-EQW78	102.94	18.43	23.52
IN-ECD73	20.34	2.10	3.24
IN-GAZ70	13.26	1.73	2.44
IN-F6L99	0.61	0.13	0.15
IN-F9N04	4.35	0.51	0.74
IN-LBA22	7.32	4.88	4.88
IN-LBA23	8.13	5.42(4.45)	5.42(4.45)
IN-LBA24	22.84	17.51	17.51

Note:
Values in brackets indicate the results for drift calculations with multiple applications when the single application results in a higher PEC.

IN-LBA23

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	1.49	---	0.00	---
	24h	0.01	0.75	**8.13**	4.06
	2d	0.01	0.38	5.93	5.52
	4d	0.00	0.19	3.16	4.96
	7d	0.00	0.11	1.23	3.71
	14d	0.00	0.06	0.14	2.10
	21d	0.00	0.04	0.01	1.42
	28d	0.00	0.03	0.00	1.07
	42d	0.00	0.02	0.00	0.71
	50 d	0.00	0.02	0.00	0.60

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	100 d	0.00	0.01	0.00	0.30

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	1.49 (1.15)	---	5.42 (4.45)	---
	24 h	0.37(0.28)	0.93(0.72)	5.26(4.25)	5.34 (4.35)
	2 d	0.09(0.07)	0.58 (0.45)	4.16(3.35)	5.02 (4.08)
	4 d	0.01	0.31 (0.24)	2.29(1.84)	4.09 (3.31)
	7 d	0.00	0.18 (0.14)	0.89(0.72)	2.99(2.41)
	14 d	0.00	0.09(0.07)	0.10(0.08)	1.67 (1.35)
	21 d	0.00	0.06 (0.05)	0.01	1.13 (0.91)
	28 d	0.00	0.04 (0.03)	0.00	0.85 (0.69)
	42 d	0.00	0.03 (0.02)	0.00	0.57 (0.46)
	50 d	0.00	0.03 (0.02)	0.00	0.48 (0.38)
	100 d	0.00	0.01	0.00	0.24 (0.19)
Southern EU	0 h	1.49(1.15)	---	5.42 (4.45)	---
	24 h	0.37(0.28)	0.93(0.72)	5.26(4.25)	5.34 (4.35
	2 d	0.09(0.07)	0.58(0.45)	4.16(3.35)	5.02 (4.08)
	4 d	0.01	0.31(0.24)	2.29(1.84)	4.09 (3.31)
	7 d	0.00	0.18(0.14)	0.89(0.72)	2.99 (2.41)
	14 d	0.00	0.09(0.07)	0.10(0.08)	1.67 (1.35)
	21 d	0.00	0.06(0.05)	0.01	1.13 (0.91)
	28 d	0.00	0.04(0.03)	0.00	0.85 (0.68)
	42 d	0.00	0.03(0.02)	0.00	0.57 (0.46)
	50 d	0.00	0.03(0.02)	0.00	0.48 (0.38)
	100 d	0.00	0.01	0.00	0.24 (0.19)

Values in brackets indicate the results for drift calculations with multiple applications when the single application results in a higher PEC.

Step 2 type calculation for applications to protected lettuce (2 x 42 g/ha, App. Int. =10 days) but modified to account for 0.2% emmission rather than spray drift. Calculation mode with no runoff or drainage selected

Time after application (days)	**PEC_{sw} (µg/L)**		
		Step 2	
PEC maximum		0.01331	

PEC in sediment for metabolites

The Reviewer notes several of the metabolites could potentially accumulate in sediment based on their soil DT_{50}s.

PEC (groundwater) (Annex IIIA, OECD Point IIIA 9.6)

Chlorantraniliprole, IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04 and IN-GAZ70

Data Gap

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

Direct photolysis in air	Not required since chlorantraniliprole is not volatile
Quantum yield of direct phototransformation	Not required since chlorantraniliprole is not volatile
Photochemical oxidative degradation in air (DT_{50})	DT_{50} of ~23 hours (Atkinson method, AOPWIN v 1.83) $OH^{\bullet}$ (24 h) concentration = 0.5 × 10^6 hydroxyl radicals per cm^3
Volatilisation	Not required since chlorantraniliprole is has low volatility (6.3 x 10^{-12} Pa at 20°C)
Metabolites	Metabolites of chlorantraniliprole are not anticipated to be volatile, no additional work was performed

PEC (air)

Method of calculation	Based on the Lyman calculation*, it is estimated that 7.973 x 10^{-7} % of applied chlorantraniliprole would be lost from a treated field into the air within 24 hours. *1982. Handbook of chemical property estimation methods

$PEC_{(a)}$

Maximum concentration	<0.01% loss of applied chlorantraniliprole from treated fields within 24 hr.

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: chlorantraniliprole, IN-EQW78, IN-ECD73, IN-F6L99, IN-GAZ70, IN-F9N04. Surface water: chlorantraniliprole,IN-EQW78, IN-ECD73, IN-F6L99, IN-GAZ70, IN-F9N04 and photoproducts: IN-LBA22, IN-LBA23, IN-LBA24. Sediment: chlorantraniliprole, IN-EQW78, IN-ECD73, IN-F6L99, IN-GAZ70, IN-F9N04 and photoproducts: IN-LBA22, IN-LBA23, IN-LBA24 Groundwater: chlorantraniliprole, IN-EQW78, IN-ECD73 IN-GAZ70, IN-F6L99 and IN-F9N04 Air: chlorantraniliprole

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

Soil (indicate location and type of Study)	No data provided - none requested
Surface water (indicate location and type of Study)	No data provided - none requested
Groundwater (indicate location and type of Study)	No data provided - none requested
Air (indicate location and type of Study)	No data provided - none requested

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Candidate for R53 as not readily biodegradable.

Chapter 2.6 Effects on Non-target Species

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Northern bobwhite quail	chlorantraniliprole	Acute	>2250	-
Northern bobwhite quail	Metabolite (IN-EQW78)	Acute	>2250	-
Northern bobwhite quail	chlorantraniliprole	Short-term	>1729	5260
Northern bobwhite quail	chlorantraniliprole	Long-term	10.1*	120*
Mammals ‡				
Rat	chlorantraniliprole	Acute	>5000	-
Rat	Metabolite (N-EQW78)	Acute	>2000	-
Mouse	Metabolite (IN-ECD73)	Acute	>2000	-
Mouse	Metabolite (IN-F6L99)	Acute	>2000	-
Rat	Metabolite (IN-LBA24)	Acute	>2000	-
Rat	chlorantraniliprole	Long-term	1199	20000
* Highest concentration tested				
Additional higher tier studies ‡				

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

Indicator species/Category	Time scale	ETE	TER	Trigger
Tier 1 (Birds) - Pome fruit, late crop growth stage- 2 x 60 g a.s./ha[1]				
Small insectivore	Acute	3.24	>694	10
Small insectivore	Short-term	1.81	>950	10
Small insectivore	Long-term	1.81	5.58	5
Tier 1 (Birds) - Leafy vegetables 2 x 42 g a.s./ha[1]				
Small insectivore	Acute	2.27	>990	10
Medium herbivore	Acute	3.89	>578	10
Small insectivore	Short-term	1.27	>1360	10
Medium herbivore	Short-term	1.96	>880	10
Small insectivore	Long-term	1.27	7.97	5
Medium herbivore	Long-term	1.08	9.38	5
Tier 1 (Birds) - drinking water exposure at max. tank mix concentration of 42 mg a.s./L				
Small insectivore	Acute	2.26	>996	10
Medium herbivore	Acute	0.737	>3053	10
Tier 1 (Birds) - food chain TER_{lt} based on max. initial PEC_{sw} and PEC_{soil}				
Fish-eating bird (chlorantraniliprole)	Long-term	0.1097	92.1	5
Earthworm-eating bird (chlorantraniliprole)	Long-term	0.45	22	5
Earthworm-eating bird IN-EQW78	Long-term	0.08	120	5
Earthworm-eating bird IN-ECD73	Long-term	0.35	29	5
Earthworm-eating bird IN-GAZ70	Long-term	0.11	90	5
Earthworm-eating bird IN-F6L99	Long-term	0.002	9359	5
Earthworm-eating bird IN-F9N04	Long-term	0.119	85	5
Tier 1 (Mammals) - Pome fruit, late crop growth stage- 2 x 60 g a.s./ ha[1]				
Small herbivore	Acute	2.76	>1809	10
Small herbivore	Long-term	0.91	1318	5
Tier 1 (Mammals) - Leafy vegetables, 2 x 42 g a.s./ha[1]				
Medium herbivore	Acute	1.43	>3490	10
Medium herbivore	Long-term	0.4	3024	5
Tier 1 (Mammals) - drinking water exposure at max. tank mix concentration of 42 mg a.s./L				
Small herbivore (chlorantraniliprole)	Acute	1.203	>4156	10
Small herbivore (IN-EQW78)	Acute	1.203	>1663	10

Indicator species/Category	Time scale	ETE	TER	Trigger
Medium herbivore (chlorantraniliprole)	Acute	0.745	>6712	10
Medium herbivore (IN-EQW78)	Acute	0.745	>2685	10
Tier 1 (Mammals) - food chain TER_{lt} based on max. initial PEC_{sw} and PEC_{soil}				
Fish-eating mammal (chlorantraniliprole)	Long-term	0.06793	17651	5
Earthworm-eating mammal (chlorantraniliprole)	Long-term	0.574	2089	5
Earthworm-eating mammal IN-EQW78	Long-term	0.11	>10000	5
Earthworm-eating mammal IN-ECD73	Long-term	0.44	2725	5
Earthworm-eating mammal IN-GAZ70	Long-term	0.14	8400	5
Earthworm-eating mammal IN-F6L99	Long-term	0.013	>350000	5
Earthworm-eating mammal IN-F9N04	Long-term	0.211	>5687	5

[1] Due to the lack of any significant metabolism of chlorantraniliprole in vegetation, exposure to metabolites (IN-EQW78, IN-ECD73, IN-F6L99, IN-LBA24) was considered to effectively be zero and no risk to herbivorous vertebrates is identified.

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[1] (mg/L)
Fish				
Sheepshead minnow	chlorantraniliprole	96 h (flow-through)	Mortality, LC_{50}	>12 m
Rainbow trout	chlorantraniliprole	90 d early life stage (flow-through)	NOEC	0.11 m
Bluegill sunfish	chlorantraniliprole 20SC	96 h (flow-through)	Mortality, LC_{50}	>9.9 n formul.n ≡ >1.84 m a.s.
Rainbow trout	chlorantraniliprole 35WG	96 h (flow-through)	Mortality, LC_{50}	>3.2 n formul.n ≡ >1.09 m a.s
Aquatic invertebrates				
Daphnia magna	chlorantraniliprole	48 h (static)	Immobility, EC_{50}	0.0116 m
Centroptilum triangulifer[2]	chlorantraniliprole	48 h (static)	Immobility, EC_{50}	0.0116 m
Chimarra atterima	chlorantraniliprole	48hr (static)	Mortality, LC_{50}	0.0117 m
Gammarus pseudolimnaeus	chlorantraniliprole	48hr (static)	Mortality, LC_{50}	0.0351 m
Crassostrea virginica	chlorantraniliprole	96 h (flow-through)	Shell growth, EC_{50}	0.0399 m
Hyallella azteca	chlorantraniliprole	48hr (static)	Mortality, LC_{50}	>0.389 m
Procambarus clarkii	chlorantraniliprole	96 hr (static)	Mortality, LC_{50}	0.951
Soyedina carolinensis	chlorantraniliprole	48hr (static)	Mortality, LC_{50}	0.258 m
Americamysis bahia	chlorantraniliprole	96 hr (static)	Mortality, LC_{50}	1.15 m
Oronectes virilis	chlorantraniliprole	48hr (static)	Mortality, LC_{50}	>1.42 m
Daphnia magna	chlorantraniliprole	21 d (semi-static)	NOEC	0.00447 m
Daphnia magna	chlorantraniliprole 20SC	48 h (static)	Immobility, EC_{50}	0.035 n formul.n ≡ 0.0071 m a.s.
Daphnia magna	chlorantraniliprole 35WG	48 h (static)	Immobility, EC_{50}	0.029 n formul.n ≡ 0.011 m a.s.
Daphnia magna	IN-EQW78	48 h (static)	Immobility, EC_{50}	>0.138[4] m
Daphnia magna	IN-ECD73	48 h (static)	Immobility, EC_{50}	>0.0138[4] m
Daphnia magna	IN-GAZ70	48 h (static)	Immobility, EC_{50}	>0.00987[4] m
Daphnia magna	IN-F6L99	48 h (static)	Immobility, EC_{50}	46.8 m
Daphnia magna	IN-F9N04	48 h (static)	Immobility, EC_{50}	0.03 m
Sediment dwelling organisms				
Chironomus riparius	chlorantraniliprole	48 h (static)	Mortality, LC_{50}	0.0859
Lumbriculus variegatus	chlorantraniliprole	48hr (static)	Mortality, LC_{50}	>1.49 m
Chironomus riparius	chlorantraniliprole	28 d (static, water spiked)	NOEC	0.0025 n
Chironomus riparius	chlorantraniliprole	28 d (static, sediment-spiked)	NOEC	0.005 mg/kg sediment n
Algae				
Pseudokirchneriella subcapitata[3]	chlorantraniliprole	120 h (static)	EC_{50} (biomass and growth rate)	>2.0 n
Pseudokirchneriella subcapitata	chlorantraniliprole 20SC	120 h (static)	EC_{50} (biomass and growth rate)	>20 n formul.n ≡ >4.0 n a.s.
Pseudokirchneriella subcapitata	chlorantraniliprole 35WG	120 h (static)	EC_{50} (biomass and growth rate)	>20 n formul.n ≡ >1.78 n a.s.

Group	Test substance	Time-scale (test type)	End point	Toxicity[1] (mg/L)
Higher plants				
Lemna gibba	chlorantraniliprole	14 d (static)	EC_{50} (frond number and biomass)	>2.0 n
Higher tier refined regulatory effects endpoint				
Based on an SSD calculated using E_TX 2.0 (Van Vlaardingen et al. 2004) for 9 species the median HC_5 value is 2.91 µg a.s./L and with an assessment factor of 5, this gives a regulatory acceptable concentration (RAC) of 0.58 µg a.s./L				

[1] Endpoints stated in terms of mean measured (m) or nominal (n) concentrations.
[2] The aquatic insect *Centroptilum triangulifer* had the same acute EC_{50} of 0.0116 as *Daphnia magna*
[3] The blue-green alga *Anabaena flos-aquae* had the same nominal 120 h EC_{50} of >2 mg a.s./L (all parameters).
[4] Limit of water solubility

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

FOCUS Step 1

Pome/stone fruit 2 x 60 g a.s./ha

Test substance	Organism group	Toxicity end point (mg/L or mg/kg sed)	Time scale	Initial PECsw or PECsed (mg/L or mg/kg sed)	TER	Trigger
chlorantraniliprole	Fish	>12	Acute	0.0348[1]	>345	100
chlorantraniliprole	Fish	0.11	Chronic	0.0348[1]	**3.16**	10
chlorantraniliprole	Aquatic invertebrates	0.0116	Acute	0.0348[1]	**0.33**	100
chlorantraniliprole	Aquatic invertebrates	0.00447	Chronic	0.0348[1]	**0.13**	10
chlorantraniliprole	Algae	>2	Chronic	0.0348[1]	>57.5	10
chlorantraniliprole	Higher plants[4]	>2	Chronic	0.0348[1]	>57.5	10
chlorantraniliprole	Sediment-dwelling organisms	0.0025	Chronic	0.0348[1]	**0.072**	10
chlorantraniliprole	Sediment-dwelling organisms	0.005 mg/kg sed	Chronic	0.0992 mg/kg sed[3]	**0.05**	10
IN-EQW78	Aquatic invertebrates	>0.138	Acute	0.0033[2]	**>41.8**	100
IN-ECD73	Aquatic invertebrates	>0.0138	Acute	0.00023[2]	**>60**	100
IN-GAZ70	Aquatic invertebrates	>0.00987	Acute	0.00023[2]	**>42.9**	100
IN-F6L99	Aquatic invertebrates	46.8	Acute	0.00042[2]	111429	100
IN-F9N04	Aquatic invertebrates	0.03	Acute	0.0015[2]	**20**	100

[1] Maximum Step 1 PECsw for pome/stone fruit uses of chlorantraniliprole 20SC
[2] Maximum Step 1 PECsw for pome/stone fruit uses of chlorantraniliprole 20SC
[3] Maximum Step 1 PECsed for pome/stone fruit uses of chlorantraniliprole 20SC
[4] Only strictly required for herbicides but included for completeness
TERs in **bold** fail the tier 1 trigger and so are carried forward to FOCUS Step 2

FOCUS Step 2

Pome Fruit 2 x 60 g a.s./ha, late growth stage

Test substance	Organism group	Toxicity end point (mg/L or mg/kg sed)	Time scale	Initial PECsw or PECsed (mg/L or mg/kg sed, for SEU or NEU)	TER	Trigger
chlorantraniliprole	Fish	0.11	Chronic	0.0072 SEU[1]	15.3	10
chlorantraniliprole	Aquatic invertebrates	0.0116	Acute	0.0072 SEU[1]	**1.6**	100
chlorantraniliprole	Aquatic invertebrates	0.00447	Chronic	0.0072 SEU[1]	**0.62**	10
chlorantraniliprole	Sediment-dwelling organisms	0.0025	Chronic	0.0072 SEU[1]	**0.35**	10
chlorantraniliprole	Sediment-dwelling organisms	0.005 mg/kg sed	Chronic	0.0205 mg/kg sed SEU[3]	**0.24**	10
IN-EQW78	Aquatic invertebrates	>0.138	Acute	0.0012 N&SEU[2]	>115	100
IN-ECD73	Aquatic invertebrates	>0.0138	Acute	0.00009 N&SEU[2]	>153	100
IN-GAZ70	Aquatic invertebrates	>0.00987	Acute	0.00009 N&SEU[2]	>110	100
IN-F9N04	Aquatic invertebrates	0.03	Acute	0.00026 SEU[2]	115	100

[1] Maximum Step 2 PECsw for pome/stone fruit uses of chlorantraniliprole 20SC in NEU or SEU
[2] Maximum Step 2 PECsw for pome/stone fruit uses of chlorantraniliprole 20SC in NEU or SEU
[3] Maximum Step 2 PECsed for pome/stone fruit uses of chlorantraniliprole 20SC in NEU or SEU
TERs in **bold** fail the tier 1 trigger and so are carried forward to FOCUS Step 3

FOCUS Step 2

Citrus 2 x 15 g a.s./ha

Test substance	Organism group	Toxicity end point (mg/L or mg/kg sed)	Time scale	Initial PECsw or PECsed (mg/L or mg/kg sed, for SEU or NEU)	TER	Trigger
chlorantraniliprole	Fish	0.11	Chronic	0.00179 SEU[1]	61.5	10
chlorantraniliprole	Aquatic invertebrates	0.0116	Acute	0.00179 SEU[1]	**6.4**	100
chlorantraniliprole	Aquatic invertebrates	0.00447	Chronic	0.00179 SEU[1]	**2.5**	10
chlorantraniliprole	Sediment-dwelling organisms	0.0025	Chronic	0.00179 SEU[1]	**1.4**	10

[1] Maximum Step 2 PECsw
TERs in **bold** fail the tier 1 trigger and so are carried forward to FOCUS Step 3

FOCUS Step 2
Glasshouse use of Chlorantraniliprole 35WG to lettuce at 2 x 42 g a.s./ha

Test substance	Organism group	Toxicity end point (mg a.s./L or mg a.s./kg sed)	Time scale	Initial PECsw or PECsed (mg a.s./L or mg a.s./kg sed)	TER	Trigger
chlorantraniliprole	Fish	0.11	Chronic	0.00005[1]	2200	10
chlorantraniliprole	Aquatic invertebrates	0.0116	Acute	0.00005[1]	232	100
chlorantraniliprole	Aquatic invertebrates	0.00447	Chronic	0.00005[1]	89	10
chlorantraniliprole	Sediment-dwelling organisms	0.0025	Chronic	0.00005[1]	50	10
chlorantraniliprole	Sediment-dwelling organisms	0.005 mg/kg sed	Chronic	0.00009 mg/kg sed[2]	55.6	10

[1] Maximum Step 2 PECsw for indoor glasshouse use of chlorantraniliprole 35WG on lettuce
[2] Maximum Step 2 PECsed for indoor glasshouse use of chlorantraniliprole 35WG on lettuce

Bioconcentration

Bioconcentration factor (BCF) chlorantraniliprole	15 (whole fish)
Clearance time (CT_{50})	1.5 days
(CT_{90})	8.9 days
Level of residues (%) in organisms after the 14-day depuration phase	>95% of total applied radioactivity is depurated

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

Test material	Oral LD_{50} (µg chlorantraniliprole /bee)	Contact LD_{50} (µg chlorantraniliprole/bee)
chlorantraniliprole technical in acetone	>104.1[1]	>4 [1]
chlorantraniliprole 35WG	>119.19	>100
chlorantraniliprole 20SC	>114.1[1]	>100[1]

[1] Signs of intoxication observed

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

Single application at 60 g a.s./ha

Test substance	Route	Application rate g a.s./ha	Hazard quotient	Trigger
chlorantraniliprole	Contact	60	<15	50
chlorantraniliprole	Oral	60	<0.57	50
chlorantraniliprole 20SC	Contact	60	<0.60	50
chlorantraniliprole 20SC	Oral	60	<0.52	50
chlorantraniliprole 35WG	Contact	60	<0.42	50
chlorantraniliprole 35WG	Oral	42	<0.35	50

Overview of the semi-fields submitted on honey bees

Test item / Guideline	Exposure scenario (Country & Year)	Crop	Application rate (g a.s./ha)	Species /sub-species
chlorantraniliprole 20SC / EPPO 170 (3)	Tunnel: Application during foraging activity (Germany, 2004)	*Phacelia tanacetifolia*	52.5	*A. m. carnica*
chlorantraniliprole 20SC / EPPO 170 (3)	Tunnel: Application during foraging activity (Spain, 2004)	*P. tanacetifolia*	52.5	*A. m. mellifera*
chlorantraniliprole 20SC / EPPO 170 (3)	Tunnel: Application during foraging activity (France, 2006)	*P. tanacetifolia*	60	*A. m. carnica*
chlorantraniliprole 20SC / CEB 230	Tunnel: Application during bee-flight and in the evening after bee-flight (France, 2005)	*P. tanacetifolia*	60	*A. m. mellifera*
chlorantraniliprole 20SC / CEB 230	Tunnel: Application during bee-flight and in the evening after bee-flight (France, 2005)	*P. tanacetifolia*	60	*A. m. carnica*
chlorantraniliprole 20SC / CEB 230	Tunnel: Application during bee-flight and in the evening after bee-flight (France, 2006)	*P. tanacetifolia*	60	*A. m. mellifera*
chlorantraniliprole 20SC / CEB 230	Tunnel: Application during bee-flight and in the evening after bee-flight (France, 2005)	Wheat	60	*A. m. mellifera*
chlorantraniliprole 20SC / CEB 230	Tunnel: Application during bee-flight and in the evening after bee-flight (France, 2005)	Wheat	60	*A. m. carnica*
chlorantraniliprole 20SC / CEB 230	Tunnel: Application during bee-flight and in the evening after bee-flight (France, 2006)	Wheat	60	*A. m. mellifera*
chlorantraniliprole 20SC / EPPO 170 (3)	Tunnel: T1: Application before + 8 days after sowing onto soil T2: Application before + 8 days after sowing onto soil plus application during bee flight/full flowering (France, 2003)	*P. tanacetifolia*	156.16 + 150 156.16 + 150 plus 75	*A. m. carnica*
chlorantraniliprole 20SC / EPPO 170 (3)	Tunnel: T1: Application before + after sowing onto soil T2: Application during bee flight/full flowering (Germany, 2005)	*P. tanacetifolia*	253.6 + 60 60	*A. m. carnica*

Test item / Guideline	Exposure scenario (Country & Year)	Crop	Application rate (g a.s./ha)	Species /sub-species
Chlorantraniliprole 200 g/L SC OECD 75	Tunnel: T: Application before + after flowering S: Application before + after flowering (Germany, 2005)	*P. tanacetifolia*	T: 2 applications of 60 g a.s./ha S: 2 applications of 120 g a.s./ha	*A. m. carnica*

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (g a.s./ha[1])
Typhlodromus pyri	chlorantraniliprole 20SC	Mortality Sub-lethal	LR_{50} >750 ER_{50} >750
	chlorantraniliprole 35WG	Mortality Sub-lethal	LR_{50} >750 ER_{50} >750
Aphidius rhopalosiphi	chlorantraniliprole 20SC	Mortality Sub-lethal	LR_{50} >750 ER_{50} >750
	chlorantraniliprole 35WG	Mortality Sub-lethal	LR_{50} >750 ER_{50} >750

[1] Preparation endpoints are expressed in units of g a.s./ha

Tier 1 non-target arthropod hazard quotients

Test substance	Species	Effect (LR_{50} g a.s./ha)	HQ in-field	HQ off-field[1]	Trigger
Pome and Stone Fruit (2 applications at 60 g a.s./ha, late)					
chlorantraniliprole 20SC	*Aphidius rhopalosiphi*	>750	<0.14	<0.016 (3 m)	2
chlorantraniliprole 20SC	*Typhlodromus pyri*	>750	<0.14	<0.016 (3 m)	2
Wine Grapes (1 application at 54 g a.s./ha, late)					
chlorantraniliprole 20SC	*Aphidius rhopalosiphi*	>750	<0.07	<0.006 (3 m)	2
chlorantraniliprole 20SC	*Typhlodromus pyri*	>750	<0.07	<0.006 (3 m)	2
Table Grapes (2 applications at 43.2 g a.s./ha, late)					
chlorantraniliprole 20SC or 35WG	*Aphidius rhopalosiphi*	>750	<0.10	<0.007 (3 m)	2
chlorantraniliprole 20SC or 35WG	*Typhlodromus pyri*	>750	<0.10	<0.007 (3 m)	2
Fruiting Vegetables (Height >50 cm, 2 applications at 40 g a.s./ha)					
chlorantraniliprole 20SC or 35WG	*Aphidius rhopalosiphi*	>750	<0.09	<0.007 (3 m)	2
chlorantraniliprole 20SC or 35WG	*Typhlodromus pyri*	>750	<0.09	<0.007 (3 m)	2
Citrus (2 applications at 15 g a.s./ha, early)					

Test substance	Species	Effect (LR_{50} g a.s./ha)	HQ in-field	HQ off-field[1]	Trigger
chlorantraniliprole 20SC	*Aphidius rhopalosiphi*	>750	<0.03	<0.004 (3 m)	2
chlorantraniliprole 20SC	*Typhlodromus pyri*	>750	<0.03	<0.004 (3 m)	2
Potatoes (2 applications at 12 g a.s./ha)					
chlorantraniliprole 20SC	*Aphidius rhopalosiphi*	>750	<0.03	<0.001 (1 m)	2
chlorantraniliprole 20SC	*Typhlodromus pyri*	>750	<0.03	<0.001 (1 m)	2

[1] drift distance used to determine off-field HQ indiacted in brackets

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g a.s./ha)[1]	% effect	Trigger value
Coccinella septempunctata; chlorantraniliprole 20SC	larvae	Rate-response extended laboratory test with dwarf bean leaves, *Phaseolus vulgaris*. Exposure of larvae to fresh-dried spray deposits on leaves for 15 days, followed by 7 day fecundity assessment beginning after adult emergence.	0.5, 1.5, 4.4, 13.3, 40.0, 120 g/ha	LR_{50} = 79.5 g a.s./ha ER_{50} = 13.3 g a.s./ha	50%
Coccinella septempunctata; chlorantraniliprole 20SC	larvae	Extended laboratory test with exposure to field-aged spray deposits of potted apple tree leaves (aged 28 and 78 days). Exposure of larvae in lab for 12 days (1st bioassay) or 11 days (2nd bioassay). Reproduction evaluated for 15 days (1st) or 10 days (2nd) in test units with bean stems, pollen, honey and aphids. Reproduction assay began after adults emerged and began ovipositing.	2 × 60 g/ha, 7-day spray interval, 28- or 78-day aging period	Control mortality: 1st: 10%, 2nd: 20% Corrected mortality 1st: 18.6%, 2nd: -7.8% Reproduction: No effects in both assays.	50%
Orius laevigatus; chlorantraniliprole 20SC	Nymphs	Rate-response extended laboratory test: with dwarf bean leaves (*P. vulgaris).* Exposure of nymphs to fresh-dried spray deposits for 9 days, followed by 2 day fecundity assessments twice beginning Day 16 and 18 after treatment.	0.5, 1.5, 4.4, 13.3, 40, 120 g/ha	LR_{50} >120 g a.s./ha ER_{50} >120 g a.s./ha	50%
Episyrphus balteatus; chlorantraniliprole 20SC	larvae	Rate-response extended laboratory test: with winter rape (*Brassica napus*) leaves. Exposure of larvae to fresh-dried spray deposits, followed by a reproduction bioassays.	0.5, 1.5, 4.4, 13.3, 40.0 g/ha	LR_{50} = 12.6 g a.s./ha ER_{50} = 13.3 g a.s./ha	50%
Episyrphus balteatus; chlorantraniliprole 35WG	larvae	Rate-response extended laboratory test with winter rape (*Brassica napus*) leaves. Exposure of larvae to fresh-dried spray deposits, followed by a reproduction bioassays.	0.5, 1.5, 4.4, 13.3, 40.0 g/ha	LR_{50} = 4.64 g a.s./ha	50%
Episyrphus balteatus; chlorantraniliprole 20SC	larvae	Extended laboratory test with exposure to field-aged spray deposits of potted apple tree leaves (aged 28 and 42 days). Exposure of larvae in lab for 12 days (1st bioassay) or 11 days (2nd bioassay). Reproduction evaluated for 15 days (1st) or 10 days (2nd) in test units with bean leaves and aphids. Reproduction assay began after adults emerged and began ovipositing.	2 × 60 g/ha, 7-day spray interval	Control Mortality 1st: 64.4%, 2nd: 28% Corrected Mortality 1st: 43.8%; 2nd: 33.5% Reproduction: No effects in both assays.	50%

Species	Life stage	Test substance, substrate and duration	Dose (g a.s./ha)[1]	% effect	Trigger value
Episyrphus balteatus; chlorantraniliprole 35WG	larvae	Extended laboratory test with exposure to field-aged spray deposits of potted apple tree leaves (aged 28 and 42 days). Exposure of larvae in lab for 12 days (1st bioassay) or 11 days (2nd bioassay). Reproduction evaluated for 15 days (1st) or 10 days (2nd) in test units with bean leaves and aphids. Reproduction assay began after adults emerged and began ovipositing.	2 × 60 g/ha, 7-day spray interval	Control Mortality 1st: 64.4%, 2nd: 28% Corrected Mortality 1st: 25%; 2nd: 3.6% Reproduction: No effects in both assays.	50%

[1] Preparation endpoints are expressed in units of g a.s./ha

Field or semi-field tests

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1]	% effect
Typhlodromus pyri; chlorantraniliprole 20SC	Natural populations	Field study in apple orchard in Italy	47.5 + 52.5 g a.s./ha, 13-day spray interval	No statistically significant reduction in predatory mite populations >50% compared to the control treatment
Typhlodromus pyri; chlorantraniliprole 35WG	Natural populations	Field study in vines in France	2 × 52.5 g/ha, 15-day spray interval	No statistically significant reduction in predatory mite populations >50% compared to the control treatment

[1] Preparation endpoints are expressed in units of g a.s./ha

Off-field Predicted Environmental Rates (PER) for main uses of the chlorantraniliprole 20SC and chlorantraniliprole 35WG compared with lowest ER_{50} for sensitive non-target arthropods

Crop/Application method and formulation used for assessment	Max. rate (g a.s. /ha)	Max. no. treatments and min. interval	MAF[1]	Spray Drift (%)[2]	VDF[3]	Off-field correction factor[4]	PER (g a.s. /ha)	ER_{50}[5] (g a.s. /ha)	Effects >50% predicted at PER?
Broadcast mist blowers									
Pome/stone fruit SC, late	60 x 0.5[6]	2 (10)	1.7	12.13	10	5	3.09	12.6	No
Grapes, wine SC, late	54 x 0.5[6]	1	1.0	8.02	10	5	1.08	12.6	No
Grapes, table WG, late	43.5 x 0.5[6]	2 (10)	1.7	7.23	10	5	1.34	4.64	No
Citrus SC, early	15	2 (10)	1.7	12.13	10	5	1.63	12.6	No
Hydraulic boom sprayers									
Fruiting vegetables WG, late	42	2 (7)	1.7	2.38	10	5	0.85	4.64	No
Lettuce WG, early	42	2 (7)	1.7	2.38	10	5	0.85	4.64	No
Potatoes SC, early	12.5	2 (10)	1.9	2.38	10	5	0.28	12.6	No

1 Default foliar Multiple Application Factor for the number of treatments taken from App. III of ESCORT 2

2 Default drift values (at 3 m for orchards & vines (both late), 1 m for vegetable & lettuce) taken from App. IV of ESCORT 2

3 Default Vegetation Distribution Factor taken from ESCORT 2

4 Default off-field correction (uncertainty) factor taken from equation to derive rates for **higher tier testing** in ESCORT 2

5 L/ER_{50} for the respective formulation when tested against the most sensitive tested species, *Episyrphus balteatus*

6 The application rate in orchards and vines was adjusted with a correction factor of 0.5 inline with ECSORT 2

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)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisnea fetida	chlorantraniliprole	Acute 14 days	LC_{50} >1000 mg a.s./kg d.w. soil
Eisnea fetida	chlorantraniliprole 20SC	Acute 14 days	LC_{50} >1000 mg product/kg d.w. soil (>200 a.s.)
Eisnea fetida	chlorantraniliprole 35WG	Acute 14 days	LC_{50} >1000 mg product/kg d.w. soil (>350 a.s.)
Eisnea fetida	chlorantraniliprole 35WG	Chronic 56 d	NOEC 1000 mg a.s./kg d.w. soil (350 a.s.)
Eisnea fetida	IN-EQW78	Acute	LC_{50} >1000 mg a.s./kg d.w. soil
Eisnea fetida	IN-EQW78	Chronic 56 d	NOEC 1000 mg a.s./kg d.w. soil
Eisnea fetida	IN-ECD73	Acute	LC_{50} >1000 mg a.s./kg d.w. soil
Eisnea fetida	IN-ECD73	Chronic 56 d	NOEC 1000 mg a.s./kg d.w. soil
Eisnea fetida	IN-F6L99	Acute	LC_{50} 632.5 mg a.s./kg d.w. soil
Eisnea fetida	IN-GAZ70	Acute	LC_{50} >1000 mg a.s./kg d.w. soil
Eisnea fetida	IN-GAZ70	Chronic 56 d	NOEC 1000 mg a.s./kg d.w. soil
Other soil macro-organisms			
Collembola and soil mites			
Folsomia candida	chlorantraniliprole	28-day Chronic	NOEC 0.39 mg a.s./kg d.w. soil (also 0.85 mg/kg EC50 for reproduction used)
Hypoaspis aculeifer	chlorantraniliprole	16-day Chronic	NOEC 100 mg a.s./kg d.w. soil
Folsomia candida	IN-EQW78	28-day Chronic	NOEC 100 mg a.s./kg d.w. soil
Folsomia candida	IN-ECD73	28-day Chronic	NOEC 100 mg a.s./kg d.w. soil
Folsomia candida	IN-F6L99	28-day Chronic	NOEC 100 mg a.s./kg d.w. soil
Folsomia candida	IN-GAZ70	28-day Chronic	NOEC 100 mg a.s./kg d.w. soil
Soil micro-organisms			
Nitrogen mineralisation	chlorantraniliprole	28 days	<25% effects at 0.700 mg a.s./kg d.w. soil
Nitrogen mineralisation	chlorantraniliprole 20SC	42 days	<25% effects at 0.814 mg a.s./kg d.w. soil
Nitrogen mineralisation	chlorantraniliprole 35WG	42 days	<25% effects at 0.802 mg a.s./kg d.w. soil
Nitrogen mineralisation	IN-EQW78	28 days	<25% effects at 0.800 mg a.s./kg d.w. soil
Nitrogen mineralisation	IN-ECD73	28 days	<25% effects at 0.800 mg a.s./kg d.w. soil
Nitrogen mineralisation	IN-GAZ70	28 days	<25% effects at 0.840 mg a.s./kg d.w. soil

Test organism	Test substance	Time scale	End point[1]
Carbon mineralisation	chlorantraniliprole	28 days	<25% effects at 0.700 mg a.s./kg d.w. soil
Carbon mineralisation	chlorantraniliprole 20SC	28 days	<25% effects at 0.814 mg a.s./kg d.w. soil
Carbon mineralisation	chlorantraniliprole 35WG	28 days	<25% effects at 0.802 mg a.s./kg d.w. soil
Carbon mineralisation	IN-EQW78	28 days	<25% effects at 0.800 mg a.s./kg d.w. soil
Carbon mineralisation	IN-ECD73	28 days	<25% effects at 0.800 mg a.s./kg d.w. soil
Carbon mineralisation	IN-GAZ70	28 days	<25% effects at 0.840 mg a.s./kg d.w. soil
Field litter bag studies Chlorantraniliprole 20SC: No effects seen on degradability of soil organic matter in 12 month litter bag study under exposure conditions simulating 10 years continual use at an annual rate of 150 g a.s./ha. Chlorantraniliprole 35WG and metabolites: No effects seen on degradability of soil organic matter in 17 month litter bag study under exposure conditions simulating 10 years continual use at an annual rate of 240 g a.s./ha.			

[1] No toxicity values were corrected for log Pow because a scientifically reasoned case was accepted for parent and metabolites.

Toxicity/exposure ratios for soil organisms

Pome fruits 2 x 60 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia foetida	chlorantraniliprole	Acute	0.44	>2273	10
Eisenia foetida	chlorantraniliprole 35WG	Chronic	0.278	1259	5

Lettuce 2 x 42 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia foetida	chlorantraniliprole	Acute	0.44	>2273	10
Eisenia foetida	chlorantraniliprole 35WG	Acute	0.44	>795	10
Eisenia foetida	IN-EQW78	Acute	0.27	>3704	10
Eisenia foetida	IN-ECD73	Acute	0.209	>4785	10
Eisenia foetida	IN-F6L99	Acute	0.012	>83333	10
Eisenia foetida	IN-F9N04*	Acute	0.108	5856	10
Eisenia foetida	IN-GAZ70	Acute	0.74	>1351	10
Eisenia foetida	chlorantraniliprole 35WG	Chronic	0.44	795	5
Eisenia foetida	IN-EQW78	Chronic	0.27	3704	5
Eisenia foetida	IN-ECD73	Chronic	0.209	4785	5
Eisenia foetida	IN-F9N04*	Chronic	0.108	3241	5

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Eisenia foetida	IN-GAZ70	Chronic	0.74	1351	5

* Toxicity is assumed to be the same as parent
[1] Highest peak plateau PEC_{soil} used (in terms of mg a.s. or metabolite/kg d.w. soil)

Toxicity/exposure ratios for other soil macro-organisms

Crop (and formulation)	Soil organism	Time scale	Maximum PEC_{soil} (mg chlorantraniliprole/kg soil)	TER_{lt}	Trigger[1]
Lettuce (WG)	*F. candida*	Chronic	0.44	**0.89**	5
Lettuce (WG)	*H. aculeifer*	Chronic	0.44	227	5
Pome/Stone fruits (SC)	*F. candida*	Chronic	0.278	**1.4**	5
Pome/Stone fruits (SC)	*H. aculeifer*	Chronic	0.278	360	5
Grapes, table (WG & SC)	*F. candida*	Chronic	0.202	**1.9**	5
Grapes, table (WG & SC)	*H. aculeifer*	Chronic	0.202	495	5
Fruiting veg. (WG & SC)	*F. candida*	Chronic	0.13	**3**	5
Fruiting veg. (WG & SC)	*H. aculeifer*	Chronic	0.13	769	5
Grapes, wine (SC)	*F. candida*	Chronic	0.126	**3.1**	5
Grapes, wine (SC)	*H. aculeifer*	Chronic	0.126	794	5
Citrus (SC)	*F. candida*	Chronic	0.0695	5.6	5
Citrus (SC)	*H. aculeifer*	Chronic	0.0695	1439	5
Potatoes (SC)	*F. candida*	Chronic	0.068	5.7	5
Potatoes (SC)	*H. aculeifer*	Chronic	0.068	1471	5

[1] Taken from EC Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002, 17 October 2002 rev. 2 final)
TER values in **bold** are less than the trigger

Worst case TERs for soil metabolites

Crop (and formulation)	Soil organism	Time scale	Maximum PEC_{soil} (mg chlorantraniliprole/kg soil)	TER_{lt}	Trigger[1]
Lettuce (IN-EQW78)	*F. candida*	Chronic	0.27	370	5
Lettuce (IN- ECD73)	*F. candida*	Chronic	0.209	479	5
Lettuce (IN- GAZ70)	*F. candida*	Chronic	0.74	135	5

[1]Taken from EC Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002, 17 October 2002 rev. 2 final)

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

Preliminary screening data and laboratory rate response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Proposed trigger[3]
Ryegrass (emergence) None (veg. vigour)	chlorantraniliprole 20SC	>300	>300	17.52 (early)	>17	5
Ryegrass (emergence)	chlorantraniliprole 20SC	>300	>300	9.4 (late)	>32	5

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Proposed trigger[3]
None (veg. vigour)						

[1] Pome fruit, 1 application of 60 g, 3m buffer, early application (29.20% drift, PERdrift = 17.52)
[1] Pome fruit, 1 application of 60 g, 3m buffer, late application (15.73% drift, PERdrift = 9.4).
[2] Preparation endpoints are expressed in units of g a.s./ha
[3]Taken from EC Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002, 17 October 2002 rev. 2 final)

Additional studies (e.g. semi-field or field studies)

Not required

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	
Activated sludge	Yes, EC_{50} >100 mg/L

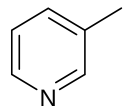
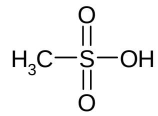
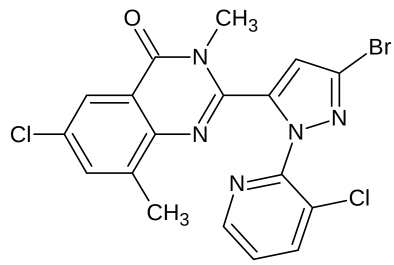
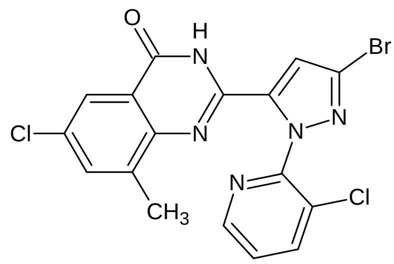
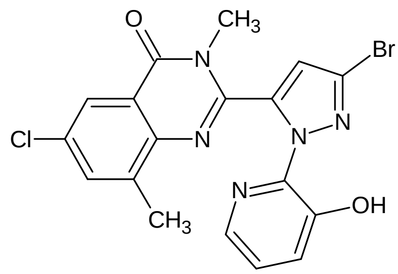
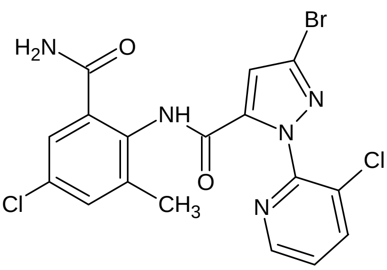
Ecotoxicologically relevant compounds

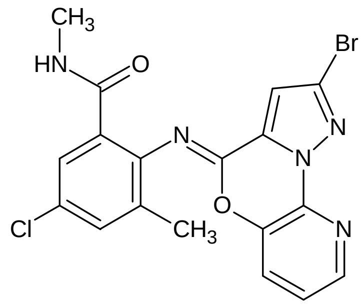
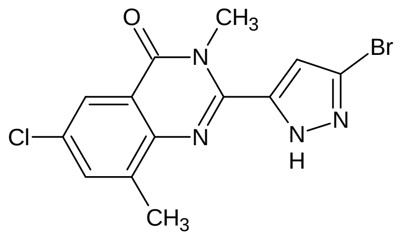
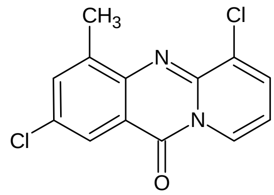
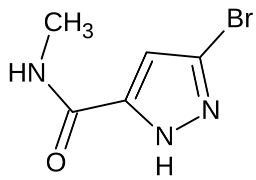
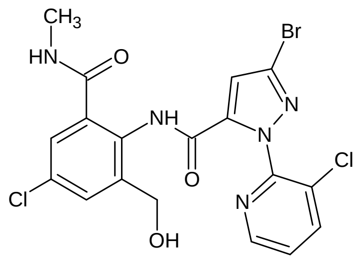
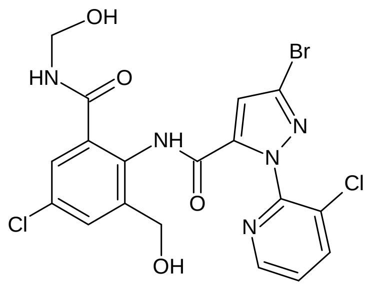
Compartment	
Soil	Parent chlorantraniliprole
Water	Parent chlorantraniliprole Data gaps need to be filled before the relevance of IN-LBA22, IN-LBA23 and IN-LBA24 can be finalised.
Sediment	Parent chlorantraniliprole
Groundwater	Parent chlorantraniliprole

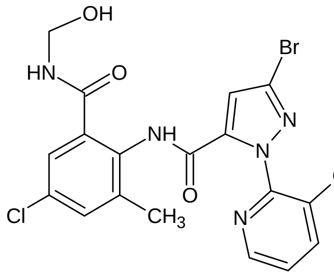
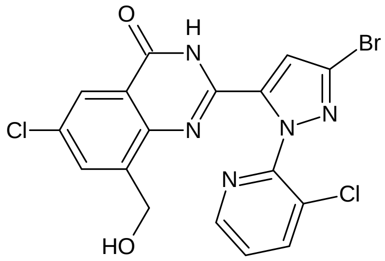
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/ peer review proposal
Parent chlorantraniliprole	N Dangerous for the environment. R50/53 Very toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
acetonitrile	acetonitrile	$H_3C-C\equiv N$
3-picoline	3-methylpyridine	
methanesulfonic acid	methanesulfonic acid	
IN-EQW78	2-[3-bromo-1-(3-chloropyridin-2-yl)-1*H*-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3*H*)-one	
IN-GAZ70	2-[3-bromo-1-(3-chloropyridin-2-yl)-1*H*-pyrazol-5-yl]-6-chloro-8-methylquinazolin-4(1*H*)-one	
IN-LBA23	2-[3-bromo-1-(3-hydroxypyridin-2-yl)-1*H*-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3*H*)-one	
IN-F9N04	3-bromo-*N*-(2-carbamoyl-4-chloro-6-methylphenyl)-1-(3-chloropyridin-2-yl)-1*H*-pyrazole-5-carboxamide	

IN-LBA22	2-{[(4*Z*)-2-bromo-4*H*-pyrazolo[1,5-*d*]pyrido[3,2-*b*][1,4]oxazin-4-ylidene] amino}-5-chloro-*N*,3-dimethylbenzamide	
IN-LBA24	2-(3-bromo-1*H*-pyrazol-5-yl)-6-chloro-3,8-dimethylquinazolin-4(3*H*)-one	
IN-ECD73	2,6-dichloro-4-methyl-11*H*-pyrido[2,1-*b*]quinazolin-11-one	
IN-F6L99	3-bromo-*N*-methyl-1*H*-pyrazole-5-carboxamide	
IN-HXH44	3-bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-(methylcarbamoyl)phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide	
IN-K9T00	3-bromo-*N*-{4-chloro-2-(hydroxymethyl)-6-[(hydroxymethyl)carbamoyl]phenyl}-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide	

IN-H2H20	3-bromo-*N*-{4-chloro-2-[(hydroxymethyl)carbamoyl]-6-methylphenyl}-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide	
IN-K7H29	2-[3-bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-8-(hydroxymethyl)-4(1*H*)-quinazolinone	

* The substance 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

(Please highlight additional entries in Turquoise)

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
ACTH	adrenal corticotropic hormone
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
BBA	German model for the protection of operators
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
cGAP	Critical good agricultural practice (GAP)
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
CLP	classification, labelling and packaging
cm	centimetre
cRfD	chronic Reference Dose
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
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
EbC_{50}	effective concentration (biomass)
EC	European Commission
EC_{50}	effective concentration
ECHA	European Chemical 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
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union

EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation 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-ECD	gas chromatography - electron capture detector
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GI	gastro-intestinal
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 chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high performance liquid chromatography with ultra violet detector
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboraotry validation
ISO	International Organisation for Standardisation
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
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LLNA	local lymph node assay
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	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
M&K	Magnusson & Kligman
mL	millilitre
mm	millimetre
mN	milli-newton
MoR	Magnitude of Residues
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NAFTA	North American Free Tade Agreement
NCE	normochromatic erythrocytes
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
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PCE	polychromatic erythrocytes
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
POEM	Predictive Operator Exposure Model
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
REACH	Registration, Evaluation, Authorisation of CHemicals
RPE	respiratory protective equipment
RUD	residue per unit dose
S9	exogenous metabolic activation system
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution

STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
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
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
UF	uncertainty factor
UV	ultraviolet
WG	water dispersible granule
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 Organisation
wk	week
yr	year