

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for chlorantraniliprole in carrots, parsnips, parsley root and celeriac¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, herewith referred to as the evaluating Member State (EMS), received an application from the Horticultural Development Company to modify the existing MRL for chlorantraniliprole in carrots, parsnips, celeriac and parsley root. In order to accommodate the intended use in the NEU, the EMS proposed to set the MRL for chlorantraniliprole in the crops under consideration at 0.04 mg/kg. The existing MRL for carrots is set at the level of 0.08 mg/kg. This MRL will expire on 1 January 2013 and after that date a MRL of 0.02 mg/kg will be applicable unless modified by a Regulation. The EMS drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA, the data are sufficient to extrapolate residue data from carrots to parsnips, parsley root and celeriac and to derive MRL proposals for all these crops in support of the NEU use. Member States granting authorisations of the use of chlorantraniliprole should implement necessary risk mitigation measures to ensure that residues do not occur in rotational/succeeding crops. Based on the risk assessment results, EFSA concludes that the intended use of chlorantraniliprole on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern. Since the peer review is not yet finalised, the conclusions reached in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the peer review.

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KEY WORDS

Chlorantraniliprole, root crops, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, anthranilic diamide insecticide

¹ On request from European Commission, Question No EFSA-Q-2012-00611, approved on 27 November 2012.

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

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005³, the United Kingdom, herewith referred to as the evaluating Member State (EMS), received an application from the Horticultural Development Company to modify the existing MRL for chlorantraniliprole in carrots, parsnips, celeriac and parsley root. In order to accommodate the intended use in the NEU, the EMS proposed to set the MRL for chlorantraniliprole in the crops under consideration at 0.04 mg/kg. The existing MRL for carrots is set at the level of 0.08 mg/kg. This MRL will expire on 1 January 2013 and after that date a MRL of 0.02 mg/kg will be applicable unless modified by a Regulation. The EMS drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 24 May 2012.

EFSA bases its assessment on the evaluation report submitted by the EMS United Kingdom, the Draft Assessment Report (DAR) and its addenda prepared under Council Directive 91/414/EEC⁴ well as the conclusions from previous EFSA opinions on chlorantraniliprole.

The toxicological profile of chlorantraniliprole has been evaluated in the DAR and the data were sufficient to propose an ADI of 1.58 mg/kg bw/day. Due to the low acute toxicity of the active substance, the setting of an ARfD was considered not necessary. Pending the finalisation of the peer review process, the assessment and the derived toxicological reference value should be considered provisional.

The metabolism of chlorantraniliprole in primary crops was investigated in fruits and fruiting vegetables, leafy vegetables, pulses and oilseeds, and cereals. Based on the results from these studies, the RMS proposed to establish a general residue definition for risk assessment and enforcement as chlorantraniliprole. For the uses assessed in this reasoned opinion, EFSA concludes that the metabolism of chlorantraniliprole is sufficiently elucidated and the proposed residue definitions are appropriate. EFSA notes that the derived residue definitions have to be considered provisional pending the outcome of the peer review.

EFSA concludes that the submitted data are sufficient to extrapolate residue data from carrots to parsnips, parsley root and celeriac and to derive MRL proposals for all these crops in support of the NEU use. Adequate analytical enforcement methods are available to control the residues of chlorantraniliprole in the crops under consideration at the validated LOQ of 0.01 mg/kg.

Specific studies investigating the magnitude of chlorantraniliprole residues in processed commodities are not required, as the residues expected in primary crops are low and the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI.

The occurrence of chlorantraniliprole residues in rotational crops was investigated in the DAR. The RMS concluded that the metabolism of chlorantraniliprole in rotational crops proceeds in a similar pathway as in primary crops and proposed to define the residue for risk assessment and enforcement as parent chlorantraniliprole. EFSA agrees with the proposal of the RMS, but notes that the derived residue definitions are provisional, pending the outcome of the peer review. From the soil accumulation studies as well as from the rotational crop field studies it is not possible to exclude that residues of chlorantraniliprole will occur in rotational crops over multiple years of consecutive applications of chlorantraniliprole on primary crop. Thus, Member States granting authorisations of the use of chlorantraniliprole should implement necessary risk mitigation measures to ensure that residues do not occur in rotational/succeeding crops.

Residues of chlorantraniliprole in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are normally not fed to livestock.

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMO). For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on carrots and these values were used as input values also for parsnips, parsley root and celeriac. The median residue values for several other crops as reported in previously issued EFSA reasoned opinions were available to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. The estimated long-term exposure was then compared with the toxicological reference value derived for chlorantraniliprole. Acute consumer exposure was not performed due to the low acute toxicity of the active substance.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMO. The total calculated intake values accounted for up to 1.9% of the ADI (NL child diet). The contribution of residues in the crops under consideration to the total consumer exposure was insignificant (below 0.01% of the ADI).

EFSA concludes that the intended use of chlorantraniliprole on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern. Since the peer review is not yet finalised, the conclusions reached in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the peer review.

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

Summary table

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Chlorantraniliprole (F)				
0213020	Carrots	0.08 ^b	0.04	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended NEU uses.
0213030	Celeriac	0.02	0.04	
0213060	Parsnips	0.02	0.04	
0213070	Parsley root	0.02	0.04	

(a): According to Annex I of Regulation (EC) No 396/2005.

(b): According to Regulation (EC) No 460/2011 MRL applicable until 31 December 2012, after that date 0.02 mg/kg will be applicable, unless modified by Regulation.

(F): Fat-soluble pesticide. MRL is expressed as mg/kg of fat contained in the whole product.

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BACKGROUND

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

The United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the Horticultural Development Company⁵ to modify the existing MRL for the active substance chlorantraniliprole in carrots, parsnips, celeriac and parsley root. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 24 May 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00611 and the following subject:

Chlorantraniliprole - Application to modify the existing MRL in carrots, celeriac, parsnip and parsley root

The EMS United Kingdom proposed to set the MRL of chlorantraniliprole in carrots at 0.04 mg/kg as from 1 January 2013. The existing temporary EU MRL for chlorantraniliprole in carrots until 31 December 2012 is set at 0.08 mg/kg and after expiry of this period, the MRL will be lowered to 0.02 mg/kg, unless modified by a new Regulation. In addition, the EMS proposes to raise the existing MRL of 0.02 mg/kg for parsnips, parsley root and celeriac to 0.04 mg/kg.

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

TERMS OF REFERENCE

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

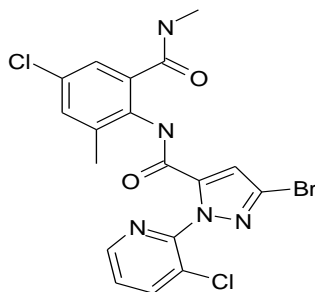
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests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

In this particular case the calculated deadline for providing the reasoned opinion is 24 August 2012.

⁵ Horticultural Development Company, North Yorkshire, YO83TZ, Cawood, The United Kingdom

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

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 chemical structure of the compound is herewith reported.



Molecular weight: 483.15

Chlorantraniliprole belongs to the anthranilic diamide chemical class. The compound is an insecticide effective against various lepidopteran pests as well as some species of Coleoptera. It acts mainly by ingestion and activates ryanodine-sensitive intracellular calcium release channels in insect neurons (ryanodine receptor agonist action). The release of calcium causes muscle contraction, resulting in paralysis and eventual death of the insect.

Chlorantraniliprole is a new active substance currently not yet approved under Regulation (EC) No 1107/2009, for which the European Commission has established the completeness of the application dossier (Decision 2007/560/EC⁶) and according to the transitional measures provided for in Regulation (EC) No 1107/2009 and Commission Regulation (EU) No 188/2011⁷, the rules of Council Directive 91/414 EC shall continue to apply. Ireland is acting as a rapporteur Member State (RMS). The Draft Assessment Report (DAR) is based on the global assessment of the substance, which was performed in 2007 by several national regulatory authorities, including Ireland, under the work-sharing project supported by the Organization for Economic Co-operation and Development (OECD). Since the peer review is in progress but not yet finalised, EFSA conclusion is not yet available.

The EU MRLs for chlorantraniliprole are established in Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). EFSA has issued three reasoned opinions on the modification of the existing MRLs for chlorantraniliprole in various crops (including carrots) and in several commodities of animal origin (EFSA, 2010, 2011, 2012). According to Regulation (EC) No 460/2011⁸, the existing EU MRL of 0.08 mg/kg for carrots is set on a temporary basis and after 31 December 2012 this MRL will be lowered to 0.02 mg/kg unless modified by a new Regulation. The existing EU MRL for parsnips, parsley root and celeriac is set at 0.02 mg/kg. Codex Alimentarius has established CXLs for chlorantraniliprole in a wide range of commodities, including carrots, for which the CXL of 0.02 mg/kg is set.

The EMS United Kingdom notified a GAP for the use of chlorantraniliprole on carrots, parsnips, celeriac and parsley root. In support of the intended GAP, the MRL of 0.02 mg/kg, which is currently set for parsley root, celeriac and parsnips and which will enter into force for carrots as from 1 January 2013, would have to be raised. The details of the intended GAP in the NEU for chlorantraniliprole are given in Appendix A.

⁶ Commission Decision of 2 August 2007 (2007/560/EC). OJ L 213, 15.08.2007, p. 29-31.

⁷ Commission Regulation (EU) No 188/2011 of 25 February 2011. OJ L 53, 26.02.2011, p. 51-55.

⁸ Commission Regulation (EU) No 460/2011 of 21 May 2011. OJ L 124, 13.5.2011, p. 23-40.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (The United Kingdom, 2012), the Draft Assessment Report (DAR) and its addenda compiled for the inclusion of the active substance in Annex I of Directive 91/414/EEC within the framework of the OECD work-sharing global assessment project (Ireland, 2008, 2011a,b) as well as the conclusions from the previous EFSA reasoned opinions on chlorantraniliprole (EFSA, 2010, 2011, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

Since the peer review according to Commission Regulation (EU) No 188/2011 is not yet finalised, the conclusions reached in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the peer review.

1. Method of analysis

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

Analytical methods for the determination of chlorantraniliprole residues in plant commodities were assessed in the DAR (Ireland, 2008) and are reported in previously issued EFSA reasoned opinions (EFSA, 2010, 2011, 2012). It is concluded that adequate analytical enforcement methods are available for the determination of chlorantraniliprole residues in high water content matrices at the validated LOQ of 0.01 mg/kg.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since the crops under consideration are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of chlorantraniliprole was assessed in the DAR prepared by the RMS for the peer review (Ireland, 2008). The data were sufficient to derive toxicological reference values for chlorantraniliprole which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Chlorantraniliprole					
ADI	IE	2008	1.58 mg/kg bw per day	Mice, 18 months chronic toxicity	100
ARfD	IE	2008	Not necessary		

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of chlorantraniliprole in primary crops was evaluated by the RMS Ireland in the framework of the peer review under Directive 91/414/EEC (Ireland, 2008). The metabolism of chlorantraniliprole in primary crops was investigated in apples, tomatoes, lettuce, cotton and rice, representative for fruits and fruiting vegetables, leafy vegetables, pulses and oilseeds and cereals crop groups. An overview of the study results has been reported in detail in the previously issued EFSA reasoned opinion (EFSA, 2012).

Based on the results from these studies, the RMS proposed to establish a general residue definition for risk assessment and enforcement as chlorantraniliprole. Although for the use assessed in this reasoned opinion no specific metabolism studies are available, EFSA concludes that the available metabolism studies with four different crop groups provide sufficient evidence that the metabolic pathway after foliar application is similar. Thus, for root crops no additional metabolism studies are considered necessary.

EFSA concludes that the metabolism of chlorantraniliprole is sufficiently elucidated and the proposed residue definitions are appropriate. EFSA notes that the derived residue definitions are provisional pending the outcome of the peer review.

3.1.1.2. Magnitude of residues

In support of the NEU use of chlorantraniliprole, the applicant submitted in total 9 GAP compliant residue trials on carrots. Residue trials have been performed in various northern European countries (France, The United Kingdom, Germany and The Czech Republic) during the growing seasons of 2009 and 2010. The applicant proposes to extrapolate residue data from carrots to parsnips, celeriac and parsley root. According to EU guidance document such an extrapolation is acceptable and a sufficient number of residue trials has been submitted (EC, 2011). The residue data indicate that a MRL of 0.04 mg/kg for chlorantraniliprole in carrots, parsnips, parsley root and celeriac is sufficient to support the use in the United Kingdom.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-1.

The storage stability of chlorantraniliprole in primary crops was investigated in the DAR (Ireland, 2008). Residues of chlorantraniliprole were found to be stable when stored at or below -20°C for up to 24 months in matrices with high water, high acid, and high fat content as well as in dry matrices. As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical method used to analyse the supervised residue trial samples has been sufficiently validated and was proven to be fit for purpose (The United Kingdom, 2012).

Table 3-1: Overview of the available residues trials data

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (Chlorantraniliprole)	Risk assessment (Chlorantraniliprole)					
Carrots → parsnips, celeriac and parsley root	NEU	Outdoor	5 x <0.01; 0.01; 0.014; 0.021; 0.027	5 x <0.01; 0.01; 0.014; 0.021; 0.027	0.01	0.027	0.04	1.0	R _{ber} =0.04 R _{max} =0.03 MRL _{OECD} = 0.04/0.04

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code) (EC, 2011).

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of chlorantraniliprole was assessed by the RMS in studies simulating conditions of pasteurization, baking/brewing/boiling and sterilization (20 minutes at 90°C, pH 4; 60 minutes at 100°C, pH 5; 20 minutes at 120°C, pH 6). Degradation was observed under conditions representative for baking, brewing, or boiling, with formation of metabolites IN-F6L99¹⁰ (13.6% AR) and IN-ECD73¹¹ (10.9% AR). However, since the parent compound was the major component of radioactive residues (87 to 86 % of the AR), the RMS proposed the same residue definition as for raw agricultural commodities (Ireland, 2008).

Specific studies to assess the magnitude of chlorantraniliprole residues during the processing of the crops under consideration have not been submitted and are not necessary as residue levels in raw agricultural commodity (RAC) did not exceed 0.1 mg/kg and as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI of chlorantraniliprole (EC, 1997d).

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All root crops under consideration can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. According to the laboratory and/or field studies reported in the DAR and in the Addendum of the DAR, the DT₉₀ values for chlorantraniliprole and certain of its soil metabolites- IN-EQW78¹², IN-ECD73, IN-F6L99, IN-GAZ70¹³ - significantly exceed the trigger value of 100 days (Ireland, 2008, 2011a). For chlorantraniliprole the DT₅₀ value according to available field studies exceeds 1000 days. Therefore the occurrence of chlorantraniliprole and related residues in rotational/succeeding crops should be further investigated.

3.1.2.2. Nature of residues

The metabolism of chlorantraniliprole in rotational crops was assessed in the DAR prepared under Directive 91/414/EEC (Ireland, 2008). The details and results of the studies have been reported in the previously issued EFSA reasoned opinion (EFSA, 2012). Based on the study results the RMS concluded that the metabolism of chlorantraniliprole in rotational crops proceeds in a similar pathway as in primary crops and proposed to define the residue for risk assessment and enforcement as parent chlorantraniliprole. EFSA agrees with the proposal of the RMS, but notes that the derived residue definitions are provisional, pending the outcome of the peer review.

3.1.2.3. Magnitude of residues

Rotational crop field studies in root crops, leafy vegetables, cereal crops and soybeans were assessed in the DAR (Ireland, 2008). The studies were performed in the United States and Canada with application rates of 200-225 or 600 g a.s./ha (*ca.* 3 times and 8 times the seasonal application rate on carrots). Rotational crops were sown/planted at the plant-back intervals (PBI) of 13-61 days, 122-151 and 238-279 days. Chlorantraniliprole residues were found only on commodities intended for livestock feed (forage, straw, hay), ranging from 0.01 to 0.2 mg/kg for the plant-back intervals of 30 to 279 days (EFSA, 2010, 2011). The residues of soil metabolites were not searched for as they were below the relevant trigger values in the confined rotational crop study.

Rotational crop field studies from northern (*study I*) and southern (*study II*) Europe have been reported and assessed by the EMS in the Addendum of the DAR (Ireland, 2011b). In these studies the active substance was applied either on a primary crop or on a bare soil at a total seasonal application rate of 0.08 kg a.s./ha (1N of the seasonal application rate on carrots).

¹⁰ See Appendix D

¹¹ See Appendix D

¹² See Appendix D

¹³ See Appendix D

In *study I* the Brussels sprout was grown as a primary crop and treated twice with chlorantraniliprole at an application rate of 0.04 kg a.s./ha. Spinach, carrots and barley were sown at the plant-back intervals (PBI) of 30-62 days, 120-185 days and 365-377 days. Residues were below the LOQ of 0.01 mg/kg in spinach, carrot roots and barley grain and less than or equal to 0.01 mg/kg (detected in the straw) in inedible parts of the crops (tops, forage, hay, straw).

In *study II* chlorantraniliprole was applied on spinach or field lettuce, or bare ground twice at an individual application rate of 0.04 kg a.s./ha. Rotational crops (carrot, spinach, lettuce, wheat) were sown at the PBI of 14-91 days, 120-183 days and 365-366 days. Similarly to study I, the residues were below the LOQ of 0.01 mg/kg in spinach/lettuce, carrot roots and wheat grain and less than or equal to 0.04 mg/kg (detected in the straw; soil application of the active substance) in inedible parts of the crops (tops, forage, hay, straw).

According to the soil accumulation studies assessed for the peer review, chlorantraniliprole did not reach a plateau concentration in soil after 20 years of consecutive uses (Ireland, 2008). The predicted exposure concentration (PEC) in soil was estimated to be 0.11 mg/kg soil (20 cm depth) following applications of chlorantraniliprole on lettuce at an annual rate of 0.08 kg a.s./ha (*ca.* 1 N) over 20 consecutive years, while the PEC in soil was calculated to be *ca.* 0.02 mg/kg after 2 applications at the total annual dose rate of 0.08 kg a.s./ha (Ireland, 2008). The rotational crop field studies performed at the annual application rate are therefore not representative for the concentration reached in soil after several years of consecutive applications. Consequently, it is not possible to exclude that the residues of chlorantraniliprole will occur in rotational crops when the active substance is annually applied on primary crops.

Thus, Member States granting authorisations of the use of chlorantraniliprole should implement necessary risk mitigation measures to ensure that residues do not occur in rotational/succeeding crops. The conclusions reached in the reasoned opinion have to be considered as provisional, pending the outcome of the peer review.

3.2. Nature and magnitude of residues in livestock

Since the crops under consideration and/or their by-products are not normally fed to livestock, the nature and magnitude of chlorantraniliprole residues in livestock was not assessed in the framework of this application.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population¹⁴ (EFSA, 2007). For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on carrots (see Table 3-1); these values were used as input values also for parsnips, parsley root and celeriac. The median residue values for several other crops as reported in previously issued EFSA reasoned opinions (EFSA, 2011, 2012) were available to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field

¹⁴ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMO is given in its reference section (EFSA, 2007).

trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (*i.e.* the ADI), a consumer health risk can be excluded with a high probability.

Acute consumer exposure was not performed due to the low acute toxicity of the active substance.

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Chlorantraniliprole				
Carrots	0.01	Median residue (Table 3-1)	Acute consumer exposure assessment not relevant	
Parsnips, parsley root, celeriac	0.01	Median residue (carrots) (Table 3-1)		
Citrus fruits	0.06	Median residue (EFSA, 2012)		
Blueberries	0.21	Median residue (EFSA, 2012)		
Radishes	0.05	Median residue (EFSA, 2012)		
Cauliflower	0.06	Median residue (EFSA, 2012)		
Beans with pods	0.12	Median residue (EFSA, 2012)		
Globe artichokes	0.08	Median residue (EFSA, 2012)		
Rice	0.12	Median residue (EFSA, 2012)		
Swine: meat	0.01	Median residue (EFSA, 2012)		
Bovine: meat	0.05	Median residue (EFSA, 2012)		
Sheep: meat	0.05	Median residue (EFSA, 2012)		
Goat: meat	0.05	Median residue (EFSA, 2012)		
Other commodities of plant and animal origin	MRL	See Appendix C		

The estimated long-term exposure was then compared with the toxicological reference value derived for chlorantraniliprole (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 1.9% of the ADI (NL child diet). The contribution of residues in the crops under consideration to the total consumer exposure was insignificant (below 0.01% of the ADI).

EFSA concludes that the intended use of chlorantraniliprole on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of chlorantraniliprole has been evaluated in the DAR and the data were sufficient to propose an ADI of 1.58 mg/kg bw/day. Due to the low acute toxicity of the active substance, the setting of an ARfD was considered not necessary. Pending the finalisation of the peer review process, the assessment and the derived toxicological reference value should be considered provisional.

The metabolism of chlorantraniliprole in primary crops was investigated in fruits and fruiting vegetables, leafy vegetables, pulses and oilseeds, and cereals. Based on the results from these studies, the RMS proposed to establish a general residue definition for risk assessment and enforcement as chlorantraniliprole. For the uses assessed in this reasoned opinion, EFSA concludes that the metabolism of chlorantraniliprole is sufficiently elucidated and the proposed residue definitions are appropriate. EFSA notes that the derived residue definitions have to be considered provisional pending the outcome of the peer review.

EFSA concludes that the submitted data are sufficient to extrapolate residue data from carrots to parsnips, parsley root and celeriac and to derive MRL proposals for all these crops in support of the NEU use. Adequate analytical enforcement methods are available to control the residues of chlorantraniliprole in the crops under consideration at the validated LOQ of 0.01 mg/kg.

Specific studies investigating the magnitude of chlorantraniliprole residues in processed commodities are not required, as the residues expected in primary crops are low and the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI.

The occurrence of chlorantraniliprole residues in rotational crops was investigated in the DAR. The RMS concluded that the metabolism of chlorantraniliprole in rotational crops proceeds in a similar pathway as in primary crops and proposed to define the residue for risk assessment and enforcement as parent chlorantraniliprole. EFSA agrees with the proposal of the RMS, but notes that the derived residue definitions are provisional, pending the outcome of the peer review. From the soil accumulation studies as well as from the rotational crop field studies it is not possible to exclude that residues of chlorantraniliprole will occur in rotational crops over multiple years of consecutive applications of chlorantraniliprole on primary crop. Thus, Member States granting authorisations of the use of chlorantraniliprole should implement necessary risk mitigation measures to ensure that residues do not occur in rotational/succeeding crops.

Residues of chlorantraniliprole in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMO). For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on carrots and these values were used as input values also for parsnips, parsley root and celeriac. The median residue values for several other crops as reported in previously issued EFSA reasoned opinions were available to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. The estimated long-term exposure was then compared with the toxicological reference value derived for chlorantraniliprole. Acute consumer exposure was not performed due to the low acute toxicity of the active substance.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMO. The total calculated intake values accounted for up to 1.9% of the ADI (NL child diet). The contribution of residues in the crops under consideration to the total consumer exposure was insignificant (below 0.01% of the ADI).

EFSA concludes that the intended use of chlorantraniliprole on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern. Since the peer review is not yet finalised, the conclusions reached in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the peer review.

Recommendations

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Chlorantraniliprole (F)				
0213020	Carrots	0.08 ^b	0.04	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended NEU uses.
0213030	Celeriac	0.02	0.04	
0213060	Parsnips	0.02	0.04	
0213070	Parsley root	0.02	0.04	

(a): According to Annex I of Regulation (EC) No 396/2005.

(b): According to Regulation (EC) No 460/2011 MRL applicable until 31 December 2012, after that date 0.02 mg/kg will be applicable, unless modified by Regulation.

(F): Fat-soluble pesticide. MRL is expressed as mg/kg of fat contained in the whole product.

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APPENDICES

A. GOOD AGRICULTURAL PRACTICE (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Carrot, parsnip, parsley root, celeriac	NEU	F		SC	350 g/kg	Foliar spray	BBCH 43-49	2	14		200-1000	0.035	21	

- Remarks:
- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
 - (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 plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions (*i.e.* feeding, grazing)

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Chlorantraniliprole										Prepare workbook for refined calculations
Status of the active substance:		Pending		Code no.:						
LOQ (mg/kg bw):		0.01		proposed LOQ:						
Toxicological end points										Undo refined calculations
ADI (mg/kg bw/day):		1.58		ARfD (mg/kg bw):		n.n.				
Source of ADI:		RMS		Source of ARfD:						
Year of evaluation:		2008		Year of evaluation:						

Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI minimum - maximum					
				0 2					
				No of diets exceeding ADI:					

	Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)
	1.9	NL child	0.5	Spinach	0.3	Scarole (broad-leaf endive)	0.2	Witloof	0.0
	1.4	WHO Cluster diet B	0.5	Lettuce	0.1	Tomatoes	0.1	Wine grapes	0.0
	1.4	FR toddler	0.9	Spinach	0.1	Milk and cream,	0.1	Apples	0.0
	1.3	DE child	0.4	Apples	0.3	Spinach	0.1	Table grapes	0.0
	1.2	IT adult	0.5	Lettuce	0.2	Other lettuce and other salad plants	0.1	Spinach	0.0
	1.1	IE adult	0.3	Other leafy brassica	0.2	Spinach	0.1	Lettuce	0.0
	1.1	ES adult	0.7	Lettuce	0.1	Beet leaves (chard)	0.1	Spinach	0.0
	1.1	NL general	0.2	Witloof	0.2	Spinach	0.2	Lettuce	0.0
	1.0	IT kids/toddler	0.4	Lettuce	0.1	Other lettuce and other salad plants	0.1	Beet leaves (chard)	0.0
	1.0	FR all population	0.3	Wine grapes	0.2	Other lettuce and other salad plants	0.2	Witloof	0.0
	1.0	ES child	0.5	Lettuce	0.1	Spinach	0.1	Beet leaves (chard)	0.0
	0.9	FR infant	0.6	Spinach	0.1	Witloof	0.1	Milk and cream,	0.0
	0.9	WHO regional European diet	0.5	Lettuce	0.0	Head cabbage	0.0	Scarole (broad-leaf endive)	0.0
	0.9	WHO cluster diet D	0.2	Chinese cabbage	0.1	Kale	0.1	Kale	0.0
	0.8	SE general population 90th percentile	0.3	Chinese cabbage	0.1	Spinach	0.1	Head cabbage	0.0
	0.8	WHO Cluster diet F	0.4	Lettuce	0.1	Chinese cabbage	0.0	Kale	0.0
	0.7	WHO cluster diet E	0.1	Lettuce	0.1	Wine grapes	0.1	Scarole (broad-leaf endive)	0.0
	0.5	DK child	0.2	Lettuce	0.1	Apples	0.0	Milk and cream,	0.0
	0.4	UK vegetarian	0.2	Lettuce	0.1	Wine grapes	0.0	Spinach	0.0
	0.4	UK Toddler	0.1	Milk and cream,	0.1	Apples	0.0	Spinach	0.0
	0.3	UK Adult	0.1	Lettuce	0.1	Wine grapes	0.0	Spinach	0.0
	0.3	PT General population	0.2	Wine grapes	0.0	Tomatoes	0.0	Apples	0.0
	0.3	UK Infant	0.1	Milk and cream,	0.0	Apples	0.0	Spinach	0.0
	0.3	PL general population	0.1	Apples	0.0	Head cabbage	0.0	Tomatoes	0.0
	0.3	FI adult	0.1	Lettuce	0.0	Chinese cabbage	0.0	Wine grapes	0.0
	0.3	LT adult	0.1	Lettuce	0.1	Apples	0.1	Head cabbage	0.0
	0.2	DK adult	0.1	Wine grapes	0.0	Apples	0.0	Chinese cabbage	0.0

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

C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 14/11/2012 13:37))

Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,7
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,7
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,7
110030	Lemons (Citron, lemon)	0,7
110040	Limes	0,7
110050	Mandarins (Clementine, tangerine and other hybrids)	0,7
110990	Others	0,7
120000	(ii) Tree nuts (shelled or unshelled)	0,05
120010	Almonds	0,05
120020	Brazil nuts	0,05
120030	Cashew nuts	0,05
120040	Chestnuts	0,05
120050	Coconuts	0,05
120060	Hazelnuts (Filbert)	0,05
120070	Macadamia	0,05
120080	Pecans	0,05
120090	Pine nuts	0,05
120100	Pistachios	0,05
120110	Walnuts	0,05
120990	Others	0,05
130000	(iii) Pome fruit	0,5
130010	Apples (Crab apple)	0,5
130020	Pears (Oriental pear)	0,5
130030	Quinces	0,5
130040	Medlar	0,5
130050	Loquat	0,5
130990	Others	0,5
140000	(iv) Stone fruit	1
140010	Apricots	1
140020	Cherries (sweet cherries, sour cherries)	1
140030	Peaches (Nectarines and similar hybrids)	1
140040	Plums (Damson, greengage, mirabelle)	1
140990	Others	1

Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	1
151010	Table grapes	1
151020	Wine grapes	1
152000	(b) Strawberries	1
153000	(c) Cane fruit	1
153010	Blackberries	1
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	1
153030	Raspberries (Wineberries)	1
153990	Others	1
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	1,5
154020	Cranberries	1
154030	Currants (red, black and white)	1
154040	Gooseberries (Including hybrids with other ribes species)	1
154050	Rose hips	1
154060	Mulberries (arbutus berry)	1
154070	Azarole (mediterranean medlar)	0,01 *
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	1
154990	Others	1
160000	(vi) Miscellaneous fruit	0,01 *
161000	(a) Edible peel	0,01 *
161010	Dates	0,01 *
161020	Figs	0,01 *
161030	Table olives	0,01 *
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,01 *
161050	Carambola (Bilimbi)	0,01 *
161060	Persimmon	0,01 *
161070	Jambolan (java plum)	0,01 *

Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
	(Java apple (water apple), pomarac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	
161990	Others	0,01 *
162000	(b) Inedible peel, small	0,01 *
162010	Kiwi	0,01 *
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,01 *
162030	Passion fruit	0,01 *
162040	Prickly pear (cactus fruit)	0,01 *
162050	Star apple	0,01 *
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0,01 *
162990	Others	0,01 *
163000	(c) Inedible peel, large	0,01 *
163010	Avocados	0,01 *
163020	Bananas (Dwarf banana, plantain, apple banana)	0,01 *
163030	Mangoes	0,01 *
163040	Papaya	0,01 *
163050	Pomegranate	0,01 *
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,01 *
163070	Guava	0,01 *
163080	Pineapples	0,01 *
163090	Bread fruit (Jackfruit)	0,01 *
163100	Durian	0,01 *
163110	Soursop (guanabana)	0,01 *
163990	Others	0,01 *
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,02
212000	(b) Tropical root and tuber vegetables	0,02
212010	Cassava (Dasheen, eddoe	0,02

Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
	(Japanese taro), tannia)	
212020	Sweet potatoes	0,02
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02
212040	Arrowroot	0,02
212990	Others	0,02
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,02
213020	Carrots	0,08 (ft)
213030	Celeriac	0,02
213040	Horseradish	0,02
213050	Jerusalem artichokes	0,02
213060	Parsnips	0,02
213070	Parsley root	0,02
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,5
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02
213100	Swedes	0,02
213110	Turnips	0,02
213990	Others	0,02
220000	(ii) Bulb vegetables	0,01 *
220010	Garlic	0,01 *
220020	Onions (Silverskin onions)	0,01 *
220030	Shallots	0,01 *
220040	Spring onions (Welsh onion and similar varieties)	0,01 *
220990	Others	0,01 *
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0,6
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino)	0,6
231040	Okra, lady's fingers	0,6
231990	Others	0,6
232000	(b) Cucurbits - edible peel	0,3
232010	Cucumbers	0,3
232020	Gherkins	0,3
232030	Courgettes (Summer	0,3

Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
	squash, marrow (patisson))	
232990	Others	0,3
233000	(c) Cucurbits-inedible peel	0,3
233010	Melons (Kiwano)	0,3
233020	Pumpkins (Winter squash)	0,3
233030	Watermelons	0,3
233990	Others	0,3
234000	(d) Sweet com	0,2
239000	(e) Other fruiting vegetables	0,2
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	1
241020	Cauliflower	0,3
241990	Others	0,3
242000	(b) Head brassica	
242010	Brussels sprouts	0,01*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	2
242990	Others	0,01*
243000	(c) Leafy brassica	20
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	20
243020	Kale (Borecole (curly kale), collards)	20
243990	Others	20
244000	(d) Kohlrabi	0,01*
250000	(v) Leaf vegetables & fresh herbs	20
251000	(a) Lettuce and other salad plants including Brassicaceae	20
251010	Lamb's lettuce (Italian comsalad)	20
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	20
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	20
251040	Cress	20

Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
251050	Land cress	20
251060	Rocket, Rucola (Wild rocket)	20
251070	Red mustard	20
251080	Leaves and sprouts of Brassica spp (Mizuna)	20
251990	Others	20
252000	(b) Spinach & similar (leaves)	20
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	20
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	20
252030	Beet leaves (chard) (Leaves of beetroot)	20
252990	Others	20
253000	(c) Vine leaves (grape leaves)	20
254000	(d) Water cress	20
255000	(e) Witloof	20
256000	(f) Herbs	20
256010	Chervil	20
256020	Chives	20
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	20
256040	Parsley	20
256050	Sage (Winter savory, summer savory,)	20
256060	Rosemary	20
256070	Thyme (marjoram, oregano)	20
256080	Basil (Balm leaves, mint, peppermint)	20
256090	Bay leaves (laurel)	20
256100	Taragon (Hyssop)	20
256990	Others	20
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,5

Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0,01*
260030	Peas (with pods) (Mangetout (sugar peas))	0,01*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,01*
260050	Lentils	0,01*
260990	Others	0,01*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,01*
270020	Cardoons	0,01*
270030	Celery	10
270040	Fennel	0,01*
270050	Globe artichokes	0,3
270060	Leek	0,01*
270070	Rhubarb	0,01*
270080	Bamboo shoots	0,01*
270090	Palm hearts	0,01*
270990	Others	0,01*
280000	(viii) Fungi	0,01*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,01*
280020	Wild (Chanterelle, Truffle, Morel,)	0,01*
280990	Others	0,01*
290000	(ix) Sea weeds	0,01*
300000	3. PULSES, DRY	0,01*
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0,01*
300020	Lentils	0,01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*
300040	Lupins	0,01*
300990	Others	0,01*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,01*
401020	Peanuts	0,01*
401030	Poppy seed	0,01*
401040	Sesame seed	0,01*
401050	Sunflower seed	0,01*
401060	Rape seed (Bird rapeseed,	0,01*

Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
	turnip rape)	
401070	Soya bean	0,01*
401080	Mustard seed	0,01*
401090	Cotton seed	0,3
401100	Pumpkin seeds	0,01*
401110	Safflower	0,01*
401120	Borage	0,01*
401130	Gold of pleasure	0,01*
401140	Hempseed	0,01*
401150	Castor bean	0,01*
401990	Others	0,01*
402000	(ii) Oilfruits	0,01*
402010	Olives for oil production	0,01*
402020	Palm nuts (palmoil kernels)	0,01*
402030	Palmfruit	0,01*
402040	Kapok	0,01*
402990	Others	0,01*
500000	5. CEREALS	
500010	Barley	0,02
500020	Buckwheat	0,02
500030	Maize	0,02
500040	Millet (Foxtail millet, teff)	0,02
500050	Oats	0,02
500060	Rice	0,4
500070	Rye	0,02
500080	Sorghum	0,02
500090	Wheat (Spelt Triticale)	0,02
500990	Others	0,02
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,02*
620000	(ii) Coffee beans	0,02*
630000	(iii) Herbal infusions (dried)	0,02*
631000	(a) Flowers	0,02*
631010	Camomille flowers	0,02*
631020	Hybiscus flowers	0,02*
631030	Rose petals	0,02*
631040	Jasmine flowers	0,02*
631050	Lime (linden)	0,02*
631990	Others	0,02*
632000	(b) Leaves	0,02*
632010	Strawberry leaves	0,02*
632020	Rooibos leaves	0,02*
632030	Maté	0,02*

Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
632990	Others	0,02*
633000	(c) Roots	0,02*
633010	Valerian root	0,02*
633020	Ginseng root	0,02*
633990	Others	0,02*
639000	(d) Other herbal infusions	0,02*
640000	(iv) Cocoa (fermented beans)	0,02*
650000	(v) Carob (st johns bread)	0,02*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,02*
800000	8. SPICES	0,02*
810000	(i) Seeds	0,02*
810010	Anise	0,02*
810020	Black caraway	0,02*
810030	Celery seed (Lovage seed)	0,02*
810040	Coriander seed	0,02*
810050	Cumin seed	0,02*
810060	Dill seed	0,02*
810070	Fennel seed	0,02*
810080	Fenugreek	0,02*
810090	Nutmeg	0,02*
810990	Others	0,02*
820000	(ii) Fruits and berries	0,02*
820010	Allspice	0,02*
820020	Anise pepper (Japan pepper)	0,02*
820030	Caraway	0,02*
820040	Cardamom	0,02*
820050	Juniper berries	0,02*
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*
820070	Vanilla pods	0,02*
820080	Tamarind	0,02*
820990	Others	0,02*
830000	(iii) Bark	0,02*
830010	Cinnamon (Cassia)	0,02*
830990	Others	0,02*
840000	(iv) Roots or rhizome	0,02*
840010	Liquorice	0,02*
840020	Ginger	0,02*
840030	Turmeric (Curcuma)	0,02*

Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
840040	Horseradish	0,02*
840990	Others	0,02*
850000	(v) Buds	0,02*
850010	Cloves	0,02*
850020	Capers	0,02*
850990	Others	0,02*
860000	(vi) Flower stigma	0,02*
860010	Saffron	0,02*
860990	Others	0,02*
870000	(vii) Ail	0,02*
870010	Mace	0,02*
870990	Others	0,02*
900000	9. SUGAR PLANTS	0,02*
900010	Sugar beet (root)	
900020	Sugar cane	0,02
900030	Chicory roots	0,5
900990	Others	0,02
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	0,01*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	
1011020	Fat free of lean meat	0,2
1011030	Liver	0,2
1011040	Kidney	0,2
1011050	Edible offal	0,2
1011990	Others	0,2
1012000	(b) Bovine	0,01*
1012010	Meat	
1012020	Fat	0,2
1012030	Liver	0,2
1012040	Kidney	0,2
1012050	Edible offal	0,2
1012990	Others	0,2

Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
1013000	(c) Sheep	0,01*
1013010	Meat	
1013020	Fat	0,2
1013030	Liver	0,2
1013040	Kidney	0,2
1013050	Edible offal	0,2
1013990	Others	0,2
1014000	(d) Goat	0,01*
1014010	Meat	
1014020	Fat	0,2
1014030	Liver	0,2
1014040	Kidney	0,2
1014050	Edible offal	0,2
1014990	Others	0,2
1015000	(e) Horses, asses, mules or hinnies	0,01*
1015010	Meat	
1015020	Fat	0,2
1015030	Liver	0,2
1015040	Kidney	0,2
1015050	Edible offal	0,2
1015990	Others	0,2
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,01*
1016010	Meat	0,01*
1016020	Fat	0,01*
1016030	Liver	0,01*
1016040	Kidney	0,01*
1016050	Edible offal	0,01*
1016990	Others	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,01*
1017010	Meat	
1017020	Fat	0,2
1017030	Liver	0,2
1017040	Kidney	0,2
1017050	Edible offal	0,2
1017990	Others	0,2
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from	0,01*

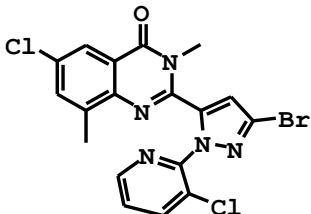
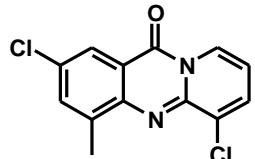
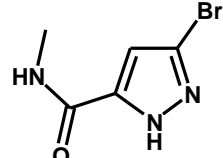
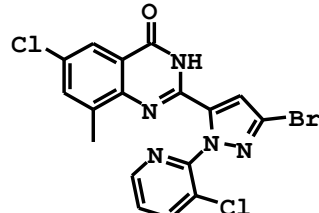
Code number	Groups and examples of individual products to which the MRL apply	Chlorantraniliprole (DPXE-2Y4S)(F)
	milk, cheese and curd	
1020010	Cattle	0,05
1020020	Sheep	0,05
1020030	Goat	0,05
1020040	Horse	0,05
1020990	Others	0,05
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05
1030010	Chicken	0,1
1030020	Duck	0,1
1030030	Goose	0,1
1030040	Quail	0,1
1030990	Others	0,1
1040000	(iv) Honey (Royal jelly, pollen)	0,1
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*
1060000	(vi) Snails	0,01*
1070000	(vii) Other terrestrial animal products	0,01*

(*) Indicates lower limit of analytical determination

(ft): MRL applicable until 31 December 2012, after that date 0.02 will be applicable unless modified by a Regulation.

(F): Fat-soluble

D. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Code/Trivial name	Chemical name	Structure
IN-EQW78	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-6-chloro-3, 8-dimethyl-4(3H)-quinazolinone	
IN-ECD73	2,6-dichloro-4-methyl-11H-pyrido[2,1-b]quinazolin-11-one	
IN-F6L99	5-Bromo-N-methyl-1H-pyrazole-3-carboxamide	
IN-GAZ70	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-6-chloro-8-methyl-4(3H)-quinazolinone	

ABBREVIATIONS

ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
DT ₉₀	period required for 90 % dissipation
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern European Union
NL	The Netherlands
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
R _{ber}	statistical calculation of the MRL by using a non-parametric method

R _{max}	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
TMDI	theoretical maximum daily intake
WHO	World Health Organisation