REASONED OPINION

Modification of the existing MRLs for chlorantraniliprole in various crops[1]

European Food Safety Authority[2]

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, herewith referred as the evaluating Member State (EMS), received an application from DuPont UK Ltd. to modify the existing MRLs and to set import tolerances for the active substance chlorantraniliprole in a number of commodities. In order to accommodate for the intended use of chlorantraniliprole, the United Kingdom proposed to raise the existing MRLs from the limit of quantification to 0.3 mg/kg for globe artichokes, from the value of 0.5 mg/kg to 0.8 mg/kg for legume vegetables (fresh) with pods and to set import tolerances of 0.7 mg/kg for citrus from South Africa, 0.02 mg/kg and 0.4 mg/kg for coffee and rice from Brazil, respectively. No MRL was proposed by the evaluating Member State for the intended use on strawberries and the import of legume vegetables from the United States. The United Kingdom 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 23 June 2011. It is noted that chlorantraniliprole is a new active substance for which the peer review process according to Commission Regulation (EU) No 188/2011 is not yet finalised.

EFSA bases its assessment on the evaluation report, the Draft Assessment Report (DAR) compiled by Ireland as rapporteur Member State (RMS), the JMPR evaluation reports as 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 as provisional.

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. Based on the results from these studies, the RMS proposed to establish the 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 in primary crops is sufficiently elucidated and the proposed residue definitions are appropriate.

Based on the results of the submitted supervised residue trials the following MRLs and import tolerances would be required to accommodate for the intended uses of chlorantraniliprole: 0.3 mg/kg

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on globe artichokes, 0.4 mg/kg on rice imported from Brazil and 0.7 mg/kg on citrus fruits imported from the Republic of South Africa. The existing MRL set at the LOQ value of 0.02 mg/kg is sufficient to accommodate the authorised use on coffee imported from Brazil. Although the submitted data on strawberries were consistent with the intended GAP regarding the timing of applications and the PHI, they exceeded the application rate by more than the acceptable variation of ± 25 %. In this particular case the available data were used to derive the tentative MRL of 0.5 mg/kg applying the principle of proportionality, which is proposed to Risk Managers for a decision. For the intended European use on beans and peas with pods and the import of legume vegetables (fresh) from the United States of America, the data were not suitable to derive MRL proposals. Analytical methods are available to enforce the proposed MRLs and import tolerance values, except for coffee beans for which the applicability of the analytical method should be demonstrated by providing the relevant validation data.

The nature of chlorantraniliprole residues did not change by processing except under baking/brewing/boiling conditions, where three degradates were formed. However the parent compound was the major component of the residues and the RMS proposed the same residue definition as for raw agricultural commodities. Specific studies investigating the magnitude of chlorantraniliprole residues in processed commodities are not required as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI. However, based on the residue trials conducted on citrus, the following median processing factor was derived and is proposed for the inclusion in Annex VI of the Regulation (EC) No 396/2005.

- Citrus, peeled: 0.27

The occurrence of chlorantraniliprole and its metabolites in rotational crops was evaluated in the peer review. Based on the available information on the nature and magnitude of the residues, EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that chlorantraniliprole is applied according to the intended GAPs.

Since citrus pomace may be used as feed product, a potential carry-over into food of animal origin was assessed. However, the dietary burden is mainly driven by the existing uses and the contribution of chlorantraniliprole residues in citrus pomace to the total livestock exposure was insignificant, therefore a modification of the existing MRLs for commodities of animal origin was not considered necessary in the framework of the current application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on the crops under consideration for which a change of the MRL value is proposed and the median residue values reported in previously issued EFSA reasoned opinions. For the remaining commodities of plant and for the commodities of animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. The estimated exposure was then compared with the toxicological reference value proposed for chlorantraniliprole.

No acute consumer assessment is required because the setting of an ARfD was considered not necessary for chlorantraniliprole.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 0.2 to 1.8 % of the ADI. Among the commodities for which the MRL is proposed, the highest contribution of residues to the total consumer exposure was given by oranges and accounted for a maximum of 0.014 % of the ADI (DE child diet). Despite uncertainties in the calculation of the MRL for strawberries, EFSA is of the opinion that there is a considerable margin of safety to consider the proposed use on strawberries as acceptable (TMDI for strawberries maximum 0.003 % of the ADI).

Consequently EFSA concludes that the proposed uses of chlorantraniliprole on citrus fruits, strawberries, globe artichokes, rice and coffee will not result in a consumer exposure exceeding the toxicological reference value and therefore will not pose a public health concern and proposes to amend the existing MRLs as reported in the table below:

Code number[(a)]	**Commodity**	**Existing EU MRL (mg/kg)**	**Proposed EU MRL (mg/kg)**	**Justification for the proposal**
Enforcement residue definition: chlorantraniliprole (F)				
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0.01*	0.7	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended import tolerance request. The proposed MRL was derived from combined data on mandarin, orange and tangelo fruits.
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.01*	0.7	
110030	Lemons (Citron, lemon)	0.01*	0.7	
110040	Limes	0.01*	0.7	
110050	Mandarins (Clementine, tangerine, mineola and other hybrids)	0.01*	0.7	
110990	Others citrus fruits	0.01*	0.7	
152000	Strawberries	0.01*	0.5 (tentative)	The tentative MRL proposal was derived by proportionally scaling-down overdosed trial results. No risk for consumers was identified for the intended use. A Risk Manager decision has to be taken whether the MRL based on the proportionality concept can be proposed from the submitted dataset.
260010	Beans (with pods) (Green bean (French beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0.5	0.5	Residue data are not sufficient to derive the MRL proposal for the intended European use of the SC formulation and for the import tolerance request and to extrapolate these uses to peas with pods.
260030	Peas (with pods) (Mangetout (sugar peas, snow peas))	0.01*	0.01*	
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0.01*	0.01*	Residue data are not adequate to derive the MRL proposal for the import tolerance request. The proposed extrapolation from green beans with pods and peas with and without pods to the whole group of legume vegetables is not acceptable in the Europe Union.
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.01*	0.01*	
260050	Lentils (fresh)	0.01*	0.01*	
260990	Other legume vegetables (fresh)	0.01*	0.01*	
270050	Globe artichokes	0.01*	0.3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended use.
500060	Rice	0.02	0.4	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the import tolerance request.

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
620000	Coffee beans	0.02*	0.02*	The MRL proposal is sufficiently supported by data. The existing MRL accommodates the use and no risk for consumers was identified for the import tolerance request. The applicability of the analytical method for coffee beans should be demonstrated by relevant validation data.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Fat-soluble pesticide.

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.

KEY WORDS

Chlorantraniliprole, citrus, strawberries, globe artichokes, legume vegetables, coffee, rice, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, diamide insecticide, IN-F6L99, IN-ECD73, IN-QW78, IN-GAZ70, IN-K9T00, IN-HXH44, IN-HXH40.

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BACKGROUND

Regulation (EC) No 396/2005[3] establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that Regulation lays down that any party having a legitimate commercial interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC[4], currently replaced by Regulation (EC) No 1107/2009[5], may submit to the designated rapporteur Member State (RMS) or to a Member State, an application to set or modify existing MRLs/import tolerances, in accordance with the provisions of Article 7 of the Regulation.

The United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the company DuPont UK Ltd.[6] to modify the existing MRLs and to set import tolerances for the active substance chlorantraniliprole in various crops. 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 of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 23 June 2011. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2011-00821 and the following subject:

Chlorantraniliprole - Application to modify the existing MRLs in various commodities

The United Kingdom proposed to modify the existing MRLs of chlorantraniliprole on globe artichokes form the limit of detection of 0.01 mg/kg to 0.3 mg/kg, on legume vegetables (fresh) with pods from 0.5 mg/kg to 0.8 mg/kg and to set import tolerances at the levels of 0.7 mg/kg, 0.4 mg/kg and 0.02 mg/kg on citrus fruits from South Africa and on rice and coffee from Brazil, respectively. The EMS considered the submitted data not sufficient to propose a new MRL for the use on strawberries and an import tolerance for legume vegetables imported from the United States of America.

EFSA then proceeded with the assessment of the application 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.

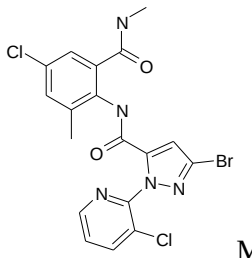
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests 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 23 September 2011.

[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.
[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.
[6] DuPont UK Ltd., Wedgwood Way, Hertfordshire SG1 4QN, Stevenage, the United Kingdom.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Chlorantraniliprole (DPX E-2Y45) 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 g/mol

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/EC[7]) and according to the transitional measures provided for in Regulation (EC) No 1107/2009 and Commission Regulation (EU) No 188/2011[8], the rules of Council Directive 91/414 EC shall continue to apply. Ireland is acting as 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, no EFSA conclusion is available at present.

The EU MRLs for chlorantraniliprole are established in Annexes IIIA of Regulation (EC) No 396/2005 (Appendix C). MRLs were recently amended by Commission Regulation (EU) No 459/2010[9] and Commission Regulation (EU) No 978/2011[10.]. In accordance with Commission Regulation (EU) No 460/2011[11], a temporary MRL for carrots is legally in force in France until 31 December 2012. EFSA has also provided comments on the acceptability of new CXLs for chlorantraniliprole (EFSA, 2011b), however the European Commission has not yet taken a decision on the inclusion in Regulation (EC) No 396/2005 of the recently adopted CXLs. The existing temporary EU MRLs for chlorantraniliprole are set at the LOQ of 0.01 mg/kg in citrus fruits, globe artichokes, legume vegetables (fresh) with the exception of beans with pods (0.5 mg/kg), at the LOQ of 0.02 in coffee beans and at the value of 0.02 mg/kg in rice. Codex Alimentarius has established CXLs for a number of commodities, including citrus fruits for which the CXL is set at 0.5 mg/kg and berry fruits for which the CXL is at 1 mg/kg. It is noted that the import tolerance request on oranges from the Republic of South Africa evaluated in the framework of this application is based on a GAP which was assessed by EFSA in 2011. EFSA concluded that the data were not adequate to derive the import tolerance value (EFSA, 2011b).

The intended GAPs for which a modification of the existing MRLs and the authorised GAPs for which the import tolerances are requested are reported in Appendix A.

[7] Commission Decision of 2 August 2007 (2007/560/EC). OJ L 213, 15.08.2007, p. 29-31.
[8] Commission Regulation (EU) No 188/2011 of 25 February 2011. OJ L 53, 26.02.2011, p. 51-55.
[9] Commission Regulation (EU) No 459/2010 of 27 May 2010. OJ L 129, 28.05.2010, p. 3-49.
[10] Commission Regulation (EU) No 978/2011 of 3 October 2011. OJ L 258, 04.10.2011, p. 12-69.
[11] Commission Regulation (EU) No 460/2011 of 12 May 2011. OJ L 124, 13.05.2011, p. 23-40.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (the United Kingdom, 2011), the Draft Assessment Report (DAR) 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), the JMPR Evaluation reports (FAO, 2009a, 2011b) as well as the conclusions from previous EFSA opinions on chlorantraniliprole (EFSA, 2010, 2011a). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[12] 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, 2011a).

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. Methods 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).

The DGF S19 multi-residue method based on liquid chromatography and tandem mass detection (LC-MS/MS) was sufficiently validated at the LOQ of 0.01 mg/kg for the determination of chlorantraniliprole residues in high water, high acid and high fat content and dry commodities. An independent laboratory validation (ILV) was performed.

Additionally, two methods for the single residue using LC-MS/MS or GC-ECD were sufficiently validated at the LOQ of 0.01 mg/kg for the determination of chlorantraniliprole residues in high water, high acid and high fat content and dry commodities. An independent laboratory validation (ILV) was performed for the LC-MS/MS method.

EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRLs for chlorantraniliprole in the crops under consideration, which belong to the groups of high water, high acid and dry commodities, except for coffee beans for which the applicability of the analytical method should be demonstrated by providing the relevant validation data (EC, 2010b).

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

Analytical methods for the determination of chlorantraniliprole residues in commodities of animal origin were evaluated in the DAR (Ireland, 2008).

The DGF S19 multi-residue method based on liquid chromatography and tandem mass detection (LC-MS/MS) was sufficiently validated at the LOQ of 0.01 mg/kg for the determination of chlorantraniliprole residues in milk, meat (muscle), liver, fat and eggs. An independent laboratory validation (ILV) was performed.

Additionally two single analyte methods using LC-MS/MS or GC-ECD were sufficiently validated at the LOQ of 0.01 mg/kg for the determination of chlorantraniliprole residue in milk, meat (muscle),

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

liver, kidney, fat and eggs. An independent laboratory validation (ILV) was performed for the LC-MS/MS method.

EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for chlorantraniliprole in food of animal origin are available.

2. Mammalian toxicology

The toxicological properties of the active substance chlorantraniliprole were evaluated in the DAR prepared by the RMS (Ireland, 2008). The toxicological reference values derived for chlorantraniliprole (Ireland, 2008) are compiled in Table 2-1. Pending the finalisation of the peer review process, the assessment and the derived toxicological reference values should be considered as provisional.

Table 2-1: Overview of the provisional toxicological reference values

	Source	**Year**	**Value**	**Study relied upon**	**Safety factor**
Chlorantraniliprole					
ADI	DAR	2008	1.58 mg/kg bw/d	mice, 18 months chronic toxicity	100
ARfD	DAR	2008	Not necessary		

JMPR established an ADI of 0-2 mg/kg bw/day based on the same documentation and also considered that an ARfD is not necessary for chlorantraniliprole (FAO, 2009a). The acute toxicity of three chlorantraniliprole metabolites (*i.e.* IN-EQW78[13], observed in animal metabolism and rice straw after soil application; IN-ECD73[14] and IN-F6L99[15], observed at low concentrations following processing at high temperature) was very low, with a LD_{50} higher than 2000 mg/kg bw. These metabolites gave also negative results in a test for reverse mutation (FAO, 2009a).

[13] IN-EQW78: see Appendix D.
[14] IN-ECD73: see Appendix D.
[15] IN-F6L99: see Appendix D.

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 in the framework of the peer review (Ireland, 2008). The overview of the metabolism study designs is presented in the table below.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position[a]	Type/(F) or (G)[b]	Application details			
				Rate	No	Sampling	Growth stage at application
Chlorantraniliprole							
Fruit and fruiting vegetables	Apples (leaf, fruit)	BC-^{14}C PC-^{14}C	Foliar (overhead)/ G	0.1 kg a.s/ha	3	Several times up to 30 d after last application	BBCH 71 BBCH 75 BBCH 77
	Tomatoes (leaf, fruit)	Mix of BC-^{14}C PC-^{14}C (1:1)	Foliar/G	0.1 kg a.s/ha	3	Several times up to 15 DALA	BBCH 19-61 BBCH 19-73 BBCH 19-81
Leafy vegetables	Lettuce	Mix of BC-^{14}C PC-^{14}C (1:1)	Foliar/F	0.1 kg a.s./ha	3	Several times up to 15 DALA	BBCH 13 BBCH 19 BBCH 19
Pulses and oilseeds	Cotton (foliage, boll)	BC-^{14}C PC-^{14}C	Foliar/G	0.15 kg a.s./ha + surfactant	1	8, 15, 22, 86 and 126 DAT	41-d old seedlings
				0.15 kg a.s./ha	1	8, 21 and 48 DAT	57-d old seedlings
	Cotton (excised foliage)	BC-^{14}C PC-^{14}C	Incubation	50 mg a.s./kg	-	At the end of incubation period (4 d)	18-d old seedlings
Cereals	Rice (plant, soil/ sediment)	Mix of BC-^{14}C PC-^{14}C (1:1)	Soil drench/F	0.3 kg a.s./ha	1	0 DAT (soil); 14, 28, 56 and 132 DAT	BBCH 11-12

(a): Radiolabelled at the benzamide carbonyl [BC-^{14}C] and at the pyrazole carbonyl [PC-^{14}C] position.
(b): Outdoor/field use (F) or glasshouse/protected crops/indoor application (G)

The metabolism studies indicate that chlorantraniliprole was not metabolised to a great extent when applied as a foliar spray with up to three consecutive applications to apples, tomatoes and lettuce,

following a single spray application or after incubation in a medicated solution for a short time (4 days) on cotton. At harvest, parent chlorantraniliprole was by far the major component of the total radioactive residues (TRR) accounting for 57 % to 92 % of the TRR and no significant metabolites (≥0.01 mg/kg) were detected. No differences in the results that can be ascribed to the two labels were observed.

When chlorantraniliprole was applied as a soil drench to rice, the metabolism showed to be more complex and numerous metabolites were formed in addition to the parent compound in the different crop parts and in the soil/sediment matrices. However, at harvest, parent chlorantraniliprole was the major component of the radioactive residues in rice grain, straw and leaves (>50 % TRR). Metabolites accounted for a maximum of 1.8 % of TRR (or 0.003 mg/kg) in grain and for a maximum of 7 % of TRR (or 0.049 mg/kg) in straw. Consequently, the results of this study suggest that the compound is translocated acropetally in plant.

As chlorantraniliprole was the main component of the radioactive residues in the three crop categories, the RMS proposed a general residue definition for monitoring and risk assessment as parent compound (Ireland, 2008).

For the uses on the crops under consideration, EFSA concludes that the metabolism of chlorantraniliprole is sufficiently addressed and the residue definitions proposed by the RMS are appropriate.

3.1.1.2. Magnitude of residues

The results of the supervised residue trials submitted to support the European and import tolerance application are herewith summarised.

a. Citrus (import tolerance)

Sixteen supervised residue trials performed in South Africa were available to support the import tolerance request for citrus fruits. Four trials on oranges, one trial on tangelo and seven trials on mandarins, including clementines, performed over two seasons were submitted in the framework of this application, while four orange residue trials were assessed in a previous reasoned opinion, but considered as not in accordance with the GAP (EFSA, 2011a). The results from these latter four orange studies can be taken into account as the additional information provided by the notifier showed that the application rate (3.5 g a.s./hL) was estimated in function of the size of the trees, the growth stage of the crops and the planting density. The EMS confirmed that the variation in the physical characteristics of the plants was accounted for in the protocol (the United Kingdom, 2011). The extrapolation to the whole group of citrus fruits was proposed and is in accordance with the provision of the EU guidance document (EC, 2011). Although two trials were conducted with a spray volume and an application rate in kg a.s./ha exceeding the maximum rates, the other parameter (rate expressed in kg a.s./hL) was complying with the South African label and the residue levels were within the observed range of residues, therefore the results were taken into consideration for the estimation. All trials can be considered as acceptable and sufficient to derive an import tolerance for the group of citrus fruits imported from South Africa.

b. Strawberries

Eight supervised decline residue trials on strawberries performed under protected conditions in Southern Europe during two seasons were provided. Strawberries are a major crop in Europe, therefore a minimum of eight trials is required to support the MRL proposal (EC, 2011). None of the trials was reflecting the proposed GAP. They were conducted applying chlorantraniliprole at a higher rate (*ca.* + 50 % the proposed nominal rate) three times instead of two.

Although the submitted data are not appropriate to derive the MRL proposal for the intended use on strawberries according to the EU guidance document because the application rate exceeded the acceptable variation of ± 25 % of the nominal application rate, in this particular case the available data may be used to predict the level of residues in the harvested fruit applying the principle of proportionality as proposed by JMPR. The assumption is that residues of insecticides and fungicides in plant commodities scale with application rate, allowing the estimation of residue levels resulting from field trials conducted using deviating application rates (FAO, 2011a). Thus, considering that the active substance is an insecticide intended for use as foliar applications on strawberries grown under protected conditions, the formulation type is identical, the submitted supervised residue trials were designed as decline studies with 7-day intervals among the applications and chlorantraniliprole concentrations were determined at least at the day of the last application (zero DALA) and at the proposed PHI (3 DALA), the applicability of the proportionality principle for the MRL estimation is possible. Although these trials were conducted with three instead of two applications, the last application prior to harvest is more relevant in predicting the terminal residue concentration (EC, 2011), therefore the results from these studies were used to derive a tentative MRL proposal.

The observed residue concentrations were down-scaled to the application rate of the intended GAP by the mean scaling factor of 0.67 and the MRL and risk assessment values were derived from the calculated residue levels. The proposed MRL is affected by uncertainties, such as the small number of trials and the inherent variability in residues from field trials, which might limit the residue scaling. Additional trials (*e.g*. bridging studies) would be desirable to confirm the applicability of the concept for the estimation of the expected residues in strawberries treated according to the intended GAP.

c. Beans with pods (outdoor use)

The intended outdoor use on beans with pods has been already assessed by EFSA in a previous reasoned opinion (EFSA, 2011a). The SEU outdoor use appeared to be the cGAP and the derived MRL of 0.5 mg/kg was included in the EU legislation.

d. Beans with pods (indoor use)

GAP: 2 x 0.063 kg a.s./ha; interval 7 d; PHI 1 d; WG formulation; EU

The intended indoor use on beans with pods has been already assessed by EFSA in a previous reasoned opinion (EFSA, 2011a).

e. Beans with pods, peas with pods (indoor use)

GAP: 2 x 0.036 kg a.s./ha; interval 7 d; PHI 3 d; SC formulation; EU

Four decline supervised residue trials on beans with pods performed under protected conditions with the suspension concentrate (SC) formulation in France, Italy and Spain were submitted. Although the extrapolation from beans with pods to peas with pods is in accordance with the guidance document because the intended use pattern is identical, beans with pods are a major crop in Europe, therefore a minimum of eight trials is theoretically required to support the MRL proposal (EC, 2011). All trials were considered as not reflecting the intended GAP because conducted at an application rate exceeding the acceptable variation of ± 25 % of the nominal application rate. In these trials the SC formulation applied to beans at a comparable rate (*2 x 53.4 to 57 kg a.s./ha with an interval of 7 days*) at longer PHI showed to produce higher residue values compared to the authorized use of the WG formulation. There was no explanation for the difference on these results. Since the total number of available trials is anyway not sufficient, EFSA is not proposing to derive a MRL value for the intended use on beans with pods and to extrapolate the value to peas with pods.

f. Fresh legume vegetables (import tolerance)

Nine supervised residue trials on beans with pods and ten supervised residue trials on peas (four trials on peas with pods and six trials on peas without pods) performed in USA and Canada over a single season (2008) were provided. Within the dataset only one decline study was performed. The proposed extrapolation to the group of legume vegetables is not in accordance with the EU guidance document (EC, 2011). Since beans with pods and peas without pods are considered major crops for import in Europe, the minimum number of trials to substantiate the import tolerance is eight per crop, while only four are sufficient for peas with pods (EC, 2011). All trials were considered as not reflecting the intended GAP, as conducted at a higher application rate compared to the nominal dose rate with a lower number of applications. Thus, the data are not adequate to derive an import tolerance proposal for legume vegetables (fresh) imported from USA.

g. Globe artichokes

Four decline supervised residue trials on globe artichokes performed in SEU during two seasons were provided. Globe artichokes are a minor crop in Europe, therefore a minimum of four trials is required to support the MRL proposal (EC, 2011). All trials were compliant with the intended GAP and considered as acceptable to derive the MRL proposal and the risk assessment input values.

h. Coffee (import tolerance)

Eight supervised residue trials on coffee performed in Brazil over two seasons were provided. Coffee is a major crop for import in Europe, therefore a minimum of eight trials is required to support the import tolerance proposal (EC, 2011). Four trials were conducted at a higher application rate (*ca*. 65 % higher than the nominal rate) with three instead of the maximum two applications intended in the GAP authorized in Brazil and were disregarded. Four trials from a single season were considered as reflecting the authorised GAP. Since chlorantraniliprole residues were only detectable (2 x <LOD; >LOD; <LOQ) in the trials reflecting the GAP, a reduction in the total number of trials is in accordance with the provision of the EU guidance document (EC, 2011). The current EU MRL of 0.02* mg/kg for chlorantraniliprole in coffee is sufficient to accommodate the use of chlorantraniliprole in Brazil.

i. Rice (import tolerance)

Eight supervised residue trials on rice performed in Brazil during a single season were provided. Rice is a major crop for import in Europe, therefore a minimum of eight trials is required to support the import tolerance proposal (EC, 2011). All trials were compliant with the intended GAP and considered as acceptable to derive the MRL proposal and the risk assessment input values.

The results of the above mentioned residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals calculated according to the OECD methodology (OECD; 2011a) are summarized in Table 3-2.

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 methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (the United Kingdom, 2011).

EFSA concludes that the following MRLs and import tolerances would be required to accommodate for the intended uses of chlorantraniliprole: 0.3 mg/kg on globe artichokes, 0.4 mg/kg on rice imported from Brazil and 0.7 mg/kg on citrus fruits imported from the Republic of South Africa. The existing MRL set at the LOQ value of 0.02 mg/kg is sufficient to accommodate the authorised use on coffee imported from Brazil. Although the submitted data on strawberries were consistent with the intended GAP regarding the timing of applications and the PHI, they exceeded the application rate by more than the acceptable variation of ± 25 %. In this particular case the available data were used to derive the tentative MRL of 0.5 mg/kg applying the principle of proportionality, which is proposed to Risk Managers for a decision. For the intended European use on beans and peas with pods and the import of legume vegetables (fresh) from the United States of America, the data were not suitable to derive MRL proposals.

Table 3-2: Overview of the available residues trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg) (d)	Median CF (e)	Comments
			Enforcement (chlorantraniliprole)	**Risk assessment (chlorantraniliprole)**					
Citrus fruits[(i)]	Import (RAS)	Outdoor	*Oranges:* 0.14; 0.15; *0.15*[(f)(h)]; 0.20[(f)]; *0.22*[(h)]; *0.22*[(f)(h)]; 0.24[(g)]; *0.27*[(h)] *Tangelo*: 0.25[(f)] *Mandarins:* 0.11; 0.14[(f)]; 0.22; 0.35[(f)] *Clementines:* 0.15; 0.18[(f)]; 0.30	*Oranges:* 0.14; 0.15; *0.15*[(f)(h)]; 0.20[(g)]; *0.22*[(h)]; *0.22*[(f)(h)]; 0.24[(g)]; *0.27*[(h)] *Tangelo*: 0.25[(f)] *Mandarins:* 0.11; 0.14[(f)]; 0.22; 0.35[(f)] *Clementines:* 0.15; 0.18[(f)]; 0.30	0.21	0.35	0.7	1	Combined datasets. R_{ber}= 0.50 R_{max}= 0.37 OECD MRL = 0.7
Strawberries	SEU	Indoor	0.05; 2 x 0.1; 0.11; 0.12; 0.15[(f)]; 0.19[(f)]; 0.42[(f)]	0.05; 2 x 0.1; 0.11; 0.12; 0.15[(f)]; 0.19[(f)]; 0.42[(f)]	0.12	0.42	-	1	Data from overdosed trials.
			Scaled residues[(l)]: 0.03; 3 x 0.07; 0.08; 0.1[(f)]; 0.13[(f)]; 0.28[(f)]	*Scaled residues* [(l)]: 0.03; 3 x 0.07; 0.08; 0.1[(f)]; 0.13[(f)]; 0.28[(f)]	0.08	0.28	0.5 (tentative)		The proposed tentative MRL was estimated based on the concept of residue proportionality (FAO, 2011a). Scaling factor: 0.67 R_{ber}= 0.25 R_{max}= 0.35 OECD MRL= 0.5
Beans (with pods)	EU	Indoor	GAP: *2 x 0.063 kg a.s./ha PHI 1 d; WG formulation*. 0.08; 3 x 0.11; 2 x 0.13; 0.14, 0.15, 0.30	0.08; 3 x 0.11; 2 x 0.13; 0.14, 0.15, 0.30	0.13	0.30	0.5	1	Data assessed in a previous reasoned opinion (EFSA, 2011a).
Beans (with pods) → Peas with pods			GAP: *2 x 0.036 kg a.s./ha PHI 3 d; SC formulation*. 0.16; 0.40; 0.40[(f)]; 0.41[(f)]	0.16; 0.40; 0.40[(f)]; 0.41[(f)]	0.40	0.41	-	1	Data from overdosed trials: Total number not sufficient to support the MRL proposal.

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg) (d)	Median CF (e)	Comments
			Enforcement (chlorantraniliprole)	**Risk assessment (chlorantraniliprole)**					
Beans with pods, peas → Legume vegetables (fresh)	Import USA	Outdoor	*Beans with pods*: <0.01; 0.10; 3 x 0.12; 0.14; 0.15; 0.16; 0.41 *Peas with pods:* 0.45; 0.48; 0.62; 0.64 *Peas without pods:* 2 x 0.01; 2 x 0.02; 0.03; 0.04	*Beans with pods:* <0.01; 0.10; 3 x 0.12; 0.14; 0.15; 0.16; 0.41 *Peas with pods:* 0.45; 0.48; 0.62; 0.64 *Peas without pods:* 2 x 0.01; 2 x 0.02; 0.03; 0.04	-	-	-	1	Data from overdosed trials conducted with two instead of four applications. Extrapolation to the whole group is not acceptable at EU level.
Globe artichokes	SEU	Outdoor	0.06; 0.07; 0.08; 0.16	0.06; 0.07; 0.08; 0.16	0.08	0.16	0.3	1	R_{ber}= 0.28 R_{max}= 0.33 OECD MRL= 0.3
Coffee	Import (BZ)	Outdoor	4 x <0.01	4 x <0.01	<0.01	<0.01	0.01*	1	Residue values: 2 x <LOD (<0.005 mg/kg); >LOD (0.006 mg/kg); <LOQ (<0.01 mg/kg). A reduction in the total number of trials is justified.
			Overdosed trials: 3x 0.053 kg a.s./ha; intervals 14 d; PHI 21 d. 2 x 0.02; 2 x 0.03	*Overdosed trials: 3x 0.053 kg a.s./ha; intervals 14 d; PHI 21 d.* 2 x 0.02; 2 x 0.03					
Rice	Import (BZ)	Outdoor	<0.01; 0.02; 0.03; 0.1; 2 x 0.13; 2 x 0.16	<0.01; 0.02; 0.03; 0.1; 2 x 0.13; 2 x 0.16	0.12	0.16	0.4	1	R_{ber}= 0.31 R_{max}= 0.29 OECD MRL= 0.4

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code).
(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): MRL calculated according to the OECD methodology (OECD, 2011a).
(e): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(f): The higher values measured at a longer PHI has been considered.
(g): Results from trial conditions exceeding the intended maximum application rate in water (L/ha) and dose rate as kg a.s./ha.
(h): Results from trials assessed in a previous reasoned opinion (EFSA, 2011a).
(i): Residues of the whole citrus fruit were calculated from the separate analysis of the pulp and peel.

(l): Scaled residues calculated by dividing the observed residues by a scaling factor to give the residues expected if the crop was treated at the intended application rate. The scaling factor represents the average of each individual scaling factor, which was obtained from the ratio of the intended GAP application rate and the actual application rate.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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 on 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 of baking, brewing, or boiling, with formation of significant amounts of the metabolites IN-F6L99 (13.6 % AR) and IN-ECD73 (10.9 % AR), while IN-EQW78 was identified in lower quantities (3.5 % AR). However the parent compound was the major component of the radioactive residues (87 to 86 % of the AR) and 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 are not necessary as the total theoretical maximum daily intake (TMDI) amounts to less than 10 % (EC, 1997d). However, EFSA recommends including the processing factor of 0.27 for peeled citrus as derived from the samples taken from the supervised residue trials. The median processing factor for peeled citrus is summarised in Table 3-3. Noteworthy is that EFSA has proposed to include aslo the processing factor of 0.2 for orange juice in Annex VI of Regulation (EC) No 396/2005 (EFSA, 2011a).

Table 3-3: Overview of the available processing studies

Processed commodity	**Number of studies**	**Median PF** [(a)]	**Median CF** [(b)]	**Residues in pulp (mg/kg)**
Enforcement residue definition: chlorantraniliprole				
Citrus, peeled[(c)]	16	0.27	1	*Oranges*: 0.04; 3 x 0.05; 2 x 0.06; 0.07; 0.08 *Tangelo*: 0.05 *Mandarins*: 0.02; 2 x 0.06; 0.07 *Clementines*: 0.04; 0.07; 0.08

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.
(c): Residues of the whole citrus fruit were calculated from the separate analysis of the pulp and peel.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Strawberry is normally not grown in rotation, however since yields may deteriorate after a few years growth in the same spot, a crop rotation can occur in agriculture practice after several years. Taking into account that the DT_{90} values for chlorantraniliprole from both laboratory and field studies proposed in the DAR (Ireland, 2008) were much longer than the trigger value of 100 days (EC, 2004), the possible occurrence of chlorantraniliprole residues in rotational crops has to be considered.

3.1.2.2. Nature of residues

The metabolism of chlorantraniliprole in succeeding crops was addressed in the DAR (Ireland, 2008). The overview of the study designs is presented in the table below.

Table 3-4: Summary of available rotational crop studies

Crop group	Crop sown	Label position	Application details				Remarks
			Method	Rate	Sowing interval	Harvest time	
Chlorantraniliprole							
Leafy vegetables	lettuce	BC-^{14}C	Spray on soil	0.3 kg a.s./ha	30 DAT	365 DAT	GLP
		PC-^{14}C			0, 30, 120, 365 DAT		
Root and tuber vegetables	red beet	BC-^{14}C	Spray on soil	0.3 kg a.s./ha	30 DAT		
		PC-^{14}C			0, 30, 120, 365 DAT		
Cereals	wheat	BC-^{14}C	Spray on soil	0.3 kg a.s./ha	30 DAT		
		PC-^{14}C			0, 30, 120, 365 DAT		
		PC-^{14}C	Spray on soil	0.9 kg a.s./ha	0, 365 DAT		
		BC-^{14}C/ PC-^{14}C	Spray on soil	0.15 kg a.s./ha	30 days	77 DAT (radish), 135 DAT (wheat), 176 DAT (soybean)	No GLP
Pulses and oilseeds	soybean	BC-^{14}C/ PC-^{14}C	Spray on soil	0.15 kg a.s./ha			
Root and tuber vegetables	radish	BC-^{14}C/ PC-^{14}C	Spray on soil	0.15 kg a.s./ha			

(a): Radiolabelled at the benzamide carbonyl [BC-^{14}C] and the pyrazole carbonyl [PC-^{14}C] position.

The results showed that following application of chlorantraniliprole to soil at 0.3 kg a.s./ha, the transfer of chlorantraniliprole and its metabolites to human food commodities (wheat grain, lettuce, red beet roots) was low, ranging form <0.01 to 0.046 mg/kg of TRR, while in animal feed items (wheat forage, hay and straw, red beet forage) the transfer rate was higher, ranging from 0.045 to 2.085 mg/kg of TRR.

Chlorantraniliprole was the major residue in the food items containing more than 0.01 mg/kg of TRR (lettuce from 0 to 365-day sowings: 64-85.2 % of TRR; wheat grain from the 120-day sowing: 47.7 % of TRR). Minor components, all individually present at a maximum of 5.2 % (or 0.002 mg/kg) of TRR could be identified only in lettuce. Chlorantraniliprole was the main component in animal feed items as well (up to 84.1 % or 1.34 mg/kg of TRR), with the exception of red beet foliage. In this crop the metabolism was quite extensive and no more than 4.8 % (or 0.005 mg/kg) of TRR was detected as parent compound together with several metabolites, individually accounting for less than 11 % (or 0.013 mg/kg) of TRR. Moreover, following the application of either labelled compound or the exaggerated dose, no relevant differences in the metabolic profile were observed.

Similarly, in the non-GLP study (considered as providing supportive information), the majority of the extracted radioactivity was identified as parent chlorantraniliprole in all commodities (45 to 87 % of TRR). The minor metabolites that were detected in various commodities were present at less than 10 % of TRR.

The data on metabolism and distribution of chlorantraniliprole in succeeding crops support the conclusion of the RMS that the metabolism of the residues in rotational crops is similar to the metabolism observed in primary crops (Ireland, 2008).

3.1.2.3. Magnitude of residues

Data from field accumulation studies on rotational crops with chlorantraniliprole at maximum application rate of 600 g a.s./ha/season (*ca*. 8.4N the maximum rate for the intended uses on strawberries) were assessed in the DAR (Ireland, 2008). Chlorantraniliprole residues were found only on commodities intended for livestock feed (0.01 to 0.2 mg/kg).

Based on the available information on the nature and magnitude of the residues, it is concluded that relevant residue levels are unlikely to occur in rotational crops provided that chlorantraniliprole is applied on strawberries according to the intended GAPs for which the tentative MRL is proposed.

3.2. Nature and magnitude of residues in livestock

The use of chlorantraniliprole resulted in significant residue levels in citrus imported from RSA, which by-products might be fed to livestock, therefore the nature and magnitude of residues in livestock is to be assessed in the framework of this application (EC, 1996).

3.2.1. Dietary burden of livestock

In order to estimate the contribution of chlorantraniliprole residues in citrus pomace to the total livestock dietary exposure and verify the need for a change in the existing MRLs on commodities of animal origin, EFSA compared the dietary burden calculated according to the agreed European methodology (EC, 1996) for the existing MRLs (EFSA, 2011a) with a dietary burden calculated after the addition of citrus pomace residues. The input values for the dietary burden calculation without the by-product under consideration (Scenario 1) were retrieved from a previous reasoned opinion (EFSA, 2011a). For the dietary burden calculation according to Scenario 2, the residue levels for citrus derived from the supervised residue trials (see Table 3-2) were multiplied by the default processing factor of 2.5 for pomace. The default processing factors used in the calculation are added in brackets.

The input values for the dietary burden calculation are summarized in Table 3-5.

Table 3-5: Input values for the dietary burden calculations

Commodity	**Median dietary burden**		**Maximum dietary burden**	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: chlorantraniliprole				
Scenario 1 (without citrus pomace residues)[(a)]				
Apple pomace	1.25	Existing MRL*PF(2.5)	1.25	Existing MRL*PF(2.5)
Cabbage	0.39	Median residue (FAO, 2011b)	1.1	Highest residue (FAO, 2011b)
Kale	7.3	Median residue (FAO, 2009a)	8.9	Highest residue (FAO, 2009a)
Maize, wheat, barley, rye, oat grain	0.01	Median residue (FAO, 2009a)	0.01	Median residue (FAO, 2009a)
Wheat, barley, rye, oat straw	0.05	Median residue (FAO, 2009a)	0.17	Highest residue (FAO, 2009a)
Wheat, rye bran	0.08	Median residue*PF(8) (FAO, 2009a)	0.08	Median residue*PF(8) (FAO, 2009a)

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Maize silage	0.01	Median residue*PF(1) (FAO, 2009a)	0.01	Highest residue*PF(1) (FAO, 2009a)
Potatoes	0.01	Median residue (FAO, 2009a)	0.01	Highest residue (FAO, 2009a)
Turnips	0.01	Median residue (FAO, 2009a)	0.01	Highest residue (FAO, 2009a)
Swedes	0.01	Median residue (FAO, 2009a)	0.01	Highest residue (FAO, 2009a)
Sugar beets	0.02	Existing MRL	0.02	Existing MRL
Fodder beets	0.02	Existing sugar beet MRL	0.02	Existing sugar beet MRL
Cotton seed	0.05	Median residue (FAO, 2009a)	0.25	Highest residue (FAO, 2009a)
Scenario 2 (with citrus pomace residue)				
Citrus pomace	0.53 (0.21*2.5)	Median residue*PF(2.5)	0.53 (0.21*2.5)	Median residue*PF(2.5)

(a): Input values retrieved from "Modification of the existing MRLs for chlorantraniliprole in various crops and in products of animal origin"(EFSA, 2011a).

The results of the dietary burden calculation are summarised in the following tables.

Table 3-6: Results of the dietary burden (scenario 1)

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)[(a)]	Trigger exceeded (Y/N)
Risk assessment residue definition: Chlorantraniliprole					
Dairy ruminants	0.812	0.666	Kale	22.33	Y
Meat ruminants	0.958	0.785	Kale	22.36	Y
Poultry	0.203	0.167	Kale	3.22	Y
Pigs	0.385	0.316	Kale	9.62	Y

Retrieved from "Modification of the existing MRLs for chlorantraniliprole in various crops and in products of animal origin"(EFSA, 2011a).
(a): Dry matter feed

Table 3-7: Results of the dietary burden (scenario 2)

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)[(a)]	Trigger exceeded (Y/N)
Risk assessment residue definition: Chlorantraniliprole					
Dairy ruminants	0.812	0.666	Kale	22.33	Y
Meat ruminants	0.958	0.785	Kale	22.36	Y
Poultry	0.203	0.167	Kale	3.22	Y

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)[(a)]	Trigger exceeded (Y/N)
Pigs	0.385	0.316	Kale	9.62	Y

(a): Dry matter feed.

From the comparison of the two scenarios it is evident that the dietary burden is mainly driven by the existing uses, and the contribution of the citrus pomace to the total livestock exposure is insignificant. Therefore a modification of the existing MRLs for commodities of animal origin was not considered necessary in the framework of the current 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 population [16] (EFSA, 2007).

For the calculation of the chronic exposure EFSA used the median residue values as derived from the residue trials on the crops under consideration for which a change of the MRL value is proposed (see Table 3-2) and the median residue values reported in previously issued EFSA reasoned opinions (EFSA, 2010, 2011a). For strawberries, the median residue value was proportionally estimated from overdosed trials (see Table 3-2). For the remaining commodities of plant and for the commodities of 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 rather conservative, 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 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.

Since the setting of an ARfD was considered not necessary for chlorantraniliprole, the acute consumer exposure was not assessed.

The input values used for the dietary exposure calculation are summarized 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				
Citrus fruits	0.06 (0.21*0.27)	Median residue*PF (import, RSA)	Not necessary.	
Strawberries	0.08	Median residue (indoor, estimated)		

[16] 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).

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Globe artichokes	0.08	Median residue (SEU)		
Coffee	0.02	Existing EU MRL[(a)]		
Rice	0.12	Median residue (import, BZ)		
Table and wine grapes	0.22	Median residue (EFSA, 2011a)		
Cane fruit	0.35	Median residue (EFSA, 2011a)		
Blueberries	0.21	Median residue (EFSA, 2011a)		
Cranberries	0.22	Median residue (EFSA, 2011a)		
Carrots	0.03	Median residue (EFSA, 2010)		
Radishes	0.05	Median residue (EFSA, 2011a)		
Cauliflower	0.06	Median residue (EFSA, 2011a)		
Beans with pods	0.12	Median residue (EFSA, 2011a)		
Swine: meat	0.01	Median residue[(b)](EFSA, 2011a)		
Bovine: meat	0.05	Median residue[(b)](EFSA, 2011a)		
Sheep: meat	0.05	Median residue[(b)](EFSA, 2011a)		
Goat: meat	0.05	Median residue[(b)](EFSA, 2011a)		
Other commodities of food and animal origin	MRL	See Appendix C		

(a): The existing MRL accommodates for the requested import of coffee from Brazil.
(b): Median residue calculated according to the latest JMPR recommendations (FAO, 2009) considering 80% of the median residue derived for muscle and 20% of the median residue derived for fat.

The estimated exposure was then compared with the toxicological reference value proposed 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 ranged from 0.2 to 1.8 % of the ADI. Among the commodities for which the MRL is proposed, the highest contribution of residues to the total consumer exposure was given by oranges and accounted for a maximum of 0.014 % of the ADI (DE child diet). Despite uncertainties in the calculation of the MRL for strawberries, EFSA is of the opinion that there is a considerable margin of safety to consider the proposed use on strawberries as acceptable (TMDI for strawberries maximum 0.003 % of the ADI).

Consequently EFSA concludes that the proposed uses of chlorantraniliprole on citrus fruits, strawberries, globe artichokes, rice and coffee will not result in a consumer exposure exceeding the toxicological reference value and therefore will not 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 as provisional.

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. Based on the results from these studies, the RMS proposed to establish the 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 in primary crops is sufficiently elucidated and the proposed residue definitions are appropriate.

Based on the results of the submitted supervised residue trials the following MRLs and import tolerances would be required to accommodate for the intended uses of chlorantraniliprole: 0.3 mg/kg on globe artichokes, 0.4 mg/kg on rice imported from Brazil and 0.7 mg/kg on citrus fruits imported from the Republic of South Africa. The existing MRL set at the LOQ value of 0.02 mg/kg is sufficient to accommodate the authorised use on coffee imported from Brazil. Although the submitted data on strawberries were consistent with the intended GAP regarding the timing of applications and the PHI, they exceeded the application rate by more than the acceptable variation of ± 25 %. In this particular case the available data were used to derive the tentative MRL of 0.5 mg/kg applying the principle of proportionality, which is proposed to Risk Managers for a decision. For the intended European use on beans and peas with pods and the import of legume vegetables (fresh) from the United States of America, the data were not suitable to derive MRL proposals. Analytical methods are available to enforce the proposed MRLs and import tolerance values, except for coffee beans for which the applicability of the analytical method should be demonstrated by providing the relevant validation data.

The nature of chlorantraniliprole residues did not change by processing except under baking/brewing/boiling conditions, where three degradates were formed. However the parent compound was the major component of the residues and the RMS proposed the same residue definition as for raw agricultural commodities. Specific studies investigating the magnitude of chlorantraniliprole residues in processed commodities are not required as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI. However, based on the residue trials conducted on citrus, the following median processing factor was derived and is proposed for the inclusion in Annex VI of the Regulation (EC) No 396/2005.

- Citrus, peeled: 0.27

The occurrence of chlorantraniliprole and its metabolites in rotational crops was evaluated in the peer review. Based on the available information on the nature and magnitude of the residues, EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that chlorantraniliprole is applied according to the intended GAPs.

Since citrus pomace may be used as feed product, a potential carry-over into food of animal origin was assessed. However, the dietary burden is mainly driven by the existing uses and the contribution of chlorantraniliprole residues in citrus pomace to the total livestock exposure was insignificant, therefore a modification of the existing MRLs for commodities of animal origin was not considered necessary in the framework of the current application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on the crops under consideration for which a change of the MRL value is proposed and the median residue values reported in previously issued EFSA reasoned opinions. For the remaining commodities of plant and for the commodities of animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. The estimated exposure was then compared with the toxicological reference value proposed for chlorantraniliprole.

No acute consumer assessment is required because the setting of an ARfD was considered not necessary for chlorantraniliprole.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 0.2 to 1.8 % of the ADI. Among the commodities for which the MRL is proposed, the highest contribution of residues to the total consumer exposure was given by oranges and accounted for a maximum of 0.014 % of the ADI (DE child diet). Despite uncertainties in the calculation of the MRL for strawberries, EFSA is of the opinion that there is a considerable margin of safety to consider the proposed use on strawberries as acceptable (TMDI for strawberries maximum 0.003 % of the ADI).

Consequently EFSA concludes that the proposed uses of chlorantraniliprole on citrus fruits, strawberries, globe artichokes, rice and coffee will not result in a consumer exposure exceeding the toxicological reference value and therefore will not pose a public health.

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.

RECOMMENDATIONS

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: chlorantraniliprole (F)				
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0.01*	0.7	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended import tolerance request. The proposed MRL was derived from combined data on mandarin, orange and tangelo fruits.
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.01*	0.7	
110030	Lemons (Citron, lemon)	0.01*	0.7	
110040	Limes	0.01*	0.7	
110050	Mandarins (Clementine, tangerine, mineola and other hybrids)	0.01*	0.7	
110990	Others citrus fruits	0.01*	0.7	
152000	Strawberries	0.01*	0.5 (tentative)	The tentative MRL proposal was derived by proportionally scaling-down overdosed trial results. No risk for consumers was identified for the intended use. A Risk Manager decision has to be taken whether the MRL based on the proportionality concept can be proposed from the submitted dataset.

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
260010	Beans (with pods) (Green bean (French beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0.5	0.5	Residue data are not sufficient to derive the MRL proposal for the intended European use of the SC formulation and for the import tolerance request and to extrapolate these uses to peas with pods.
260030	Peas (with pods) (Mangetout (sugar peas, snow peas))	0.01*	0.01*	
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0.01*	0.01*	Residue data are not adequate to derive the MRL proposal for the import tolerance request. The proposed extrapolation from green beans with pods and peas with and without pods to the whole group of legume vegetables is not acceptable in the Europe Union.
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.01*	0.01*	
260050	Lentils (fresh)	0.01*	0.01*	
260990	Other legume vegetables (fresh)	0.01*	0.01*	
270050	Globe artichokes	0.01*	0.3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended use.
500060	Rice	0.02	0.4	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the import tolerance request.
620000	Coffee beans	0.02*	0.02*	The MRL proposal is sufficiently supported by data. The existing MRL accommodates the use and no risk for consumers was identified for the import tolerance request. The applicability of the analytical method for coffee beans should be demonstrated by relevant validation data.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Fat-soluble pesticide.

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Appendix A. GOOD AGRICULTURAL PRACTICES (GAPs)

(GAPs not assessed in the framework of this evaluation are shaded in grey)

Crop and/or situation (a)	Member State or Country or EU zone	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (k)	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		
Strawberries	EU	G	*Spodoptera* sp. *Tetranychus* sp. *Liriomyza* sp.	SC	Chlorantraniliprole 45 g/L Abamectin 18 g/L	Foliar spray	BBCH 12-89	2	7		200–1000	0.036	3	
Globe artichoke	SEU	F	*Spodoptera exigua*, *Spodoptera littoralis*, *Chrysodeixis chalcites*	ZC	Chlorantraniliprole 100 g/L Lambda-cyhalothrin 50 g/L	Foliar spray	BBCH 12-49	2	14		200–1000	0.030	3	
Beans (with pods)	NEU/ SEU	F	*H. armigera* *O. nubilalis* *S. littoralis* *P. gamma*	WG	350 g/kg	tractor mounted hydraulic sprayer	BBCH 15-89	1-2	7-10		250-1000	0.042 (120 g fp/ha)	1	GAP assessed in a previous Reasoned Opinion
	EU	G	*S. exigua* *S. littoralis* *H. armigera*	WG	350 g/kg	broadcast, high pressure mist blower	BBCH 15-89	1-2	7-14	0.0028-0.0042	500-1500	0.063 (180 g fp/ha)	1	Maximum seasonal rate = 80 g fp/ ha GAP assessed in a previous Reasoned Opinion
			Spodoptera sp. *Tetranychus* sp. *Liriomyza* sp.	SC	Chlorantraniliprole 45 g/L Abamectin 18 g/L	Foliar spray	BBCH 12-89	2	7		200–1000	0.036	3	
Peas (with pods)	EU	G	*Spodoptera* sp. *Tetranychus* sp. *Liriomyza* sp.	SC	Chlorantraniliprole 45 g/L Abamectin 18 g/L	Foliar spray	BBCH 12-89	2	7		200–1000	0.036	3	

Crop and/or situation (a)	Member State or Country or EU zone	F G or I (b)	Pest or group of pests controlled (c)	Formulation type (d - f)	Formulation conc. of a.s. (i)	Application method kind (f - h)	Application growth stage & season (j)	Application number min max (k)	Application interval min max	Application rate per treatment kg as/hL min max	Application rate per treatment water L/ha min max	Application rate per treatment kg a.s./ha min max	PHI (days) (k)	Remarks (m)
Citrus	RSA	F	False codling moth; *Thaumatotibia leucotreta*	SC	200 g/L	mist blower & directed boom/hand guns	BBCH 74-88	1-2	30	0.0035	2000-8500	0.070-0.2975 (350-1487.5 mL fp/ha)	7	
Legume vegetables[(o)], except soybean	U.S.A.	F	Corn earworm, Beet armyworm, European corn borer, Fall armyworm	SC	200 g/L	Low vol. spraying – broadcast by ground; Low vol. spraying - aerial	BBCH 12-89	1-4	3		93-935 (ground) 10-100 gpa 47-93 (aerial) 5-10	0.050-0.075	1	Maximum seasonal application rate = 225 g a.s./ ha
Coffee	Brazil	F	Coffee Leaf miner (*Leucoptera coffeella*)	WG	350 g/kg	Ground foliar	BBCH 60-89	1-2	45		400	0.0315	21	
Rice	Brazil	F	Rice water weevil (*Oryzophagus oryzae*)	WG	350 g/kg	Ground or aerial foliar	Up to BBCH 21	1	-		Ground 100-200	0.030	n.a.	
			Army worms (*Pseualetia adultera; Pseudaletia sequax*)				BBCH 75-85				Aerial 40		15	

Crop and/or situation (a)	Member State or Country or EU zone	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (k)	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		

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 suckling 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
(o) Bean (*Lupinus* spp. – includes grain lupin, sweet lupin, white lupin, and white sweet lupin); bean (*Phaseolus* spp. - includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean, tepary bean, wax bean); bean/pea (*Vigna* spp. - includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, Crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, yardlong bean); broad bean (succulent); chickpea; guar; jackbean; lablab bean; lentil; pea (*Pisum* spp.) (includes dwarf pea, edible-pod pea, English pea, field pea, garden pea, green pea, snow pea, sugar snap pea); pigeon pea; soybean (immmature seeds); sword bean.
(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)

Appendix B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Chlorantraniliprole

Status of the active substance:	pending	Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**1.58**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**DAR**	Source of ARfD:	**DAR**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

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

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum	
	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	pTMRLs at LOQ (in % of ADI)
1.8	NL child	0.5	Spinach	0.3	Scarole (broad-leaf endive)	0.2	Witloof	0.0
1.3	FR toddler	0.9	Spinach	0.1	Milk and cream,	0.1	Apples	0.0
1.3	WHO Cluster diet B	0.5	Lettuce	0.1	Tomatoes	0.1	Chinese cabbage	0.0
1.2	IT adult	0.5	Lettuce	0.2	Other lettuce and other salad plants	0.1	Spinach	0.0
1.2	DE child	0.4	Apples	0.3	Spinach	0.1	Lettuce	0.0
1.0	ES adult	0.7	Lettuce	0.1	Beet leaves (chard)	0.1	Spinach	0.0
1.0	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	ES child	0.5	Lettuce	0.1	Spinach	0.1	Beet leaves (chard)	0.0
1.0	IE adult	0.3	Other leafy brassica	0.2	Spinach	0.1	Lettuce	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	FR infant	0.6	Spinach	0.1	Witloof	0.1	Apples	0.0
0.9	WHO cluster diet D	0.2	Chinese cabbage	0.1	Kale	0.1	Kale	0.0
0.8	FR all population	0.2	Other lettuce and other salad	0.2	Witloof	0.1	Lettuce	0.0
0.8	SE general population 90th percentile	0.3	Chinese cabbage	0.1	Spinach	0.1	Head cabbage	0.0
0.7	WHO Cluster diet F	0.4	Lettuce	0.1	Chinese cabbage	0.0	Kale	0.0
0.6	WHO cluster diet E	0.1	Lettuce	0.1	Scarole (broad-leaf endive)	0.1	Herbs	0.0
0.4	DK child	0.2	Lettuce	0.1	Apples	0.0	Milk and cream,	0.0
0.4	UK vegetarian	0.2	Lettuce	0.0	Spinach	0.0	Tomatoes	0.0
0.3	UK Toddler	0.1	Apples	0.1	Milk and cream,	0.0	Spinach	0.0
0.3	UK Adult	0.1	Lettuce	0.0	Spinach	0.0	Tomatoes	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	LT adult	0.1	Lettuce	0.1	Apples	0.1	Head cabbage	0.0
0.2	FI adult	0.1	Lettuce	0.0	Chinese cabbage	0.0	Tomatoes	0.0
0.2	PT General population	0.0	Wine grapes	0.0	Tomatoes	0.0	Apples	0.0
0.2	DK adult	0.0	Apples	0.0	Wine grapes	0.0	Chinese cabbage	0.0

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

Appendix C. EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS)

(Pesticides - Web Version - EU MRLs (File created on 28/10/2011 11:51)

Code number	Groups and examples of individual products to which the MRLs apply	Chlorantraniliprole (DPX E-2Y45) (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,01*
110030	Lemons (Citron, lemon)	0,01*
110040	Limes	0,01*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,01*
110990	Others	0,01*
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
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	1
151010	Table grapes	1
151020	Wine grapes	1
152000	(b) Strawberries	0,01*
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	0,7
154030	Currants (red, black and white)	0,01*
154040	Gooseberries (Including hybrids with other ribes species)	0,01*
154050	Rose hips	0,01*
154060	Mulberries (arbutus berry)	0,01*
154070	Azarole (mediteranean medlar)	0,01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,01*
154990	Others	0,01*
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) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,01*
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 mammey 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 (Japanese taro), tannia)	0,02
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*

Code number	Groups and examples of individual products to which the MRLs apply	Chlorantraniliprole (DPX E-2Y45) (F)
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 squash, marrow (patisson))	0,3
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 corn	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 Brassicacea	20
251010	Lamb´s lettuce (Italian corn salad)	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, curld leave endive, sugar loaf)	20
251040	Cress	20
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, glassworth)	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 cisely 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	Tarragon (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
260020	Beans (without pods) (Broad beans, Flageolets, 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	0,01*
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, flageolets, 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, turnip rape)	0,01*
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	0,02
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	0,02
500070	Rye	0,02

Code number	Groups and examples of individual products to which the MRLs apply	Chlorantraniliprole (DPX E-2Y45) (F)
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*
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*

Code number	Groups and examples of individual products to which the MRLs apply	Chlorantraniliprole (DPX E-2Y45) (F)
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*
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) Aril	0,02*
870010	Mace	0,02*
870990	Others	0,02*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,02
900020	Sugar cane	0,01*
900030	Chicory roots	0,02
900990	Others	0,01*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
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	

Code number	Groups and examples of individual products to which the MRLs apply	Chlorantraniliprole (DPX E-2Y45) (F)
	preparations based on these	
1011000	(a) Swine	
1011010	Meat	0,04
1011020	Fat free of lean meat	0,04
1011030	Liver	0,03
1011040	Kidney	0,03
1011050	Edible offal	0,03
1011990	Others	0,01*
1012000	(b) Bovine	
1012010	Meat	0,2
1012020	Fat	0,2
1012030	Liver	0,15
1012040	Kidney	0,09
1012050	Edible offal	0,15
1012990	Others	0,01*
1013000	(c) Sheep	
1013010	Meat	0,2
1013020	Fat	0,2
1013030	Liver	0,15
1013040	Kidney	0,09
1013050	Edible offal	0,15
1013990	Others	0,01*
1014000	(d) Goat	
1014010	Meat	0,2
1014020	Fat	0,2
1014030	Liver	0,15
1014040	Kidney	0,09
1014050	Edible offal	0,15
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	0,01*
1015010	Meat	0,01*
1015020	Fat	0,01*
1015030	Liver	0,01*
1015040	Kidney	0,01*
1015050	Edible offal	0,01*
1015990	Others	0,01*
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*

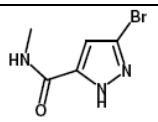
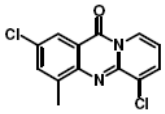
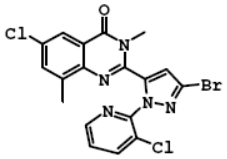
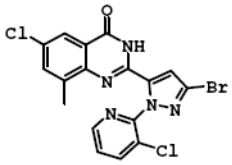
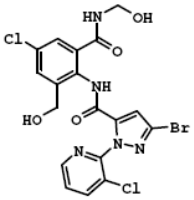
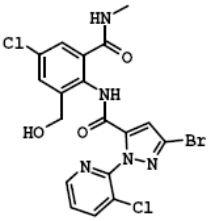
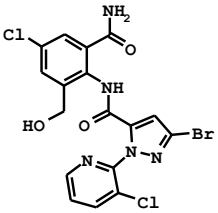
Code number	Groups and examples of individual products to which the MRLs apply	Chlorantraniliprole (DPX E-2Y45) (F)
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,01*
1017010	Meat	0,01*
1017020	Fat	0,01*
1017030	Liver	0,01*
1017040	Kidney	0,01*
1017050	Edible offal	0,01*
1017990	Others	0,01*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,04
1020010	Cattle	0,04
1020020	Sheep	0,04
1020030	Goat	0,04
1020040	Horse	0,04
1020990	Others	0,04
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	0,08
1030010	Chicken	0,08
1030020	Duck	0,08
1030030	Goose	0,08
1030040	Quail	0,08
1030990	Others	0,08
1040000	(iv) Honey (Royal jelly, pollen)	0,01*
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

0213020 Carrots

MRL applicable until 31 December 2012, after that date 0.02 will be applicable unless modified by a Regulation

Appendix D. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	**Structure**
IN-F6L99	5-Bromo-*N*-methyl-1*H*-pyrazole-3-carboxamide	
IN-ECD73	2,6-dichloro-4-methyl-11*H*-pyrido[*2,1-b*]quinazolin-11-one	
IN-EQW78	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-3, 8-dimethyl-4(3*H*) -quinazolinone	
IN-GAZ70[(a)]	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-8-methyl-4(3*H*)-quinazolinone	
IN-K9T00[(a)]	3-Bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[[(hydroxymethyl)amino) carbonyl] phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide	
IN-HXH44[(a)]	3-Bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide	
IN-HXH40[(a)]	*N*-[2-Aminocarbonyl]-4-chloro-6-(hydroxymethyl)phenyl]-3-bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide	

(a): Metabolites reported in the keywords section.

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
ca.	circa, approximately
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CS	capsule suspension
CXL	Codex Maximum Residue Limit (Codex MRL)
cGAP	critical GAP
d	day
DALA	days after last application
DBLA	days before the last application
DAR	Draft Assessment Report
DAT	days after treatment
EC	European Community
EFSA	European Food Safety Authority
e.g.	for example (*exempli gratia*, *Latin)*
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
fp	formulated product
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detector
ha	hectare
i.e.	that is (*id est*, *Latin*)
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
LC-MS/MS	liquid chromatography coupled with tandem mass spectrometry

LOQ	limit of quantification (determination)
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organization for Economic Co-operation and Development
PF	processing factor
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
RMS	rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water dispersible granule
WHO	World Health Organisation
ZC	mixed formulation of CS and SC