European Food Safety Authority

EFSA Journal 2011;9(3):2099

REASONED OPINION

Modification of the existing MRLs for chlorantraniliprole in various crops and in products of animal origin[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 set import tolerances for the active substance chlorantraniliprole in oranges from Brazil and South Africa (0.5 mg/kg), table and wine grapes from Canada and USA (1.5 mg/kg), cane fruit and blueberries from Canada and USA (2 mg/kg), cranberries from Canada and USA (1.5 mg/kg), radishes from USA (0.5 mg/kg), rice from USA (0.15 mg/kg), ruminants meat, liver and kidney (0.02, 0.15 and 0.08 mg/kg, respectively), milk (0.02 mg/kg) and eggs (0.04 mg/kg). In the same application a modification of the existing MRLs for chlorantraniliprole in cauliflower and other flowering brassicas (0.3 mg/kg) and beans with pods (0.4 mg/kg) was also requested. 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 13 September 2010.

It is noted that chlorantraniliprole is a new active substance for which the peer review process under Directive 91/414/EEC is not yet finalised.

EFSA bases its assessment on the evaluation report, 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 work-sharing global assessment project, the JMPR evaluation reports, as well as the conclusions from the previous EFSA opinion on chlorantraniliprole.

The toxicological profile of chlorantraniliprole has been evaluated in the DAR prepared by the rapporteur Member State (RMS) 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, these values 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. From these studies the RMS proposed to establish the residue definition for risk assessment and enforcement as chlorantraniliprole. For the intended import tolerances and EU uses,

[1] On request from the European Commission, Question No EFSA-Q-2010-01114, issued on 07 March 2011.

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Suggested citation: European Food Safety Authority; Modification of the existing MRLs for chlorantraniliprole in various crops and in products of animal origin. EFSA Journal 2011;9(3):2099. [45 pp.] doi:10.2903/j.efsa.2011.2099. Available online: www.efsa.europa.eu/efsajournal

EFSA concluded that the metabolism of chlorantraniliprole in primary crops is sufficiently elucidated and that the derived residue definitions are appropriate.

The supervised residue trials are sufficient and adequate to derive MRL proposals for the intended uses on table and wine grapes, cane fruit, blueberries, cranberries, radishes, cauliflower and other flowering brassicas (in northern Europe) and beans with pods. For the intended import tolerances on oranges and rice, supervised residues trials were not representative for the intended GAPs, thus data were not suitable for deriving MRL proposals and risk assessment values. The studies demonstrated that the following import tolerances and MRLs would be appropriate for the use of chlorantraniliprole on: table and wine grapes, cane fruit and blueberries: 1.5 mg/kg; cranberries: 0.7 mg/kg; radishes: 0.5 mg/kg; beans with pods: 0.5 mg/kg; cauliflower and other flowering brassica: 0.3 mg/kg. Analytical methods are available to enforce the proposed MRLs on the commodities under consideration.

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, the applicant submitted a processing study carried out on oranges processed into juice. The following processing factor has been derived:

- Oranges, juice: 0.21

Since in the current application no MRL proposal is possible for oranges, the derived processing factor is not applicable. However EFSA proposes to include the derived processing factor for orange juice in Annex VI of Regulation (EC) No 396/2005 to have it available in case of a future MRL proposal for chlorantraniliprole in oranges.

The occurrence of chlorantraniliprole residues in rotational crops for the intended uses in EU was investigated in the DAR. Based on the available information on the nature and magnitude of the residues, it was concluded that relevant residue levels are unlikely to occur in rotational crops provided that chlorantraniliprole is applied on flowering brassica and beans according to the proposed GAPs.

The applicant requested a modification of the existing EU MRLs for animal commodities from livestock raised outside the EU. Considering that livestock diet in extra EU countries includes a number of fodder crops for which there are no authorizations or MRLs set in the EU, dietary burden was calculated by the applicant using the Environmental Protection Agency (EPA) model. The dietary burden calculated according to the EPA model indicated that the trigger value of 0.1 mg/kg dry matter (DM) was exceeded for all relevant livestock species with corn stover and alfalfa meal representing the main contributing commodities. EFSA noticed that dietary burden calculations as recently published in the JMPR report on chlorantraniliprole are significantly lower than the dietary burden calculated by the applicant. EMS should verify the reliability of the dietary burden calculation as proposed by the applicant.

In addition EFSA derived maximum and mean dietary burdens using the agreed European methodology. The calculated dietary burden indicated that the trigger value of 0.1 mg/kg dry matter (DM) was exceeded for all relevant livestock species with kale representing the main contributing commodity.

Dietary burdens derived with both methodologies were compared and the highest values for each livestock species selected for the estimation of the expected chlorantraniliprole residue levels in animal commodities.

The metabolism of chlorantraniliprole in livestock was adequately elucidated and the RMS proposed a general residue definition for risk assessment and monitoring in animal commodities as chlorantraniliprole. The current residue definition set in Regulation (EC) No 396/2005 is identical

with the enforcement residue definition proposed by the RMS. EFSA concluded that the residue definition established in Regulation (EC) No 396/2005 is applicable. However, the possibility to set a different residue definition for milk including also metabolites IN-K9T00 and IN-HXH44 and for eggs including also the metabolite IN-GAZ70 should be further investigated under the framework of the peer review. Thus, the residue definition should be considered as provisional pending the completion of the peer review under the Directive 91/914/EEC. According to the Log P_{ow} value that for chlorantraniliprole is 2.86 at pH 7, residues are likely to be considered as fat soluble. The metabolism studies confirmed that the residues are mainly accumulating in fat and should therefore be classified as fat-soluble.

The dietary burdens calculated by both EPA model and EU methodology and the results of livestock feeding studies were used to derive the following MRL proposals: ruminants (bovine, sheep and goat) meat, fat, liver, kidney and edible offal: 0.2, 0.2, 0.15, 0.09 and 0.15 mg/kg, respectively; swine meat and fat: 0.04 mg/kg; swine liver, kidney and edible offal: 0.03 mg/kg; milk: 0.04 mg/kg; eggs: 0.08 mg/kg.

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 table and wine grapes, cane fruit, blueberries, cranberries, radishes, cauliflower, other flowering brassica and beans with pods, the median residue values reported in the JMPR report on chlorantraniliprole and in previously issued EFSA reasoned opinion. For the commodities of animal origin under evaluation, the MRL proposals were used as input values since median values as derived from dietary burden calculations and animal feeding studies were not reliable. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values.

Acute consumer exposure was not performed since the setting of an ARfD was considered not necessary for chlorantraniliprole.

The estimated exposure was then compared with the toxicological reference value proposed 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. The highest contribution of residues to the total consumer exposure was given by wine grapes and accounted for a maximum of 0.056% of the ADI (FR, all population diet).

Consequently EFSA concludes that the occurrence of residues at the proposed MRLs in commodities of plant and animal origin will not result in a consumer exposure posing a consumer health risk. Thus EFSA proposes to amend the current MRLs as proposed 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)				
110020	Oranges	0.01*	-	Residue data are not sufficient for deriving an MRL proposal.
151010	Table and wine grapes	1	1.5	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended import tolerances.
153000	Cane fruit	0.01*	1.5	
154010	Blueberries	0.01*	1.5	
154020	Cranberries	0.01*	0.7	
213080	Radishes	0.02	0.5	

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
241020	Cauliflower	0.01*	0.3	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses.
241990	Flowering brassica, others	0.01*	0.3	
260010	Beans with pods	0.01*	0.5	
500060	Rice	0.02	-	Residue data are not sufficient for deriving an MRL proposal.
1011010	Swine: meat	0.01*	0.04 (F)	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended import tolerances.
1011020	Swine: fat	0.01*	0.04	
1011030	Swine: liver	0.01*	0.03	
1011040	Swine: kidney	0.01*	0.03	
1011050	Swine: edible offal	0.01*	0.03	
1012010 1013010 1014010	Bovine, sheep, goat: meat	0.01*	0.2 (F)	
1012020 1013020 1014020	Bovine, sheep, goat: fat	0.01*	0.2	
1012030 1013030 1014030	Bovine, sheep, goat: liver	0.01*	0.15	
1012040 1013040 1014040	Bovine, sheep, goat: kidney	0.01*	0.09	
1012050 1013050 1014050	Bovine, sheep, goat: edible offal	0.01*	0.15	
1020000	Milk and cream	0.01*	0.04	
1030000	Birds' eggs	0.01*	0.08	

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.

Since the peer review under Directive 91/414/EEC has not yet been 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, oranges, table and wine grapes, cane fruit, blueberries, cranberries, radishes, broccoli, cauliflower, beans with pods, rice, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, diamide insecticide, IN-F6L99, IN-ECD73, IN-EQW78, 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], may submit to the rapporteur Member State (RMS) designated pursuant to Council Directive 91/414/EEC or to a Member State, an application to set an import tolerance or to set or modify an MRL, respectively, in accordance with the provisions of Article 7 of that Regulation.

The United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the company DuPont UK Ltd.[5] to set import tolerances for the active substance chlorantraniliprole in oranges, table and wine grapes, cane fruit, blueberries, cranberries, radishes, rice and several commodities of animal origin. In the same application a modification of the existing MRLs for chlorantraniliprole in cauliflower and other flowering brassicas and in beans with pods was also requested. 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 13 September 2010. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2010-01114 and the following subject:

Chlorantraniliprole – Application to modify the existing MRLs in various crops and in products of animal origin

The United Kingdom proposed to modify the existing MRLs of chlorantraniliprole according to the table below:

Code number[(a)]	**Commodity**	**Existing EU MRL (mg/kg)**	**Proposed EU MRL (mg/kg)**	**Comments**
Enforcement residue definition: chlorantraniliprole				
110020	Oranges	0.01*	0.5	Import tolerance request
151010	Table and wine grapes	1	1.5	
153000	Cane fruit	0.01*	2	
154010	Blueberries	0.01*	2	
154020	Cranberries	0.01*	1.5	
213080	Radishes	0.02	0.5	
241020	Cauliflower	0.01*	0.3	MRL request for new uses in EU
241990	Flowering brassica, others	0.01*	0.3	
260010	Beans with pods	0.01*	0.4	
500060	Rice	0.02	0.15	Import tolerance request
1012010 1013010 1014010	Bovine, sheep, goat: meat	0.01*	0.02	Import tolerance request
1012030 1013030 1014030	Bovine, sheep, goat: liver	0.01*	0.015	

[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] DuPont UK Ltd., Wedgwood Way, Hertfordshire SG1 4QN, Stevenage, United Kingdom.

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comments
1012040 1013040 1014040	Bovine, sheep, goat: kidney	0.01*	0.08	
1012050 1013050 1014050	Bovine, sheep, goat: edible offal	0.01*	0.15	
1020000	Milk and cream	0.01*	0.02	
1030000	Birds' eggs	0.01*	0.04	

(*): Indicates that the MRL is set at the limit of analytical quantification.

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

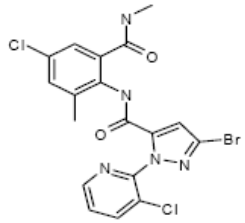
In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

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 13 December 2010.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Chlorantraniliprole is the ISO common name for 3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide (IUPAC). The chemical structure of the compound is herewith reported.



Molecular weight: 483.15 g/mol

Chlorantraniliprole is an insecticide belonging to the anthranilic diamide chemical class. 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 controls various *lepidopterous* pests.

Chlorantraniliprole is a new active substance under evaluation for inclusion in Annex I of Directive 91/414/EEC with Ireland designated as rapporteur Member State (RMS). The representative uses proposed by the applicant for the European Union are: table grape, aubergine, tomato, pepper, lettuce and cucurbits (edible and inedible peel) grown indoor; aubergine, tomato, pepper, and lettuce grown in field cultivation. The peer review is currently in progress and a final decision concerning the inclusion in Annex I of Directive 91/414/EEC is not expected within the next months. The Draft Assessment Report (DAR) dated December 2008 has been submitted to EFSA in February 2010. It 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 global assessment project.

The EU MRLs for chlorantraniliprole are established in Annexes IIIA of Regulation (EC) No 396/2005 (Appendix C). MRLs were amended by the Commission Regulation (EU) No 459/2010[6] including in Regulation (EC) No 396/2005 the CXLs evaluated in the JMPR (FAO, 2009a) and adopted by the Codex Alimentarius Commission on 4 July 2009. An MRL proposal for carrots was recently assessed by EFSA (EFSA, 2010), voted at the Standing Committee on the Food Chain and Animal Health (SCFCAH) but not yet legally enforced. The existing EU MRLs for chlorantraniliprole are set at the LOQ of 0.01 mg/kg in oranges, cane fruit, blueberries, cranberries, cauliflower, beans with pods and commodities of animal origin, at 0.02 mg/kg in radishes and rice and at 1 mg/kg in table and wine grapes and in broccoli. The setting of new CXLs for chlorantraniliprole in a wide range of commodities, including some of the commodities of plant and animal origin under consideration in the present application, is still ongoing.

The GAPs for which the import tolerances are requested are reported in Appendix A. The GAPs for which the intended EU uses are requested are also reported in Appendix A of the present reasoned opinion.

[6] Commission Regulation (EU) No 459/2010 of 27 May 2010. OJ L 129, 28.05.2010, p. 3-49.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (the United Kingdom, 2010), 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, 2008, 2010) as well as the conclusions from the previous EFSA opinion on chlorantraniliprole (EFSA, 2010). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorisation of Plant Protection Products set out in Annex VI to Council Directive 91/414/EEC 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, 2004, 2008, 2010).

Since the peer review under Directive 91/414/EEC has not yet been 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 under Directive 91/414/EEC (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 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 high water, high acid and high fat content and dry commodities. An independent laboratory validation (ILV) was performed for the LC-MS/MS method.

Methods for the determination of metabolites IN-EQW78[7], IN-ECD73[8], IN-F6L99[9] in processed commodities of plant origin are also available.

Since the commodities under consideration belong to the groups of high water, high acid, high fat content and dry commodities, EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRLs for chlorantraniliprole in the crops under consideration.

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

The analytical methods for the determination of chlorantraniliprole residues in commodities of animal origin were evaluated in the DAR prepared under Directive 91/414/EEC (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.

[7] IN-EQW78: see Appendix D
[8] IN-ECD73: see Appendix D
[9] IN-F6L99: see Appendix D

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

Methods for the determination of metabolites IN-EQW78[10], IN-GAZ70[11], IN-K9T00[12], IN-HXH44[13] in commodities of animal origin are also available.

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 profile of the active substance chlorantraniliprole has been 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, these values should be considered as provisional.

Table 2-1: Overview of the 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		

It is noted that JMPR established an ADI of 0-2 mg/kg bw/day based on the same documentation. JMPR also considered an ARfD as not necessary (FAO, 2009a).

JMPR assessed the toxicity of some metabolites: IN-EQW78 (observed in animal feeding studies); IN-ECD73[14] and IN-F6L99[15] (observed at low concentrations following processing at high temperature). In studies of acute toxicity, these three chlorantraniliprole metabolites had LD_{50}s of > 2000 mg/kg bw. These metabolites gave negative results in a test for reverse mutation (FAO, 2009a).

[10] IN-EQW78: see Appendix D
[11] IN-GAZ70: see Appendix D
[12] IN-K9T00: see Appendix D
[13] IN-HXH44: 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 (Ireland, 2008) in the framework of the peer review under Directive 91/414/EEC. 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
	Cotton (foliage, boll)	BC-^{14}C PC-^{14}C	Foliar/G	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	14, 28, 56 and 132 DAT[d]	BBCH 11 - 12

(a): Radiolabelled ate 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)
(c): With 0.5 % non-ionic surfactant.
(d): Soil samples taken at DAT 0, water and sediment samples were taken at 14, 28, 56 and 128 DAT.

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.

The metabolism of chlorantraniliprole was sufficiently elucidated in three crop categories and the RMS proposed a general residue definition for risk assessment and monitoring as parent compound (Ireland, 2008). The current residue definition set in Regulation (EC) No 396/2005 is identical with the enforcement residue definition proposed by the RMS.

Even if a specific study investigating metabolism in rice following seed treatment is not available, the results from the metabolism study after soil drench can be considered as representative for the intended use on rice. EFSA concludes that the metabolism of chlorantraniliprole is sufficiently addressed and the residue definition established in Regulation (EC) No 396/2005 is applicable.

3.1.1.2. Magnitude of residues

a. Oranges

In support to the intended import tolerance, the applicant submitted eight outdoor supervised residue trials: four carried out in Brazil during 2008 and four carried out in South Africa during 2009. All the trials from Brazil were performed by applying chlorantraniliprole at a lower rate (0.7N the maximum intended rate) three times instead of two. Moreover the active substance was applied as suspension concentrate formulation (SC) and not as mixed heterogeneous formulation of capsule and concentrate suspensions (ZC) which can result in different residue behaviour. Thus, according to the EU guidelines, specific trials would be required for this formulation type (EU, 2008). In these trials foliar spray application was done 21 days after soil drench with chlorantraniliprole. It was not possible to verify if the soil drench application was done at the intended dose since the application rate as reported in the supervised trials and in the GAP were not comparable (expressed as kg a.s. per plant in the trials and as kg a.s. per hectare in the GAP). Three trials from South Africa were performed by applying chlorantraniliprole at a lower rate (0.35-0.71N maximum intended rate). Only one study was in compliance with the intended GAP. In this trial the highest residue compared to the results of the under dosed trials was observed. Since most of the trials were not matching with the reported GAPs, no MRL proposal could be derived.

b. Table and wine grapes

In support to the intended import tolerance from USA and Canada, the applicant submitted twelve outdoor supervised residue trials carried out in several regions of the USA during 2005. Three trials were performed on wine grapes (varieties Chardonnay and Merlot). The studies were in compliance with the intended GAPs regarding PHI, application rate and number of application but were

performed without adding any adjuvant. In order to test the adjuvant effect on the residue level, the applicant submitted three more trials carried out in Canada on grapes with and without adjuvant. For calculating the MRL proposal the data from USA were combined with the data from Canada, considering the trials carried out with adjuvant in the same location as replicate and with the highest residues from the trial plot selected for estimating the maximum residue level. It is noted that in the trials with the adjuvant, the residues were in the same range.

c. Cane fruit

In support of the intended import tolerance, the applicant submitted eight outdoor supervised residue trials: three carried out on blackberries and raspberries in several regions of the USA during 2006 and five carried out on raspberries in several regions of Canada during 2006. The extrapolation from blackberries and raspberries to the whole group of cane fruit is envisaged. According to the EU Guidance document such an extrapolation is possible (EU, 2008). All the trials were performed by applying chlorantraniliprole without adjuvant two times instead of three. Since the maximum rate applied per season matched with the GAP and considering that the first application done with lower application rate is expected to have a low impact on the final residues, EFSA considered these trials as representative for the intended GAP. In order to test the adjuvant effect on the residue level in blackberries and raspberries, the applicant submitted eight trials carried out on stone fruits and three trials carried out on grapes with and without adjuvant. Based on these trials the applicant derived an adjuvant factor of 2 to be applied to the residue levels in raspberries and blackberries. EFSA is of the opinion that such an adjuvant factor can not be applied to cane fruit, since adjuvant effect on residue levels in stone fruits and grapes was measured at a PHI considerable longer (10 or 14 days) than the intended for cane fruit (3 days). EFSA derived am MRL proposal based on the actual residue concentrations measured in the supervised residue trials without applying a conversion factor as proposed by the applicant.

d. Blueberries and cranberries

In support of the intended import tolerance, the applicant submitted eleven outdoor supervised residue trials on blueberries (seven carried out in several regions of the USA during 2007 and four carried out in several regions of Canada during 2007) and six trials on cranberries (four carried out in several regions of the USA during 2007 and two carried out in different regions of Canada during 2007). All the trials were performed by applying chlorantraniliprole without adjuvant two times instead of three. Since the maximum rate applied per season matched with the GAP and considering that the first application done with lower application rate is expected to have a low impact on the final residues, EFSA considered these trials as representative for the intended GAP. In fourteen trials, residue was measured at a shorter PHI compared to the intended (1 instead of 3 days). In order to test the adjuvant effect on the residue level in blueberries and cranberries, the applicant referred to the eight trials carried out on stone fruits and the three trials carried out on grapes with and without adjuvant. Based on these trials the applicant derived an adjuvant factor of 2 to be applied to the residue levels in blueberries and cranberries. EFSA is of the opinion that such an adjuvant factor can not be applied to blueberries and cranberries, since adjuvant effect on residue levels in stone fruits and grapes was measured at a PHI considerable longer (10 or 14 days) than the intended for blueberries and cranberries (3 days). EFSA derived an MRL proposal based on the actual measured residue concentrations in the supervised residue trials without applying a conversion factor as proposed by the applicant.

e. Radishes

In support of the intended import tolerance, the applicant submitted six outdoor supervised residue trials: five carried out in several regions of the USA during 2008 and one carried out in Canada during

2008. All the trials were performed by applying chlorantraniliprole with an adjuvant (0.125-1% (v/v)) two times instead of four. Since the maximum rate applied per season matched with GAP and considering that the first and second applications done with lower application rate are expected to have a low impact on the final residues, EFSA considered these trials as representative for the intended GAP.

f. Cauliflowers and broccoli

In support of the intended use in Europe, the applicant submitted fourteen outdoor supervised residue trials: five (three on broccoli and two on cauliflowers) carried out in southern Europe during 2006 and 2007 and nine (four on broccoli and five on cauliflowers) carried out in northern Europe during 2006 and 2007. All the studies were in compliance with the intended GAP. One trial on broccoli from southern Europe and three trials (one with cauliflower and two on broccoli) from northern Europe were carried out with two different formulations but this is not expected to have an impact on the residue behaviour. The data generated following application in the same test location of two different formulations were combined and the value from the trial plot with the highest residues was selected for estimating the maximum residue level. The extrapolation from broccoli and cauliflower to the whole group of flowering brassica is envisaged. According to the EU guidance document, data from SEU are not sufficient and in total eight trials would be required to derive a group tolerance (EU, 2008). Thus, MRL proposals and risk assessment values for flowering brassica (except broccoli for which the EU MRL is set at 1 mg/kg) were derived from the northern Europe residue trials.

g. Beans without pods

In support of the intended use, the applicant submitted ten outdoor supervised residue trials (five carried out in southern Europe during 2007 and five carried out in northern Europe during 2007) and nine indoor supervised residues trials carried out in southern Europe during 2006 and 2007. All the studies were in compliance with the intended GAP. Since the southern outdoor trials showed slightly higher residues, EFSA derived MRL proposal, and risk assessment values from these trials.

h. Rice

In support of the intended import tolerance, the applicant submitted sixteen outdoor supervised residue trials carried out in several regions of the USA during 2007. All the studies were disregarded since they were performed by applying chlorantraniliprole at rate higher (3.7-7.5N) than the intended. Since no study was compliant with the reported GAP, no MRL proposal could be derived.

The results of the above mentioned residue trials for the crops under consideration, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarized in Table 3-2.

The storage stability of chlorantraniliprole in primary crops was investigated in the DAR under Directive 91/414/EEC (Ireland, 2008). Residues of chlorantraniliprole were found to be stable at temperatures ≤-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 supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (the United Kingdom, 2010).

EFSA considers that the data on table and wine grapes, cane fruit, blueberries, cranberries, cauliflower, other flowering brassica, radishes and beans with pods are sufficient to derive MRL

proposals and concludes that the following import tolerances and MRLs would be appropriate for the use of chlorantraniliprole on: table and wine grapes, cane fruit and blueberries: 1.5 mg/kg; cranberries: 0.7 mg/kg; radishes and beans with pods: 0.5 mg/kg; cauliflower and other flowering brassica: 0.3 mg/kg.

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)	Median CF [d]	Comments
			Enforcement (chlorantraniliprole)	**Risk assessment** (chlorantraniliprole)					
Oranges	Import (Brazil and South Africa)	Outdoor	0.06[e]; 0.08[e]; 0.13[e]; 0.15[e]; 0.15[f]; 2x0.22[f]; 0.27	0.06[e]; 0.08[e]; 0.13[e]; 0.15[e]; 0.15[f]; 2x0.22[f]; 0.27	-	-	-	1	Data not sufficient for deriving an MRL proposal
Table and wine grapes	Import (USA and Canada)	Outdoor	0.014; 0.058; 0.086; 0.1[g]; 0.113; 0.132; 0.197[g]; 0.217; 0.226[h]; 0.310[h]; 0.365[h]; 0.385[i]; 0.528[g]; 0.589; 0.591	0.014; 0.058; 0.086; 0.1[g]; 0.113; 0.132; 0.197[g]; 0.217; 0.226[h]; 0.310[h]; 0.365[h]; 0.385[i]; 0.528[g]; 0.589; 0.591	0.22	0.59	1.5	1	R_{ber}= 1.18 R_{max}= 0.76
Cane fruit (blackberries, raspberries)	Import (USA and Canada)	Outdoor	0.088[j]; 0.092[i,k]; 0.108[k]; 0.246[k]; 0.445[j]; 0.521[k]; 0.536[k]; 0.543[k]	0.088[j]; 0.092[i,k]; 0.108[k]; 0.246[k]; 0.445[j]; 0.521[k]; 0.536[k]; 0.543[k]	0.35	0.54	1.5	1	R_{ber}= 1.08 R_{max}= 0.99 Trials carried out without adjuvant
Blueberries	Import (USA and Canada)	Outdoor	0.140[l]; 0.143[l]; 0.150[l]; 0.167[l]; 0.206[l]; 0.210[l]; 0.223[l]; 0.247; 0.426; 0.826[l]; 0.908[l]	0.140[l]; 0.143[l]; 0.150[l]; 0.167[l]; 0.206[l]; 0.210[l]; 0.223[l]; 0.247; 0.426; 0.826[l]; 0.908[l]	0.21	0.91	1.5	1	R_{ber}= 0.85 R_{max}= 1.11 Trials carried out without adjuvant
Cranberries	Import (USA and Canada)	Outdoor	0.131[l]; 0.145[l]; 0.154[l]; 0.279[l]; 0.331[l]; 0.351[l]	0.131[l]; 0.145[l]; 0.154[l]; 0.279[l]; 0.331[l]; 0.351[l]	0.22	0.35	0.7	1	R_{ber}= 0.67 R_{max}= 0.60 Trials carried out without adjuvant
Radishes	Import (USA and Canada)	Outdoor	0.029; 0.04; 0.047; 0.061; 0.077; 0.26	0.029; 0.04; 0.047; 0.061; 0.077; 0.26	0.054	0.26	0.5	1	R_{ber}= 0.25 R_{max}= 0.41 Adjuvant added

Commodity	Region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (chlorantraniliprole)	**Risk assessment** (chlorantraniliprole)					
Flowering brassica	SEU	Outdoor	0.012[(m)]; 0.036[(m)]; 0.10[(n)]; 0.19[(n)]; 0.37[(n)]	0.012[(m)]; 0.036[(m)]; 0.10[(n)]; 0.19[(n)]; 0.37[(n)]	-	-	-	-	Data not sufficient to derive group tolerance or individual MRL proposals for broccoli or cauliflower.
	NEU	Outdoor	0.004[(m)]; 0.006[(m)]; 0.019[(m)]; 0.045[(m)]; 0.064[(n)]; 0.082[(m)]; 0.10[(n)]; 0.12[(n)]; 0.14[(n)]	0.004[(m)]; 0.006[(m)]; 0.019[(m)]; 0.045[(m)]; 0.064[(n)]; 0.082[(m)]; 0.10[(n)]; 0.12[(n)]; 0.14[(n)]	0.064	0.14	0.3	1	R_{ber}= 0.22 R_{max}= 0.22 Since a higher MRL of 1 mg/kg is set for broccoli, a new MRL is proposed only for cauliflowers and other flowering brassica.
Beans with pods	SEU	Outdoor	0.083; 0.088; 0.12; 0.16; 0.25	0.083; 0.088; 0.12; 0.16; 0.25	**0.12**	**0.25**	**0.5**	1	R_{ber}= 0.41 R_{max}= 0.43
	NEU	Outdoor	0.024; 0.031; 0.055; 0.093; 0.19	0.024; 0.031; 0.055; 0.093; 0.19	0.06	0.19	0.4	1	R_{ber}= 0.28 R_{max}= 0.36
	EU	Indoor	0.081; 3x 0.11; 2x0.13; 0.14; 0.15; 0.30	0.081; 3x 0.11; 2x0.13; 0.14; 0.15; 0.30	0.13	0.30	0.4	1	R_{ber}= 0.29 R_{max}= 0.33
Rice	Import (USA)	Outdoor	0.011; 0.029; 0.031; 2x0.033; 0.044; 0.048; 0.049; 0.050; 0.051; 0.053; 0.054; 0.061; 0.064; 0.074; 0.087	0.011; 0.029; 0.031; 2x0.033; 0.044; 0.048; 0.049; 0.050; 0.051; 0.053; 0.054; 0.061; 0.064; 0.074; 0.087	-	-	-	-	Since all trials were done at application rates 3.7N-7.5N the intended, data are not suitable for deriving an MRL proposal.

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): Results from trials carried out in Brazil by applying chlorantraniliprole at lower application rate three times instead of two.
(f): Results from trials carried out in South Africa by applying chlorantraniliprole at lower application rate.
(g): Results from trials carried out in Canada by adding non-ionic surfactant as adjuvant.
(h): Results from trials carried out on wine grapes.
(i): In the decline study the higher residue found at longer PHI has been considered.
(j): Results from trials carried out on blackberries.
(k): Results from trials carried out on raspberries.
(l): Residues measured at a shorter PHI.
(m): Results from trials carried out on cauliflower.
(n): Results from trials carried out on broccoli.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of chlorantraniliprole was investigated in studies performed at three test conditions representing 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). The studies were reported in the DAR (Ireland, 2008). During conditions representative of baking, brewing, or boiling degradation of chlorantraniliprole led to the formation of the metabolites IN-F6L99[16] (13.6% of AR for the [pyrazole carbonyl-^{14}C]-chlorantraniliprole), IN-ECD73[17] (10.93% of AR for the [benzamide carbonyl-^{14}C]-chlorantraniliprole) and IN-EQW78[18] (2.85-3.54% of AR for both labelled compound, respectively). However, parent chlorantraniliprole was the major component of the radioactive residues accounting for 87 and 86% AR for [benzamide carbonyl-^{14}C]- and [pyrazole carbonyl-^{14}C]-chlorantraniliprole, respectively. Thus, also for commodities processed at high temperature the same residue definition as for raw agricultural commodities (RAC) is applicable.

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, in the framework of this import tolerance the applicant submitted a processing study carried out on oranges. Samples of orange taken from the supervised residue trials were processed into juice. Chlorantraniliprole residues were analysed in raw oranges and in juice. Chlorantraniliprole residues ranged from 0.06 to 0.15 mg/kg in the raw commodity and decreased with processing (the United Kingdom, 2010). The following processing factor has been derived for orange juice.

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition: chlorantraniliprole				
Oranges, juice	4	0.21	1	Chlorantraniliprole in orange juice ranged from 0.01 to 0.03 mg/kg

(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.

Since in the current application no MRL proposal is possible for oranges, the derived processing factor is not applicable. However EFSA proposes to include the derived processing factor for orange juice in Annex VI of Regulation (EC) No 396/2005 to make it available in case of a future MRL proposal for chlorantraniliprole in oranges.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Flowering brassica and beans can be grown in crop rotation. Taking also into account that the DT_{90} values for chlorantraniliprole from both laboratory and field studies proposed in the DAR (Ireland,

[16] IN-F6L99: see Appendix D
[17] IN-ECD73: see Appendix D
[18] IN-EQW78: see Appendix D

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 for to the intended UE uses was addressed in the DAR (Ireland, 2008). The overview of the study designs is presented in the table below.

Table 3-4: Table 3-3. **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 sandy loam soil	0.3 kg a.s./ha	30 DAT	365 DAT	GLP
Root and tuber vegetables	red beet	PC-^{14}C		0.3 kg a.s./ha	0, 30, 120 and 365 DAT		
Cereals	wheat						
Cereals	wheat	PC-^{14}C	Spray on sandy loam soil	0.9 kg a.s./ha	0 and 365 DAT	365 DAT	GLP
Cereals	wheat	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						
Root and tuber vegetables	radish						

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

The results show 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% TRR). The minor metabolites that were detected in various commodities were present at less than 10% 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.

3.1.2.3. Magnitude of residues

Rotational field crop studies in root crops, leafy vegetables, cereal crops and soybeans were assessed in the DAR (Ireland, 2008). The studies were performed in the United States and Canada with a maximum application rate of 600 g a.s./ha/season (*ca.* 8.5N and 4.8N the maximum rate for the intended uses on flowering brassica and beans). The residues in samples declined after each plant back interval (short: 13-61 days; intermediate: 122-151 days; long: 238-279 days). Chlorantraniliprole residues were found only on commodities intended for livestock feed (forage, straw, hay), ranging from 0.01 to 0.2 mg/kg for the plant-back intervals from 30 to 279 days.

Based on the available information on the nature and magnitude of the residues, it was concluded that relevant residue levels are unlikely to occur in rotational crops provided that chlorantraniliprole is applied on flowering brassica and beans according to the proposed GAPs.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

The applicant requested a modification of the existing EU MRLs for animal commodities from livestock raised outside the EU. Considering that livestock diet in extra EU countries includes a number of fodder crops for which there are no authorizations or MRLs set in the EU, dietary burden was calculated using the Environmental Protection Agency (EPA) model. The calculated dietary burden as reported in the following table was proposed by the applicant.

Table 3-5: Results of the dietary burden calculation as calculated according to the EPA model

	Dietary burden (mg/kg diet as received)	**Dietary burden** (mg/kg bw/d) [(a)]	**Highest contributing commodity**	**Trigger exceeded**(Y/N)
Risk assessment residue definition: Chlorantraniliprole				
Dairy ruminants	54.4	2.1	Corn stover	Y
Meat ruminants	18.46	0.31	Corn stover	Y
Poultry	2.71	0.17	Alfalfa meal	Y
Pigs	2.51	0.078	Alfalfa meal	Y

(a): Based on a 615 kg bw dairy cow consuming 24 kg feed DM/day or on a 545 kg/bw feedlot beef consuming 9.1 kg feed DM/day or on a 1.9 kg bw hen consuming 0.152 kg feed DM/day or on a pig 100 kg bw consuming 3.1 kg feed DM/day.

The calculated dietary burden indicated that the trigger value of 0.1 mg/kg dry matter (DM) was exceeded for all relevant livestock species with corn stover and alfalfa meal representing the main contributing commodities. Since it is not specified if the maximum or the mean values are calculated, the reported dietary burden is considered as the maximum. EFSA noticed that dietary burden calculations recently published in the JMPR report on chlorantraniliprole are significantly lower than the dietary burden calculated by the applicant. EMS should verify the reliability of the dietary burden calculation as proposed by the applicant.

In addition EFSA derived maximum and mean dietary burden using the agreed European methodology (EC, 1996) including the crops for which MRLs are established in the EU legislation. According to the EU approach, the input values for the dietary burden calculation were selected following the latest FAO recommendations (FAO, 2009b) considering the livestock intake from all feed products on which the use of chlorantraniliprole is authorized by Regulation (EC) No 396/2005 (e.g. for which the existing EU MRL is set above the LOQ). To refine the calculations, EFSA used the risk assessment values reported in the JMPR report on chlorantraniliprole (FAO, 2009a, 2010). The following default processing factors were used: 2.5 for pomace, 1 for silage, 4 for hay, 8 for bran, 1.3/2 for press-cake of oilseeds containing 20%/50% of fat. The input values for the dietary burden calculation are summarized in Table 3-6.

Table 3-6: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value** (mg/kg)	**Comment**
Risk assessment residue definition: chlorantraniliprole				
Cabbage	0.385	Median residue (FAO, 2010)	1.1	Highest residue (FAO, 2010)
Kale	7.3	Median residue (FAO, 2009a)	8.9	Highest residue (FAO, 2009a)
Maize silage	0.01	Median residue*PF (FAO, 2009a)	0.01	Highest residue (FAO, 2009a)
Apple pomace	1.25	MRL*PF	1.25	MRL*PF
Wheat grain	0.01	Median residue (FAO, 2009a)	0.01	Highest residue (FAO, 2009a)
Barley grain	0.01	Median residue (FAO, 2009a)	0.01	Highest residue (FAO, 2009a)
Rye grain	0.01	Median residue (FAO, 2009a)	0.01	Highest residue (FAO, 2009a)
Oat grain	0.01	Median residue (FAO, 2009a)	0.01	Highest residue (FAO, 2009a)
Maize grain	0.01	Median residue (FAO, 2009a)	0.01	Highest residue (FAO, 2009a)
Wheat bran	0.08	Median residue*PF (FAO, 2009a)	0.08	Highest residue*PF (FAO, 2009a)
Rye bran	0.08	Median residue*PF (FAO, 2009a)	0.08	Highest residue*PF (FAO, 2009a)
Wheat straw	0.051	Median residue (FAO, 2009a)	0.17	Highest residue (FAO, 2009a)
Barley straw	0.051	Median residue (FAO, 2009a)	0.17	Highest residue (FAO, 2009a)
Rye straw	0.051	Median residue (FAO, 2009a)	0.17	Highest residue (FAO, 2009a)
Oat straw	0.051	Median residue (FAO, 2009a)	0.17	Highest residue (FAO, 2009a)

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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	MRL	0.02	MRL
Fodder beets	0.02	MRL	0.02	MRL
Cotton seed	0.049	Median residue (FAO, 2009a)	0.25	Highest residue (FAO, 2009a)

The results of the dietary burden calculation as derived following the EU methodology are summarized in the following table.

Table 3-7: Results of the dietary burden as calculated according to the EU methodology

	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	0.812110	0.665704	Kale	22.333018	Y
Meat ruminants	0.958450	0.784907	Kale	22.363837	Y
Poultry	0.203226	0.167136	Kale	3.217752	Y
Pigs	0.384662	0.316090	Kale	9.616540	Y

(a): Dry matter feed

The calculated dietary burden indicated that the trigger value of 0.1 mg/kg dry matter (DM) was exceeded for all relevant livestock species with kale representing the main contributing commodity.

Dietary burdens derived with both the methodologies were compared and the highest values for each livestock species selected for the estimation of the expected chlorantraniliprole residue levels in animal commodities.

3.2.2. Nature of residues

The metabolism of chlorantraniliprole in livestock was assessed in the DAR prepared under Directive 91/414/EEC (Ireland, 2008).

The metabolic fate of chlorantraniliprole in livestock was investigated in studies performed on laying hens and lactating goats with chlorantraniliprole radiolabelled at the benzamide-carbonyl or at the pyrazole-carbonyl sites.

Following oral administration for 14 days of 10 mg chlorantraniliprole/kg feed (corresponding to 0.8 mg/kg bw per day) to laying hens, chlorantraniliprole and its metabolites were eliminated, primarily in the excreta (>98% of the dose). Eggs and edible tissues contained ca. 3% of the total administered dose. A number of metabolites were identified in tissues and eggs. The major components of the radioactivity observed in eggs at plateau were parent chlorantraniliprole (0.256 mg/kg chlorantraniliprole equivalent) and IN-GAZ70[19] (0.377 mg/kg). In hen tissues, the major component of the radioactivity was represented by parent chlorantraniliprole accounting for <0.001, 0.009 and 0.017 mg/kg in muscle, skin with fat and liver, respectively.

When ^{14}C-chlorantraniliprole was orally administered to a lactating goat at 10 mg chlorantraniliprole/kg feed, a large proportion of the dose was eliminated in the excreta (93.57% of the dose). Milk, liver, and kidney combined contained ca. 1% of the administered total dose. Parent chlorantraniliprole was the major component of the extracted radioactivity identified in kidney, muscle, and fat samples and was also identified in liver.

In milk in addition to unchanged chlorantraniliprole which accounted for 23.58% TRR (0.016 mg/kg, 0.19% dose) three metabolites were identified: IN-K9T00[20] at 26.1% TRR (0.017 mg/kg, 0.21% dose), IN-HXH44[21] at 26.92% TRR (0.018 mg/kg, 0.21% dose) and IN-HXH40[22] at 5.87% TRR (0.004 mg/kg; 0.05% dose). The presence of metabolites IN-K9T00 and IN-HXH44 at equal proportions to parent chlorantraniliprole in goat milk, suggests that they may be considered relevant for inclusion in the residue definition for animal commodities.

The metabolism of chlorantraniliprole in livestock was adequately elucidated and the RMS proposed a general residue definition for risk assessment and monitoring in animal commodities as chlorantraniliprole (Ireland, 2008). The current residue definition set in Regulation (EC) No 396/2005 is identical with the enforcement residue definition proposed by the RMS. EFSA concluded that the residue definition established in Regulation (EC) No 396/2005 is applicable. However the possibility to set a different residue definition for milk including also metabolites IN-K9T00 and IN-HXH44 and for eggs including also the metabolite IN-GAZ70 should be further investigated under the framework of the peer review. Thus, the residue definition should be considered as provisional pending the completion of the peer review under the Directive 91/914/EEC.

Sufficiently validated analytical methods are available for the enforcement of chlorantraniliprole in commodities of animal origin (see section 1.2). According to the Log P_{ow} value that for chlorantraniliprole is 2.86 at pH 7, residues are likely to be considered as fat soluble. The metabolism studies confirmed that the residues are mainly accumulating in fat and should therefore be classified as fat-soluble.

3.2.3. Magnitude of residues

Livestock feeding studies were carried out on dairy cows (dose levels of 1, 3, 10 and 50 mg/kg feed per day for 28 consecutive days) and assessed in the DAR (Ireland, 2008). The results from the metabolism study performed on hens were used to estimate the residue levels in poultry tissues. Since the animal metabolism studies indicate that the metabolic pathways do not differ between monogastric (poultry) and ruminant livestock (goat), a separate pig feeding study was not required.

[19] IN-GAZ70: see Appendix D.
[20] IN-K9T00: see Appendix D.
[21] IN HXH44: see Appendix D.
[22] IN-HXH40: see Appendix D.

In the feeding study on dairy cows, samples of meat, fat, liver, kidney and milk (whole, skimmed and cream) were taken from dosed animals and analysed for chlorantraniliprole and metabolites (IN-K9T00, IN-HXH44, IN-GAZ70, IN-EQW78[23]) concentrations.

Residues of chlorantraniliprole, IN-HXH44, and IN-K9T00 were only detected (<0.003 mg/kg) in whole milk from the lowest dose group (1 mg/kg feed) but were dose dependent, increasing at higher doses.

Residues of chlorantraniliprole, IN-HXH44, and IN-K9T00 were detected in fat, kidney, liver, and muscle. In particular IN-HXH44 was always present at levels higher than chlorantraniliprole. Residues were dose dependent, increasing with higher doses. Residues of IN-GAZ70 or IN-EQW78 were not detected (<0.003 mg/kg) in any sample from any dose group with the exception of a residue of 0.003 mg/kg for IN-EQW78 in fat from the 50 mg/kg feed group. Chlorantraniliprole residues in fat are 4.7N higher than in muscle.

In order to derive the MRL proposals, the results from the feeding study carried out on dairy cows and from the metabolism study carried out on hens were interpolated with the highest dietary burden calculations derived by both EU and EPA methodologies.

Based on the results of the feeding studies carried out with chlorantraniliprole, and considering the dietary burden as reported in tables 3.5 and 3.7, the existing EU MRLs for animal origin commodities should be amended as follow: ruminants (bovine, sheep and goat) meat, fat, liver, kidney and edible offal at levels of 0.2, 0.2, 0.15, 0.09 and 0.15 mg/kg, respectively, swine fat and meat at 0.04 mg/kg, swine liver, kidney and edible offal at 0.03 mg/kg, milk and eggs at 0.04 and 0.08 mg/kg, respectively.

Since chlorantraniliprole is fat soluble the MRL for meat, taking into account the wording of the footnote in Regulation (EC) No 600/2010[24] should be expressed on fat basis[25].

[23] IN-EQW78: see Appendix D.

[24] Commission Regulation (EC) No 600/2010 of 8 July 2010. OJ L 174, 09.07.2010, p. 18-39.

[25] Footnote 5 of Regulation (EC) No 600/2010 reads: "….Where a pesticide and/or metabolite (included in the residue definition is/are fat soluble (log P_{ow} greater or equal to 3) the MRL is expressed as mg/kg fat contained in the meat, preparations of meat, offal and animal fats. In case of foodstuffs with a fat content of 10 % or less by weight, the residue is related to the total weight of the boned foodstuff. In such cases, the maximum level is one-tenth of the value related to fat content, but must be no less than 0.01 mg/kg."

Table 3-8: Overview of the values derived from the livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) (c)	Highest residue (mg/kg) (d)	MRL proposal (mg/kg) (e)	CF for RA
	Median (mg/kg bw/d) [mg/kg feed DM] (a)	Max. (mg/kg bw/d) [mg/kg feed DM]	Dose Level (mg/kg bw/d) [mg/kg feed DM] (b)	No	Result for enf. RD		Result for RA RD					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition: chlorantraniliprole												
Ruminant muscle	-	2.1 (54.4)	0.029 (1)	3	ND	ND	ND	ND	0.021	0.032	0.2 (F)	1
			0.084 (3)	3	0.003	0.004	0.003	0.004				
			0.280 (10)	3	0.007	0.009	0.007	0.009				
			1.375 (50)	3	0.019	0.029	0.019	0.029				
Ruminant fat	-	2.1 (54.4)	0.029 (1)	3	0.003	0.004	0.003	0.004	0.15	0.17	0.2	1
			0.084 (3)	3	0.009	0.015	0.009	0.015				
			0.280 (10)	3	0.029	0.036	0.029	0.036				
			1.375 (50)	3	0.14	0.16	0.14	0.16				
Ruminant liver	-	2.1 (54.4)	0.029 (1)	3	0.004	0.005	0.004	0.005	0.14	0.14	0.15	1
			0.084 (3)	3	0.010	0.014	0.010	0.014				
			0.280 (10)	3	0.029	0.035	0.029	0.035				
			1.375 (50)	3	0.13	0.13	0.13	0.13				
Ruminant kidney	-	2.1 (54.4)	0.029 (1)	3	ND	ND	ND	ND	0.075	0.09	0.09	1
			0.084 (3)	3	0.006	0.009	0.006	0.009				
			0.280 (10)	3	0.022	0.035	0.022	0.035				
			1.375 (50)	3	0.068	0.081	0.068	0.081				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) (c)	Highest residue (mg/kg) (d)	MRL proposal (mg/kg) (e)	CF for RA
	Median (mg/kg bw/d) [mg/kg feed DM] (a)	Max. (mg/kg bw/d) [mg/kg feed DM]	Dose Level (mg/kg bw/d) [mg/kg feed DM] (b)	No	Result for enf. RD		Result for RA RD					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Poultry muscle	0.17 (2.74)	0.20 (3.22)	0.8 (10)	5	0.001	0.001	0.001	0.001	0.001	0.001	0.01	1
Poultry fat	0.17 (2.74)	0.20 (3.22)	0.8 (10)	5	0.009	-	0.009	-	0.002	-	0.01	1
Poultry liver	0.17 (2.74)	0.20 (3.22)	0.8 (10)	5	0.017	-	-	-	0.004	-	0.01	1
Pig muscle	0.32 (7.89)	0.39 (9.62)	0.029 (1)	3	ND	ND	ND	ND	0.005	0.007	0.04 (F)	1
			0.084 (3)	3	0.003	0.004	0.003	0.004				
			0.280 (10)	3	0.007	0.009	0.007	0.009				
			1.375 (50)	3	0.019	0.029	0.019	0.029				
Pig fat	0.32 (7.89)	0.39 (9.62)	0.029 (1)	3	0.003	0.004	0.003	0.004	0.023	0.034	0.04	1
			0.084 (3)	3	0.009	0.015	0.009	0.015				
			0.280 (10)	3	0.029	0.036	0.029	0.036				
			1.375 (50)	3	0.14	0.16	0.14	0.16				
Pig liver	0.32 (7.89)	0.39 (9.62)	0.029 (1)	3	0.004	0.005	0.004	0.005	0.023	0.030	0.03	1
			0.084 (3)	3	0.010	0.014	0.010	0.014				
			0.280 (10)	3	0.029	0.035	0.029	0.035				
			1.375 (50)	3	0.13	0.13	0.13	0.13				
Pig kidney	0.32 (7.89)	0.39 (9.62)	0.029 (1)	3	ND	ND	ND	ND	0.016	0.022	0.03	1
			0.084 (3)	3	0.006	0.009	0.006	0.009				
			0.280 (10)	3	0.022	0.035	0.022	0.035				
			1.375 (50)	3	0.068	0.081	0.068	0.081				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) (c)	Highest residue (mg/kg) (d)	MRL proposal (mg/kg) (e)	CF for RA
	Median (mg/kg bw/d) [mg/kg feed DM] (a)	Max. (mg/kg bw/d) [mg/kg feed DM]	Dose Level (mg/kg bw/d) [mg/kg feed DM] (b)	No	Result for enf. RD		Result for RA RD					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Milk	-	2.1 (54.4)	0.029 (1)	21	ND	ND	ND	ND	0.023	0.037	0.04	1
			0.084 (3)	21	ND	ND	ND	ND				
			0.280 (10)	21	0.005	0.009	0.005	0.009				
			1.375 (50)	21	0.021	0.034	0.021	0.034				
Eggs	0.17 (2.74)	0.20 (3.22)	0.8 (10)	5	0.282	0.308	0.282	0.308	0.06	0.08	0.08	1

(a): Based on a 615 kg/bw dairy cattle consuming 24 kg feed DM/day and on a 1.9 kg/bw hen consuming 0.12 kg feed DM/day (EPA model).
(b): Based on a 650 kg/bw dairy cattle consuming 17 kg feed DM/day or based on a 1.8 kg/bw hen consuming 0.163 kg feed DM/day.
(c): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden.
(d): Highest residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for maximum dietary burden.
(e): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for the appropriate feeding level.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
ND: Not detectable residues (<0.003 mg/kg).
(-): indicates that the data were not available because not reported in the evaluation report or in the DAR.

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 [26] (EFSA, 2007).

For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on table and wine grapes, cane fruit, blueberries, cranberries, radishes, flowering brassicas (cauliflower and other flowering brassica) and beans with pods (see Table 3-2), the median residue values reported in the JMPR report on chlorantraniliprole (FAO, 2009a), and in previously issued EFSA reasoned opinion (EFSA, 2010). For the commodities of animal origin under evaluation, MRLs were used as input values since median values as derived from dietary burden calculations and animal feeding studies are not reliable (see Table 3-8). For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. The model assumptions for the long-term exposure assessment are considered to be 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.

Acute consumer exposure was not performed since the setting of an ARfD was considered not necessary for chlorantraniliprole.

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				
Table and wine grapes	0.22	Median residue	Not relevant	
Cane fruit	0.35	Median residue		
Blueberries	0.21	Median residue		
Cranberries	0.22	Median residue		
Radishes	0.05	Median residue		
Flowering brassica (cauliflower and other flowering brassica)	0.06	Median residue		
Beans with pods	0.12	Median residue		
Carrots	0.025	Median residue (EFSA, 2010)		

[26] 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
Swine: meat	0.01	Median residue[(a)]		
Swine: fat	0.04	MRL		
Swine: liver	0.03	MRL		
Swine: kidney	0.03	MRL		
Swine: edible offal	0.03	MRL		
Bovine: meat	0.05	Median residue[(a)]		
Bovine: fat	0.2	MRL		
Bovine: liver	0.15	MRL		
Bovine: kidney	0.09	MRL		
Bovine: edible offal	0.15	MRL		
Sheep: meat	0.05	Median residue[(a)]		
Sheep: fat	0.2	MRL		
Sheep: liver	0.15	MRL		
Sheep: kidney	0.09	MRL		
Sheep: edible offal	0.15	MRL		
Goat: meat	0.05	Median residue[(a)]		
Goat: fat	0.2	MRL		
Goat: liver	0.15	MRL		
Goat: kidney	0.09	MRL		
Goat: edible offal	0.15	MRL		
Milk and cream	0.04	MRL		
Birds' eggs	0.08	MRL		
Other commodities of food and animal origin	MRL	See Appendix C		

(a): median residue calculated according to the latest JMPR recommendations (FAO, 2009b) 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. The highest contribution of residues to the total consumer exposure was given by wine grapes and accounted for a maximum of 0.056% of the ADI (FR, all population diet).

Consequently EFSA concludes that the intended import tolerance of chlorantraniliprole on table and wine grapes, cane fruit, blueberries, cranberries, radishes, and commodities of animal origin and the intended uses on flowering brassicas (cauliflower and other flowering brassicas) and beans with pods will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of chlorantraniliprole has been evaluated in the DAR prepared by the rapporteur Member State (RMS) 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, these values 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. From these studies the RMS proposed to establish the residue definition for risk assessment and enforcement as chlorantraniliprole. For the intended import tolerances and EU uses, EFSA concluded that the metabolism of chlorantraniliprole in primary crops is sufficiently elucidated and that the derived residue definitions are appropriate.

The supervised residue trials are sufficient and adequate to derive MRL proposals for the intended uses on table and wine grapes, cane fruit, blueberries, cranberries, radishes, cauliflower and other flowering brassicas (in northern Europe) and beans with pods. For the intended import tolerances on oranges and rice, supervised residues trials were not representative for the intended GAPs, thus data were not suitable for deriving MRL proposals and risk assessment values. The studies demonstrated that the following import tolerances and MRLs would be appropriate for the use of chlorantraniliprole on: table and wine grapes, cane fruit and blueberries: 1.5 mg/kg; cranberries: 0.7 mg/kg; radishes: 0.5 mg/kg; beans with pods: 0.5 mg/kg; cauliflower and other flowering brassica: 0.3 mg/kg. Analytical methods are available to enforce the proposed MRLs on the commodities under consideration.

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, the applicant submitted a processing study carried out on oranges processed into juice. The following processing factor has been derived:

- Oranges, juice: 0.21

Since in the current application no MRL proposal is possible for oranges, the derived processing factor is not applicable. However EFSA proposes to include the derived processing factor for orange juice in Annex VI of Regulation (EC) No 396/2005 to have it available in case of a future MRL proposal for chlorantraniliprole in oranges.

The occurrence of chlorantraniliprole residues in rotational crops for the intended uses in EU was investigated in the DAR. Based on the available information on the nature and magnitude of the residues, it was concluded that relevant residue levels are unlikely to occur in rotational crops provided that chlorantraniliprole is applied on flowering brassica and beans according to the proposed GAPs.

The applicant requested a modification of the existing EU MRLs for animal commodities from livestock raised outside the EU. Considering that livestock diet in extra EU countries includes a number of fodder crops for which there are no authorizations or MRLs set in the EU, dietary burden was calculated by the applicant using the Environmental Protection Agency (EPA) model. The dietary burden calculated according to the EPA model indicated that the trigger value of 0.1 mg/kg dry matter (DM) was exceeded for all relevant livestock species with corn stover and alfalfa meal representing the main contributing commodities. EFSA noticed that dietary burden calculations as recently published in the JMPR report on chlorantraniliprole are significantly lower than the dietary burden

calculated by the applicant. EMS should verify the reliability of the dietary burden calculation as proposed by the applicant.

In addition EFSA derived maximum and mean dietary burdens using the agreed European methodology. The calculated dietary burden indicated that the trigger value of 0.1 mg/kg dry matter (DM) was exceeded for all relevant livestock species with kale representing the main contributing commodity.

Dietary burdens derived with both methodologies were compared and the highest values selected for the estimation of the expected chlorantraniliprole residue levels in animal commodities.

The metabolism of chlorantraniliprole in livestock was adequately elucidated and the RMS proposed a general residue definition for risk assessment and monitoring in animal commodities as chlorantraniliprole. The current residue definition set in Regulation (EC) No 396/2005 is identical with the enforcement residue definition proposed by the RMS. EFSA concluded that the residue definition established in Regulation (EC) 396/2005 is applicable. However, the possibility to set a different residue definition for milk including also metabolites IN-K9T00 and IN-HXH44 and for eggs including also the metabolite IN-GAZ70 should be further investigated under the framework of the peer review. Thus, the residue definition should be considered as provisional pending the completion of the peer review under the Directive 91/914/EEC. According to the Log P_{ow} value that for chlorantraniliprole is 2.86 at pH 7, residues are likely to be considered as fat soluble. The metabolism studies confirmed that the residues are mainly accumulating in fat and should therefore be classified as fat-soluble.

The dietary burdens calculated by both EPA model and EU methodology and the results of livestock feeding studies were used to derive the following MRL proposals: ruminants (bovine, sheep and goat) meat, fat, liver, kidney and edible offal: 0.2, 0.2, 0.15, 0.09 and 0.15 mg/kg, respectively; swine meat and fat: 0.04 mg/kg; swine liver, kidney and edible offal: 0.03 mg/kg; milk: 0.04 mg/kg; eggs: 0.08 mg/kg.

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 table and wine grapes, cane fruit, blueberries, cranberries, radishes, cauliflower, other flowering brassica and beans with pods, the median residue values reported in the JMPR report on chlorantraniliprole and in previously issued EFSA reasoned opinion. For the commodities of animal origin under evaluation, the MRL proposals were used as input values since median values as derived from dietary burden calculations and animal feeding studies were not reliable. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values.

Acute consumer exposure was not performed since the setting of an ArfD was considered not necessary for chlorantraniliprole.

The estimated exposure was then compared with the toxicological reference value proposed 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. The highest contribution of residues to the total consumer exposure was given by wine grapes and accounted for a maximum of 0.056% of the ADI (FR, all population diet).

Consequently EFSA concludes that the occurrence of residues at the proposed MRLs in commodities of plant and animal origin will not result in a consumer exposure posing a consumer health risk.

Since the peer review under Directive 91/414/EEC has not yet been 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)				
110020	Oranges	0.01*	-	Residue data are not sufficient for deriving an MRL proposal.
151010	Table and wine grapes	1	1.5	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended import tolerances.
153000	Cane fruit	0.01*	1.5	
154010	Blueberries	0.01*	1.5	
154020	Cranberries	0.01*	0.7	
213080	Radishes	0.02	0.5	
241020	Cauliflower	0.01*	0.3	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses.
241990	Flowering brassica, others	0.01*	0.3	
260010	Beans with pods	0.01*	0.5	
500060	Rice	0.02	-	Residue data are not sufficient for deriving an MRL proposal.
1011010	Swine: meat	0.01*	0.04 (F)	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended import tolerances.
1011020	Swine: fat	0.01*	0.04	
1011030	Swine: liver	0.01*	0.03	
1011040	Swine: kidney	0.01*	0.03	
1011050	Swine: edible offal	0.01*	0.03	
1012010 1013010 1014010	Bovine, sheep, goat: meat	0.01*	0.2 (F)	
1012020 1013020 1014020	Bovine, sheep, goat: fat	0.01*	0.2	
1012030 1013030 1014030	Bovine, sheep, goat: liver	0.01*	0.15	
1012040 1013040 1014040	Bovine, sheep, goat: kidney	0.01*	0.09	
1012050 1013050 1014050	Bovine, sheep, goat: edible offal	0.01*	0.15	
1020000	Milk and cream	0.01*	0.04	
1030000	Birds' eggs	0.01*	0.08	

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.

REFERENCES

EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95 rev.4. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm.

EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev.4. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2004. Residue analytical methods. For post-registration control. SANCO/825/00-rev.7. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2008. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.8. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2010. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalized in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.

EFSA (European Food Safety Authority), 2010. Reasoned opinion on the modification of the existing MRL for chlorantraniliprole in carrots prepared by EFSA Pesticide Risk Assessment Peer Review (PRAPeR) Unit. EFSA Journal 2010; 8(10):1859, 27 pp.

EFSA (European Food Safety Authority), 2007. Pesticide Residues Intake Model for assessment of acute and chronic consumer exposure to pesticide residues-rev.2. Available from http://www.efsa.europa.eu/en/mrls/mrlteam.htm

FAO (Food and Agriculture Organization of the United Nations), 2010. Chlorantraniliprole. In: Pesticide residues in food –2010. Report of the Joint Meeting of the FAO Panel of Experts on

Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 200, 67-75 pp.

FAO (Food and Agriculture Organization of the United Nations), 2009a. Chlorantraniliprole. In: Pesticide residues in food—2008. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 194, 353-546 pp.

FAO (Food and Agriculture Organization of the United Nations), 2009b. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed**.** Pesticide Residues. 2nd Ed.

Ireland, 2008. Draft assessment report on the active substance chlorantraniliprole prepared by the rapporteur Member State Ireland in the framework of Council Directive 91/414/EEC, December 2008.

The United Kingdom, 2010. Evaluation report on the modification of MRLs for Chlorantraniliprole in various crops prepared by the evaluating Member State the United Kingdom under Article 8 of Regulation (EC) No 396/2005, June 2010, 97 pp.

Appendix A. GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and/or situation	Member State or Country	F G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
				type	conc. of a.s.	method kind	growth stage & season	number min max	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
(a)		(b)	(c)	(d - f)	(i)	(f - h)	(j)	(k)					(k)	(m)
Oranges	Import (Brazil)	F	*Diaphorina citri, Phyllocnistis citrella, Aleurocanthus woglumi, Ecdytolopha aurantiana*	ZC	100 g/kg (+ 50 g/kg lambda cyhalothrin)	Foliar spray	-	2	21 days	0.0015-0.0045	2000	0.03-0.09	5	-
	Import (Brazil)	F	*Toxoptera citricida, Diaphorina citri, Phyllocnistis citrell*	SC	100 g/kg (+ 200 g/kg lambda thiamethoxam)	Soil drench	-	1	-	-	-	0.12-0.24	5	Apply 1-2 mL product/metre of medium height of plants
	Import (South Africa)	F	*False codling moth Thaumatotibia leucotreta*	SC	200 g/L	Mist blower & directed boom/ha	BBCH 74-88	1-2	30 days	0.0035	2000-8500	0.07-0.298	7	-
Grapes (table and wine)	Import (USA)	F	*E. viteana, H. americana, H. brillians, P. Stultana, chewing insects*	WP	350 g/kg	Broadcast ground sprayer (high volume) Aerial spraying (low volume)	BBCH 53-89	1-4	7 days	-	Ground: 467-2337 Aerial: 93-140	0.05-0.111	14	Maximum seasonal application rate 0.221 kg a.s./ha + non-ionic surfactant

Crop and/or situation	Member State or Country	F G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
				type	conc. of a.s.	method kind	growth stage & season	number min max	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
(a)		(b)	(c)	(d - f)	(i)	(f - h)	(j)	(k)					(k)	(m)
Cane fruit	Import (USA and Canada)	F	*Raspberry Crown Borer Chewing pests*	WG	350 g/kg	Ground	BBCH 11-89	1-3	14 days	-	280-2337	0.074-0.111	3	Maximum seasonal application rate 0.225 kg a.s./ha Aerial GAP also approved in USA but not supported for this import tolerance. + non-ionic surfactant.
Blueberries and cranberries	Import (USA and Canada)	F	*Raspberry Crown Borer Chewing pests*	WG	350 g/kg	Ground	BBCH 11-89	1-3	14 days	-	280-2337	0.074-0.111	3	Maximum seasonal application rate 0.225 kg a.s./ha + non-ionic surfactant
Radishes	Import (USA)	F	*L. decemlineata, O. nubilalis, T. ni Chewing insects*	SC	200 g/L	Ground sprayer (low volume); aerial spraying (low volume) and drip	BBCH 12-89	1-4	Foliar spray: 3 days Drip chemigation: 10 days	-	Ground: 93 – 935 L/ha Aerial: 47 – 93 L/ha	0.029 – 0.110	1	Maximum seasonal application rate = 0.219 kg a.s./ha

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (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		
						chemigation (high volume)								
Cauliflower	NEU	F	*Plutella spp., M. Brassicae, P. Brassicae, P. Rapae, S. exigua, S. littoralis*	WG	350 g/kg	Tractor mounted hydraulic sprayer	When pests are present	1-2	7-10 days	-	200-800	0.035	1	Minimum recommended application rate is 0.026 kg a.s./ha
Beans with pods	SEU	G	*S. exigua, S. littoralis, H. armigera*	WG	350 g/kg	broadcast high pressure mist blower	BBCH 15 – 89	1-2	7-14 days	0.0028-0.0042	500-15000	0.063	1	Minimum recommended application rate is 0.028 kg a.s./ha
	EU	F	*H. armigera, O. nubilalis, S. littoralis, P. gamma*	WG	350 g/kg	Tractor mounted hydraulic sprayer	BBCH 15 – 89	1-2	7-10 days	-	250-1000	0.042	1	-
Rice	Import (USA)	F	*Rice water weevil, chewing pests*	SF	625 g/L	Seed treatment	BBCH 0-49	1	-	-	-	0.15	-	

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
(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:	0.01
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**

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
1.2	IT adult	0.5	Lettuce	0.2	Other lettuce and other salad plants	0.1	Spinach	0.0
1.2	WHO Cluster diet B	0.5	Lettuce	0.1	Tomatoes	0.1	Chinese cabbage	0.0
1.1	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
0.9	IE adult	0.3	Other leafy brassica	0.2	Spinach	0.1	Lettuce	0.0
0.9	ES child	0.5	Lettuce	0.1	Spinach	0.1	Beet leaves (chard)	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 18/01/2011 11:51)

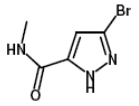
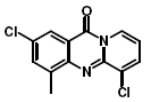
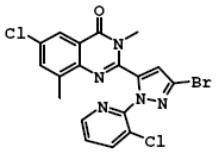
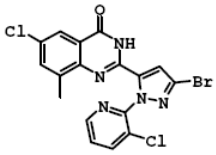
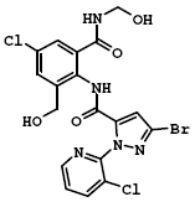
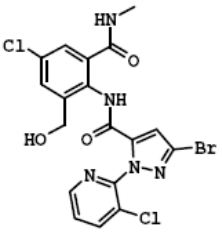
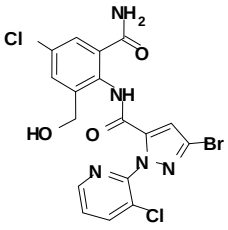
Code number	Groups and examples of individual products to which the MRLs apply	Chlorantraniliprole
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto 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	0,01*
153010	Blackberries	0,01*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,01*
153030	Raspberries (Wineberries)	0,01*
153990	Others	0,01*
154000	(d) Other small fruit & berries	0,01*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,01*
154020	Cranberries	0,01*
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**[(a)]
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)	0,02
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
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	0,01*
241990	Others	0,01*
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 cornsalad)	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	20
	leaves, lovage, angelica, sweet cisely and other Apiacea)	
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)	0,01*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,01*
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,	0,01*
	Truffle, Morel ,)	
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
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*
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	0,01*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,01*
1011000	(a) Swine	0,01*
1011010	Meat	0,01*
1011020	Fat free of lean meat	0,01*
1011030	Liver	0,01*
1011040	Kidney	0,01*
1011050	Edible offal	0,01*
1011990	Others	0,01*
1012000	(b) Bovine	0,01*
1012010	Meat	0,01*
1012020	Fat	0,01*
1012030	Liver	0,01*
1012040	Kidney	0,01*
1012050	Edible offal	0,01*
1012990	Others	0,01*
1013000	(c) Sheep	0,01*
1013010	Meat	0,01*
1013020	Fat	0,01*
1013030	Liver	0,01*
1013040	Kidney	0,01*
1013050	Edible offal	0,01*
1013990	Others	0,01*
1014000	(d) Goat	0,01*
1014010	Meat	0,01*
1014020	Fat	0,01*
1014030	Liver	0,01*
1014040	Kidney	0,01*
1014050	Edible offal	0,01*
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*
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	0,01*
1020010	Cattle	0,01*
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
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	0,01*
1030010	Chicken	0,01*
1030020	Duck	0,01*
1030030	Goose	0,01*
1030040	Quail	0,01*
1030990	Others	0,01*
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*

[a] Temporary MRL value as proposed by EFSA in its reasoned opinion (EFSA,2010) and voted at the SCFCAH on 9-10 December 2010. SANCO 13123/2010. Not legally enforced by 18 January 2011.
(*) indicates lower limit of analytical determination

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	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-6-chloro-8-methyl-4(3H)-quinazolinone	
IN-K9T00	3-Bromo-N-[4-chloro-2-(hydroxymethyl)-6-[[(hydroxymethyl)amino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1Hpyrazole-5-carboxamide	
IN-HXH44	3-Bromo-N-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide	
IN-HXH40	N-[2-Aminocarbonyl]-4-chloro-6-(hydroxymethyl)phenyl]-3-bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide	

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
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DM	dry matter
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FS	flowable concentrate for seed treatment
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detector
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
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
L	litre
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
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
SCFCAH	Standing Committee on the Food Chain and Animal Health
SEU	Southern European Union
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultra-violet (detection or detector)
WG	water dispersible granule
WHO	World Health Organisation
ZC	Mixed heterogeneous formulation of capsule and concentrate suspensions