

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for chromafenozide in pome fruits and grapes¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Hungary, hereafter referred to as the evaluating Member State (EMS), received an application from Arysta LifeScience on behalf of Nippon Kayaku Co. Ltd to modify the existing MRLs for the active substance chromafenozide in pome fruits and grapes. In order to accommodate for the intended uses of chromafenozide, Hungary proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 mg/kg in grapes and pome fruits except apples and from 0.3 mg/kg in apples to 1.5 mg/kg in grapes, 0.4 mg/kg in apples and 0.5 mg/kg in the other pome fruits. Hungary drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA. According to EFSA the data are sufficient to derive MRL proposals of 0.6 mg/kg and 1.5 mg/kg for the intended uses on pome fruits and grapes, respectively. As alternative option, risk managers may consider the MRL of 0.5 mg/kg for the group of pome fruits. An analytical enforcement method is available to control the residues of chromafenozide on the commodities under consideration. Based on the risk assessment results, EFSA concludes that the proposed uses of chromafenozide on pome fruits and table and wine grapes will not result in a consumer exposure exceeding the toxicological reference value and therefore are unlikely to pose a consumer health risk.

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KEY WORDS

chromafenozide, pome fruits, grapes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, diacylhydrazine insecticide

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Hungary, hereafter referred to as the evaluating Member State (EMS), received an application from Arysta LifeScience on behalf of Nippon Kayaku Co. Ltd to modify the existing MRLs for the active substance chromafenozide in pome fruits and grapes. In order to accommodate for the intended uses of chromafenozide, Hungary proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 mg/kg in grapes and pome fruits except apples and from 0.3 mg/kg in apples to 1.5 mg/kg in grapes, 0.4 mg/kg in apples and 0.5 mg/kg in the other pome fruits. Hungary drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 3 April 2012. EFSA identified some data requirements, which prevented EFSA to conclude on the consumer risk assessment. On 20 December 2013 the EMS provided the reply in a revised evaluation report, which replaces the previous document.

EFSA bases its assessment on the revised evaluation report, the Draft Assessment Report (DAR) and its final addendum prepared under Council Directive 91/414/EEC and the EFSA conclusion on the peer review of the active substance chromafenozide.

The toxicological profile of chromafenozide was assessed during the peer review and the data were sufficient to propose an ADI of 0.27 mg/kg bw per day. No ARfD was deemed necessary.

Based on the results from the metabolism study on apples after foliar applications, the peer review proposed the parent chromafenozide as residue definition for enforcement and risk assessment in the fruits and fruiting vegetables. For the uses on pome fruits and grapes, EFSA concludes that the metabolism of chromafenozide is sufficiently addressed and the residue definitions for enforcement and risk assessment proposed during the peer review are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals of 0.6 mg/kg and 1.5 mg/kg for the intended uses on pome fruits and grapes, respectively. As alternative option, risk managers may consider the MRL of 0.5 mg/kg for the group of pome fruits. An analytical enforcement method is available to control the residues of chromafenozide on the commodities under consideration at the validated LOQ of 0.01 mg/kg. EFSA confirms the data gap identified in the peer review regarding the lack of information demonstrating the efficiency of the extraction step involved in the sample preparation. However, this data gap is considered as being of minor relevance and should be addressed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005.

Specific studies investigating the nature of chromafenozide residues in processed commodities are not available. Although desirable, such studies are not required as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI. The results of the processing studies on grape processed products submitted in the framework of the current MRL application give evidence that a reduction of chromafenozide residues in grape juice, must and wine occurs. EFSA does not recommend the inclusion of the derived processing factors in Annex VI of Regulation (EC) No 396/2005 due to the uncertainties (high variability of results, limited number of studies) of the processing studies.

Since the proposed uses of chromafenozide are on permanent crops, investigations of residues in rotational crops are not required.

Apple pomace is used as feed product in the ruminant diet, therefore a potential carry-over into food of animal origin should be considered. According to the results of the metabolism study in lactating goats, significant residue levels of chromafenozide are not expected in food of animal origin at the calculated dietary burdens. Therefore, the setting of MRLs in commodities of animal origin is not required in the framework of the current application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). For the calculation of the chronic exposure EFSA used the median residue values as derived from the residue trials on apples, pears and grapes and the existing MRLs for the other commodities of plant origin. No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for less than 1 % of the ADI (German child diet). Wine grapes and apples were the main contributors to the dietary burden accounting for a maximum of 0.6 % and 0.5 % of the ADI, respectively. No acute exposure calculation was necessary because of the low acute toxicity of chromafenozide.

EFSA concludes that the proposed uses of chromafenozide on pome fruits and table and wine grapes will not result in a consumer exposure exceeding the toxicological reference value and therefore are unlikely to pose a consumer health risk.

Since a decision concerning the approval of the active substance chromafenozide in accordance with Regulation (EC) No 1107/2009 has not been made, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the regulatory procedure.

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

SUMMARY TABLE

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: chromafenozide				
130000	Pome fruit	0.3 (apples)	0.6 or 0.5	The MRL proposal, derived by extrapolation from residue trials on apples and pears, is sufficiently supported by data and no risk for consumers was identified for the intended NEU and SEU use on pome fruits. As risk manager option, the MRL of 0.6 mg/kg is derived from the dataset of NEU residue trials (more critical residue situation), whereas the MRL of 0.5 mg/kg is derived combining the NEU and SEU residue trials in a single dataset.
		0.01* (other pome fruits)		
151000	Table and wine grapes	0.01*	1.5	The MRL proposal, derived from residue trials on grapes, is sufficiently supported by data and no risk for consumers was identified for the intended NEU and SEU use on grapes.

(A): According to Annex Me of Regulation (EC) No 396/2005.

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

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BACKGROUND

Regulation (EC) No 396/2005³ establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, shall submit to a Member State, when appropriate, an application to set or modify a MRL in accordance with the provisions of Article 7 of that Regulation.

Hungary, hereafter referred to as the evaluating Member State (EMS), received an application from the company Arysta LifeScience⁶ on behalf of Nippon Kayaku Co. Ltd to modify the existing MRLs for the active substance chromafenozide in pome fruits and grapes. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 3 April 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00483 and the following subject:

Chromafenozide - Application to modify the existing MRLs in pome fruit and grapes.

Hungary proposed to raise the existing MRLs of chromafenozide from the LOQ of 0.01 mg/kg in table and wine grapes and pome fruits, except apples, and from 0.3 mg/kg in apples to 1.5 mg/kg in grapes, 0.4 mg/kg in apples and 0.5 mg/kg in the other pome fruits. EFSA identified some data gaps, which prevented EFSA to conclude on the consumer risk assessment. On 20 December 2013 the EMS provided a revised evaluation report addressing those data gaps, which was taken into consideration by EFSA for the finalization of this reasoned opinion.

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

TERMS OF REFERENCE

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

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

In this particular case the deadline for providing the reasoned opinion is 20 December 2013⁷.

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

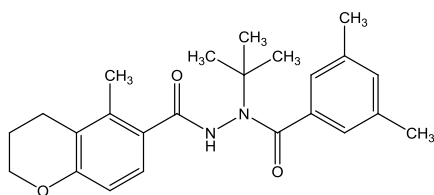
⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

⁶ Arysta LifeScience, Route d'Artix, BP 80, 64150, Noguères, France.

⁷ Date of submission of additional information to EFSA.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Chromafenozide is the ISO common name for *N'*-*tert*-butyl-5-methyl-*N'*-(3, 5-xyloyl)chromane-6-carbohydrazide (IUPAC). The chemical structure of the compound is reported below.



Molecular weight: 394.5 g/mol

Chromafenozide belongs to the diacylhydrazine chemical class. The compound has contact and stomach action activity and is considered to be non-systemic in plants (Hungary, 2013a). Chromafenozide is intended to be used as an insecticide on orchards; it interferes with the production of the natural insect moulting hormone, ecdysone.

Chromafenozide is a new active substance currently not yet approved under Regulation (EC) No 1107/2009, for which the European Commission has established the completeness of the application dossier (Commission Decision 2006/586/EC⁸). According to the transitional measures provided for in Regulation (EC) No 1107/2009, the procedure of Council Directive 91/414/EEC shall continue to apply. Hungary is acting as the rapporteur Member State (RMS). The representative uses proposed by the applicant were foliar applications on apples. The Draft Assessment Report (DAR) of chromafenozide has been peer reviewed by EFSA. The EFSA conclusion has been published recently (EFSA, 2013). The regulatory procedure is currently in progress and a final decision concerning the approval of the pesticide active substance chromafenozide under Regulation (EC) No 1107/2009 has not yet been taken.

The EU MRLs for chromafenozide are established in Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). The existing EU MRLs for chromafenozide on table and wine grapes and pome fruits, except apples, are set at the LOQ of 0.01 mg/kg and on apples at 0.3 mg/kg. Codex Alimentarius has not established CXLs for chromafenozide.

The details of the intended GAPs for chromafenozide on pome fruits and grapes in Europe are given in Appendix A.

ASSESSMENT

EFSA bases its assessment on the revised evaluation report submitted by the EMS (Hungary, 2013b), the Draft Assessment Report (DAR) and its final addendum prepared under Council Directive 91/414/EEC (Hungary, 2012; 2013a) and the conclusion on the peer review of the pesticide risk assessment of the active substance chromafenozide (EFSA, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

⁸ Commission Decision (2006/586/EC) of 25 August 2006 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of chromafenozide, halosulfuron, tembotrione, valiphenal and Zucchini yellow mosaic virus — weak strain in Annex I to Council Directive 91/414/EEC. OJ L 236 of 31.08.2006, p. 31-33.

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

Since a decision concerning the approval of the active substance chromafenozide in accordance with Regulation (EC) No 1107/2009 has not been made, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the regulatory procedure.

1. Method of analysis

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

An analytical enforcement method is available to monitor chromafenozide residues in high water (apple, pears) and acid (grape) content commodities with a LOQ of 0.01 mg/kg (EFSA, 2013). The determination is carried out by high performance liquid chromatography (HPLC) with a diode array detector or UV detector. However, data gaps were identified for verification of the extraction efficiency for commodities with high water content and for confirmatory method/data for high water and high acid content matrices (EFSA, 2013).

A confirmatory method validated on high water (apple) and high acid (grape) content matrices was submitted in the revised evaluation report (Hungary, 2013b). Analyses were performed by HPLC with tandem mass spectrometry (MS/MS). Additionally, a new HPLC-MS/MS method monitoring two ion transitions was proposed for enforcement purpose on high water (apple), high acid (grapes), high oil (olive) content commodities and on wheat straw. The method was sufficiently validated in terms of specificity, linearity, precision, accuracy at the LOQ of 0.01 mg/kg (Hungary, 2013b).

Since the commodities under consideration belong to the group of high water and high acid content commodities, EFSA concludes that a sufficiently validated analytical method for enforcing the proposed MRLs for chromafenozide on pome fruits and grapes is available. The data gap regarding the extraction efficiency is still open. However, since this deficiency is considered as a minor point, it should be addressed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005.

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

Since the setting of MRLs for chromafenozide in commodities of animal origin is not proposed in the framework of the current MRL application (see Section 3.2), EFSA confirms the conclusion of the peer review that analytical methods for the determination of residues in food of animal origin are not required (EFSA, 2013).

2. Mammalian toxicology

The toxicological profile of the active substance chromafenozide was assessed during the peer review (Hungary, 2012; EFSA, 2013) and the data were sufficient to derive toxicological reference values for chromafenozide which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Chromafenozide					
ADI	EFSA	2013	0.27 mg/kg bw per day	Dog, 1-year study	100
ARfD	EFSA	2013	Not necessary.		

Since a final decision concerning the approval of the pesticide active substance chromafenozide under Regulation (EC) No 1107/2009 has not been taken, the assessment and the derived toxicological reference value should be considered as provisional.

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 chromafenozide in primary crops was investigated during the peer review on fruits and fruiting vegetables (apples), pulses and oilseed (soybeans) and cereals (rice) using ^{14}C -labelled chromafenozide after foliar applications. The details of the metabolism studies are reported in the DAR (Hungary, 2013a). Based on the results from the metabolism study on apples, the peer review proposed the parent chromafenozide as residue definition for enforcement and risk assessment in the fruits and fruiting vegetables crop group (EFSA, 2013). The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

For the uses on pome fruits and grapes, EFSA concludes that the metabolism of chromafenozide is sufficiently addressed and the residue definitions for enforcement and risk assessment proposed during the peer review are applicable.

3.1.1.2. Magnitude of residues

a. Pome fruits

NEU. Ten GAP-compliant supervised residue trials on apples assessed during the peer review (EFSA, 2013) and one GAP-compliant supervised residue trial on pears conducted in northern France were provided. The extrapolation of data on apples or pears (with a minimum of 4 trials on apples) to the whole group of pome fruits is acceptable (EC, 2011). The data were sufficient to derive a MRL of 0.6 mg/kg for the proposed use of chromafenozide on pome fruits in the NEU.

SEU. Fourteen GAP-compliant supervised residue trials on apples assessed during the peer review (EFSA, 2013) and two GAP-compliant supervised residue trials on pears conducted in Spain were provided. The extrapolation of data on apples or pears (with a minimum of 4 trials on apples) to the whole group of pome fruits is acceptable (EC, 2011). The data were sufficient to derive a MRL of 0.4 mg/kg for the proposed use of chromafenozide on pome fruits in the SEU.

As proposed by the EMS, the NEU and SEU datasets can be combined because they showed to belong to similar populations (Mann-Whitney U-Test, FAO, 2009). The MRL proposal of 0.5 mg/kg for pome fruits is derived from the combined dataset of apple/pear residue trials.

b. Grapes

NEU. Fifteen GAP compliant supervised residue trials on grapes (within the 25 % deviation in application rate) conducted in Germany, Hungary and northern France over more than two seasons were submitted. The results from two trials conducted in Germany with three instead of the intended two applications were included in the calculation as the first application occurred before the consumable part of the plant is formed¹⁰ and the results at harvest were within the observed range of values. Data on wine grapes can be extrapolated to table grapes and vice versa (EC, 2011). The data were sufficient to derive a MRL of 1.0 mg/kg for the proposed use of chromafenozide on table and wine grapes in the NEU.

SEU. Nineteen GAP compliant supervised residue trials on grapes conducted in Italy, Spain and Southern France over more than two seasons were submitted. Data on wine grapes can be extrapolated

¹⁰ First application at BBCH 57 (inflorescences fully developed; flowers separating).

to table grapes and vice versa (EC, 2011). The data were sufficient to derive a MRL of 1.5 mg/kg for the proposed use of chromafenozide on table and wine grapes in the SEU.

The same MRL proposal of 1.5 mg/kg for grapes is derived pooling the NEU and SEU residue trials in a combined dataset.

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

Based on the results of a storage stability study on apples, the peer review concluded that residues of chromafenozide were stable at $\leq -15^{\circ}\text{C}$ for up to 13 months in high water content matrices (EFSA, 2013). The storage stability in high acid content commodities has not been investigated.

As the samples of the supervised residue trials on apples and pears were stored under conditions for which integrity of the samples was demonstrated (Hungary, 2013b; EFSA, 2013), EFSA concludes that the residue data on pome fruits are valid with regard to storage stability. The samples of the residue trials on grapes were stored deep frozen for up to 10 months. Grapes are classified as a matrix type with high acid content; in reality the acidity of grapes (pH 2.9 to 3.5) is very similar to the acidity of apples (pH 3.2). Thus, although no specific storage stability data for high acid content commodities are available, EFSA is of the opinion that in this particular case the results of the storage stability data on apples can be considered to support the validity of the residue trials on grapes with regard to storage stability.

According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for the purpose (Hungary, 2013b).

EFSA concludes that the data are sufficient to derive MRL proposals of 0.6 mg/kg and 1.5 mg/kg for the intended uses on pome fruits and grapes, respectively. As alternative option, risk managers may consider the MRL of 0.5 mg/kg derived combining the NEU and SEU residue trials in a single dataset. Since the magnitude of residues was similar in the NEU and the SEU, it is rather likely that the agricultural practice and the pre-harvest climate in each European region do not have a strong influence on chromafenozide residue at harvest in the crops under consideration.

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

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (chromafenozide)	Risk assessment (chromafenozide)					
Enforcement residue definition: chromafenozide									
Apples, pears → Pome fruits	NEU	Outdoor	Apples: 0.024; 0.028; 0.052; 0.064; 0.072; 0.078; 0.142; 2 x 0.154; 0.313 Pears: 0.282	0.024; 0.028; 0.052; 0.064; 0.072; 0.078; 0.142; 2 x 0.154; 0.282; 0.313	0.08	0.31	0.6	1	R _{ber} = 0.31 R _{max} = 0.4 MRL _{OECD} = 0.52/0.6
	SEU	Outdoor	Apples: 0.027; 0.054; 0.071; 0.074; 0.075; 0.079; 0.083; 0.091; 0.124; 0.131; 0.133; 0.148; 0.168; 0.256 Pears: 0.151; 0.251	0.027; 0.054; 0.071; 0.074; 0.075; 0.079; 0.083; 0.091; 0.124; 0.131; 0.133; 0.148; 0.151; 0.168; 0.251; 0.256	0.11	0.26	0.4	1	R _{ber} = 0.3 R _{max} = 0.28 MRL _{OECD} = 0.38/0.4
	NEU/SEU	Outdoor	Combined NEU/SEU dataset. ^(g)	Combined NEU/SEU dataset. ^(g)	0.09	0.31	0.5	1	R _{ber} = 0.26 R _{max} = 0.3 MRL _{OECD} = 0.43/0.5
Wine↔Table grapes	NEU	Outdoor	0.044; 0.08; 0.086; 0.16; 0.18; 0.199; 0.242; 0.245; 0.259 ^(f) ; 0.35; 0.376 ^(f) ; 2 x 0.41; 0.42; 0.43; 0.453; 0.678	0.044; 0.08; 0.086; 0.16; 0.18; 0.199; 0.242; 0.245; 0.259 ^(f) ; 0.35; 0.376 ^(f) ; 2 x 0.41; 0.42; 0.43; 0.453; 0.678	0.26	0.68	1.0	1	R _{ber} = 0.83 R _{max} = 0.71 MRL _{OECD} = 0.96/1.0
	SEU	Outdoor	0.012; 0.133; 0.164; 0.172; 0.174; 0.181; 0.19; 0.35; 0.351; 0.43; 0.436; 0.464; 0.478; 0.482; 0.514; 0.55; 0.665; 0.7; 0.81	0.012; 0.133; 0.164; 0.172; 0.174; 0.181; 0.19; 0.35; 0.351; 0.43; 0.436; 0.464; 0.478; 0.482; 0.514; 0.55; 0.665; 0.7; 0.81	0.43	0.81	1.5	1	R _{ber} = 1.03 R _{max} = 0.91 MRL _{OECD} = 1.26/1.5
	NEU/SEU	Outdoor	Combined NEU/SEU dataset. ^(g)	Combined NEU/SEU dataset. ^(g)	0.35	0.81	1.5	1	R _{ber} = 0.87 R _{max} = 0.77 MRL _{OECD} = 1.13/1.5

- (a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).
- (b): Median value of the individual trial results according to the enforcement residue definition.
- (c): Highest value of the individual trial results according to the enforcement residue definition.
- (d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.
- (e): Statistical estimation of MRLs according to the EU methodology (Rber, Rmax; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).
- (f): Results from trials conducted at the intended application rate but with three instead of two applications.
- (g): The NEU and SEU datasets were statistically assessed (Mann-Whitney U-Test, FAO, 2009) prior to be combined.

3.1.1.3. Effect of industrial processing and/or household preparation

No study has been submitted to investigate the effects of processing on the nature of chromafenozide for the relevant processing operations representing pasteurisation, baking/brewing/boiling and sterilisation (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6). Although desirable, such studies are not required as the TMDI is expected to be less than 10 % ADI (see Section 4).

The results from studies investigating the magnitude of chromafenozide residues in processed apple products were assessed in the conclusion on the peer review (EFSA, 2013) and in processed grape products in the framework of the current MRL application (Hungary, 2013b). Processing factors (PFs) were derived (see Table 3-2) based on the assumption that the residue definition in processed products is identical to the residue definition for raw agricultural commodities (RAC).

The details of the processing studies on apples are reported in the DAR (Hungary, 2013a). Regarding the processing studies on grapes, samples from the field trials were used to produce juice and white and red wine following standard production practice. Chromafenozide residues ranged from 0.1 to 0.44 mg/kg in red wine grapes and from 0.08 to 0.26 mg/kg in white wine grapes (unprocessed commodity). EFSA noted a large variation (<50 %) regarding the estimated PFs on juice (red and white grape), must (red grape) and must/wine (white grape). However, the results of the processing studies reported in Table 3-2 give evidence that a reduction of chromafenozide residues in grape juice, must and wine occurs. Samples of processed products from the studies assessed by the EMS were stored under frozen conditions for up to 8 months (Hungary, 2013b).

Table 3-2: Overview of the available processing studies

Processed commodity	Number of studies	Median PF ^(a)	Median CF ^(b)	Individual PFs/Comments
Enforcement residue definition: chromafenozide (to be confirmed)				
apple, peeled	2	0.3	-	Reference: EFSA, 2013
apple, juice	3	0.5	-	
apple, puree	3	0.2	-	
apple, wet pomace	3	1.9	-	
grape, juice (pasteurised)	7	0.3	-	Red wine: 0.09; 0.1; 0.26; 0.3; 0.62 ^(c) White wine: 0.29; 0.63
red grape, must	4	0.9	-	0.5; 0.7; 1.15; 1.47 (PF not included: 14.6) ^(c)
red grape, wine	4	0.49	-	at bottle: 0.34; 0.48; 0.5; 0.6 (PF not included: 1.85) ^(c)
white grape must	2	0.45	-	0.27; 0.63
white grape, wine	2	0.23		at bottle: 0.38; 6-month old: 0.08

- (a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study. The table is reporting the values rounded up to the second decimal. Until the nature of residues in processed commodities has been fully elucidated, the PFs derived should be considered preliminary (EFSA, 2013).
- (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. CFs can not be calculated until the residue definition for processed products is established.
- (c): PFs derived from the same processing study; the individual PF for red must and wine were excluded from the calculation (outlier) because considered as not providing a reliable estimation of the true residue originated in the processed commodity.

EFSA does not recommend the inclusion of the derived processing factors in Annex VI of Regulation (EC) No 396/2005 due to the uncertainties (high variability of results, limited number of studies) of the processing studies. However, processing studies are not required for the time being as they are not expected to affect the outcome of the risk assessment.

3.1.2. Rotational crops

Since the proposed uses of chromafenozide are on permanent crops, investigations of residues in rotational crops are not required.

3.2. Nature and magnitude of residues in livestock

Apple pomace is used as feed product in the ruminant diet; therefore a potential carry-over into food of animal origin should be considered (EC, 1996).

The intended use on apples corresponds to the representative use assessed during the peer review (EFSA, 2013). Hence, the dietary burdens for beef and dairy cattle presented in the DAR (Hungary, 2013a) are still valid and do not need to be updated. It is noted that the calculation is very conservative because the RMS used the highest (4.26 rounded to 5) instead of the median (1.9) preliminary PF derived from the processing studies on apple pomace (Hungary, 2013a). The use of the default PF of 2.5 for pomace would also produce lower estimated intakes for chromafenozide in cattle.

According to the results of the metabolism study in lactating goats, the peer review concluded that significant residues levels of chromafenozide are not expected in food of animal origin at the calculated dietary burdens (EFSA, 2013). These conclusions are still valid and the setting of MRLs in commodities of animals is not required in the framework of the current MRL application.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population¹¹ (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the median residue values as derived from the residue trials on pome fruits and grapes (see Table 3-1). For the remaining commodities of plant origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values.

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

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

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

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment

¹¹ 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
Risk assessment residue definition: chromafenozide				
Pome fruit	0.11	Median residue (apple/pear, SEU ^(a))	Acute risk assessment was not performed since no ARfD is necessary for chromafenozide.	
Table and wine grapes	0.43	Median residue (SEU ^(a))		
Other commodities of plant origin	MRL	See Appendix C		

a): For the chronic exposure assessment the median residue derived from the more critical residue situation was selected.

The estimated exposure was then compared with the toxicological reference value derived for chromafenozide (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 accounted for less than 1 % of the ADI (German child diet). Wine grapes and apples were the main contributors to the dietary burden accounting for a maximum of 0.6 % (French all population diet) and 0.5 % (German child diet) of the ADI, respectively. Table grapes contributed for 0.2 % of the ADI, whereas the contribution of the remaining commodities was insignificant (lower than 0.03 % of the ADI).

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

EFSA concludes that the intended uses of chromafenozide on pome fruits and grapes will not result in a consumer exposure exceeding the toxicological reference value and therefore are unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of chromafenozide was assessed during the peer review and the data were sufficient to propose an ADI of 0.27 mg/kg bw per day. No ARfD was deemed necessary.

Based on the results from the metabolism study on apples after foliar applications, the peer review proposed the parent chromafenozide as residue definition for enforcement and risk assessment in the fruits and fruiting vegetables. For the uses on pome fruits and grapes, EFSA concludes that the metabolism of chromafenozide is sufficiently addressed and the residue definitions for enforcement and risk assessment proposed during the peer review are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals of 0.6 mg/kg and 1.5 mg/kg for the intended uses on pome fruits and grapes, respectively. As alternative option, risk managers may consider the MRL of 0.5 mg/kg for the group of pome fruits. An analytical enforcement method is available to control the residues of chromafenozide on the commodities under consideration at the validated LOQ of 0.01 mg/kg. EFSA confirms the data gap identified in the peer review regarding the lack of information demonstrating the efficiency of the extraction step involved in the sample preparation. However, this data gap is considered as being of minor relevance and should be addressed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005.

Specific studies investigating the nature of chromafenozide residues in processed commodities are not available. Although desirable, such studies are not required as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI. The results of the processing studies on

grape processed products submitted in the framework of the current MRL application give evidence that a reduction of chromafenozide residues in grape juice, must and wine occurs. EFSA does not recommend the inclusion of the derived processing factors in Annex VI of Regulation (EC) No 396/2005 due to the uncertainties (high variability of results, limited number of studies) of the processing studies.

Since the proposed uses of chromafenozide are on permanent crops, investigations of residues in rotational crops are not required.

Apple pomace is used as feed product in the ruminant diet, therefore a potential carry-over into food of animal origin should be considered. According to the results of the metabolism study in lactating goats, significant residue levels of chromafenozide are not expected in food of animal origin at the calculated dietary burdens. Therefore, the setting of MRLs in commodities of animal origin is not required in the framework of the current application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). For the calculation of the chronic exposure EFSA used the median residue values as derived from the residue trials on apples, pears and grapes and the existing MRLs for the other commodities of plant origin. No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMO. The total calculated intake accounted for less than 1 % of the ADI (German child diet). Wine grapes and apples were the main contributors to the dietary burden accounting for a maximum of 0.6 % and 0.5 % of the ADI, respectively. No acute exposure calculation was necessary because of the low acute toxicity of chromafenozide.

EFSA concludes that the proposed uses of chromafenozide on pome fruits and table and wine grapes will not result in a consumer exposure exceeding the toxicological reference value and therefore are unlikely to pose a consumer health risk.

Since a decision concerning the approval of the active substance chromafenozide in accordance with Regulation (EC) No 1107/2009 has not been made, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the regulatory procedure.

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: chromafenozide				
130000	Pome fruit	0.3 (apples)	0.6 or 0.5	The MRL proposal, derived by extrapolation from residue trials on apples and pears, is sufficiently supported by data and no risk for consumers was identified for the intended NEU and SEU use on pome fruits. As risk manager option, the MRL of 0.6 mg/kg is derived from the dataset of NEU residue trials (more critical residue situation), whereas the MRL of 0.5 mg/kg is derived combining the NEU and SEU residue trials in a single dataset.
		0.01* (other pome fruits)		
151000	Table and wine grapes	0.01*	1.5	The MRL proposal, derived from residue trials on grapes, is sufficiently supported by data and no risk for consumers was identified for the intended NEU and SEU use on grapes.

(A): According to Annex Me of Regulation (EC) No 396/2005.

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

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APPENDICES

A. GOOD AGRICULTURAL PRACTICE (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Pome fruits	NEU	F	Tortrix moth, Leaf miner, Codling moth	SC	50 g/L	Foliar spray	BBCH 70-81	2	14 d		800-1500	0.1	21	
	SEU													
Grapes	NEU	F	Grape tortrix	SC	50 g/L	Foliar spray	BBCH 72-85	2	14 d		400-800	0.125	21	
	SEU													

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

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

chromafenozide Status of the active substance: pending Code no. LOQ (mg/kg bw): 0.02 proposed LOQ: Toxicological end points ADI (mg/kg bw/day): 0.27 ARfD (mg/kg bw): n.n. Source of ADI: EFSA Source of ARfD: EFSA Year of evaluation: 2013 Year of evaluation: 2013									
Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI					
				minimum - maximum					
				0 1					
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	pTMDRs at LOQ (in % of ADI)
	0.8	DE child	0.5	Apples	0.2	Table grapes	0.03	Pears	0.1
	0.7	FR all population	0.6	Wine grapes	0.02	Apples	0.02	Table grapes	0.0
	0.6	PT General population	0.4	Wine grapes	0.04	Table grapes	0.04	Apples	0.1
	0.5	WHO Cluster diet B	0.3	Wine grapes	0.1	Table grapes	0.04	Apples	0.1
	0.5	NL child	0.3	Apples	0.1	Table grapes	0.02	Potatoes	0.1
	0.4	IE adult	0.2	Wine grapes	0.04	Table grapes	0.03	Apples	0.1
	0.4	WHO cluster diet E	0.3	Wine grapes	0.03	Apples	0.02	Table grapes	0.1
	0.3	DK adult	0.2	Wine grapes	0.03	Apples	0.01	Table grapes	0.0
	0.3	UK Toddler	0.1	Sugar beet (root)	0.07	Apples	0.04	Table grapes	0.1
	0.2	UK Adult	0.2	Wine grapes	0.02	Apples	0.01	Sugar beet (root)	0.0
	0.2	NL general	0.1	Wine grapes	0.05	Apples	0.04	Table grapes	0.0
	0.2	FR toddler	0.1	Apples	0.03	Table grapes	0.02	Potatoes	0.1
	0.2	DK child	0.1	Apples	0.03	Table grapes	0.03	Pears	0.1
	0.2	UK vegetarian	0.1	Wine grapes	0.02	Apples	0.01	Sugar beet (root)	0.0
	0.2	WHO Cluster diet F	0.1	Wine grapes	0.03	Apples	0.02	Table grapes	0.1
	0.2	WHO cluster diet D	0.1	Wine grapes	0.03	Table grapes	0.03	Apples	0.1
	0.2	FR infant	0.1	Apples	0.02	Potatoes	0.01	Pears	0.1
	0.2	UK Infant	0.1	Apples	0.04	Sugar beet (root)	0.01	Potatoes	0.1
	0.2	PL general population	0.1	Apples	0.1	Table grapes	0.01	Potatoes	0.0
	0.2	ES adult	0.1	Wine grapes	0.03	Apples	0.01	Pears	0.0
	0.2	WHO regional European diet	0.04	Wine grapes	0.03	Apples	0.02	Table grapes	0.1
	0.1	ES child	0.05	Apples	0.02	Pears	0.02	Wheat	0.1
	0.1	IT kids/toddler	0.04	Apples	0.02	Wheat	0.02	Table grapes	0.1
	0.1	SE general population 90th percentile	0.04	Apples	0.02	Potatoes	0.01	Pears	0.1
	0.1	LT adult	0.1	Apples	0.01	Potatoes	0.01	Pears	0.0
	0.1	IT adult	0.03	Apples	0.02	Table grapes	0.02	Wheat	0.0
	0.1	FI adult	0.05	Wine grapes	0.02	Apples	0.005	Potatoes	0.0
Conclusion: The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMDRs were below the ADI. A long-term intake of residues of chromafenozide is unlikely to present a public health concern.									

C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 06/01/2014 18:40))

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
100000	1. FRUIT FRESH OR FROZEN NUTS	
110000	(i) Citrus fruit	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,01*
110030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactylis))	0,01*
110040	Limes	0,01*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata x sinensis))	0,01*
110990	Others	0,01*
120000	(ii) Tree nuts	0,01*
120010	Almonds	0,01*
120020	Brazil nuts	0,01*
120030	Cashew nuts	0,01*
120040	Chestnuts	0,01*
120050	Coconuts	0,01*
120060	Hazelnuts (Filbert)	0,01*
120070	Macadamia	0,01*
120080	Pecans	0,01*
120090	Pine nuts	0,01*
120100	Pistachios	0,01*
120110	Walnuts	0,01*
120990	Others	0,01*
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	0,3
130020	Pears (Oriental pear)	0,01*
130030	Quinces	0,01*
130040	Medlar	0,01*
130050	Loquat	0,01*
130990	Others	0,01*
140000	(iv) Stone fruit	0,01*
140010	Apricots	0,01*
140020	Cherries (Sweet cherries, sour cherries)	0,01*
140030	Peaches (Nectarines and	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
	similar hybrids)	
140040	Plums (Damson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	0,01*
140990	Others	0,01*
150000	(v) Berries & small fruit	0,01*
151000	(a) Table and wine grapes	0,01*
151010	Table grapes	0,01*
151020	Wine grapes	0,01*
152000	(b) Strawberries	0,01*
153000	(c) Cane fruit	0,01*
153010	Blackberries	0,01*
153020	Dewberries (Loganberries, tayberries, boysenberries, cloudberries and other Rubus hybrids)	0,01*
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x Rubus idaeus))	0,01*
153990	Others	0,01*
154000	(d) Other small fruit & berries	0,01*
154010	Blueberries (Bilberries)	0,01*
154020	Cranberries (Cowberries/red bilberries (V. vitis-idaea))	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 (mediterranean medlar) (Kiwiberly (Actinidia arguta))	0,01*
154080	Elderberries (Black chokeberry/appleberry, mountain ash, buckthorn/sea sawlowthorn, hawthorn, serviceberries, and other	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
	treeberries)	
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, limequats (Citrus aurantifolia x Fortunella spp.))	0,01*
161050	Carambola (Bilimbi)	0,01*
161060	Persimmon	0,01*
161070	Jambolan (java plum) (Java apple/water apple, pomarac, rose apple, Brazilian cherry, Surinam cherry/grumichama (Eugenia uniflora))	0,01*
161990	Others	0,01*
162000	(b) Inedible peel, small	0,01*
162010	Kiwi	0,01*
162020	Lychee (Litchi) (Pulasan, rambutan/hairy litchi, longan, mangosteen, langsat, salak)	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, mammeey 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	Chirimoya (Custard apple, sugar apple/sweetsop,	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
	ilama (Annona diversifolia) and other medium sized Annonaceae fruits)	
163070	Guava (Red pitaya/dragon fruit (Hylocereus undatus))	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	0,01*
210000	(i) Root and tuber vegetables	0,01*
211000	(a) Potatoes	0,01*
212000	(b) Tropical root and tuber vegetables	0,01*
212010	Cassava (Dasheen, eddoe/Japanese taro, tannia)	0,01*
212020	Sweet potatoes	0,01*
212030	Yams (Potato bean/yam bean, Mexican yam bean)	0,01*
212040	Arrowroot	0,01*
212990	Others	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,01*
213010	Beetroot	0,01*
213020	Carrots	0,01*
213030	Celeriac	0,01*
213040	Horseradish (Angelica roots, lovage roots, gentiana roots)	0,01*
213050	Jerusalem artichokes (Crosne)	0,01*
213060	Parsnips	0,01*
213070	Parsley root	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
213090	Salsify (Scorzonera, Spanish salsify/Spanish oysterplant, edible burdock)	0,01*
213100	Swedes	0,01*
213110	Turnips	0,01*
213990	Others	0,01*
220000	(ii) Bulb vegetables	0,01*
220010	Garlic	0,01*
220020	Onions (Other bulb onions, silverskin onions)	0,01*
220030	Shallots	0,01*
220040	Spring onions and welsh onions (Other green onions and similar varieties)	0,01*
220990	Others	0,01*
230000	(iii) Fruiting vegetables	0,01*
231000	(a) Solanacea	0,01*
231010	Tomatoes (Cherry tomatoes, Physalis spp., goji berry, wolfberry (Lycium barbarum and L. chinense), tree tomato)	0,01*
231020	Peppers (Chilli peppers)	0,01*
231030	Aubergines (egg plants) (Pepino, antroewa/white eggplant (S. macrocarpon))	0,01*
231040	Okra (lady's fingers)	0,01*
231990	Others	0,01*
232000	(b) Cucurbits — edible peel	0,01*
232010	Cucumbers	0,01*
232020	Gherkins	0,01*
232030	Courgettes (Summer squash, marrow (patisson), lauki (Lagenaria siceraria), chayote, sopropo/bitter melon, snake gourd, angled luffa/teroi)	0,01*
232990	Others	0,01*
233000	(c) Cucurbits-inedible peel	0,01*
233010	Melons (Kiwano)	0,01*
233020	Pumpkins (Winter squash, marrow (late variety))	0,01*
233030	Watermelons	0,01*
233990	Others	0,01*
234000	(d) Sweet com (Baby com)	0,01*
239000	(e) Other fruiting vegetables	0,01*
240000	(iv) Brassica vegetables	0,01*
241000	(a) Flowering brassica	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
241010	Broccoli (Calabrese, Broccoli raab, Chinese broccoli)	0,01*
241020	Cauliflower	0,01*
241990	Others	0,01*
242000	(b) Head brassica	0,01*
242010	Brussels sprouts	0,01*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*
242990	Others	0,01*
243000	(c) Leafy brassica	0,01*
243010	Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi, choi sum, Peking cabbage/petsai)	0,01*
243020	Kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0,01*
243990	Others	0,01*
244000	(d) Kohlrabi	0,01*
250000	(v) Leaf vegetables & fresh herbs	0,01*
251000	(a) Lettuce and other salad plants including Brassicaceae	0,01*
251010	Lamb's lettuce (Italian com salad)	0,01*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,01*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curly leaf endive, sugar loaf (C. endivia var. crispum/C. intybus var. foliosum), dandelion greens)	0,01*
251040	Cress (Mung bean sprouts, alfalfa sprouts)	0,01*
251050	Land cress	0,01*
251060	Rocket, Rucola (Wild rocket (Diplotaxis spp.))	0,01*
251070	Red mustard	0,01*
251080	Leaves and sprouts of	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
	Brassica spp. including turnip greens (Mizuna, leaves of peas and radish and other baby leaf crops, including brassica crops (crops harvested up to 8 true leaf stage), kohlrabi leaves)	
251990	Others	0,01*
252000	(b) Spinach & similar (leaves)	0,01*
252010	Spinach (New Zealand spinach, amaranthus spinach (pak-khom, tampara), tajar leaves, bitterblad/bitawiri)	0,01*
252020	Purslane (Winter purslane/miner's lettuce, garden purslane, common purslane, sorrel, glasswort, agretti (Salsola soda))	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,01*
252990	Others	0,01*
253000	(c) Vine leaves (grape leaves) (Malabar nightshade, banana leaves, climbing wattle (Acacia pennata))	0,01*
254000	(d) Water cress (Morning glory/Chinese convolvulus/water convolvulus/water spinach/kangkung (Ipomea aquatica), water clover, water mimosa)	0,01*
255000	(e) Witloof	0,01*
256000	(f) Herbs	0,01*
256010	Chervil	0,01*
256020	Chives	0,01*
256030	Celery leaves (Fennel leaves, coriander leaves, dill leaves, caraway leaves, lovage, angelica, sweet cicely and other Apiacea leaves, culantro/stinking/long coriander/stink weed (Eryngium foetidum))	0,01*
256040	Parsley (leaves of root)	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
	parsley)	
256050	Sage (Winter savory, summer savory, Borago officinalis leaves)	0,01*
256060	Rosemary	0,01*
256070	Thyme (Marjoram, oregano)	0,01*
256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil, edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)	0,01*
256090	Bay leaves (laurel) (Lemon grass)	0,01*
256100	Tanagon (Hyssop)	0,01*
256990	Others	0,01*
260000	(vi) Legume vegetables (fresh)	0,01*
260010	Beans (with pods) (Green bean/French beans/snap beans, scarlet runner bean, slicing bean, yard long beans, guar beans, soya beans)	0,01*
260020	Beans (without pods) (Broad beans, flageolets, jack bean, lima bean, cowpea)	0,01*
260030	Peas (with pods) (Mangetout/sugar peas/snow 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)	0,01*
270010	Asparagus	0,01*
270020	Cardoons (Borago officinalis stems)	0,01*
270030	Celery	0,01*
270040	Fennel	0,01*
270050	Globe artichokes (Banana flower)	0,01*
270060	Leek	0,01*
270070	Rhubarb	0,01*
270080	Bamboo shoots	0,01*
270090	Palm hearts	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
270990	Others	0,01*
280000	(viii) Fungi	0,01*
280010	Cultivated fungi (Common mushroom, oyster mushroom, shiitake, fungus mycelium (vegetative parts))	0,01*
280020	Wild fungi (Chanterelle, truffle, morel, cep)	0,01*
280990	Others	0,01*
290000	(ix) Sea weeds	0,01*
300000	3. PULSES, DRY	0,01*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,01*
300020	Lentils	0,01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*
300040	Lupins	0,01*
300990	Others	0,01*
400000	4. OILSEEDS AND OILFRUITS	0,01*
401000	(i) Oilseeds	0,01*
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	0,01*
401100	Pumpkin seeds (Other seeds of Cucurbitaceae)	0,01*
401110	Safflower	0,01*
401120	Borage (Purple viper's bugloss/Canary flower (Echium plantagineum), Com Gromwell (Buglossoides arvensis))	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*

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
402030	Palmfruit	0,01*
402040	Kapok	0,01*
402990	Others	0,01*
500000	5. CEREALS	0,01*
500010	Barley	0,01*
500020	Buckwheat (Amaranthus, quinoa)	0,01*
500030	Maize	0,01*
500040	Millet (Foxtail millet, teff, finger millet, pearl millet)	0,01*
500050	Oats	0,01*
500060	Rice (Indian/wild rice (Zizania aquatica))	0,01*
500070	Rye	0,01*
500080	Sorghum	0,01*
500090	Wheat (Spelt, triticale)	0,01*
500990	Others (Canary grass seeds (Phalaris canariensis))	0,01*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*
610000	(i) Tea	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 (Elderflowers (Sambucus nigra))	0,02*
631050	Lime (linden)	0,02*
631990	Others	0,02*
632000	b) Leaves	0,02*
632010	Strawberry leaves	0,02*
632020	Roobos leaves (Ginkgo 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 beans (fermented or dried)	0,02*
650000	(v) Carob (st johns bread)	0,02*
700000	7. HOPS (dried)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
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	Sichuan pepper (Anise pepper, Japan pepper)	0,02*
820030	Caraway	0,02*
820040	Cardamom	0,02*
820050	Juniper berries	0,02*
820060	Pepper, black, green 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	0,01*
900010	Sugar beet (root)	0,01*
900020	Sugar cane	0,01*
900030	Chicory roots	0,01*
900990	Others	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
1010000	(i) Tissue	
1011000	(a) Swine	
1011010	Muscle	
1011020	Fat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Muscle	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Muscle	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	
1014010	Muscle	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Muscle	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Muscle	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	

Code number	Groups and examples of individual products to which the MRLs apply	Chromafenozide
1017000	(g) Other farm animals (Rabbit, kangaroo, deer)	
1017010	Muscle	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others	
1030000	(iii) Bird eggs	
1030010	Chicken	
1030020	Duck	
1030030	Goose	
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen, honey comb with honey (comb honey))	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products (Wild game)	

(*) Indicates lower limit of analytical determination

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
d	day
DAR	Draft Assessment Report
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
<i>i.e.</i>	that is (id est, <i>Latin</i>)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RMS	rapporteur Member State

SC	suspension concentrate
SEU	southern European Union
UV	ultra-violet (detector)
WHO	World Health Organization