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Setting of an import tolerance for chlorothalonil in cranberries

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), the Netherlands, received an application from the Cranberry Marketing Committee USA to set an import tolerance for the active substance chlorothalonil in cranberries from import country USA at the proposed level of 10 mg/kg. The Netherlands 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. Although no consumer risk was identified related to the MRL proposed by the applicant, EFSA concluded that the setting of an MRL for chlorothalonil in cranberries at a higher level than 5 mg/kg, the MRL from the origin country, is not appropriate. Adequate analytical enforcement methods are available to control the residues of chlorothalonil and its metabolite SDS-3701 in cranberries.

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Keywords: chlorothalonil, cranberries, MRL application, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), the Netherlands, received an application from the Cranberry Marketing Committee USA to set an import tolerance for the active substance chlorothalonil in cranberries from the USA at a level of 10 mg/kg. The Netherlands 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 the European Food Safety Authority EFSA on 8 May 2015.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) (and its addendum/addenda) prepared under Council Directive 91/414/EEC, the Commission review report on chlorothalonil, the JMPR Evaluation report as well as the conclusions from previous EFSA opinions on chlorothalonil.

The toxicological profile of chlorothalonil and its metabolite were assessed in the framework of the peer review. Data were sufficient to derive an acceptable daily intake (ADI) of 0.015 mg/kg bw per day and an acute reference dose (ARfD) of 0.6 mg/kg bw for chlorothalonil. An ADI of 0.01 mg/kg bw per day and an ARfD of 0.01 mg/kg bw was proposed for its metabolite SDS-3701.

The plant residue definitions were reconsidered in the framework of the review of the existing MRLs according Article 12 of Regulation (EC) No 396/2005. Based on the metabolism studies conducted in five different crop groups following foliar application, EFSA recommended to establish two separate residue definitions for enforcement and risk assessment as chlorothalonil and as 2,5,6-trichloro-4-hydroxyphtalonitrile (SDS-3701) separately. Finally, for plant commodities, MRLs were set for chlorothalonil only under Regulation (EC) No 396/2005. EFSA concludes that the metabolism of chlorothalonil in primary crops has been sufficiently addressed and that the residue definitions are applicable.

The submitted trials conducted in the USA support the setting of an import tolerance of 10 mg/kg. However since the MRL currently in force on cranberries in the USA is 5 mg/kg and according to the approach agreed in the PAFF meeting of December 2014, EFSA recommends to set the import tolerance value for cranberries at a level of 5 mg/kg only.

Studies investigating the nature of chlorothalonil residues under standard hydrolysis conditions were assessed during the MRL review where the same residue definition for processed commodities as for raw agricultural commodities (RAC) was recommended. Studies investigating the magnitude of chlorothalonil residues in processed commodities are not required, as the contribution of the residues in cranberries to the total theoretical maximum daily intake (TMDI) is below 10 % of the ADI.

As the proposed use of chlorothalonil is on an imported crop, investigations of residues in rotational crops are not required.

Residues of chlorothalonil in commodities of animal origin were not assessed, since cranberries are not normally fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of existing MRLs for chlorothalonil according to Article 12 of Regulation (EC) 396/2005, a comprehensive long-term exposure assessment was performed considering all the uses at EU level and the acceptable CXLs. EFSA has updated this risk assessment with the median value for cranberries derived from the supervised residue trials.

There is no consumer European risk concern related to the MRL of 10 mg/kg for chlorothalonil in cranberries proposed by the applicant, however EFSA is of the opinion that setting the MRL at a higher level than 5 mg/kg, the MRL in place in the origin country, is not appropriate.

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: chlorothalonil[(F)]				
0154020	Cranberries	0.01*	5	The submitted trials support the setting of an import tolerance of 10 mg/kg. However since the MRL currently in force on cranberries in the USA is 5 mg/kg only and according to the procedure agreed in the PAFF meeting of December 2014, EFSA recommends setting the import tolerance value at a level of 5 mg/kg only.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005
(*): indicates that the MRL is set at the limit of analytical quantification (LOQ)
(F): fat soluble

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Background

Regulation (EC) No 396/2005[1] establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC,[2] repealed by Regulation (EC) No 1107/2009,[3] shall submit to a Member State, when appropriate, an application to set an import tolerance in accordance with the provisions of Article 7 of the Regulation.

The Netherlands, hereafter referred to as the evaluating Member State (EMS), received from the company Cranberry Marketing Committee USA[4] an application to set an import tolerance for the active substance chlorothalonil in cranberries. This application was notified to the European Commission and the European Food Safety Authority (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 and to EFSA on 8 May 2015.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00285 and the following subject:

Chlorothalonil: Modification of existing MRL in cranberries

The Netherlands proposed to raise the existing MRL of chlorothalonil in cranberries from the limit of quantification (LOQ) of 0.01 mg/kg to 10 mg/kg.

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

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

In accordance with Article 11 of the 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 if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The active substance and its use pattern

Chlorothalonil is the ISO common name for tetrachloroisophthalonitrile (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix C. Chlorothalonil has been approved for uses as a fungicide.

Chlorothalonil was evaluated in the framework of Directive 91/414/EEC with the Netherlands designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2005/53/EC[5] which entered into force on 1 March 2006 for use as fungicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[6] chlorothalonil is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

[1] 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.
[2] 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.
[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
[4] Cranberry Marketing Committee USA, Main Street 219A, Wareham, MA 02571, USA.
[5] Commission Directive 2005/53/EC of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances. OJ L 241, 17.9.2005, p. 51-56.
[6] Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.06.2011, p. 1–186.

The representative uses evaluated in the peer review were outdoor foliar applications on wheat. The draft assessment report (DAR) was not peer reviewed by EFSA, therefore no EFSA conclusion is available.

The EU MRLs for chlorothalonil are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued two reasoned opinions on the modification of MRLs for chlorothalonil. The proposals from these reasoned opinions have been considered in the preparation of EU legislation. The MRL changes that were reported in the EU legislation since the entry into force of the regulation are summarised in Table 1.

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure[(a)]	Considered by Regulation	Remarks
Art. 10 (EFSA, 2010)	(EU) No 765/2010	Barley
Art. 12 (EFSA, 2012)	(EU) No 1146/2014	Review of existing MRLs
Implementation of CXL (EFSA, 2011)	(EU) No 441/2012	CAC 2011

(a): Art. 10: Assessment of MRL application according to Article 6 to 10 of Regulation (EC) No 396/2005
Art. 12: Review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005
Art. 43 Implementation of CXL: EFSA scientific opinion according to Article 43 of Regulation (EC) No 396/2005

Codex Alimentarius has established maximum residue limits (CXL) for a wide range of commodities, including cranberries for which the CXL is set at 5 mg/kg. The MRL established in the USA for chlorothalonil and its metabolite SDS-3701 in cranberries is 5 mg/kg[7].

The details of the intended GAP for chlorothalonil are given in Appendix A.

Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (Netherlands, 2015), the DAR (and its addendum/addenda) prepared under Directive 91/414/EEC (Netherlands, 2000, 2001, 2004), the Commission review report on chlorothalonil (European Commission, 2006), the JMPR Evaluation report (FAO, 2010, 2012) as well as the conclusions from previous EFSA opinions on chlorothalonil (EFSA, 2010, 2011, 2012, 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 546/2011[8] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a, b; 2011; OECD, 2011).

1. Method of analysis

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

Analytical methods for the determination of chlorothalonil residues in plant commodities (high water, acidic, high oil content) were assessed during the peer review under Directive 91/414/EEC. The analytical method was based on GC-MS quantification achieving an LOQ of 0.01 mg/kg. Sufficient validation and independent laboratory validation (ILV) data were submitted to conclude that the analytical method has been adequately validated to enforce chlorothalonil residues in high water, high acid, high oil, content commodities and in dry/protein and dry/starch matrices at the LOQ of 0.01 mg/kg.

[7] Include source of information, e.g. US Code of Federal Regulations 40 CFR 180.275 Chlorothalonil: tolerances for residues.
[8] 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.

In addition, a fully validated LC-MS/MS method for determination of chlorothalonil and SDS-3701 in cranberries at the LOQ of 0.01 mg/kg was submitted under the current MRL application (Netherlands, 2015).

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 and using GC-MS/MS detection is also applicable to analyse chlorothalonil residues in high water, high acid, high oil content commodities and in dry/protein and dry/starch matrices at the LOQ of 0.01mg/kg (CEN, 2008).

Based on the above information EFSA concludes, that sufficiently validated analytical methods are available for enforcing the proposed MRL for chlorothalonil and its metabolite SDS-3701 in cranberries.

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

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

2. Mammalian toxicology

The toxicological profile of the active substance chlorothalonil was assessed in the framework of the peer review under Directive 91/414/EEC. The data were sufficient to derive toxicological reference values for chlorothalonil and its metabolites SDS-3701 and SDS-46851 that are compiled in Table 2.

Table 2: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Chlorothalonil					
ADI	EC	2006	0.015 mg/kg bw per day	90-day rat	100
ARfD	EC	2006	0.6 mg/kg bw	28-day rat	100
2,5,6-trichloro-4-hydroxyphtalonitrile (metabolite SDS-3701)					
ADI	EC	2006	0.01 mg/kg bw per day	90-day dog	100
ARfD	EC	2006	0.01 mg/kg bw	90-day dog	100
3-carboxy-2,5,6-trichloro benzamide (metabolite SDS-46851)					
ADI	EC	2006	0.5 mg/kg bw per day	90-day dog	100
ARfD	EC	2006	0.5 mg/kg bw	90-day dog	100

It is noted that JMPR established an ADI of 0.02 mg/kg bw per day and an ARfD of 0.6 mg/kg bw for chlorothalonil and an ADI of 0.008 mg/kg bw per day and an ARfD of 0.03 mg/kg for its metabolite SDS-3701 (FAO, 2012).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Studies on the metabolism of chlorothalonil in plants were made available during the review of the existing MRLs under Article 12 of Regulation 396/2005 (EFSA, 2012). The metabolism in primary crops was evaluated in the fruit, leafy, cereals, root, and pulses/oilseeds crop groups. An overview of the available metabolism studies is presented in Table 3.

Table 3: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling[(a)] (day, DAT)	Comments
Fruit	Tomato	Foliar, (3x 2330 g/ha)	1,7, 14 DAT	
		Foliar, (1x 1600 g/ha)	0, 14, 21, 28 DAT	
Leafy	Celery	Foliar, (12x 2500 g/ha)	7,21 DAT	
	Lettuce	Foliar, (4x 1750 g/ha, BBCH 50)	1,3, 7, 10, 14, 21 DAT	
Root	Carrot	Foliar, (3x 1600 g/ha)	1, 7, 14, 21 DAT	
Pulses/Oilseeds	Snap bean	Foliar (4x 2460 g/ha)	7, 28 DAT	
	Pea	Foliar (1x 1000 g/ha)	0, 7, 14, 30, 41 DAT	
Cereal	Wheat	Foliar (2x 100 g/ha BBCH 51/73)	0, 28 DAT	

(a): DAT, days after treatment

While limited to chlorothalonil only in the conclusion of the peer review, based on the submitted metabolism studies and since metabolite SDS-3701 follows different toxicological mechanisms than the parent chlorothalonil, two separate residue definitions for monitoring and risk assessment were recommended by EFSA in the framework of the Article 12 MRL review; as chlorothalonil and as metabolite SDS-3701 separately (EFSA, 2012). Finally, the plant residue definition for enforcement was limited to chlorothalonil only in Regulation (EC) No 396/2005 and no MRLs are set for the metabolite SDS-3701.

It is noted that JMPR proposed to include chlorothalonil only in the enforcement residue definition and chlorothalonil and SDS-3701 separately for risk assessment (FAO, 2010);

For the uses on cranberries, EFSA concludes that the metabolism of chlorothalonil is sufficiently addressed and the residue definitions for enforcement and risk assessment proposed during the MRL review are applicable.

3.1.1.2. Magnitude of residues

To support the MRL proposal, the applicant made available five residue trials conducted in the USA during the 2012 growing season according to the US GAP with a total of three applications at the highest application rate of 5400 to 5900 g/ha per treatment. All samples were analysed for the parent chlorothalonil and its metabolite SDS-3701. Residue levels were in the range of 1.4 to 5.4 mg/kg for chlorothalonil and were all below the LOQ level of 0.02 mg/kg for SDS-3701.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposal are summarised in Table 4.

The stability of chlorothalonil residues in plant matrices under storage conditions prior to analysis was assessed during the peer review and detailed information is presented in the Art 12 MRL review (EFSA, 2012). Residues of chlorothalonil were concluded to be stable for 48 months in high water matrices and 24 months in high oil matrices when stored at -7°C and for 12 months in dry/starch commodities at -18°C. As the samples were stored for approximately six months before the analysis, under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability. Additional storage stability studies for acidic commodities which confirmed the stability of chlorothalonil for 24 months at -18°C were made available under the current application. For the metabolite SDS-3701 two storage stability studies covering four crop groups including acid matrices (grapes, strawberries) were submitted in the support of this MRL application. One study was disregarded since it was conducted with residue levels closed to LOQs. Contradictory results were observed for acid matrices in the second study where SDS-3701 was seen to be stable for no more than 3 months in grapes (recovery 70% and 62% after 3 and 6 months respectively) while up to 2 years in strawberries (recovery 79%). As the samples from the residue trials conducted on cranberries were stored at *ca.* -18/-20°C before the analysis for around six months and considering that recoveries in high acid matrices after a storage period of 6 months were estimated to be close to the threshold recovery level of 70% (62 % in grapes and 76 % in

strawberries), EFSA considers that stability in acid matrices for 6 months is acceptable and the residue trials are valid for the residue stability.

According to the EMS, the analytical method used to analyse the residue trial samples has been sufficiently validated and was proven to be fit for purpose (Netherlands, 2015).

EFSA is of the opinion that setting the MRL at a higher level than 5 mg/kg, the MRL in place in the origin country, is not appropriate.

Table 4: Overview of the available residues trials data

Crop (GAPs)	**Region/ Indoor**[a]	**Residue levels observed in the supervised residue trials**[b] (mg/kg)	**Recommendations/comments**[c]	**MRL proposal** (mg/kg)	**HR**[d] (mg/kg)	**STMR**[e] (mg/kg)
Cranberries	**USA** (Massachusetts New Jersey Oregon and Wisconsin)	Chlorothalonil: 1.4, 2.65, 3.15, 3.2, 5.4	The submitted trials support the setting of an import tolerance of 10 mg/kg (MRL_{OECD}: 9.5/10). However, since the current MRL in force on cranberries in the USA is 5 mg/kg and according to the approach agreed in the PAFF meeting of December 2014, EFSA recommends setting the import tolerance value at a level of 5 mg/kg only.	5	5.4	3.15
		SDS-3701: 5x <0.02*		-	0.02	0.02

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Individual residue levels considered for MRL calculation are reported in ascending order.
(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values).
(d): HR: Highest residue level according to the residue definition for risk assessment.
(e): STMR: Median residue level according to residue definition for risk assessment.
* indicates that the value is at the limit of quantification (LOQ)

3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the nature of chlorothalonil residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed during the MRL review, where for processed commodities the same residue definition as for raw agricultural commodities was recommended (EFSA, 2012).

Specific studies to assess the magnitude of chlorothalonil residues during the processing of cranberries are not necessary as the total theoretical maximum daily intake (TMDI) amounts to less than 10 % of the ADI (European Commission, 1997d).

3.1.2. Rotational crops

As the proposed use of chlorothalonil is on imported crops, the investigation of residues in rotational crops is not required and is therefore not considered in this reasoned opinion.

3.2. Nature and magnitude of residues in livestock

As cranberries are normally not fed to livestock, the nature and magnitude of chlorothalonil residues in livestock is not assessed in the framework of this application (European Commission, 1996).

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[9] (EFSA, 2007).

In the framework of the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed for chlorothalonil taking into account the existing uses at the EU level and the acceptable CXLs (EFSA, 2012). A tentative chronic risk assessment was also undertaken for metabolite SD-3701 considering the expected residue levels in animal commodities, but having regard to the lack of information on SD-3701 residue in the raw and processed plant commodities, EFSA was unable to conclude whether consumer exposure to SDS-3701 resulting from the use of chlorothalonil is acceptable.

EFSA updated these risk assessments with the median residue levels (STMR) derived from the residue trials conducted on cranberries (see Table 4). The food commodities, for which no uses were reported in the framework of the Article 12 review, were excluded from the exposure calculation, assuming that there is no use of chlorothalonil on these crops.

The acute exposure assessment was performed only with regard to cranberries assuming the consumption of a large portion of the food item as reported in the national food surveys and that these items contained residues at the highest residue level (HR) as observed in supervised field trials (see Table 4). A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 5.

[9] 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).

Table 5: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Risk assessment residue definition for plant commodities: chlorothalonil				
Cranberries	3.15	STMR	5.4	HR
Risk assessment residue definition for plant commodities: SDS-3701				
Cranberries	0.02	STMR	0.02	HR
Other commodities	See Table 4.1 and 4.2 in EFSA Reasoned Opinion on the Article 12 MRL review (EFSA, 2012)			

The estimated exposure was compared with the toxicological reference values derived for chlorothalonil and its metabolite SDS-3701 (see Table 2). The results of the intake calculation are presented in Appendix B of this reasoned opinion.

For chlorothalonil, the maximum chronic intake calculated accounted for up to 88 % of the ADI (WHO cluster diet). The contribution of residues in cranberries to the total consumer exposure accounted for a maximum of 0.2 % of the ADI (WHO cluster diet F).

An acute consumer risk was not identified relating to the short term exposure for cranberries. The highest acute consumer exposure was calculated to be 1.1 % of the ARfD for cranberries (DE, population).

For SDS-3701, the maximum chronic intake calculated accounted for up to 5.9% of the ADI (NL, child) with insignificant contribution of cranberries, lower than 0.01%. The highest acute consumer exposure was calculated to be 0.2 % of the ARfD for cranberries (DE, child).

Although there is no indication of consumer risk related to the MRL of 10 mg/kg for chlorothalonil in cranberries proposed by the applicant, EFSA is of the opinion that setting the MRL at a higher level than 5 mg/kg, the MRL in place in the origin country, is not appropriate.

Conclusions and recommendations

The information submitted was sufficient to propose the MRL summarised in the table below:

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: chlorothalonil[(F)]				
0154020	Cranberries	0.01*	5 (import tolerance USA)	The submitted trials support the setting of an import tolerance of 10 mg/kg (MRL_{OECD}: 9.5/10). However since the MRL currently in force on cranberries in the USA is 5 mg/kg and according to the procedure agreed in the PAFF meeting of December 2014, EFSA recommends to set the import tolerance value at a level of 5 mg/kg only.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005
(*): indicates that the MRL is set at the limit of analytical quantification (LOQ)
(F): fat soluble

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Abbreviations

a.s.	active substance
ACD	Advanced Chemistry Development
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex maximum residue limit (Codex MRL)
DAR	draft assessment report
DAT	days after treatment
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GLP	Good Laboratory Practice
GS	growth stage
HR	highest residue
ILV	Independent Laboratory Validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	limit of detection
LOQ	limit of quantification
LC	liquid chromatography
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
PAFF	Plant, Animals, Food and Feed

PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – Good Agricultural Practice (GAPs)

Crop and/or situation[a]	MS or NEU/SEU 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. a.s.[i]	Method kind[f-h]	Growth stage & season[j]	Number min-max (k)	Interval min-max	g/hL min-max	Water L/ha min-max	g/ha min-max		
Cranberry	USA	F	Fruit rots, Lophodermium leaf/twig blight (*L. hypophyllium*), Upright dieback (*Phomopsis vaccinii*)	WG/SC	82.5%/ 54.0%	Spray	Not specified	1-3		-	-	3360-5500	50	

Remarks:

(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage 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), water soluble granule (WG)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) all abbreviations 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 µg/L
(j) Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 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

Appendix B – Pesticide Residue Intake Model (PRIMo)- Chlorothalonil

Chlorothalonil			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.015	ARfD (mg/kg bw):	0.6
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2006	Year of evaluation:	2006

Prepare workbook for refined

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum	maximum
13	88

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)
87.8	WHO Cluster diet B	47.3	Tomatoes	11.4	Wine grapes	4.5	Aubergines (egg plants)	0.8
58.1	DE child	16.5	Apples	14.8	Tomatoes	8.1	Table grapes	0.5
47.1	FR toddler	11.9	Tomatoes	10.3	Beans (with pods)	7.2	Leek	0.5
45.1	IE adult	8.0	Wine grapes	6.2	Tomatoes	4.3	Aubergines (egg plants)	0.3
41.8	NL child	9.6	Tomatoes	8.7	Apples	4.8	Table grapes	0.7
41.7	FR all population	25.5	Wine grapes	6.6	Tomatoes	1.4	Leek	0.3
37.9	PT General population	15.8	Wine grapes	13.7	Tomatoes	2.4	Peaches	0.6
34.1	IT kids/toddler	21.9	Tomatoes	2.3	Peaches	1.6	Courgettes	0.5
33.8	WHO cluster diet E	10.2	Wine grapes	8.1	Tomatoes	2.6	Beans (with pods)	0.6
33.7	WHO regional European diet	16.9	Tomatoes	2.2	Peas (with pods)	1.9	Beans (with pods)	0.5
31.8	DK child	14.2	Cucumbers	8.2	Tomatoes	3.2	Apples	0.8
30.9	FR infant	7.8	Beans (with pods)	5.8	Courgettes	4.2	Leek	0.3
30.2	WHO cluster diet D	15.5	Tomatoes	2.3	Wine grapes	1.7	Cucumbers	0.8
30.0	IT adult	17.8	Tomatoes	2.5	Peaches	1.7	Aubergines (egg plants)	0.3
27.9	SE general population 90th percentile	11.7	Tomatoes	2.7	Cucumbers	1.4	Gherkins	0.5
24.7	ES child	15.1	Tomatoes	2.2	Beans (with pods)	1.6	Apples	0.4
23.8	NL general	6.5	Tomatoes	4.0	Wine grapes	2.3	Beans (with pods)	0.3
23.7	ES adult	12.0	Tomatoes	2.7	Wine grapes	2.2	Beans (with pods)	0.2
23.2	WHO Cluster diet F	10.5	Tomatoes	3.8	Wine grapes	1.0	Cucumbers	0.5
23.1	UK vegetarian	9.5	Tomatoes	5.2	Wine grapes	0.9	Cucumbers	0.2
22.7	PL general population	13.5	Tomatoes	2.8	Apples	2.0	Table grapes	0.3
22.2	DK adult	8.9	Wine grapes	6.3	Tomatoes	2.3	Cucumbers	0.3
22.0	UK Toddler	9.0	Tomatoes	2.3	Apples	1.8	Beans	0.5
19.1	UK Adult	6.9	Wine grapes	6.7	Tomatoes	0.6	HOPS (dried),	0.2
17.4	LT adult	9.5	Tomatoes	3.4	Cucumbers	2.6	Apples	0.4
17.3	UK Infant	5.6	Tomatoes	2.1	Apples	1.8	Strawberries	0.4
13.3	FI adult	6.5	Tomatoes	2.3	Cucumbers	1.9	Wine grapes	0.2

Conclusion:

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

Acute risk assessment /children - refined calculations

Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
1.1	Cranberries	5.4 / -	1.1	Cranberries	5.4 / -						

Appendix B – Pesticide Residue Intake Model (PRIMo)- SDS-3701

4-Hydroxy-2,5,6-trichloroisopphtaloniytile (SDS-3701)

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2006**	Year of evaluation:	**2006**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
	6
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)
5.9	NL child	5.1	Milk and milk products: Cattle	0.3	Swine: Meat	0.1	Swine: Liver	
4.6	FR infant	4.4	Milk and milk products: Cattle	0.1	Bovine: Meat	0.1	Poultry: Meat	
3.0	ES child	2.2	Milk and milk products: Cattle	0.2	Swine: Meat	0.2	Bovine: Meat	
2.8	DE child	2.5	Milk and milk products: Cattle	0.1	Birds' eggs	0.1	Swine: Meat	
2.2	SE general population 90th percentile	2.1	Milk and milk products: Cattle	0.1	Birds' eggs	0.0	Cranberries	
1.5	NL general	1.1	Milk and milk products: Cattle	0.2	Swine: Meat	0.1	Bovine: Meat	
1.5	WHO regional European diet	0.8	Milk and milk products: Cattle	0.3	Swine: Meat	0.1	Bovine: Meat	
1.3	ES adult	0.9	Milk and milk products: Cattle	0.1	Swine: Meat	0.1	Bovine: Meat	
1.2	WHO Cluster diet B	0.5	Milk and milk products: Cattle	0.2	Swine: Meat	0.1	Bovine: Kidney	
1.2	WHO Cluster diet F	0.7	Milk and milk products: Cattle	0.2	Swine: Meat	0.1	Bovine: Meat	
1.1	WHO cluster diet D	0.8	Milk and milk products: Cattle	0.1	Bovine: Meat	0.1	Swine: Fat free of lean meat	
1.1	LT adult	0.7	Milk and milk products: Cattle	0.2	Swine: Meat	0.1	Swine: Fat free of lean meat	
1.0	WHO cluster diet E	0.5	Milk and milk products: Cattle	0.1	Swine: Fat free of lean meat	0.1	Swine: Meat	
0.8	IE adult	0.5	Milk and milk products: Cattle	0.1	Swine: Meat	0.1	Sheep: Liver	
0.7	FR all population	0.5	Milk and milk products: Cattle	0.1	Poultry: Meat	0.1	Bovine: Meat	
0.4	FR toddler	0.2	Bovine: Meat	0.1	Birds' eggs	0.1	Poultry: Meat	
0.2	UK Infant	0.1	Birds' eggs	0.0	Bovine: Kidney	0.0	Bovine: Liver	
0.1	DK child	0.1	Birds' eggs	0.0	Bovine: Liver		FRUIT (FRESH OR FROZEN)	
0.1	DK adult	0.1	Bovine: Meat	0.0	Birds' eggs	0.0	Bovine: Liver	
0.1	UK Toddler	0.1	Birds' eggs	0.0	Bovine: Kidney	0.0	Bovine: Liver	
0.0	UK vegetarian	0.0	Birds' eggs	0.0	Poultry: Meat		FRUIT (FRESH OR FROZEN)	
0.0	UK Adult	0.0	Birds' eggs	0.0	Bovine: Kidney	0.0	Bovine: Liver	
0.0	FI adult	0.0	Birds' eggs	0.0	Cranberries		FRUIT (FRESH OR FROZEN)	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of 4-Hydroxy-2,5,6-trichloroisopphtaloniytile (SDS-3701) is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations

Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

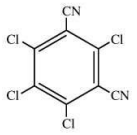
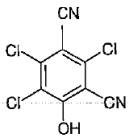
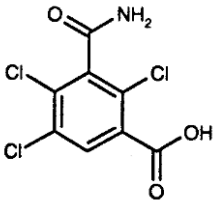
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
0.2	Cranberries	0.02 / -	0.2	Cranberries	0.02 / -						

Appendix C – Used compound code(s)

Code/Trivial name	Chemical name[(a)]	Structural formula[(a)]
chlorothalonil	Tetrachloroisophthalonitrile	
SDS-3701	2,5,6-trichloro-4-hydroxyphtalonitrile	
SDS-46851	3-carboxy-2,5,6-trichloro benzamide	

(a): ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).