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## **Modification of the existing maximum residue levels for acequinocyl in cherries and plums**

**European Food Safety Authority (EFSA)**

### **Abstract**

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Germany, received an application from Landwirtschaftliches Technologiezentrum Augustenberg to modify the existing maximum residue levels (MRLs) for the active substance acequinocyl in cherries and plums. In order to accommodate for the intended Northern Europe (NEU) uses of acequinocyl, Germany proposed to raise the existing MRLs from the limit of quantification of 0.01 mg/kg to 0.1 mg/kg for cherries and to 0.02 mg/kg for plums. Germany 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 0.1 mg/kg for cherries and 0.02 mg/kg for plums in support of the proposed use of acequinocyl in Germany. Based on the risk assessment results, EFSA concludes that the proposed use of acequinocyl on cherries and plums will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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**Keywords:** acequinocyl, cherries, plums, 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) Germany, received an application from Landwirtschaftliches Technologiezentrum Augustenberg to modify the existing maximum residue levels (MRLs) for the active substance acequinocyl in cherries and plum. In order to accommodate for the intended uses of acequinocyl, Germany proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 mg/kg to the MRL of 0.1 mg/kg for cherries and to 0.02 mg/kg for plums. Germany 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 1 December 2014.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC, the Commission review report on acequinocyl, the conclusion on the peer review of the pesticide risk assessment of the active substance acequinocyl, as well as the conclusions from previous EFSA reasoned opinions on acequinocyl.

The toxicological profile of acequinocyl was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.023 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.08 mg/kg bw.

The metabolism of acequinocyl in primary crops was investigated in fruit crop group following foliar application. For the fruit crop group the residue for the enforcement and risk assessment was defined as parent acequinocyl. EFSA concludes that the metabolism of acequinocyl is sufficiently addressed and that the derived residue definitions are applicable.

EFSA concludes that the submitted residue trials are sufficient to derive a MRL proposal of 0.1 mg/kg for cherries and 0.02 mg/kg for plums. Adequate analytical enforcement methods are available to monitor the residues of acequinocyl in high water and high acid content plant matrices at the validated LOQ of 0.01 mg/kg.

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

As the proposed uses of acequinocyl are on permanent crops and since the crops under consideration are normally not fed to livestock, investigation of residues in rotational crops and livestock is not required.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). The highest calculated chronic intake accounted for 8 % of the ADI (DE child). An acute consumer risk was not identified in relation to the MRL proposals for plums and cherries (highest acute consumer exposure was calculated to be 1 % of the ARfD for cherries and plums).

EFSA concludes that the intended use of acequinocyl on cherries and plums will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a health risk to consumers.

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

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
<b>Enforcement residue definition: Acequinocyl</b>				
0140020	Cherries (sweet)	0.01*	0.1	NEU trials
0140040	Plums	0.01*	0.02	NEU trials

(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)

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## Background

Regulation (EC) No 396/2005<sup>1</sup> 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,<sup>2</sup> repealed by Regulation (EC) No 1107/2009,<sup>3</sup> shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of the Regulation.

Germany, hereafter referred to as the evaluating Member State (EMS), received an application from the Landwirtschaftliches Technologiezentrum Augustenberg<sup>4</sup> to modify the existing MRLs for the active substance acequinocyl in cherries and plums. 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 1 December 2014. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00930 and the following subject:

*Acequinocyl - Application to modify the existing MRLs in cherries and plums.*

Germany proposed to raise the existing MRLs of acequinocyl in cherries and plums from the limit of quantification (LOQ) of 0.01 mg/kg to 0.1 mg/kg for cherries and to 0.02 mg/kg for plums.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation. On 21 January 2015 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, addressing those data requirements, was submitted by the EMS on 18 August 2015 and taken into consideration by EFSA for finalization of this reasoned opinion.

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

Acequinocyl is the ISO common name for 3-dodecyl-1,4-dihydro-1,4-dioxo-2-naphthyl acetate (IUPAC). The chemical structure of the active substance is reported in Appendix C. The active substance has been approved for the uses as acaricide.

Acequinocyl 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 Commission Implementing Regulation (EU) No 496/2014<sup>5</sup> which entered into force on 4 June 2014 for

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.

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<sup>5</sup> Commission Implementing Regulation (EU) No 496/2014 of 14 May 2014 approving the active substance acequinocyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 143, 15.5.2014, p. 1–5.

use as acaricide only. In accordance with Regulation (EU) No 540/2011<sup>6</sup> acequinocyl is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The representative uses evaluated in the peer review were field and greenhouse foliar applications on ornamentals, apples and pears. The draft assessment report (DAR) has been peer reviewed by EFSA (EFSA, 2013a).

The EU MRLs for acequinocyl are established in Annex IIIA of Regulation (EC) No 396/2005. Since the entry into force of this regulation EFSA has issued several reasoned opinions on the modification of MRLs for acequinocyl. 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 (EC) No 396/2005, are summarised in Table 1.

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

Procedure <sup>(a)</sup>	Considered by Regulation	Remarks
Art. 10 (EFSA, 2010a)	(EC) No 893/2010	oranges, mandarins, peaches, grapes, tomatoes and aubergines
Art. 10 (EFSA, 2010b)	(EC) No 813/2011	hops
Art. 10 (EFSA, 2013b)	(EC) No 814/2013	cucumbers, melons and pumpkins

(a): Art. 10: Assessment of MRL application according to Article 6 to 10 of Regulation (EC) No 396/2005

No CXLs are established for acequinocyl. The details of the intended GAPs for acequinocyl on plums and cherries in Germany are given in Appendix A.

## Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (Germany, 2015), the DAR (and its addenda) prepared under Directive 91/414/EEC (The Netherlands, 2005; 2007 and 2013), the Commission review report on acequinocyl (European Commission, 2014), the conclusion on the peer review of the pesticide risk assessment of the active substance acequinocyl (EFSA, 2013a) as well as the conclusions from previous EFSA opinions on acequinocyl (EFSA, 2010a, b; EFSA, 2013b). 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<sup>7</sup> 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 acequinocyl residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (The Netherlands, 2005). For the determination of acequinocyl in matrices with high water and high acid content an HPLC-MS/MS method has been validated at the LOQ of 0.01 mg/kg (EFSA, 2013a). An independent laboratory validation (ILV) study has been submitted.

EFSA concludes that sufficiently validated analytical methods are available to control residues of acequinocyl in the crops under consideration.

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

Analytical methods for the determination of acequinocyl residues in food of animal origin are not assessed in the current application, since plums and cherries or their by-products are normally not fed to livestock.

<sup>6</sup> 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.

<sup>7</sup> 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.

## 2. Mammalian toxicology

The toxicological profile of the active substance acequinocyl was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2013a). The data were sufficient to derive toxicological reference values compiled in Table 2.

**Table 2:** Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
<b>acequinocyl</b>					
ADI	EFSA	2013	0.023 mg/kg bw per day	2-year, rat	100
ARfD	EFSA	2013	0.08 mg/kg bw	Mechanistic studies, single dose, rat	100

## 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 acequinocyl in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC in fruit crop group only (apples, aubergines and oranges) following foliar treatment (The Netherlands, 2005). The study details are summarised in Table 3.

**Table 3:** Overview of plant metabolism studies

Crop Group	Crop	Application	Sampling <sup>(a)</sup> (day, DAT)	Remarks
Fruit	Apple	Foliar: 1x 750 g/ha	14, 21, 30 DAT	
	Aubergine	Soil and foliar: 1x 600 g/ha	7, 14 DAT	
	Orange	Foliar: 1x 1050 g/ha	14, 21, 30 DAT	

(a): DAT; Days after Treatment

Based on the available metabolism studies, the residue definition for monitoring and risk assessment was proposed as "acequinocyl" and limited to the fruit crop group only in the conclusion of the peer review (EFSA, 2013a). The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

Since the uses under consideration in this MRL application are referring to crops belonging to the fruit crop group, EFSA concludes that the metabolism of acequinocyl is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the peer review are applicable.

##### 3.1.1.2. Magnitude of residues

a. Cherries (northern Europe good agricultural practice (NEU GAP): 1 x 93.75 g/m crown height, pre-harvest interval (PHI) 21 days)

The applicant submitted in total 9 residue trials on cherries which were performed in various places of Germany in 2010, 2011 and 2012. Four trials were carried out on sour cherries and five on sweet cherries. In one trial, residues below the LOQ of 0.01 mg/kg (0.006 and 0.007 mg/kg) were observed in the control samples collected at 0 and 21 day PHI, whereas residues accounted for 0.47 and 0.011 mg/kg in the samples from treated trees. The sample from this trial was disregarded from the data set, although the EMS proposed to include these data given that residues in this sample were at the lower end of the data population. The number of residue trials is sufficient to derive a MRL proposal of 0.1 mg/kg.

b. Plums (NEU GAP: 1 x 93.75 g/m crown height, PHI 21 days)

The applicant submitted trials on plums conducted in 8 different experimental locations in Germany in the growing seasons of 2010, 2011 and 2012. In one location, two plots were treated according the

same experimental conditions (trials RU 1043/2 and trial RU 1043) and therefore these trials were considered not independent and a mean value was selected for the MRL calculation. In one trial the control sample on 0 d PHI contained residues up to 0.023 mg/kg but, as the sample from the treated plot at the 21 day PHI did not contain residues above the LOQ, this trial was not disregarded. The number of submitted residue trials is sufficient to derive a MRL proposal of 0.02 mg/kg.

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

The stability of acequinocyl residues in plant matrices under frozen storage conditions prior to analysis was assessed during the peer review under Directive 91/414/EEC (EFSA, 2013a). Residues of acequinocyl were found to be stable at  $\leq -18^{\circ}\text{C}$  for up to 18 months in high water content matrices (apples). As the trial samples were stored for a maximum period of 17 months under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical methods used to analyse the residue trial samples have been sufficiently validated and were proven to be fit for the purpose (Germany, 2015).

EFSA concludes that the data are sufficient to derive the following MRL proposals:

- 0.1 mg/kg cherries in NEU
- 0.02 mg/kg plums in NEU

**Table 4:** Overview of the available residues trials data

Crop (GAPs)	Region/ Indoor <sup>(a)</sup>	Residue levels observed in the supervised residue trials <sup>(b)</sup> (mg/kg)	Recommendations/comments <sup>(c)</sup>	MRL proposal (mg/kg)	HR <sup>(d)</sup> (mg/kg)	STMR <sup>(e)</sup> (mg/kg)
<b>Cherries</b>  (2x 93.75 g/m canopy, PHI 21 days)	NEU	<0.01; <u>0.012</u> ; 0.013; 0.025; 0.029; 0.033; 0.05; 0.06	<u>Underlined value:</u> sample taken at 28 day PHI; for this trial sampling at the PHI of 21 d not done. MRL <sub>OECD</sub> : 0.10/0.1	<b>0.1</b>	0.06	0.027
<b>Plums</b>  (2x 93.75 g/m canopy, PHI 21 days)	NEU	6x <0.01; 0.012; 0.013	MRL <sub>OECD</sub> : 0.016/0.02	<b>0.02</b>	0.013	0.01

(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, PHI: pre-harvest interval

(b): Individual residue levels considered for MRL calculation are reported in ascending order (2x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.10, 0.15, 0.17).

(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.

### 3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the nature of acequinocyl residues under processing conditions representative of pasteurisation, boiling and sterilisation have not been made available and were not requested by the peer review, given low residues in raw commodities and low consumer exposure (EFSA, 2013a). New studies on the effect of processing on the nature and magnitude of acequinocyl residues have not been submitted under the current application and are not requested 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 acequinocyl is on permanent 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 crops under consideration and their by-products are not normally fed to livestock, the nature and magnitude of acequinocyl 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<sup>8</sup> (EFSA, 2007).

To calculate the chronic exposure, EFSA used median residue values (STMR) derived from the residue trials conducted on plums and cherries and reported in Table 4. For several other commodities the median residue values available from previously issued EFSA reasoned opinions were considered to refine the exposure calculation (EFSA, 2013b). For the remaining commodities of plant and animal origin, the existing MRLs as established in Regulation (EU) No 834/2013<sup>9</sup> were used as input values.

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items 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.

The estimated exposure was then compared with the toxicological reference values derived for acequinocyl (see Table 1). The results of the intake calculation are presented in Appendix B of this reasoned opinion.

<sup>8</sup> 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).

<sup>9</sup> Commission Regulation (EU) No 834/2013 of 30 August 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, bixafen, diazinon, difenoconazole, etoxazole, fenhexamid, fludioxonil, isopyrazam, lambda-cyhalothrin, profenofos and prothioconazole in or on certain products. OJ L 233, 31.8.2013, p. 11–42

**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
<b>Risk assessment residue definition:</b> Acequinocyl				
Plums	0.01	STMR (Table 4)	0.013	HR (Table 4)
Cherries	0.027	STMTR (Table 4)	0.06	HR (Table 4)
Oranges	0.01	STMR (EFSA, 2013b)	Acute risk assessment undertaken only with regard to the crops under consideration	
Mandarins	0.02			
Peaches	0.014			
Table and wine grapes	0.045			
Tomatoes	0.1			
Aubergines	0.1			
Cucumbers	0.02			
Hops	2.6			
Other plant and animal commodities	MRL	MRLs in Regulation (EU) No 834/2013		

The total chronic intake calculated accounted for up to 8 % of the ADI (DE child). The contribution of residues in cherries and plums to the total consumer exposure accounted for a maximum of 0.1 % of the ADI.

An acute consumer risk was not identified in relation to the MRL proposals for plums and cherries. The highest acute consumer exposure was calculated to be 1 % of the ARfD for cherries and plums.

EFSA concludes that the intended use of acequinocyl on cherries and plums will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

## Conclusions and recommendations

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

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
<b>Enforcement residue definition:</b> Acequinocyl				
0140020	Cherries (sweet)	0.01*	0.1	NEU trials
0140040	Plums	0.01*	0.02	NEU trials

(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)

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## Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit (Codex MRL)
DAR	draft assessment report
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
GAP	good agricultural practice
GS	growth stage
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
wk	week
yr	year

## Appendix A – Good Agricultural Practice (GAPs)

Crop and/or situation <sup>(a)</sup>	MS or NEU/ SEU or Country	F G or I <sup>(b)</sup>	Pest or group of pests controlled <sup>(c)</sup>	Formulation		Application			Application rate per treatment			PHI (days) <sup>(l)</sup>	Remarks <sup>(m)</sup>
				type <sup>(d-f)</sup>	conc. a.s. <sup>(i)</sup>	Method kind <sup>(f-h)</sup>	Growth stage & season <sup>(j)</sup>	Number min-max <sup>(k)</sup>	g/hL min-max	Water L/ha min-max	g/ha min-max		
Cherries	Germany	F	Red spider mites	SC	150 g/L	Foliar spraying	BBCH 75-81	1	18.75 (/m crown height)	500 (/m crown height)	93.75 (/m crown height)	21	
Plums	Germany	F	Red spider mites	SC	150 g/L	Foliar spraying	BBCH 75-81	1	18.75 (/m crown height)	500 (/m crown height)	93.75 (/m crown height)	21	

### 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, 2<sup>nd</sup> 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



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 variability 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):					
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	IESTI 1		*)	**)		IESTI 2		*)	**)		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	Cherries	0,06 / -	1	Cherries	0,06 / -	0	Cherries	0,06 / -	0	Cherries	0,06 / -			
1	Plums	0,013 / -	0	Plums	0,013 / -	0	Plums	0,013 / -	0	Plums	0,013 / -				
No of critical MRLs (IESTI 1)						No of critical MRLs (IESTI 2)									
---						---									
Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:					
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	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.															
**) pTMRL: provisional temporary MRL															
***) pTMRL: provisional temporary MRL for unprocessed commodity															
<b>Conclusion:</b>															
For Acequinocyl IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.															
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.															
For processed commodities, no exceedance of the ARfD/ADI was identified.															

## Appendix C – Used compound codes

Code/Trivial name	Chemical name	Structural formula
acequinocyl	3-dodecyl-1,4-dihydro-1,4-dioxo-2-naphthyl acetate  MW: 384.5	