

## REASONED OPINION

### Modification of the existing MRLs for acibenzolar-S-methyl in peaches and apricots<sup>1</sup>

European Food Safety Authority<sup>2</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

According to Article 6 of Regulation (EC) No 396/2005, France received an application from Syngenta Agro S.A.S. to modify the existing MRLs for acibenzolar-S-methyl in peaches and apricots. In order to accommodate for intended uses of acibenzolar-S-methyl in southern EU Member States, it is proposed to raise the existing MRLs in peaches and apricots from 0.02 mg/kg which is equivalent to the limit of quantification, to 0.2 mg/kg. France drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 20 July 2009.

EFSA derived the following conclusions based on the above mentioned evaluation report and the Draft Assessment Report (DAR) prepared by France under Directive 91/414/EEC.

The toxicological profile for acibenzolar-S-methyl was investigated in the peer review and data were sufficient to conclude on an ADI value of 0.1 mg/kg. No ARfD was established because of the low acute toxicity of the active substance.

Metabolism of acibenzolar-S-methyl in primary plants was investigated in the framework of the peer review on cereals (wheat), fruiting vegetables (tomatoes) and leafy vegetables (tobacco). An additional metabolism study on lettuce was evaluated in the evaluation report prepared by France in support of the given application. The residue definition established in the peer review for risk assessment and enforcement for all crop groups was *acibenzolar-S-methyl and acibenzolar acid (CGA 210007), expressed as acibenzolar-S-methyl*.

A sufficiently validated analytical method is available to enforce MRLs in peaches for the enforcement residue definition.

From the supervised field trials on peaches which can also be used to extrapolate to the expected residue behaviour for apricots it is concluded that a MRL of 0.2 mg/kg is required to accommodate the intended uses in these crops.

The chronic dietary consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model) and included the existing MRLs as established in Annex III of Regulation 396/2005 as well as the STMR values derived for the intended uses on peaches and apricots and for several other crops where further information was available.

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1 On request from the European Commission, Question No EFSA-Q-2009-00729, issued on 16 November 2009.

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The calculations demonstrate that no consumer health risk is expected from crops treated according to the authorised Good Agricultural Practice, including the intended uses on peaches and apricots. In all diets included in the EFSA PRIMo, the dietary intake accounted for less than 2% of the ADI. The contribution of peaches and apricots is insignificant (in both cases less than 0.02% of the ADI).

An acute dietary risk assessment is not necessary because of the low acute toxicity of the active substance for which no ARfD has been considered necessary.

EFSA concludes that the intended use of acibenzolar-S-methyl in peaches and apricots is acceptable with regard to the consumer exposure and the following MRLs are recommended to be included in Annex II of Regulation (EC) No 396/2005:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl)			
Peaches (including nectarines and similar hybrids)	0.02*	0.2	The proposed MRLs are sufficiently supported by data. No risk for consumers was identified for the proposed MRLs.
Apricots	0.02*	0.2	

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

#### KEY WORDS

Acibenzolar-S-methyl, peaches, apricots, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, benzthiadiazoles, acibenzolar acid (CGA 210007)

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## BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from the company Syngenta Agro S.A.S<sup>3</sup> to modify the existing MRLs for the active substance acibenzolar-S-methyl in peaches and apricots. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 20 July 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00729 and the following subject:

*Acibenzolar-S-methyl - Application to modify the existing MRLs in peaches and apricots*

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

## TERMS OF REFERENCE

According to 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.

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

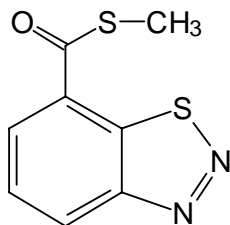
In this particular case the calculated deadline for providing the reasoned opinion is 20 October 2009.

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## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Acibenzolar-S-methyl is the ISO common name for S-methyl benzo[1,2,3]thiadiazole-7-carbothioate (IUPAC). In older studies, the development code is used which is CGA 245704.



Molecular weight: 210.3

Acibenzolar-S-methyl belongs to the class of benzothiadiazoles.

Acibenzolar-S-methyl is used to stimulate the natural, inherent defence mechanisms of plants to prevent plant diseases. The naturally occurring phenomenon of this defence response is called Systemic Activated Resistance (SAR), also known as systemic acquired resistance or systemic induced resistance. SAR is a broad physiological immunization in plants that occurs in nature. Acibenzolar-S-methyl imitates the natural biological SAR induction by activation of the same biochemical changes in plants as after a biological induction. Through this activation, control of *Erysiphe graminis* (powdery mildew of cereals), *Peronospora tabacina* (blue mould of tobacco), and Black Sigatoka of banana is achieved. It has been shown that the substance as such does not have an intrinsic fungicidal activity.

Acibenzolar-S-methyl is a new active substance according to the definition of Directive 91/414/EEC. France was designated as the Rapporteur Member State (RMS). After having passed successfully the peer review, acibenzolar-S-methyl was included in Annex I of Directive 91/414/EEC by Directive 2001/87/EC which entered into force on 1 November 2001. The uses evaluated in the peer review were the uses on wheat, spring barley and tobacco.

MRLs for acibenzolar-S-methyl have been established at EU level for the first time in 2003 which were modified in 2008 to accommodate for the new uses authorised in Member States. The MRLs established under the previous European MRL legislation were transferred to Annex II of Regulation 396/2005. The residue definition for enforcement was established as *acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl)*. The currently valid MRLs can be found in Appendix C of this report. Codex Alimentarius did not establish CXLs for this active substance.

The current MRLs for peaches and apricots are set at the LOQ of 0.02 mg/kg. According to the proposal made by the Evaluating Member State it would be necessary to raise these MRLs to 0.2 mg/kg.

The GAP for which an authorisation is intended refers to outdoor foliar applications of acibenzolar-S-methyl on peaches and apricots. The water dispersible granule has to be applied five times a year with an interval between applications of 10 to 14 days at the rate of 75 g a.s./ha for each application; the PHI is 7 days. The intended GAP is summarized in Appendix A.

EFSA bases its assessment on the evaluation report submitted by France (2009a) and the draft assessment report prepared under Directive 91/414/EEC (France, 1998).

## ASSESSMENT

### 1. Methods of analysis

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

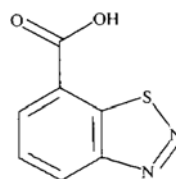
Analytical methods for the determination of acibenzolar-S-methyl in commodities with high water content have been evaluated in the framework of the peer review under Directive 91/414/EEC (France, 1998). The methods are based on HPLC with UV-detection.

In addition, the EMS reported analytical methods applicable to the quantitative determination of the combined residues of acibenzolar-S-methyl and its metabolite CGA 210007<sup>4</sup> in peach fruits (France, 2009). Acibenzolar-S-methyl and metabolites containing the CGA 210007 moiety are hydrolysed to CGA 210007 by heating the homogenised sample in a sodium hydroxide solution followed by an acid/alkaline/acid partition. The final determination of CGA 210007 is performed by a two column HPLC switching system with diode-array detection (detection at 235 nm). The LOQ achievable is 0.02 mg/kg. The conversion factor for CGA 210007 (molecular weight: 180) to acibenzolar-S-methyl (molecular weight 210.3) is 1.17.

It is concluded that for the intended use in peaches and apricots a sufficiently validated analytical method is available to enforce the currently established residue definition.

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

Peaches and apricots are not used as livestock feed. Therefore there is no need to provide an analytical method for food of animal origin in the framework of this application. Nevertheless, it should be mentioned that validated analytical methods based on HPLC/UV are available for products of animal origin.



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<sup>4</sup> CGA 210007: Benzo[1,2,3]thiadiazole-7-carboxylic acid

## 2. Mammalian toxicology

In the peer review under Directive 91/414/EEC an ADI of 0.1 mg/kg bw/d was derived. Due to the low acute toxicity it was concluded that no ARfD has to be established (France, 1998 and European Commission, 2002).

The summarised toxicological reference values can be found in Table 2-1.

**Table 2-1.** Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
<b>Acibenzolar-S-methyl</b>					
ADI	COM (review report)	2002	0.1	90 d and 12 month dog study	100
ARfD	COM (review report)	2002	-	Not necessary	

The only metabolite, which was included in the residue definition, is the acibenzolar acid (CGA 210007). This metabolite was also observed in the rat metabolism. No further toxicological studies were therefore considered necessary for this compound.

### 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 acibenzolar-S-methyl in primary crops (wheat, tomatoes and tobacco) have been assessed in the framework of the peer review under Directive 91/4141/EEC (France, 1998). In addition, a new metabolism study on lettuce was reported in the Evaluation Report (France, 2009a). All metabolism studies were performed with [phenyl-U-<sup>14</sup>C] labelled acibenzolar-S-methyl.

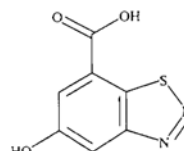
- Cereals: wheat (foliar application at 4 leaf stage: application rate: 50 g ai/ha)  
wheat (foliar application at the end of tillering, application rate 50 g ai/ha)
- Fruits and fruiting vegetables: tomato (foliar application, growth stage 69, 3\*15.2 g ai/hl)
- Leafy vegetables: tobacco (3 foliar applications, total rate 170 g ai/ha)  
lettuce (foliar application with 4\*35 g ai/ha and 3\*100 g ai/ha)

For the crops assessed in the peer review (wheat, tomato, tobacco) it was concluded that the metabolic pathway proceeds via the hydrolysis of the parent compound to CGA 210007 followed by ester conjugation with sugars in tomatoes, wheat and tobacco. Subsequent oxidation of the phenyl ring leads to CGA 324041<sup>5</sup> and CGA 323060<sup>6</sup> which were identified in tomatoes and tobacco followed by sugar conjugation as O-glycoside. It was concluded that the metabolic pathways in plants are qualitatively similar in all crops tested.

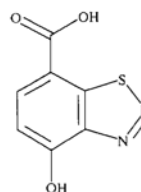
In conclusion, a general residue definition was derived for all crops which comprises the *sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl*. This residue definition is applicable for risk assessment and monitoring.

The metabolism study in lettuce which was not evaluated in the peer review confirmed the proposed metabolic pathway. The total residues at harvest (one week after the last application) were 1.014 mg/g for the low dose rate (1N) and 3.668 mg/kg for the high dose rate (3N). The minor part of the radioactivity was found on the lettuce surface (20.2% and 23%, respectively) whereas the major portion of the total radioactivity has penetrated the leaves. The surface wash and the washed leaves were analysed separately for characterisation and identification of metabolites. On the surface, the parent compound was the predominant compound (16.5% of TRR (1N), 19.3% of TRR (3N); the

<sup>5</sup> CGA 324041 (I5a): 5-hydroxy-benzo[1,2,3]thiadiazole-7-carboxylic acid



<sup>6</sup> CGA 323060 (I5b): 4-Hydroxy-benzo[1,2,3]thiadiazole-7-carboxylic acid





metabolites were in all cases below 1% TRR or 0.007 mg/kg. In the washed leaves, four minor metabolites occurring in concentrations of 0.9 to 4.4% of the TRR (1N trial) were identified which confirm the assumed metabolic pathway as proposed in the peer review. In addition, in the trial with 1N dose rate three metabolites were detected (I2 (25%TRR, 0.25 mg/kg, I3 (10.3%TRR, 0.104 mg/kg) and I4 (9.6%TRR, 0.097 mg/kg)). In the 3N trial, an additional metabolite was detected in a significant concentration (I1b, 12.6%). The same metabolites were also observed in the tomato study. In this study the metabolite fraction I1a to I4 was identified as sugar conjugates of CGA 323060 and CGA 210007. All other metabolites identified in the 1N and 3N dose rate trial in lettuce were below 10% of TRR.

EFSA concludes that the nature of residues resulting from the use of acibenzolar-S-methyl is elucidated. The metabolic pathway of acibenzolar-S-methyl in all crops proceeds via hydrolysis of the parent compound to acibenzolar acid (CGA 210007), followed by ester conjugation with sugars in tomato, wheat and leafy vegetables. Subsequent oxidation of the phenyl ring of CGA 210007 led to the formation of further metabolites which finally formed sugar conjugates (O-glycosides). The residue definition established in the peer review for risk assessment and enforcement for all crop groups was *acibenzolar-S-methyl and acibenzolar acid (CGA 210007), expressed as acibenzolar-S-methyl*.

#### 3.1.1.2. Magnitude of residues

The applicant submitted eight supervised field trials on peaches which were performed according to the intended GAP in Italy in 2002 and 2003. Six of these trials were designed as decline studies. The results of the trials are compiled in Table 3-1.

The residue data on peaches demonstrate that a MRL of 0.2 mg/kg would be required to accommodate the intended GAP for peaches. According to guidance document on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2008), the trials on peaches can also be used to propose MRLs for apricots.

Prior to analysis, the peach samples were stored deep frozen for not more than 104 days. The stability of residues (parent compound and CGA 210007) under storage conditions has been investigated in tobacco, lettuce, tomatoes, wheat, cabbage, squash and turnips. No significant degradation was observed within 20 months of storage under freezer conditions at -20°C.

The samples were analysed with a method which was sufficiently validated. Thus, it is concluded that the MRL application is sufficiently supported by valid studies.

**Table 3-1.** Overview of the available residues trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
<b>Acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl)</b>									
Peaches → apricots	SEU	Outdoor	4*0.02; 0.048; 0.049; 0.05; 0.09	4*0.02; 0.048; 0.049; 0.05; 0.09	0.034	0.09	0.2	1	Data on peaches are used to derive MRL for peaches and apricots Rber= 0.099 Rmax= 0.119

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

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

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

No hydrolysis study simulating heat treatment of food such as pasteurization, boiling baking, brewing or sterilization is available.

As the theoretical maximum daily intake represents less than 10 % of the ADI and as the residue levels do not exceed the trigger value of 0.1 mg/kg in the residue trials (HR=0.09 mg/kg), no processing study is required.

### 3.1.2. Rotational crops

As peaches, nectarines and apricots are perennial crops, no rotational crop studies are necessary.

## 3.2. Nature and magnitude of residues in livestock

Peaches, nectarines and apricots or any of their by-products are not part of the livestock diet. Therefore no further considerations are relevant regarding residues in feed and their transfer into food of animal origin.

## 4. Consumer risk assessment

The consumer intake calculation was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model), using the STMR value derived from the supervised field trials in peaches and MRLs as established in Regulation (EC) No 396/2005. For some commodities, STMR values could be derived from the Pesticide Residue Overview File (PROFile) which was provided by France in support of the MRL review according to Article 12(2) of Regulation 396/2005 (France, 2009b). No acute risk assessment was performed because an ARfD has not been established. The input values for the dietary intake calculation are summarised in Table 4-1.

**Table 4-1.** Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl)				
Hazelnuts	0.04	STMR (France, 2009b)	Acute risk assessment was not performed since no ARfD is established for acibenzolar-S-methyl.	
Apricots	0.034	STMR		
Peaches	0.034	STMR		
Bananas	0.02	STMR (France, 2009b)		
Mangoes	0.24	STMR (France, 2009b)		
Tomatoes	0.19	STMR (France, 2009b)		
Spinach	0.14	STMR (France, 2009b)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Other commodities of plant or animal origin	MRL	See Appendix C		

The results of the consumer risk assessment are attached in Appendix B. The calculations demonstrate that no consumer health risk is expected from crops treated according to the authorised GAPs, including the intended uses on peaches and apricots. In all diets included in the EFSA PRIMo, the dietary intake accounted for less than 2% of the ADI. The contribution of peaches and apricots is insignificant (in both cases less than 0.02% of the ADI).

EFSA concludes that the intended use of acibenzolar-S-methyl in peaches and apricots is acceptable with regard to the consumer exposure.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

Metabolism of acibenzolar-S-methyl in primary plants was investigated in the framework of the peer review on cereals (wheat), fruiting vegetables (tomatoes) and leafy vegetables (tobacco). An additional metabolism study on lettuce was evaluated in the evaluation report prepared by France in support of the given application. The metabolic pathway of acibenzolar-S-methyl in all crops proceeds via hydrolysis of the parent compound to acibenzolar acid (CGA 210007), followed by ester conjugation with sugars in tomato, wheat and leafy vegetables. Subsequent oxidation of the phenyl ring of CGA 210007 led to the formation of further metabolites which finally formed sugar conjugates (O-glycosides). The residue definition established in the peer review for risk assessment and enforcement for all crop groups was *acibenzolar-S-methyl and acibenzolar acid (CGA 210007), expressed as acibenzolar-S-methyl*. A sufficiently validated analytical method is available to enforce MRLs in peaches for the enforcement residue definition.

From the supervised field trials on peaches it is concluded that a MRL of 0.2 mg/kg is required to accommodate the intended uses in this crop. The MRL can be extrapolated to apricots since the GAP is identical and the residue behaviour is expected to be similar.

The chronic dietary consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model) and included the existing MRLs as established in Annex III of Regulation 396/2005 as well as the STMR values derived for the intended uses on peaches and apricots and for several other crops where further information was provided by the RMS.

The calculations demonstrate that no consumer health risk is expected from crops treated according to the authorised uses, including the intended uses on peaches and apricots. In all diets included in the EFSA PRIMo, the dietary intake accounted for less than 2% of the ADI. The contribution of peaches and apricots is insignificant (in both cases less than 0.02% of the ADI).

An acute dietary risk assessment is not necessary because of the low acute toxicity of the active substance for which no ARfD has been considered necessary.

EFSA concludes that the intended use of acibenzolar-S-methyl in peaches and apricots is acceptable with regard to the consumer exposure.

### RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl)			
Peaches (including nectarines and similar hybrids)	0.02*	0.2	The proposed MRLs are sufficiently supported by data. No risk for consumers was identified for the proposed MRLs.
Apricots	0.02*	0.2	

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

**REFERENCES**

- European Commission, 2002. Review Report for the active substance acibenzolar-S-methyl finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 29 June 2001 in [view of the inclusion of CGA 245 704 (acibenzolar-S-methyl) in Annex I of Directive 91/414/EEC. 6506/VI/99-final, 21 May 2002
- European Commission, 2008. Appendix D – Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525//VI/95 rev.8, 1 February 2008.
- France, 1998. Draft Assessment Report (DAR) on the active substance acibenzolar-S-methyl prepared by the Rapporteur Member State France in the framework of Directive 91/414/EEC, December 1998.
- France, 2009a. Evaluation report on the setting of MRLs for acibenzolar-S-methyl in peaches (including nectarines) and apricots prepared by the evaluating Member State France under Article 8 of Regulation (EC) No 396/2005, 09 July 2009.
- France, 2009b. Pesticide Residues Overview File (PROFile) on acibenzolar-S-methyl, prepared by the Rapporteur Member State France. Submitted to EFSA on 14 April 2009.

**APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)**

GAP of intended uses

Crop and/or situation	Member State or Country	F, G or I	Pests or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
				type	conc of as	method kind	growth stage	number (range)	interval (days)	as (kg/ha)	water (l/ha)	as (kg/ha)		
Peaches	SEU	F		WG	500 g/kg	Foliar application		5	10-14		1200 - 1500	0.075	7	
Apricots	SEU	F		WG	500 g/kg	Foliar application		5	10-14		1200 - 1500	0.075	7	

**APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)**

<b>Acibenzolar-S-methyl</b>			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0,02	proposed LOQ:	
<b>Toxicological end points</b>			
ADI (mg/kg bw/day):	<b>0,1</b>	ARfD (mg/kg bw):	<b>n.n.</b>
Source of ADI:	<b>COM</b>	Source of ARfD:	<b>COM</b>
Year of evaluation:	<b>2002</b>	Year of evaluation:	<b>2002</b>

The toxicological reference as reported in the review report (Doc. 6506/VI/99 final, 21 May 2002) were used in this risk assessment

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

The pTMRLs have been submitted to EFSA in September 2006.

**Chronic risk assessment - refined calculations**

		TMDI (range) in % of ADI minimum - maximum						
		0	2					
		No of diets exceeding ADI:						
		---						
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
1,9	WHO Cluster diet B	0,6	Tomatoes	0,4	Wheat	0,1	Maize	0,6
1,7	NL child	0,6	Milk and cream,	0,2	Wheat	0,1	Apples	1,2
1,7	FR toddler	0,8	Milk and cream,	0,1	Tomatoes	0,1	Wheat	1,3
1,6	UK Infant	0,8	Milk and cream,	0,2	Sugar beet (root)	0,1	Wheat	1,3
1,5	UK Toddler	0,5	Sugar beet (root)	0,4	Milk and cream,	0,2	Wheat	1,1
1,4	DE child	0,3	Milk and cream,	0,2	Apples	0,2	Wheat	0,9
1,2	DK child	0,3	Wheat	0,3	Milk and cream,	0,2	Rye	0,6
1,1	IE adult	0,1	Maize	0,1	Maize	0,1	Tomatoes	0,6
1,1	ES child	0,3	Milk and cream,	0,2	Wheat	0,2	Tomatoes	0,6
1,0	WHO cluster diet D	0,3	Wheat	0,2	Tomatoes	0,1	Milk and cream,	0,3
1,0	FR infant	0,5	Milk and cream,	0,1	Potatoes	0,1	Spinach	0,9
0,9	WHO cluster diet E	0,2	Wheat	0,1	Tomatoes	0,1	Potatoes	0,4
0,9	SE general population 90th percentile	0,2	Milk and cream,	0,2	Wheat	0,1	Tomatoes	0,5
0,9	WHO regional European diet	0,2	Tomatoes	0,1	Wheat	0,1	Milk and cream,	0,4
0,8	WHO Cluster diet F	0,2	Wheat	0,1	Tomatoes	0,1	Milk and cream,	0,3
0,8	IT kids/toddler	0,3	Wheat	0,3	Tomatoes	0,1	Other cereal	0,1
0,7	PT General population	0,2	Wheat	0,2	Tomatoes	0,1	Potatoes	0,3
0,6	NL general	0,1	Milk and cream,	0,1	Wheat	0,1	Tomatoes	0,4
0,6	ES adult	0,1	Tomatoes	0,1	Wheat	0,1	Milk and cream,	0,3
0,6	IT adult	0,2	Tomatoes	0,2	Wheat	0,0	Other cereal	0,1
0,6	FR all population	0,2	Wheat	0,1	Tomatoes	0,1	Wine grapes	0,3
0,5	UK vegetarian	0,1	Tomatoes	0,1	Wheat	0,1	Sugar beet (root)	0,3
0,5	LT adult	0,1	Tomatoes	0,1	Milk and cream,	0,1	Potatoes	0,3
0,5	DK adult	0,1	Milk and cream,	0,1	Wheat	0,1	Tomatoes	0,3
0,5	UK Adult	0,1	Wheat	0,1	Tomatoes	0,1	Sugar beet (root)	0,3
0,4	FI adult	0,1	Milk and cream,	0,1	Tomatoes	0,0	Wheat	0,2
0,3	PL general population	0,2	Tomatoes	0,1	Potatoes	0,0	Apples	0,2

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



## APPENDIX C – EXISTING EC MRLs

Pesticides - Web Version - EU MRLs (File created on 05/11/2009 11:51)

Residue definition: Acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)	Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)	Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)	Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)
100000	1. FRUIT FRESH OR FROZEN; NUTS		140990	Others	0,02*	162010	Kiwi	0,02*		vegetables except sugar beet	
110000	(i) Citrus fruit	0,02*	150000	(v) Berries & small fruit	0,02*	162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*	213010	Beetroot	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*	151000	(a) Table and wine grapes	0,02*	162030	Passion fruit	0,02*	213020	Carrots	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*	151010	Table grapes	0,02*	162040	Prickly pear (cactus fruit)	0,02*	213030	Celeriac	0,02*
110030	Lemons (Citron, lemon)	0,02*	151020	Wine grapes	0,02*	162050	Star apple	0,02*	213040	Horseradish	0,02*
110040	Limes	0,02*	152000	(b) Strawberries	0,02*	162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0,02*	213050	Jerusalem artichokes	0,02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,02*	153000	(c) Cane fruit	0,02*				213060	Parsnips	0,02*
110990	Others	0,02*	153010	Blackberries	0,02*				213070	Parsley root	0,02*
120000	(ii) Tree nuts (shelled or unshelled)		153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,02*	162990	Others	0,02*	213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*
120010	Almonds	0,02*	153030	Raspberries (Wineberries)	0,02*	163000	(c) Inedible peel, large		213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02*
120020	Brazil nuts	0,02*	153990	Others	0,02*	163010	Avocados	0,02*	213100	Swedes	0,02*
120030	Cashew nuts	0,02*	154000	(d) Other small fruit & berries	0,02*	163020	Bananas (Dwarf banana, plantain, apple banana)	0,1	213110	Turnips	0,02*
120040	Chestnuts	0,02*	154010	Blueberries (Bilberries cownberries (red bilberries))	0,02*	163030	Mangoes	0,5	213990	Others	0,02*
120050	Coconuts	0,02*	154020	Cranberries	0,02*	163040	Papaya	0,02*	220000	(ii) Bulb vegetables	0,02*
120060	Hazelnuts (Filbert)	0,1	154030	Currants (red, black and white)	0,02*	163050	Pomegranate	0,02*	220010	Garlic	0,02*
120070	Macadamia	0,02*	154040	Gooseberries (Including hybrids with other ribes species)	0,02*	163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,02*	220020	Onions (Silverskin onions)	0,02*
120080	Pecans	0,02*	154050	Rose hips	0,02*				220030	Shallots	0,02*
120090	Pine nuts	0,02*	154060	Mulberries (arbutus berry)	0,02*	163070	Guava	0,02*	220040	Spring onions (Welsh onion and similar varieties)	0,02*
120100	Pistachios	0,02*	154070	Azarole (mediterranean medlar)	0,02*	163080	Pineapples	0,02*	220990	Others	0,02*
120110	Walnuts	0,02*	154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,02*	163090	Bread fruit (Jackfruit)	0,02*	230000	(iii) Fruiting vegetables	
120990	Others	0,02*	154990	Others	0,02*	163100	Durian	0,02*	231000	(a) Solanacea	
130000	(iii) Pome fruit	0,02*	160000	(vi) Miscellaneous fruit		163110	Soursop (guanabana)	0,02*	231010	Tomatoes (Cherry tomatoes, )	1
130010	Apples (Crab apple)	0,02*	161000	(a) Edible peel	0,02*	163990	Others	0,02*	231020	Peppers (Chilli peppers)	0,02*
130020	Pears (Oriental pear)	0,02*	161010	Dates	0,02*	200000	2. VEGETABLES FRESH OR FROZEN		231030	Aubergines (egg plants) (Pepino)	0,02*
130030	Quinces	0,02*	161020	Figs	0,02*	210000	(i) Root and tuber vegetables	0,02*	231040	Okra, lady's fingers	0,02*
130040	Medlar	0,02*	161030	Table olives	0,02*	211000	(a) Potatoes	0,02*	231990	Others	0,02*
130050	Loquat	0,02*	161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*	212000	(b) Tropical root and tuber vegetables	0,02*	232000	(b) Cucurbits - edible peel	0,02*
130990	Others	0,02*	161050	Carambola (Bilimbi)	0,02*	212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*	232010	Cucumbers	0,02*
140000	(iv) Stone fruit	0,02*	161060	Persimmon	0,02*	212020	Sweet potatoes	0,02*	232020	Gherkins	0,02*
140010	Apricots	0,02*	161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,02*	212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*	232030	Courgettes (Summer squash, marrow (patisson))	0,02*
140020	Cherries (sweet cherries, sour cherries)	0,02*	161990	Others	0,02*	212040	Arrowroot	0,02*	232990	Others	0,02*
140030	Peaches (Nectarines and similar hybrids)	0,02*	162000	(b) Inedible peel, small	0,02*	212990	Others	0,02*	233000	(c) Cucurbits-inedible peel	0,02*
140040	Plums (Damson, greengage, mirabelle)	0,02*				213000	(c) Other root and tuber	0,02*	233010	Melons (Kiwano)	0,02*
									233020	Pumpkins (Winter squash)	0,02*
									233030	Watermelons	0,02*
									233990	Others	0,02*
									234000	(d) Sweet corn	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	0,02*
241000	(a) Flowering brassica	0,02*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,02*
241020	Cauliflower	0,02*
241990	Others	0,02*
242000	(b) Head brassica	0,02*
242010	Brussels sprouts	0,02*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,02*
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,02*
243020	Kale (Borecole (curly kale), collards)	0,02*
243990	Others	0,02*
244000	(d) Kohlrabi	0,02*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicaceae	0,02*
251010	Lamb's lettuce (Italian comsalad)	0,02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,02*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,02*
251040	Cress	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket)	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, tumip greens (tumip tops))	0,3
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane,	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)
	sorrel, glasswort)	
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	0,02*
256010	Chervil	0,02*
256020	Chives	0,02*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,02*
256040	Parsley	0,02*
256050	Sage (Winter savory, summer savory, )	0,02*
256060	Rosemary	0,02*
256070	Thyme (marjoram, oregano)	0,02*
256080	Basil (Balm leaves, mint, peppermint)	0,02*
256090	Bay leaves (laurel)	0,02*
256100	Tarragon (Hyssop)	0,02*
256990	Others	0,02*
260000	(vi) Legume vegetables (fresh)	0,02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,02*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	0,02*
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes	0,02*
270060	Leek	0,02*
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild (Chanterelle, Truffle, Morel, )	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	
300000	3. PULSES, DRY	0,02*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,02*
300020	Lentils	0,02*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*
300040	Lupins	0,02*
300990	Others	0,02*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0,05*
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	0,05*
500010	Barley	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	0,02*
900010	Sugar beet (root)	0,02*
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
100000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
101000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,02*
101100	(a) Swine	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)
0		
101101	Meat	0,02*
101102	Fat free of lean meat	0,02*
101103	Liver	0,02*
101104	Kidney	0,02*
101105	Edible offal	0,02*
101199	Others	0,02*
101200	(b) Bovine	0,02*
101201	Meat	0,02*
101202	Fat	0,02*
101203	Liver	0,02*
101204	Kidney	0,02*
101205	Edible offal	0,02*
101299	Others	0,02*
101300	(c) Sheep	0,02*
101301	Meat	0,02*
101302	Fat	0,02*
101303	Liver	0,02*
101304	Kidney	0,02*
101305	Edible offal	0,02*
101399	Others	0,02*
101400	(d) Goat	0,02*
101401	Meat	0,02*
101402	Fat	0,02*
101403	Liver	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)
101404	Kidney	0,02*
101405	Edible offal	0,02*
101499	Others	0,02*
101500	(e) Horses, asses, mules or hinnies	0,02*
101501	Meat	0,02*
101502	Fat	0,02*
101503	Liver	0,02*
101504	Kidney	0,02*
101505	Edible offal	0,02*
101599	Others	0,02*
101600	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,02*
101601	Meat	0,02*
101602	Fat	0,02*
101603	Liver	0,02*
101604	Kidney	0,02*
101605	Edible offal	0,02*
101699	Others	0,02*
101700	(g) Other farm animals (Rabbit, Kangaroo)	0,02*
101701	Meat	0,02*
101702	Fat	0,02*
101703	Liver	0,02*
101704	Kidney	0,02*
101705	Edible offal	0,02*
101799	Others	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Acibenzolar-S-methyl (see residue definition)
102000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,02*
102001	Cattle	0,02*
102002	Sheep	0,02*
102003	Goat	0,02*
102004	Horse	0,02*
102099	Others	0,02*
103000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,02*
103001	Chicken	0,02*
103002	Duck	0,02*
103003	Goose	0,02*
103004	Quail	0,02*
103099	Others	0,02*
104000	(iv) Honey (Royal jelly, pollen)	
105000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
106000	(vi) Snails	
107000	(vii) Other terrestrial animal products	

(\*) Indicates lower limit of analytical determination

**ABBREVIATIONS**

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
ECD	electron capture detection
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionization detection
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry

JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million ( $10^{-6}$ )
PRIMo	Pesticide Residues Intake Model
RMS	rappporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WG	water dispersible granule
WHO	World Health Organisation