

## REASONED OPINION OF EFSA

### Modification of the existing MRLs for azoxystrobin in broccoli and beet leaves (chard)<sup>1</sup>

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00367)

Issued on 24 April 2009

#### SUMMARY

Germany (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) received the information from the manufacturer Syngenta on the intended authorizations for use of azoxystrobin and considered a need to modify the existing MRLs for azoxystrobin in broccoli and beet leaves (chard). In order to accommodate the intended uses of azoxystrobin on these crops, it is proposed to raise the existing MRLs. Germany as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 30 January 2009. It should be mentioned that the MRL proposal for broccoli is based on the intended GAP for the use of azoxystrobin in Southern Member States for which according to EFSA's current knowledge new authorizations have not yet been requested in the Member States concerned.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report and the Draft Assessment Report prepared by Germany in the framework of Directive 91/414/EEC.

The toxicological profile of azoxystrobin was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.1 mg/kg bw/d. No ARfD was established in the peer review under Directive 91/414/EEC. Although the RMS concluded that no ARfD is necessary, the evaluation of the acute toxicological properties should be performed at European level. EFSA recommends performing this assessment in the framework of the renewal of the Annex I inclusion for azoxystrobin.

The metabolism of azoxystrobin in primary and rotational crops is elucidated and residue definitions have been derived for all commodities of plant origin. The residue definition for risk assessment and enforcement is set as parent azoxystrobin only. Adequate analytical methods are available to enforce the proposed MRLs in broccoli and beet leaves (chard).

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<sup>1</sup> For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRLs for azoxystrobin in broccoli and beet leaves (chard). *EFSA Scientific Report* (2009) 283, 1-25

Submitted supervised residues field trials indicate that the current MRLs do not accommodate the intended GAPs and higher MRLs would be required.

Residues of azoxystrobin in processed commodities are not of concern for the current application since the contribution of broccoli and beet leaves (chard) to the total dietary intake is insignificant, not being higher than 0.03% of the ADI.

The occurrence of azoxystrobin residues in rotational crops was also investigated. EFSA concluded that significant residue levels in rotational crops are not expected provided that azoxystrobin is applied according to the intended GAPs.

Nature and magnitude of azoxystrobin residues in livestock was not investigated in the framework of this application since broccoli and beet leaves (chard) are not used as a livestock feeding stuff.

Consumer intake calculations were performed with revision 2 of the EFSA PRIMo using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use on broccoli and beet leaves (chard). No acute risk assessment was undertaken since no ARfD value has been established. The chronic dietary intake calculations did not reveal consumer intake concerns for any European diets. The contribution of broccoli and beet leaves (chard) to the total dietary intake is insignificant, being not higher than 0.03% of the ADI for broccoli (FR toddler diet). The calculated total intake values ranged from 4 to 26% of the ADI.

EFSA concludes that the intended use of azoxystrobin on broccoli and beet leaves (chard) is acceptable with regard to consumer safety. However, before the risk management decision is taken on the MRL proposal for broccoli it should be clarified whether it is acceptable to amend MRLs on the basis of intended GAPs notified by the manufacturer of the active substance.

### Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Azoxystrobin			
Broccoli	0.5	1.0	The MRL proposals are fully supported by data and no risk for consumers was identified for the intended uses.
Beet leaves (chard)	0.05	0.5	

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

**Key words: Azoxystrobin, broccoli, beet leaves (chard), MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurins, fungicide**

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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 where a Member State considers that the modification of an MRL is necessary, that Member State may compile and evaluate an application to modify the MRL in accordance with the provisions of Article 7 of that regulation.

Germany, hereafter referred to as the Evaluating Member State (EMS), received the information on the intended authorisations for azoxystrobin and considered a need to modify the existing MRLs for azoxystrobin in broccoli and beet leaves (chard). 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 30 January 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00367 and the following subject:

*Azoxystrobin-Application to modify the existing MRL for azoxystrobin in beet leaves (chard) from 0.05\*mg/kg to 0.5 mg/kg and in broccoli from 0.5 mg/kg to 1 mg/kg.*

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

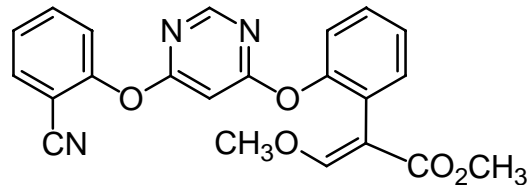
## TERMS OF REFERENCE

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 30 April 2009.

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Azoxystrobin is the ISO common name for methyl (E)-2-{2-[6-(2-cyanophenoxy) pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate (IUPAC).



Azoxystrobin belongs to the class of strobilurins; it is a synthetic analogue of naturally occurring fungal metabolites of strobilurins and oudemansins. It is a fungicide with protectant, curative, eradicant, translaminar and systemic properties. It is used against a wide range of diseases in fruit, vegetables, and cereals.

Azoxystrobin is considered as a new active substance according to the definition of Directive 91/414/EEC. Germany was designated as the Rapporteur Member State. It was included in Annex I to Directive 91/414/EEC with Directive 1998/47/EC which entered into force on 1 July 1998. The uses evaluated in the peer review were the uses on wheat, barley, rye, triticale and vines. In addition, an import tolerance was evaluated for the use of azoxystrobin on bananas. In 2007 the inclusion in Annex I of the mentioned directive was extended until 31 December 2011 (Directive 2007/21/EC).

MRLs for azoxystrobin were set at EU level for the first time with Directive 1999/71/EC which was modified several times to accommodate for new uses authorised in Member States since then. The MRLs established under the Directives 86/362/EEC 86/363/EEC and 90/642/EEC have been transferred to Annex II of Regulation (EC) No 396/2005. In Annex III temporary MRLs have been established for crops that were not covered by the previous Community MRL legislation. The existing EU MRLs are summarized in Appendix B to this reasoned opinion. In the Appendix B EFSA also included the MRL proposals for turnips and passion fruit which were recently assessed by EFSA and recommendations made by EFSA were voted in the SCFAH of 30 January 2009. No CXLs are established for azoxystrobin by Codex Alimentarius.

The intended GAP for the use of azoxystrobin on beet leaves (chard) in Germany refers to an application of the active substance three times at an application rate of 0.25 kg a.s./ha. The minimum waiting period is 21 day.

Regarding broccoli the existing MRL of 0.5 mg/kg is based on the existing NEU uses (Germany, 2003). Now the manufacturer applies for a more critical use of azoxystrobin on broccoli in Germany and the Southern European Member States. The respective GAP refers to an application of the active substance twice at an application rate of 0.25 kg a.s./ha. The minimum waiting period is 14 days.

It should be noted, that currently no information is available if an application on the SEU use of azoxystrobin on broccoli has already been submitted in the Member States concerned.

## ASSESSMENT

### 1. Methods of analysis

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

In the framework of the peer review several analytical methods were evaluated which are suitable to determine residues of azoxystrobin in plant material (Germany, 1997). In general, for the determination of azoxystrobin residues in matrices with high water and high acid content as well as in dry commodities, the multi-method DFG S 19 is sufficiently validated at the LOQ of 0.01 mg/kg. In addition, HPLC methods with UV detection can also be applied.

Aside from the methods provided by the applicant in the framework of the peer review, laboratories responsible for official control of MRLs have developed their own methods or have included the active substance in the established multi-methods. In the database developed by the Community Reference Laboratories (CRL) for Residues of Pesticides ([www.crl-pesticides.eu](http://www.crl-pesticides.eu)), in total more than 1370 validation datasets (status April 2009) have been submitted regarding methods routinely used to determine azoxystrobin residues in different matrices. Most of the validation data refer to the QuEChERS method; in some cases the ChemElut method was validated. For commodities with high water content, where broccoli and beet leaves (chard) belong to, the validation data are available for lettuce, cucumbers, tomatoes, peppers, potatoes, cauliflower, etc. In the Table 1-1 the validation data for high water content matrices are summarised.

Table 1-1. Validation data for high water content matrices<sup>2</sup>

Chr	Matrix Type	Level min	Level max	Rec Median	Rec Mean	CV [%]	# of rec	% Rec (70-120%)	# of Labs
GC	Water containing	0,005	4	100	100	8,1	160	98	5
LC	Water containing	0,01	0,5	96	94	15,9	559	92	13

From the available data EFSA concluded that adequate analytical methods are available to enforce the proposed MRLs on broccoli and beet leaves (chard).

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

Broccoli and beet leaves (chard) are not a livestock feeding stuff. Therefore analytical methods for the determination of azoxystrobin in food of animal origin are not of relevance with regard to the current application.

### 2. Mammalian toxicology

An ADI value for azoxystrobin was derived in the peer review under Directive 91/414/EEC (European Commission, 1998). In 1998 when the peer review of azoxystrobin was finalised, no ARfD was assessed, because this was not routinely done at that time. The RMS Germany mentioned in an evaluation report prepared in 1999 that an ARfD is not necessary due to the

<sup>2</sup> Source: Website of Community Reference Laboratories (CRL) for Pesticide Residues [www.crl-pesticides.eu](http://www.crl-pesticides.eu). April, 2009

low acute toxicity seen in various studies. However, EFSA is of the opinion that an evaluation of potential acute properties according to the current scientific standards would be advisable. In the framework of the renewal of the Annex I inclusion of azoxystrobin a full evaluation of the acute toxicity profile of the active substance should be performed.

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

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Azoxystrobin					
ADI	COM	1998	0.1	90 d dog, 1 yr dog	100
ARfD	DE	1999	ARfD not assessed		

### 3. Residues

#### 3.1. Nature and magnitude of residues in plant

##### 3.1.1. Primary crops

###### 3.1.1.1. Nature of residues

Metabolism studies of azoxystrobin in plants are reported in the DAR for the following crops (Germany, 1997):

- Wheat (foliar spray 2 x 0.5 kg a.s./ha)
- Grapes (foliar spray 4 x 0.25 kg a.s./ha, 2 x 1.0 kg a.s./ha and 0.25 kg a.s./ha)
- Peanuts (foliar spray 0.85 kg a.s./ha and 0.3 g a.s./ha )

These studies cover the foliar use on three crop groups (fruits and fruiting vegetables, pulses and oilseeds, and cereals). It was concluded that the major residue in the edible commodities is azoxystrobin. Besides this compound a wide range of metabolites were identified or characterised. Although some of the metabolites occurred at levels exceeding 0.01 mg/kg or 10% of the TRR, they were considered as not relevant and have not been included in the residue definition. In the peer review it was concluded that metabolism in all commodities of plant origin proceeds in a similar pathway and a general residue definition for risk assessment and enforcement purposes should be set as azoxystrobin (parent only). In that regard EFSA concludes that metabolism of azoxystrobin in leafy crops which broccoli and beet leaves (chard) belong to, is sufficiently addressed and no additional studies are required.

###### 3.1.1.2. Magnitude of residues

In support of the intended GAPs, eight supervised residue field trials on broccoli (four trials for the NEU use, four trials for the SEU use) and five trials on beet leaves (chard) for the NEU use were submitted. The residue levels in all trials for broccoli were in the range of < 0.01 – 0.58 mg/kg and 0.01- 0.25 mg/kg for beet leaves (chard). The number of trials is sufficient to derive the MRL proposals.

Supervised residue field trials data are summarized in Table 3-1.

The intended use of azoxystrobin on broccoli in Southern European Member States compared to the use in Northern European Member States is more critical and was therefore used for deriving the risk assessment values and the MRL proposal.

The storage stability of azoxystrobin residues in treated crops is reported in the DAR (Germany, 1997) and in additional studies that were made available by notifier after submission of the DAR (Germany, 1999). Available studies demonstrate storage stability of azoxystrobin for at least 2 years when stored below -18°C in dry commodities (wheat, wheat straw), commodities with high acid (grapes), high water (apples, cucumbers, tomatoes, bananas) and high oil content (rape seed, pecans, peanuts).

According to the evaluation of the EMS, the supervised residues field trials data are considered valid both with regards to analytical methods and storage stability.



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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) <sup>(b)</sup>	HR (mg/kg) <sup>I</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Azoxystrobin									
Broccoli	NEU	Outdoor	<0.01; 0.01; 0.04; 0.09	<0.01; 0.01; 0.04; 0.09	0.03	0.09	0.50	1.00	The MRL proposal and risk assessment values are obtained from the intended use of azoxystrobin in the SEU considering that it is most critical (indicated in bold). MRL proposal is derived taking into account the highest residue value resulting from the SEU use. R <sub>berNEU</sub> =0.155 mg/kg R <sub>maxNEU</sub> =0.232mg/kg R <sub>berSEU</sub> =0.95 mg/kg R <sub>maxSEU</sub> =1.53 mg/kg
	SEU	Outdoor	2 x 0.04; 0.11; 0.58	<b>2 x 0.04; 0.11; 0.58</b>	<b>0.08</b>	<b>0.58</b>	<b>1.00</b>	<b>1.00</b>	
Beet leaves (chard)	NEU	Outdoor	0.01; 0.02; 0.05; 0.11; 0.25	0.01; 0.02; 0.05; 0.11; 0.25	0.05	0.25	0.50	1.00	R <sub>ber</sub> =0.36mg/kg R <sub>max</sub> = 0.50 mg/kg

(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.

I: 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

Studies on the effect of processing on the nature of azoxystrobin residues have not been reported in the DAR (Germany, 1997).

Studies on the effect of processing on the magnitude of azoxystrobin residues with regard to broccoli and beet leaves (chard) have not been submitted but are not considered relevant, taking into account the small contribution – less than 0.03% of the ADI – of these crops to the total dietary intake.

## 3.1.2. Rotational crops

### 3.1.2.1. Preliminary considerations

Broccoli and beet leaves (chard) can both be grown in rotation. The rate of degradation of azoxystrobin in soil was investigated during the peer review (Germany, 1997). The highest  $DT_{90lab}$  as reported in the DAR amounted for up to 435 days. This means, rotational crop studies are required with regard to the current application.

### 3.1.2.2. Nature of residues

The nature of azoxystrobin residues was investigated in three rotational crop studies with  $^{14}C$ -radiolabelled active substance (cyanophenyl-, pyrimidinyl- and phenylacrylate labelling) at application rates of 2.2 kg a.s./ha. Lettuce, radish and wheat were planted 30, 200 and 365 days after the treatment of the soil. The metabolism in succeeding crops was found to be similar for all the analysed crops and also similar with the primary crops. The metabolites observed in rotational crop studies were also observed in the primary crops. Many metabolites are glucose- or amino acid- conjugates of the metabolites identified in the primary crops.

The conclusion in the peer review was that there is no need to derive a different residue definition for rotational crops.

### 3.1.2.3. Magnitude of residues

The peer review concluded that the application of azoxystrobin according to the GAPs evaluated in the peer review will not result in significant residues in rotational crops. The intended use on broccoli and beet leaves (chard) at an application rate of 0.75 kg a.s./ha is less critical than the application rate investigated in the rotational crop studies. The setting of MRLs for rotational crops or the setting of planting restrictions is not necessary for this GAP.

## 3.2. Nature and magnitude of residues in livestock

Broccoli and beet leaves (chard) are not used as a livestock feed. Therefore nature and magnitude of azoxystrobin residues in livestock are not of relevance regarding the current MRL application.

## 4. Consumer risk assessment

Consumer intake calculations were performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model), using the MRLs as established in Annex II and Annex IIIB of

Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use on broccoli and beet leaves (chard). In addition, for passion fruit and turnips the STMR values were used as obtained in the previously issued EFSA reasoned opinions on the modification of the existing MRLs for azoxystrobin (EFSA 2008a, 2008b). Since the safety margin regarding the chronic intake is still large, EFSA did not look for the available STMR values for other commodities from previous EC MRL proposals over the years. No acute risk assessment was undertaken since no ARfD value has been established. Input values are summarized 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
Azoxystrobin				
Broccoli	0.08	STMR	Acute risk assessment was not undertaken since no ARfD value is established.	
Beet leaves (chard)	0.05	STMR		
Turnips	0.06	STMR (EFSA, 2008a)		
Passion fruit	1.1	STMR (EFSA, 2008b)		

The summary of intake calculations can be found in Appendix C. The chronic dietary intake calculations did not reveal any consumer intake concerns for any European diets. The contribution of broccoli and beet leaves (chard) to the total dietary intake is insignificant, being not higher than 0.03% of the ADI for FR toddler diet (broccoli). The calculated total intake values ranged from 4 to 26% of the ADI.

EFSA concludes that the intended use of azoxystrobin on broccoli and beet leaves (chard) is acceptable with regard to consumer safety.

## CONCLUSIONS AND RECOMMENDATIONS

Germany (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) received the information from the manufacturer Syngenta on the intended authorizations for use of azoxystrobin and considered a need to modify the existing MRLs for azoxystrobin in broccoli and beet leaves (chard). In order to accommodate the intended uses of azoxystrobin on these crops, it is proposed to raise the existing MRLs. Germany as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 30 January 2009. It should be mentioned that the MRL proposal for broccoli is based on the intended GAP for the use of azoxystrobin in Southern Member States for which according to EFSA's current knowledge new authorizations have not yet been requested in the Member States concerned.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report and the Draft Assessment Report prepared by Germany in the framework of Directive 91/414/EEC.

The toxicological profile of azoxystrobin was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.1 mg/kg bw/d. No ARfD was established in the peer review under Directive 91/414/EEC. Although the RMS concluded that no ARfD is necessary, the evaluation of the acute toxicological properties should be performed at European level. EFSA recommends performing this assessment in the framework of the renewal of the Annex I inclusion for azoxystrobin.

The metabolism of azoxystrobin in primary and rotational crops is elucidated and residue definitions have been derived for all commodities of plant origin. The residue definition for risk assessment and enforcement is set as parent azoxystrobin only. Adequate analytical methods are available to enforce the proposed MRLs in broccoli and beet leaves (chard).

Submitted supervised residues field trials indicate that the current MRLs do not accommodate the intended GAPs and higher MRLs would be required.

Residues of azoxystrobin in processed commodities is not of concern for the current application since the contribution of broccoli and beet leaves (chard) to the total dietary intake is insignificant, not being higher than 0.03% of the ADI.

The occurrence of azoxystrobin residues in rotational crops was also investigated. EFSA concluded that significant residue levels in rotational crops are not expected provided that azoxystrobin is applied according to the intended GAPs.

Nature and magnitude of azoxystrobin residues in livestock was not investigated in the framework of this application since broccoli and beet leaves (chard) are not used as a livestock feeding stuff.

Consumer intake calculations were performed with revision 2 of the EFSA PRIMo using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use on broccoli and beet leaves (chard). No acute risk assessment was undertaken since no ARfD value has been established. The chronic dietary intake calculations did not reveal consumer intake concerns for any European diets. The contribution of broccoli and beet leaves (chard) to the total dietary intake is insignificant, being not higher than 0.03% of the ADI for broccoli (FR toddler diet). The calculated total intake values ranged from 4 to 26% of the ADI.

EFSA concludes that the intended use of azoxystrobin on broccoli and beet leaves (chard) is acceptable with regard to consumer safety. However, before the risk management decision is taken on the MRL proposal for broccoli it should be clarified whether it is acceptable to amend MRLs on the basis of intended GAPs notified by the manufacturer of the active substance.

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Azoxystrobin			
Broccoli	0.5	1.0	The MRL proposals are fully supported by data and no risk for consumers was identified for the intended uses.
Beet leaves (chard)	0.05	0.5	

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

#### DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRL for azoxystrobin in broccoli and beet leaves (chard) under Regulation (EC) No 396/2005. 6 November 2008. Submitted in EFSA on 30 January 2009. Prepared by the BfR, Germany.

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

Crop and/or situation (a)	Country	F or G (b)	Formulation rate per treatment		Application			Application rate per treatment			PHI (days) (k)	Remarks
			Type (d-f)	Conc. Of a.s. (i)	method, kind, if other than spray (f-h)	growth stage (j)	No appl.	Kg a.s./hl, where appropriate	water L/ha	kg a.s./ha, where appropriate		
Broccoli	SEU, Germany	F	SC	250 g/L	spraying	BBCH 43-46	2	0.042-0.063	400-600	0.25	14	Interval between applications 12 days
Beet leaves (chard)	Germany	F	SC	250 g/L	spraying	BBCH 43-46	3	0.042	600	0.25	21	Interval between applications 8 to 12 days

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure).
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application.  
I e.g. biting and suckling insects, soil born insects, foliar fungi, weeds.
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
- (e) GCPF Codes – GIFAP Technical Monograph No 2, 1989.
- (f) All abbreviations used must be explained.
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated.
- (I) g/kg or g/L.
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application.
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use.
- (l) PHI – minimum pre-harvest interval.
- (m) Remarks may include: extent of use/economic importance/restrictions.

**APPENDIX B – EXISTING EC MRLs**

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	1
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	1
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	1
110030	Lemons (Citron, lemon )	1
110040	Limes	1
110050	Mandarins (Clementine, tangerine and other hybrids)	1
110990	Others	1
120000	(ii) Tree nuts (shelled or unshelled)	0,1*
120010	Almonds	0,1*
120020	Brazil nuts	0,1*
120030	Cashew nuts	0,1*
120040	Chestnuts	0,1*
120050	Coconuts	0,1*
120060	Hazelnuts (Filbert)	0,1*
120070	Macadamia	0,1*
120080	Pecans	0,1*
120090	Pine nuts	0,1*
120100	Pistachios	0,1*
120110	Walnuts	0,1*
120990	Others	0,1*
130000	(iii) Pome fruit	0,05*
130010	Apples (Crab apple)	0,05*
130020	Pears (Oriental pear)	0,05*
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage, rench ra)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	2
151010	Table grapes	2
151020	Wine grapes	2
152000	(b) Strawberries	2
153000	© Cane fruit	
153010	Blackberries	3
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0,05*
153030	Raspberries (Wineberries )	3
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediterranean medlar)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea salallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*[4] <sup>a</sup>
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
163000	© Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	2
163030	Mangoes	0,2
163040	Papaya	0,2
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,05*
213020	Carrots	0,2
213030	Celeriac	0,3



Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
213040	Horseradish	0,2
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,2
213070	Parsley root	0,2
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,2
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,2
213100	Swedes	0,05*
213110	Turnips	0,05*[0.2] <sup>a</sup>
213990	Others	0,05*
220000	(ii) Bulb vegetables	
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	2
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	2
231010	Tomatoes (Cherry tomatoes, )	2
231020	Peppers (Chilli peppers)	2
231030	Aubergines (egg plants) (Pepino)	2
231040	Okra, lady's fingers	2
231990	Others	2
232000	(b) Cucurbits – edible peel	1
232010	Cucumbers	1
232020	Gherkins	1
232030	Courgettes (Summer squash, marrow (patisson))	1
232990	Others	1
233000	c) Cucurbits-inedible peel	0,5

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
233010	Melons (Kiwano )	0,5
233020	Pumpkins (Winter squash)	0,5
233030	Watermelons	0,5
233990	Others	0,5
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,5
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,5
241020	Cauliflower	0,5
241990	Others	0,5
242000	(b) Head brassica	0,3
242010	Brussels sprouts	0,3
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,3
242990	Others	0,3
243000	© Leafy brassica	5
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	5
243020	Kale (Borecole (curly kale), collards)	5
243990	Others	5
244000	(d) Kohlrabi	0,2
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	3

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
251010	Lamb's lettuce (Italian cornsalad)	3
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	3
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	3
251040	Cress	3
251050	Land cress	3
251060	Rocket, Rucola (Wild rocket)	3
251070	Red mustard	3
251080	Leaves and sprouts of Brassica spp (Mizuna)	3
251990	Others	3
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	3
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,2
256000	(f) Herbs	3
256010	Chervil	3
256020	Chives	3

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisel and other Apiacea)	3
256040	Parsley	3
256050	Sage (Winter savory, summer savory, )	3
256060	Rosemary	3
256070	Thyme ( marjoram, oregano)	3
256080	Basil (Balm leaves, mint, peppermint)	3
256090	Bay leaves (laurel)	3
256100	Tarragon (Hyssop)	3
256990	Others	3
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (rench beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	1
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,2
260030	Peas (with pods) (Mangetout (sugar peas))	0,5
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,2
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,05*
270020	Cardoons	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
270030	Celery	5
270040	Fennel	5
270050	Globe artichokes	1
270060	Leek	2
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	
300000	3. PULSES, DRY	0,1
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,1
300020	Lentils	0,1
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1
300040	Lupins	0,1
300990	Others	0,1
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
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)	0,5
401070	Soya bean	0,5
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*

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	0,3
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,3
500060	Rice	5
500070	Rye	0,3
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,3
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	
631000	(a) Flowers	50
631010	Camomille flowers	50
631020	Hybiscus flowers	50
631030	Rose petals	50
631040	Jasmine flowers	50
631050	Lime (linden)	50
631990	Others	50
632000	(b) Leaves	50
632010	Strawberry leaves	50
632020	Rooibos leaves	50
632030	Maté	50
632990	Others	50

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
633000	© Roots	50
633010	Valerian root	50
633020	Ginseng root	50
633990	Others	50
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	20
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,3
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry – chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Azoxystrobin
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,01*
1020010	Cattle	0,01*
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

<sup>A</sup> – MRL proposals as voted in the SCFAH on 30 January, but not adopted in legislation by 24 April 2009

## APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

<b>Azoxystrobin</b>			
Status of the active substance:	Included	Code no.	#N/A
LOQ (mg/kg bw):	0.05	proposed LOQ:	
<b>Toxicological end points</b>			
ADI (mg/kg bw/day):	0.1	ARfD (mg/kg bw):	n.n.
Source of ADI:	COM	Source of ARfD:	DE
Year of evaluation:	1998	Year of evaluation:	1999

Input values chronic RA- broccoli- 0.08 mg/kg; beet leaves (chard)-0.05 mg/kg; turnips-0.06 mg/kg; passion fruit- 1.1 mg/kg

**Chronic risk assessment - refined calculations**

		TMDI (range) in % of ADI minimum - maximum						
		4                      26						
		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	pTMRs at LOQ (in % of ADI)
25.6	WHO Cluster diet B	6.2	Tomatoes	3.6	Wine grapes	2.6	Rice	
20.2	DE child	3.8	Oranges	3.1	Bananas	2.5	Table grapes	1.2
20.0	NL child	3.4	Bananas	3.1	Oranges	1.8	Rice	1.3
19.4	UK Toddler	6.9	Sugar beet (root)	2.9	Rice	2.2	Bananas	0.6
17.3	IE adult	2.5	Wine grapes	1.6	Bananas	1.0	Oranges	1.0
16.1	FR toddler	2.6	Bananas	2.0	Oranges	1.8	Rice	1.0
15.3	PT General population	5.0	Wine grapes	3.9	Rice	1.8	Tomatoes	0.4
14.4	FR all population	8.0	Wine grapes	1.0	Wheat	0.9	Tomatoes	0.3
14.2	UK Infant	3.2	Rice	3.0	Sugar beet (root)	2.9	Bananas	0.8
14.0	SE general population 90th percentile	3.6	Bananas	2.0	Rice	1.5	Tomatoes	0.5
13.6	WHO cluster diet D	2.8	Rice	2.0	Tomatoes	2.0	Wheat	0.5
13.3	ES child	2.4	Rice	2.2	Oranges	2.0	Bananas	0.7
13.0	WHO cluster diet E	3.2	Wine grapes	1.2	Wheat	1.1	Tomatoes	0.6
11.7	DK child	2.3	Bananas	1.7	Wheat	1.6	Cucumbers	0.7
11.2	WHO Cluster diet F	1.4	Tomatoes	1.2	Wine grapes	1.1	Bananas	0.5
11.1	IT kids/toddler	2.9	Tomatoes	2.0	Wheat	1.1	Bananas	0.2
10.9	WHO regional European diet	2.2	Tomatoes	1.1	Lettuce	1.0	Rice	0.6
10.4	UK vegetarian	1.9	Rice	1.6	Wine grapes	1.2	Tomatoes	0.2
10.1	NL general	1.5	Oranges	1.3	Wine grapes	0.9	Tomatoes	0.4
9.9	ES adult	1.6	Lettuce	1.6	Tomatoes	1.3	Oranges	0.4
9.5	IT adult	2.3	Tomatoes	1.2	Wheat	1.1	Lettuce	0.2
9.4	UK Adult	2.2	Wine grapes	1.8	Rice	1.2	Sugar beet (root)	0.2
8.7	FR infant	1.4	Bananas	1.0	Strawberries	0.9	Oranges	0.7
7.4	DK adult	2.8	Wine grapes	0.8	Tomatoes	0.8	Bananas	0.3
5.6	FI adult	1.0	Oranges	0.9	Tomatoes	0.6	Wine grapes	0.2
4.6	LT adult	1.2	Tomatoes	1.1	Rice	0.4	Cucumbers	0.4
4.1	PL general population	1.8	Tomatoes	0.6	Table grapes	0.4	Bananas	0.3

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

## GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany (Federal Office of Consumer Protection and Food Safety)
Bw	body weight
CAC	Codex Alimentarius Commission
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DT <sub>90lab</sub>	period required for 90 percent dissipation (laboratory method)
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FR	France
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry



LOAEL	lowest observed adverse effect level
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SC	suspension concentrate
SCFAH	Standing Committee on Food Chain and Animal Health
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WHO	World Health Organisation