REASONED OPINION

Modification of the existing MRL for azoxystrobin in swedes[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the Evaluating Member State (EMS), has compiled an application to modify the existing MRL for azoxystrobin in swedes. In order to accommodate for a new use of azoxystrobin in Belgium, it was proposed to raise the existing MRL for swedes from 0.05 mg/kg to 0.2 mg/kg. Belgium drafted an evaluation report according to Article 8 of the regulation which was submitted to the European Commission and forwarded to EFSA on 29 May 2009.

EFSA derives the following conclusions regarding the application, based on the above mentioned evaluation report as well as the Draft Assessment Report prepared by Germany and the JMPR evaluation 2008.

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 and by JMPR in its recent evaluation.

The metabolism of azoxystrobin in primary and rotational crops is elucidated. The residue definition for risk assessment and enforcement is set as parent azoxystrobin only. Adequate analytical methods are available to enforce the proposed MRL in swedes.

The submitted supervised field trials performed on carrots are sufficient to extrapolate to the expected residue concentrations in swedes. It is concluded that an MRL of 0.2 mg/kg as proposed by the EMS is required to accommodate for the intended use in swedes.

The possible occurrence of azoxystrobin residues in rotational crops was deliberated. EFSA concluded that significant residues in crops grown in crop rotation after swedes are not expected provided that azoxystrobin is applied according to the intended GAP.

The nature and magnitude of azoxystrobin in livestock were also considered, but since the use on swedes does not lead to a more critical dietary intake of livestock, EFSA does not see the need to change the established MRLs for products of animal origin.

The chronic consumer intake calculation was performed with revision 2 of the EFSA PRIMo using the MRLs and the STMRs derived in recently published EFSA reasoned opinions. Since the calculated

1 On request from the European Commission, Question No EFSA-Q-2009-00653, issued on 04 September 2009.
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exposure is well below the ADI for all European diets (max. 26% of the ADI in the WHO cluster diet B), EFSA concludes that the use of azoxystrobin on swedes according to the intended GAP does not pose a consumer health risk. An acute risk assessment was not necessary because no ARfD has been established for azoxystrobin.

EFSA concludes that the intended use of azoxystrobin in swedes is supported by data and no risk for consumers is identified. Thus, the following amendment of Annex II of Regulation (EC) No 396/2005 is recommended:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Azoxystrobin			
Swedes	0.05(*)	0.2	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended use.

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

KEY WORDS

Azoxystrobin, swedes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurins, fungucide

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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.

Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRL for the active substance azoxystrobin in swedes. This application was notified to the European Commission and EFSA and subsequently evaluated 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 29 May 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00653 and the following subject:

Azoxystrobin - Application to modify the existing MRL for azoxystrobin in swedes from 0.05 mg/kg to 0.2 mg/kg*

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

TERMS OF REFERENCE

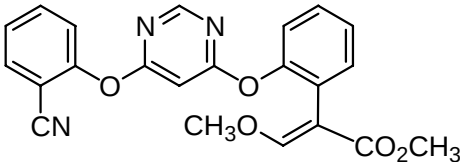
According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

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 29 August 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 strobilurines; it is a synthetic analogue of naturally occurring fungal metabolites of strobilurins and oudemansins. It is a fungicide with protective, curative, eradicant, translaminar and systemic properties. It is used against a wide range of diseases in fruit, vegetables and cereals.

Azoxystrobin is a new active substance according to the definition of Directive 91/414/EEC. Germany was designated as the Rapporteur Member State (RMS). After having passed successfully the peer review azoxystrobin was included in Annex I of 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). For the process of renewal of the Annex I inclusion the United Kingdom was appointed as new Rapporteur Member State. In May 2009, the Annex-I renewal Draft Assessment Report (AIR-DAR) has been submitted to EFSA. The peer review process is of the Annex I-renewal (AIR) procedure is currently ongoing.

MRLs for azoxystrobin were set at EU level for the first time 1999 which were modified several times to accommodate for new uses authorised in Member States. The MRLs established under the old European MRL legislation were transferred to Annex II of Regulation 396/2005. Since 1 September 2008, the entry into force of this regulation, EFSA issued three reasoned opinions regarding the modification of MRLs of turnips, broccoli, beet leaves and passion fruit (EFSA 2008a, EFSA 2008b, and EFSA 2009). The currently valid MRLs, which can be found in Appendix C to this report, are established in Annex II of Regulation (EC) No. 396/2005. It is noted that two further Regulations are under preparation which will modify MRLs of azoxystrobin, taking into account the recommendations provided by EFSA in the recent reports.

Belgium intends the authorisation of a plant protection products containing azoxystrobin to protect swedes against fungal diseases. The product should be applied up to two times by foliar application 14 days before harvest with an application rate of 250 g a.s./ha. The details of the intended GAP are reported in Appendix A.

The current MRL for azoxystrobin on swedes is established at the level of 0.05 mg/kg, equivalent to the limit of quantification. According to the proposal made by the EMS it would be necessary to raise the MRL to 0.2 mg/kg to accommodate for the intended use in Belgium. Recently, Codex Alimentarius adopted a wide range of new CXLs, among them also a CXL for root and tuber vegetables at the level of 1 mg/kg.

ASSESSMENT

1. Methods of analysis

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

Validated analytical methods are available to enforce MRLs for azoxystrobin in commodities with high water content, high acid content and dry commodities (EFSA 2008a, EFSA 2008b and EFSA 2009). Validation data demonstrated that the limit of determination achievable in routine MRL enforcement is 0.01 mg/kg. These methods are also applicable to enforce MRLs in swedes.

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

Analytical methods to determine residues of azoxystrobin and the Z-isomer in animal tissues, eggs and milk are available and have been evaluated in the peer review. The LOQ for azoxystrobin is 0.01 mg/kg for liver, muscle, eggs and fat and 0.001 mg/kg for milk.

2. Mammalian toxicology

In the peer review under Directive 91/414/EEC an ADI value of 0.1 mg/kg bw/d was derived for azoxystrobin. In 1998, when the peer review was finalised, the setting of an ARfD was not considered routinely, but Germany performed an evaluation and concluded that no ARfD is necessary because of the low acute risk of the active substance.

In the AIR-DAR prepared by the United Kingdom (2009), RMS United Kingdom concluded to propose the same ADI value as established in 1998, but the value is based on a different NOAEL.

The key information on the toxicological reference values are summarised 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
ADI	COM	1998	0.1	90 d dog, 1 yr dog	100
ADI	AIR-DAR	2009	0.1	90 d rat, 1 yr dog, rat developmental study	200
ARfD	DE	1999		Not necessary	
ARfD	DAR	2009		Not necessary	

It is noted that the JMPR evaluated azoxystrobin in 2008 and came to the conclusion that an ARfD is not necessary. The ADI established by JMPR is 0.2 mg/kg based on a 2-year carcinogenicity study in rats.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of azoxystrobin in primary crops has been investigated in different crops representative for fruits and fruiting vegetables, pulses and oilseeds and cereals. In the peer review it was concluded that qualitatively similar metabolism occurred in these crops (Germany, 1997). The parent compound was identified as the major component of the residue in treated crops. The peer review concluded to set the residue definitions for enforcement and risk assessment as parent compound azoxystrobin only. The JMPR came to the same conclusions regarding residue definitions in its recent review (WHO/FAO, 2008).

Since no differences were observed in the different crop groups, it is most likely that the metabolism in root and tuber vegetables is similar to the crop groups investigated. Thus, no additional studies are required for the application to modify the MRL in swedes.

3.1.1.2. Magnitude of residues

The EMS reported eight supervised field trials in carrots performed Germany and the United Kingdom in 1998 and 1999. According to the European guidance documents, trials on carrots can be extrapolated to swedes if the pesticide is used up to or close to harvest. In these trials the residue behaviour was investigated after the crop was treated by foliar application 4 times with 250 g/ha between BBCH 45 (50% of the expected root diameter reached) to BBCH 49 (Expansion complete; typical form and size of roots reached). Four of the residue trials were designed as residue decline studies where the roots were analysed immediately after the last treatment and one, three, 7 and 9 or 10 days after the last application. In the remaining four trials the residues were measured on day 10 and 28. It is noted that the intended GAP on swedes differs from the GAP used in the supervised field trials regarding the number of treatments. Although the GAP in swedes foresees only two treatments, the trials performed with four treatments are considered acceptable, because from the decline studies it became evident that the residues in the roots remained at a constant level over a period of 28 days. The transfer from aerial parts of the crop to the roots is expected to be slow and thus, the number of treatments is not expected to have a major impact on the final residues in the edible part of the crop. The results of the trials are summarised in Table 3-1.

It is concluded that sufficient studies on carrots are available to derive a MRL proposal which can be extrapolated to carrots. To accommodate for the use on swedes the MRL has to be raised to 0.2 mg/kg.

The stability of residues in treated crops under storage conditions has been evaluated in the DAR. No significant degradation of azoxystrobin was observed in samples of wheat straw, wheat grain, grapes and wine stored for at least 14 months at -15°C. Although not explicitly mentioned it is assumed that the storage stability has been acceptable because the residue trials in carrots have been accepted by the RMS for setting MRLs on carrots in 2001.

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 (d)	Comments
			Enforcement Azoxystrobin	Risk assessment Azoxystrobin					
Carrot → Swedes	NEU	Outdoor	0.02; 0.03; 0.04; 2*0.05; 0.07; 0.09; 0.1	0.02; 0.03; 0.04; 2*0.05; 0.07; 0.09; 0.1	0.05	0.1	0.2	1	The residue trials performed on carrots are used to extrapolate to swedes. Rmax: 0.146 mg/kg Rber:0.15mg/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.
(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

In the DAR prepared by Germany, no hydrolysis studies with radiolabelled azoxystrobin are reported. However, JMPR assessed the stability of azoxystrobin simulating industrial processing at temperatures ranging form 90 to 120°C at pH 4 to 6. It was concluded that azoxystrobin can be considered stable under these conditions.

Processing studies are available for different crops, but not for swedes. However, considering the low dietary intake related to swedes, no processing studies are necessary.

3.1.2. Rotational crops

Swedes are a crop for which crop rotation is relevant. The DT_{90} values derived under field conditions ranged from 87 to 433 days. Since the trigger value is exceeded, the nature and magnitude of azoxystrobin in rotational crops has to be addressed. The nature and magnitude in succeeding crops has been discussed in the previous EFSA reasoned opinions on azoxystrobin (EFSA 2008a, EFSA 2008b and EFSA2009). The conclusion that the setting MRLs for rotational crops or the setting of planting restrictions is not necessary is also applicable to the intended use in swedes.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

EFSA performed a dietary burden calculation for azoxystrobin when the intended use on turnips was assessed (EFSA, 2008a). It was concluded that the trigger value of 0.1 mg/kg (DM) is exceeded for dairy and meat ruminants, poultry and pigs.

Turnips and swedes both belong to the same feed crop group and can be considered as alternatives in animal diet. Since the residues in these two crops are expected to be in the same order of magnitude, the dietary burden calculation performed with turnips is also valid for swedes.

3.2.2. Nature of residues

The peer review concluded that the residue definition for products of animal origin should only comprise the parent compound azoxystrobin. More details are reported in EFSA's reasoned opinions on turnips (EFSA, 2008a).

3.2.3. Magnitude of residues

Assessing the application to modify the MRLs of azoxystrobin in turnips, EFSA concluded that the MRLs for products of animal origin do not have to be changed (EFSA, 2008a). The same conclusion is applicable in the case of MRL amendment in swedes.

4. Consumer risk assessment

The consumer intake calculation was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model), using the MRLs as established in Regulation (EC) No. 396/2005. For the commodities which were subject to previous EFSA assessment under Article 10 of this Regulation (turnips, passion fruit, broccoli and beet leaves), the MRLs were replaced by the STMRs derived in the respective assessments (EFSA 2008a, EFSA 2008b and EFSA 2009).

EFSA is aware that the approach using the MRLs instead of the STMR values derived from supervised field trials leads to an overestimation of the consumer intake. However, since the safety margin regarding the chronic intake is still large, EFSA considers it is unnecessary to retrieve the STMR values reported in the MRL proposals prepared by the RMS between1999 and 2008.

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
Swedes	0.05	STMR	Not relevant since no ARfD is established for azoxystrobin	
Broccoli	0.08	STMR (EFSA, 2009)		
Beat leaves (chard)	0.05	STMR (EFSA, 2009)		
Turnips	0.06	STMR (EFSA, 2008a)		
Passion fruit	1.1	STMR (EFSA, 2008b)		

The results of the chronic intake calculations are attached in Appendix B. The chronic dietary intake calculations did not reveal any consumer intake concerns for any of the European diets. The contribution of swedes to the total dietary intake is insignificant, being less than 0.01% of the ADI in all diets. The calculated total intake values for azoxystrobin ranged from 4.1 to 26 % of the ADI.

EFSA concludes that the intended use of azoxystrobin on swedes according to the reported GAP is acceptable with regard to consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

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 and by JMPR in its recent evaluation.

The metabolism of azoxystrobin in primary and rotational crops is elucidated. The residue definition for risk assessment and enforcement is set as parent azoxystrobin only. Adequate analytical methods are available to enforce the proposed MRL in swedes.

The submitted supervised field trials performed on carrots are sufficient to extrapolate to the expected residue concentrations in swedes. It is concluded that an MRL of 0.2 mg/kg as proposed by the EMS is required to accommodate for the intended use in swedes.

The possible occurrence of azoxystrobin residues in rotational crops was deliberated. EFSA concluded that significant residues in crops grown in crop rotation after swedes are not expected provided that azoxystrobin is applied according to the intended GAP.

The nature and magnitude of azoxystrobin in livestock were also considered, but since the use on swedes does not lead to a more critical dietary intake of livestock, EFSA does not see the need to change the established MRLs for products of animal origin.

The chronic consumer intake calculation was performed with revision 2 of the EFSA PRIMo using the MRLs and the STMRs derived in recently published EFSA reasoned opinions. Since the calculated exposure is well below the ADI for all European diets (max. 26% of the ADI in the WHO cluster diet B), EFSA concludes that the use of azoxystrobin on swedes according to the intended GAP does not pose a consumer health risk. An acute risk assessment was not necessary because no ARfD has been established for azoxystrobin.

EFSA concludes that the intended use of azoxystrobin in swedes is supported by data and no risk for consumers is identified. Thus, the following amendment of Annex II of Regulation (EC) No 396/2005 is recommended:

RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Azoxystrobin			
Swedes	0.05(*)	0.2	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended use.

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

REFERENCES

Belgium, 2009. Evaluation report on azoxystrobin, MRL proposal for swede prepared by the evaluating Member State Belgium under Article 8 of Regulation (EC) No 396/2005, May 2009.

Germany, 1997. Draft Assessment Report (DAR) on the active substance azoxystrobin prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, January 1997.

EFSA (European Food Safety Authority), 2008a. Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for azoxystrobin in turnips. *EFSA Scientific Report* (2008) 200, 1-29.

EFSA (European Food Safety Authority), 2008b. Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on setting of an import tolerance for azoxystrobin in passion fruits. *EFSA Scientific Report* (2008) 209, 1-25.

EFSA (European Food Safety Authority), 2009. Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for azoxystrobin in broccoli and beet leaves (chard). *EFSA Scientific Report* (2009) 283, 1-25.

European Commission, 1998. Review Report for the active substance azoxystrobin finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 22.4.1998 in view of the inclusion of azoxystrobin in Annex I of Directive 91/414/EEC.

United Kingdom, 2009. Draft Assessment Report on the active substance azoxystrobin prepared by the Rapporteur Member State United Kingdom in the framework of renewal of the inclusion in Annex I of Directive 91/414/EED (AIR-DAR), May, 2009.

WHO/FAO, 2008. Pesticide residues in food – 2008. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 193, 2008.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Federal Public Service Health, Food Chain Safety and Environment,
DG Plants, Animals and Food
Eurostation Bloc II
Place Victor Horta, 40 bte 10
1060 BRUSSELS

Date : May 2009
Country : Belgium
Reference : Ch. Vervaet

Pesticide(s) (common name(s)) : Azoxystrobin
Trade name(s) : Orativa & Amistar
Main Uses e.g. insecticide, fungicide : Fungicide

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between application s (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Swede	Belgium (Northern EU)	G	Mycosphaerella Alternaria	SC	250 g/l	Spraying		1-2	14 days			0.25	14	

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

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Azoxystrobin			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0,05	proposed LOQ:	
Toxicological end points			
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**

Explain choice of toxicological reference values.

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
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	pTMRLs at LOQ (in % of ADI)
25,6	WHO Cluster diet B	6,2	Tomatoes	3,6	Wine grapes	2,6	Rice	1,0
20,2	DE child	3,8	Oranges	3,1	Bananas	2,5	Table grapes	1,1
19,9	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	0,9
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
13,5	WHO cluster diet D	2,8	Rice	2,0	Tomatoes	2,0	Wheat	0,5
13,2	ES child	2,4	Rice	2,2	Oranges	2,0	Bananas	0,6
12,9	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
5,5	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 pTMRLs were below the ADI.

A long-term intake of residues of Azoxystrobin is unlikely to present a public health concern.

APPENDIX C – EXISTING EC MRLS

Pesticides - Web Version - EU MRLs (File created on 03/09/2009 15:38)

Code number	Groups and examples of individual products to which the MRLs apply (a)	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*
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, mirabelle)	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	(c) Cane fruit	
153010	Blackberries	3
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	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 (mediteranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), 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, Brazilean 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 [3]
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*
163000	(c) 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
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	0,2
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
233010	Melons (Kiwano)	0,5
233020	Pumpkins (Winter squash)	0,5
233030	Watermelons	0,5
233990	Others	0,5

[3] MRL voted in the SCFCAH on 30 March 2009

Code number	Groups and examples of individual products to which the MRLs apply (a)	Azoxystrobin
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)	0,5/1[4]
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	(c) 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
251010	Lamb´s lettuce (Italian comsalad)	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

[4] MRL voted in SCFCAH on 3 July 2009

Code number	Groups and examples of individual products to which the MRLs apply (a)	Azoxystrobin
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, glassworth)	3
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*/0.5[5]
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
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely 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 (french 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*

[5] See footnote on broccoli

Code number	Groups and examples of individual products to which the MRLs apply (a)	Azoxystrobin
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,05*
270020	Cardoons	0,05*
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	0,05*
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*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Azoxystrobin
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
633000	(c) 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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Azoxystrobin
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*
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*
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*
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	0,01*
1030010	Chicken	0,01*
1030020	Duck	0,01*
1030030	Goose	0,01*
1030040	Quail	0,01*
1030990	Others	0,01*
1040000	(iv) Honey (Royal jelly, pollen)	0,01*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*
1060000	(vi) Snails	0,01*
1070000	(vii) Other terrestrial animal products	0,01*

(*) Indicates lower limit of analytical determination

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
AIR	Annex I renewal: renewal of the inclusion in Annex I of Directive 91/414
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
DP	dustable powder
DT_{90}	period required for 90 percent dissipation (define method of estimation)
DTU	Danish Technical University
dw	dry weight
EC	European Community
ECD	electron capture detection
EDI	estimated daily intake
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
K_{oc}	organic carbon adsorption coefficient
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
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	rapporteur Member State
SC	suspension concentrate
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