

## REASONED OPINION OF EFSA

### Modification of the existing MRLs for trifloxystrobin in parsnips, parsley root, salsify, swedes and turnips<sup>1</sup>

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00464)

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#### SUMMARY

In order to authorize the use of trifloxystrobin on several minor crops, the Belgian authorities compiled on their own initiative an application to modify the existing MRLs for trifloxystrobin in parsley root, parsnips, salsify, swedes and turnips. Belgium as the Evaluating Member State (EMS) 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 10 March 2009.

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

The metabolism of trifloxystrobin was investigated in the framework of the peer review in two crop categories - cereals and fruit and fruiting vegetables - and the residue definition for enforcement and risk assessment for these crop groups were set as parent trifloxystrobin only. An additional metabolism study on sugar beets indicates that trifloxystrobin metabolite (E,E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113) might be considered for the inclusion in the risk assessment definition for plant commodities. Data from the supervised residue trials which were submitted by The Netherlands in the framework of setting the MRLs for several leafy crops, confirmed that metabolite CGA 321113 is present at significant amounts in several plant commodities. In addition, the metabolite is already included in the residue definition for risk assessment and enforcement in commodities of animal origin and it was also included by Codex Alimentarius in the definition for risk assessment in commodities of plant origin. The need for a new residue definition for risk assessment in plant commodities will be considered by EFSA when performing full risk assessment of trifloxystrobin under Article 12(2) of Regulation (EC) No 396/2005.

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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 trifloxystrobin in parsnips, parsley root, salsify, swedes and turnips. *EFSA Scientific Report* (2009) 314, 1-27

The MRL application for crops under consideration does not require additional metabolism studies. Adequate analytical methods are available to enforce the residue definition.

Submitted supervised residues field trials data indicate that a lower MRL of 0.04 mg/kg than proposed by Belgium (0.05 mg/kg) would be required in order to accommodate the intended GAP in Belgium. Processing studies are not necessary with regard to the current MRL application, since contribution of crops under consideration to the dietary intake is very low.

The occurrence of trifloxystrobin or its metabolites in rotational crops was also investigated. EFSA concluded that significant residue levels in rotational crops are not expected provided that trifloxystrobin is applied according to the proposed GAPs.

The livestock dietary burden was calculated considering the existing and the proposed MRLs for trifloxystrobin. The impact of swedes and turnips to the total livestock dietary burden is insignificant. Nevertheless, taking into account the extension of uses of trifloxystrobin on commodities that are potential livestock feed items and taking into account the high intake of trifloxystrobin residues by livestock, the need for setting the MRLs for commodities of animal origin will be considered by EFSA in the framework of Article 12 (2) of Regulation (EC) No 396/2005.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use of trifloxystrobin on the crops under consideration. In addition, for several leafy commodities the input values were used as derived in the previously issued EFSA reasoned opinion. No chronic consumer intake concerns were identified for any of the European diets. The total calculated dietary intake values ranged from 2 to 23% of the ADI. The contribution of the crops under consideration to the total dietary intake was insignificant. No acute intake assessment was undertaken since no ARfD is established for trifloxystrobin.

Consequently, EFSA concludes that the intended uses of trifloxystrobin on turnips, swedes, salsify, parsnip and parsley roots are acceptable with regard to consumer safety.

### Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Parsnips, parsley roots, salsify, turnips and swedes	0.02*	0.04	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses.

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

**Key words:** trifloxystrobin, parsnips, parsley roots, salsify, turnips, swedes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurin class fungicides

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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 trifloxystrobin in parsnips, parsley root, salsify, swedes and turnips. 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 10 March 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00464 and the following subject:

*Trifloxystrobin - Application to modify the existing MRLs for cga279202 (parent ee isomer) in parsnips from 0.02 mg/kg to 0.05 mg/kg, in parsley root from 0.02 mg/kg to 0.05 mg/kg, in salsify from 0.02 mg/kg to 0.05 mg/kg, in swedes from 0.02 mg/kg to 0.05 mg/kg and in turnips from 0.02 mg/kg to 0.05 mg/kg.*

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

## TERMS OF REFERENCE

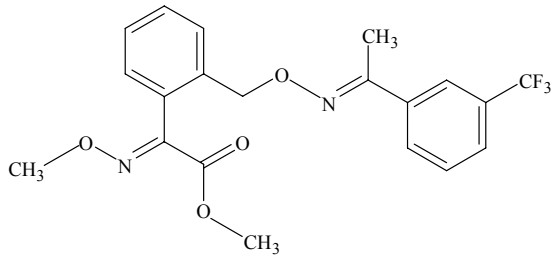
According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the Evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

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 was 10 June 2009.

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Trifloxystrobin is the ISO common name for methyl (E)-methoxyimino-{(E)-a-[1-a-(a,a,a-trifluoro-m-tolyl)ethylideneaminoxy]-o-tolyl}acetate with the following chemical structure:



Trifloxystrobin is a broad-spectrum contact fungicide belonging to the strobilurin class of fungicides. Trifloxystrobin possesses penetrative properties and is a synthetic derivative of the naturally occurring strobilurins found in several genera of wood-decaying fungi such as *Strobilurus tenacellus*. They have been shown to inhibit mitochondrial respiration by blocking electron transfer within the respiratory chain. Trifloxystrobin is active against fungi from all four classes: *Ascomycetes*, *Deuteromycetes*, *Basidiomycetes* and *Oomycetes*. It is used on a wide range of agricultural and horticultural crops that are cultivated in temperate, sub tropical and tropical climates in open fields or protected.

Trifloxystrobin was peer reviewed according to Directive 91/414/EEC as a new active substance with The United Kingdom being the designated Rapporteur Member State. It was included in Annex I to this Directive by Directive 2003/68/EC which entered into force on 1 October 2003. The representative uses evaluated in the peer review were foliar treatment on grapes, apples, cucumber, wheat, barley and melons. The Annex I inclusion is restricted to uses as a fungicide only. Trifloxystrobin has not been peer reviewed by EFSA.

The EC MRLs for trifloxystrobin were first set in Directives 86/362/EEC and 90/642/EEC by Commission Directive 2005/37/EC. After the entry into force of Regulation (EC) No 396/2005, the MRLs established under Directives 86/362/EEC and 90/642/EEC were transferred to Annex II to Regulation (EC) No 396/2005. In Annex III to the Regulation temporary MRLs were established for crops that were not covered by previous Community MRL legislation. The current EC MRLs are summarized in Appendix B. For celery, blueberry, head cabbage, Brussels sprouts, lettuce, scarole and herbs the MRL proposals were recently assessed by EFSA (EFSA, 2009), but the recommendations made by EFSA are still awaiting the decision of the SCoFCAH.

The current EC MRLs for trifloxystrobin in all the crops under consideration are set at the LOQ of 0.02 mg/kg. Codex Alimentarius has set the CXLs for a wide range of commodities, but no CXLs are established for the crops under consideration.

The applicant has requested an authorization for the outdoor uses of trifloxystrobin on turnip, swedes, parsnips, parsley roots and salsify. The active substance will be applied 1-2 times at a rate of 0.075 kg a.s./ha on parsnips and parsley roots and 0.1 kg a.s./ha on turnips, swedes and salsify. The minimum waiting period is 21 day. The proposed GAPs are provided in Appendix A.

## ASSESSMENT

### 1. Methods of analysis

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

The analytical methods for the determination of trifloxystrobin in the foodstuffs of plant origin were evaluated in the framework of the peer review of Directive 91/414/EEC (The United Kingdom, 2000). In general, for the determination of trifloxystrobin and its metabolite CGA 321113<sup>2</sup> in matrices with high water content, high acid content and dry commodities three analytical methods are sufficiently validated:

- 1) Method DP 57464, where samples for trifloxystrobin are analysed by HPLC-UV. The validated LOQ is 0.02 mg/kg for high water content and high acid content commodities (apples, potatoes and grapes)
- 2) Method DP 57465 where samples for trifloxystrobin and CGA 321113 are analysed by GC-ECD. The validated LOQ is 0.02 mg/kg for dry commodities and high water content commodities (wheat, barley and banana)
- 3) Method DP 57467 where samples for trifloxystrobin and CGA 321113 are analysed by GC-NPD. For this method the validated LOQ is 0.02 mg/kg is reported for high water content and high acid content commodities (potatoes, bananas, cucumbers, apples, melons, grapes) and peanut hay.

It is concluded that there are adequate analytical methods available for the enforcement of the proposed MRLs for the crops under consideration.

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

The availability of analytical methods for enforcement of residues in food of animal origin was not investigated as the uses supported in the framework of this application are not expected to significantly affect the dietary burden of livestock to trifloxystrobin residues (See section 3.2.).

### 2. Mammalian toxicology

Toxicological reference values for trifloxystrobin were derived at Community level during the peer review of Directive 91/414/EEC (European Commission, 2003). It was concluded that trifloxystrobin does not possess acute toxicological properties; therefore the ARfD value was not established. An overview of the toxicological reference values is provided 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	2003	0.1	2 yr rat studies	100
ARfD	COM	2003	n.n.	n.n.	n.n.

n.n. - not necessary

<sup>2</sup> (E, E)-methoxyimino- $\{2-[1-(3\text{-trifluoromethyl-phenyl})\text{-ethylideneamino-oxymethyl}]\text{-phenyl}\}$ -acetic acid

### 3. Residues

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

##### 3.1.1. Primary crops

###### 3.1.1.1. Nature of residues

Two metabolism studies of trifloxystrobin in cereals and fruit and fruiting vegetables are reported in the DAR (The United Kingdom, 2000). A third study on sugar beets was submitted by The Netherlands in the framework of the MRL setting according to Article 10 of Regulation (EC) No 396/2005 (EFSA, 2009). In general, metabolism of trifloxystrobin was investigated in the following crops:

- cereals: wheat - foliar spray 2 x 0.25 kg a.s./ha; cucumbers - foliar spray 3 x 0.312 kg a.s./ha
- fruits and fruiting vegetables: apples - foliar spray 4 x 0.1 kg a.s./ha
- root and tuber vegetables: sugar beet - application at 0.39 kg a.s./ha for qualitative distribution and 1.17 kg a.s./ha for quantitative distribution.

Metabolism studies were performed with <sup>14</sup>C labelled trifloxystrobin either on the trifluoromethyl-phenyl ring or on the glyoxyl-phenyl ring. The metabolism of trifloxystrobin in plants is complex and mainly proceeds via cis/trans isomerisation (Z/E isomer, Z/Z isomer, E/Z isomer) and cleavage of the methyl ester group to form (E, E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113). Metabolite CGA 321113 was below the trigger value of 10% of the TRR in all crop samples. In the peer review it was concluded that metabolism in fruits and fruiting vegetables and cereals proceeds according to a similar pattern and residues in these crop groups should be defined as parent trifloxystrobin only.

In sugar beets two metabolites CGA 321113 and II<sub>19a</sub><sup>3</sup> were encountered at levels exceeding the trigger value of 10% in roots 0, 21 and 45 DAT. II<sub>19a</sub> in roots was 19.6% (0 DAT) and 14.9% (45 DAT) of the TRR, while CGA 321113 was 10.8 % (21 and 45 DAT) of the TRR. In leaves parent trifloxystrobin was the main component of the TRR.

During assessment EFSA came to the conclusion that trifloxystrobin metabolite (E, E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113) might be considered for the inclusion in the risk assessment definition for plant commodities. Data from supervised residue field trials submitted by The Netherlands in the framework of setting the MRLs for trifloxystrobin in several leafy commodities (EFSA, 2009), confirmed that metabolite CGA 321113 is present at significant amounts in several leafy crops. In addition, metabolite CGA 321113 is already included in the residue definition for risk assessment and enforcement in commodities of animal origin and it was also included by Codex Alimentarius in the definition for risk assessment in commodities of plant origin (WHO/FAO, 2004).

The need for a new residue definition for risk assessment for plant commodities will be considered by EFSA when performing full risk assessment of trifloxystrobin under Article 12(2) of Regulation (EC) No 396/2005.

<sup>3</sup> {2-[1-(2,3-dihydroxy-5-methyl-phenyl)-2-hydroxy-ethylideneamino-oxymethyl]-phenyl}-methoxy-imino -acetic acid

Regarding the crops under consideration EFSA concludes that metabolism of trifloxystrobin is sufficiently addressed and no additional metabolism studies are required.

#### 3.1.1.2. Magnitude of residues

In support of the proposed GAPs, Belgium reported 4 outdoor trials on carrots for the extrapolation to turnips, swedes, salsify, parsnips and parsley roots. The trials were performed in accordance with a proposed GAP and samples were analysed for parent trifloxystrobin and its metabolite CGA 321113. Trifloxystrobin residues were in the range of <0.01 - 0.02 mg/kg. The levels of metabolite CGA 321113 were below the LOQ of 0.01 mg/kg in all trials. The risk assessment values were derived according to a residue definition which includes metabolite CGA 321113, assuming that the metabolite is present at 0.01 mg/kg (worst case assumption). The number of submitted residue trials is sufficient for extrapolation since crops under consideration are classified as either minor or very minor crops according to the EU Guidance document 7525/VI/95 rev.8 (European Commission, 2008). Taking into account the residue values from the supervised field trials, an MRL of 0.04 mg/kg would be necessary to authorize the intended GAP in Belgium.

In addition, Belgium reported data from 7 other outdoor trials on carrots which were performed at more critical GAP (3 x 0.25 kg a.s/ha), but EFSA considered those not applicable since they were performed at significantly higher GAP than intended for the crops under consideration. Nevertheless, in all those trials trifloxystrobin was encountered at levels  $\leq 0.02$  mg/kg.

The storage stability of trifloxystrobin and metabolite CGA 321113 in treated crops has been evaluated under the peer review of Directive 91/414/EEC (The United Kingdom, 2000). Studies demonstrated that residues of trifloxystrobin and CGA 321113 are stable for 18 months at -20 °C in apple, apple pomace, peanut, peanut hay, peanut oil, potato granules, grape juice and for 2 years at -18 °C in grapes, cucumbers, potatoes and wheat (grain, straw and whole plant).

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) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Residue definition for enforcement: trifloxystrobin Residue definition for risk assessment: sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin									
Turnip, swedes, salsify, parsnip, parsley root.	NEU	Outdoor	3 x <0.01; 0.02	3 x <0.02; 0.03	0.01	0.02	0.04	2.0	Residues trials were performed on carrots but can be extrapolated to the crops under consideration. R <sub>ber</sub> =0.035 mg/kg R <sub>max</sub> =0.038 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.

(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.

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

The effect of processing on the nature of trifloxystrobin residues was investigated in the peer review in a hydrolysis study where pH ranged between 1-13 and temperatures ranged between 25-60°C (The United Kingdom, 2000). Results indicated that trifloxystrobin is stable at pH 5 and no isomerisation of the parent compound occurred. In neutral and alkaline conditions, CGA 321113 was the major metabolite.

The effect of processing on the magnitude of trifloxystrobin residues was investigated in the processing studies with apples, grapes, and barley and several processing factors were obtained. No residue definition in the peer review was derived for processed commodities even though trifloxystrobin and its metabolite CGA 321113 were considered as the main metabolites in processed commodities.

Under the current application no processing studies have been submitted and they are not considered necessary since the contribution of these crops to the dietary intake is insignificant.

## 3.1.2. Rotational crops

### 3.1.2.1. Preliminary considerations

All crops under consideration can be grown in rotation. According to the soil degradation studies performed in the framework of the peer review the DT<sub>90</sub> value of trifloxystrobin based on the field and laboratory studies is less than 100 days. More persistent in the soil are two trifloxystrobin metabolites: CGA 321113 with the DT<sub>90</sub> value of more than 500 days and CGA 373466<sup>4</sup> with the highest DT<sub>90</sub> value of 290 days (The United Kingdom, 2000). In this case further investigation of behaviour of trifloxystrobin residues in rotational crops is necessary.

### 3.1.2.2. Nature of residues

Rotational crop studies were performed by applying <sup>14</sup>C trifloxystrobin on a bare soil at an application rate of 0.5 kg a.s./ha. From the soil analysis it was evident that after 31 day the amounts of parent trifloxystrobin in soil decreased (from 86.7 % to 3.6%) while the amounts of CGA 321113 increased (2.5% to 46.2%). The metabolism was investigated in three rotational crops (lettuce, radish and wheat) planted 30, 120, 174 and 356 days after treatment (DAT). At harvest in all crops that were planted 30 DAT, the total residues were not higher than 0.075 mg/kg (wheat straw). The major metabolite was trifluoroacetic acid accounting for up to 65.7% of the TRR (0.016 mg/kg) in radish tops at 120 day rotation. Trifloxystrobin and its isomers were detected in immature wheat (10.5% TRR or 0.006 mg/kg) and in radish roots (15.0% TRR or 0.005 mg/kg). The levels of CGA 321113 did not exceed 0.003 mg/kg (wheat straw).

In the peer review it was concluded that metabolism of trifloxystrobin in rotational or succeeding crops proceeds in a similar pattern than in primary crops.

<sup>4</sup> (Z, E)-methoxyimino- {2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminoxy-methyl]-phenyl}-acetic acid

### 3.1.2.3. Magnitude of residues

Considering that application rates proposed in the framework of this application is lower and that a part of the applied substance is intercepted by the treated crop, it is concluded that significant residue levels in rotational crops are not expected provided that trifloxystrobin is applied according to the proposed GAPs.

## 3.2. Nature and magnitude of residues in livestock

### 3.2.1. Dietary burden

According to the EU Guidance document on livestock feeding studies Appendix G (Document 7031/VI/95 rev.4), turnips and swedes are potential feed item for chicken, dairy ruminants, meat ruminants and pig (European Commission, 1996).

The dietary burden for different types of livestock was calculated using the EFSA livestock dietary burden calculator. For swedes and turnips the input values were as obtained from the supervised residue field trials (Table 3-1). For head cabbage the input values were as obtained in EFSA reasoned opinion on the modification of the existing MRLs for trifloxystrobin in several leafy crops (EFSA, 2009). For pome fruit and citrus fruit pomace the default processing factor of 2.5 was applied; for wheat and rye bran the default processing factor of 8 was used. For barley and apple, the data on STMR and HR values are available, but they were not in line with the existing MRLs for these commodities. EFSA therefore used the current MRLs as input values for these crops. For remaining commodities that might be used as feed items, the existing MRLs are set at the LOQ and therefore not considered in the calculation. The summary of the input values is available in Table 3-2.

Table 3-2. Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin				
Swedes, turnips	0.02	STMR*CF	0.04	HR*CF
Cabbage	0.05	STMR*CF	0.31	HR*CF
Sugar beet leaves	0.05	STMR (Spain, 2003)	0.13	HR (Spain, 2003)
Citrus pomace	0.23	STMR*PF (2.5) (The United Kingdom, 2003)	0.23	STMR*PF (2.5) (The United Kingdom, 2003)
Apple pomace	1.25	MRL*PF (2.5)	1.25	MRL*PF (2.5)
Barley grain	0.3	MRL	0.3	MRL
Wheat, rye grain	0.02	STMR (The United Kingdom, 2000)	0.02	HR (The United Kingdom, 2000)
Wheat, rye bran	0.16	STMR*PF (8)	0.16	STMR*PF (8)
Wheat, rye straw	0.69	STMR (The United Kingdom, 2000)	2.31	HR (The United Kingdom, 2000)

In order to estimate the contribution of swedes and turnips to the total livestock dietary burden, EFSA first performed dietary burden calculations for all commodities excluding swedes and turnips (Table 3-3) and compared them to the second dietary burden calculation, which was performed including swedes and turnips (Table 3-4).

**Table 3-3. Results of the dietary burden calculation (excluding swedes and turnips)**

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Intake of residues (mg/kg/DM)	Dietary burden triggered?
Risk assessment residue definition: sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin					
Dairy ruminants	0.05243	0.03067	Apple pomace	1.44	Yes
Meat ruminants	0.13042	0.09006	Apple pomace	3.04	Yes
Poultry	0.02233	0.01637	Barley grain	0.56	Yes
Pigs	0.02428	0.01366	Barley grain	0.38	Yes

**Table 3-4. Results of the dietary burden calculation (including swedes and turnips)**

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Intake of residues (mg/kg/DM)	Dietary burden triggered?
Risk assessment residue definition: sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin					
Dairy ruminants	0.05362	0.03285	Apple pomace	1.47	Yes
Meat ruminants	0.13086	0.09006	Apple pomace	3.05	Yes
Poultry	0.02738	0.01910	Barley grain	0.68	Yes
Pigs	0.02620	0.01366	Barley grain	0.41	Yes

The calculated dietary burdens in both cases exceed the trigger value of 0.1 mg/kg DM for all relevant livestock species, but are mainly driven by existing MRLs for apple and barley. As the supported use of trifloxystrobin on swedes and turnips does not affect the dietary burden significantly, the need for the setting of MRLs in food of animal origin was not further investigated in the framework of this application.

Nevertheless, taking into account the extended uses of trifloxystrobin on commodities that are potential livestock feed items and taking into account the expected high intake of trifloxystrobin residues by livestock, the need for setting the MRLs for commodities of animal origin will be considered by EFSA in the framework of Article 12 (2) of Regulation (EC) No 396/2005.

#### 4. Consumer risk assessment

The consumer risk assessment is performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). For the chronic intake assessment EFSA used the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use of trifloxystrobin on the crops under consideration. In addition, for several leafy commodities the input values were used as derived in the previously issued EFSA reasoned opinion. 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 years 2003-2008. Input values are summarized in Table 4-1.

No acute risk assessment was undertaken since no ARfD value has been established.

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
Residue definition for risk assessment: sum of trifloxystrobin and its metabolite CGA 321113, expressed as trifloxystrobin				
Swedes, turnips, salsify, parsnips, parsley root	0.02	STMR*CF	The acute risk assessment was not undertaken since ARfD value is not established and is not considered necessary.	
Blueberry	0.63	STMR* CF (EFSA, 2009)		
Celery	0.10	STMR*CF (EFSA, 2009)		
Head cabbage	0.05	STMR*CF (EFSA, 2009)		
Brussels sprouts	0.13	STMR*CF (EFSA, 2009)		
Lettuce, scarole (broad-leaf endive), herbs	5.5	STMR* CF (EFSA, 2009)		

The summary of the intake calculations can be found in Appendix C. Regarding chronic consumer risk assessment no consumer intake concerns were identified. Total dietary intake values ranged from 2 to 23% of the ADI. The contribution of the crops under consideration to the total dietary intake was insignificant.

EFSA concludes that the intended uses of trifloxystrobin on turnips, swedes, salsify, parsnip and parsley roots are acceptable with regard to consumer safety.

## CONCLUSIONS AND RECOMMENDATIONS

In order to authorize the use of trifloxystrobin on several minor crops, the Belgian authorities compiled on their own initiative an application to modify the existing MRLs for trifloxystrobin in parsley root, parsnips, salsify, swedes and turnips. Belgium as the Evaluating Member State (EMS) 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 10 March 2009.

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

The metabolism of trifloxystrobin was investigated in the framework of the peer review in two crop categories - cereals and fruit and fruiting vegetables - and the residue definition for enforcement and risk assessment for these crop groups were set as parent trifloxystrobin only. An additional metabolism study on sugar beets indicates that trifloxystrobin metabolite (E,E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113) might be considered for the inclusion in the risk assessment definition for plant commodities. Data from the supervised residue trials which were submitted by The Netherlands in the framework of setting the MRLs for several leafy crops, confirmed that metabolite CGA 321113 is present at significant amounts in several plant commodities. In addition, the metabolite is already included in the residue definition for risk assessment and enforcement in commodities of animal origin and it was also included by Codex Alimentarius in the definition for risk assessment in commodities of plant origin. The need for a new residue definition for risk assessment in plant commodities will be considered by EFSA when performing full risk assessment of trifloxystrobin under Article 12(2) of Regulation (EC) No 396/2005.

The MRL application for crops under consideration does not require additional metabolism studies. Adequate analytical methods are available to enforce the residue definition.

Submitted supervised residues field trials data indicate that a lower MRL of 0.04 mg/kg than proposed by Belgium (0.05 mg/kg) would be required in order to accommodate the intended GAP in Belgium. Processing studies are not necessary with regard to the current MRL application, since contribution of crops under consideration to the dietary intake is very low.

The occurrence of trifloxystrobin or its metabolites in rotational crops was also investigated. EFSA concluded that significant residue levels in rotational crops are not expected provided that trifloxystrobin is applied according to the proposed GAPs.

The livestock dietary burden was calculated considering the existing and the proposed MRLs for trifloxystrobin. The impact of swedes and turnips to the total livestock dietary burden is insignificant. Nevertheless, taking into account the extension of uses of trifloxystrobin on commodities that are potential livestock feed items and taking into account the high intake of trifloxystrobin residues by livestock, the need for setting the MRLs for commodities of animal origin will be considered by EFSA in the framework of Article 12 (2) of Regulation (EC) No 396/2005.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use of trifloxystrobin on the crops under consideration. In addition, for several leafy

commodities the input values were used as derived in the previously issued EFSA reasoned opinion. No chronic consumer intake concerns were identified for any of the European diets. The total calculated dietary intake values ranged from 2 to 23% of the ADI. The contribution of the crops under consideration to the total dietary intake was insignificant. No acute intake assessment was undertaken since no ARfD is established for trifloxystrobin.

Consequently, EFSA concludes that the intended uses of trifloxystrobin on turnips, swedes, salsify, parsnip and parsley roots are acceptable with regard to consumer safety.

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Parsnips, parsley roots, salsify, turnips and swedes	0.02*	0.04	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses.

(\*): 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 trifloxystrobin swedes, turnips, salsify, parsnip and parsley root prepared by the Belgium under Regulation (EC) No 396/2005. Submitted to EFSA on 10 March 2009.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

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)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	No. min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Turnip & swede	Belgium (NEU)	F	leaf blight, black spot, powdery mildew	WG	25% (+ 50% tebuconazole)	Spray	At appearance of the first symptoms	1-2	21 days			0.1	21	
Parsnip & parsley root	Belgium (NEU)	F	leaf blight, powdery mildew	WG	25% (+ 50% tebuconazole)	Spray	At appearance of the first symptoms	1-2	21 days			0.075	21	
Salsify	Belgium (NEU)	F	powdery mildew, white rust	WG	25% (+ 50% tebuconazole)	Spray	At appearance of the first symptoms	1-2	21 days			0.1	21	

(a) In case of group of crops the Codex classification should be used

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) e.g. biting and sucking insects, soil born insects, foliar fungi

(d) Suspension concentrate (= flowable concentrate) (SC)

(e) Use CIPAC/FAO Codes where appropriate

(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 plants

(i) g/kg or g/l

(j) Growth stage at last treatment

(k) PHI = Pre-harvest interval

(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications



**APPENDIX B – EXISTING EC MRLs**

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,3
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,3
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,3
110030	Lemons (Citron, lemon )	0,3
110040	Limes	0,3
110050	Mandarins (Clementine, tangerine and other hybrids)	0,3
110990	Others	0,3
120000	(ii) Tree nuts (shelled or unshelled)	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	0,5
130010	Apples (Crab apple)	0,5
130020	Pears (Oriental pear)	0,5
130030	Quinces	0,5
130040	Medlar	0,5
130050	Loquat	0,5

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
130990	Others	0,5
140000	(iv) Stone fruit	
140010	Apricots	1
140020	Cherries (sweet cherries, sour cherries)	1
140030	Peaches (Nectarines and similar hybrids)	1
140040	Plums (Damson, greengage, mirabelle)	0,2
140990	Others	0,02*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	5
151010	Table grapes	5
151020	Wine grapes	5
152000	(b) Strawberries	0,5
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,02*
153030	Raspberries (Wineberries )	0,02*
153990	Others	0,02*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	0,02* [2.0] <sup>a</sup>
154020	Cranberries	0,02*
154030	Currants (red, black and white)	1
154040	Gooseberries (Including hybrids with other ribes species)	1
154050	Rose hips	0,02*
154060	Mulberries (arbutus berry)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
154070	Azarole (mediterranean medlar)	0,02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries)	0,02*
154990	Others	0,02*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,3
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	0,02*
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,02*
162990	Others	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
163000	(c) Inedible peel, large	
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05
163030	Mangoes	0,5
163040	Papaya	1
163050	Pomegranate	0,02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,02*
163070	Guava	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,02*
213020	Carrots	0,05
213030	Celeriac	0,02*
213040	Horseradish	0,02*
213050	Jerusalem artichokes	0,02*
213060	Parsnips	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
213070	Parsley root	0,02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02*
213100	Swedes	0,02*
213110	Turnips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	0,02*
220010	Garlic	0,02*
220020	Onions (Silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes, )	0,5
231020	Peppers (Chilli peppers)	0,3
231030	Aubergines (egg plants) (Pepino)	0,02*
231040	Okra, lady's fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,2
232010	Cucumbers	0,2
232020	Gherkins	0,2
232030	Courgettes (Summer squash, marrow (patisson))	0,2
232990	Others	0,2
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano )	0,3
233020	Pumpkins (Winter squash)	0,2
233030	Watermelons	0,2

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
233990	Others	0,02*
234000	(d) Sweet corn	0,02*
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)	0,05
241020	Cauliflower	0,05
241990	Others	0,02*
242000	(b) Head brassica	0,02*
242010	Brussels sprouts	0,02*[0.5] <sup>a</sup>
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,02*[0.3] <sup>a</sup>
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	0,02*
251000	(a) Lettuce and other salad plants including Brassicacea	0,02*
251010	Lamb's lettuce (Italian cornsalad)	0,02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,02*[10] <sup>a</sup>

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,02*[10] <sup>a</sup>
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)	0,02*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,02*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,02*
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*[10] <sup>a</sup>
256010	Chervil	0,02*[10] <sup>a</sup>
256020	Chives	0,02*[10] <sup>a</sup>
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,02*[10] <sup>a</sup>
256040	Parsley	0,02*[10] <sup>a</sup>
256050	Sage (Winter savory, summer savory, )	0,02*[10] <sup>a</sup>
256060	Rosemary	0,02*[10] <sup>a</sup>

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
256070	Thyme ( marjoram, oregano)	0,02*[10] <sup>a</sup>
256080	Basil (Balm leaves, mint, peppermint)	0,02*[10] <sup>a</sup>
256090	Bay leaves (laurel)	0,02*[10] <sup>a</sup>
256100	Tarragon (Hyssop)	0,02*[10] <sup>a</sup>
256990	Others	0,02*[10] <sup>a</sup>
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,5
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	0,2
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
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*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
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	0,05*
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	0,05*
402010	Olives for oil production	0,3
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	0,02*
500030	Maize	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	0,02*
500060	Rice	0,02*
500070	Rye	0,05
500080	Sorghum	0,02*
500090	Wheat (Spelt Triticale)	0,05
500990	Others	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i> )	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	30
800000	8. SPICES	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
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*
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*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
870990	Others	0,05*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,05
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
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	
1011000	(a) Swine	
1011010	Meat	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
1014010	Meat	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry - chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others	
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	
1030010	Chicken	
1030020	Duck	
1030030	Goose	
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	
<p>* - indicates the limit of quantification of the analytical method</p> <p><sup>a</sup> – MRL proposals as supported by EFSA in EFSA reasoned opinion on the modification of the existing MRLs for trifloxystrobin in various crops (EFSA, 2009). Not voted in SCoFCAH by 16 June 2009.</p>		

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



<b>Trifloxystrobin</b>			
Status of the active substance:	<b>Included</b>	Code no.:	<b>#N/A</b>
LOQ (mg/kg bw):		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>2003</b>	Year of evaluation:	<b>2003</b>

**Chronic risk assessment - refined calculations**

		TMDI (range) in % of ADI minimum - maximum							
		2                      23							
		<b>No of diets exceeding ADI:                      ---</b>							
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)	
22.7	FR all population	20.0	Wine grapes	0.5	Table grapes	0.5	Lettuce		
18.6	WHO Cluster diet B	9.0	Wine grapes	2.0	Lettuce	1.7	Table grapes		
17.4	DE child	6.3	Table grapes	6.0	Apples	1.1	Oranges		
16.3	PT General population	12.4	Wine grapes	1.4	Table grapes	0.5	Apples		
12.6	IE adult	6.3	Wine grapes	1.3	Table grapes	0.6	Peaches		
12.5	WHO cluster diet E	8.0	Wine grapes	0.8	Table grapes	0.5	Lettuce		
12.3	NL child	3.8	Table grapes	3.2	Apples	1.1	Scarole (broad-leaf endive)		
8.6	DK adult	7.0	Wine grapes	0.4	Apples	0.4	Table grapes		
7.9	NL general	3.1	Wine grapes	1.1	Table grapes	0.7	Lettuce		
7.7	UK Adult	5.4	Wine grapes	0.6	Lettuce	0.3	Table grapes		
7.6	ES adult	2.9	Lettuce	2.1	Wine grapes	0.4	Tomatoes		
7.3	WHO Cluster diet F	3.0	Wine grapes	1.7	Lettuce	0.6	Table grapes		
7.0	UK vegetarian	4.1	Wine grapes	0.8	Lettuce	0.4	Table grapes		
6.9	WHO regional European diet	2.1	Lettuce	1.2	Wine grapes	0.8	Table grapes		
5.6	ES child	2.3	Lettuce	0.7	Oranges	0.6	Apples		
5.6	FR toddler	1.3	Apples	1.0	Table grapes	0.6	Oranges		
5.5	WHO cluster diet D	1.8	Wine grapes	0.9	Table grapes	0.5	Tomatoes		
5.4	UK Toddler	1.2	Table grapes	1.1	Sugar beet (root)	0.9	Apples		
5.3	IT adult	2.1	Lettuce	0.7	Table grapes	0.6	Tomatoes		
5.1	IT kids/toddler	1.6	Lettuce	0.7	Tomatoes	0.5	Table grapes		
4.9	DK child	1.2	Apples	0.9	Table grapes	0.8	Lettuce		
3.8	PL general population	1.6	Table grapes	1.0	Apples	0.4	Tomatoes		
3.5	FR infant	1.3	Apples	0.4	Beans (with pods)	0.4	Table grapes		
3.2	FI adult	1.5	Wine grapes	0.4	Lettuce	0.3	Oranges		
3.1	UK Infant	0.8	Apples	0.5	Sugar beet (root)	0.4	Oranges		
2.7	SE general population 90th percentile	0.5	Apples	0.4	Tomatoes	0.2	Oranges		
2.2	LT adult	0.9	Apples	0.3	Lettuce	0.3	Tomatoes		

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

## GLOSSARY / 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
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/EEC)
DAT	days after treatment
DT <sub>90</sub>	period required for 90 percent dissipation
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
GAP	good agricultural practice
GC	gas chromatography
GC-NPD	gas chromatography with nitrogen-phosphorus detection
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
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
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
ppm	parts per million ( $10^{-6}$ )
PRIMo	Pesticide Residues Intake Model
PROFile	Pesticide Residues Overview File
RMS	Rapporteur Member State
SEU	Southern European Union
SCoFCAH	Standing Committee on Food Chain and Animal Health
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WHO	World Health Organisation