REASONED OPINION OF EFSA

Modification of the existing MRLs for trifloxystrobin in various crops[1]

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00222)

Issued on 20 April 2009

SUMMARY

The Netherlands received an application from Bayer CropScience B.V. to modify the existing MRLs for trifloxystrobin in blueberries, head cabbage, Brussels sprouts, lettuce, scarole (broad-leaf endive), herbs and celery. In order to accommodate the new use of trifloxystrobin on these crops, the applicant proposes to raise the existing MRLs. The Netherlands as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 14 January 2009.

EFSA derives the following conclusions regarding the application, based on the 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 evaluated in the framework of the peer review in two crop categories - fruits and fruiting vegetables and cereals - and the residue definition for enforcement and risk assessment for these crop categories was proposed as parent trifloxystrobin only. Since two crop groups were insufficient to address the metabolism of trifloxystrobin in the crops under consideration, the EMS submitted an additional metabolism study on sugar beets. During the assessment EFSA came to the conclusion that the residue definition for risk assessment in the crops under consideration should also include the metabolite (E,E) – methoxyimino -{2 - [1-(3-trifluoromethyl-phenyl) – ethylideneamino - oxymethyl] -phenyl}-acetic acid (CGA 321113). This is confirmed by data from submitted supervised residues field trials where in some commodities (Brussels sprouts, head cabbage) the metabolite was present in higher amounts than parent trifloxystrobin. 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. For the crops under consideration EFSA derived conversion factors for risk assessment and applied them in the consumer intake calculations. For all other plant commodities the need for a new residue definition for risk assessment might be reconsidered when performing full risk assessment of trifloxystrobin under Article 12(2) of Regulation (EC) No 396/2005.

[1] For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRLs for trifloxystrobin in various crops. *EFSA Scientific Report* (2009) 273, 1-27

Submitted supervised residues field trials indicate that the current MRLs of 0.02 mg/kg for all the crops under consideration do not accommodate the intended GAP in The Netherlands and higher MRLs are proposed (see table below). Adequate analytical methods are available to enforce the proposed MRLs.

The 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. Since the dietary burden was mainly driven by the existing MRLs in apple and barley, the need for the setting of MRLs was not further investigated in the framework of this application. Nevertheless, EFSA strongly recommends the setting of the MRLs in food of animal origin because the calculated dietary burdens exceeded the trigger value of 0.1 mg/kg DM for all livestock species.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo, using the MRLs as established in Annex II and Annex III of Regulation (EC) 396/2005 as well as the STMR values derived for the intended use on celery, blueberries, head cabbage, Brussels sprouts, lettuce, scarole (broad-leaf endive) and herbs, multiplied by conversion factors for risk assessment. The chronic dietary intake calculations did not identify consumer intake concerns for any European diet. The intake values ranged from 2 to 23% of the ADI. Acute risk assessment was not performed as no ARfD value was established. EFSA concludes that the intended uses of trifloxystrobin on celery, blueberries, head cabbage, Brussels sprouts, lettuce, scarole (broad-leaf endive) and herbs 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
Blueberries	0.02*	2	The MRL proposals are fully supported by data and no risk for consumers was identified for the intended uses.
Head cabbage	0.02*	0.3	
Brussels sprouts	0.02*	0.5	
Lettuce, scarole (broad-leaf endive), herbs	0.02*	10	
Celery	0.02*	0.3	

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

Regarding the risk assessment of current MRLs for trifloxystrobin, they will be subject to a full risk assessment according to Article 12 (2) of Regulation (EC) No 396/2005.

Key words: Trifloxystrobin, blueberry, celery, head cabbage, lettuce, scarole (broad-leaf endive), parsley, Brussels sprouts, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurin class of 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 a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

The Netherlands, hereafter referred to as the Evaluating Member State (EMS), received an application from the Bayer CropScience B.V.[2] to modify the existing MRLs for trifloxystrobin in celery, blueberries, head cabbage, Brussels sprouts, lettuce, scarole (broad-leaf endive) and herbs. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission, who forwarded the application, the evaluation report and the supporting dossier to EFSA on 14 January 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00222 and the following subject:

Trifloxystrobin - Application to modify the existing MRLs for cga 279202 (parent ee isomer) in celery from 0.02 mg/kg to 0.3 mg/kg, in blueberries from 0.02* mg/kg to 2 mg/kg, in head cabbage from 0.02* mg/kg to 0.3 mg/kg, in lettuce from 0.02* mg/kg to 10 mg/kg, in scarole (broad-leaf scarole (broad-leaf endive)) from 0.02* mg/kg to 10 mg/kg, in Brussels sprouts from 0.02*mg/kg to 0.5 mg/kg and in herbs from 0.02* mg/kg to 10 mg/kg*

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

On 11 March 2009 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, addressing those data requirements, was submitted by the EMS on 18 March 2009 and taken into consideration by EFSA for finalization of this reasoned opinion.

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.

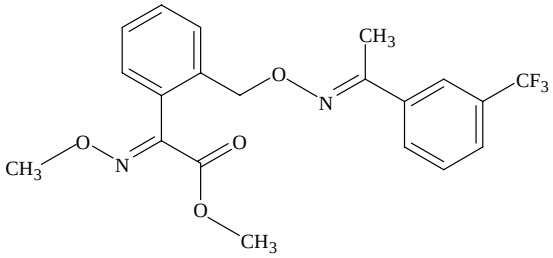
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 21 April 2009.

[2] Bayer CropScience B.V., Energieweg 1, 3641 RT, Mijdrecht, The Netherlands

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)ethylideneaminooxyl]-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: *Ascomycete*s, *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 under glass or plastic.

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 11 July 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 use as a fungicide only. Trifloxystrobin has not been peer reviewed by EFSA.

The current MRLs for trifloxystrobin are set in the Annexes II and III to Regulation (EC) No 396/2005. The MRLs established under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC have been transferred to Annex II to Regulation (EC) No 396/2005. In Annex III temporary MRLs have been established for crops that were not covered by previous Community MRL legislation. The current EC MRL for trifloxystrobin in all the crops under consideration is set at the LOQ of 0.02 mg/kg.

The applicant has requested an authorization for the indoor and/or outdoor uses of trifloxystrobin on celery, blueberry, head cabbage, Brussels sprouts, scarole (broad-leaf endive), lettuce and herbs. The applicant has submitted multiple GAPs where application rates vary from 2-3 x 0.125 -0.2 kg a.s./ha. The minimum waiting periods range from 7 to 14 days. The summary of proposed GAPs is 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[3] 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 HLPC-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 321113are 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 in the framework of the as the uses supported in the framework of this application are not expected to affect significantly 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

[3] (E, E)-methoxyimino- {2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-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

The metabolism studies of trifloxystrobin in plants are reported in the DAR (The United Kingdom, 2000) for 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

Metabolism studies were performed with ^{14}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). The main component of the radioactivity in fruits and fruiting crops was parent trifloxystrobin (E/E isomer). In wheat, trifloxystrobin was extensively metabolised. Parent compound and its isomers represented minor fraction of the TRR, while metabolites I_{10} (Z/Z isomer) and I_{12} (E/Z isomer) and their sugar conjugates accounted for in total up to 23.7% TRR (forage), 9% TRR (grain) and 10.7% TRR (straw). In wheat up to 47% (grain) and 46% (straw) remained unextracted. In the peer review it was concluded that metabolism in fruits and fruiting vegetables and cereals proceeds according to similar pattern and residues in these crop groups should be defined as parent trifloxystrobin only. The toxicity of metabolite CGA321113 was investigated in the peer review and it was concluded that it is lower than for parent trifloxystrobin.

Since two crop groups were insufficient to propose a general residue definition for all commodities of plant origin, the EMS submitted an additional metabolism study on sugar beets (application at 0.39 kg a.s./ha for qualitative distribution and 1.17 kg a.s./ha for quantitative distribution), representing the group of root and tuber vegetables. In sugar beets two metabolites CGA 321113 and II_{19a}[4] were encountered at levels exceeding the trigger value of 10% in roots 0, 21 and 45 DAT. II_{19a} 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.

From the available data it can be concluded that at the proposed application rates which are higher than in the metabolism study, metabolite CGA 321113 is expected to occur in several primary crops. This is confirmed by data from submitted supervised residues field trials where in some commodities (Brussels sprouts, head cabbage) the metabolite CGA 321113 was present in amounts exceeding the levels of parent trifloxystrobin. 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. For the crops under consideration EFSA derived conversion factors for risk assessment from submitted residues

[4] {2-[1-(2,3-dihydroxy-5-methyl-phenyl)-2-hydroxy-ethylideneamino-oxymethyl]-phenyl}-methoxy-imino –acetic acid

field trials and applied them in the consumer intake calculations. For all other plant commodities the need for a new residue definition for risk assessment might be reconsidered when performing full risk assessment of trifloxystrobin under Article 12(2) of Regulation (EC) No 396/2005.

3.1.1.2. Magnitude of residues

In support of the proposed GAPs the applicant submitted several supervised trials on celery, black currants (for extrapolation to blueberries), head cabbage, Brussels sprouts, lettuce (for extrapolation to herbs) and scarole (broad-leaf endive). A sufficient number of trials was submitted to propose MRLs for the crops under consideration. All trials have been designed as residue decline studies. In addition, the applicant provided data on the levels of metabolite CGA 321113 in all crops under consideration. EFSA used these data and obtained the conversion factors for the risk assessment purposes, taking into account the amounts of metabolite CGA 321113 in several crops. Residues trials data are summarized in Table 3-1.

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 analytical methods applied for analysing supervised residue field trial samples are sufficiently validated and fit for purpose.

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	Risk assessment					
Celery	NEU	Outdoor	0.04; 0.06; 0.10; 0.17	0.05; 0.08; 0.13; 0.22	0.08	0.17	0.3	1.30	R_{ber}=0.31 mg/kg R_{max}=0.39 mg/kg
Blueberry	NEU	Outdoor	0.43; 0.76; 0.8; 1.1	0.43; 0.76; 0.8; 1.1	0.63	1.1	2.00	1.00	Studies were performed on blackcurrant, but can be extrapolated to blueberries. R_{ber}=2.05 mg/kg R_{max}= 2.18mg/kg
Head cabbage	NEU	Outdoor	<0.01; 0.01; 0.02; 2 x 0.03; 0.06; 0.16; 0.18	0.02; 0.03; 0.04; 2 x 0.05; 0.1; 0.21; 0.2	0.03	0.18	0.3	1.7	R_{ber}=0.27 mg/kg R_{max}=0.28 mg/kg
Brussels sprouts	NEU	Outdoor	0.02; 2 x 0.06; 0.07; 0.13; 0.14; 0.24; 0.35	0.04; 0.15; 0.095; 0.15; 0.16; 0.21; 0.26; 0.45	0.10	0.35	0.5	1.30	R_{ber}= 0.43 mg/kg R_{max}=0.49 mg/kg
Lettuce, scarole (broad-leaf endive), herbs	EU	Indoor	2.4; 2.5; 2.7; 5.4; 5.6; 5.7; 6.6; 7.2	2.4; 2.7; 2.7; 5.4; 5.65; 5.8; 6.7; 7.2	**5.5**	**7.2**	**10**	**1.00**	MRL proposal and risk assessment values are based on the indoor use on lettuce, considering that it is the most critical (indicated in bold). The extrapolation from lettuce to endives and herbs is possible, since GAPs are similar. $R_{ber\ indoor}$= 12.75 mg/kg $R_{max\ indoor}$= 10.94 mg/kg $R_{ber\ outdoor}$=2.45 mg/kg $R_{max\ outdoor}$= 2.2 mg/kg
	NEU	Outdoor	0.43; 0.61; 0.79; 1.1; 1.2; 1.3	0.46; 0.63; 0.85; 1.12; 1.2; 1.3	0.95	1.3	2.00	1.00	

(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

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 leafy crops under consideration can be grown in rotation. According to the soil degradation studies performed in the framework of the peer review the DT_{90} 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_{90} value of more than 500 days and CGA 373466[5] with the highest DT_{90} value of 290 days (The United Kingdom, 2000). In this case further investigation of behaviour in rotational crops is relevant.

3.1.2.2. Nature of residues

Rotational crop studies were performed by applying ^{14}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 (in 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.

[5] (Z, E)-methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid

3.1.2.3. Magnitude of residues

Considering that application rates with regard to current application are lower or only slightly higher (0.6 kg a.s./ha) than in rotational crop studies 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 GAP.

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), head cabbage is a potential feed item for chicken, dairy ruminants, meat ruminants and pig.

The dietary burden for different types of livestock was calculated using the EFSA livestock dietary burden calculator. For head cabbage the input values were multiplied by the conversion factor of 1.7 for risk assessment as obtained from submitted supervised residues field trials (Table 3-1). 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				
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)

The results of the calculations are reported in Table 3-3 and Table 3-4. In order to estimate the contribution of head cabbage to the total livestock dietary burden, EFSA first performed

dietary burden calculations for all commodities including head cabbage (Table 3-3) and compared them to the second dietary burden calculation, which was performed excluding head cabbage (Table 3-4). 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 head cabbage does not have a critical impact on the dietary burden, the need for the setting of MRLs was not further investigated in the framework of this application. Nevertheless, EFSA strongly recommends the setting of MRLs for trifloxystrobin in food of animal origin, as a significant intake of residues by livestock was identified.

It should be noted that trifloxystrobin will undergo full risk assessment according to Article 12(2) of Regulation (EC) No 396/2005.

Table 3-3. **Results of the dietary burden calculation (including head cabbage)**

	Maximum dietary burden (mg/kg bw/d)	**Median dietary burden (mg/kg bw/d)**	**Highest contributing commodity**	**Dietary burden triggered?**
Risk assessment residue definition: sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin				
Dairy ruminants	0.05243	0.03067	Apple pomace	Yes
Meat ruminants	0.13042	0.09006	Apple pomace	Yes
Poultry	0.02233	0.01657	Barley grain	Yes
Pigs	0.02427	0.01366	Barley grain	Yes

Table 3-4. **Results of the dietary burden calculation (excluding head cabbage)**

	Maximum dietary burden (mg/kg bw/d)	**Median dietary burden (mg/kg bw/d)**	**Highest contributing commodity**	**Dietary burden triggered?**
Risk assessment residue definition: sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin				
Dairy ruminants	0.04437	0.03067	Apple pomace	Yes
Meat ruminants	0.13042	0.09006	Apple pomace	Yes
Poultry	0.01542	0.01542	Barley grain	Yes
Pigs	0.01859	0.01366	Barley grain	Yes

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model), using the MRLs as established in Annex II and Annex III of Regulation (EC) 396/2005 as well as the STMR values multiplied by conversion factor for risk assessment as derived for the intended use on celery, blueberries, head cabbage, Brussels sprouts and lettuce, scarole (broad-leaf endive) and herbs. 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. No acute risk assessment was undertaken since no ARfD value has been established. Input values are summarized in Table 4-1.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition for risk assessment: Sum of trifloxystrobin and its metabolite CGA 321113, expressed as trifloxystrobin				
Celery	0.10	STMR*CF (1.30)	The acute risk assessment was not undertaken since ARfD value is not established and is not considered necessary.	
Blueberry	0.63	STMR* CF(1.00)		
Head cabbage	0.05	STMR*CF (1.70)		
Brussels sprouts	0.13	STMR*CF (1.30)		
Lettuce, scarole (broad-leaf endive), herbs	5.5	STMR* CF (1.00)		

The summary of the intake calculation 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. From all the crops under consideration, the highest contribution to dietary intake was for lettuce amounting up to 3% of the ADI for ES adult diet.

In the consumer intake calculations EFSA did not consider the conversion factors for other plant commodities since no data are available. Regarding the risk assessment of the existing MRLs for trifloxystrobin, they will be subject to a full risk assessment according to Article 12 (2) of Regulation (EC) No 396/2005.

EFSA concludes that the intended uses of trifloxystrobin on blueberries, head cabbage, Brussels sprouts, lettuce, scarole (broad-leaf endive) and herbs are acceptable with regard to consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

The Netherlands received an application from Bayer CropScience B.V. to modify the existing MRLs for trifloxystrobin in blueberries, head cabbage, Brussels sprouts, lettuce, scarole (broad-leaf endive), herbs and celery. In order to accommodate the new use of trifloxystrobin on these crops, the applicant proposes to raise the existing MRLs. The Netherlands as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 14 January 2009.

EFSA derives the following conclusions regarding the application, based on the 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 evaluated in the framework of the peer review in two crop categories - fruits and fruiting vegetables and cereals - and the residue definition for enforcement and risk assessment for these crop categories was proposed as parent trifloxystrobin only. Since two crop groups were insufficient to address the metabolism of trifloxystrobin in the crops under consideration, the EMS submitted an additional metabolism study on sugar beets. During the assessment EFSA came to the conclusion that the residue definition for risk assessment in the crops under consideration should also include the metabolite (E,E) – methoxyimino -{2 - [1-(3-trifluoromethyl-phenyl) – ethylideneamino - oxymethyl] -phenyl}-acetic acid (CGA 321113). This is confirmed by data from submitted supervised residues field trials where in some commodities (Brussels sprouts, head cabbage) the metabolite was present in higher amounts than parent trifloxystrobin. 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. For the crops under consideration EFSA derived conversion factors for risk assessment and applied them in the consumer intake calculations. For all other plant commodities the need for a new residue definition for risk assessment might be reconsidered when performing full risk assessment of trifloxystrobin under Article 12(2) of Regulation (EC) No 396/2005.

Submitted supervised residues field trials indicate that the current MRLs of 0.02 mg/kg for all the crops under consideration do not accommodate the intended GAP in The Netherlands and higher MRLs are proposed (see table below). Adequate analytical methods are available to enforce the proposed MRLs. The 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. Since the dietary burden was mainly driven by the existing MRLs in apple and barley, the need for the setting of MRLs was not further investigated in the framework of this application. Nevertheless, EFSA strongly recommends the setting of the MRLs in food of animal origin because the calculated dietary burdens exceeded the trigger value of 0.1 mg/kg DM for all livestock species.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo, using the MRLs as established in Annex II and Annex III of Regulation (EC) 396/2005 as well as the STMR values derived for the intended use on celery, blueberries, head cabbage, Brussels sprouts, lettuce, scarole (broad-leaf endive) and herbs, multiplied by conversion factors for risk assessment. The chronic dietary intake calculations did not identify consumer intake concerns for any European diet. The intake values ranged from 2 to 23% of the ADI. Acute risk assessment was not performed as no ARfD value was established. EFSA concludes that the intended uses of trifloxystrobin on celery, blueberries, head cabbage, Brussels sprouts, lettuce, scarole (broad-leaf endive) and herbs 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
Blueberries	0.02*	2	The MRL proposals are fully supported by data and no risk for consumers was identified for the intended uses.
Head cabbage	0.02*	0.3	
Brussels sprouts	0.02*	0.5	
Lettuce, scarole (broad-leaf endive), herbs	0.02*	10	
Celery	0.02*	0.3	

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

Regarding the risk assessment of current MRLs for trifloxystrobin, they will be subject to a full risk assessment according to Article 12 (2) of Regulation (EC) No 396/2005.

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRL for trifloxystrobin in several crops under Regulation (EC) No 396/2005. May 2008. Revision February and March 2009. Prepared by the Ctgb, The Netherlands.

REFERENCES

European Commission, 2003. Review report for the active substance trifloxystrobin. April, 2003.

Spain, 2003. Proposal of MRL in peaches and sugar beet. Part D: new a.s.-Post Annex I inclusion. June, 2003.

The United Kingdom, 2003. MRL proposals for trifloxystrobin. June, 2003.

The United Kingdom, 2000. Draft Assessment Report on trifloxystrobin prepared by the PSD under Directive 91/414/EEC. April 2000.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and/or situation (a)	F or G (b)	Pest or group of pests controlled (c)	Formulation		Application		Application rate per treatment				PHI (days) (k)	Remarks (l)
			Type (d-f)	Conc. of a.i. (i)	method, kind (f-h)	growth stage (j)	number (range)	kg. a.i./ha	Water l/ha	kg a.i./hL.		
Head cabbage	F	*Albugo cadida*	WG	500g/kg	Foliar spraying	41-79	3	0.2	200-800	0.025-0.1	14	Interval 14d
Brussels Sprouts	F	*Albugo cadida*	WG	500g/kg	Foliar spraying	41-79	3	0.2	200-800	0.025-0.1	14	Interval 14d
Bleached celery	F	*Septoria spp.*	WG	500g/kg	Foliar spraying	At occurrence	3	0.125	200-600	0.021-0.063	14	Interval 14d
Lettuce	G	*Botrytis, Sclerotinia*	WG	500g/kg	Foliar spraying	19 - 49	2-3	0.2	200-800	0.025-0.1	7	Interval 7d
Scarole (broad-leaf endive)	F	*Botrytis, Sclerotinia*	WG	500g/kg	Foliar spraying	19 - 49	2	0.2	200-800	0.025-0.1	7	Interval 7d
Blueberries	F	*Anthracnose / Botrytis*	WG	500g/kg	Foliar spraying	19 - 91	3	0.2	1000-1200	0.0167-0.02	7	Interval 7d
Herbs	G / F	*Downey mildew*	WG	500g/kg	Foliar spraying	20 - 49	3	0.2	200-800	0.025-0.1	7	Interval 7d

(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
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*
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 (mediteranean medlar)	0,02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), 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, Brazilean 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*
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*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
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*
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
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*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,02*
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
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*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,02*
251040	Cress	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket)	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	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, glassworth)	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*
256010	Chervil	0,02*
256020	Chives	0,02*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,02*
256040	Parsley	0,02*
256050	Sage (Winter savory, summer savory,)	0,02*
256060	Rosemary	0,02*
256070	Thyme (marjoram, oregano)	0,02*
256080	Basil (Balm leaves, mint, peppermint)	0,02*
256090	Bay leaves (laurel)	0,02*
256100	Tarragon (Hyssop)	0,02*
256990	Others	0,02*
260000	(vi) Legume vegetables (fresh)	
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*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin
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*
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*
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 Camellia sinensis)	0,05
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*

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

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

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

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Trifloxystrobin

Status of the active substance:	**Inlcuded**	Code no.	**#N/A**
LOQ (mg/kg bw):		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:	**COM**
Year of evaluation:	**2003**	Year of evaluation:	**2003**

Input values for chronic RA: blueberry - STMR 0.63 mg/kg, head cabbage - 0.05mg/kg (STMR*CF of 1.7); Brussels sprouts - 0.13 mg/kg (STMR*CF of 1.30), celery- 0.10 mg/kg (STMR * CF of 1.30) lettuce, endives, herbs - 5.5 mg/kg (STMR), celery - 0.10 mg/kg (

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
2 23

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)
22.7	FR all population	20.0	Wine grapes	0.5	Table grapes	0.5	Lettuce	
18.5	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	
16.2	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	
6.8	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	
5.5	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 pTMRLs 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
Ctgb	Board for the Authorisation of Plant Protection Products and Biocides
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/EEC)
DAT	days after treatment
DT_{90}	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
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WHO	World Health Organisation