

REASONED OPINION OF EFSA

Modification of the existing MRLs for spirotetramat in various fruit crops¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-720)

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SUMMARY

According to Article 6(2) of Regulation (EC) No 396/2005, Austria received an application from the company Bayer CropScience to modify the existing MRLs of spirotetramat in several fruit crops. In particular, these modifications were requested in order to allow for import of fruits treated according to authorized uses in the USA and Canada. The subsequent evaluation report drafted by Austria was forwarded to EFSA on 02 September 2008 according to Article 9 of the Regulation. On 20 November 2008 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 on 19 February 2009.

Based on the evaluation report and the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) Austria under Directive 91/414/EEC, EFSA derives the following conclusions regarding the application. As the DAR has not yet been peer reviewed by EFSA, conclusions reached in this reasoned opinion are temporary and might be reconsidered after finalization of the peer review.

Metabolism of spirotetramat was investigated by foliar applications in cotton, lettuce, potatoes and apples. Three different crop groups are covered by the available studies and the relevant residue for enforcement and risk assessment in all plant commodities was defined by the RMS as the sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat. An analytical method for enforcement of this residue definition in the fruit crops under evaluation is also available.

A sufficient number of supervised residues trials supporting the reported GAPs for spirotetramat is available. These trials allow estimating the expected residue concentrations in the relevant plant commodities and deriving appropriate MRLs.

The effect of industrial and household processing on the nature of residues was investigated. As the processing of fruits usually doesn't involve sterilization, it was concluded that processing of fruits is not expected to affect the nature of residues in the processed

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commodities. Studies on the magnitude of residues in a large number of processed commodities were submitted as well, but not considered sufficient to propose robust processing factors in most of the cases. Only the following processing factor for enforcement of the sum of spirotetramat and its 4 metabolites, expressed as spirotetramat, can be recommended:

- Grapefruit, juice: 0.4
- Oranges, juice: 0.4
- Lemons, juice: 0.4
- Limes, juice: 0.4
- Mandarins, juice: 0.4

The possible occurrence of spirotetramat residues in rotational crops was not investigated. As the GAPs supported in the framework of this application are authorized outside the EC, possible occurrence of residues in rotational crops is not considered relevant to the European consumer exposure.

The livestock dietary burden for livestock was calculated considering both the existing and the new proposed MRLs for spirotetramat. Occurrence of residues in foods of animal origin was not further investigated in the framework of this application as the dietary burden was mainly driven by the existing MRL in kale. Nevertheless, EFSA strongly recommends the setting of MRLs in products of animal origin because the calculated burdens exceeded the trigger value of 0.1 mg/kg DM for all livestock species.

Finally, chronic and acute intake calculations considering the new proposed MRLs were performed with revision 2 of the EFSA PRIMo. For the chronic intake calculations, all the existing MRLs for the active substance were considered as well. As no intake concerns were identified for all available European diets, the proposed MRLs are not expected to pose any risk to the European consumer.

The recommendations resulting from the assessment are summarized in the table below. These recommendations should be considered for inclusion in Annex III of the Regulation as the peer review of the active substance under Directive 91/414/EEC is not yet finalized.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<u>Residue definition for risk assessment:</u> sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-mono-hydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat			
Grapefruit	0.1*	1	MRL proposals are fully supported by data but should be considered as provisional as the peer review of the active substance under Directive 91/414/EEC is not yet finalised. A risk to consumers was not identified.
Oranges	0.1*	1	
Lemons	0.1*	1	
Limes	0.1*	1	
Mandarins	0.1*	1	
Apples	0.1*	1	
Pears	0.1*	1	
Apricots	0.1*	2	

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Peaches	0.1*	2	
Table grapes	0.1*	2	
Wine grapes	0.1*	2	

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

Key words: spirotetramat, various fruit crops, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, tetramic acid insecticides, BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy, BYI 03380-enol-glucoside

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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 any party having a legitimate commercial interest may submit to the Rapporteur Member State (RMS) designated pursuant to Directive 91/414/EEC an application to set an import tolerance in accordance with the provisions of Article 7 of that regulation.

Austria, as the RMS for spirotetramat, received from the company Bayer Cropscience² an application to modify the existing MRLs for the active substance spirotetramat in various fruit crops. This application was notified to the European Commission and EFSA and subsequently evaluated by the RMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the RMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 02 September 2008. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2008-720 and the following subject:

Spirotetramat - Application to modify the existing MRLs for spirotetramat and the metabolites byi 08330-enol, byi 08330-ketohydroxy, byi08330-enol-glc, and byi 08330-mono-hydroxy in lemons from 0.1 to 1 mg/kg, in oranges from 0.1* to 1 mg/kg, in mandarins from 0.1* to 1 mg/kg, in grapefruit from 0.1* to 1 mg/kg, in apples from 0.1* to 1 mg/kg, in pears from 0.1* to 1 mg/kg, in apricots from 0.1* to 2 mg/kg, in peaches from 0.1* to 2 mg/kg, in table grapes from 0.1* to 2 mg/kg and in wine grapes from 0.1* to 2 mg/kg.*

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

On 20 November 2008 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 RMS on 19 February 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 Rapporteur Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

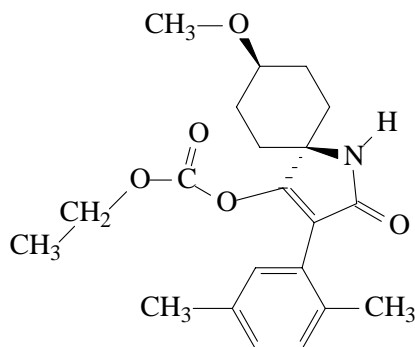
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 01 March 2009.

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THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Spirotetramat is the ISO common name for cis-4-(ethoxycarbonyloxy)-8-methoxy-3-(2,5-xylyl)-1-azaspiro[4.5]dec-3-en-2-one (IUPAC).



Spirotetramat belongs to the class of tetramic acid insecticides. The active substance is systemic and requires oral ingestion or feeding from the plants by the insect. It then acts on acetyl CoA carboxylase inhibiting the lipid biosynthesis.

Spirotetramat is evaluated in the framework of Directive 91/414/EEC as a new active substance with Austria being the designated Rapporteur Member State (RMS) and a Draft Assessment Report (DAR) resulting from the OECD Joint Review Project between Canada, USA and Austria was submitted. The representative uses evaluated in the DAR are foliar applications on citrus and lettuce but the peer review of this DAR by EFSA is not yet finalised. A decision on the inclusion of the active substance in Annex I to the Directive has therefore not yet been taken.

Although representative uses in the framework of Directive 91/414/EEC are only for citrus fruits and lettuce, the use of spirotetramat is intended for a broad range of crops. Provisional authorisations for spirotetramat in several vegetable crops have already been issued by Member States and temporary EC MRLs accommodating for these provisional authorisations have been set by Regulation (EC) No 839/2008, which entered into force on 01 September 2008 (Appendix B). The setting of CXLs for spirotetramat is currently under discussion but not yet finalised (FAO/WHO, 2009).

The RMS Austria now reported GAPs which are authorized in the USA and in Canada and which require the setting of import tolerances. A detailed overview of the GAPs is available in Appendix A. It concerns foliar outdoor applications in citrus fruits, pome fruits, stone fruits and grapes which are performed close to the harvest. It should be noted that during the evaluation process application rates have been modified which resulted in application rates matching the available data. EFSA is however not in the position to judge whether these application rates are actually authorized in the USA or in Canada.

In support of the MRL application, Austria submitted an evaluation report. As some issues were not fully addressed in the evaluation report, EFSA also relied on the DAR prepared by Austria under Directive 91/414/EEC. Awaiting the peer review of this DAR to be finalized, conclusions reached in this reasoned opinion are temporary and might be reconsidered after finalization of the peer review.

ASSESSMENT

1. Methods of analysis

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

An analytical method was evaluated in the DAR prepared by Austria in the framework of Directive 91/414/EEC (Austria, 2008). The analytical method reported is based on the LC-ESI-MS/MS principle and is able to analyse for spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside. The method has been validated for commodities with a high water content (tomatoes, potatoes), high acid content (citrus) and high oil content (avocados) with a LOQ of 0.01 mg/kg for each analyte. In hops the analytical method was validated with a LOQ of 0.1 mg/kg for each analyte. The commodities evaluated in the framework of this application are covered by the available data as they belong to the group of commodities with high water and high acid content.

It is noted that an independent laboratory validation was not provided for the analytical method reported but Regulation (EC) No 396/2005 lays down temporary EC MRLs for the sum of spirotetramat and its 4 metabolites in all plant commodities, which have been accepted by Member States. It is therefore assumed that Member States have the analytical capacity to enforce spirotetramat and its 4 metabolites in all plant commodities.

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 affect the dietary burden of livestock to spirotetramat residues (see section 3.2).

2. Mammalian toxicology

The toxicological properties of spirotetramat have been evaluated in the DAR prepared under Directive 91/414/EEC (Austria, 2008) and reference values have been derived. These reference values are summarized in Table 2-1. It is noted that a lower ARfD of 0.1 mg/kg bw/d has been used by EFSA for the assessment of the temporary EC MRL (EFSA, 2008). The ARfD of 1 mg/kg, however, results from a more recent assessment and it was also confirmed by the 2008 JMPR.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Spirotetramat					
ADI	DAR	2008	0.05	1 year dog study	100
ARfD	DAR	2008	1	acute rat neurotoxicity study	100

3. Residues

3.1. Nature and magnitude of residues in plant

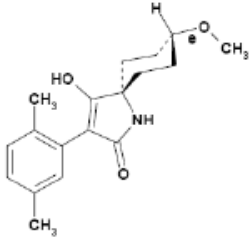
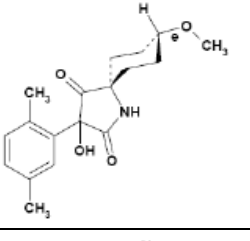
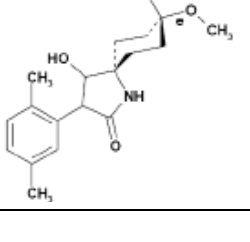
3.1.1. Primary crops

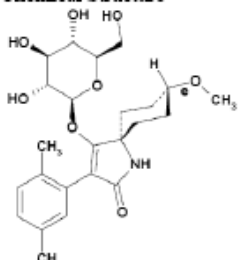
3.1.1.1. Nature of residues

Plant metabolism for spirotetramat was investigated in apples, potatoes, lettuce and cotton and a detailed evaluation of the studies is provided in the DAR (Austria, 2008). According to the RMS, metabolism in the different crop groups was found to be similar and nature of residues in plant commodities is adequately understood. Overall, a high level of identification was obtained with the major part of the residue being composed of spirotetramat, BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside. Other metabolites were identified but not further considered because they were present in lower amounts.

These findings are also in accordance with the temporary residue definition that has been established for spirotetramat in all plant commodities by Regulation (EC) No 839/2008. Awaiting the finalisation of the peer review of the DAR, it is therefore proposed to temporarily define the residue definition for enforcement and risk assessment in all plant commodities as *the sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat*.

Table 3-1. Overview of the metabolites identified in the primary crops

Metabolite	CAS Name	Chemical structure
BYI 03380-enol	<i>cis</i> -3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one	
BYI 03380-ketohydroxy	<i>cis</i> -3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione	
BYI 03380-monohydroxy	<i>cis</i> -3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-Dglucopyranoside	

Metabolite	CAS Name	Chemical structure
BYI 03380-enol-glucoside	<i>cis</i> -3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one	

3.1.1.2. Magnitude of residues

The RMS reported a large set of residues trials supporting the GAPs authorized for the different fruit crops in the USA and Canada. This dataset includes residues trials performed with both SC and OD formulations. As the results obtained with SC formulations were generally lower than results obtained with the OD formulations, mainly the trials using the OD formulations were selected for assessment. The results of these residues trials, as reported by the RMS, are summarized in Table 3-2.

Regarding the available data on citrus fruits, it is noted that according to the European extrapolation guidelines 8 additional trials on mandarins would be required. Considering however that a large dataset covering smaller and larger citrus species is available, additional data are not required.

Storage stability of total spirotetramat residues, including the 4 metabolites, was demonstrated for a period of 15 months at -18°C in commodities with high water content (tomatoes, potatoes, lettuce, French beans and tomato paste) and high oil content (almond nutmeat). For commodities with high acid content (orange juice and prunes) storage stability was only demonstrated for a period of 5 months due to the limit time period defined in the study design. Nevertheless, considering the overall availability of storage stability data and the fact that tomatoes are on the borderline between high acid and high water content, total spirotetramat residues are also considered stable for a period of 15 months in commodities with high acid content. As all the residues trial samples, including commodities with high water and high acid content, were stored in accordance with these conditions, degradation of residues during storage of the trial samples is not expected.

It is concluded that the available residues data are sufficient to derive MRL proposals and risk assessment values for all commodities under evaluation (see also Table 3-2). It is noted that the RMS proposed separate STMR and HR values for apples and pears but EFSA is of the opinion that, as for the MRL, these values should be derived from the combined dataset.

It should also be noted that during the evaluation process application rates have been modified which resulted in application rates matching the available residues trials. EFSA is however not in the position to judge whether these application rates are actually authorized in the USA or in Canada.

Table 3-2. 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					
<i>Residue definition for enforcement and risk assessment: sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat</i>									
Grapefruit Oranges Lemons Limes Mandarins	Import (US)	Outdoor	<0.25; <0.25; <0.25; 0.32; 0.34; 0.34; 0.35; 0.38; 0.42; 0.43; 0.28; 0.33; 0.34; 0.36; 0.47; <0.25; <0.25; <0.25; <0.25; 0.26; 0.35	<0.25; <0.25; <0.25; 0.32; 0.34; 0.34; 0.35; 0.38; 0.42; 0.43; 0.28; 0.33; 0.34; 0.36; 0.47; <0.25; <0.25; <0.25; <0.25; 0.26; 0.35	0.33	0.47	1	1.0	Combined dataset available on oranges (10), lemons (5) and grapefruit (6), which can be used for all citrus types. R _{max} = 0.480 R _{ber} = 0.700
Apples Pears	Import (US, CA)	Outdoor	0.07; 0.07; 0.08; 0.12; 0.13; 0.14; 0.17; 0.18; 0.18; 0.34; 0.37; 0.38; 0.11; 0.12; 0.21; 0.22; 0.37; 0.41	0.07; 0.07; 0.08; 0.12; 0.13; 0.14; 0.17; 0.18; 0.18; 0.34; 0.37; 0.38; 0.11; 0.12; 0.21; 0.22; 0.37; 0.41	0.18	0.41	1	1.0	Combined dataset on apples (12) and pears (6). R _{max} = 0.491 R _{ber} = 0.620
Apricots Peaches	Import (US, CA)	Outdoor	0.53; 0.56; 0.69; 0.69; 0.70; 0.77; 0.77; 0.81; 0.82; 1.23	0.53; 0.56; 0.69; 0.69; 0.70; 0.77; 0.77; 0.81; 0.82; 1.23	0.74	1.23	2	1.0	Dataset available on peaches, which can be extrapolated to apricots. R _{max} = 1.317 R _{ber} = 1.600
Table grapes Wine grapes	Import (US, CA)	Outdoor	0.11; 0.24; 0.26; 0.32; 0.40; 0.42; 0.48; 0.49; 0.65; 0.79; 0.84; 1.29	0.11; 0.24; 0.26; 0.32; 0.40; 0.42; 0.48; 0.49; 0.65; 0.79; 0.84; 1.29	0.45	1.29	2	1.0	R _{max} = 1.415 R _{ber} = 1.370

(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.

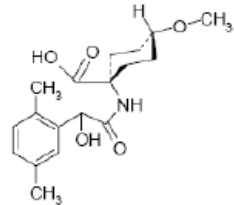
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

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

3.1.1.3. Effect of industrial processing and/or household preparation

Studies investigating the effect of processing on the nature of residues and simulating hydrolytic conditions during pasteurization, baking/brewing and sterilization, are reported in the DAR (Austria, 2008). Although hydrolysis of both spirotetramat and BYI 03380-enol-glucoside to BYI 03380-enol was observed, the total spirotetramat residue can be considered as stable when subject to conditions for pasteurization (20 min at 90°C, pH 4) or baking/brewing (60 min at 100° C, pH 5). Under these conditions only minor amounts of a new metabolite, BYI 03380-MA-amide, were identified. Under sterilization conditions (20 min at 120°C, pH 6) BYI 03380-ketohydroxy was completely hydrolyzed to BYI 03380-MA-amide and inclusion of this metabolite in the residue definition for processed commodities should be considered. However, processed commodities obtained from the fruit crops under evaluation for this application are usually not subject to sterilization conditions. The same residue definition as for the raw agricultural commodities can therefore be applied. This conclusion should be revised if crops subject to sterilization practices are supported in the future.

Table 3-3. Overview of the metabolite identified in the hydrolysis study

Metabolite	CAS Name	Chemical structure
BYI 03380-MA-amide	1-[[[(2,5-dimethylphenyl)(hydroxy)acetyl]amino]-4-methoxycyclohexanecarboxylic acid	

Regarding the magnitude of residues a large number of processing studies was reported by the RMS (Austria, 2009) and are summarized in Table 3-4. From the available studies, processing factors of 1.27 and 1.9 are derived for citrus and apple pomace, respectively. Although these factors are based on 1 trial only, these factors can be used for the calculation of the dietary burden of livestock, rather than the default processing factor of 2.5. Some studies also investigated the effect of washing for several fruit crops but are not included in Table 3-4 as washing is not considered to be relevant, neither for enforcement, nor for risk assessment.

For enforcement purposes, it is only possible to recommend a processing factor for citrus juice because 3 different trials are available (2 in oranges and 1 in lemons). For the remaining processed commodities there are not enough trials to recommend robust processing factors for enforcement.

Table 3-4. Overview of the available processing studies

Processed commodity	Number of studies	Median PF ^(a)	Median CF ^(b)	Comments
<u>Residue definition for enforcement and risk assessment: sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat</u>				
Citrus, juice	3	0.40	1.0	Recommended for enforcement Proposed processing factors cannot be recommended for enforcement purposes as only 1 or 2 studies are available for each type of processing.
Citrus, dry pomace	2	1.27	1.0	
Citrus, peeled	2	0.60	1.0	
Citrus, peel	1	1.00	1.0	
Citrus, oil	2	13.5	1.0	
Apples, peeled	1	0.20	1.0	
Apples, juice	1	0.40	1.0	
Apples, wet pomace	1	1.90	1.0	
Apples, sauce	1	0.10	1.0	
Apples, dried	1	1.00	1.0	
Plums, dried (prunes)	1	2.20	1.0	
Cherries, cooked	1	1.00	1.0	
Peaches, juice	1	0.40	1.0	
Peaches, cooked	1	0.20	1.0	
Peaches, dried	1	2.90	1.0	
Grapes, juice	1	0.66	1.0	
Grapes, raisins	1	2.61	1.0	
Grapes, jelly	1	0.28	1.0	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

3.1.2. Rotational crops

As the GAPs supported in the framework of this application are authorized outside the EC, possible occurrence of residues in rotational crops is not considered relevant for the European consumer exposure.

3.2. Nature and magnitude of residues in livestock

From all the crops supported in the framework of this application only apples and citrus fruits might be fed to livestock. In particular, the pomaces resulting from the juice production are commonly used as feed items. The dietary burden for the different types of livestock was therefore calculated using the EFSA livestock dietary burden calculator.

As fruit pomaces are processed commodities, the STMR values derived in Table 3-2 were multiplied by the processing factors derived in Table 3-4, both for the calculation of the median and the maximum dietary burden. It is noted that for citrus pomace the processing factor was derived for dry pomace while dietary burden is calculated from the wet pomace consumption. This approach is expected to overestimate the real situation but is also considered to be more realistic than the default processing factor of 2.5. For the remaining commodities that might be used as feed items, no data were available to EFSA. Therefore the MRL was used when it was higher than the LOQ. A summary of the input values is available in Table 3-5.

The results of the calculations are reported in Table 3-6. The calculated dietary burdens exceed the trigger value of 0.1 mg/kg DM for all relevant livestock species and are mainly driven by the existing MRL for kale. As the supported uses have a very small 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 spirotetramat in food of animal origin, as a significant intake of residues by livestock was identified. MRLs for foods of animal origin were also recommended by the most recent JMPR meeting (FAO/WHO, 2009).

Table 3-5. Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<i>Residue definition for risk assessment: sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat</i>				
Cabbage	0.50	MRL	0.50	MRL
Kale	2.00	MRL	2.00	MRL
Citrus pomace	0.42	STMR*PF	0.42	STMR*PF
Apples pomace	0.34	STMR*PF	0.34	STMR*PF

Table 3-6. Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Dietary burden triggered?
<i>Residue definition for risk assessment: sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat</i>				
Dairy ruminants	0.18182	0.18182	Kale	Yes
Meat ruminants	0.21429	0.21429	Kale	Yes

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Dietary burden triggered?
Poultry	0.04511	0.04511	Kale	Yes
Pigs	0.08571	0.08571	Kale	Yes

4. Consumer risk assessment

In order to assess the consumer safety of the proposed MRLs, both chronic and acute intake calculations were performed using revision 2 of the EFSA PRIMo. The input values for the several crops under assessment in this application are summarized in Table 4-1.

For the chronic intake calculations, EFSA is also required to consider other crops with registered uses. As detailed information on STMR values for these crops is not available, the chronic calculations for the remaining commodities were conducted using the existing MRLs as input values (Appendix B). Considering that the residue definitions for enforcement and risk assessment are the same, this approach is expected to overestimate real exposure to spirotetramat residues.

The detailed results of the intake calculations are reported in Appendix C to this document. Intake calculations for all European diets resulted in a chronic exposure not higher than 30.5% of the ADI. For the crops evaluated in the framework of this application, all acute intakes represented less than 10% of the ARfD. Consequently, the proposed MRLs are not expected to pose any risk to the European consumer.

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
<i>Residue definition for risk assessment: sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat</i>				
Grapefruit	0.33	STMR	0.47	HR
Oranges	0.33	STMR	0.47	HR
Lemons	0.33	STMR	0.47	HR
Limes	0.33	STMR	0.47	HR
Mandarins	0.33	STMR	0.47	HR
Apples	0.18	STMR	0.41	HR
Pears	0.18	STMR	0.41	HR
Apricots	0.74	STMR	1.23	HR
Peaches	0.74	STMR	1.23	HR
Table grapes	0.45	STMR	1.29	HR
Wine grapes	0.45	STMR	1.29	HR

CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(2) of Regulation (EC) No 396/2005, Austria received an application from the company Bayer Cropscience to modify the existing MRLs of spirotetramat in several fruit crops. In particular, these modifications were requested in order to allow for import of fruits treated according to authorized uses in the USA and Canada. The subsequent evaluation report drafted by Austria was forwarded to EFSA on 02 September 2008 according to Article 9 of the Regulation. On 20 November 2008 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 on 19 February 2009.

Based on the evaluation report and the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) Austria under Directive 91/414/EEC, EFSA derives the following conclusions regarding the application. As the DAR has not yet been peer reviewed by EFSA, conclusions reached in this reasoned opinion are temporary and might be reconsidered after finalization of the peer review.

Metabolism of spirotetramat was investigated by foliar applications in cotton, lettuce, potatoes and apples. Three different crop groups are covered by the available studies and the relevant residue for enforcement and risk assessment in all plant commodities was defined by the RMS as the sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat. An analytical method for enforcement of this residue definition in the fruit crops under evaluation is also available.

A sufficient number of supervised residues trials supporting the reported GAPs for spirotetramat is available. These trials allow estimating the expected residue concentrations in the relevant plant commodities and deriving appropriate MRLs.

The effect of industrial and household processing on the nature of residues was investigated. As the processing of fruits usually doesn't involve sterilization, it was concluded that processing of fruits is not expected to affect the nature of residues in the processed commodities. Studies on the magnitude of residues in a large number of processed commodities were submitted as well, but not considered sufficient to propose robust processing factors in most of the cases. Only the following processing factor for enforcement of the sum of spirotetramat and its 4 metabolites, expressed as spirotetramat, can be recommended:

- Grapefruit, juice: 0.4
- Oranges, juice: 0.4
- Lemons, juice: 0.4
- Limes, juice: 0.4
- Mandarins, juice: 0.4

The possible occurrence of spirotetramat residues in rotational crops was not investigated. As the GAPs supported in the framework of this application are authorized outside the EC, possible occurrence of residues in rotational crops is not considered relevant to the European consumer exposure.

The livestock dietary burden for livestock was calculated considering the both the existing and the new proposed MRLs for spirotetramat. Occurrence of residues in foods of animal origin was not further investigated in the framework of this application as the dietary burden

was mainly driven by the existing MRL in kale. Nevertheless, EFSA strongly recommends the setting of MRLs in products of animal origin because the calculated burdens exceeded the trigger value of 0.1 mg/kg DM for all livestock species.

Finally, chronic and acute intake calculations considering the new proposed MRLs were performed with revision 2 of the EFSA PRIMo. For the chronic intake calculations, all the existing MRLs for the active substance were considered as well. As no intake concerns were identified for all available European diets, the proposed MRLs are not expected to pose any risk to the European consumer.

The recommendations resulting from the assessment are summarized in the table below. These recommendations should be considered for inclusion in Annex III of the Regulation as the peer review of the active substance under Directive 91/414/EEC is not yet finalized.

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<i>Residue definition for risk assessment: sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat</i>			
Grapefruit	0.1*	1	MRL proposals are fully supported by data but should be considered as provisional as the peer review of the active substance under Directive 91/414/EEC is not yet finalised. A risk to consumers was not identified.
Oranges	0.1*	1	
Lemons	0.1*	1	
Limes	0.1*	1	
Mandarins	0.1*	1	
Apples	0.1*	1	
Pears	0.1*	1	
Apricots	0.1*	2	
Peaches	0.1*	2	
Table grapes	0.1*	2	
Wine grapes	0.1*	2	

(*): 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 MRLs for spirotetramat in several fruit crops prepared by the Rapporteur Member State Austria under Regulation (EC) No 396/2005. Submitted to EFSA on 02 September 2008. Updated on 19 February 2009.

REFERENCES

- Austria, 2008. Draft Assessment Report on spirotetramat prepared by the Rapporteur Member State Austria under Directive 91/414/EEC. April 2008.
- EFSA, 2008. Addendum to the reasoned opinion of EFSA prepared by PRAPeR on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to Regulation (EC) 396/2005 on maximum residue levels of pesticides in food and feed of plant and animal origin. *EFSA Scientific Report (2008) 132, 1-317*.
- FAO/WHO, 2009. Pesticide residues in food – 2008. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 193.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Product name / PPP: Movento SC 240/OD 150 Active substance/s: Spirotetramat Content: > 96%

Type of formulation: SC/OD

Crop and/or situation	Member State or Country	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)	Remarks
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	kg as/hL min – max (l)	water L/ha min – max	kg as/ha min – max (l)		
Citrus all types	USA	F	scales, aphids, mealy bugs, mites	OD	150	Spray	BBCH 78 at (last application)	1-3	21		---	0.088 – 0.176	1	Max. dose per season is 0.351 kg/ha
				SC	240									
Pome Fruits Apples Pears	USA/ Canada	F	Aphids, scales, mealy bugs, Psylla pyri	OD	150	spray	BBCH 81 (last application)	1-3	14		---	0.088 – 0.154	7	Max. dose per season is 0.439 kg/ha
				SC	240									
Stone fruit Peaches Apricots	USA/ Canada	F	aphids, scales, mealy bugs	OD	150	spray	BBCH 81 (last application)	1-3	14		---	0.088 – 0.154	7	Max. dose per season is 0.263 kg/ha
				SC	240									
Grapes	USA/ Canada	F	Mealy bugs, phylloxera, mites, scales	OD	150	spray		2	30		---	0.088 – 0.132	7	Max. dose per season is 0.219 kg/ha
				SC	240									

APPENDIX B – LIST OF EXISTING EC MRLS

Pesticides - Web Version - EU MRLs (File created on 24/02/2009 14:09)		
Code number	Groups and examples of individual products to which the MRLs apply (a)	Spirotetramat and its 4 metabolites BY108330-enol, BY108330-ketohydroxy, BY108330-mono-hydroxy, and BY108330-enol-glucoside, expressed as spirotetramat
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,1*
110000	(i) Citrus fruit	0,1*
110010	Grapefruit (Shadblacks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,1*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,1*
110030	Lemons (Citron, lemon)	0,1*
110040	Limes	0,1*
110050	Mandarin (Clementine, tangerine and other hybrids)	0,1*
110990	Others	0,1*
120000	(ii) Tree nuts (shelled or unshelled)	0,1*
120010	Almonds	0,1*
120020	Brazil nuts	0,1*
120030	Cashew nuts	0,1*
120040	Chestnuts	0,1*
120050	Coconuts	0,1*
120060	Hazelnuts (Filbert)	0,1*
120070	Macadamia	0,1*
120080	Pecans	0,1*
120090	Pine nuts	0,1*
120100	Pistachios	0,1*
120110	Walnuts	0,1*
120990	Others	0,1*
130000	(iii) Pome fruit	0,1*
130010	Apples (Crab apple)	0,1*
130020	Pears (Oriental pear)	0,1*
130030	Quinces	0,1*
130040	Medlar	0,1*
130050	Loquat	0,1*
130990	Others	0,1*
140000	(iv) Stone fruit	0,1*
140010	Apricots	0,1*
140020	Cherries (sweet cherries, sour cherries)	0,1*
140030	Peaches (Nectarines and similar hybrids)	0,1*

140040	Plums (Damson, greengage, mirabelle)	0,1*
140990	Others	0,1*
150000	(v) Berries & small fruit	0,1*
151000	(a) Table and wine grapes	0,1*
151010	Table grapes	0,1*
151020	Wine grapes	0,1*
152000	(b) Strawberries	0,1*
153000	(c) Cane fruit	0,1*
153010	Blackberries	0,1*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,1*
153030	Raspberries (Wineberries)	0,1*
153990	Others	0,1*
154000	(d) Other small fruit & berries	0,1*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,1*
154020	Cranberries	0,1*
154030	Currants (red, black and white)	0,1*
154040	Gooseberries (Including hybrids with other ribes species)	0,1*
154050	Rose hips	0,1*
154060	Mulberries (arbutus berry)	0,1*
154070	Azardle (mediterranean medlar)	0,1*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azardle, buckhorn (sea sawtooth), hawthorn, service berries, and other treeberries)	0,1*
154990	Others	0,1*
160000	(vi) Miscellaneous fruit	0,1*
161000	(a) Edible peel	0,1*
161010	Dates	0,1*
161020	Figs	0,1*
161030	Table olives	0,1*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,1*
161050	Carambola (Bilimbi)	0,1*
161060	Persimmon	0,1*
161070	Jambolan (java plum) (Java apple (water apple), pommerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,1*
161990	Others	0,1*
162000	(b) Inedible peel, small	0,1*
162010	Kiwi	0,1*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,1*
162030	Passion fruit	0,1*
162040	Prickly pear (cactus fruit)	0,1*
162050	Star apple	0,1*

162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammei sapote)	0,1*	220040	Spring onions (Welsh onion and similar varieties)	0,1*
162990	Others	0,1*	220990	Others	0,1*
163000	(c) Inedible peel, large	0,1*	230000	(ii) Fruiting vegetables	
163010	Avocados	0,1*	231000	(a) Solanacea	
163020	Bananas (Dwarf banana, plantain, apple banana)	0,1*	231010	Tomatoes (Cherry tomatoes,)	2
163030	Mangoes	0,1*	231020	Peppers (Chili peppers)	2
163040	Papaya	0,1*	231030	Aubergines (egg plants) (Pepino)	2
163050	Pomegranate	0,1*	231040	Okra, lady s fingers	0,1*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), lama and other medium sized Annonaceae)	0,1*	231990	Others	0,1*
163070	Guava	0,1*	232000	(b) Cucurbits - edible peel	0,2
163080	Pineapples	0,1*	232010	Cucumbers	0,2
163090	Bread fruit (Jackfruit)	0,1*	232020	Gherkins	0,2
163100	Durian	0,1*	232030	Courgettes (Summer squash, marrow (patisson))	0,2
163110	Soursop (guanabana)	0,1*	232990	Others	0,2
163990	Others	0,1*	233000	(c) Cucurbits inedible peel	0,2
200000	2. VEGETABLES FRESH OR FROZEN		233010	Melons (Kiwano)	0,2
210000	(i) Root and tuber vegetables	0,1*	233020	Pumpkins (Winter squash)	0,2
211000	(a) Potatoes	0,1*	233030	Watermelons	0,2
212000	(b) Tropical root and tuber vegetables	0,1*	233990	Others	0,2
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,1*	234000	(d) Sweet corn	0,1*
212020	Sweet potatoes	0,1*	239000	(e) Other fruiting vegetables	0,1*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,1*	240000	(iv) Brassica vegetables	
212040	Arrowroot	0,1*	241000	(a) Flowering brassica	1
212990	Others	0,1*	241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	1
213000	(c) Other root and tuber vegetables except sugar beet	0,1*	241020	Cauliflower	1
213010	Beetroot	0,1*	241990	Others	1
213020	Carrots	0,1*	242000	(b) Head brassica	
213030	Celeriac	0,1*	242010	Brussels sprouts	0,3
213040	Horseradish	0,1*	242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,5
213050	Jerusalem artichokes	0,1*	242990	Others	0,1*
213060	Parsnips	0,1*	243000	(c) Leafy brassica	2
213070	Parsley root	0,1*	243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsa), cow cabbage)	2
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,1*	243020	Kale (Borecole (curly kale), collards)	2
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oyster plant))	0,1*	243990	Others ()	2
213100	Swedes	0,1*	244000	(d) Kohlrabi	2
213110	Tunips	0,1*	250000	(v) Leaf vegetables & fresh herbs	
213990	Others	0,1*	251000	(a) Lettuce and other salad plants including Brassicaceae	
220000	(ii) Bulb vegetables	0,1*	251010	Lamb's lettuce (Italian corn salad)	0,1*
220010	Garlic	0,1*	251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	5
220020	Onions (Silver skin onions)	0,1*			
220030	Shalots	0,1*			

251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	0,1*	270000	(vi) Stem vegetables (fresh)	0,1*
251040	Cress	0,1*	270010	Asparagus	0,1*
251050	Land cress	0,1*	270020	Cardoons	0,1*
251060	Rocket, Rucola (Wild rocket)	0,1*	270030	Celery	0,1*
251070	Red mustard	0,1*	270040	Fennel	0,1*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,1*	270050	Globe artichokes	0,1*
251990	Others	0,1*	270060	Leek	0,1*
252000	(b) Spinach & similar (leaves)	0,1*	270070	Rhubarb	0,1*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,1*	270080	Bamboo shoots	0,1*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,1*	270090	Palm hearts	0,1*
252030	Beet leaves (chard) (Leaves of beetroot)	0,1*	270990	Others	0,1*
252990	Others	0,1*	280000	(vii) Fungi	0,1*
253000	(c) Vine leaves (grape leaves)	0,1*	280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,1*
254000	(d) Water cress	0,1*	280020	Wild (Chanterelle, Truffle, Morel,)	0,1*
255000	(e) Willow	0,1*	280990	Others	0,1*
256000	(f) Herbs	0,1*	290000	(ix) Sea weeds	0,1*
256010	Chervil	0,1*	300000	3. PULSES, DRY	0,1*
256020	Chives	0,1*	300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,1*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,1*	300020	Lentils	0,1*
256040	Parsley	0,1*	300030	Peas (Chickpeas, field peas, chickling vetch)	0,1*
256050	Sage (Winter savory, summer savory,)	0,1*	300040	Lupins	0,1*
256060	Rosemary	0,1*	300990	Others	0,1*
256070	Thyme (marjoram, oregano)	0,1*	400000	4. OILSEEDS AND OILFRUITS	0,1*
256080	Basil (Balm leaves, mint, peppermint)	0,1*	401000	(j) Oilseeds	0,1*
256090	Bay leaves (laurel)	0,1*	401010	Linseed	0,1*
256100	Tarragon (Hyssop)	0,1*	401020	Peanuts	0,1*
256990	Others	0,1*	401030	Poppy seed	0,1*
260000	(vi) Legume vegetables (fresh)	0,1*	401040	Sesame seed	0,1*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, string bean, yardlong beans)	0,1*	401050	Sunflower seed	0,1*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,1*	401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
260030	Peas (with pods) (Mangelout (sugar peas))	0,1*	401070	Soya bean	0,1*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,1*	401080	Mustard seed	0,1*
260050	Lentils	0,1*	401090	Cotton seed	0,1*
260990	Others	0,1*	401100	Pumpkin seeds	0,1*
			401110	Safflower	0,1*
			401120	Borage	0,1*
			401130	Gold of pleasure	0,1*
			401140	Hempseed	0,1*
			401150	Castor bean	0,1*
			401990	Others	0,1*
			402000	(i) Oilfruits	0,1*
			402010	Olives for oil production	0,1*
			402020	Palm nuts (palm oil kernels)	0,1*
			402030	Palm fruit	0,1*
			402040	Kapok	0,1*
			402990	Others	0,1*
			500000	5. CEREALS	0,1*
			500010	Barley	0,1*

500020	Buckwheat	0,1*	820030	Caraway	0,1*
500030	Maize	0,1*	820040	Cardamom	0,1*
500040	Millet (Foxtail millet, teff)	0,1*	820050	Juniper berries	0,1*
500050	Oats	0,1*	820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
500060	Rice	0,1*	820070	Vanilla pods	0,1*
500070	Rye	0,1*	820080	Tamarind	0,1*
500080	Sorghum	0,1*	820090	Others	0,1*
500090	Wheat (Spelt/Triticale)	0,1*	830000	(ii) Bark	0,1*
500990	Others	0,1*	830010	Cinnamon (Cassia)	0,1*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*	830990	Others	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i>)	0,1*	840000	(iv) Roots or rhizome	0,1*
620000	(ii) Coffee beans	0,1*	840010	Liquorice	0,1*
630000	(iii) Herbal infusions (dried)	0,1*	840020	Ginger	0,1*
631000	(a) Flowers	0,1*	840030	Turmeric (Curcuma)	0,1*
631010	Camomile flowers	0,1*	840040	Horse-radish	0,1*
631020	Hibiscus flowers	0,1*	840990	Others	0,1*
631030	Rose petals	0,1*	850000	(v) Buds	0,1*
631040	Jasmine flowers	0,1*	850010	Cloves	0,1*
631050	Lime (Linden)	0,1*	850020	Capers	0,1*
631990	Others	0,1*	850990	Others	0,1*
632000	(b) Leaves	0,1*	860000	(vi) Flower stigma	0,1*
632010	Strawberry leaves	0,1*	860010	Saffron	0,1*
632020	Rooibos leaves	0,1*	860990	Others	0,1*
632030	Maté	0,1*	870000	(vii) Ail	0,1*
632990	Others	0,1*	870010	Mace	0,1*
633000	(c) Roots	0,1*	870990	Others	0,1*
633010	Valerian root	0,1*	900000	9. SUGAR PLANTS	0,1*
633020	Ginseng root	0,1*	900010	Sugar beet (root)	0,1*
633990	Others	0,1*	900020	Sugarcane	0,1*
639000	(d) Other herbal infusions	0,1*	900030	Chicory roots	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*	900990	Others	0,1*
650000	(v) Carb (st johns bread)	0,1*	1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	10	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	
800000	8. SPICES	0,1*	1011000	(a) Swine	
810000	(i) Seeds	0,1*	1011010	Meat	
810010	Anise	0,1*	1011020	Fat free of lean meat	
810020	Black caraway	0,1*	1011030	Liver	
810030	Celery seed (Lovage seed)	0,1*	1011040	Kidney	
810040	Coriander seed	0,1*	1011050	Edible offal	
810050	Cumin seed	0,1*	1011990	Others	
810060	Dill seed	0,1*	1012000	(b) Bovine	
810070	Fennel seed	0,1*	1012010	Meat	
810080	Fenugreek	0,1*	1012020	Fat	
810090	Nutmeg	0,1*	1012030	Liver	
810990	Others	0,1*	1012040	Kidney	
820000	(ii) Fruits and berries	0,1*	1012050	Edible offal	
820010	Allspice	0,1*			
820020	Anise pepper (Japan pepper)	0,1*			

1012990	Others		1030010	Chicken	
1013000	(c) Sheep		1030020	Duck	
1013010	Meat		1030030	Goose	
1013020	Fat		1030040	Quail	
1013030	Liver		1030990	Others	
1013040	Kidney		1040000	(iv) Honey (Royal jelly, pollen)	
1013050	Edible offal		1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1013990	Others		1060000	(vi) Snails	
1014000	(c) Goat		1070000	(vii) Other terrestrial animal products	
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	(i) 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	(ii) 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				

Pesticide residues and maximum residue levels (mg/kg)
 (*) Indicates lower limit of analytical determination

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Spirotetramat			
Status of the active substance:	Pending	Code no.	
LOQ (mg/kg bw):	0.1	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	1
Source of ADI:	DAR	Source of ARfD:	DAR
Year of evaluation:	2008	Year of evaluation:	2008

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		5	30						
		No of diets exceeding ADI:							

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)	
30.4	WHO Cluster diet B	12.3	Tomatoes	3.6	Lettuce	2.0	Peppers	5.3	
19.7	DE child	4.3	Apples	3.9	Tomatoes	2.5	Oranges	2.9	
16.5	NL child	2.5	Tomatoes	2.3	Apples	2.1	Oranges	3.7	
15.6	IE adult	1.6	Tomatoes	1.1	Wine grapes	1.1	Aubergines (egg plants)	4.5	
14.3	WHO regional European diet	4.4	Tomatoes	3.8	Lettuce	0.8	Potatoes	2.4	
13.7	ES child	4.2	Lettuce	3.9	Tomatoes	1.4	Oranges	2.3	
13.6	IT kids/toddler	5.7	Tomatoes	2.9	Lettuce	1.3	Wheat	2.3	
13.0	ES adult	5.4	Lettuce	3.1	Tomatoes	0.9	Oranges	1.4	
12.8	UK Toddler	4.6	Sugar beet (root)	2.4	Tomatoes	1.3	Oranges	7.0	
12.7	IT adult	4.7	Tomatoes	3.8	Lettuce	0.8	Wheat	1.5	
11.7	WHO Cluster diet F	3.0	Lettuce	2.7	Tomatoes	0.7	Wheat	2.7	
11.7	WHO cluster diet D	4.0	Tomatoes	1.3	Wheat	0.8	Potatoes	3.2	
11.3	PT General population	3.6	Tomatoes	2.2	Wine grapes	1.1	Potatoes	2.8	
11.3	WHO cluster diet E	2.1	Tomatoes	1.4	Wine grapes	0.9	Lettuce	3.4	
11.1	FR toddler	3.1	Tomatoes	1.3	Oranges	1.0	Potatoes	3.3	
10.8	SE general population 90th percentile	3.1	Tomatoes	0.8	Potatoes	0.8	Chinese cabbage	2.6	
10.3	DK child	2.1	Tomatoes	1.4	Lettuce	1.1	Wheat	3.2	
9.4	FR all population	3.6	Wine grapes	1.7	Tomatoes	0.9	Lettuce	1.4	
9.0	NL general	1.7	Tomatoes	1.2	Lettuce	1.0	Oranges	1.7	
8.8	UK vegetarian	2.5	Tomatoes	1.4	Lettuce	0.8	Sugar beet (root)	2.0	
8.6	UK Infant	2.0	Sugar beet (root)	1.5	Tomatoes	0.9	Oranges	4.6	
7.2	UK Adult	1.7	Tomatoes	1.2	Lettuce	1.0	Wine grapes	1.8	
7.1	PL general population	3.5	Tomatoes	0.7	Apples	0.7	Potatoes	1.1	
6.0	FR infant	0.9	Apples	0.8	Potatoes	0.6	Oranges	2.3	
6.0	LT adult	2.5	Tomatoes	0.7	Apples	0.6	Potatoes	1.3	
5.7	DK adult	1.7	Tomatoes	1.3	Wine grapes	0.4	Peppers	1.2	
5.2	FI adult	1.7	Tomatoes	0.8	Lettuce	0.6	Oranges	0.9	

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

Acute risk assessment /children - refined calculations

Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	8.4	Table grapes	1.29 / -	8.4	Table grapes	1.29 / -	4.1	Table grapes	1.29 / -	4.1	Table grapes	1.29 / -
	7.3	Peaches	1.23 / -	5.4	Peaches	1.23 / -	3.1	Wine grapes	1.29 / -	3.1	Wine grapes	1.29 / -
	6.2	Oranges	0.47 / -	4.5	Oranges	0.47 / -	2.1	Peaches	1.23 / -	1.7	Peaches	1.23 / -
	4.2	Grapefruit	0.47 / -	4.2	Grapefruit	0.47 / -	1.2	Oranges	0.47 / -	1.0	Oranges	0.47 / -
	4.0	Apples	0.41 / -	3.0	Apricots	1.23 / -	0.9	Grapefruit	0.47 / -	0.8	Apricots	1.23 / -
	No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---		

Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
5.0	Orange juice	1 / -	1.0	Orange juice	1 / -	
3.5	Tomato juice	2 / -	0.4	Tomato (preserved-fresh)	2 / -	
0.5	Apple juice	0.1 / -	0.1	Apple juice	0.1 / -	
0.4	Carrot, juice	0.1 / -	0.0	Bread/pizza	0.1 / -	
0.3	Grape juice	0.1 / -	0.0	Wine	0.1 / -	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

***) pTMRL: provisional temporary MRL

****) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Spirotetramat IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

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
CAS	Chemical Abstracts Service
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)
DM	dry matter
EC	European Community
EFSA	European Food Safety Authority
EU	European union
GAP	good agricultural practice
ha	hectare
hL	hectolitre
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC-ESI- MS/MS	liquid chromatography with electrospray ionization and tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
OD	oil dispersion
PF	processing factor
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SC	suspension concentrate

STMR	supervised trials median residue
TRR	total radioactive residue
USA	United States of America