

REASONED OPINION OF EFSA

Modification of the existing MRLs for spirotetramat in plums and cherries¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00460)

Issued on 09 June 2009

SUMMARY

According to Article 6(1) of Regulation (EC) No 396/2005, Austria received an application from the company Bayer CropScience to modify the existing MRLs for spirotetramat in plums and cherries. As Austria intends to authorize the use of spirotetramat in these crops, the applicant proposed to raise the existing MRLs, which are currently set at the LOQ of 0.1 mg/kg, to 0.5 mg/kg. The subsequent evaluation report drafted by Austria was forwarded to EFSA on 10 March 2009 according to Article 9 of the Regulation.

Based on the above mentioned 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 As the DAR has not yet been peer reviewed by EFSA, conclusions reached in this reasoned opinion are temporary and might be reconsidered after finalization of the peer review.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 Austria 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 plums and cherries is also available.

A sufficient number of supervised residues trials supporting the intended GAPs for spirotetramat in plums and cherries is available. These trials allow estimating the expected residue concentrations in the relevant plant commodities and deriving appropriate MRLs. Although an MRL of 0.5 mg/kg was initially applied for, an MRL of 2 mg/kg is recommended based on the available data.

The effect of industrial and household processing on the nature of residues was investigated. As the processing of fruits usually doesn't involve sterilization at high temperature and high

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pH, it was concluded that processing of fruits is not expected to affect the nature of residues. Trials on the magnitude of residues in preserved cherries was submitted as well and a robust processing factor for enforcement of spirotetramat and its 4 metabolites, expressed as spirotetramat, can be recommended:

- Cherries, canned: 0.5

The possible occurrence of spirotetramat residues in succeeding crops was not further investigated in the framework of this application because plums and cherries are not grown in rotation. Also the occurrence of residues in food of animal origin was not investigated as plums and cherries are not fed to livestock.

Finally, chronic and acute intake calculations considering the new proposed MRLs for plums and cherries were performed with revision 2 of the EFSA PRIMo. For the chronic intake calculations, all the existing MRLs for the active substance as well as the MRLs previously recommended by EFSA were considered and no exceedances of the ADI or ARfD were identified. The highest chronic exposure was calculated for the WHO Cluster diet B, representing 30.5% of the ADI. The contribution of cherries and plums to this chronic exposure was less than 0.4 % of the ADI. The highest acute exposure was calculated for plums, representing 2.7% of the ARfD. It is therefore concluded that the proposed use of spirotetramat in cherries and plums is not expected to pose any risk with regard to consumer exposure and that the proposed MRLs are acceptable.

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
<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>			
Cherries	0.1*	2	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.
Plums	0.1*	2	

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

Key words: spirotetramat, cherries, plums, 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 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.

Austria, hereafter referred to as the Evaluating Member State (EMS), received an application from the company Bayer CropScience² to modify the existing MRL for the active substance spirotetramat in plums and cherries. 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 10 March 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00460 and the following subject:

Spirotetramat - Application to modify the existing MRLs for spirotetramat and its 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy, and BYI08330 enol-glucoside, expressed as spirotetramat, in cherries from 0.1 mg/kg to 0.5 mg/kg and in plums from 0.1*mg/kg to 0.5 mg/kg.*

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

TERMS OF REFERENCE

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

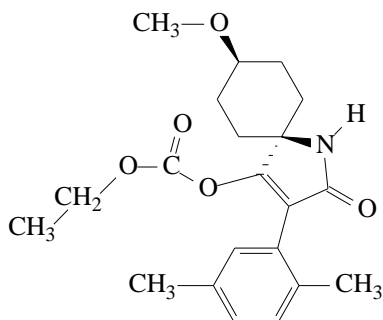
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 10 June 2009.

² Bayer Cropscience, Alfred-Nobel-Strasse 50, 40789 Monheim/Rhein, Germany

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Spirotetramat is the ISO common name for *cis*-4-(ethoxycarbonyloxy)-8-methoxy-3-(2,5-xylol)-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). New MRL proposals to accommodate for the use of spirotetramat on several fruit crops in the USA and in Canada have recently been assessed (EFSA, 2009), but not yet legally implemented. Also the setting of CXLs for spirotetramat is currently under discussion but not yet finalised (FAO/WHO, 2009).

The RMS Austria now intends to authorize the use of spirotetramat in plums and cherries, requiring the modification of the existing MRLs, which are currently set at the LOQ of 0.1 mg/kg. A detailed overview of the intended GAPs is available in Appendix A. It concerns 2 foliar outdoor applications with a PHI of 21 days.

In support of the MRL application, Austria submitted an evaluation report but for consideration of some general aspects of the pesticides residues risk assessment 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 acid content.

It is noted that an independent laboratory validation was not provided for the above reported method. Nevertheless, 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 adopted by the Member States and the European Commission. 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 spirotetramat residues in food of animal origin was not considered in the framework of this application as plums and cherries are not fed to livestock.

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 (FAO/WHO, 2009).

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

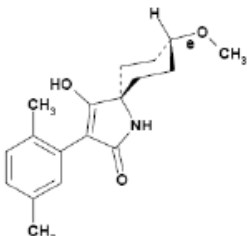
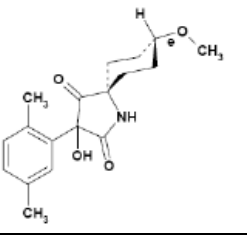
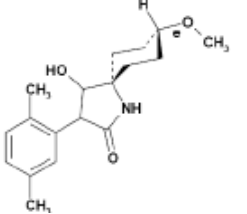
3.1.1. Primary crops

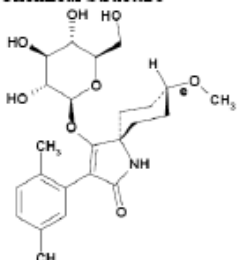
3.1.1.1. Nature of residues

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	 <p>The chemical structure shows a spirocyclic system. One ring is a decan-2-one derivative with a 2,5-dimethylphenyl group at the 3-position and a hydroxyl group at the 4-position. The other ring is a five-membered azaspiro ring containing a nitrogen atom and a methoxy group at the 8-position. The two rings are connected at the 1-position. The hydroxyl group at the 4-position is in the enol form, forming a double bond with the adjacent carbon and having a hydroxyl group attached to that carbon. The glucose moiety is attached to the 4-position carbon via an oxygen atom.</p>

3.1.1.2. Magnitude of residues

In its evaluation report, Austria reported a sufficient number of residues trials for cherries and plums. All trials were performed between 2004 and 2006 in Northern Europe and are in compliance with the intended GAP based on the spray concentration. It is noted that trials were performed with OD formulations while the intended GAP was reported for a SC formulation. This is however not expected to impact the outcome significantly. The analytical methods used in the residues trials were also demonstrated to be sufficiently validated with a combined LOQ of 0.05 mg/kg for spirotetramat and its 4 metabolites. Trial results were selected in accordance with the intended GAP unless higher residue levels were identified at longer PHIs. Results are summarized in Table 3-2.

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 limited 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 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 plums and cherries (see also Table 3-2). It is noted that MRLs of 0.5 mg/kg for both crops were initially requested in the application form but based on the data provided an MRL of 2 mg/kg is expected to be more appropriate.

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					
<u>Residue definition for enforcement and risk assessment:</u> sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat									
Plums	NEU	Outdoor	0.119; 0.159; 0.193; 0.353; 0.416; 0.511; 0.582; 0.828	0.119; 0.159; 0.193; 0.353; 0.416; 0.511; 0.582; 0.828	0.38	0.83	2	1.0	8 trials on plums complying with the intended GAP. Rmax = 1.17 Rber = 1.06
Cherries	NEU	Outdoor	0.248; 0.285; 0.295; 0.427; 0.524; 0.583; 0.826; 0.939	0.248; 0.285; 0.295; 0.427; 0.524; 0.583; 0.826; 0.939	0.48	0.94	2	1.0	4 trials on sour cherries and 4 trials on sweet cherries complying with the intended GAP. Rmax = 1.33 Rber = 1.29

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(b): Median value of the individual trial results according to the enforcement residue definition.

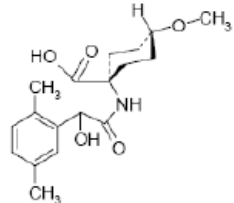
(c): Highest value of the individual trial results according to the enforcement residue definition.

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

3.1.1.3. Effect of industrial processing and/or household preparation

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 plums or cherries are usually not subject to the sterilization conditions, as tested in the available study. 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 (with high temperature and high pH) 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-methoxycyclohexanecarboxylicacid	

Regarding the magnitude of residues in processed commodities of cherries, 4 processing studies for preserved cherries were reported by Austria and are summarized in Table 3-4. From the available trials, a processing factor of 0.5 can be derived. As specific consumption data on preserved cherries are not available, it is not possible to include this factor for refinement of the consumer intake calculations. Nevertheless, the processing factor is sufficiently supported by data to be recommended for enforcement purposes.

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:</u> sum of spirotetramat and its 4 metabolites BYI 03380-enol, BYI 03380-ketohydroxy, BYI 03380-monohydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat				
Cherries, canned	4	0.50	1.0	Recommended for enforcement

(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

The possible occurrence of spirotetramat residues in succeeding crops was not further investigated in the framework of this application. Both plums and cherries are permanent crops which are not grown in rotation.

3.2. Nature and magnitude of residues in livestock

The occurrence of residues in food of animal origin was not further investigated in the framework of this application as plums and cherries are not fed to livestock.

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. For the chronic intake calculations, EFSA is also required to consider other crops with registered uses. STMR values derived for several fruit crops in the framework of a previous application were therefore also considered (EFSA, 2009). Above mentioned input values are summarized in Table 4-1.

As detailed information on STMR values for all other authorized crops is currently not available to EFSA, 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 and no exceedances of the ADI or ARfD were identified. The highest chronic exposure was calculated for the WHO Cluster diet B, representing 30.5% of the ADI. The contribution of cherries and plums to this chronic exposure was less than 0.4 % of the ADI. The highest acute exposure was calculated for plums, representing 2.7% of the ARfD. It is therefore concluded that the proposed use of spirotetramat in cherries and plums is not expected to pose any risk with regard to consumer exposure and that the proposed MRLs are acceptable.

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-mono-hydroxy and BYI 03380-enol-glucoside, expressed as spirotetramat</i>				
Cherries	0.48	STMR	0.94	HR
Plums	0.38	STMR	0.83	HR
Citrus fruits	0.33	STMR (EFSA, 2009)	Not considered for acute exposure assessment in the framework of this application.	
Apples and pears	0.18	STMR (EFSA, 2009)		
Apricots and peaches	0.74	STMR (EFSA, 2009)		
Table and wine grapes	0.45	STMR (EFSA, 2009)		

CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(1) of Regulation (EC) No 396/2005, Austria received an application from the company Bayer CropScience to modify the existing MRLs for spirotetramat in plums and cherries. As Austria intends to authorize the use of spirotetramat in these crops, the applicant proposed to raise the existing MRLs, which are currently set at the LOQ of 0.1 mg/kg, to 0.5 mg/kg. The subsequent evaluation report drafted by Austria was forwarded to EFSA on 10 March 2009 according to Article 9 of the Regulation.

Based on the above mentioned 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 Austria 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 plums and cherries is also available.

A sufficient number of supervised residues trials supporting the intended GAPs for spirotetramat in plums and cherries is available. These trials allow estimating the expected residue concentrations in the relevant plant commodities and deriving appropriate MRLs. Although an MRL of 0.5 mg/kg was initially applied for, an MRL of 2 mg/kg is recommended based on the available data.

The effect of industrial and household processing on the nature of residues was investigated. As the processing of fruits usually doesn't involve sterilization at high temperature and high pH, it was concluded that processing of fruits is not expected to affect the nature of residues. Trials on the magnitude of residues in preserved cherries was submitted as well and a robust processing factor for enforcement of spirotetramat and its 4 metabolites, expressed as spirotetramat, can be recommended:

- Cherries, canned: 0.5

The possible occurrence of spirotetramat residues in succeeding crops was not further investigated in the framework of this application because plums and cherries are not grown in rotation. Also the occurrence of residues in food of animal origin was not investigated as plums and cherries are not fed to livestock.

Finally, chronic and acute intake calculations considering the new proposed MRLs for plums and cherries were performed with revision 2 of the EFSA PRIMo. For the chronic intake calculations, all the existing MRLs for the active substance as well as the MRLs previously recommended by EFSA were considered and no exceedances of the ADI or ARfD were identified. The highest chronic exposure was calculated for the WHO Cluster diet B, representing 30.5% of the ADI. The contribution of cherries and plums to this chronic exposure was less than 0.4 % of the ADI. The highest acute exposure was calculated for plums, representing 2.7% of the ARfD. It is therefore concluded that the proposed use of

spirotetramat in cherries and plums is not expected to pose any risk with regard to consumer exposure and that the proposed MRLs are acceptable.

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 <i>BYI 03380-enol</i> , <i>BYI 03380-ketohydroxy</i> , <i>BYI 03380-monohydroxy</i> and <i>BYI 03380-enol-glucoside</i> , expressed as spirotetramat			
Cherries	0.1*	2	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.
Plums	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 plums and cherries prepared by the Rapporteur Member State Austria under Regulation (EC) No 396/2005. Submitted to EFSA on 10 March 2009.

REFERENCES

- Austria, 2008. Draft Assessment Report on spirotetramat prepared by the Rapporteur Member State Austria under Directive 91/414/EEC. April 2008.
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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Product name / PPP: Movento SC 240 Active substance/s: Spirotetramat Content: > 96%
 Type of formulation: SC

Crop and/or situation	Member State or Country	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			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)		
stone fruit plum, sour and sweet cherry	EU-N	F	aphids, scales, mealy bugs	SC	240 & Mero	spray	BBCH 81 at last application	2	14	0.0144	500 L/ha and m CH* max 1500 L/ha	0.072 kg as /ha and m CH*, max 0.216 kg as./ha	21	all application data refer to meter CH* (canopy height, max. height referred to is three (3) metres. Max. total rate per season:

APPENDIX B – EXISTING EC MRLs

Pesticides - Web Version - EU MRLs (File created on 27/05/2009 16:56)		
Code number	Groups and examples of individual products to which the MRLs apply (a)	Spirote tramat and its 4 metabolites BY1083 30-enol, BY1083 30-ketohydroxy, and BY1083 30-monohydroxy, and BY1083 30-enol-glucoside, expressed as spirote tramat
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,1*
110000	(i) Citrus fruit	[1] ^a
110010	Grapefruit (Shaddock), pomelos, sweeties, tangelo, ugli and other hybrids	[1] ^a
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	[1] ^a
110030	Lemons (Citron, lemon)	[1] ^a
110040	Limes	[1] ^a
110050	Mandarins (Clementine, tangerine and other hybrids)	[1] ^a
110990	Others	[1] ^a

120000	(i) 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	(ii) Pome fruit	
130010	Apples (Crabapple)	[1] ^a
130020	Pears (Oriental pear)	[1] ^a
130030	Quinces	0,1*
130040	Medlar	0,1*
130050	Loquat	0,1*
130990	Others	0,1*
140000	(iv) Stone fruit	
140010	Apricots	[2] ^a
140020	Cherries (sweet cherries, sour cherries)	0,1*
140030	Peaches (Nectarines and similar hybrids)	[2] ^a
140040	Plums (Damsion, greengage, mirabelle)	0,1*
140990	Others	0,1*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	[2] ^a
151010	Table grapes	[2] ^a
151020	Wine grapes	[2] ^a
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) Others 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	Azarole (Mediterranean medlar)	0,1*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (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 (Marumikumquats, naganikumquats)	0,1*
161050	Carambola (Bilimbi)	0,1*
161060	Persimmon	0,1*
161070	Jambolan (Java plum) (Java apple (water apple), pomeraç, 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) (Pulesan, 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 mammeysapote)	0,1*
162990	Others	0,1*
163000	(c) Inedible peel, large	0,1*
163010	Avocados	0,1*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,1*
163030	Mangoes	0,1*
163040	Papaya	0,1*
163050	Pomegranate	0,1*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), lama and other	0,1*

163070	medium sized Annonaceae	0,1*
163080	Guava	0,1*
163090	Pineapples	0,1*
163100	Breadfruit (Jackfruit)	0,1*
163110	Durian	0,1*
163120	Soursop (guanabana)	0,1*
163990	Others	0,1*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,1*
211000	(a) Potatoes	0,1*
212000	(b) Tropical root and tuber vegetables	0,1*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,1*
212020	Sweet potatoes	0,1*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,1*
212040	Arrowroot	0,1*
212990	Others	0,1*
213000	(c) Other root and tuber vegetables except sugar beet	0,1*
213010	Beetroot	0,1*
213020	Carrots	0,1*
213030	Celeriac	0,1*
213040	Horseradish	0,1*
213050	Jerusalem artichokes	0,1*
213060	Parsnips	0,1*
213070	Parsley root	0,1*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,1*
213090	Salsify (Scorzenera, Spanish salsify (Spanish oyster plant))	0,1*
213100	Swedes	0,1*
213110	Turnips	0,1*
213990	Others	0,1*
220000	(ii) Bulb vegetables	0,1*
220010	Garlic	0,1*
220020	Onions (Silverskin onions)	0,1*
220030	Shallots	0,1*
220040	Spring onions (Welsh onion and similar varieties)	0,1*
220990	Others	0,1*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	2

231020	Peppers (Chili peppers)	2
231030	Aubergines (egg plants) (Pepino)	2
231040	Okra, lady's fingers	0,1*
231990	Others	0,1*
232000	(b) Cucurbits - edible peel	0,2
232010	Cucumbers	0,2
232020	Gherkins	0,2
232030	Courgettes (Summersquash, marrow (patisson))	0,2
232990	Others	0,2
233000	(c) Cucurbits - inedible peel	0,2
233010	Melons (Kiwano)	0,2
233020	Pumpkins (Wintersquash)	0,2
233030	Watermelons	0,2
233990	Others	0,2
234000	(d) Sweetcom	0,1*
239000	(e) Other fruiting vegetables	0,1*
240000	(f) Brassica vegetables	
241000	(a) Flowering brassica	1
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	1
241020	Cauliflower	1
241990	Others	1
242000	(b) Head brassica	
242010	Brussels sprouts	0,3
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,5
242990	Others	0,1*
243000	(c) Leafy brassica	2
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (taigoo choi), peking cabbage (pe-tsai), cow cabbage)	2
243020	Kale (Borecole (curly kale), collards)	2
243990	Others	2
244000	(d) Kohlrabi	2
250000	(v) Leafy vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicaceae	
251010	Lamb's lettuce (Italian cornsalad)	0,1*
251020	Lettuce (Head lettuce, lol rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	5
251030	Scarole (broad leaf endive) (Wild chicory, red leaved chicory, radicchio)	0,1*

	curd leaf endive, sugar loaf)	
251040	Cress	0,1*
251050	Land cress	0,1*
251060	Rocket, Rucola (Wild rocket)	0,1*
251070	Red mustard	0,1*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,1*
251990	Others	0,1*
252000	(b) Spinach & similar (leaves)	0,1*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,1*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,1*
252030	Beet leaves (chard) (Leaves of beetroot)	0,1*
252990	Others	0,1*
253000	(c) Vine leaves (grape leaves)	0,1*
254000	(d) Water cress	0,1*
255000	(e) Witloof	0,1*
256000	(f) Herbs	0,1*
256010	Chervil	0,1*
256020	Chives	0,1*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,1*
256040	Parsley	0,1*
256050	Sage (Winter savory, summer savory,)	0,1*
256060	Rosemary	0,1*
256070	Thyme (marjoram, oregano)	0,1*
256080	Basil (Balm leaves, mint, peppermint)	0,1*
256090	Bay leaves (laurel)	0,1*
256100	Tarragon (Hyssop)	0,1*
256990	Others	0,1*
260000	(vi) Legume vegetables (fresh)	0,1*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yard long beans)	0,1*
260020	Beans (without pods) (Broad beans, Figeolets, jack bean, lima bean, cowpea)	0,1*
260030	Peas (with pods) (Mangetout	0,1*

	(sugar peas))	
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,1*
260050	Lentils	0,1*
260990	Others	0,1*
270000	(vii) Stem vegetables (fresh)	0,1*
270010	Asparagus	0,1*
270020	Cardoons	0,1*
270030	Celery	0,1*
270040	Fennel	0,1*
270050	Globe artichokes	0,1*
270060	Leek	0,1*
270070	Rhubarb	0,1*
270080	Bamboo shoots	0,1*
270090	Palm hearts	0,1*
270990	Others	0,1*
280000	(viii) Fungi	0,1*
280010	Cultivated (Common mushroom, Oyster mushroom, Shiitake)	0,1*
280020	Wild (Chanterelle, Truffle, Morel,)	0,1*
280990	Others	0,1*
290000	(ix) Sea weeds	0,1*
300000	3. PULSES, DRY	0,1*
300010	Beans (Broad beans, navy beans, figeolets, jack beans, lima beans, field beans, cowpeas)	0,1*
300020	Lentils	0,1*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1*
300040	Lupins	0,1*
300990	Others	0,1*
400000	4. OILSEEDS AND OIL FRUITS	0,1*
401000	(i) Oilseeds	0,1*
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rapeseed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	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	(ij) Oil fruits	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*
500030	Maize	0,1*
500040	Millet (Foxtail millet, teff)	0,1*
500050	Oats	0,1*
500060	Rice	0,1*
500070	Rye	0,1*
500080	Sorghum	0,1*
500090	Wheat (Spelt, Triticale)	0,1*
500990	Others	0,1*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomile flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*

639000	(c) Other herbal infusions	0,1*
640000	(M) Cocoa (fermented beans)	0,1*
650000	(N) Carob (stjohnsbread)	0,1*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	10
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(i) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(ii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vi) Avil	0,1*

870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0,1*
900010	Sugar beet (root)	0,1*
900020	Sugarcane	0,1*
900030	Chicory roots	0,1*
900990	Others	0,1*
1000000	10. PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	
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	
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	(vi) Other terrestrial animal products	

(*) Indicates lower limit of analytical determination

(^a) previously recommended by EFSA but not yet legally implemented.

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 31						
		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)
30.5	WHO Cluster diet B	12.3	Tomatoes	3.6	Lettuce	2.0	Peppers	5.3
20.0	DE child	4.3	Apples	3.9	Tomatoes	2.5	Oranges	2.8
16.6	NL child	2.5	Tomatoes	2.3	Apples	2.1	Oranges	3.7
15.7	IE adult	1.6	Tomatoes	1.1	Wine grapes	1.1	Aubergines (egg plants)	4.4
14.4	WHO regional European diet	4.4	Tomatoes	3.8	Lettuce	0.8	Potatoes	2.4
13.8	ES child	4.2	Lettuce	3.9	Tomatoes	1.4	Oranges	2.2
13.7	IT kids/toddler	5.7	Tomatoes	2.9	Lettuce	1.3	Wheat	2.3
13.1	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
12.8	IT adult	4.7	Tomatoes	3.8	Lettuce	0.8	Wheat	1.5
11.8	WHO cluster diet D	4.0	Tomatoes	1.3	Wheat	0.8	Potatoes	3.1
11.7	WHO Cluster diet F	3.0	Lettuce	2.7	Tomatoes	0.7	Wheat	2.6
11.4	WHO cluster diet E	2.1	Tomatoes	1.4	Wine grapes	0.9	Lettuce	3.3
11.3	PT General population	3.6	Tomatoes	2.2	Wine grapes	1.1	Potatoes	2.8
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
10.4	DK child	2.1	Tomatoes	1.4	Lettuce	1.1	Wheat	3.2
9.5	FR all population	3.6	Wine grapes	1.7	Tomatoes	0.9	Lettuce	1.4
9.1	NL general	1.7	Tomatoes	1.2	Lettuce	1.0	Oranges	1.7
8.9	UK vegetarian	2.5	Tomatoes	1.4	Lettuce	0.8	Sugar beet (root)	2.0
8.7	UK Infant	2.0	Sugar beet (root)	1.5	Tomatoes	0.9	Oranges	4.6
7.3	PL general population	3.5	Tomatoes	0.7	Apples	0.7	Potatoes	1.0
7.2	UK Adult	1.7	Tomatoes	1.2	Lettuce	1.0	Wine grapes	1.8
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	1.1
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
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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)
	2.7 1.1	Plums Cherries	0.83 / - 0.94 / -	2.2 1.1	Plums Cherries	0.83 / - 0.94 / -	0.8 0.4	Plums Cherries	0.83 / - 0.94 / -	0.6 0.4	Plums Cherries	0.83 / - 0.94 / -
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)
0.5	Plums juice	0.38 / -				

*) 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 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
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
EMS	Evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
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
L	litre
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
OD	oil dispersion
PF	processing factor
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model

RMS	Rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organisation