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Setting of maximum residue levels for spirotetramat in pomegranates and various vegetables

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer SAS CropScience submitted an application to the competent national authority in Austria to modify the maximum residue levels (MRLs) for the active substance spirotetramat in pomegranates and various vegetables. On the basis of the Austrian evaluation report, EFSA concluded that for chicory roots and the crops belonging to the group of other root and tuber vegetables (except sugar beets) the data submitted in support of the MRL application are compliant with the data requirements; for pomegranate, a data gap was identified as regards the storage stability of residue trials. Adequate analytical enforcement methods are available to control the residues of spirotetramat in the plant matrices under consideration. Based on the risk assessment results, EFSA concluded that the proposed uses of spirotetramat on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

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Keywords: spirotetramat, pomegranates, root and tuber vegetables, MRL application, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Austria, received an application from Bayer SAS CropScience to set maximum residue levels (MRLs) for the active substance spirotetramat in pomegranates, all crops belonging to the group of other root and tuber vegetables, except sugar beets, and chicory roots. Austria drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 6 June 2016. Austria proposed to set MRLs for the recently proposed residue definition (i.e. sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat) at 0.4 mg/kg in pomegranates and 0.05 mg/kg in the vegetables.

EFSA bases its assessment on the amended evaluation report submitted by the EMS, the draft assessment report (DAR) and its addendum prepared under Directive 91/414/EEC, the Commission review report on spirotetramat, the conclusion on the peer review of the pesticide risk assessment of the active substance spirotetramat, the Joint Meeting on Pesticide Residues (JMPR) evaluation reports as well as the conclusions from previous EFSA opinions on spirotetramat.

The toxicological profile of spirotetramat was assessed in the framework of the peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.05 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 1.0 mg/kg bw.

The metabolism of spirotetramat in primary crops was investigated in four crop groups following foliar applications. Based on these studies, in 2013, the peer review concluded on a risk assessment residue definition as the 'sum of spirotetramat, spirotetramat-enol, spirotetramat-enol-glucoside, spirotetramat-ketohydroxy and spirotetramat-monohydroxy, expressed as spirotetramat'. For enforcement, the residue definition was limited to the 'sum of spirotetramat, spirotetramat-enol, expressed as spirotetramat'. The current residue definition for enforcement in Regulation (EC) No 396/2005 is wider and comparable to the definition for risk assessment comprising all four metabolites.

EFSA concluded that the submitted residue trials are sufficient to derive MRL proposal for the current residue definition set in Regulation (EC) No 396/2005 of 0.1 mg/kg for carrots and, by extrapolation, for the other root and tuber vegetables (except sugar beets) and chicory roots. For pomegranates, the available studies give an indication that a MRL of 0.5 mg/kg would be appropriate. It is noted the storage period of samples derived in residue trials in pomegranates exceeded the period for which integrity of the samples was demonstrated. A study to address this data gap is currently in progress.

Anticipating that the residue definition for enforcement may be changed in accordance with the recommendation of the peer review, EFSA also derived MRL proposals for the simplified residue definition (i.e. sum spirotetramat, spirotetramat-enol, expressed as spirotetramat).

Adequate analytical enforcement methods are available to monitor the residues of spirotetramat in the commodities under consideration.

For processed commodities, the same residue definition as for raw agricultural commodities is applicable. Processing studies on the crops under consideration were not submitted and are not required considering the low exposure resulting from the intended uses.

The occurrence of spirotetramat residues in rotational crops was investigated in the framework of the peer review. Taking into account that the rotational crop field study was performed with a lower seasonal application rate than the application rate envisaged in the root and tuber vegetables, residues in succeeding crops cannot be fully excluded. Thus, EFSA recommends that the Member States before granting national authorisations should consider the need of defining restrictions in order to avoid residues in succeeding crops.

A change of the existing MRLs in products of animal origin is not required.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). To calculate the chronic exposure, EFSA used median residue values (STMR) derived from the residue trials for the crop under consideration to update the long-term exposure assessment previously performed, taking into account recently assessed Codex maximum residue limits (CXLs). The acute risk assessment was performed only with regard to the crops under consideration.

Long-term or short-term consumer intake concerns were not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake accounted for 22.5% of the ADI (WHO cluster diet B). For the crops under consideration in this MRL application, the highest acute intake was calculated to be 0.6% of the ARfD for pomegranate and 0.5% for carrots. The short-term exposure for the other commodities accounted for less than 0.5% of the ARfD.

EFSA concludes that the proposed uses of spirotetramat on pomegranates, carrots and the other root and tuber vegetables (except sugar beets) and chicory roots will not result in an exposure exceeding the toxicological reference values and therefore are unlikely to pose a health risk to consumers.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)		Comment/justification
		(spi + 4) ^(b)	(spi + 4) ^(b)	(spi + enol) ^(c)	
Existing enforcement residue definition: Spirotetramat and its four metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy and BYI08330 enol-glucoside, expressed as spirotetramat (spi + 4) (R)					
Proposed new enforcement residue definition: Sum of spirotetramat and spirotetramat-enol (spi + enol)					
0163050	Granate apples/ pomegranates	0.1*	Further risk management considerations required		The submitted residue trials support a MRL of 0.5 mg/kg (spi + 4) or 0.4 mg/kg (spi + enol); a data gap was identified with regard to the storage stability of the trials. Applicant made a commitment to perform storage stability studies. No risk for the consumer was identified for the intended SEU use
0213010	Beetroots	0.1*	0.1	0.07	NEU and SEU uses are sufficiently supported and no risk for the consumer was identified. The MRL proposal reflects the more critical residue situation in NEU and was derived by extrapolation from data on carrots
0213020	Carrots	0.1*	0.1	0.07	
0213030	Celeriacs	0.1*	0.1	0.07	
0213040	Horseradishes	0.1*	0.1	0.07	
0213050	Jerusalem artichokes	0.1*	0.1	0.07	
0213060	Parsnips	0.1*	0.1	0.07	
0213070	Parsley roots	0.1*	0.1	0.07	
0213080	Radishes	0.1*	0.1	0.07	
0213090	Salsifies	0.1*	0.1	0.07	
0213100	Swedes	0.1*	0.1	0.07	
0213110	Turnips	0.1*	0.1	0.07	
0213990	Other crops belonging to the group of root and tuber vegetables, except sugar beets	0.1*	0.1	0.07	
0900030	Chicory roots	0.1*	0.1	0.07	

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.

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

(R): The residue definition differs for the following combinations pesticide-code number: Code 1000000, except 1040000: spirotetramat and its metabolite BYI08330-enol expressed as spirotetramat.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(b): spi + 4: MRLs derived according to the current residue definition in Regulation (EC) No 396/2005.

(c): spi + enol: MRLs derived according to the residue definition proposed during the peer review (sum of spirotetramat, spirotetramat-enol, expressed as spirotetramat) not yet implemented in Regulation (EC) No 396/2005.

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Background

Regulation (EC) No 396/2005¹ (hereinafter referred to as 'the Regulation') establishes the rules governing the setting of pesticide maximum residue levels (MRLs) in the European Union (EU). Article 6 of the MRL regulation lays down that commercially interested parties such as manufacturer or importers have to submit an application in accordance with the provisions of Article 7 of the Regulation where the new authorisation of the pesticides requires a modification of the existing MRL.

The competent national authority in Austria, hereafter referred to as the evaluating Member State (EMS), received an application from the company Bayer SAS CropScience² to modify the existing MRLs for the active substance spirotetramat for pomegranates, chicory roots and all crops belonging to the group of other root and tuber vegetables (except sugar beets). This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission and to EFSA on 6 June 2016. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00381 and the following subject:

Spirotetramat – MRLs in various crops

Austria proposed to raise the MRLs for spirotetramat which are currently set at the limit of quantification (LOQ) of 0.1 mg/kg to 0.4 mg/kg for pomegranates and to 0.05 mg/kg for the other crops under consideration.

During the completeness check of the application, EFSA identified some data gaps or points which needed further clarifications. On 4 August 2016, the EMS submitted the reply in an amended evaluation report, which replaces the previous document dated 10 May 2016.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

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

The evaluation report submitted by the EMS (Austria, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and are therefore made publicly available.

In accordance with Article 11 of the Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months (which may be extended to 6 months if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The active substance and its use pattern

Spirotetramat is the ISO common name for the isomer *cis*-4-(ethoxycarbonyloxy)-8-methoxy-3-(2,5-xylyl)-1-azaspiro[4.5]dec-3-en-2-one (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix B.

The details of the intended uses for spirotetramat (intended good agricultural practices (GAPs)), which are the basis for the MRL application, are reported in Appendix A.

Spirotetramat is an active substance approved in accordance with Regulation (EC) No 1107/2009³ and included in the Annex of Regulation (EU) No 540/2011⁴ by Regulation (EU) No 1177/2013⁵, which entered into force on 1 May 2014 for use as an insecticide. The representative uses evaluated in the

¹ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

² Bayer SAS CropScience, 16 rue Jean-Marie Leclair, 69009 Lyon, France.

³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

⁴ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

⁵ Commission Implementing Regulation (EU) No 1177/2013 of 20 November 2013 approving the active substance spirotetramat, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 312, 21.11.2013, p. 28–32.

peer review were foliar applications on citrus and lettuce. The draft assessment report (DAR) has been peer reviewed by EFSA (EFSA, 2013a).

The EU MRLs for spirotetramat are established in Annex III of Regulation (EC) No 396/2005. Since the entry into force of the MRL regulation, EFSA has issued several reasoned opinions on the modification of MRLs for spirotetramat, the most recent being an MRL application for small fruits and berries, kaki, kiwi and artichokes (EFSA, 2016a). The Article 12 MRL review for spirotetramat is in progress.

Assessment

EFSA has based its assessment on the amended evaluation report submitted by the EMS (Austria, 2016), the DAR and its addendum prepared under Directive 91/414/EEC (Austria, 2008, 2013), the Commission review report on spirotetramat (European Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance spirotetramat (EFSA, 2013a), the Joint Meeting on Pesticide Residues (JMPR) evaluation reports (FAO, 2008, 2011, 2015), as well as the conclusions from previous EFSA opinions and scientific reports on spirotetramat (EFSA, 2009a,b, 2012, 2013b,c, 2016a,b). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁶ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2015; OECD, 2011, 2013).

1. Method of analysis

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

The commodities under consideration belong to the crop group with high water and high acid content; a sufficiently validated analytical method is available to enforce spirotetramat and spirotetramat-enol (residue definition proposed by the peer review) at a LOQ of 0.02 mg/kg (0.01 mg/kg per analyte) in these matrices (EFSA, 2013a).

The current residue definition set in the MRL regulation covers spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside. A high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) analytical method was reported in the DAR which is appropriate to analyse all components of the residue definition. The method has been reported to be validated in matrices with high water (tomato, potato) and high acid content (citrus) at a LOQ of 0.05 mg/kg (Austria, 2008, 2013).

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

Analytical methods for the determination of residues in food of animal origin are not assessed since a change of the existing MRLs is not proposed for the uses of spirotetramat in the crops under evaluation which may be fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance spirotetramat was assessed in the framework of the peer review under Regulation (EC) No 1107/2009 (EFSA, 2013a; European Commission, 2013). The data were sufficient to derive toxicological reference values compiled in Table 1.

Table 1: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Spirotetramat					
ADI	European Commission	2013	0.05 mg/kg bw per day	Dog, 1-year study	100
ARfD		2013	1.0 mg/kg bw	Rat, acute neurotoxicity	100

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

⁶ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

The peer review concluded that the toxicological reference values set for spirotetramat are applicable to spirotetramat-enol and spirotetramat-enol-glucoside and that spirotetramat-ketohydroxy and spirotetramat-monohydroxy are unlikely to be more toxic than spirotetramat (EFSA, 2013a).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of spirotetramat in primary crops was evaluated in the framework of the peer review (Austria, 2008; EFSA, 2013a) and by the JMPR (FAO, 2008). An overview of the key parameters of the available metabolism studies is presented in Table 2.

Table 2: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling ^(a)	Comments
Fruit	Apple	Foliar: 2 × 576 g/ha, BBCH 69/71	63 DALA	Total: 1,100 g/ha
Root	Potato	Foliar: 3 × 96 g/ha, BBCH 75, 85, 93	14 DALA	Total: 308 g/ha
Leafy	Lettuce	Foliar: 2 × 72 g/ha, BBCH 41/45	7 DALA	Total: 167 g/ha
Pulses/oilseeds	Cotton	Foliar: 2 × 92/172 g/ha, BBCH 15/85	19 DAT ₁ , 39 DALA	Total: 264 g/ha

BBCH: growth stages of mono- and dicotyledonous plants.

(a): DALA, days after last application; DAT₁, days after first treatment.

Based on these studies and considering that spirotetramat was not stable under frozen storage conditions where it degraded to spirotetramat-enol, the residue definition for enforcement was proposed as 'sum spirotetramat, spirotetramat-enol, expressed as spirotetramat'. For risk assessment, the residue definition was concluded as the 'sum of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside, expressed as spirotetramat' (EFSA, 2013a).

The residue definition for enforcement currently set under Regulation (EC) No 396/2005 includes the four spirotetramat metabolites and it is therefore similar to the residue definition proposed for risk assessment in the conclusion of the peer review.

3.1.1.2. Magnitude of residues

In support of the MRL application, supervised residue trials conducted on pomegranates and carrots (for extrapolation to other vegetables) with the suspension concentrate (SC) formulation were submitted. The intended GAPs foresee also the use of the oil dispersion (OD) formulation. The comparative trials on two crop groups (fruit and leafy) submitted by the applicant showed that the different formulations did not influence residue behaviour significantly. The same conclusion was achieved on a third crop group (oilseeds) from side-by-side trials comparing residues in soyabean seeds (EFSA, 2010).

All samples were analysed for spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside. EFSA derived MRL proposals according to the residue definition for enforcement currently still in place (hereafter referred to as 'spi + 4') and the proposed new residue definition (referred to as 'spi + enol').

a. Pomegranates GAP: 2 × 150 g/ha, preharvest interval (PHI) 14 days (southern Europe (SEU))

Based on four GAP-compliant residue trials, EFSA derived a MRL proposal of 0.5 mg/kg (spi + 4) and 0.4 mg/kg (spi + enol).

b. Carrots and the other root and tuber vegetables GAP: 4 × 75 g/ha, PHI 21 days (northern Europe (NEU)/SEU)

Eight GAP-compliant residue trials on carrots in NEU and SEU were submitted. The statistical test for comparability of the NEU and SEU data has limited power due to the high level of censored data. Additionally, the MRLs calculated individually differ significantly.⁷ Thus, EFSA did not merge the two

⁷ The calculated MRL did not fall in the same MRL or in neighbouring MRL classes (European Commission, 2015).

data sets; the MRL proposals are based on the more critical residue situation in NEU use (0.1 mg/kg (spi + 4) and 0.07⁸ mg/kg (spi + enol)).

According to the EU extrapolation rules (European Commission, 2015), results from trials on carrots can be extrapolated to the whole group of other root and tuber vegetables.

c. Chicory roots GAP: 4 × 75 g/ha, PHI 21 days (NEU/SEU)

According to the EU extrapolation rules (European Commission, 2015), results from trials on carrots can be extrapolated to chicory roots. Based on the more critical residue situation in NEU use, the MRL of 0.1 mg/kg (spi + 4) and 0.07 mg/kg (spi + enol) is proposed for chicory roots.

The results of the residue trials, the median (STMR) and highest (HR) residue values and the MRL proposals derived according to the residue definition as (spi + 4) and limited to (spi + enol) are summarised in Table 3.

Spirotetramat was shown to degrade to spirotetramat-enol under frozen conditions in plant matrices (Austria, 2008; EFSA, 2013a, 2016a). However, it was concluded that in high water, high water/starch and high oil content matrices storage stability for the sum of spirotetramat and spirotetramat-enol for at least 18 months was sufficient. Stability in high acid content matrices (orange juice) was demonstrated for a period up to 5 months. In tomato fruit and tomato paste, storage stability was demonstrated for up to 18 months (sum of spirotetramat and spirotetramat-enol). Although tomatoes are, according to the EU guidance document, a commodity with high water content, the pH of tomatoes and tomato paste has an acidity close to the crops classified as high acid commodities. However, the extrapolation of storage stability results was not recommended, considering the overall low stability (EFSA, 2016a).

As the samples from the residue trials on carrots were stored for a maximum period of 17 months under conditions for which integrity of the samples was demonstrated, it is concluded that these residue data are valid with regard to storage stability. The samples from the residue trials on pomegranates were stored for a period exceeding the demonstrated storage stability in high acid content commodities (between 7 and 14 months). The applicant informed the EMS that a storage stability study for acidic commodities is in progress; interim results for 14 months storage period will be available in December 2017. The final study will be available in 2019 (Austria, 2016).

According to the EMS, the analytical methods used to analyse the residue trial samples have been sufficiently validated and were proven to be fit for the purpose (Austria, 2016).

Conversion factors (CF) from enforcement to risk assessment were calculated from each individual trial at the different preharvest intervals (Austria, 2016). At the intended PHI, the median CF of 1.5 for pomegranates and 2.1 from carrots (from the three trials with measurable residues at PHI of 21 days) are obtained. Thus, these data confirm the previously proposed overall default CF of 2 (EFSA, 2013a, 2016a).

⁸ The EMS proposed the MRL of 0.05 mg/kg for the residue definition (spi + enol) only by combining the NEU and SEU data sets.

Table 3: Overview of the available residues trials data

Crop (GAPs)	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials ^(b) (mg/kg)	Recommendations/ comments ^(c)	MRL proposal (mg/kg)	HR ^(d) (mg/kg)	STMR ^(e) (mg/kg)
Residue definition for enforcement and risk assessment in plants: Spirotetramat and its four metabolites BY108330-enol, BY108330-ketohydroxy, BY108330-monohydroxy and BY108330 enol-glucoside, expressed as spirotetramat (Regulation (EU) No 396/2005)						
Pomegranates (2 × 150 g/ha, PHI 14 days)	SEU	Mo/RA: 0.05; 0.20; 0.20; 0.23 ^(f)	MRL _{OECD} 0.51/0.50 Data gap regarding storage stability	0.5	0.23	0.20
	NEU SEU	Mo/RA: 6 × < 0.05; 0.06; 0.08 Mo/RA: 7 × < 0.05; 0.06	MRL _{OECD} 0.10/0.10 (NEU) MRL _{OECD} 0.07/0.07 (SEU) Extrapolation to the other root and tuber vegetables, except sugar beets Extrapolation to chicory roots	0.1 0.07	0.08 0.06	0.05 0.05
Enforcement residue definition for plants: Sum spirotetramat, spirotetramat-enol expressed as spirotetramat (EFSA, 2013a, 2016a,b)						
Residue definition for risk assessment in plants: Spirotetramat and its four metabolites BY108330-enol, BY108330-ketohydroxy, BY108330-monohydroxy and BY108330 enol-glucoside, expressed as spirotetramat						
Pomegranates (2 × 150 g/ha, PHI 14 days)	SEU	Mo: 0.02; 0.14; 0.16; 0.15 ^(f) ; RA: 0.05; 0.20; 0.20; 0.23 ^(f)	MRL _{OECD} : 0.38/0.40 Data gap regarding storage stability	0.4	0.23	0.20
	NEU SEU	Mo: 6 × < 0.02; 0.03; 0.05 RA: 6 × < 0.05; 0.06; 0.08 Mo: 7 × < 0.02; 0.03 RA: 7 × < 0.05; 0.06	MRL _{OECD} : 0.06/0.07 (NEU) MRL _{OECD} : 0.03/0.03 (SEU) Extrapolation to the other root and tuber vegetables, except sugar beets Extrapolation to chicory roots	0.07 0.03	0.08 0.06	0.05 0.05

PHI: preharvest interval; MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Individual residue levels considered for MRL calculation are reported in ascending order.

Mo: Residue level according to the monitoring residue definition.

RA: Residue level according to the residue definition for risk assessment

(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values).

(d): HR: Highest residue level according to the residue definition for risk assessment.

(e): STMR: Median residue level according to residue definition for risk assessment.

(f): Residue from sample taken at a longer PHI (21 days) than the intended PHI.

3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies with spirotetramat and its metabolites were assessed during the peer review; based on these studies, the same residue definition as for raw agricultural commodities (RAC) was set for processed commodities (EFSA, 2013a).

Specific studies on the magnitude of spirotetramat residues in the processed vegetables under concern are not required as residue levels in the RAC are below the trigger value of 0.1 mg/kg (European Commission, 1997d). The distribution of residues in peel and pulp of pomegranates was not investigated.

Several processing factors (PF) in fruit and vegetable processed products were derived in the framework of the peer review and previous MRL applications (EFSA, 2009a,b, 2013a,c, 2016a) and in processed potato products in the evaluation report (Austria, 2016). The individual PFs for potato waste and dry pulp, which are relevant for the dietary burden calculation in livestock, are summarised in Table 4.

Table 4: Overview of the available processing studies relevant for the dietary burden calculation

Crop (RAC), processed product	Number of studies	Processing factor (PF)		Median PF		Conversion factor (CF _P) for RA ^(a)
		Individual values				
Residue definition		(spi + enol)	(spi + 4)			
Potato, processed waste	1	0.76	1.20	–	–	1.58
Potato, dry pulp	1	1.19	1.13	–	–	0.94

RAC: raw agricultural commodity; RA: risk assessment.

(a): When the residue definition for risk assessment (spi + 4) differs from the residue definition for monitoring (spi + enol).

3.1.2. Rotational crops

Studies on the nature and magnitude of spirotetramat residues in rotational crops were assessed in the framework of the peer review (Austria, 2008; EFSA, 2013a). It was concluded that the residue definitions set for primary crops are also applicable to rotational crops and that significant residues are not expected in rotational crops at 30 days plant-back interval when the active substance is applied on primary crops up to a total application rate of 180 kg a.s./ha (0.6N the intended seasonal application rate on carrots and the other vegetables under assessment).

Taking into account that the rotational crop field study was performed with a lower application rate, residues in succeeding crops cannot be fully excluded. Therefore, EFSA recommends that the Member States before granting national authorisations consider the need of defining restrictions in order to avoid residues in succeeding crops.

3.2. Nature and magnitude of residues in livestock

Since carrots, swedes and turnips might be fed to livestock, the nature and magnitude of spirotetramat residues in livestock was assessed in the framework of this MRL application (European Commission, 1996).

3.2.1. Dietary burden of livestock

EFSA calculated the indicative median and maximum dietary burden for livestock using the animal feedstuff Table reported in the OECD guidance document (OECD, 2009) and the animal model calculator developed by EFSA. EFSA considered the livestock intake from the feed products under assessment and the feed products on which there are currently authorised uses of spirotetramat (e.g. for which the existing EU MRL is set above the LOQ: citrus, coconuts, apples, potatoes, head cabbages, kale, legumes, pulses, soyabean and cotton seeds). Residue data for turnip leaves were not available. To refine the calculation, EFSA used the risk assessment values reported in a previous reasoned opinion (EFSA, 2016a) or by the JMPR (FAO, 2008, 2011). For processed products where no PF was available (Table 4; EFSA, 2016a; FAO, 2008, 2011), default PFs were used to estimate the residue levels in the feed items. The input values for the dietary burden calculation are summarised in Table 5. Considering that the comprehensive MRL review under Art. 12 of the Regulation has not yet been performed, the calculations should be considered as indicative only.

Table 5: Input values for the dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Cabbage head	0.23	STMR (EFSA, 2016a)	0.92	HR (EFSA, 2016a)
Kale leaves	3.7	STMR (EFSA, 2016a)	5.5	HR (EFSA, 2016a)
Carrot cull	0.05	STMR (carrot, NEU)	0.08	HR (carrot, NEU)
Potato cull	0.12	STMR (EFSA, 2016a)	0.46	HR (EFSA, 2016a)
Swede, Turnip root	0.05	STMR (carrot, NEU)	0.08	HR (carrot, NEU)
Bean seed (dry)	0.21	STMR (EFSA, 2016a)		
Cotton seed	0.1	STMR (EFSA, 2016a)		
Cowpea seed	0.21	STMR (EFSA, 2016a)		
Lupin seed	0.21	STMR (EFSA, 2016a)		
Pea seed (dry)	0.21	STMR (EFSA, 2016a)		
Soyabean seed	0.45	STMR (EFSA, 2016a)		
Apple (wet) pomace	0.32	STMR (EFSA, 2016a) × PF (EFSA, 2013a)	(0.17 × 1.9)	
Citrus, dry pulp	0.43	STMR × PF (FAO, 2008)	(0.33 × 1.3)	
Coconut meal	0.13	STMR (EFSA, 2016a) × default PF	(0.084 × 1.5)	
Cotton meal	0.12	STMR × PF (FAO, 2011)	(0.095 × 1.25)	
Lupin seed meal	0.23	STMR (EFSA, 2016a) × default PF	(0.21 × 1.1)	
Potato, waste	0.14	STMR × PF (Table 5)	(0.12 × 1.20)	
Potato, dry pulp	0.14	STMR × PF (Table 5)	(0.12 × 1.13)	
Soyabean meal	0.62	STMR × PF (FAO, 2011)	(0.45 × 1.37)	
Soyabean hulls	0.40	STMR × PF (FAO, 2011)	(0.45 × < 1)	

HR: highest residue; STMR: supervised trials median residue; PF: processing factor; FAO: Food and Agriculture Organization of the United Nations; NEU: northern Europe.

The results of the dietary burden calculation are summarised in Table 6.

Table 6: Results of the dietary burden calculation

Animals	Median dietary burden	Maximum dietary burden (MDB)	Above trigger (> 0.1 mg/kg DM)	Maximum burden	Highest contributing commodities	
	(mg/kg bw)	(mg/kg bw)		(mg/kg DM)		
Beef cattle	0.135	0.205	Yes	8.55	Kale	Leaves
Dairy cattle	0.212	0.324	Yes	8.43	Kale	Leaves
Ram/Ewe	0.106	0.163	Yes	4.89	Kale	Leaves
Lamb	0.126	0.190	Yes	4.47	Kale	Leaves
Pig (breeding)	0.071	0.118	Yes	5.11	Kale	Leaves
Pig (finishing)	0.018	0.044	Yes	1.45	Potato	Culls
Poultry broiler	0.030	0.042	Yes	0.60	Potato	Culls
Poultry layer	0.026	0.053	Yes	0.78	Cabbage	Leaves
Turkey	0.036	0.060	Yes	0.84	Potato	Culls

bw: body weight; DM: dry matter.

The calculated dietary burden calculated exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all animal species. However, the crops under consideration were only minor contributors which do not change the total exposure of livestock significantly. Thus, EFSA concluded that in the framework of this MRL application there is no need to perform a detailed assessment of the residue situation in food of animal origin. A comprehensive re-evaluation of pesticide residues expected in food of animal origin should be performed in the framework of the MRL review under Article 12 of the Regulation.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population⁹ (EFSA, 2007).

To calculate the chronic exposure, EFSA used median residue values (STMR) derived from the residue trials for the crop under consideration and reported in Table 3 to update the long-term exposure assessment previously performed, taking into account recently assessed Codex maximum residue limits (CXLs) (EFSA, 2016a,b).

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest residue (HR) level as observed in supervised field trials (Table 3). A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 7.

Table 7: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition for plant products: Sum spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside, expressed as spirotetramat				
Pomegranate	0.20	STMR	0.23	HR
Carrots	0.05	STMR (carrots, NEU)	0.08	HR (carrots, NEU)
Other root and tuber vegetables, except sugar beets ^(a)	0.05	STMR (carrots, NEU)	0.08	HR (carrots, NEU)
Chicory roots	0.05	STMR (carrots, NEU)	0.08	HR (carrots, NEU)
Guava	0.55	STMR (FAO, 2015)	Acute risk assessment undertaken only with regard to the crops under consideration	
Sweet corns	0.31	STMR (FAO, 2015)		
Other plant origin commodities	See table 10a (Input values for the consumer exposure assessment (plant products)) of the Reasoned Opinion on the modification of the existing MRLs for spirotetramat in various crops (EFSA, 2016a)			
Risk assessment residue definition for animal products: Sum of spirotetramat-enol and spirotetramat-enol-GA, expressed as spirotetramat				
Animal products	See table 10b (Input values for the consumer exposure assessment (animal products)) of the previously published opinion of EFSA (EFSA, 2016a)			

HR: highest residue; STMR: supervised trials median residue; FAO: Food and Agriculture Organization of the United Nations; NEU: northern Europe.

(a): Beetroots, celeriacs, horseradish, Jerusalem artichokes, parsnips, parsley roots, radishes, salsifis, swedes and turnips.

The estimated exposure was then compared with the toxicological reference values derived for spirotetramat (Table 1). The result of the intake calculation using the EFSA PRIMo is a key supporting document and is made publicly available as a background document to this reasoned opinion.

No long-term and short-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake accounted for 22.5% of the acceptable daily intake (ADI) (WHO cluster diet B), with carrots being the highest contributor to the chronic intake (0.3% of the ADI) among the crops under consideration. For the crops under consideration in this MRL application, the highest acute intake was calculated to be 0.6% of the acute

⁹ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from the Member States surveys plus one regional and four cluster diets from the WHO GEMS Food database; for the acute exposure assessment, the most critical large portion consumption data from 19 national diets collected from Member States surveys are used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

reference dose (ARfD) for pomegranates (British toddler) and 0.5% for carrots. The short-term exposure for the other commodities accounted for less than 0.5% of the ARfD.

EFSA concludes that the intended uses of spirotetramat in beetroots, celeriacs, horseradish, Jerusalem artichokes, parsnips, parsley roots, radishes, salsifies, swedes, turnips and chicory roots will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a concern for public health. For pomegranate, no intake concern was identified either. However, lacking a storage stability study for high acid commodities covering the whole period of sample storage of the pomegranate residue trials, the results are affected by an additional uncertainty element.

Conclusions and recommendations

The information submitted was sufficient to propose the MRLs summarised in the table below:

Code ^(a)	Commodity	Existing EU MRL (mg/kg) (spi + 4) ^(b)	Proposed EU MRL (mg/kg)		Comment/justification
			(spi + 4) ^(b)	(spi + enol) ^(c)	
Existing enforcement residue definition: Spirotetramat and its four metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-mono-hydroxy and BYI08330 enol-glucoside, expressed as spirotetramat (spi + 4) (R)					
Proposed new enforcement residue definition: Sum of spirotetramat and spirotetramat-enol (spi + enol)					
0163050	Granate apples/ pomegranates	0.1*	Further risk management considerations required		The submitted residue trials support a MRL of 0.5 mg/kg (spi + 4) or 0.4 mg/kg (spi + enol); a data gap was identified with regard to the storage stability of the trials. Applicant made a commitment to perform storage stability studies. No risk for the consumer was identified for the intended use
0213010	Beetroots	0.1*	0.1	0.07	NEU and SEU uses are sufficiently supported and no risk for the consumer was identified The MRL proposal reflects the more critical residue situation in NEU and was derived by extrapolation from data on carrots
0213020	Carrots	0.1*	0.1	0.07	
0213030	Celeriacs	0.1*	0.1	0.07	
0213040	Horseradishes	0.1*	0.1	0.07	
0213050	Jerusalem artichokes	0.1*	0.1	0.07	
0213060	Parsnips	0.1*	0.1	0.07	
0213070	Parsley roots	0.1*	0.1	0.07	
0213080	Radishes	0.1*	0.1	0.07	
0213090	Salsifies	0.1*	0.1	0.07	
0213100	Swedes	0.1*	0.1	0.07	
0213110	Turnips	0.1*	0.1	0.07	
0213990	Others root and tuber vegetables, except sugar beets	0.1*	0.1	0.07	
0900030	Chicory roots	0.1*	0.1	0.07	

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.

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

(R): The residue definition differs for the following combinations pesticide-code number: Code 1000000, except 1040000: spirotetramat and its metabolite BYI08330-enol expressed as spirotetramat.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(b): spi + 4: MRLs derived according to the current residue definition in Regulation (EC) No 396/2005.

(c): spi + enol: MRLs derived according to the residue definition proposed during the peer review (sum of spirotetramat, spirotetramat-enol, expressed as spirotetramat) not yet implemented in Regulation (EC) No 396/2005.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DAT ₁	days after first treatment.
DM	dry matter
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MDB	maximum dietary burden
MRL	maximum residue level
MW	molecular weight
NEU	northern Europe
OD	oil dispersion
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RAC	raw agricultural commodity
RMS	rapporteur Member State
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
WHO	World Health Organization

Appendix A – Good Agricultural Practice

Crop	NEU, SEU, MS or country	F, G or I (a)	Pests or Group of pests controlled	Preparation		Application			Application rate per treatment			PHI (days) ^(d)	Remarks	
				Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min-max	Interval between application	g/hL min-max	Water L/ha min-max			g/ha min-max
Pomegranates	SEU	F	Sucking pests	SC	100 g/L	Spraying	BBCH 69-81	2	14 days	30	500-1000	150	14	–
				OD	150 g/L		BBCH 69-89							
Carrots, other roots and tuber vegetables (except sugar beets), chicory roots	NEU	F	Sucking pests	SC	100 g/L	Spraying	BBCH 12-49	4	14 days	38	200-800	75	21	–
				OD	150 g/L									
	SEU	F	Sucking pests	SC	100 g/L	Spraying	BBCH 12-49	4	14 days	38	200-800	75	21	–
				OD	150 g/L									

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate; OD: oil dispersion.

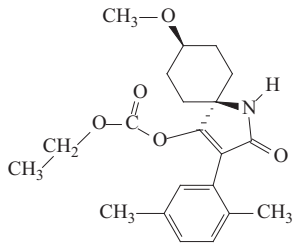
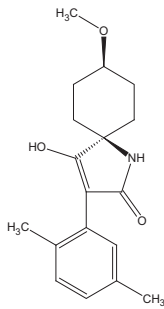
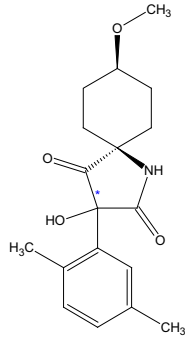
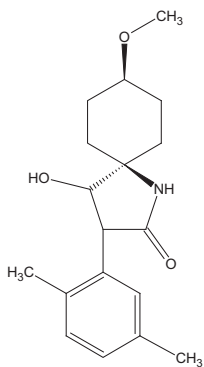
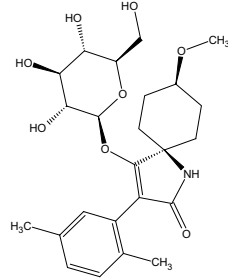
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

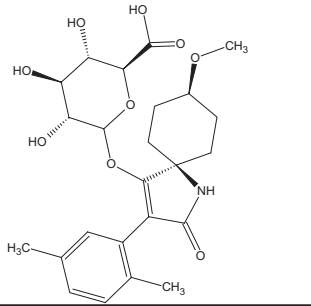
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.

Appendix B – Used compound codes

Trivial name/code	Chemical name	Structural formula
Spirotetramat (BYI 08330)	<i>cis</i> -4-(Ethoxycarbonyloxy)-8-methoxy-3-(2,5-xyllyl)-1-azaspiro[4.5]dec-3-en-2-one MW: 373.45 g/mol	
Spirotetramat-enol (BYI 08330-enol)	(5 <i>S</i> ,8 <i>S</i>)-3-(2,5-Dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one MW: 301.38 g/mol	
Spirotetramat-ketohydroxy (BYI 08330- <i>cis</i> -ketohydroxy)	(5 <i>S</i> ,8 <i>S</i>)-3-(2,5-Dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione Enantiomer composition unspecified MW: 317.38 g/mol	
Spirotetramat-monohydroxy (BYI 08330-monohydroxy)	(5 <i>S</i> ,8 <i>S</i>)-3-(2,5-Dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2-one Isomer composition unspecified MW: 303.40 g/mol	
Spirotetramat-enol-glucoside Spirotetramat-enol-Glc (BYI 08330-enol-Glc)	(5 <i>S</i> ,8 <i>S</i>)-3-(2,5-Dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl β-D-glucopyranoside MW: 463.52 g/mol	

Trivial name/code	Chemical name	Structural formula
Spirotetramat-enol-GA (BYI 08330-enol-GA)	(5 <i>S</i> ,8 <i>S</i>)-3-(2,5-Dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl β -glucopyranosiduronic acid	 The image shows the chemical structure of Spirotetramat-enol-GA. It consists of a spirocyclic core where a 2,5-dimethylphenyl group is attached to a 1-azaspiro[4.5]decane system. This system is further substituted with a methoxy group and a 2-oxo group. The spiro ring is linked to a D-glucopyranosiduronic acid moiety via an enol linkage. The glucose ring has hydroxyl groups at the 2, 3, and 6 positions, and a methoxy group at the 8 position.

MW: molecular weight.