

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for spinosad in celery, fennel, raspberries and blackberries¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS-BE), compiled an application to modify the existing MRLs for the active substance spinosad in celery and fennel. In order to accommodate for the intended use of spinosad, Belgium proposed to raise the existing MRLs from the value of 2 mg/kg on celery and 0.2 mg/kg on fennel to 5 mg/kg. Belgium 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 EFSA. In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, hereafter referred to as the evaluating Member State (EMS-UK), received an application from the Horticultural Development Company to modify the existing MRLs for the active substance spinosad in raspberries and blackberries. In order to accommodate for the intended use of spinosad, the United Kingdom proposed to raise the existing MRLs in both berries from 0.3 mg/kg to 1.5 mg/kg. The United Kingdom 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 EFSA. For reasons of efficiency EFSA combined both applications in one reasoned opinion. According to EFSA the data are sufficient to derive a MRL proposal of 1.5 mg/kg for the intended indoor use on raspberries and blackberries in the United Kingdom and of 5 mg/kg for the intended indoor use on celery and fennel in Belgium, whereas the intended outdoor use on celery and fennel is not adequately supported by residue data and no MRL is therefore proposed. Adequate analytical enforcement methods are available to control the residues of spinosad in the crops under consideration at the validated combined LOQ of 0.02 mg/kg. Based on the risk assessment results, EFSA concludes that the proposed use of spinosad on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

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KEY WORDS

Spinosad, celery, fennel, raspberries and blackberries, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, spinosyn class.

¹ On request from European Commission, Question No EFSA-Q-2011-01261 and EFSA-Q-2012-00608, approved on 12 June 2012

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS-BE), compiled an application to modify the existing MRLs for the active substance spinosad in celery and fennel. In order to accommodate for the intended use of spinosad, Belgium proposed to raise the existing MRLs from the value of 2 mg/kg on celery and 0.2 mg/kg on fennel to 5 mg/kg. Belgium 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 EFSA on 29 November 2011.

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, hereafter referred to as the evaluating Member State (EMS-UK), received an application from the Horticultural Development Company to modify the existing MRLs for the active substance spinosad in raspberries and blackberries. In order to accommodate for the intended use of spinosad, the United Kingdom proposed to raise the existing MRLs in both berries from 0.3 mg/kg to 1.5 mg/kg. The United Kingdom 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 EFSA on 24 May 2012.

For reasons of efficiency EFSA combined both applications in one reasoned opinion. EFSA bases its assessment on the evaluation reports submitted by the EMS-BE and EMS-UK, the Draft Assessment Report (DAR) and its addenda prepared under Council Directive 91/414/EEC, the Commission Review Report on spinosad, the JMPR Evaluation reports as well as the conclusions from previous EFSA opinions, including the EFSA reasoned opinion on the review of the existing MRLs for spinosad according to Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of spinosad was evaluated in the framework of Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.024 mg/kg bw per day. No ARfD value was deemed necessary for spinosad.

The metabolism of spinosad in primary crops was investigated in grapes, apples, tomatoes, cabbage, turnips and cotton, covering four different crop groups. The review of the existing MRLs for spinosad performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review that the relevant residue for enforcement and risk assessment in all plant commodities treated by foliar application is spinosad (sum of spinosyn A and spinosyn D). EFSA proposed to delete the indication that the residues should be expressed in spinosad equivalents reported in Regulation (EC) No 396/2005. For the uses under consideration EFSA concludes that the metabolism of spinosad is sufficiently addressed and that the residue definition for enforcement and risk assessment as proposed in the previous EFSA reasoned opinion on MRL review are applicable.

EFSA considers that the submitted supervised residue trials are sufficient to derive a MRL proposal of 1.5 mg/kg for the intended indoor use on raspberries and blackberries in the United Kingdom and of 5 mg/kg for the intended indoor use on celery and fennel in Belgium, whereas the intended outdoor use on celery and fennel is not adequately supported by residue data and no MRL is therefore proposed. Adequate analytical enforcement methods are available to control the residues of spinosad in the crops under consideration at the validated combined LOQ of 0.02 mg/kg.

Studies on the nature and magnitude of spinosad in processed commodities are not available and were considered necessary in the framework of Article 12 review.

Celery and fennel can be grown in a crop rotation and therefore the nature and magnitude of spinosad residues in rotational/succeeding crops has to be further investigated. Based on the available information on the nature and magnitude of residues in succeeding crops, EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that the spinosad is used according to the proposed GAP (Good Agricultural Practice).

Nature and magnitude of spinosad residues in livestock were not assessed since the crops under consideration are not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). In the framework of the review of the existing MRLs for spinosad according to Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account the existing uses of spinosad at EU level supported by data and the existing acceptable Codex limits (CXLs). EFSA now updates this risk assessment with the median residue value as derived from the supervised residue trials on raspberries and celery. No acute consumer risk assessment was performed because of the low acute toxicity of spinosad.

It is noted that the long-term consumer exposure calculation is based on the conclusions and recommendations derived in the review of the existing MRLs for spinosad under Article 12 of Regulation (EC) No 396/2005. Under the assumption that the MRLs will be amended as proposed in the Article 12 review, no long-term consumer intake concerns were identified. The total calculated intake accounted for 57 % of the ADI. The contribution of residues on the crops under consideration to the total consumer exposure was very low, accounting with respect to the ADI for a maximum of 0.18 % on raspberries, 0.17 % on blackberries, 0.35 % on celery and 0.26 % on fennel.

EFSA concludes that the proposed use of spinosad on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

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

Summary table

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Proposed enforcement residue definition: Spinosad (sum of spinosyn A and spinosyn D) (F)				
153010	Blackberries	0.3	1.5	The MRL proposals are sufficiently supported by data on raspberries and no risk for consumers was identified for the intended use.
153030	Raspberries	0.3	1.5	
270030	Celery	2	5	The MRL proposals are sufficiently supported by data on celery and no risk for consumers was identified for the intended indoor use. The outdoor use is not sufficiently supported by data.
270040	Fennel	0.2	5	

(a): According to Annex I of Regulation (EC) No 396/2005.

(F): Fat-soluble pesticide.

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BACKGROUND

Regulation (EC) No 396/2005³ establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

Belgium, hereafter referred to as the evaluating Member State (EMS-BE), compiled an application to modify the existing MRLs for the active substance spinosad in celery and fennel. This application was notified to the European Commission and EFSA and was subsequently evaluated in accordance with Article 8 of the Regulation.

The United Kingdom, hereafter referred to as the evaluating Member State (EMS-UK), received an application from the Horticultural Development Company⁶ to modify the existing MRLs for the active substance spinosad in raspberries and blackberries. This application was notified to the European Commission and EFSA and was subsequently evaluated in accordance with Article 8 of the Regulation.

After completion, the evaluation reports were submitted to the European Commission who forwarded the applications, the evaluation reports and the supporting dossiers to EFSA on 29 November 2011 and 24 May 2012, respectively.

The applications were included in the EFSA Register of Questions with the reference numbers EFSA-Q-2011-01261 and EFSA-Q-2012-00608 and the following subjects:

Spinosad - Application to modify the existing MRLs in celery and fennel.

Spinosad - Application to modify the existing MRLs in raspberries and blackberries.

Belgium proposed to raise the existing MRLs of spinosad in celery and fennel from the value of 2 mg/kg and 0.2 mg/kg, respectively, to 5 mg/kg, whereas the United Kingdom proposed to raise the existing MRLs of spinosad in raspberries and blackberries from 0.3 mg/kg to 1.5 mg/kg.

EFSA proceeded with the assessment of the applications and the evaluation reports as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with 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.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) 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 deadlines for providing the reasoned opinion are 29 February 2012 and 24 August 2012, respectively.

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

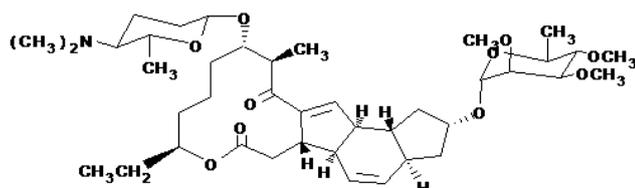
⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.

⁶ Horticultural Development Company, Bradbourne House, ME19 6DZ, East Malling, United Kingdom.

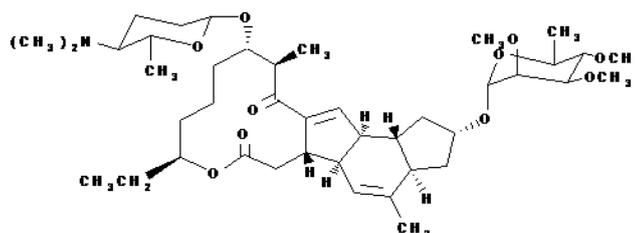
THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Spinosad is the ISO common name for a mixture of spinosyn A and spinosyn D (in a ratio between 95:5 and 50:50). The IUPAC names are as follows:

- 2*R*,3*aS*,5*aR*,5*bS*,9*S*,13*S*,14*R*,16*aS*,16*bR*)-2-(6-deoxy-2,3,4-tri-*O*-methyl- α -*L*-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy- β -*D*-erythro-pyranosyloxy)-9-ethyl-2,3,3*a*,5*a*,5*b*,6,7,9,10,11,12,13,14,15,16*a*,16*b*-hexadeca-hydro-14-methyl-1*H*-as-indaceno[3,2-*d*]oxacyclododecine-7,15-dione (spinosyn A);



- 2*S*,3*aR*,5*aS*,5*bS*,9*S*,13*S*,14*R*,16*aS*,16*bS*)-2-(6-deoxy-2,3,4-tri-*O*-methyl- α -*L*-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy- β -*D*-erythro-pyranosyloxy)-9-ethyl-2,3,3*a*,5*a*,5*b*,6,7,9,10,11,12,13,14,15,16*a*,16*b*-hexadeca-hydro-4,14-dimethyl-1*H*-as-indaceno[3,2-*d*]oxacyclododecine-7,15-dione (spinosyn D).



Molecular mass: 732.0 (spinosyn A); 746.0 (spinosyn D)

Spinosad is an active substance belonging to the spinosyn class of insecticides. The compound is obtained from natural products after fermentation. It is used in a wide range of crops for the control of *Lepidoptera*, thrips and leaf-miners, *Diptera*, *Hymenoptera*, *Siphonaptera*, *Thysanoptera* and certain *Coleoptera*. Spinosad acts by contact and ingestion causing paralysis of the insect by activation of the nicotinic acetylcholine receptor, but at a different site than nicotine or the neonicotinoids. The log P_{ow} of 4.0 for spinosyn A and of 4.5 for spinosyn D (pH 7, 23°C) is indicating that spinosad is a fat soluble compound (EC, 2006). Spinosad is also approved to be used as a biocide according to Commission Directive 2010/72/EC⁷.

Spinosad was evaluated in the framework of Council Directive 91/414/EEC with the Netherlands designated as rapporteur Member State (RMS). It was included in Annex I of the aforementioned Directive by Directive 2007/6/EC⁸ which entered into force on 1 February 2007 for use as insecticide only. In accordance with Commission Implementing Regulation (EU) No 540/2011⁹ spinosad is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated in the peer review were outdoor and glasshouse foliar applications on various crops (fruits, vegetables, ornamental plants). As EFSA was not involved in the peer review of spinosad, a conclusion of EFSA on this active substance is not available.

⁷ Commission Directive 2010/72/EU of 4 November 2010. OJ L 288, 05.11.2010, p. 20-22.

⁸ Commission Directive 2007/6/EC of 14 February 2007. OJ L 43, 15.02.2007, p. 13-18.

⁹ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011. OJ L 153, 11.06.2011, p. 1-186.

The EU MRLs for spinosad are established in Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). In 2010 a MRL application for herbal infusions (flowers, leaves and roots) and some aromatic herbs was submitted, however EFSA did not identify the need to amend the existing MRLs (EFSA, 2010). The MRLs for bananas, radishes and parsley were amended by the Commission Regulation (EU) No 270/2012¹⁰ taking into account the recommendation from EFSA (EFSA, 2011). In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005, EFSA has issued a reasoned opinion (EFSA, 2012a), which reviewed all uses authorised at EU level and certain Codex limits (CXLs). Modifications of the existing MRLs were proposed for several crops, including fennel (new proposal 0.6 mg/kg) but not for celery, blackberries and raspberries. The conclusions derived in the framework of this comprehensive MRL review have not yet been discussed at the Standing Committee on the Food Chain and Animal Health (SCFCAH). For the emergency use authorised in France on raspberries, EFSA has recently proposed the temporary MRL of 0.9 mg/kg (EFSA, 2012b).

The existing EU MRLs for spinosad on the crops under consideration are the following: celery 2 mg/kg, fennel 0.2 mg/kg, raspberries and blackberries 0.3 mg/kg. Codex Alimentarius has established CXLs for several commodities, including celery (CXL of 2 mg/kg). Recently, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) proposed new CXLs of 1 mg/kg for raspberries and blackberries (FAO, 2012), which were discussed at the 44th session of the Codex Committee on Pesticide Residues (CCPR) meeting and were forwarded to the Codex Alimentarius Commission (CAC) for adoption at the meeting in July 2012.

The GAPS for the intended indoor and outdoor uses on celery, fennel in Belgium and the indoor use on raspberries and blueberries in the United Kingdom are attached in Appendix A.

¹⁰ Commission Regulation (EU) No 270/2012 of 26 March 2012. OJ L89, 26 March 2012, p. 5-63.

ASSESSMENT

EFSA bases its assessment on the evaluation reports submitted by the EMS-BE and EMS-UK (Belgium, 2011; United Kingdom, 2012), the Draft Assessment Report (DAR) and its addenda prepared under Council Directive 91/414/EEC (The Netherlands, 2001, 2002, 2006), the Commission Review Report on spinosad (EC, 2006), the JMPR Evaluation reports (FAO, 2001, 2012) as well as the conclusions from previous EFSA opinions, including the EFSA reasoned opinion on the review of the existing MRLs for spinosad according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2010, 2011, 2012a, 2012b). 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 546/2011¹¹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

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

The analytical HPLC method using UV detection assessed during the peer review is adequate to monitor spinosad (sum of spinosyn A and spinosyn D) residues in high water (tomatoes, apples, peppers) and high acid (strawberries, grapes) content commodities at the LOQ of 0.01 mg/kg for each component (The Netherlands, 2001; EFSA, 2012a).

Additionally, analytical HPLC methods using UV or MS detection were evaluated by the JMPR for the determination of spinosad (sum of spinosyn A and spinosyn D) in high water content, acidic content, dry and high oil content commodities with a LOQ of 0.01 mg/kg for each component (FAO, 2001).

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 using HPLC-MS/MS is also applicable for the determination of residues of each component of the mixture in high water content, high acid content and dry commodities with a LOQ of 0.01 mg/kg (CEN, 2008).

EFSA concludes that validated methods are available to enforce the proposed MRLs in the crops under consideration. Since the LOQ for each of the two individual components of the active substance is 0.01 mg/kg, the achievable combined LOQ is 0.02 mg/kg.

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

The availability of analytical methods for enforcement of residues in products of animal origin was not investigated because the crops under consideration are not used as livestock feed.

¹¹ Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

2. Mammalian toxicology

The toxicological profile of the active substance spinosad was assessed in the framework of the peer review under Directive 91/414/EEC (EC, 2006). The data were sufficient to derive toxicological reference values for spinosad which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Spinosad					
ADI	EC	2006	0.024 mg/kg bw per d	Rat, 2 yr study	100
ARfD	EC	2006	Not necessary		

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 spinosad after foliar application was investigated in grapes, apples, tomatoes, cabbage, turnips and cotton, representing the crop groups of fruit and fruiting vegetables, leafy vegetables, root and tuber vegetables and oil seed/pulses. The details of the metabolism studies are reported in the DAR and the EFSA reasoned opinion on the review of the existing MRLs (The Netherlands, 2001; EFSA, 2012a). Although the metabolic patterns in the different studies were not shown to be similar - results on leafy vegetables (cabbage, turnip leaves) were not in line with the ones obtained on fruits (apples, grapes) and fruiting vegetables (tomatoes) - these differences were considered having no consequence on the outcome of the risk assessment.

The peer review established the residue definition for risk assessment and enforcement as “spinosad, sum of spinosyn A and spinosyn D, expressed as spinosad”. In the framework of the MRL review, EFSA confirmed the residue definition for enforcement, which is established in Regulation (EC) No 396/2005. However, EFSA recommended rewording the text into “spinosad, sum of spinosyn A and spinosyn D”, taking into account that the parent compound spinosad is a mixture of two compounds which have slightly different molecular weights. The MRL review identified a minor deficiency regarding the lack of characterisation of some unknown metabolites occurring in the primary crop metabolism studies. However, it was concluded that spinosyn A and spinosyn D are good markers for enforcement and risk assessment and that the unidentified component of the residues is very likely incorporated into natural plant components (EFSA, 2012a).

For the uses under consideration, EFSA concludes that the metabolism of spinosad is sufficiently addressed and that the residue definitions as proposed in the previous EFSA reasoned opinion on MRL review are applicable.

3.1.1.2. Magnitude of residues

a. Celery, fennel

Indoor: the EMS-BE submitted four supervised residue trials on celery performed in Belgium under protected conditions during 2009. The SC formulation was applied on celery in a spray volume of 713-833 L/ha at a growth stage of 47-49 (BBCH). None of the submitted trials was designed as decline study. Three trials fully matched the intended GAP. In one trial the sample was analysed for spinosad residues at the PHI of 4 days, which is slightly exceeding the acceptable 25 % limit. However the deviation was accepted and this trial was also considered valid. A great variability is

noted in the results: the higher residues were observed in the trials conducted in October/November while the lower at the longer PHI of 4 days. Celery is a minor crop in Europe, therefore a minimum of four GAP compliant trials is required to support the MRL proposal and the extrapolation of residues from celery to fennel is also acceptable (EC, 2011). EFSA considers that these data are sufficient to support the MRL proposal of 5 mg/kg.

Outdoor: the EMS-BE submitted two supervised residue trials on celery performed in Belgium during a single season complying with the intended GAP. The extrapolation of residues from celery to fennel is acceptable, however the minimum number of GAP compliant studies required supporting the MRL proposal of four according to the EU guidance document (EC, 2011) is not available. Furthermore, the studies belong to a single season (EC, 1997b). Thus, no MRL can be proposed for the intended field use in Belgium.

b. Raspberries, blackberries

Four GAP compliant supervised residue trials on raspberries performed under protected conditions during two seasons (2007 and 2010) were submitted. Although in one trial the spray volume exceeded the acceptable 25 % deviation (due to the morphology of the plants), the correct spray concentration (9.6 g/hL) was used and the trial can be considered valid. Raspberries are a minor crop in Europe, therefore a minimum of four GAP compliant trials is required to support the MRL proposal and the extrapolation of residues from raspberries to blackberries is acceptable (EC, 2011). EFSA considers that these data are sufficient to support the MRL proposal of 1.5 mg/kg.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-1.

The storage stabilities of spinosyn A and D were demonstrated for a period of 19 months at -20 °C in high water content (pepper) and acidic (grapes, strawberries) commodities (The Netherlands, 2001; EFSA, 2012a). Since both sets of supervised residue trial samples were stored for a length of period (up to 4 months) and under conditions for which integrity of the samples was demonstrated (Belgium, 2011; United Kingdom, 2012), it is concluded that the residue data are valid with regard to storage stability.

According to the EMS-UK, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (United Kingdom, 2012). Belgium highlighted the low recovery for spinosyn A and spinosyn D obtained from the analysis of the trial samples at certain fortification levels. Since the mean recovery of the three fortification levels was above 70 % the method was considered suitable (Belgium, 2011).

EFSA considers that the data are sufficient to derive a MRL proposal of 1.5 mg/kg for the intended indoor use on raspberries and blackberries in the United Kingdom and of 5 mg/kg for the intended indoor use on celery and fennel in Belgium, whereas the intended outdoor use on celery and fennel is not adequately supported by residue data and no MRL is therefore proposed.

Table 3-1: Overview of the available residues trials data

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (Spinosad (sum of spinosyn A and spinosyn D))	Risk assessment (Spinosad (sum of spinosyn A and spinosyn D))					
Enforcement and risk assessment residue definition: Spinosad (sum of spinosyn A and spinosyn D).									
Celery→ Fennel	NEU	Indoor	0.06; 0.26 ^(f) ; 1.05; 1.98	0.06; 0.26 ^(f) ; 1.05; 1.98	0.65	1.98	5	1	R _{ber} = 3.5 R _{max} = 5.34 MRL _{OECD} = 4.34/5
	NEU	Outdoor	0.39; 0.42	0.39; 0.42	Number of studies is not sufficient to derive a MRL proposal.				
Raspberries→ Blackberries	EU	Indoor	0.14 ^(g) ; 0.23; 0.47; 0.58 ^(f)	0.14 ^(g) ; 0.23; 0.47; 0.58 ^(f)	0.35	0.58	1.5	1	R _{ber} = 1.11 R _{max} = 1.14 MRL _{OECD} = 1.17/1.5

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code) (EC, 2011).

(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 residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

(f): Result from trial conditions deviating more than +25 % compare to the intended GAPs. Celery: PHI of 4 days instead of 3 days; raspberries: spray volume of 1342 L/ha instead of 1000 L/ha (last application).

(g): The highest values measured at a longer PHI of 3 days (decline study).

3.1.1.3. Effect of industrial processing and/or household preparation

Since the effect of processing on the nature of spinosad was not investigated, studies performed at three test conditions representing pasteurization, baking/brewing/boiling and sterilization were considered necessary in the framework of Article 12 review (EFSA, 2012a).

Specific studies to assess the magnitude of spinosad residues during the processing of stem vegetables and berries (selection of the crop better representing the whole group) are not available. As the residue levels in raw agricultural commodities (RAC) exceeded the trigger value of 0.1 mg/kg and the total theoretical maximum daily intake (TMDI) amounts to more than 10 % of the ADI, such studies are required (EC, 1997d). However, considering that the crops under consideration are minor contributors to the overall exposure calculation, the chronic consumer risk assessment performed in the framework of this MRL evaluation is not expected to be significantly affected.

3.1.2. Rotational crops

Celery and fennel can be grown in a crop rotation with other plants and the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. Following the assessment of the confined rotational crop study during the peer review of spinosad, it was concluded that the metabolic pattern in rotational crops is similar to primary crops and that no significant residue levels are expected in rotational crops (the Netherlands, 2011, 2006; EFSA, 2012a). Considering that the above study was performed with a higher application rate of 1.1 kg a.s./ha, EFSA concluded that for the uses assessed during the MRL review the residues of spinosad resulting from the soil uptake are not expected to exceed 0.01 mg/kg (EFSA, 2012a).

Based on the available information on the nature and magnitude of the residues, EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that the compound is used on celery and fennel according to the proposed GAP (Good Agricultural Practice).

3.2. Nature and magnitude of residues in livestock

Nature and magnitude of spinosad residues in livestock were not assessed since the crops under consideration are not a potential feedingstuff for livestock.

4. Consumer risk assessment

In the framework of the review of the existing MRLs for spinosad according to Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account only the existing uses of spinosad at EU level supported by data and the existing acceptable CXLs. Those food commodities for which no uses of spinosad were reported in the framework of Article 12 of Regulation (EC) No 396/2005 were excluded from the exposure calculation assuming that there is no use on these crops (EFSA, 2012a). The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population ¹² (EFSA, 2007).

EFSA now updates the risk assessment performed under the Article 12 review with the median residue value as derived from the residue trials on raspberries and celery (see Table 3-1). The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at the median residue levels identified in supervised field trials. EFSA is of the opinion that if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (*i.e.* the ADI), a consumer health risk can be excluded with a high probability.

An acute exposure assessment was not performed due to the low acute toxicity of the active substance, which did not require the setting of an ARfD.

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Spinosad (sum of spinosyn A and spinosyn D)				
Raspberries	0.35	Median residue (raspberries, indoor)	No acute risk assessment necessary (no ARfD established)	
Blackberries	0.35	Median residue (raspberries, indoor)		
Celery	0.65	Median residue (celery, indoor)		
Fennel	0.65	Median residue (celery, indoor)		
Other commodities of plant and animal origin	See Appendix D			

The estimated exposure was compared with the toxicological reference value derived for spinosad (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

¹² The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 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 MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

It is noted that the long-term consumer exposure calculation is based on the conclusions and recommendations derived in the review of the existing MRLs for spinosad under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2012a). Under the assumption that the MRLs will be amended as proposed in the Article 12 review, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 57 % of the ADI (WHO Cluster diet B). The contribution of residues on the crops under consideration to the total consumer exposure was very low, accounting with respect to the ADI for a maximum of 0.18 % on raspberries, 0.17 % on blackberries, 0.35 % on celery and 0.26 % on fennel.

EFSA concludes that the intended use of spinosad on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of spinosad was evaluated in the framework of Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.024 mg/kg bw per day. No ARfD value was deemed necessary for spinosad.

The metabolism of spinosad in primary crops was investigated in grapes, apples, tomatoes, cabbage, turnips and cotton, covering four different crop groups. The review of the existing MRLs for spinosad performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review that the relevant residue for enforcement and risk assessment in all plant commodities treated by foliar application is spinosad (sum of spinosyn A and spinosyn D). EFSA proposed to delete the indication that the residues should be expressed in spinosad equivalents reported in Regulation (EC) No 396/2005. For the uses under consideration EFSA concludes that the metabolism of spinosad is sufficiently addressed and that the residue definition for enforcement and risk assessment as proposed in the previous EFSA reasoned opinion on MRL review are applicable.

EFSA considers that the submitted supervised residue trials are sufficient to derive a MRL proposal of 1.5 mg/kg for the intended indoor use on raspberries and blackberries in the United Kingdom and of 5 mg/kg for the intended indoor use on celery and fennel in Belgium, whereas the intended outdoor use on celery and fennel is not adequately supported by residue data and no MRL is therefore proposed. Adequate analytical enforcement methods are available to control the residues of spinosad in the crops under consideration at the validated combined LOQ of 0.02 mg/kg.

Studies on the nature and magnitude of spinosad in processed commodities are not available and were considered necessary in the framework of Article 12 review.

Celery and fennel can be grown in a crop rotation and therefore the nature and magnitude of spinosad residues in rotational/succeeding crops has to be further investigated. Based on the available information on the nature and magnitude of residues in succeeding crops, EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that the spinosad is used according to the proposed GAP (Good Agricultural Practice).

Nature and magnitude of spinosad residues in livestock were not assessed since the crops under consideration are not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for spinosad according to Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account the existing uses of spinosad at EU level supported by data and the existing acceptable Codex limits (CXLs). EFSA now updates this risk assessment with the median residue value as derived from the supervised residue trials on raspberries and celery. No acute consumer risk assessment was performed because of the low acute toxicity of spinosad.

It is noted that the long-term consumer exposure calculation is based on the conclusions and recommendations derived in the review of the existing MRLs for spinosad under Article 12 of Regulation (EC) No 396/2005. Under the assumption that the MRLs will be amended as proposed in the Article 12 review, no long-term consumer intake concerns were identified. The total calculated intake accounted for 57 % of the ADI. The contribution of residues on the crops under consideration to the total consumer exposure was very low, accounting with respect to the ADI for a maximum of 0.18 % on raspberries, 0.17 % on blackberries, 0.35 % on celery and 0.26 % on fennel.

EFSA concludes that the proposed use of spinosad on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Proposed enforcement residue definition: Spinosad (sum of spinosyn A and spinosyn D) (F)				
153010	Blackberries	0.3	1.5	The MRL proposals are sufficiently supported by data on raspberries and no risk for consumers was identified for the intended use.
153030	Raspberries	0.3	1.5	
270030	Celery	2	5	The MRL proposals are sufficiently supported by data on celery and no risk for consumers was identified for the intended indoor use. The outdoor use is not sufficiently supported by data.
270040	Fennel	0.2	5	

(a): According to Annex I of Regulation (EC) No 396/2005.

(F): Fat-soluble pesticide

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APPENDICES

A. GOOD AGRICULTURAL PRACTICE (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Celery, Fennel	BE	I	Leaf-miner flies, leaf noctuid caterpillars, thrips	SC	480 g/L	Spraying		1-3	7-10 days			0.096	3	
Celery, Fennel	BE	F	Leaf-miner flies, leaf noctuid caterpillars, thrips	SC	480 g/L	Spraying		1-3	7-10 days			0.096	3	
Raspberries, blackberries	UK	G	Insects	SC	480 g/L	To be applied by conventional hydraulic sprayers, including air assisted sprayer and hand held sprayers.	Earliest time of application is not specified	3 per annum	7-10 days	9.6	1000	20 ml product per 100L water (1000L/ha) Equivalent to: 96 g a.s./ha	1	Height of target plant is up to 2 meters. Estimated period of use is June to October. Resistance strategy Statement

- Remarks:
- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions (*i.e.* feeding, grazing)

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Spinosad									
Status of the active substance:		Included		Code no.					
LOQ (mg/kg bw):		0.02		proposed LOQ:					
Toxicological end points									
ADI (mg/kg bw/day):		0.024		ARfD (mg/kg bw):		n.n.			
Source of ADI:		EC		Source of ARfD:		EC			
Year of evaluation:		2006		Year of evaluation:		2006			
Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI minimum - maximum					
				4 57					
				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)	
56.9	WHO Cluster diet B	24.7	Wheat	7.2	Maize	6.4	Lettuce	0.5	
43.5	NL child	13.7	Wheat	7.6	Spinach	4.4	Bananas	0.8	
40.0	DK child	15.9	Wheat	12.8	Rye	2.9	Bananas	0.2	
37.3	DE child	11.9	Wheat	4.2	Spinach	4.0	Bananas	0.5	
34.9	ES child	12.8	Wheat	7.5	Lettuce	2.6	Bananas	0.4	
33.3	WHO cluster diet D	18.8	Wheat	1.6	Rice	1.5	Maize	0.4	
33.1	FR toddler	14.4	Spinach	7.6	Wheat	3.3	Bananas	0.6	
32.5	IT kids/toddler	19.2	Wheat	5.2	Lettuce	1.5	Tomatoes	0.1	
32.5	IE adult	6.6	Maize	6.6	Maize	3.6	Barley	0.4	
29.8	WHO cluster diet E	11.4	Wheat	2.3	Barley	2.1	Parsley	0.4	
27.1	ES adult	9.6	Lettuce	6.8	Wheat	1.6	Beet leaves (chard)	0.2	
27.0	WHO Cluster diet F	10.4	Wheat	5.4	Lettuce	2.2	Rye	0.5	
26.9	WHO regional European diet	8.6	Wheat	6.7	Lettuce	1.1	Tomatoes	0.5	
26.7	IT adult	12.0	Wheat	6.7	Lettuce	1.9	Spinach	0.1	
24.0	SE general population 90th percentile	9.3	Wheat	4.6	Bananas	1.4	Spinach	0.4	
21.2	UK Infant	7.6	Wheat	3.7	Bananas	3.0	Maize	0.3	
20.6	UK Toddler	11.3	Wheat	2.8	Bananas	1.7	Rice	0.4	
20.3	NL general	6.0	Wheat	2.9	Spinach	2.1	Lettuce	0.4	
20.3	FR infant	9.0	Spinach	2.4	Wheat	2.4	Milk and milk products: Cattle	0.4	
20.2	PT General population	11.3	Wheat	2.3	Rice	1.4	Maize	0.5	
18.2	FR all population	9.5	Wheat	1.6	Lettuce	1.4	Wine grapes	0.2	
14.2	UK vegetarian	5.9	Wheat	2.5	Lettuce	1.1	Rice	0.2	
12.6	LT adult	3.1	Rye	3.0	Wheat	1.1	Lettuce	0.3	
12.1	DK adult	5.8	Wheat	2.0	Rye	1.0	Bananas	0.1	
11.5	UK Adult	4.9	Wheat	2.1	Lettuce	1.1	Rice	0.2	
9.2	FI adult	2.8	Wheat	2.0	Rye	1.4	Lettuce	0.2	
3.8	PL general population	0.9	Tomatoes	0.5	Bananas	0.4	Apples	0.3	
Conclusion:									
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.									
A long-term intake of residues of Spinosad is unlikely to present a public health concern.									

C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

Pesticides - Web Version - EU MRLs (File created on 06/06/2012 15:30)

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
100000	1. FRUIT FRESH OR FROZEN; NUTS		
110000	(i) Citrus fruit	0,3	0,3
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,3	0,3
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,3	0,3
110030	Lemons (Citron, lemon)	0,3	0,3
110040	Limes	0,3	0,3
110050	Mandarins (Clementine, tangerine and other hybrids)	0,3	0,3
110990	Others	0,3	0,3
120000	(ii) Tree nuts (shelled or unshelled)		
120010	Almonds	1	0,02*
120020	Brazil nuts	0,05	0,02*
120030	Cashew nuts	0,05	0,02*
120040	Chestnuts	0,05	0,02*
120050	Coconuts	0,05	0,02*
120060	Hazelnuts (Filbert)	0,05	0,02*
120070	Macadamia	0,05	0,02*
120080	Pecans	0,05	0,02*
120090	Pine nuts	0,05	0,02*
120100	Pistachios	0,05	0,02*
120110	Walnuts	0,05	0,02*
120990	Others	0,05	
130000	(iii) Pome fruit		
130010	Apples (Crab apple)	1	0,3
130020	Pears (Oriental pear)	1	0,3
130030	Quinces	0,5	0,3
130040	Medlar	0,5	0,3
130050	Loquat	0,5	0,3
130990	Others	0,5	
140000	(iv) Stone fruit	1	
140010	Apricots	1	0,6
140020	Cherries (sweet cherries, sour cherries)	1	0,2
140030	Peaches (Nectarines and similar hybrids)	1	0,6

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
140040	Plums (Damson, greengage, mirabelle)	1	0,2
140990	Others	1	
150000	(v) Berries & small fruit		
151000	(a) Table and wine grapes	0,5	
151010	Table grapes	0,5	0,5
151020	Wine grapes	0,5	0,5
152000	(b) Strawberries	0,3	0,3
153000	(c) Cane fruit		
153010	Blackberries	0,3	0,3
153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,02*	0,02*
153030	Raspberries (Wineberries)	0,3	0,3 ^(b)
153990	Others	0,02*	
154000	(d) Other small fruit & berries		
154010	Blueberries (Bilberries cowberries (red bilberries))	0,3	
154020	Cranberries	0,02*	
154030	Currants (red, black and white)	0,3	
154040	Gooseberries (Including hybrids with other ribes species)	0,3	
154050	Rose hips	0,3	
154060	Mulberries (arbutus berry)	0,02*	
154070	Azarole (mediterranean medlar)	0,3	
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sawthorn), hawthorn, service berries, and other treeberries)	0,3	
154990	Others	0,02*	
160000	(vi) Miscellaneous fruit		
161000	(a) Edible peel		
161010	Dates	0,02*	
161020	Figs	0,02*	
161030	Table olives	0,02*	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*	
161050	Carambola (Bilimbi)	0,02*	
161060	Persimmon	0,05	
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose	0,02*	

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
	apple, Brazilian cherry (grumichama), Surinam cherry)		
161990	Others	0,02*	
162000	(b) Inedible peel, small		
162010	Kiwi	0,2	0,05
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*	
162030	Passion fruit	0,5	0,5
162040	Prickly pear (cactus fruit)	0,02*	
162050	Star apple	0,02*	
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0,02*	
162990	Others	0,02*	
163000	(c) Inedible peel, large		
163010	Avocados	0,02*	
163020	Bananas (Dwarf banana, plantain, apple banana)	2	2
163030	Mangoes	0,02*	
163040	Papaya	0,5	0,5
163050	Pomegranate	0,02*	
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,02*	
163070	Guava	0,02*	
163080	Pineapples	0,02*	
163090	Bread fruit (Jackfruit)	0,02*	
163100	Durian	0,02*	
163110	Soursop (guanabana)	0,02*	
163990	Others	0,02*	
200000	2. VEGETABLES FRESH OR FROZEN		
210000	(i) Root and tuber vegetables		
211000	(a) Potatoes	0,02*	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*	
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*	
212020	Sweet potatoes	0,02*	
212030	Yams (Potato bean (yam bean),	0,02*	

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
	Mexican yam bean)		
212040	Arrowroot	0,02*	
212990	Others	0,02*	
213000	(c) Other root and tuber vegetables except sugar beet		
213010	Beetroot	0,02*	
213020	Carrots	0,02*	
213030	Celeriac	0,02*	
213040	Horse radish	0,02*	
213050	Jerusalem artichokes	0,02*	
213060	Parsnips	0,02*	
213070	Parsley root	0,02*	
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,3	0.3
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,02*	
213100	Swedes	0,02*	0.02*
213110	Tumips	0,02*	0.02*
213990	Others	0,02*	
220000	(ii) Bulb vegetables		
220010	Garlic	0,1	0.07
220020	Onions (Silverskin onions)	0,2	0.07
220030	Shallots	0,1	0.07
220040	Spring onions (Welsh onion and similar varieties)	0,2	0.2
220990	Others	0,1	
230000	(iii) Fruiting vegetables		
231000	(a) Solanacea		
231010	Tomatoes (Cherry tomatoes,)	1	0.7
231020	Peppers (Chilli peppers)	2	2
231030	Aubergines (egg plants) (Pepino)	1	0.7
231040	Okra, lady's fingers	1	
231990	Others	1	
232000	(b) Cucurbits - edible peel		
232010	Cucumbers	1	0.3
232020	Gherkins	0,2	0.3
232030	Courgettes (Summer squash, marrow (patisson))	0,2	0.3
232990	Others	0,2	
233000	(c) Cucurbits-inedible peel	1	1
233010	Melons (Kiwano)	1	1
233020	Pumpkins (Winter squash)	1	1
233030	Watermelons	1	1
233990	Others	1	1
234000	(d) Sweet com	0,02*	0.02*

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
239000	(e) Other fruiting vegetables	0,02*	
240000	(iv) Brassica vegetables	2	
241000	(a) Flowering brassica		2
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	2	2
241020	Cauliflower	2	2
241990	Others	2	2
242000	(b) Head brassica	2	
242010	Brussels sprouts	2	2
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	2	2
242990	Others	2	
243000	(c) Leafy brassica	2	2
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	2	2
243020	Kale (Borecole (curly kale), collards)	2	2
243990	Others	2	2
244000	(d) Kohlrabi	2	2
250000	(v) Leaf vegetables & fresh herbs		
251000	(a) Lettuce and other salad plants including Brassicacea	10	
251010	Lamb's lettuce (Italian cornsalad)	10	10
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	10	10
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	10	10
251040	Cress	10	10
251050	Land cress	10	10
251060	Rocket, Rucola (Wild rocket)	10	10
251070	Red mustard	10	10
251080	Leaves and sprouts of Brassica spp (Mizuna)	10	15
251990	Others	10	15
252000	(b) Spinach & similar (leaves)	10	
252010	Spinach (New Zealand spinach, tumip greens (tumip tops))	10	15
252020	Purslane (Winter purslane (miner's lettuce), garden purslane,	10	10

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
	common purslane, sorrel, glasswort)		
252030	Beet leaves (chard) (Leaves of beetroot)	10	15
252990	Others	10	
253000	(c) Vine leaves (grape leaves)	10	10
254000	(d) Water cress	10	10
255000	(e) Willow	10	10
256000	(f) Herbs		
256010	Chervil	10	15
256020	Chives	10	15
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	10	15
256040	Parsley	60	60
256050	Sage (Winter savory, summer savory,)	10	15
256060	Rosemary	10	15
256070	Thyme (marjoram, oregano)	10	15
256080	Basil (Balm leaves, mint, peppermint)	10	15
256090	Bay leaves (laurel)	10	15
256100	Tarragon (Hyssop)	10	15
256990	Others	10	
260000	(vi) Legume vegetables (fresh)		
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,5	0.3
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,3	0.3
260030	Peas (with pods) (Mangetout (sugar peas))	0,5	0.3
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,3	0.3
260050	Lentils	0,3	0.3
260990	Others	0,3	
270000	(vii) Stem vegetables (fresh)		
270010	Asparagus	0,2	
270020	Cardoons	0,2	
270030	Celery	2	2
270040	Fennel	0,2	0.6
270050	Globe artichokes	0,2	0.15
270060	Leek	0,5	0.2

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
270070	Rhubarb	0,2	
270080	Bamboo shoots	0,2	
270090	Palm hearts	0,2	
270990	Others	0,2	
280000	(viii) Fungi	0,02*	
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*	
280020	Wild (Chanterelle, Truffle, Morel)	0,02*	
280990	Others	0,02*	
290000	(ix) Sea weeds	0,02*	
300000	3. PULSES, DRY	0,02*	
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0,02*	
300020	Lentils	0,02*	
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*	
300040	Lupins	0,02*	
300990	Others	0,02*	
400000	4. OILSEEDS AND OILFRUITS	0,02*	
401000	(i) Oilseeds	0,02*	
401010	Linseed	0,02*	
401020	Peanuts	0,02*	
401030	Poppy seed	0,02*	
401040	Sesame seed	0,02*	
401050	Sunflower seed	0,02*	
401060	Rape seed (Bird rapeseed, turnip rape)	0,02*	
401070	Soya bean	0,02*	0,02*
401080	Mustard seed	0,02*	
401090	Cotton seed	0,02*	0,02*
401100	Pumpkin seeds	0,02*	
401110	Safflower	0,02*	
401120	Borage	0,02*	
401130	Gold of pleasure	0,02*	
401140	Hempseed	0,02*	
401150	Castor bean	0,02*	
401990	Others	0,02*	
402000	(ii) Oilfruits	0,02*	
402010	Olives for oil production	0,02*	0,02*
402020	Palm nuts (palmoil kernels)	0,02*	
402030	Palmfruit	0,02*	
402040	Kapok	0,02*	
402990	Others	0,02*	

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
500000	5. CEREALS	1	2
500010	Barley	1	2
500020	Buckwheat	1	2
500030	Maize	1	2
500040	Millet (Foxtail millet, tefi)	1	2
500050	Oats	1	2
500060	Rice	1	2
500070	Rye	1	2
500080	Sorghum	1	2
500090	Wheat (Spelt Triticale)	1	2
500990	Others	1	2
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA		
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*	
620000	(ii) Coffee beans	0,02*	
630000	(iii) Herbal infusions (dried)	0,05*	
631000	(a) Flowers	0,05*	
631010	Camomille flowers	0,05*	
631020	Hybiscus flowers	0,05*	
631030	Rose petals	0,05*	
631040	Jasmine flowers	0,05*	
631050	Lime (linden)	0,05*	
631990	Others	0,05*	
632000	(b) Leaves	0,05*	
632010	Strawberry leaves	0,05*	
632020	Rooibos leaves	0,05*	
632030	Maté	0,05*	
632990	Others	0,05*	
633000	(c) Roots	0,05*	
633010	Valerian root	0,05*	
633020	Ginseng root	0,05*	
633990	Others	0,05*	
639000	(d) Other herbal infusions	0,05*	
640000	(iv) Cocoa (fermented beans)	0,02*	
650000	(v) Carob (st johns bread)	0,02*	
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	22	
800000	8. SPICES		
810000	(i) Seeds	0,02*	
810010	Anise	0,02*	
810020	Black caraway	0,02*	
810030	Celery seed (Lovage seed)	0,02*	
810040	Coriander seed	0,02*	

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
810050	Cumin seed	0,02*	
810060	Dill seed	0,02*	
810070	Fennel seed	0,02*	
810080	Fenugreek	0,02*	
810090	Nutmeg	0,02*	
810990	Others	0,02*	
820000	(ii) Fruits and berries	0,02*	
820010	Allspice	0,02*	
820020	Anise pepper (Japan pepper)	0,02*	
820030	Caraway	0,02*	
820040	Cardamom	0,02*	
820050	Juniper berries	0,02*	
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*	
820070	Vanilla pods	0,02*	
820080	Tamarind	0,02*	
820990	Others	0,02*	
830000	(iii) Bark	0,02*	
830010	Cinnamon (Cassia)	0,02*	
830990	Others	0,02*	
840000	(iv) Roots or rhizome	0,02*	
840010	Liquorice	0,02*	
840020	Ginger	0,02*	
840030	Turmeric (Curcuma)	0,02*	
840040	Horseradish	0,02*	
840990	Others	0,02*	
850000	(v) Buds		
850010	Cloves	0,02*	
850020	Capers	0,4	
850990	Others	0,02*	
860000	(vi) Flower stigma	0,02*	
860010	Saffron	0,02*	
860990	Others	0,02*	
870000	(vii) Aritl	0,02*	
870010	Mace	0,02*	
870990	Others	0,02*	
900000	9. SUGAR PLANTS	0,05	
900010	Sugar beet (root)	0,05	
900020	Sugar cane	0,05	
900030	Chicory roots	0,05	
900990	Others	0,05	
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS		
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh		

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
	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	0,05	2
1011020	Fat free of lean meat	1	2
1011030	Liver	0,5	0,5
1011040	Kidney	0,3	0,5
1011050	Edible offal	0,5	
1011990	Others		
1012000	(b) Bovine		
1012010	Meat	0,3	3
1012020	Fat	3	3
1012030	Liver	2	2
1012040	Kidney	1	1
1012050	Edible offal	0,5	
1012990	Others		
1013000	(c) Sheep		
1013010	Meat	0,05	2
1013020	Fat	2	2
1013030	Liver	0,5	0,6
1013040	Kidney	0,5	0,5
1013050	Edible offal	0,5	
1013990	Others		
1014000	(d) Goat		
1014010	Meat	0,05	2
1014020	Fat	2	2

(a): For details on the derived MRLs see the table footnotes of the reasoned opinion on the review of the

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
1014030	Liver	0,5	0,6
1014040	Kidney	0,5	0,5
1014050	Edible offal	0,5	
1014990	Others		
1015000	(e) Horses, asses, mules or hinnies		
1015010	Meat	0,05	
1015020	Fat	2	
1015030	Liver	0,5	
1015040	Kidney	0,5	
1015050	Edible offal	0,5	
1015990	Others		
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon		
1016010	Meat	0,2	1
1016020	Fat	1	1
1016030	Liver	0,2	0,2
1016040	Kidney	0,2	0,2
1016050	Edible offal	0,2	
1016990	Others		
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,02*	
1017010	Meat	0,02*	
1017020	Fat	0,02*	
1017030	Liver	0,02*	
1017040	Kidney	0,02*	
1017050	Edible offal	0,02*	
1017990	Others	0,02*	

existing maximum residue levels for spinosad (EFSA, 2012a).

Code number	Groups and examples of individual products to which the MRLs apply	Spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad (F)	Spinosad: sum of spinosyn A and spinosyn D (F) MRLs derived under Article 12 review ^(a)
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,5	0,2
1020010	Cattle	0,5	0,2
1020020	Sheep	0,5	0,2
1020030	Goat	0,5	0,2
1020040	Horse	0,5	0,2
1020990	Others	0,5	0,2
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,2	0,2
1030010	Chicken	0,2	0,2
1030020	Duck	0,2	0,2
1030030	Goose	0,2	0,2
1030040	Quail	0,2	0,2
1030990	Others	0,2	0,2
1040000	(iv) Honey (Royal jelly, pollen)	0,01*	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*	
1060000	(vi) Snails	0,01*	
1070000	(vii) Other terrestrial animal products	0,01*	

(b): The temporary MRL of 0.9 mg/kg proposed by EFSA in its reasoned opinion (EFSA, 2012b) not yet voted at SCFCAH by 6 June 2012.

(*) Indicates lower limit of analytical determination.

D. LIST OF AVAILABLE MEDIAN RESIDUE VALUES FOR CHRONIC RISK ASSESSMENT

Existing uses assessed under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2012a)

Commodity	Input value (mg/kg)	Comments
Citrus fruit	0.01	STMR (edible portion) (CXL)
Tree nuts	0.01	Median residue
Pome fruit	0.05	Median residue
Apricots	0.21	Median residue
Cherries	0.03	STMR (CXL)
Peaches	0.21	Median residue
Plums	0.03	STMR (CXL)
Table, wine grapes	0.08	STMR (CXL)
Strawberries	0.12	Median residue
Dewberries	0.02	EU MRL (=LOQ)
Table olives	0.02	Median residue (=LOQ)
Kiwi	0.02	STMR (CXL)
Passion fruit	0.08	Median residue
Bananas	0.62	Median residue
Papaya	0.21	Median residue
Potatoes	0.02	Median residue (=LOQ)
Radishes	0.08	Median residue
Swedes	0.02	EU MRL (=LOQ)
Tumips	0.02	EU MRL (=LOQ)
Garlic	0.05	Median residue
Onions	0.05	Median residue
Shallots	0.05	Median residue
Spring onions	0.03	Median residue
Tomatoes	0.25	Median residue
Peppers	0.33	Median residue
Aubergines	0.25	Median residue

Commodity	Input value (mg/kg)	Comments
Cucurbits with edible peel	0.08	Median residue
Cucurbits with inedible peel	0.14	Median residue
Sweet corn	0.01	STMR (CXL)
Flowering brassica	0.13	Median residue (tentative)
Brussels sprout	0.27	STMR (CXL)
Head cabbage	0.27	STMR (CXL)
Leafy brassica	0.27	STMR (CXL)
Kohlrabi	0.27	STMR (CXL)
Lamb's lettuce	1.90	STMR (CXL)
Lettuce	4.29	Median residue
Scarole (broad-leaf endive)	1.9 ^(a)	STMR (CXL)
Cress	1.90	STMR (CXL)
Land cress	1.90	STMR (CXL)
Rocket, Rucola	1.9 ^(a)	STMR (CXL)
Red mustard	1.90	STMR (CXL)
Leaves, sprouts of Brassica spp	4.90	Median residue
Spinach	4.90	Median residue (tentative)
Purslane	1.90	STMR (CXL)
Beet leaves	4.90	Median residue
Vine leaves	1.90	STMR (CXL)
Water cress	1.90	STMR (CXL)
Witloof	1.90	STMR (CXL)
Parsley	10	Median residue

Commodity	Input value (mg/kg)	Comments
Herbs (except parsley)	4.90	Median residue
Beans (fresh, with pods)	0.07	Median residue
Beans (fresh, without pods)	0.04	STMR (CXL)
Peas (fresh, with pods)	0.04	STMR (CXL)
Peas (fresh, without pods)	0.04	STMR (CXL)
Lentils (fresh)	0.04	STMR (CXL)
Globe artichokes	0.03	Median residue (tentative)
Leek	0.07	Median residue
Soya bean	0.01	STMR (CXL)
Cotton seed	0.01	Median residue
Olive for oil production	0.02	Median residue (=LOQ)
Cereals grain	0.70	Median residue (tentative)
Swine meat	0.01	STMR (CXL)
Swine fat	0.32	STMR (CXL)
Swine liver	0.24	Median residue
Swine kidney	0.03	STMR (CXL)
Bovine meat	0.08	STMR (CXL)
Bovine fat	0.08	STMR (CXL)
Bovine liver	0.66	STMR (CXL)
Bovine kidney	0.31	STMR (CXL)
Sheep meat	0.01	STMR (CXL)
Sheep fat	0.32	STMR (CXL)
Sheep liver	0.28	Median residue

Commodity	Input value (mg/kg)	Comments
Sheep kidney	0.03	STMR (CXL)
Goat meat	0.01	STMR (CXL)
Goat fat	0.32	STMR (CXL)
Goat liver	0.28	Median residue
Goat kidney	0.03	STMR (CXL)
Poultry meat	0.2	EU MRL ^(b)
Poultry fat	1	EU MRL
Poultry liver	0.8	EU MR*CF ^(c)
Ruminant milk	0.02	STMR (CXL)
Birds' eggs ^(c)	0.3	EU MR*CF ^(c)

(a): A typographical error was made in page 50 and 51 of the reasoned opinion on the review of the existing maximum residue levels (MRLs) for spinosad (EFSA, 2012a). The value used for scarole and rucola in PRIMO is 1.9 mg/kg.

(b): Recalculated for 20 % of fat.

(c): Proposed risk assessment residue definition: spinosad, sum of spinosyn A, spinosyn D, *O*-demethyl spinosyn D and *N*-demethyl spinosyn D (EFSA 2012a).

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
BE	Belgium
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation, <i>French</i>)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
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
GCPF	Global Crop Protection Federation (former GIFAP)
GLP	Good Laboratory Practice
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development

PHI	pre-harvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RMS	rappporteur Member State
SC	suspension concentrate
SCFCAH	Standing Committee on the Food Chain and Animal Health
STMR	supervised trials median residue
UK	the United Kingdom
UV	ultra-violet (detector)
WHO	World Health Organisation
yr	year