

## REASONED OPINION

### Setting of an import tolerance for spinetoram in peaches (including nectarines) and apricots<sup>1</sup>

European Food Safety Authority<sup>2</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

The United Kingdom as designated RMS for the active substance spinetoram has received an application from the company Poyntz Consulting to set import tolerances for the active substance spinetoram. In particular, for peaches/nectarines and apricots the United Kingdom concluded that the existing MRLs have to be raised from 0.05 mg/kg to 0.3 mg/kg. The evaluation report prepared by the RMS on this subject and the application were submitted to the European Commission and were forwarded to EFSA on 30 January 2009.

Based on this evaluation report, an addendum to this report and the JMPR evaluation, EFSA derives the following conclusions regarding the application.

The toxicological profile of spinetoram was assessed by the RMS. The data were sufficient to conclude on a provisional ADI value of 0.021 mg/kg and an ARfD of 0.3 mg/kg.

The metabolism of spinetoram was investigated for three different crop groups (fruits and fruiting vegetables, leafy vegetables and root and tuber vegetables) in which the metabolism was found to be similar. EFSA concluded that the current enforcement residue definition (spinetoram (sum of XDE-175-J and XDE-175-L)) should be maintained. However, the residue definition for risk assessment should be established as spinetoram (sum of XDE-175-J and XDE-175-L), N-demethyl-XDE-J and N-formyl-XDE-175-J, expressed as spinetoram.

An analytical method based on LC/MS/MS is available to enforce spinetoram MRLs in stone fruit.

The submitted residue trials performed in peaches were sufficient to derive an MRL proposal of 0.2 mg/kg which can be extrapolated also to nectarines and apricots. This MRL would cover the intended use of spinetoram in third countries (South Africa, Argentina, Chile, New Zealand and Israel) for which currently the authorisation procedure is ongoing.

The possible occurrence of residues in rotational crops was not considered in the framework of this evaluation since the GAPs assessed refer to authorisations on perennial crops outside the EC. The nature and magnitude of spinetoram residues in livestock was also not relevant for this application because peaches, nectarines and apricots are not fed to animals.

---

1 On request from the European Commission, Question No EFSA-Q-2009-00365, issued on 14 September 2009.

2 Correspondence: [praper.mrl@efsa.europa.eu](mailto:praper.mrl@efsa.europa.eu)

For spinetoram, the chronic and acute intake resulting from the proposed import tolerances were calculated using the EFSA PRIMo rev.2. The long-term exposure is calculated on the basis of the STMRs derived from the supervised field trials on peaches and apricots and the MRLs established for other crops. The total calculated intake ranged from 4.9 -27.5% of the ADI. The short term exposure calculated on the basis of the HR values derived in the supervised field trials in peaches resulted in a maximum exposure of 3.2% of the ARfD for peaches and 1.7% for apricots.

EFSA concludes that the use of spinetoram on peaches/nectarines and apricots according to the notified GAP intended in third countries is sufficiently supported by data and no risk for consumer health was identified.

EFSA recommends amending the temporary MRLs for peaches/nectarines and apricots in Annex III of Regulation 396/2005 as summarised in the table below:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: Spinetoram (sum of XDE-175-J and XDE-175-L)</b>			
Peaches (including nectarines)	0.05(*)	0.2	MRL proposal is supported by data and no risk for consumers was identified for this import tolerance.
Apricots	0.05(*)	0.2	

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

EFSA also recommends not to change the residue definition for enforcement but to maintain it as currently established in Annex III of Regulation 396/2005 as Spinetoram (XDE-175) which comprises the compounds XDE-175-J and XDE-175-L.

**Since the peer review for spinetoram is not yet completed, all the conclusions derived in this assessment are provisional. They have to be reviewed in the light of the decisions taken in the peer review.**

#### KEY WORDS

Spinetoram (XDE-175), peaches, nectarines, apricots, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, spinosyn group

**TABLE OF CONTENTS**

Summary .....	1
Table of contents .....	3
Background .....	4
Terms of reference.....	4
The active substance and its use pattern.....	5
Assessment .....	8
Assessment .....	8
1. Methods of analysis.....	8
1.1. Methods for enforcement of residues in food of plant origin .....	8
1.2. Methods for enforcement of residues in food of animal origin .....	8
2. Mammalian toxicology.....	9
3. Residues.....	10
3.1. Nature and magnitude of residues in plant.....	10
3.1.1. Primary crops.....	10
3.1.2. Rotational crops.....	14
3.2. Nature and magnitude of residues in livestock.....	14
4. Consumer risk assessment.....	15
Conclusions and recommendations .....	17
References .....	18
Appendix A – Good Agricultural Practices (GAPs).....	19
Appendix B – Pesticide Residues Intake Model (PRIMo).....	21
Appendix C – Existing EC MRLs.....	23
Abbreviations .....	26

## BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that any party having a legitimate commercial interest may submit to the rapporteur Member State designated pursuant to Directive 91/414/EEC an application to set an import tolerance in accordance with the provisions of Article 7 of that regulation.

The United Kingdom, hereafter referred to as the evaluating Member State (EMS), received from the company Poyntz Consulting<sup>3</sup>, on behalf of Dow Agrosiences, an application to modify the existing MRLs for the active substance spinetoram in peaches (incl. nectarines) and apricots. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 16 January 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00396 and the following subject:

*Spinetoram (XDE-175) - Application to modify the existing MRL for XDE-175 (sum of XDE-175-J and XDE-175-L) and the N-demethyl-175-J and N-formyl-J metabolites, expressed as XDE-175 in apricots from 0.05\* mg/kg to 0.3 mg/kg and in peaches from 0.05\* mg/kg to 0.3 mg/kg*

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

## TERMS OF REFERENCE

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

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months, in specific cases within 6 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 30 July 2009.

---

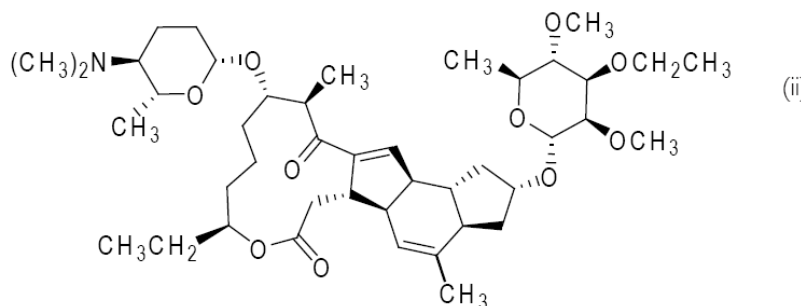
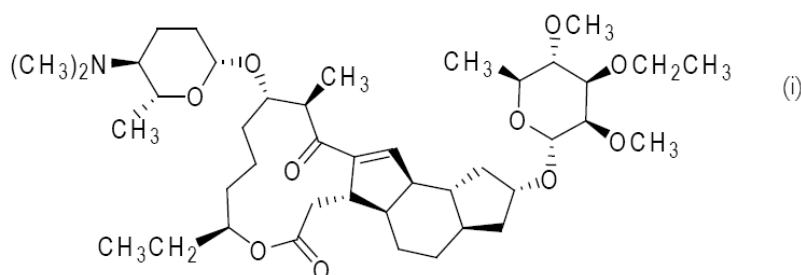
<sup>3</sup> Poyntz Consulting, Hilton House, Mayles Lane, PO17 5 ND, Wickham, Hampshire, United Kingdom

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Spinetoram is the ISO common name for a mixture of 3'-O-ethyl-5,6-dihydro spinosyn J ((2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)-2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl- $\alpha$ -Lmannopyranosyl)oxy]-13-[[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2Hpyran-2-yl]oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,10,11,12,13,14,16a,16b-hexadecahydro-14-methyl-1H-asindaceno[3,2-d]oxacyclododecin-7,15-dione) and 3'-O-ethyl Spinosyn L ((2R,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl- $\alpha$ -Lmannopyranosyl)oxy]-13-[[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2Hpyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1H-asindaceno[3,2-d]oxacyclododecin-7,15-dione) (IUPAC nomenclature).

The ratio of the two spinosyns, also referred to as factor J and factor L, ranges from 70:30 to 90:10.

The development code for the active substance is XDE-175.



(i) 3'-O-ethyl-5,6-dihydro spinosyn J (major component), XDE-175-J

(ii) 3'-O-ethyl spinosyn L, XDE-175-L

Spinetoram is an active substance belonging to the spinosyn class of insecticides like spinosad. Spinosyn J and L, the starting materials for spinetoram produced by the soil Actinomycete, *Saccharopolyspora spinosa*, are chemically modified to produce spinetoram.

Spinetoram containing plant protection products have been developed to control pests such as codling moth, oriental fruit moth, leafminers, thrips, grape berry moth, and a range of other insects on pome fruit, stone fruit, tree nuts, crucifers, leafy vegetables, fruiting vegetables, citrus, grapes, corn, etc. Spinetoram causes excitation of the insect nervous system by activation of the nicotinic acetylcholine receptor, but at a different site than nicotine or the neonicotinoids. It also affects the GABA ( $\gamma$ -aminobutyric acid) receptors.

The log  $P_{ow}$  of 4.09 (pH7, 19°C) is indicating that spinetoram is a fat soluble compound.

In the context of Directive 91/414/EEC, spinetoram is a “new” active substance. Dow Agrosiences submitted the dossier for the active substance to the responsible authorities of the United Kingdom on

17 October 2007 with an application to obtain its inclusion in Annex I of Directive 91/414/EEC. The dossier was found to be complete and satisfied the data and information requirements of the mentioned Directive. The decision regarding the completeness of the dossier was published in the Official Journal on 18 September 2008 (Decision 2008/740/EC). Since a Draft Assessment Report has not yet been finalised by the nominated RMS (United Kingdom), the peer review process is not yet initiated.

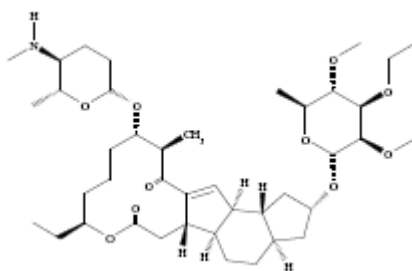
In the European Community temporary MRLs have been established for spinetoram in Annex III of Regulation (EC) No. 396/2005 (Appendix C). The residue definition for enforcement purposes was set as parent compound only.

Codex Alimentarius has recently evaluated spinetoram. CXLs have been established for several plant commodities and products of animal origin, but not for the crops under consideration. Although residue data for peaches and apricots have been presented to the JMPR, it was concluded that no CXLs should be established for the time being since the proposed GAP in Australia has not yet been approved at the time the evaluation was performed. Codex residue definition for enforcement was defined as spinetoram whereas for risk assessment N-demethyl- and N-formyl-metabolites of the major spinetoram component were included in the residue definition.

In its Evaluation Report (UK, 2008), the EMS reported that Poyntz Consulting, on behalf of Dow Agrosciences, has submitted an application for the establishment of EC import tolerances on a wide range of crops. The GAPs for these uses as submitted are attached in Appendix A. The EMS concluded that only the use on peaches/nectarines and apricots requires the modification of the existing MRLs at European level. The other uses reported (plums, cherries, potatoes, tropical root and tuber vegetables, onions, garlic, shallots and tree nuts) are already covered by the current MRLs and no amendment of the legislation is necessary. Thus, they are not subject to the current assessment.

Since the Evaluation Report did not report the countries for which the import tolerances were requested, EFSA requested further clarifications. The EMS forwarded information provided by the manufacturer that currently the authorisation procedure is ongoing in South Africa, Argentina, Chile, New Zealand and Israel for GAPs which are comparable to that submitted in this import tolerance request. The EMS concluded that for these uses the existing MRLs have to be raised. It is also noted that use of spinetoram on stone fruit is already authorised in North America, Canada and Australia. However, in these countries the authorised GAPs differ significantly from the GAPs reported in the evaluation report (UK, 2008) regarding the PHI (14 days instead of 7 days). It should also be mentioned that the USA, Canada and Australia have established national MRLs at the level of 0.2 mg/mg.

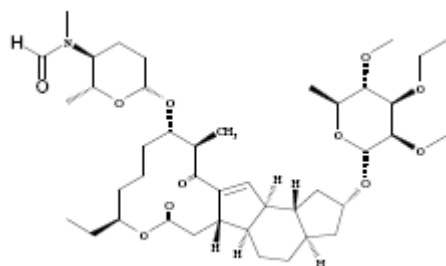
The RMS proposed not only to raise the MRLs for peaches/nectarines and apricots, but also to modify the residue definitions for enforcement and risk assessment to *spinetoram* (sum of XDE-175-J and XDE-175-L), *N-demethyl-175-J<sup>4</sup>* and *N-formyl-175-J<sup>5</sup>* metabolites, expressed as spinetoram taking



<sup>4</sup> N-demethyl-175-J:

into account that certain metabolites are formed in the crops in significant concentrations which contribute to the dietary burden (UK, 2008).

EFSA based its evaluation on the Evaluation Report submitted by the EMS (UK, 2008), the additional information provided in the Addendum to the Evaluation Report (UK, 2009) and the JMPR Report (WHO/FAO, 2008).



<sup>5</sup> N-formyl-175-J:

## ASSESSMENT

### 1. Methods of analysis

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

The United Kingdom evaluated an analytical method provided by the applicant which is capable of measuring spinetoram (XDE-175) and the metabolites N-demethyl-XDE-175-J and N-formyl-XDE-175-J. The residues of XDE-175 and its metabolites are extracted from plant matrices with acetonitrile/water. The final quantification is performed by HPLC with positive ion electrospray ionisation tandem mass spectrometry which allow a separate measurement of the individual components of the residue definition. The method was validated for crops with high acid, high water content, dry crops and crops with high fat content for the individual components of the residue definition. The recoveries were acceptable for all fortification levels (0.01 mg/kg 1 mg/kg, in crops with high water content also 10 mg/kg). The ILV data also confirmed the suitability of the method described for MRL enforcement.

It is concluded that a validated method is available to enforce MRLs in the crops under consideration. The method is applicable for the current residue definition which comprises only XDE-175-J and XDE-175-L, and for an extended residue definition containing the relevant metabolites N-demethyl-XDE-175-J and N-formyl-XDE-175-J. Since the LOQ for each of the four individual components of the residue definition is 0.01 mg/kg, the overall LOQ achievable is 0.02 mg/kg for the current residue definition or 0.04 mg/kg for the extended residue definition.

#### 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.



## 2. Mammalian toxicology

Since the evaluation of spinetoram in the framework of Directive 91/414/EEC is still in the stage of drafting the DAR and the peer review process did not yet start, currently no agreed European toxicological reference values are available. However, the RMS has already evaluated the toxicological studies presented by the applicant and proposed the following ADI and ARfD values which will also be presented in the DAR:

**Table 2-1.** Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
<b>Spinetoram</b>					
ADI	UK	2009	0.021	1 yr dog	100
ARfD	UK	2009	0.3	Rabbit developmental study	100

The RMS concluded that the metabolites N-demethyl-XDE-175-J and N-formyl-XDE-175-J are covered by the toxicological reference values proposed for spinetoram.

It is noted that JMPR in its evaluation (WHO/FAO, 2008) came to the conclusion to establish the ADI for spinetoram at the level of 0.05 mg/kg b.w. Because of the low acute toxicity, no ARfD was established by JMPR.

The risk assessment regarding the potential health risk related to residues in peaches and apricots will be based on the ADI and ARfD proposed by the UK. However, if the peer review comes to a different conclusion, in particular if the ADI or ARfD will be established at a lower level, the risk assessment has to be reviewed to ensure that no unacceptable consumer health risk is associated with the MRL proposals discussed in this evaluation.

### 3. Residues

#### 3.1. Nature and magnitude of residues in plant

##### 3.1.1. Primary crops

###### 3.1.1.1. Nature of residues

Metabolism studies in apples, lettuce and turnips, intended to elucidate the fate of spinetoram after foliar application, were evaluated by the RMS and by JMPR (WHO/FAO, 2008). The studies were performed with <sup>14</sup>C-XDE-J or <sup>14</sup>C-XDE-175-L uniformly labelled with <sup>14</sup>C in the macrolide ring. The details of the metabolism studies are reported in the evaluation report (UK, 2008) and in the JMPR evaluation (WHO/FAO, 2008).

The following overall conclusions could be drawn from the metabolism studies:

- Metabolism of spinetoram was observed to be similar in the three crops groups investigated, i.e. fruits, leafy vegetables and root and tuber vegetables.
- Washing with dichloromethane and acetonitrile removed the major amount of TRR from leaves and treated apples. Thus, no or little translocation in the treated crops is expected.
- Residues were readily extractable; the concentration of non-extractable radioactive residues was low (most less than 10% of TRR, in turnip roots 10-30%).
- The level of aqueous soluble residues, indicating the formation of conjugated residues in plants, was low.
- Among the two spinetoram components, XDE-175-L (the minor component of the active substance) tended to be metabolised faster than XDE-175-J.
- XDE-175-J was the predominant component of the residue at harvest identified in apples, lettuce and turnips (35 – 69% of TRR). XDE-175-L is also present, but in lower concentrations.
- The major metabolites identified were N-demethyl-175-J, N-formyl-175-J, to a lower extent N-demethyl-175-L and N-formyl-175-L.

Based on the results of the submitted metabolism studies, three metabolic pathways were found to be responsible for the breakdown of spinetoram in plants. The first involves changes of the N-dimethyl-moiety on the forosamine sugar to give N-demethyl- and N-formyl- metabolites. The second involves cleavage of the macrolide ring system at one or more positions, resulting in a complex residue mixture consisting of numerous components. The third pathway, which pertains only the XDE-175-J component, involves changes to the rhamnose sugar leading to the 3-O-deethyl and C9-pseudoaglycone-175-J metabolites. The degradation products produced in the 1<sup>st</sup> and 3<sup>rd</sup> pathway further undergo a metabolism as described in the 2<sup>nd</sup> pathway (cleavage of the macrolide ring system).

Based on the results of the metabolism studies, the EMS proposed the following residue definition for both, risk assessment and monitoring purposes:

Spinetoram (sum of XDE-175-J, XDE-175-L), N-demethyl-175-J and N-formyl-175-J, expressed as spinetoram.

EFSA agrees with the arguments and the proposed residue definition for risk assessment.

Regarding the residue definition for enforcement, EFSA is of the opinion that, considering the following facts, the current residue definition established in Annex III as parent compound only should not be amended:

- The component XDE-175-J was found to be the predominant compound identified in the metabolism studies. It is therefore a good marker for identifying if a commodity was treated with spinetoram.
- Maintaining the current residue definition also avoids unnecessary burden for the enforcement laboratories for validating and acquisition of analytical standards.
- Changing the residue definition would require to amend the currently established MRLs taking into account the proportion of N-demethyl-175-J and N-formyl-175-J present on treated crops.
- The proposed MRLs are temporary MRLs only which will be reviewed after the peer review for the active substance is completed. It should be avoided that the residue definitions are changed several times, unless it is justified for consumer safety reasons.
- The current residue definition is identical with the Codex residue definition. No recalculation of Codex CXLs is thus required if the current residue definition is maintained.
- For risk assessment of peaches and apricots, reliable conversion factors can be retrieved from the supervised field trials available.

EFSA therefore recommends the following residue definitions:

Residue definition for enforcement:	Spinetoram (sum of XDE-175-J and XDE-175-L)
Residue definition for risk assessment:	Spinetoram (sum of XDE-175-J and XDE-175-L), N-demethyl-XDE-J and N-formyl-XDE-175-J, expressed as spinetoram

However, EFSA would like to stress that the conclusions reached in the framework of this application are only provisional, and have to be revised after the peer review has been completed.

### 3.1.1.2. Magnitude of residues

In support of the import tolerance request for spinetoram on peaches/nectarines and apricots the applicant submitted 10 supervised field trials on peaches performed in Spain and Southern France in the years 2006 and 2007. Four trials were performed as residue decline studies with sampling prior to the last application (in two trials only) and at a PHI of 0, 3, 7, 10 and 14 days. The trials were in accordance with the intended GAP for several countries for which the registration procedure is still ongoing (South Africa, Argentina, Chile, New Zealand, Israel) regarding the application rate (100 g a.s./ha) and the PHI (7 days). Although in six trials the active substance was applied only 3 instead of 4 times, as specified in the critical GAP, the samples were considered acceptable because the last treatment is expected to have the main impact on the final residue in the harvested crop. A justification was provided that the Southern European Member States, where the trials were conducted, were considered representative of all regions where these crops would be likely to be grown due to the climatic conditions necessary for the cultivation of these particular fruits.

The results of the residue trials are summarised in Table 3-1. It is noted that in the Evaluation Report submitted in support of this application (UK, 2008), the results were reported as sum of XDE-175-J,

XDE-175-L, N-demethyl-J and N-formyl-J. In the addendum of the Evaluation Report (UK, 2009), the results for the PHI of 7 days were reported also as sum of XDE-175-J and XDE-175-L, which is in line with the residue definition for enforcement proposed by EFSA.

From the supervised field trials a MRL proposal of 0.2 mg/kg for peaches, nectarines and apricots was derived. The HR and STMR values to be used in the exposure assessment are 0.138 and 0.091 mg/kg, respectively.

The storage stability for spinetoram and for the metabolites N-demethyl-XDE-175-J and N-formyl-XDE-175-J has been investigated for wheat grain, soybean, orange, lettuce and sugar beet, representing dry commodities, commodities with high oil content, high acid content, and high water content. The stability of spinetoram related residues was demonstrated for at least one year. The EMS confirms that the samples were stored frozen for a maximum of 276 days before analysis (UK, 2009). Thus, the maximum period for storage stability was not exceeded.

The analytical method used for analysing the samples was basically the same as proposed for post-registration monitoring with the only difference that an additional purification step was introduced for the extract before the final quantification with LC/MS/MS. The validation data demonstrated that the method provides reliable residue results.

**Table 3-1.** Overview of the available residues trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)						STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement Spinetoram (sum of XDE-175-J and XDE-175-L)			Risk assessment (Spinetoram (sum of XDE-175-J and XDE-175-L), N-demethyl-XDE-J and N-formyl-XDE-175-J, expressed as spinetoram)							
Peaches	Import	Outdoor	0.064; 0.075 <sup>1</sup> ; 0.127; 0.108 <sup>1</sup>	0.054; 0.058; 0.047 <sup>1</sup>	0.075 <sup>1</sup> ; 0.070; 0.064 <sup>1</sup>	0.084; 0.048 <sup>1</sup> ; 0.162 <sup>1</sup> ; 0.138 <sup>1</sup>	0.083; 0.082; 0.067 <sup>1</sup>	0.098 <sup>1</sup> ; 0.098; 0.112 <sup>1</sup>	0.091	0.162	1.36	0.2	Residue trials were performed on peaches, but can be extrapolated to nectarines and apricots. R <sub>ber</sub> = 0.17 R <sub>max</sub> =0.15

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

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

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

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

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

(1) The trial was performed with 3 instead of 4 applications.

#### 3.1.1.3. Effect of industrial processing and/or household preparation

Processing studies were not reported by the EMS because according to the calculations of the United Kingdom, the chronic exposure did not exceed the trigger value of 10% of the ADI.

#### **3.1.2. Rotational crops**

Usually, the possible occurrence of residues in rotational crops is not considered relevant for European consumer exposure if the GAPs are authorised outside the EC or if the GAPs concern uses on perennial crops. Since both waivers apply to the given application, no further consideration is given to the presence of residues in rotational crops.

#### **3.2. Nature and magnitude of residues in livestock**

Nature and magnitude of spinetoram residues in livestock was not assessed since the crops under consideration (peaches, nectarines and apricots) are not a potential feeding stuff for livestock.

#### 4. Consumer risk assessment

EFSA performed a chronic and acute consumer risk assessments with the EFSA PRIMo rev. 2 using the MRLs as established in Annex III of Regulation (EC) No. 396/2005 and the STMR and HR values derived for the uses on peaches/nectarines and apricots. The input values are summarised in Table 4-1.

The calculation of the chronic consumer intake is affected by two major uncertainties:

- Firstly, the calculation was performed with the MRLs instead of the STMR. It is expected that this would lead to an overestimation of exposure. This approach was taken because the STMR values are not available for the currently established temporary MRLs.
- Secondly, the calculation was performed with the MRLs established for the parent compound only, not including the additional metabolites included in the risk assessment residue definition (N-demethyl-XDE-175-J and N-formyl-XDE-175-J) which also contribute to the dietary burden. For the MRLs established in Annex III no conversion factors for residue definition enforcement to risk assessment are available. A conversion factor could be retrieved for peaches and apricots, indicating that the residues expressed according to the risk assessment residue definition are ca. 30% higher than the residues expressed as residue definition for enforcement (CF = 1.36). Thus, assuming a similar conversion factor for the other crops for which MRLs have been established above the LOQ, the real exposure might be 30 % higher.

The toxicological reference values used in the risk assessment are the ADI and ARfD proposed by the RMS. If during the peer review the ADI or ARfD values will be lowered, the risk assessment has to be revised. The results presented here are therefore only considered as provisional.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition: Spinetoram (sum of XDE-175-J and XDE-175-L), N-demethyl-XDE-175-J and N-formyl-XDE-175-J, expressed as spinetoram</b>				
Peaches/nectarines	0.091	STMR	0.162	HR
Apricots	0.091	STMR	0.162	HR
Other crops	MRLs	See Appendix C	Not relevant	
Products of animal origin	Not considered	Currently no MRLs are set.	Not relevant	

The summary intake calculation can be found in Appendix B.

No long term intake concerns were identified for any of the European diets. The total calculated intake values ranged from 4.9 -27.5% of the ADI. The contribution of peaches/nectarines and apricots to the total dietary intake is less than 1%, (0.25% for peaches and 0.16% for apricots). The safety margin is considered high enough to compensate for possible inaccuracies in the chronic risk assessment as described above.

In the acute risk assessment the maximum exposure was calculated to be 3.2% of the ARfD for peaches and 1.7% for apricots.

EFSA concludes that the use of spinetoram on peaches/nectarines and apricots according to the notified GAP in third countries would not lead to residues on the treated commodities which pose a consumer health risk.



## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

Based on this evaluation report, an addendum to this report and the JMPR evaluation, EFSA derives the following conclusions regarding the application.

The toxicological profile of spinetoram was assessed by the RMS. The data were sufficient to conclude on a provisional ADI value of 0.021 mg/kg and an ARfD of 0.3 mg/kg.

The metabolism of spinetoram was investigated for three different crop groups (fruits and fruiting vegetables, leafy vegetables and root and tuber vegetables) in which the metabolism was found to be similar. EFSA concluded that the current enforcement residue definition (spinetoram (sum of XDE-175-J and XDE-175-L)) should be maintained. However, the residue definition for risk assessment should be established as spinetoram (sum of XDE-175-J and XDE-175-L), N-demethyl-XDE-J and N-formyl-XDE-175-J, expressed as spinetoram.

An analytical method based on LC/MS/MS is available to enforce spinetoram MRLs in stone fruit.

The submitted residue trials performed in peaches were sufficient to derive an MRL proposal of 0.2 mg/kg which can be extrapolated also to nectarines and apricots. This MRL would cover the intended use of spinetoram in third countries (South Africa, Argentina, Chile, New Zealand and Israel) for which currently the authorisation procedure is ongoing.

The possible occurrence of residues in rotational crops was not considered in the framework of this evaluation since the GAPs assessed refer to authorisations on perennial crops outside the EC. The nature and magnitude of spinetoram residues in livestock was also not relevant for this application because peaches, nectarines and apricots are not fed to animals.

For spinetoram, the chronic and acute intake resulting from the proposed import tolerances were calculated using the EFSA PRIMo rev.2. The long-term exposure is calculated on the basis of the STMRs derived from the supervised field trials on peaches and apricots and the MRLs established for other crops. The total calculated intake ranged from 4.9 -27.5% of the ADI. The short term exposure calculated on the basis of the HR values derived in the supervised field trials in peaches resulted in a maximum exposure of 3.2% of the ARfD for peaches and 1.7% for apricots.

EFSA concludes that the use of spinetoram on peaches/nectarines and apricots according to the notified GAP intended in third countries is sufficiently supported by data and no risk for consumer health was identified.

**Since the peer review for spinetoram is not yet completed, all the conclusions derived in this assessment are provisional. They have to be reviewed in the light of the decisions taken in the peer review.**

### RECOMMENDATIONS

EFSA recommends amending the temporary MRLs for peaches/nectarines and apricots in Annex III of Regulation 396/2005 as summarised in the table below:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: Spinetoram (sum of XDE-175-J and XDE-175-L)</b>			

<b>Commodity</b>	<b>Existing EC MRL (mg/kg)</b>	<b>Proposed EC MRL (mg/kg)</b>	<b>Justification for the proposal</b>
Peaches (including nectarines)	0.05(*)	0.2	MRL proposal is supported by data and no risk for consumers was identified for this import tolerance.
Apricots	0.05(*)	0.2	

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

EFSA also recommends not to change the residue definition for enforcement but to maintain it as currently established in Annex III of Regulation 396/2005 as Spinetoram (XDE-175) which comprises the compounds XDE-175-J and XDE-175-L.

## REFERENCES

- WHO/FAO, 2008. Pesticide residues in food – 2008. Evaluations 2008, Part I – Residues. FAO Plant Production and Protection paper, 194, 2008.
- WHO/FAO, 2008. Pesticide residues in food – 2008. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 193, 2008.
- United Kingdom, 2008. Import tolerance filenote: COP 2008/01276: Import tolerance application (category 3) for XDE-175 for use as an insecticide on various crops prepared by the Rapporteur Member State United Kingdom, 3 December 2008.
- United Kingdom, 2009. Import tolerance filenote (Addendum): COP 2008/01276: Import tolerance application (category 3) for XDE-175 for use as an insecticide on various crops prepared by the Rapporteur Member State United Kingdom, September 2009.

## APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Pesticide(s) (common name(s)):	XDE-175 (spinetoram)	Responsible body for reporting (name, address):	PSD
Trade name(s):	n/a	Reporting Country:	UK
Main uses:	Insecticide	Date application submitted:	12/09/2008

Crop and/or situation (a)	Country	Product name (or code number)	F, G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-e)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applic'ns (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		

Stone fruit Peaches/Nectarines/Apricots	USA	GF-1640	F	Lepidopteran insect pests	WG	250 g/kg	High vol. spray	Through season	1-4	10d	1.67-10.0	1000-3000	50-100	7	
Stone fruit Plums <sup>1</sup>	"	GF-1640	F	"	WG	250 g/kg	"	"	1-4	10d	1.67-10.0	1000-3000	50-100	14	
Stone fruit Cherries <sup>1</sup>	"	GF-1640	F	"	WG	250 g/kg	"	"	1-4	14d	1.67-10.0	1000-3000	50-100	14	
Potatoes, Tropical root and tuber vegetables <sup>1</sup>	"	GF-1640 GF-1587	F	"	WG SC	250 g/kg 120 g/l	"	"	1-4	7d	4.0-30.0	200-1000	40-60	1	Use adjuvant ±
Bulb onions, garlic, shallots <sup>1</sup>	"	GF-1640 GF-1587	F	"	WG SC	250 g/kg 120 g/l	"	"	1-5	5d	2.5-12.5	500-1000	25-62.5	1	Use adjuvant ±
Tree nuts (shelled or unshelled) <sup>1</sup>	"	GF-1640 GF-1587 GF-1629	F	"	WG SC SC	250 g/kg 120 g/l 60 g/l	"	"	1-5	7d	2.0-24.6	500-2000	40-123	7	

<sup>1</sup> According to the conclusions of the EMS, these GAPs do not require the amendment of existing MRLs and are therefore not further considered by EFSA.

Remarks;	
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)	(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(i) g/kg or g/l
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds	(j) Growth stage at 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) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989	(l) PHI - minimum pre-harvest interval
(f) All abbreviations used must be explained	(m) Remarks may include: Extent of use/economic importance/restrictions
(g) Method, e.g. high volume spraying, low volume spraying, spreading,	

dusting, drench	
-----------------	--

## APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

<b>Spinetoram</b>			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0,05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	<b>0,021</b>	ARfD (mg/kg bw):	<b>0,3</b>
Source of ADI:	<b>UK</b>	Source of ARfD:	<b>UK</b>
Year of evaluation:	<b>2008</b>	Year of evaluation:	<b>2008</b>

ADI and ARfD proposed by RMS. DAR not yet completed.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum - maximum						
		5                      27						
		No of diets exceeding ADI:						
		---						
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
27,5	DE child	11,5	Apples	3,6	Oranges	3,0	Table grapes	3,4
25,0	WHO Cluster diet B	7,3	Tomatoes	4,3	Wine grapes	2,0	Wheat	6,6
19,3	NL child	6,0	Apples	3,0	Oranges	1,8	Table grapes	4,6
16,2	IE adult	3,0	Wine grapes	1,0	Oranges	1,0	Tomatoes	5,6
14,9	UK Toddler	5,4	Sugar beet (root)	1,9	Oranges	1,6	Apples	8,4
14,9	PT General population	5,9	Wine grapes	2,1	Tomatoes	1,3	Potatoes	3,4
14,4	FR all population	9,5	Wine grapes	1,0	Tomatoes	0,8	Wheat	1,8
12,7	FR toddler	2,5	Apples	1,9	Oranges	1,8	Tomatoes	3,8
12,3	WHO cluster diet E	3,8	Wine grapes	1,3	Tomatoes	0,9	Wheat	4,0
11,1	DK child	2,2	Apples	1,6	Cucumbers	1,3	Wheat	4,0
10,0	WHO cluster diet D	2,4	Tomatoes	1,5	Wheat	1,0	Potatoes	4,1
9,8	UK Infant	2,4	Sugar beet (root)	1,5	Apples	1,2	Oranges	5,5
9,8	ES child	2,3	Tomatoes	2,1	Oranges	1,1	Apples	2,7
9,4	SE general population 90th percentile	1,8	Tomatoes	1,0	Apples	1,0	Potatoes	3,4
9,3	WHO regional European diet	2,6	Tomatoes	1,0	Potatoes	0,7	Wheat	3,1
9,3	IT kids/toddler	3,4	Tomatoes	1,6	Wheat	0,8	Apples	2,8
9,2	WHO Cluster diet F	1,6	Tomatoes	1,4	Wine grapes	0,9	Wheat	3,2
9,0	NL general	1,5	Wine grapes	1,4	Oranges	1,1	Apples	2,1
8,4	FR infant	2,4	Apples	1,0	Potatoes	0,9	Oranges	2,6
8,3	UK vegetarian	1,9	Wine grapes	1,5	Tomatoes	0,9	Sugar beet (root)	2,5
8,0	ES adult	1,9	Tomatoes	1,2	Oranges	1,0	Wine grapes	1,7
7,7	DK adult	3,3	Wine grapes	1,0	Tomatoes	0,7	Apples	1,4
7,5	IT adult	2,8	Tomatoes	1,0	Wheat	0,8	Apples	1,9
7,4	UK Adult	2,6	Wine grapes	1,0	Tomatoes	1,0	Sugar beet (root)	2,2
6,9	PL general population	2,1	Tomatoes	1,9	Apples	0,8	Potatoes	1,4
5,7	LT adult	1,8	Apples	1,5	Tomatoes	0,8	Potatoes	1,6
4,9	FI adult	1,0	Tomatoes	0,9	Oranges	0,7	Wine grapes	1,0

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

**Acute risk assessment /children - refined calculations**

**Acute risk assessment / adults / general population - refined calculations**

The acute risk assessment is based on the ARfD.

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

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

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

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

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1		*)	IESTI 2		*)	IESTI 1		*)	IESTI 2		*)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
3,2	Peaches	0,162 / -	2,4	Peaches	0,162 / -	0,9	Peaches	0,162 / -	0,7	Peaches	0,162 / -	
1,7	Apricots	0,162 / -	1,3	Apricots	0,162 / -	0,4	Apricots	0,162 / -	0,3	Apricots	0,162 / -	
<b>No of critical MRLs (IESTI 1)</b>			---			<b>No of critical MRLs (IESTI 2)</b>			---			
Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---			---			---		
			***)			***)			***)			***)
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
1,2	Peach juice	0,2 / -				0,1	Peach preserved with	0,2 / -				
<p>*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values &gt; 90% of ARfD are reported.</p> <p>**) pTMRL: provisional temporary MRL</p> <p>***) pTMRL: provisional temporary MRL for unprocessed commodity</p>												
<p><b>Conclusion:</b>                      For Spinetoram IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity.</p> <p>For processed commodities, no exceedance of the ARfD/ADI was identified.</p>												

## APPENDIX C – EXISTING EC MRLs

Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	02
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	02
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	02
110030	Lemons (Citron, lemon )	02
110040	Limes	02
110050	Mandarins (Clementine, tangerine and other hybrids)	02
110990	Others	02
120000	(ii) Tree nuts (shelled or unshelled)	005*
120010	Almonds	005*
120020	Brazil nuts	005*
120030	Cashew nuts	005*
120040	Chestnuts	005*
120050	Coconuts	005*
120060	Hazelnuts (Filbert)	005*
120070	Macadamia	005*
120080	Pecans	005*
120090	Pine nuts	005*
120100	Pistachios	005*
120110	Walnuts	005*
120990	Others	005*
130000	(iii) Pome fruit	02
130010	Apples (Crab apple)	02
130020	Pears (Oriental pear)	02
130030	Quinces	02
130040	Medlar	02
130050	Loquat	02
130990	Others	02
140000	(iv) Stone fruit	005*
140010	Apricots	005*
140020	Cherries (sweet cherries, sour cherries)	005*
140030	Peaches (Nectarines and similar hybrids)	005*
140040	Plums (Damson, greengage, mirabelle)	005*
140990	Others	005*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	05
151010	Table grapes	05
151020	Wine grapes	05
152000	(b) Strawberries	02
153000	(c) Cane fruit	005*
153010	Blackberries	005*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	005*
153030	Raspberries (Wineberries )	005*
153990	Others	005*
154000	(d) Other small fruit & berries	005*
154010	Blueberries (Bilberries cowberries (red bilberries))	005*
154020	Cranberries	005*
154030	Currants (red, black and white)	005*
154040	Gooseberries (Including hybrids with other ribes species)	005*
154050	Rose hips	005*
154060	Mulberries (arbutus berry)	005*
154070	Azarole (mediterranean medlar)	005*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries)	005*
154990	Others	005*
160000	(vi) Miscellaneous fruit	005*
161000	(a) Edible peel	005*
161010	Dates	005*
161020	Figs	005*
161030	Table olives	005*
161040	Kumquats (Manumi kumquats, nagami kumquats)	005*
161050	Carambola (Bilimbi)	005*
161060	Persimmon	005*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	005*
161990	Others	005*
162000	(b) Inedible peel, small	005*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
162010	Kiwi	005*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	005*
162030	Passion fruit	005*
162040	Prickly pear (cactus fruit)	005*
162050	Star apple	005*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammeiy sapote)	005*
162990	Others	005*
163000	(c) Inedible peel, large	005*
163010	Avocados	005*
163020	Bananas (Dwarf banana, plantain, apple banana)	005*
163030	Mangoes	005*
163040	Papaya	005*
163050	Pomegranate	005*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	005*
163070	Guava	005*
163080	Pineapples	005*
163090	Bread fruit (Jackfruit)	005*
163100	Durian	005*
163110	Soursop (guanabana)	005*
163990	Others	005*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	005*
211000	(a) Potatoes	005*
212000	(b) Tropical root and tuber vegetables	005*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	005*
212020	Sweet potatoes	005*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	005*
212040	Arrowroot	005*
212990	Others	005*
213000	(c) Other root and tuber vegetables except sugar beet	005*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
213010	Beetroot	005*
213020	Carrots	005*
213030	Celeriac	005*
213040	Horseradish	005*
213050	Jerusalem artichokes	005*
213060	Parsnips	005*
213070	Parsley root	005*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	005*
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	005*
213100	Swedes	005*
213110	Turnips	005*
213990	Others	005*
220000	(ii) Bulb vegetables	005*
220010	Garlic	005*
220020	Onions (Silverskin onions)	005*
220030	Shallots	005*
220040	Spring onions (Welsh onion and similar varieties)	005*
220990	Others	005*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	05
231010	Tomatoes (Cherry tomatoes, )	05
231020	Peppers (Chilli peppers)	05
231030	Aubergines (egg plants) (Pepino)	05
231040	Okra, lady's fingers	05
231990	Others	05
232000	(b) Cucurbits - edible peel	02
232010	Cucumbers	02
232020	Gherkins	02
232030	Courgettes (Summer squash, marrow (patisson))	02
232990	Others	02
233000	(c) Cucurbits-inedible peel	005*
233010	Melons (Kiwano )	005*
233020	Pumpkins (Winter squash)	005*
233030	Watermelons	005*
233990	Others	005*
234000	(d) Sweet corn	005*
239000	(e) Other fruiting vegetables	005*
240000	(iv) Brassica vegetables	005*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
241000	(a) Flowering brassica	005*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	005*
241020	Cauliflower	005*
241990	Others	005*
242000	(b) Head brassica	005*
242010	Brussels sprouts	005*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	005*
242990	Others	005*
243000	(c) Leafy brassica	005*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	005*
243020	Kale (Borecole (curly kale), collards)	005*
243990	Others	005*
244000	(d) Kohlrabi	005*
250000	(v) Leaf vegetables & fresh herbs	005*
251000	(a) Lettuce and other salad plants including Brassicaceae	005*
251010	Lamb's lettuce (Italian comsalad)	005*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	005*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	005*
251040	Cress	005*
251050	Land cress	005*
251060	Rocket, Rucola (Wild rocket)	005*
251070	Red mustard	005*
251080	Leaves and sprouts of Brassica spp (Mizuna)	005*
251990	Others	005*
252000	(b) Spinach & similar (leaves)	005*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	005*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	005*
252030	Beet leaves (chard) (Leaves of	005*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
	beetroot)	
252990	Others	005*
253000	(c) Vine leaves (grape leaves)	005*
254000	(d) Water cress	005*
255000	(e) Willow	005*
256000	(f) Herbs	005*
256010	Chervil	005*
256020	Chives	005*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	005*
256040	Parsley	005*
256050	Sage (Winter savory, summer savory, )	005*
256060	Rosemary	005*
256070	Thyme ( marjoram, oregano)	005*
256080	Basil (Balm leaves, mint, peppermint)	005*
256090	Bay leaves (laurel)	005*
256100	Tarragon (Hyssop)	005*
256990	Others	005*
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	01
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	005*
260030	Peas (with pods) (Mangetout (sugar peas))	01
260040	Peas (without pods) (Garden pea, green pea, chickpea)	005*
260050	Lentils	005*
260990	Others	005*
270000	(vii) Stem vegetables (fresh)	005*
270010	Asparagus	005*
270020	Cardoons	005*
270030	Celery	005*
270040	Fennel	005*
270050	Globe artichokes	005*
270060	Leek	005*
270070	Rhubarb	005*
270080	Bamboo shoots	005*
270090	Palm hearts	005*
270990	Others	005*
280000	(viii) Fungi	005*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	005*
280020	Wild (Chanterelle, Truffle, Morel, )	005*
280990	Others	005*
290000	(ix) Sea weeds	005*
300000	3. PULSES, DRY	005*
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	005*
300020	Lentils	005*
300030	Peas (Chickpeas, field peas, chickling vetch)	005*
300040	Lupins	005*
300990	Others	005*
400000	4. OILSEEDS AND OILFRUITS	005*
401000	(i) Oilseeds	005*
401010	Linseed	005*
401020	Peanuts	005*
401030	Poppy seed	005*
401040	Sesame seed	005*
401050	Sunflower seed	005*
401060	Rape seed (Bird rapeseed, turnip rape)	005*
401070	Soya bean	005*
401080	Mustard seed	005*
401090	Cotton seed	005*
401100	Pumpkin seeds	005*
401110	Safflower	005*
401120	Borage	005*
401130	Gold of pleasure	005*
401140	Hempseed	005*
401150	Castor bean	005*
401990	Others	005*
402000	(ii) Oilfruits	005*
402010	Olives for oil production	005*
402020	Palm nuts (palmoil kernels)	005*
402030	Palmfruit	005*
402040	Kapok	005*
402990	Others	005*
500000	5. CEREALS	005*
500010	Barley	005*
500020	Buckwheat	005*
500030	Maize	005*
500040	Millet (Foxtail millet, teff)	005*
500050	Oats	005*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
500060	Rice	005*
500070	Rye	005*
500080	Sorghum	005*
500090	Wheat (Spelt Triticale)	005*
500990	Others	005*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	01*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	01*
620000	(ii) Coffee beans	01*
630000	(iii) Herbal infusions (dried)	01*
631000	(a) Flowers	01*
631010	Camomille flowers	01*
631020	Hybiscus flowers	01*
631030	Rose petals	01*
631040	Jasmine flowers	01*
631050	Lime (linden)	01*
631990	Others	01*
632000	(b) Leaves	01*
632010	Strawberry leaves	01*
632020	Rooibos leaves	01*
632030	Maté	01*
632990	Others	01*
633000	(c) Roots	01*
633010	Valerian root	01*
633020	Ginseng root	01*
633990	Others	01*
639000	(d) Other herbal infusions	01*
640000	(iv) Cocoa (fermented beans)	01*
650000	(v) Carob (st johns bread)	01*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	01*
800000	8. SPICES	01*
810000	(i) Seeds	01*
810010	Anise	01*
810020	Black caraway	01*
810030	Celery seed (Lovage seed)	01*
810040	Coriander seed	01*
810050	Cumin seed	01*
810060	Dill seed	01*
810070	Fennel seed	01*
810080	Fenugreek	01*
810090	Nutmeg	01*
810990	Others	01*
820000	(ii) Fruits and berries	01*
820010	Allspice	01*
820020	Anise pepper (Japan pepper)	01*



Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
820030	Caraway	0.1*
820040	Cardamom	0.1*
820050	Juniper berries	0.1*
820060	Pepper, black and white (Long pepper, pink pepper)	0.1*
820070	Vanilla pods	0.1*
820080	Tamarind	0.1*
820990	Others	0.1*
830000	(iii) Bark	0.1*
830010	Cinnamon (Cassia)	0.1*
830990	Others	0.1*
840000	(iv) Roots or rhizome	0.1*
840010	Liquorice	0.1*
840020	Ginger	0.1*
840030	Turmeric (Curcuma)	0.1*
840040	Horseradish	0.1*
840990	Others	0.1*
850000	(v) Buds	0.1*
850010	Cloves	0.1*
850020	Capers	0.1*
850990	Others	0.1*
860000	(vi) Flower stigma	0.1*
860010	Saffron	0.1*
860990	Others	0.1*
870000	(vii) Aril	0.1*
870010	Mace	0.1*
870990	Others	0.1*
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*
100000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
101000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
101100	(a) Swine	
101101	Meat	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
101102	Fat free of lean meat	
101103	Liver	
101104	Kidney	
101105	Edible offal	
101199	Others	
101200	(b) Bovine	
101201	Meat	
101202	Fat	
101203	Liver	
101204	Kidney	
101205	Edible offal	
101299	Others	
101300	(c) Sheep	
101301	Meat	
101302	Fat	
101303	Liver	
101304	Kidney	
101305	Edible offal	
101399	Others	
101400	(d) Goat	
101401	Meat	
101402	Fat	
101403	Liver	
101404	Kidney	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
101405	Edible offal	
101499	Others	
101500	(e) Horses, asses, mules or hinnies	
101501	Meat	
101502	Fat	
101503	Liver	
101504	Kidney	
101505	Edible offal	
101599	Others	
101600	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl, ostrich, pigeon	
101601	Meat	
101602	Fat	
101603	Liver	
101604	Kidney	
101605	Edible offal	
101699	Others	
101700	(g) Other farm animals (Rabbit, Kangaroo)	
101701	Meat	
101702	Fat	
101703	Liver	
101704	Kidney	
101705	Edible offal	
101799	Others	
102000	(ii) Milk and cream, not	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Spinetoram (XDE-175)
0	concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
102001	Cattle	
102002	Sheep	
102003	Goat	
102004	Horse	
102099	Others	
103000	(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	
103001	Chicken	
103002	Duck	
103003	Goose	
103004	Quail	
103099	Others	
104000	(iv) Honey (Royal jelly, pollen)	
105000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
106000	(vi) Snails	
107000	(vii) Other terrestrial animal products	

(\*) Indicates lower limit of analytical determination

## ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DP	dustable powder
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
ECD	electron capture detection
EDI	estimated daily intake
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionization detection
GABA	$\gamma$ -aminobutyric acid
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue

ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K <sub>oc</sub>	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10 <sup>-6</sup> )
PRIMo	Pesticide Residues Intake Model
RMS	rappporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UK	United Kingdom
UVD	ultra-violet detection
WHO	World Health Organisation