

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for methoxyfenozide in various leafy vegetables¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Spain, herewith referred to as the evaluating Member State (EMS), received an application from the company Dow AgroSciences to modify the existing MRLs for the active substance methoxyfenozide in leafy vegetables and fresh herbs (except vine leaves, water cress and witloof). In order to accommodate for the intended use of methoxyfenozide in the SEU, the EMS proposed to raise the existing MRLs in these crops (except in scarole) from the limit of quantification (LOQ) of 0.02 mg/kg to 4 mg/kg. Spain drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA.

EFSA considers that the submitted supervised residue trials are sufficient to support the proposed residue data extrapolation from lettuce to other crops under consideration and to derive a MRL proposal of 4 mg/kg for the proposed use on lettuce and other salad plants including Brassicaceae, the whole group of spinach and similar leaves and the whole group of herbs. Adequate analytical enforcement methods are available to control the residues of methoxyfenozide in the commodities under consideration.

EFSA concludes that the intended uses on the leafy vegetables under consideration (except on scarole) will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern. EFSA confirms the conclusion of the EMS that the intended use of methoxyfenozide on scarole is not acceptable due to acute consumer intake concerns identified.

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KEY WORDS

Methoxyfenozide, leaf vegetables and fresh herbs, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, diacylhydrazine insecticide.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Spain, herewith referred to as the evaluating Member State (EMS), received an application from the company Dow AgroSciences to modify the existing MRLs for the active substance methoxyfenozide in leafy vegetables and fresh herbs (except vine leaves, water cress and witloof). In order to accommodate for the intended use of methoxyfenozide in the SEU, the EMS proposed to raise the existing MRLs in these crops (except in scarole) from the limit of quantification (LOQ) of 0.02 mg/kg to 4 mg/kg. Spain drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 13 September 2011.

EFSA bases its assessment on the evaluation report submitted by the EMS (Spain, 2011), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (UK, 2002), the Commission Review Report on methoxyfenozide (EC, 2004), the JMPR Evaluation of methoxyfenozide (FAO, 2004) as well as the conclusions from a previous EFSA opinion on methoxyfenozide (EFSA, 2010).

The toxicological profile of methoxyfenozide was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI value of 0.1 mg/kg bw/day and an ARfD value of 0.2 mg/kg bw.

The metabolism of methoxyfenozide in primary plants has been investigated in fruits and fruiting vegetables (apples, grapes), pulses and oilseeds (cotton) and cereals (rice) in the framework of the peer review of Directive 91/414/EEC. Although metabolism studies with leafy vegetables are not available, a consistent metabolism of methoxyfenozide in three crop groups is demonstrated to conclude that in primary crops after foliar treatment parent methoxyfenozide is the relevant residue for enforcement and risk assessment purposes. EFSA concludes that for the crops under consideration no additional metabolism studies have to be performed and parent methoxyfenozide is the appropriate residue definition for risk assessment and enforcement.

EFSA considers that the submitted supervised residue trials are sufficient to support the proposed residue data extrapolation from lettuce to other crops under consideration and to derive a MRL proposal of 4 mg/kg for the proposed use on lettuce and other salad plants including Brassicaceae, the whole group of spinach and similar leaves and the whole group of herbs. Adequate analytical enforcement methods are available to control the residues of methoxyfenozide in the commodities under consideration.

The effect of processing on the nature of methoxyfenozide residues has been investigated in a hydrolysis study simulating sterilisation, pasteurization and baking/brewing/boiling. No degradation of methoxyfenozide occurs and therefore for processed commodities the same residue definition as for raw agricultural commodities is applicable. Specific studies to assess the magnitude of methoxyfenozide residues during the processing of the crops under consideration have not been submitted. Such studies are desirable for the crops which are consumed processed to refine the acute consumer exposure.

The crops under consideration can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding/rotational crops resulting from the use of the active substance on primary crops was further assessed, considering the slow degradation of methoxyfenozide in soil. Although the metabolism of methoxyfenozide in succeeding/rotational crops is more extensive, it proceeds in a similar pathway as in primary plants with methoxyfenozide being the major residue in individual crops investigated; the same residue definitions are therefore applicable. The reported rotational crop field studies have been performed with a significantly higher season application rate (9N) than the application rate in the intended use. Residues of methoxyfenozide at significant levels are not expected in edible matrices of rotational crops when grown in crop rotation with leafy vegetables treated according to the intended use. However, in animal feed commodities (straw, forage, hay), a possible occurrence of methoxyfenozide residues cannot be excluded and therefore EFSA

recommends Member States to implement necessary risk mitigation measures when granting authorizations of plant protection products containing methoxyfenozide.

Since the crops under consideration are normally not fed to livestock, the nature and magnitude of methoxyfenozide residues in livestock was not assessed in the framework of this application

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMO). For the calculation of the chronic exposure, EFSA used the median residue value as derived from the residue trials on lettuce. The same input value was used for other salad plants including Brassicaceae, the whole group of herbs and the whole group of spinach and similar leaves. For some crops the risk assessment values were available to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values. The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMO. The total calculated intake values accounted for up to 37.5% of the ADI (DE child diet). The individual contribution of residues in the crops under consideration to the total consumer exposure was below 1% of the ADI.

Short-term consumer risk was identified in relation to the MRL proposal for scarole (**104.5%** of the ARfD), confirming the findings of the EMS. With regard to other crops under consideration no short-term consumer intake concerns were identified and the calculated maximum exposure in percentage of the ARfD was 32.2 % for lettuce, 27% for spinach, 21% for beet leaves, 18.1% for purslane and below 10% for the rest of the crops.

EFSA concludes that the intended uses on the leafy vegetables under consideration (except on scarole) will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern. EFSA confirms the conclusion of the EMS that the intended use of methoxyfenozide on scarole is not acceptable due to acute consumer intake concerns identified.

Thus EFSA proposes to amend the current 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
Enforcement residue definition: Methoxyfenozide				
0251000 (except 0251030)	Lettuce and other salad plants including Brassicacea (except scarole)	0.02*	4	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses.
0252000	Spinach and similar (leaves)	0.02*	4	
0256000	Herbs	0.02*	4	
0251030	Scarole (broad-leaf endive)	0.02*	No new proposal	EFSA confirms the views of the EMS that for the MRL proposal acute risk to consumers cannot be excluded.

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

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

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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 an MRL in accordance with the provisions of Article 7 of that Regulation.

Spain, hereafter referred to as the evaluating Member State (EMS), received an application from the company Dow AgroSciences⁶ to modify the existing MRLs for the active substance methoxyfenozide in leafy vegetables, fresh herbs (except vine leaves, water cress and witloof). 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 was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 13 September 2011.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2011-01031 and the following subject:

Methoxyfenozide - Application to modify the existing MRLs in several leafy vegetables.

Spain proposed to modify the existing MRLs of methoxyfenozide in the crops under consideration from 0.02* mg/kg (the limit of quantification (LOQ)) to 4 mg/kg. For scarole no modification of the existing MRL of 0.02* mg/kg was proposed (due to acute consumer exposure concerns).

EFSA proceeded with the assessment of the application and the evaluation report 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 deadline for providing the reasoned opinion is 13 December 2011.

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.

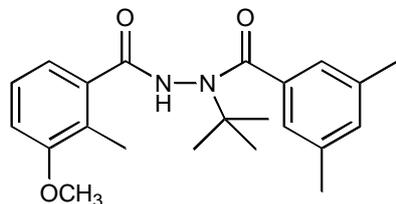
⁴ Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

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 Dow AgroSciences, Calle Ribera del Loira 4-6, Edificio Iris – 4ª planta, 28042, Madrid, Spain

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Methoxyfenozide is the ISO common name for N-tert-butyl-N'-(3-methoxy-o-toluoyl)-3,5-xylohydrazide (IUPAC). The chemical structure of the active substance is as follows:



Molecular weight: 368.47 g/mol

Methoxyfenozide is a diacylhydrazine insecticide. It acts as an ecdysone agonist and is active primarily by ingestion. Methoxyfenozide is active on all the feeding larval stages of *Lepidoptera*. Upon ingestion it causes cessation of feeding and premature lethal moult. The active substance does not have translaminar or phloem-systemic properties. The active substance is fat-soluble.

Methoxyfenozide has been peer reviewed in the framework of Directive 91/414/EEC. By Commission Directive 2005/3/EC⁷ methoxyfenozide is included in the Annex I to Directive 91/414/EEC for the use as insecticide. The representative uses for the peer review were indoor or outdoor foliar applications of the active substance on apples, pears, grapes, oranges, mandarins, peaches, nectarines, tomatoes and peppers. An EFSA conclusion on the peer review of methoxyfenozide is not available.

The existing EU MRLs for methoxyfenozide are established in Annexes II and IIIB of the Regulation (EC) No 396/2005 (Appendix C). The existing EU MRL for all the crops under consideration is set at the limit of quantification (LOQ) of 0.02 mg/kg. EFSA previously issued a reasoned opinion on the modification of the existing MRLs for methoxyfenozide in various fruits (EFSA, 2010). Codex Alimentarius Commission has established a CXL of 15 mg/kg in head lettuce, 30 mg/kg in leaf lettuce and mustard greens.

The details of the intended GAPs for methoxyfenozide are given in Appendix A.

⁷ Commission Directive 2005/3/EC of 19 January 2005, OJ L 20, 22.1.2005, p.19-23

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Spain, 2011), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (UK, 2002), the Commission Review Report on methoxyfenozide (EC, 2004), the JMPR Evaluation of methoxyfenozide (FAO, 2004) as well as the conclusions from a previous EFSA opinion on methoxyfenozide (EFSA, 2010). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁸ 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

Analytical methods for the determination of methoxyfenozide residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (UK, 2002) and the availability of enforcement methods was discussed in the previously issued EFSA reasoned opinion on the modification of the existing MRLs for methoxyfenozide (EFSA, 2010).

It was concluded that sufficiently validated analytical enforcement methods (reverse phase HPLC-UV with LOQ of 0.05 mg/kg and a multi-residue method QuEChERS (HPLC-MS) with a LOQ of 0.01 mg/kg) are available to monitor methoxyfenozide residues in high water content matrices (EFSA, 2010).

In the framework of the current MRL application the applicant submitted validation data of LC-MS/MS method for the determination of methoxyfenozide residues in matrices with high water content. Various matrices (carrots, onions, potato, radish and beet roots and tops) were fortified at 3 fortification levels with methoxyfenozide (0.02 mg/kg, 0.1 mg/kg and 1 mg/kg). For the lowest fortification level 2-3 determinations were made although a minimum of 5 determinations per fortification level should be made (EC, 2000). Acceptable recoveries were demonstrated. An independent laboratory validation (ILV) was also performed; the LC-MS/MS method is acceptable for the determination of methoxyfenozide residues in high water content commodities at the validated LOQ of 0.02 mg/kg.

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

Analytical methods for the determination of methoxyfenozide residues in food of animal origin are not assessed in the current application, since the crops under consideration are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of methoxyfenozide was investigated in the framework of the peer review of Directive 91/414/EEC and the studies were sufficient to establish the toxicological reference values as compiled in Table 2-1.

⁸ Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Methoxyfenozide					
ADI	EC	2004	0.1 mg/kg bw/d	Rat, chronic	100
ARfD	EC	2004	0.2 mg/kg bw	2 week dog	100

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 methoxyfenozide residues in primary plants has been investigated in fruits and fruiting vegetables (apples, grapes), pulses and oilseeds (cotton), cereals (rice) in the framework of the peer review of Directive 91/414/EEC (UK, 2002). In 2003 the JMPR also performed the evaluation of methoxyfenozide (FAO, 2004). The overview of the study results and outcome is discussed in detail in the previously issued EFSA reasoned opinion (EFSA, 2010).

As the representative use for the peer review was on the fruit and fruiting vegetables group, the peer review concluded that for this crop category the metabolism of methoxyfenozide is sufficiently addressed and the risk assessment and enforcement residue definition was established as parent methoxyfenozide. This residue definition has been taken over in Regulation (EC) No 396/2005 for all plant commodities and is also in line with the residue definitions established by the Codex Alimentarius Commission for all plant commodities.

The metabolism studies indicated a similar metabolic pathway of methoxyfenozide in all crop groups investigated. Methoxyfenozide was the main residue in all matrices analysed.

Although metabolism studies with leafy vegetables are not available, a consistent metabolism of methoxyfenozide in three crop groups is demonstrated to conclude that in primary crops after foliar treatment parent methoxyfenozide is the relevant residue for enforcement and risk assessment purposes.

EFSA concludes that for the crops under consideration no additional metabolism studies have to be performed and parent methoxyfenozide is the appropriate residue definition for risk assessment and enforcement.

3.1.1.2. Magnitude of residues

In support of the intended use the applicant submitted in total 10 GAP compliant residue trials on lettuce, which were performed in Italy and Spain in 2007 and 2008. Out of all trials 2 were performed with head forming lettuce varieties, whereas the rest of 8 trials were performed with leaf lettuce varieties. The applicant proposes to extrapolate the residue data from lettuce to the whole group of lettuce and other salad plants including Brassicaceae, the whole group of spinach and similar, and the whole group of herbs. Such an extrapolation is acceptable according to the currently applicable EU guidance documents (EC, 2011) and the submitted number of trials is sufficient. The two residue trials with head forming lettuce varieties were not used for the proposed extrapolation.

The results of the residue trials on open leaf lettuce varieties, the related risk assessment input values (highest residue, median residue) and the MRL proposal are summarized in Table 3-2.

The storage stability of methoxyfenozide residues was investigated in the framework of the peer review of Directive 91/414/EEC (UK, 2002). In frozen matrices with high water content methoxyfenozide is stable for 365 days. As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated (maximum storage for 257 days under deep frozen conditions), it is concluded that the residue data are valid with regard to storage stability.

The analytical method, based on LC-MS/MS principle, which was proposed for the enforcement under the current application (see section 1.1.), was used to analyse the residue trial samples. The analytical method has been sufficiently validated and was proven to be fit for purpose (Spain, 2011).

EFSA considers that the data are sufficient to derive a MRL proposal of 4 mg/kg in lettuce and other salad plants including Brassicaceae, the whole group of spinach and similar leaves and the whole group of herbs in support of the use of methoxyfenozide on these crops in SEU.

Table 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 (Methoxyfenozide)	Risk assessment (Methoxyfenozide)					
Lettuce → lamb's lettuce, cress, scarole rocket/ rucola, red mustard, leaves and sprouts of Brassica spp. (Group code ^f : 0251000) Lettuce → Herbs group (chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil, bay leaves, tarragon) (Group code ^f : 0256000) Lettuce → Spinach and similar group (spinach, beet leaves (chard), purslane) (Group code ^f : 0252000)	SEU	Outdoor	0.36; 0.87; 0.881; 1.106; 1.15; 1.335; 1.89; 2.385	0.36; 0.87; 0.881; 1.106; 1.15; 1.335; 1.89; 2.385	1.13	2.39	4	1	$R_{ber}=3.50$ $R_{max}=3.27$ $MRL_{OECD} = 3.78/4$

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

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of methoxyfenozide residues was investigated in a hydrolysis study in the framework of the peer review of Directive 91/414/EEC (UK, 2002). Under conditions simulating sterilisation, pasteurization and baking/brewing/boiling no degradation of methoxyfenozide occurs. Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable.

Specific studies to assess the magnitude of methoxyfenozide residues during the processing of the crops under consideration have not been submitted. Such studies are desirable for crops which are consumed processed to refine the acute consumer exposure.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

The crops under consideration can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding/rotational crops resulting from the use of the active substance on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of methoxyfenozide is very slow with the maximum $DT_{90\text{field}}$ above 1000 days (EC, 2004). In the soil degradation studies, soil metabolites above 10% of the applied radioactivity (AR) were not found; in the field studies metabolites were not analyzed for (EC, 2004).

Thus, further studies investigating the nature and magnitude of the compound uptake in rotational crops are required.

3.1.2.2. Nature of residues

The metabolism of methoxyfenozide in rotational crops was assessed by the RMS United Kingdom in the DAR (UK, 2002); the same studies have been assessed by the JMPR (FAO, 2004). The overview of the study designs is presented in the table below.

Table 2: Overview of the available confined rotational crop studies

Crop group	Crop sown	Label position	Application details				Remarks
			Method	Rate (kg a.s./ha)	Sowing intervals	Harvest time	
Methoxyfenozide							
Leafy vegetable	mustard	¹⁴ C-methoxy phenyl-, or ¹⁴ C-dimethyl phenyl-, or ¹⁴ C-t-butyl methoxy-fenozide	Soil treatment	3 x 0.75	31, 91, 364 DALA	At an intermediate state and at maturity	
Root and tuber vegetables	radish	¹⁴ C-dimethyl phenyl-, or ¹⁴ C-t-butyl methoxy-fenozide	Soil treatment	3 x 0.75	31, 91, 364 DALA	At an intermediate state and at maturity	
Cereals	wheat	¹⁴ C-t-butyl methoxy-fenozide	Soil treatment	3 x 0.75	31, 91, 364 DALA	At an intermediate state and at maturity	

The total radioactivity was similar for all labels and decreased with increased plant-back time. The TRR in crops planted 30 DAT accounted for a maximum of 0.89 mg eq./kg in immature mustard leaf, 0.13 mg eq./kg in mature mustard leaf, 1.46 mg eq./kg in immature wheat forage, 3.96 mg eq./kg in

wheat straw, 0.054 mg eq./kg in wheat grain, 0.27 mg eq./kg mature radish leaf and 0.095 mg eq./kg in radish root.

In mature crops from 91 day plant-back period, the TRR accounted for a maximum of 0.05 mg eq./kg in mustard leaf, 1.72 mg eq./kg in wheat straw, 0.05 mg eq./kg in wheat grain and 0.05 mg eq./kg in radish roots.

In mature crops from 364 day plant-back period, the TRR accounted for a maximum of 0.04 mg eq./kg in mustard leaf, 0.44 mg eq./kg in wheat straw and 0.02 mg eq./kg in radish roots. The characterisation of the TRR indicated that methoxyfenozide is extensively metabolised in rotational crops.

In **mustard leaves**, regardless of the radiolabel, parent methoxyfenozide (% of the TRR) was identified at levels up to 21% in the crop planted 30 DAT (0.027 mg/kg), up to 17% in the crop planted 90 DAT (0.007 mg/kg) and for up to 18% in the crop planted 365 DAT (0.007 mg/kg). Main identified compounds were metabolite M15 (RH-151055)⁹ (glucose conjugate of the methoxyphenyl ring) and metabolite M12 (RH-152068)¹⁰, which together accounted for up to 33% TRR in the crop planted 30 DAT (0.037 mg/kg), up to 16% TRR in the crop planted 90 DAT (0.009 mg/kg) and up to 30% TRR in the crop planted 365 DAT (0.012 mg/kg). Metabolite M44 (RH-152067)¹¹ was identified for both shortest plant-back intervals (30 days and 90 days) at levels of for up to 18% TRR (0.014-0.024 mg/kg) and 21% TRR (0.01 mg/kg).

Radish roots contained the highest levels of non-metabolised methoxyfenozide; regardless of the radiolabel, it was identified (% of the TRR) at levels up to 41% in the crop planted 30 DAT (0.033 mg/kg), up to 35% in the crop planted 90 DAT (0.012 mg/kg) and up to 32% in the crop planted 365 DAT (0.007 mg/kg). Metabolites M15 (RH-151055) and M12 (RH-152068) together were present in samples from the shortest plant back intervals and accounted for up to 13% TRR (0.005 - 0.011 mg/kg).

In **wheat forage**, regardless of the radiolabel, the main residue (% of the TRR) at both shortest plant back intervals was metabolite M40 (RH- 152072)¹², accounting for up to 48% in the crop planted 30 DAT (0.7 mg/kg) and for up to 47% in the crop planted 90 DAT (0.35 mg/kg). At the plant back interval of 365 days, metabolite M15 (RH-151055) and M41 (RH-152078)¹³ were identified together for up to 35% TRR (0.037 mg/kg). Metabolite M15 (RH-151055) alone accounted for up to 25- 28% TRR in the crop planted 30 DAT (0.36 -0.2 mg/kg) and was found in one study at 25% TRR in the crop planted 90 DAT (0.13 mg/kg). Parent methoxyfenozide was below 1% TRR in all studies at all plant-back intervals.

Wheat straw contained the highest TRR of all crops, but only *ca.* 45-50% of the radioactivity could be extracted. In wheat straw, regardless of the radiolabel, main residue at both shortest plant back intervals was metabolite M14 (RH-117236), accounting for 32-37% 30 DAT (0.65-1.14 mg/kg) and for 27.5-35% 90 DAT (0.32-0.6 mg/kg).

Wheat grain contained the lowest residue levels of the crops and materials tested (*ca.*0.05 mg eq./kg). Only 11-23 % of the radioactivity could be extracted. Metabolite M14 (RH-117236) (in the t-butyl study) was the main component of the TRR, accounting for up to 15% (0.009 mg/kg).

Since the representative use for the peer review was on perennial crops, the peer review did not derive conclusions regarding the metabolic pathway of methoxyfenozide in rotational crops. Instead, it was concluded that due to an extensive metabolism observed, the importance of residues in succeeding crops should be considered by Member States (EC, 2004).

⁹ See Appendix D

¹⁰ See Appendix D

¹¹ See Appendix D

¹² See Appendix D

¹³ See Appendix D

The results of the metabolism studies indicate that methoxyfenozide is extensively metabolised in all succeeding crops. The residue levels of metabolites were <0.05 mg/kg, except for those in wheat forage and straw (M15 (RH-151055) which was also identified in primary crops, and M40 (RH-152072)). Parent is the main residue in radish roots and is the second most abundant residue in mustard leaves; it has not been identified at all or has been identified at insignificant levels in wheat grain, straw, forage. The metabolite M15 (RH-151055) (together with metabolite M12 (RH-152068)) is the main residue in mustard leaves; it is present above 10% TRR in radish roots and either alone or together with metabolite M41 (RH-152078) accounts for significant levels in wheat forage. In wheat straw and grain metabolite M14 (RH-117236) is the main residue.

Metabolite M14 (RH-117236) was identified as a predominant metabolite in rat metabolism and further toxicity studies indicated that it is of a lower toxicity than the parent compound (UK, 2002). The rest of the plant metabolites, with exception of metabolite M12 (RH-152068), were not identified in the rat metabolism. Metabolites M15 (RH-151055) and M40 (RH-152072) are the conjugates of M14 (RH-117236) and thus their toxicity could be assumed to be similar to that of metabolite M14 (RH-117236).

Although the metabolism of methoxyfenozide in succeeding/rotational crops is more extensive, it proceeds in a similar pathway as in primary plants. Therefore it is concluded that parent methoxyfenozide is defined as the relevant residue in rotational/succeeding crops for enforcement and risk assessment purposes.

3.1.2.3. Magnitude of residues

The magnitude of methoxyfenozide residues in rotational/succeeding crops has not been assessed in the framework of the peer review, because of no relevance for the perennial crops assessed. However, rotational crop field studies have been assessed by the JMPR (FAO, 2004) and additional new studies have been submitted by the applicant in the framework of the current MRL application (Spain, 2011).

Study I

On leaf lettuce grown as a primary crop, methoxyfenozide was applied 5 times with 7-10 day interval at an individual application rate of 0.448 kg a.s/ha. Mature lettuce was harvested *ca.* 2 months later (1-3 DALA) and the following rotational crops were planted 7 DALA: mustard greens, tomatoes, cucumbers, turnips, wheat, soybeans and onions. At maturity crops were harvested. Dry commodities (wheat and soybean matrices) were analyzed for four compounds: methoxyfenozide, metabolite M14 (RH-117236), metabolite M15 (RH-151055) and metabolite M40 (RH-152072) (which during analyses converted to M15 (RH-151055)). The lowest residues of all compounds were in wheat grain and in soybean (\leq LOQ of 0.02 mg/kg). In wheat straw (harvested >300 DALA) methoxyfenozide accounted for up to 0.057 mg/kg with metabolite M15 (RH-151055) being present for up to 2.1 mg/kg and metabolite M14 (RH-117236) up to 2.2 mg/kg.

In other matrices the amounts of parent methoxyfenozide were as follows: <LOD of 0.006 mg/kg in tomatoes (harvest 118/109 DALA), <LOQ of 0.02 mg/kg in cucumbers (92/73 DALA), up to 0.055 mg/kg in onions (132/137 DALA), up to 0.021 mg/kg in turnip roots (88-89 DALA), up to 0.064 mg/kg in turnip tops and up to 0.12 mg/kg in mustard greens (79/73 DALA).

Study II

Study II had identical treatment conditions and analytical approach as study I. In wheat grain all compounds were below the LOD. In soya beans parent methoxyfenozide and metabolite M14 (RH-117236) were below the LOD of 0.006 mg/kg, whereas metabolite M15 (RH-151055) accounted for an average levels of 0.77 mg/kg. Wheat straw contained methoxyfenozide at 0.023 mg/kg, metabolite M14 (RH-117236) at 0.84 mg/kg and metabolite M15 (RH-151055) at 0.85 mg/kg. In wheat forage the highest residues were observed, with methoxyfenozide accounting for 0.016 mg/kg, M14 (RH-117236) for 0.038 mg/kg and M15 (RH-151055) for 1.32 mg/kg. In all inedible dry commodities (soya

bean hay, forage and wheat hay, forage and straw) metabolites were present at higher levels than parent methoxyfenozide.

In other matrices the residue levels of parent methoxyfenozide were as follows: 0.013 mg/kg in turnip roots, 0.038 mg/kg in turnip tops, 0.03 mg/kg in mustard greens, 0.009 mg/kg in tomato, 0.011 mg/kg in cucumbers and 0.06 mg/kg in green onions. No information was provided on the time period elapsed between the last treatment and the crop harvest. The residue trial samples prior to analyses were stored for 429 (dry commodities) and 514 (high water content commodities) days which is longer than the storage stability period investigated (see section 3.1.1.2.). According to the JMPR evaluation, methoxyfenozide is stable in dry commodities (maize grain) for up to 397 days; in deep frozen wheat forage sample methoxyfenozide and the investigated metabolites (M15, M14 and M40) are stable for 4 years (FAO, 2004).

Study III

In study III the active substance was applied on lettuce at the same application rate as in the previous studies. One to three days after the last application the lettuce was harvested and 7-9 DALA rice, sorghum, beans, peas, potatoes, radish, carrots, sugar beets, green and bulb onions were planted. Crops were sampled at normal maturity, but no information was provided on the time period elapsed between the last treatment and the crop harvest. High water content matrices were analysed for parent methoxyfenozide whereas dry commodities were in addition analysed for metabolites M14 (RH-117236) and M15 (RH-151055) (total glucose conjugates). In dry beans and dry peas none of the compounds were found. None of the metabolites were found in sorghum grain; parent methoxyfenozide was below 0.01 mg/kg. In rice grain parent methoxyfenozide was not detected, metabolites M14 (RH-117236) accounted for 0.042 mg/kg and M15 (RH-151055) for 0.02 mg/kg. In all dry inedible matrices (rice straw, bean hay, sorghum forage, sorghum stover and pea hay) metabolites were identified at significantly higher levels than parent methoxyfenozide. Methoxyfenozide, metabolite M14 (RH-117236) and M15 (RH-151055) were present in rice straw at 0.04 mg/kg, 1.1 mg/kg and 2.1 mg/kg, in dry bean hay at 0.11 mg/kg, 0.036 mg/kg and 0.4 mg/kg, in sorghum forage at 0.26 mg/kg, 0.04 mg/kg and 1.14 mg/kg, respectively.

In other plant matrices the following residue levels of parent methoxyfenozide were identified: <0.02 mg/kg in sugar beet roots and tops, 0.09 mg/kg in carrot roots, 0.066 mg/kg in radish roots, 0.04 mg/kg in radish tops, 0.07 mg/kg in green onions, 0.01 mg/kg in bulb onions and 0.04 mg/kg in potato tubers. The residue trial samples prior to analyses were stored for 153 (dry commodities) and 448 (high water content commodities) days which for high water content matrices is longer than the storage stability period investigated (see section 3.1.1.2.).

In study II and study III rotational crop samples prior to analysis were stored longer, exceeding the period for which the stability of methoxyfenozide residues is demonstrated in dry matrices and high water content matrices. However, in all available storage stability studies no decline of methoxyfenozide residues was observed at the storage intervals investigated. It is therefore unlikely that significant degradation of methoxyfenozide residues occurred in rotational crop samples stored for longer periods; the results are thus considered valid.

The reported rotational crop studies have been performed with a significantly higher season application rate (2.25 kg a.s./ha) than the application rate in the intended use (0.24 kg a.s./ha). It is expected that residues of methoxyfenozide will not occur at significant levels in the edible matrices of all crops investigated when grown in the crop rotation with leafy crops treated according to the intended use. However, in animal feed commodities (straws, forage, hay), a possible occurrence of methoxyfenozide residues cannot be excluded.

To avoid occurrence of methoxyfenozide residues in rotational/succeeding crops used as animal feed, EFSA recommends Member States to implement necessary risk mitigation measures when granting authorizations of plant protection products containing methoxyfenozide.

3.2. Nature and magnitude of residues in livestock

Since the crops under consideration are normally not fed to livestock, the nature and magnitude of methoxyfenozide residues in livestock is not assessed in the framework of this application.

4. Consumer risk assessment

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 population¹⁴ (EFSA, 2007).

For the calculation of the chronic exposure, EFSA used the median residue value as derived from the residue trials on lettuce (see Table 3-2). The same input value was used for other salad plants including Brassicaceae (lamb's lettuce, scarole, cress, land cress, rocket/rucola, red mustard, leaves and sprouts of Brassica), the whole group of herbs (chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil, bay leaves, tarragon) and the whole group of spinach and similar leaves (spinach, beet leaves (chard), purslane). For some crops (plums, avocados, pomegranates) the risk assessment values were available from a previously issued EFSA reasoned opinion and were used to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values.

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 levels of the median residue values identified in supervised field trials. However, 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.

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

The input values used for the dietary exposure calculation are summarized 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: Methoxyfenozide				
Lettuce	1.13	Median residue	2.39	Highest residue

¹⁴ 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).

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Lamb's lettuce, scarole, cress, land cress, rocket/rucola, red mustard, leaves and sprouts of Brassica, chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil, bay leaves, tarragon, spinach, beet leaves (chard), purslane	1.13	Median residue (lettuce)	2.39	Highest residue (lettuce)
Avocados, pomegranates	0.13	Median residue (EFSA, 2010)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Plums	0.03	Median residue (EFSA, 2010)		
Other commodities of food and animal origin	MRL	See Appendix C		

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

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 37.5% of the ADI (DE child diet). The individual contribution of residues in the crops under consideration to the total consumer exposure was insignificant (below 1% of the ADI).

An acute consumer risk was identified in relation to the MRL proposal for scarole (**104.5%** of the ARfD), confirming the findings of the EMS. With regard to other crops under consideration no acute consumer intake concerns were identified and the calculated maximum exposure in percentage of the ARfD was 32.2 % for lettuce, 27% for spinach, 21% for beet leaves, 18.1% for purslane and below 10% for the rest of the crops.

EFSA concludes that intended uses on the leafy vegetables under consideration (except on scarole) will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern. EFSA confirms the conclusion of the EMS that the intended use of methoxyfenozide on scarole is not acceptable due to acute consumer intake concerns identified.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of methoxyfenozide was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI value of 0.1 mg/kg bw/day and an ARfD value of 0.2 mg/kg bw.

The metabolism of methoxyfenozide in primary plants has been investigated in fruits and fruiting vegetables (apples, grapes), pulses and oilseeds (cotton) and cereals (rice) in the framework of the peer review of Directive 91/414/EEC. Although metabolism studies with leafy vegetables are not available, a consistent metabolism of methoxyfenozide in three crop groups is demonstrated to conclude that in primary crops after foliar treatment parent methoxyfenozide is the relevant residue for enforcement and risk assessment purposes. EFSA concludes that for the crops under consideration no additional metabolism studies have to be performed and parent methoxyfenozide is the appropriate residue definition for risk assessment and enforcement.

EFSA considers that the submitted supervised residue trials are sufficient to support the proposed residue data extrapolation from lettuce to other crops under consideration and to derive a MRL proposal of 4 mg/kg for the proposed use on lettuce and other salad plants including Brassicaceae, the whole group of spinach and similar leaves and the whole group of herbs. Adequate analytical enforcement methods are available to control the residues of methoxyfenozide in the commodities under consideration.

The effect of processing on the nature of methoxyfenozide residues has been investigated in a hydrolysis study simulating sterilisation, pasteurization and baking/brewing/boiling. No degradation of methoxyfenozide occurs and therefore for processed commodities the same residue definition as for raw agricultural commodities is applicable. Specific studies to assess the magnitude of methoxyfenozide residues during the processing of the crops under consideration have not been submitted. Such studies are desirable for the crops which are consumed processed to refine the acute consumer exposure.

The crops under consideration can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding/rotational crops resulting from the use of the active substance on primary crops was further assessed, considering the slow degradation of methoxyfenozide in soil. Although the metabolism of methoxyfenozide in succeeding/rotational crops is more extensive, it proceeds in a similar pathway as in primary plants with methoxyfenozide being the major residue in individual crops investigated; the same residue definitions are therefore applicable. The reported rotational crop field studies have been performed with a significantly higher season application rate (9N) than the application rate in the intended use. Residues of methoxyfenozide at significant levels are not expected in edible matrices of rotational crops when grown in crop rotation with leafy vegetables treated according to the intended use. However, in animal feed commodities (straw, forage, hay), a possible occurrence of methoxyfenozide residues cannot be excluded and therefore EFSA recommends Member States to implement necessary risk mitigation measures when granting authorizations of plant protection products containing methoxyfenozide.

Since the crops under consideration are normally not fed to livestock, the nature and magnitude of methoxyfenozide residues in livestock was not assessed in the framework of this application

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMO). For the calculation of the chronic exposure, EFSA used the median residue value as derived from the residue trials on lettuce. The same input value was used for other salad plants including Brassicaceae, the whole group of herbs and the whole group of spinach and similar leaves. For some crops the risk assessment values were available to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and

IIIB of Regulation (EC) No 396/2005 were used as input values. The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 37.5% of the ADI (DE child diet). The individual contribution of residues in the crops under consideration to the total consumer exposure was below 1% of the ADI.

Short-term consumer risk was identified in relation to the MRL proposal for scarole (**104.5%** of the ARfD), confirming the findings of the EMS. With regard to other crops under consideration no short-term consumer intake concerns were identified and the calculated maximum exposure in percentage of the ARfD was 32.2 % for lettuce, 27% for spinach, 21% for beet leaves, 18.1% for purslane and below 10% for the rest of the crops.

EFSA concludes that the intended uses on the leafy vegetables under consideration (except on scarole) will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern. EFSA confirms the conclusion of the EMS that the intended use of methoxyfenozide on scarole is not acceptable due to acute consumer intake concerns identified.

RECOMMENDATIONS

Thus EFSA proposes to amend the current 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
Enforcement residue definition: Methoxyfenozide				
0251000 (except 0251030)	Lettuce and other salad plants including Brassicacea (except scarole)	0.02*	4	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses.
0252000	Spinach and similar (leaves)	0.02*	4	
0256000	Herbs	0.02*	4	
0251030	Scarole (broad-leaf endive)	0.02*	No new proposal	EFSA confirms the views of the EMS that for the MRL proposal acute risk to consumers cannot be excluded.

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

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

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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		
Lettuce	Spain	F	Lepidopteran pests <i>Heliothis armigera</i> <i>Spodoptera sp.</i>	SC	240 g a.s./L	Broadcast - Foliar	BBCH 20 - 49 March-June Sep.-Nov.	1 - 2	14 d	0.012 - 0.024	500 - 1000	0.120	3	
Lettuce & other salads	Italy	F	Lepidopteran pests <i>Heliothis armigera</i> <i>Spodoptera sp.</i>	SC	240 g a.s./L	Broadcast - Foliar	BBCH 20 - 49 May-Nov.	1 - 2	14 d	0.016 - 0.030	400 - 800	0.096 - 0.120	3	No more than 3 sprays/season as total of products containing methoxyfenozide or tebufenozide
Fresh herbs	Italy	F	Lepidopteran pests <i>Heliothis armigera</i> <i>Spodoptera sp.</i>	SC	240 g a.s./L	Broadcast - Foliar	BBCH 20 - 49 May-Nov.	1 - 2	14 d	0.016 - 0.030	400 - 800	0.096 - 0.120	3	No more than 3 sprays/season as total of products containing methoxyfenozide or tebufenozide
Spinach and similar leaves	Italy	F	Lepidopteran pests <i>Heliothis armigera</i> <i>Spodoptera sp.</i>	SC	240 g a.s./L	Broadcast - Foliar	BBCH 20 - 49 May-Nov.	1 - 2	14 d	0.016 - 0.030	400 - 800	0.096 - 0.120	3	No more than 3 sprays/season as total of products containing methoxyfenozide or tebufenozide

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		
<p>Remarks:</p> <p>(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)</p> <p>(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</p> <p>(i) g/kg or g/l</p> <p>(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</p> <p>(k) The minimum and maximum number of application possible under practical conditions of use must be provided</p> <p>(l) PHI - minimum pre-harvest interval</p> <p>(m) Remarks may include: Extent of use/economic importance/restrictions (<i>i.e.</i> feeding, grazing)</p>														

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Methoxyfenozide									
Status of the active substance:		Included		Code no.		Prepare workbook for refined calculations			
LOQ (mg/kg bw):		0.02		proposed LOQ:					
Toxicological end points									
ADI (mg/kg bw/day):		0.1		ARfD (mg/kg bw):		0.2			
Source of ADI:		EC		Source of ARfD:		EC			
Year of evaluation:		2004		Year of evaluation:		2004			
Chronic risk assessment - refined calculations									
TMDI (range) in % of ADI minimum - maximum									
5 38									
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)	
37.5	DE child	24.1	Apples	3.8	Oranges	1.9	Tomatoes	0.2	
25.6	NL child	12.7	Apples	3.1	Oranges	1.5	Milk and cream,	0.2	
20.6	UK Toddler	6.9	Sugar beet (root)	3.9	Beans	3.4	Apples	0.1	
18.7	WHO Cluster diet B	6.2	Tomatoes	2.0	Apples	1.8	Wine grapes	0.3	
18.3	FR toddler	5.2	Apples	2.2	Beans (with pods)	2.0	Oranges	0.2	
15.0	UK Infant	3.1	Apples	3.0	Sugar beet (root)	2.5	Beans	0.1	
13.3	FR infant	5.0	Apples	1.7	Beans (with pods)	1.3	Carrots	0.2	
11.9	IE adult	1.6	Apples	1.3	Pears	1.3	Wine grapes	0.3	
11.5	ES child	2.3	Apples	2.2	Oranges	2.0	Tomatoes	0.1	
10.9	PT General population	2.5	Wine grapes	2.1	Apples	1.8	Tomatoes	0.1	
10.3	DK child	4.6	Apples	1.4	Pears	1.1	Tomatoes	0.1	
9.7	WHO cluster diet E	1.7	Apples	1.6	Wine grapes	1.2	Soya bean	0.2	
8.9	NL general	2.4	Apples	1.5	Oranges	0.9	Tomatoes	0.1	
8.6	ES adult	1.6	Tomatoes	1.5	Apples	1.3	Oranges	0.1	
8.6	FR all population	4.0	Wine grapes	1.0	Apples	0.9	Tomatoes	0.1	
8.6	IT kids/toddler	2.9	Tomatoes	1.8	Apples	0.7	Pears	0.1	
8.6	UK vegetarian	1.8	Beans	1.2	Tomatoes	1.2	Apples	0.1	
8.5	WHO Cluster diet F	1.4	Tomatoes	1.3	Apples	1.3	Soya bean	0.1	
8.5	WHO regional European diet	2.2	Tomatoes	1.3	Apples	0.5	Oranges	0.2	
8.3	SE general population 90th percentile	2.1	Apples	1.5	Tomatoes	0.7	Oranges	0.2	
7.5	PL general population	4.1	Apples	1.8	Tomatoes	0.6	Pears	0.1	
7.5	WHO cluster diet D	2.0	Tomatoes	1.3	Apples	0.7	Soya bean	0.2	
7.4	IT adult	2.3	Tomatoes	1.6	Apples	0.5	Pears	0.0	
6.8	UK Adult	1.2	Sugar beet (root)	1.1	Beans	1.1	Wine grapes	0.1	
6.4	LT adult	3.7	Apples	1.2	Tomatoes	0.3	Pears	0.1	
5.7	DK adult	1.6	Apples	1.4	Wine grapes	0.8	Tomatoes	0.1	
4.5	FI adult	1.0	Oranges	0.9	Tomatoes	0.8	Apples	0.1	
Conclusion:									
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.									
A long-term intake of residues of Methoxyfenozide 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):		
	1			1			---			---		
	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)
	104.5	Scarole (broad-leaf)	2.39 / 2.28	104.5	Scarole (broad-leaf)	2.39 / 2.28	13.1	Lettuce	2.39 / -	11.2	Purslane	2.39 / -
	32.2	Lettuce	2.39 / -	27.0	Spinach	2.39 / -	12.3	Purslane	2.39 / -	10.7	Spinach	2.39 / -
	27.0	Spinach	2.39 / -	19.3	Lettuce	2.39 / -	10.7	Spinach	2.39 / -	10.6	Scarole (broad-leaf endive)	2.39 / -
	21.0	Beet leaves (chard)	2.39 / -	15.9	Beet leaves	2.39 / -	10.6	Scarole (broad-leaf)	2.39 / -	7.9	Lettuce	2.39 / -
	18.1	Purslane	2.39 / -	13.7	Purslane	2.39 / -	8.9	Beet leaves (chard)	2.39 / -	7.5	Beet leaves (chard)	2.39 / -
	6.9	Celery leaves	2.39 / -	6.9	Celery leaves	2.39 / -	2.2	Lamb's lettuce	2.39 / -	2.2	Lamb's lettuce	2.39 / -
	3.7	Rocket, Rucola	2.39 / -	3.7	Rocket, Rucola	2.39 / -	1.4	Parsley	2.39 / -	1.4	Parsley	2.39 / -
	3.4	Lamb's lettuce	2.39 / -	3.4	Lamb's lettuce	2.39 / -	0.5	Cress	2.39 / -	0.5	Cress	2.39 / -
	1.5	Chervil	2.39 / -	1.5	Chervil	2.39 / -	0.2	Celery leaves	2.39 / -	0.2	Celery leaves	2.39 / -
0.9	Parsley	2.39 / -	0.9	Parsley	2.39 / -	0.1	Chives	2.39 / -	0.1	Chives	2.39 / -	
0.8	Basil	2.39 / -	0.8	Basil	2.39 / -	0.0	Basil	2.39 / -	0.0	Basil	2.39 / -	
0.5	Thyme	2.39 / -	0.5	Thyme	2.39 / -							
0.4	Rosemary	2.39 / -	0.4	Rosemary	2.39 / -							
0.3	Cress	2.39 / -	0.3	Cress	2.39 / -							
0.3	Chives	2.39 / -	0.3	Chives	2.39 / -							
0.1	Bay leaves (laurel)	2.39 / -	0.1	Bay leaves (laurel)	2.39 / -							
0.0	Sage	2.39 / -	0.0	Sage	2.39 / -							
No of critical MRLs (IESTI 1)			1			No of critical MRLs (IESTI 2)			1			
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)				
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.												
**) pTMRL: provisional temporary MRL												
***) pTMRL: provisional temporary MRL for unprocessed commodity												
Conclusion:												
For Methoxyfenozide IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.												
The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 1 commodities.												
Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.												
For processed commodities, no exceedance of the ARfD/ADI was identified.												

C. EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs)

(Pesticides - Web Version - EU MRLs (Pesticides - Web Version - EU MRLs (File created on 28/03/2012 17:05))

Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	1
110010	Grapefruit (Shaddock, pomelo, sweetie, tangelo, ugli and other hybrids)	1
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	1
110030	Lemons (Citron, lemon)	1
110040	Limes	1
110050	Mandarins (Clementine, tangerine and other hybrids)	1
110990	Others	1
120000	(ii) Tree nuts (shelled or unshelled)	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	2
130010	Apples (Crab apple)	2
130020	Pears (Oriental pear)	2
130030	Quinces	2
130040	Medlar	2
130050	Loquat	2
130990	Others	2
140000	(iv) Stone fruit	
140010	Apricots	0,3
140020	Cherries (sweet cherries, sour cherries)	0,02*
140030	Peaches (Nectarines and similar hybrids)	0,3
140040	Plums (Damson, greengage,	0,1

Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
	mirabelle)	
140990	Others	0,02*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	1
151010	Table grapes	1
151020	Wine grapes	1
152000	(b) Strawberries	2
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,02*
153030	Raspberries (Wineberries)	0,02*
153990	Others	0,02*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	4
154020	Cranberries	0,7
154030	Currants (red, black and white)	0,02*
154040	Gooseberries (Including hybrids with other ribes species)	0,02*
154050	Rose hips	0,02*
154060	Mulberries (arbutus berry)	0,02*
154070	Azarole (mediterranean medlar)	0,02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries)	0,02*
154990	Others	0,02*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
	kumquats)	
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomereac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	
162010	Kiwi	1
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	0,02*
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	0,7
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,02*
163040	Papaya	1
163050	Pomegranate	0,6
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	

Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
	OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoo (Japanese taro), tannia)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,02*
213020	Carrots	0,5
213030	Celeriac	0,02*
213040	Horseshoe 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)	0,4
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,02*
213100	Swedes	0,02*
213110	Tumips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	0,02*
220010	Garlic	0,02*
220020	Onions (Silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	2
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants)	0,5

Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
	(Pepino)	
231040	Okra, lady's fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,02*
232010	Cucumbers	0,02*
232020	Gherkins	0,02*
232030	Courgettes (Summer squash, marrow (patisson))	0,02*
232990	Others	0,02*
233000	(c) Cucurbits-inedible peel	0,02*
233010	Melons (Kiwano)	0,02*
233020	Pumpkins (Winter squash)	0,02*
233030	Watermelons	0,02*
233990	Others	0,02*
234000	(d) Sweet com	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	0,02*
241000	(a) Flowering brassica	0,02*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,02*
241020	Cauliflower	0,02*
241990	Others	0,02*
242000	(b) Head brassica	0,02*
242010	Brussels sprouts	0,02*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,02*
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,02*
243020	Kale (Borecole (curly kale), collards)	0,02*
243990	Others	0,02*
244000	(d) Kohlrabi	0,02*
250000	(v) Leaf vegetables & fresh herbs	0,02*
251000	(a) Lettuce and other salad plants including Brassicacea	0,02*
251010	Lamb's lettuce (Italian comsalad)	0,02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,02*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
	chicory, radicchio, curd leave endive, sugar loaf)	
251040	Cress	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket)	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	0,02*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,02*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sornel, glasswort)	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	0,02*
256010	Chervil	0,02*
256020	Chives	0,02*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,02*
256040	Parsley	0,02*
256050	Sage (Winter savory, summer savory,)	0,02*
256060	Rosemary	0,02*
256070	Thyme (marjoram, oregano)	0,02*
256080	Basil (Balm leaves, mint, peppermint)	0,02*
256090	Bay leaves (laurel)	0,02*
256100	Tarragon (Hyssop)	0,02*
256990	Others	0,02*
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	2

Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0,3
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,3
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	0,02*
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes	0,02*
270060	Leek	0,02*
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
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	
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	5
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	
401000	(i) Oilseeds	
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*
401070	Soya bean	2
401080	Mustard seed	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
401090	Cotton seed	2
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	0,05*
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt) Triticale)	0,05*
500990	Others	0,05*
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	0,05*
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*

Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*

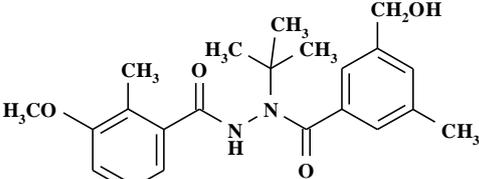
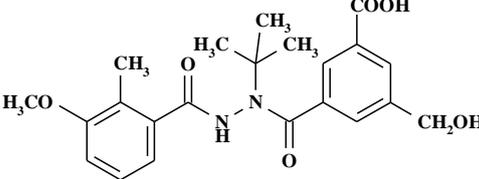
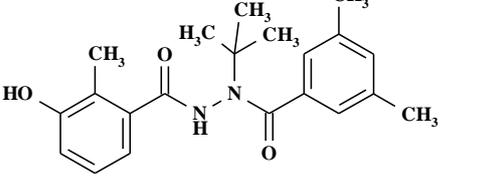
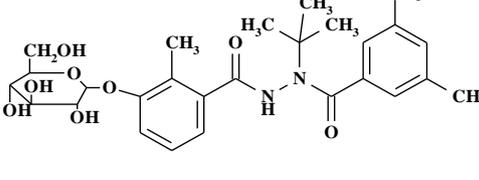
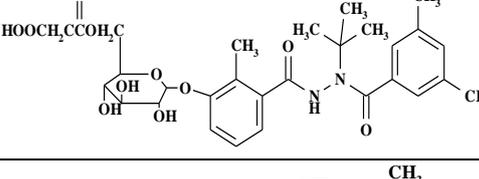
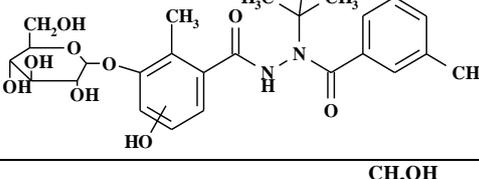
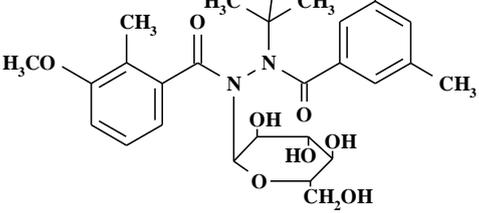
Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,3
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	0,2
1011020	Fat free of lean meat	0,2
1011030	Liver	0,1
1011040	Kidney	0,1
1011050	Edible offal	0,1
1011990	Others	0,01*
1012000	(b) Bovine	
1012010	Meat	0,2
1012020	Fat	0,2
1012030	Liver	0,1
1012040	Kidney	0,1
1012050	Edible offal	0,1

Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
1012990	Others	0,01*
1013000	(c) Sheep	
1013010	Meat	0,2
1013020	Fat	0,2
1013030	Liver	0,1
1013040	Kidney	0,1
1013050	Edible offal	0,1
1013990	Others	0,01*
1014000	(d) Goat	
1014010	Meat	0,2
1014020	Fat	0,2
1014030	Liver	0,1
1014040	Kidney	0,1
1014050	Edible offal	0,1
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	0,2
1015020	Fat	0,2
1015030	Liver	0,1
1015040	Kidney	0,1
1015050	Edible offal	0,1
1015990	Others	0,01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,01*
1016010	Meat	0,01*
1016020	Fat	0,01*
1016030	Liver	0,01*
1016040	Kidney	0,01*
1016050	Edible offal	0,01*
1016990	Others	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	0,2
1017020	Fat	0,2
1017030	Liver	0,1
1017040	Kidney	0,1
1017050	Edible offal	0,1

Code number	Groups and examples of individual products to which the MRLs apply	Methoxyfenozide (F)
1017990	Others	0,01*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05
1020010	Cattle	0,05
1020020	Sheep	0,05
1020030	Goat	0,05
1020040	Horse	0,05
1020990	Others	0,05
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	0,01*
1030010	Chicken	0,01*
1030020	Duck	0,01*
1030030	Goose	0,01*
1030040	Quail	0,01*
1030990	Others	0,01*
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*

(*): Indicates lower limit of analytical determination
(F): Fat-soluble

D. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	Chemical name	Chemical structure
M02 (RH-131364)	3-hydroxymethyl-5-methylbenzoic acid N-tert-butyl-N'-(3-methoxy-2-methylbenzoyl)-hydrazide	
M12 (RH-152068)	3-[N-tert-butyl-N'-(3-methoxy-2-methylbenzoyl)-hydrazinocarbonyl]-5-hydroxybenzoic acid	
M14 (RH-117236)	3,5-dimethylbenzoic acid N-tert-butyl-N'-(3-hydroxy-2-methylbenzoyl)-hydrazide	
M15 (RH-151055)	3,5-dimethylbenzoic acid N-tert-butyl-N'-[3-(β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide	
M40 (RH-152072)	Malonylglycosyl conjugate of the methoxyphenyl ring	
M41 (RH-152078)	Glycosyl conjugate of the methoxyphenyl ring diphenol	
M 44 (RH-152067)	Proposed as N-conjugate of M02	

ABBREVIATIONS

ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
DE	Germany
DT ₉₀	period required for 90 % dissipation
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
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
kg	kilogram

L	litre
LC	Liquid chromatography
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry
MW	molecular weight
OECD	Organization for Economic Co-operation and Development
PHI	pre-harvest interval
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
RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultra-violet (detector)
WHO	World Health Organisation
wk	week
yr	year