

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for metalaxyl-M in currant (red, black and white)¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the Horticultural Development Company to modify the existing MRL for the active substance metalaxyl-M in currants. In order to accommodate for the intended use of metalaxyl-M, the United Kingdom proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.05 mg/kg to 0.4 mg/kg. The United Kingdom drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA the data are sufficient to derive a MRL proposal of 0.4 mg/kg for the proposed use on currants (red, black and white). Adequate analytical enforcement methods are available to control the residues of metalaxyl-M in currants. Based on the risk assessment results, EFSA concludes that the proposed use of metalaxyl-M on currants (red, black and white) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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KEY WORDS

metalaxyl-M, currants, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, phenylamide fungicide, metalaxyl.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the Horticultural Development Company to modify the existing MRL for the active substance metalaxyl-M in currants. In order to accommodate for the intended use of metalaxyl-M, the United Kingdom proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.05 mg/kg to 0.4 mg/kg. The United Kingdom drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 4 December 2012.

EFSA bases its assessment on the evaluation report, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC, the Commission Review Report on metalaxyl-M, the JMPR Evaluation reports as well as the conclusion from previous EFSA opinions on metalaxyl-M.

The toxicological profile of metalaxyl-M was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.08 mg/kg bw per day and an ARfD of 0.5 mg/kg bw.

The metabolism of metalaxyl-M in primary crops was investigated in fruits and fruiting vegetables (grapes), root and tuber vegetables (potatoes) and in leafy vegetables (lettuce and tobacco) using the compound metalaxyl. The data on the metabolism of metalaxyl are applicable to metalaxyl-M. In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 EFSA proposed the residue for enforcement and risk assessment in all plant commodities as metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers). For the use on currants, EFSA concludes that the metabolism of metalaxyl-M in primary crops is sufficiently addressed and that the residue definitions derived are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.4 mg/kg for the proposed use on currants (red, black and white). Adequate analytical enforcement methods are available to control the residues of metalaxyl-M in currants according to the proposed residue definition at the validated LOQ of 0.02 mg/kg.

A hydrolysis study demonstrated that under conditions simulating sterilization, pasteurization and baking/boiling, metalaxyl-M does not undergo degradation. Specific studies investigating the magnitude of residues in processed currants are not required because of the low exposure to metalaxyl-M residues via currants. One study investigating the magnitude of metalaxyl-M residues in processed strawberry products is available which indicated that residues do not accumulate in strawberry jam, juice, sauce and in canned strawberries.

Since the proposed use of metalaxyl-M is on a semi-permanent crop, investigations of residues in rotational crops are not required.

Residues of metalaxyl-M in commodities of animal origin were not assessed in the framework of this application, since the crop under consideration is normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residue Intake Model (PRIMO). For the calculation of the chronic exposure, EFSA used the median residue value as derived from the submitted residue trials on currants and the median residue values on lettuce and other salad plants derived in a previously issued EFSA reasoned opinion. 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 risk assessment was undertaken only with regard to the crop under consideration. The estimated exposure was then compared with the toxicological reference values derived for metalaxyl-M.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 26 % of the ADI (DE child diet). The contribution of residues in currants to the total consumer exposure accounted for a maximum of 0.004 % of the ADI (UK toddler diet). No acute consumer risk was identified in relation to the MRL proposal for currants. The calculated maximum exposure for currants was 0.3 % of the ARfD (DE child diet).

EFSA concludes that the proposed use of metalaxyl-M on currants (red, black and white) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

EFSA emphasises that the consumer risk assessment should be regarded as provisional. Residues of metalaxyl-M (R-enantiomer) may also be generated from the use of metalaxyl, which is the mixture of metalaxyl-M and the S-enantiomer. A comprehensive risk assessment for both metalaxyl and metalaxyl-M will be performed in the framework of the review of the existing MRLs for metalaxyl according to Article 12 of Regulation (EC) No 396/2005.

Thus EFSA proposes to amend the existing MRL 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: Metalaxyl, including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)^(b)				
154030	Currants (red, black and white)	0.05*	0.4	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended use on this crop.

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

(b): As reworded in the framework of the review of the existing MRLs for metalaxyl-M according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011).

(*): 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 a MRL in accordance with the provisions of Article 7 of that Regulation.

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

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 4 December 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00975 and the following subject:

Metalaxyl-M - Application to modify the existing MRL in currants.

The United Kingdom proposed to raise the existing MRL of metalaxyl-M in currants from the LOQ of 0.05 mg/kg to 0.4 mg/kg.

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 deadline for providing the reasoned opinion is 4 March 2013.

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

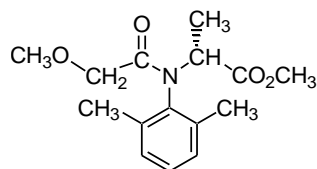
⁴ Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

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

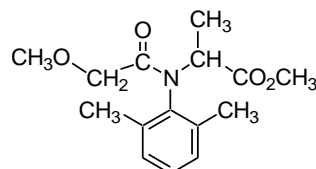
⁶ Horticultural Development Company (HDC), c/o Stockbridge Technology Centre (STC), Cawood, North Yorkshire, YO8 3TZ, United Kingdom.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Metalaxyl-M is the ISO common name for methyl *N*-(methoxyacetyl)-*N*-(2,6-xylyl)-*D*-alaninate (IUPAC). Metalaxyl-M is the R-enantiomer of metalaxyl, the racemic mixture of the R- and S-enantiomers which is also used as in plant protection products. The chemical structure of both compounds is reported below.



Metalaxyl-M (R-isomer)



Metalaxyl (S-isomer and R-isomer)

Metalaxyl-M and metalaxyl are systemic fungicides belonging to the phenylamide chemical family. They inhibit mycelial growth and spore formation by selectively interfering with the synthesis of the ribosomal ribonucleic acid (RNA) in fungi. Metalaxyl-M contains the biologically active R-enantiomer, which is effective in controlling diseases caused by fungi belonging to the group of oomycetes.

Metalaxyl-M was evaluated in the framework of Council Directive 91/414/EEC with Belgium designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by of Commission Directive 2002/64/EC⁷, which entered into force on 1 October 2002 for use as fungicide. In accordance with Commission Implementing Regulation (EU) No 540/2011⁸ metalaxyl-M is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated in the peer review were foliar field treatments of grapes and various annual crops (potatoes, onions, tomatoes, cucumbers, melons, broccoli, spinach, artichoke and tobacco) and outdoor and indoor treatments of lettuce. The Draft Assessment Report (DAR) of metalaxyl-M was not peer reviewed by EFSA, therefore no EFSA conclusion is available.

As metalaxyl-M contains one enantiomer of the racemic mixture metalaxyl, the MRLs of these active substances are closely related. At the EU level the MRLs established in Annexes II and IIIB of Regulation (EC) No 396/2005 apply to both metalaxyl and metalaxyl-M (Appendix C). MRL proposals on the crops belonging to the group of lettuce and other salad plants including *Brassicaceae* were evaluated by EFSA (EFSA, 2012) and new temporary MRLs were established through the Commission Regulation (EC) No 441/2012⁹. In 2011, EFSA issued a reasoned opinion on the review of the existing MRLs for metalaxyl-M according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011) which reviewed all uses authorised at the EU level and the CXLs adopted by Codex. The MRL recommendations derived by EFSA for metalaxyl-M have not yet been implemented in the European legislation as the review of the existing MRLs for metalaxyl is not finalised.

The existing EU MRL for currants is set at the LOQ of 0.05 mg/kg (residue definition: metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)). Codex Alimentarius has established CXLs for a wide range of commodities, but no CXL has been set for the crop under consideration. The CXLs refer to metalaxyl and the residues of metalaxyl-M are considered covered by this residue definition.

The details of the intended GAP for metalaxyl-M on currants are given in Appendix A.

⁷ Commission Directive 2002/64/EC of 15 July 2002, OJ L 189, 18.07.2002, p. 27-32.

⁸ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011. OJ L 153, 11.06.2011, p. 1-186.

⁹ Commission Regulation (EU) No 441/2012 of 24 May 2012. OJ L 135; 24.05.2012, p. 4-56.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (United Kingdom, 2012), the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Belgium 1999, 2001), the Commission Review Report on metalaxyl-M (EC, 2002), the JMPR Evaluation reports (FAO, 2002, 2005) as well as the conclusion from previous EFSA opinions on metalaxyl-M (EFSA, 2011, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011¹⁰ 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 metalaxyl-M residues in plant commodities were assessed during the peer review under Directive 91/414/EEC and in the framework of the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (Belgium, 2001; EFSA, 2011).

Adequate analytical enforcement methods are available to monitor residues of metalaxyl-M according to the residue definition, which refers to metalaxyl (sum of mixture of constituent isomers) in high water, high acid and high oil content commodities and in dry commodities. The methods were successfully validated at an LOQ of 0.02 mg/kg (EFSA, 2011). The use of chiral columns allows the determination of the R- and S-isomer separately (Belgium, 2001; EFSA, 2011).

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 is also applicable. The liquid chromatography coupled with tandem mass spectrometry detection (LC-MS/MS) method analyses metalaxyl/metalaxyl-M (as sum of isomers) in matrices with high water, high acid content and in dry commodities at the LOQ of 0.01 mg/kg (CEN, 2008).

Since the commodity under consideration belongs to the group of high acid content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRL for metalaxyl-M are available.

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

Analytical methods for the determination of metalaxyl-M residues in food of animal origin are not assessed in the current application, since currants are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance metalaxyl-M was assessed in the framework of the peer review under Council Directive 91/414/EEC (Belgium, 1999). Toxicity studies were conducted with metalaxyl (mixture of R- and S-enantiomers) or metalaxyl-M (R-enantiomer). The S-enantiomer is not expected to have a higher toxicity (Belgium, 1999). The data were sufficient to derive toxicological reference values for metalaxyl and metalaxyl-M which are compiled in Table 2-1.

¹⁰ 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
Metalaxyl-M/metalaxyl					
ADI	EC	2002	0.08 mg/kg bw per day	Dog, 2 yr study ^(a)	100
ARfD	EC	2002	0.5 mg/kg bw	Rat, developmental study ^(b)	100

(a): Study performed with metalaxyl (Belgium, 1999).

(b): Study performed with metalaxyl-M (Belgium, 1999).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

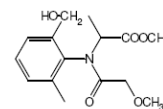
3.1.1.1. Nature of residues

The metabolism of metalaxyl-M in primary crops was investigated during the peer review on fruits and fruiting vegetables (grapes), root and tuber vegetables (potatoes) and leafy vegetables (lettuce) after foliar applications and on tobacco (leafy crop) after soil treatment. The studies were performed with ¹⁴C labelled metalaxyl (racemic mixture) in the phenyl ring. One study investigating the enantiomeric ratio was performed in lettuce. The details of the metabolism studies are reported in the DAR and the EFSA reasoned opinion on the review of the existing MRLs (Belgium, 1999; EFSA, 2011).

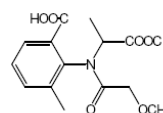
Metalaxyl was taken up rapidly, translocated and degraded into more than eight identified metabolites in plants. At harvest, the unchanged compound accounted for 64 % of the TRR in grapes, 20 % in lettuce, 57 % in potato tubers (FAO, 2005) and only 3 % of the TRR in potato leaves. The metabolite CGA 94689¹¹ (free and conjugated) was found in relevant amounts in grapes and in lettuce (20 % and 25 % of the TRR, respectively). The metabolite CGA 108905¹² accounted for 47 % of the TRR in potato leaves. These metabolites were considered as less toxic than the parent compound (EC, 2002). All other metabolites were below the trigger value of 10 % of the TRR. A comparative investigation of the metabolism of metalaxyl-M and metalaxyl in lettuce suggested similar degradation rates for both isomers and very little interconversion (Belgium, 1999; EFSA, 2011).

Although the peer review recommended the residue definition for enforcement in commodities of plant origin as metalaxyl-M only, to facilitate enforcement practice the residue definition in Regulation (EC) No 396/2005 was established as “metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers))”. In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 it was proposed to re-wording of the existing residue definition for enforcement and risk assessment to: “metalaxyl, including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)” (EFSA, 2011).

¹¹ CGA 94689: *N*-(2-hydroxymethylene-6-methylphenyl)-*N*-(methoxyacetyl)alanine methyl ester.



¹² CGA 108905: *N*-(2-carboxy-6-methylphenyl)-*N*-(methoxyacetyl)alanine methyl ester.



For the uses on currants, EFSA concludes that the metabolism of metalaxyl-M is sufficiently addressed and the residue definitions for enforcement and risk assessment as reworded during the MRL review are applicable.

3.1.1.2. Magnitude of residues

In support to the intended use the applicant submitted four GAP-compliant residue trials conducted on blackcurrants in the United Kingdom. Since currants are not a major crops in the EU (EC, 2011), the number of trials is sufficient to derive a MRL proposal of 0.4 mg/kg.

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

The storage stability of metalaxyl-M in primary crops was assessed in the DAR under Directive 91/414/EEC and in the framework of the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (Belgium, 1999; EFSA, 2011). Residues of metalaxyl-M were found to be stable at $\leq -20^{\circ}\text{C}$ for at least 30 months in matrices with high water and high acid content and for at least 24 months in matrices with high oil content and dry matrices. The supervised residue trial samples were stored frozen for less than 1 month indicating that the residue data are valid with regard to storage stability (United Kingdom, 2012).

According to the EMS, the analytical method (GC-MS) used to analyse the supervised residue trial samples has been sufficiently validated at the LOQ of 0.02 mg/kg and was proven to be fit for the purpose. The method measures the residues of metalaxyl-M according to the established residue definition, which includes both the R- and the S-isomer (United Kingdom, 2012).

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.4 mg/kg reflecting intended use on currants (red, black and white) in the United Kingdom.

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

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (Metalaxyl, including other mixtures of constituent isomers including metalaxyl-M (sum of isomers))	Risk assessment (Metalaxyl, including other mixtures of constituent isomers including metalaxyl-M (sum of isomers))					
Enforcement residue definition: Metalaxyl, including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)									
Currants	NEU	Outdoor	2 x <0.02; 0.024; 0.17	2 x <0.02; 0.024; 0.17	0.022	0.17	0.4	1	R _{ber} = 0.27 R _{max} = 0.44 MRL _{OECD} = 0.36/0.4

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

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

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

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

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

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

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of metalaxyl-M was investigated in studies performed at three test conditions representing pasteurisation, baking/brewing/boiling and sterilisation (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6). The studies were assessed in the DAR and under the framework of the MRL review (Belgium, 2001; EFSA, 2011). Since the analytical method was not enantiomer-selective, a possible change in the enantiomeric ratio during processing was not investigated (FAO, 2005). EFSA concluded that the compound is hydrolytically stable under the representative processing conditions. Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable (EFSA, 2011).

Specific studies to assess the magnitude of metalaxyl-M residues during the processing of currants were not submitted and are not required because of the low exposure to metalaxyl-M residues via currants. One study investigating the magnitude of metalaxyl-M residues in processed strawberry products is available which indicated that residues do not accumulate in strawberry jam, juice, sauce and in canned strawberries.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Since the proposed use of metalaxyl-M is a semi-permanent crop, investigations of residues in rotational crops are not required (OECD, 2007)

3.2. Nature and magnitude of residues in livestock

Since currants are normally not fed to livestock, the nature and magnitude of metalaxyl-M residues in livestock is not assessed in the framework of this application (EC, 1996).

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 population¹³ (EFSA, 2007).

For the calculation of the chronic exposure, EFSA used the median residue value as derived from the residue trials on currants (see Table 3-1). The median residue value derived on lettuce in a previously issued EFSA reasoned opinion was used as input value for the group of lettuce and other salad plants including *Brassicacea* (EFSA, 2012). 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 risk assessment values for plant and animal origin commodities derived in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 have not been used since the MRL review for metalaxyl is not yet completed and the data on metalaxyl-M would not allow a comprehensive exposure assessment.

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 commodity under consideration assuming the consumption of a large portion of the food item as reported in the national food surveys and that these items contained residues at the highest level as observed in supervised field trials.

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

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

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Metalaxyl, including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)				
Currants	0.022	Median residue	0.17	Highest residue
Lettuce and other salad plants including <i>Brassicacea</i>	1.05	Median residue (EFSA, 2012)	Acute risk assessment was undertaken only with regard to the crop under consideration.	
Other commodities of plant and animal origin	MRL	See Appendix C		

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

¹³ 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).

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 26 % of the ADI (DE child diet). The contribution of residues in currants to the total consumer exposure accounted for a maximum of 0.004 % of the ADI (UK toddler diet).

No acute consumer risk was identified in relation to the MRL proposal for currants. The calculated maximum exposure was 0.3 % of the ARfD (DE child diet).

EFSA concludes that the intended use of metalaxyl-M on currants (red, black and white) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

EFSA emphasises that the consumer risk assessment should be regarded as provisional. Residues of metalaxyl-M (R-enantiomer) may also be generated from the use of metalaxyl, which is the mixture of metalaxyl-M and the S-enantiomer. A comprehensive risk assessment for both metalaxyl and metalaxyl-M will be performed in the framework of the review of the existing MRLs for metalaxyl according to Article 12 of Regulation (EC) No 396/2005, when information on all the uses of metalaxyl in plant commodities is available.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of metalaxyl-M was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.08 mg/kg bw per day and an ARfD of 0.5 mg/kg bw.

The metabolism of metalaxyl-M in primary crops was investigated in fruits and fruiting vegetables (grapes), root and tuber vegetables (potatoes) and in leafy vegetables (lettuce and tobacco) using the compound metalaxyl. The data on the metabolism of metalaxyl are applicable to metalaxyl-M. In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 EFSA proposed the residue for enforcement and risk assessment in all plant commodities as metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers). For the use on currants, EFSA concludes that the metabolism of metalaxyl-M in primary crops is sufficiently addressed and that the residue definitions derived are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.4 mg/kg for the proposed use on currants (red, black and white). Adequate analytical enforcement methods are available to control the residues of metalaxyl-M in currants according to the proposed residue definition at the validated LOQ of 0.02 mg/kg.

A hydrolysis study demonstrated that under conditions simulating sterilization, pasteurization and baking/boiling, metalaxyl-M does not undergo degradation. Specific studies investigating the magnitude of residues in processed currants are not required because of the low exposure to metalaxyl-M residues via currants. One study investigating the magnitude of metalaxyl-M residues in processed strawberry products is available which indicated that residues do not accumulate in strawberry jam, juice, sauce and in canned strawberries.

Since the proposed use of metalaxyl-M is on a semi-permanent crop, investigations of residues in rotational crops are not required.

Residues of metalaxyl-M in commodities of animal origin were not assessed in the framework of this application, since the crop under consideration is normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residue Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA used the median residue value as derived from the submitted residue trials on currants and the median residue values on lettuce and other salad plants derived in a previously issued EFSA reasoned opinion. 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 risk assessment was undertaken only with regard to the crop under consideration. The estimated exposure was then compared with the toxicological reference values derived for metalaxyl-M.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 26 % of the ADI (DE child diet). The contribution of residues in currants to the total consumer exposure accounted for a maximum of 0.004 % of the ADI (UK toddler diet). No acute consumer risk was identified in relation to the MRL proposal for currants. The calculated maximum exposure for currants was 0.3 % of the ARfD (DE child diet).

EFSA concludes that the proposed use of metalaxyl-M on currants (red, black and white) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

EFSA emphasises that the consumer risk assessment should be regarded as provisional. Residues of metalaxyl-M (R-enantiomer) may also be generated from the use of metalaxyl, which is the mixture of metalaxyl-M and the S-enantiomer. A comprehensive risk assessment for both metalaxyl and

metalaxyl-M will be performed in the framework of the review of the existing MRLs for metalaxyl according to Article 12 of Regulation (EC) No 396/2005.

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Metalaxyl, including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)^(b)				
154030	Currants (red, black and white)	0.05*	0.4	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended use on this crop.

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

(b): As reworded in the framework of the review of the existing MRLs for metalaxyl-M according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011).

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

REFERENCES

- Belgium, 1999. Draft assessment report on the active substance metalaxyl-M prepared by the rapporteur Member State Belgium in the framework of Council Directive 91/414/EEC, July 1999.
- Belgium, 2001. Addendum to the draft assessment report on the active substance metalaxyl-M prepared by the rapporteur Member State Belgium in the framework of Council Directive 91/414/EEC, September 2011.
- CEN (European Committee for Standardisation), 2008. Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE. QuEChERS-method. EN 15662.2008. November 2008.
- EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95-rev.4.
- EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.
- EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realisation of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6.
- EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.
- EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.
- EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.
- EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.
- EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95.
- EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414). SANCO/3029/99-rev.4.
- EC (European Commission), 2002. Review report for the active substance metalaxyl-M. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 19 April 2002 in view of the inclusion of metalaxyl-M in Annex I of Council Directive 91/414/EEC. SANCO/3037/99-final, 18 September 2002, 32 pp.
- EC (European Commission), 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.
- EC (European Commission), 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1.
- EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9.
- EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs.
- EFSA (European Food Safety Authority), 2011. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for metalaxyl-M according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011; 9(12):2494, 74 pp.
- EFSA (European Food Safety Authority), 2012. Reasoned opinion on the modification of the existing MRLs for metalaxyl-M in lettuce and other salad plants. EFSA Journal 2012; 10(1): 2549, 25 pp.

- FAO (Food and Agriculture Organisation of the United Nations), 2002. Metalaxyl-M and Metalaxyl. In: Pesticide residues in food - 2002. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper 172, 186-192.
- FAO (Food and Agriculture Organisation of the United Nations), 2005. Metalaxyl-M. In: Pesticide residues in food - 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper 178, 106-115.
- FAO (Food and Agriculture Organisation of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.
- OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues.
- United Kingdom, 2012. Evaluation report on the modification of MRLs for metalaxyl-M in blackcurrants prepared by the evaluating Member State the United Kingdom under Article 8 of Regulation (EC) No 396/2005, 18 October 2012, 29 pp.

APPENDICES

Appendix 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		
Currants	United Kingdom	F	Fungi	SC	37.5	Foliar spray	Up to BBCH 51	2			200	0.075	42	

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

Appendix B. Pesticide Residue Intake Model (PRIMO)

Metalaxyl-M									
Status of the active substance:		included		Code no.					
LOQ (mg/kg bw):		0.05		proposed LOQ:					
Toxicological end points									
ADI (mg/kg bw/day):		0.08		ARfD (mg/kg bw):		0.5			
Source of ADI:		EC		Source of ARfD:		EC			
Year of evaluation:		2002		Year of evaluation:		2002			
Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI minimum - maximum					
				3 26					
				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)	
25.7	DE child	15.1	Apples	3.2	Table grapes	2.4	Oranges	1.9	
18.1	NL child	7.9	Apples	1.9	Oranges	1.9	Table grapes	3.2	
11.2	WHO Cluster diet B	2.2	Wine grapes	1.3	Apples	0.9	Table grapes	1.9	
10.6	FR toddler	3.3	Apples	2.5	Milk and cream,	1.3	Oranges	3.5	
10.1	UK Toddler	2.9	Sugar beet (root)	2.1	Apples	1.3	Milk and cream,	2.1	
9.0	IE adult	1.6	Wine grapes	1.0	Apples	0.8	Pears	1.7	
8.4	UK Infant	2.4	Milk and cream,	2.0	Apples	1.3	Sugar beet (root)	3.2	
8.2	DK child	2.9	Apples	1.0	Cucumbers	0.8	Pears	1.8	
8.2	FR all population	5.0	Wine grapes	0.6	Apples	0.3	Table grapes	0.6	
7.6	PT General population	3.1	Wine grapes	1.3	Apples	0.7	Table grapes	0.8	
7.6	FR infant	3.1	Apples	1.6	Milk and cream,	0.6	Oranges	2.3	
7.2	WHO cluster diet E	2.0	Wine grapes	1.1	Apples	0.4	Table grapes	1.3	
6.7	ES child	1.4	Apples	1.4	Oranges	0.8	Milk and cream,	1.8	
6.6	NL general	1.5	Apples	0.9	Oranges	0.8	Wine grapes	1.0	
6.2	SE general population 90th percentile	1.3	Apples	0.8	Head cabbage	0.8	Milk and cream,	1.6	
5.7	WHO regional European diet	0.8	Apples	0.5	Lettuce	0.5	Head cabbage	1.3	
5.4	WHO Cluster diet F	0.8	Apples	0.7	Wine grapes	0.5	Oranges	1.2	
5.2	PL general population	2.6	Apples	0.8	Table grapes	0.5	Head cabbage	0.3	
5.2	ES adult	1.0	Apples	0.8	Oranges	0.7	Lettuce	0.9	
5.2	WHO cluster diet D	0.8	Apples	0.5	Table grapes	0.5	Wine grapes	1.4	
4.7	DK adult	1.7	Wine grapes	1.0	Apples	0.3	Milk and cream,	0.7	
4.7	UK vegetarian	1.0	Wine grapes	0.7	Apples	0.5	Oranges	0.6	
4.4	LT adult	2.3	Apples	0.5	Head cabbage	0.2	Milk and cream,	0.8	
4.3	IT kids/toddler	1.1	Apples	0.4	Pears	0.4	Wheat	0.7	
4.2	UK Adult	1.4	Wine grapes	0.5	Apples	0.5	Sugar beet (root)	0.5	
3.9	IT adult	1.0	Apples	0.5	Lettuce	0.3	Table grapes	0.5	
3.0	FI adult	0.6	Oranges	0.5	Apples	0.4	Wine grapes	0.6	
Conclusion:									
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Metalaxyl-M 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 leads to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1		*)	IESTI 2		*)	IESTI 1		*)	IESTI 2		*)
	Highest % of ARfD/ADI		Commodities	Highest % of ARfD/ADI		Commodities	Highest % of ARfD/ADI		Commodities	Highest % of ARfD/ADI		Commodities
	0.3	0.17 / -	0.17 / -	0.3	0.17 / -	0.17 / -	0.1	0.17 / -	0.17 / -	0.1	0.17 / -	0.17 / -
Currants (red, black and white)			Currants (red, black and white)			Currants (red, black and white)			Currants (red, black and white)			
No of critical MRLs (IESTI 1)						No of critical MRLs (IESTI 2)						
---						---						
Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---			---			---		
	Highest % of ARfD/ADI		Processed commodities	Highest % of ARfD/ADI		Processed commodities	Highest % of ARfD/ADI		Processed commodities	Highest % of ARfD/ADI		Processed commodities
0.04	0.022 / -	0.022 / -										
Cuurant juice												
*) 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 Metalaxyl-M IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.												
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.												
For processed commodities, no exceedance of the ARfD/ADI was identified.												

Appendix C. Existing EU maximum residue levels (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 26/06/2013 14:59))

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/ metalaxyl-M ^(a)
100000	1. FRUIT FRESH OR FROZEN NUTS	
110000	(i) Citrus fruit	0,5
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), uglı and other hybrids)	0,5
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,5
110030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactylis))	0,5
110040	Limes	0,5
110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata x sinensis))	0,5
110990	Others	0,5
120000	(ii) Tree nuts	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	1
130010	Apples (Crab apple)	1
130020	Pears (Oriental pear)	1
130030	Quinces	1
130040	Medlar	1
130050	Loquat	1
130990	Others	1
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*
140020	Cherries (Sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/ metalaxyl-M ^(a)
	mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	
151010	Table grapes	2
151020	Wine grapes	1
152000	(b) Strawberries	0,5
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, tayberries, boysenberries, cloudberrıes and other Rubus hybrids)	0,05*
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x Rubus idaeus))	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries)	0,05*
154020	Cranberries (Cowberries/red bilberries (V. vitis-idaea))	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other Ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (Arbutus berry)	0,05*
154070	Azarole (mediteranean medlar) (Kiwiberry (Actinidia arguta))	0,05*
154080	Elderberries (Black chokeberry/appleberry, mountain ash, buckthorn/sea shallowthorn, hawthorn, serviceberries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	0,05*
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantifolia x Fortunella	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/ metalaxyl-M ^(a)
	spp.))	
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple/water apple, pomerac, rose apple, Brazilian cherry, Surinam cherry/grumichama (Eugenia uniflora))	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan/hairy litchi, longan, mangosteen, langsat, salak)	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel/yellow sapote, mammy sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple/sweetsop, ilama (Annona diversifolia) and other medium sized Annonaceae fruits)	0,05*
163070	Guava (Red pitaya/dragon fruit (Hylocereus undatus))	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(j) Root and tuber vegetables	
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/ metalaxyl-M ^(a)
	vegetables	
212010	Cassava (Dasheen, eddoe/Japanese taro, tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean/yam bean, Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,05*
213020	Carrots	0,1
213030	Celeriac	0,05*
213040	Horseradish (Angelica roots, lovage roots, gentiana roots)	0,1
213050	Jerusalem artichokes (Crosne)	0,05*
213060	Parsnips	0,1
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,1
213090	Salsify (Scorzonerı, Spanish salsify/Spanish oysterplant, edible burdock)	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	
220010	Garlic	0,5
220020	Onions (Other bulb onions, silverskin onions)	0,5
220030	Shallots	0,5
220040	Spring onions and welsh onions (Other green onions and similar varieties)	0,2
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes, Physalis spp., gojiberry, wolfberry (Lycium barbarum and L. chinense), tree tomato)	0,2
231020	Peppers (Chilli peppers)	0,5
231030	Aubergines (egg plants) (Pepino,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/metalaxyl-M ⁽⁶⁾
	antreowa/white eggplant (S. macrocarpon)	
231040	Okra (lady's fingers)	0,05*
231990	Others	0,05*
232000	(b) Cucurbits — edible peel	
232010	Cucumbers	0,5
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson), lauki (Lagenaria siceraria), chayote, sopropo/bitter melon, snake gourd, angled luffia/teroi)	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	0,2
233020	Pumpkins (Winter squash, marrow (late variety))	0,05*
233030	Watermelons	0,2
233990	Others	0,05*
234000	(d) Sweet corn (Baby corn)	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,2
241010	Broccoli (Calabrese, Broccoli raab, Chinese broccoli)	0,2
241020	Cauliflower	0,2
241990	Others	0,2
242000	(b) Head brassica	
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	1
242990	Others	0,05*
243000	(c) Leafy brassica	
243010	Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi, choi sum, Peking cabbage/pe-tsai)	0,05*
243020	Kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0,2
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicaceae	3
251010	Lamb's lettuce (Italian corn salad)	3
251020	Lettuce (Head lettuce, lollo rosso)	3

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/metalaxyl-M ⁽⁶⁾
	(cutting lettuce, iceberg lettuce, romaine (cos) lettuce)	
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curly leaf endive, sugar loaf (C. endivia var. crispum/C. intybus var. foliosum), dandelion greens)	3
251040	Cress (Mung bean sprouts, alfalfa sprouts)	3
251050	Land cress	3
251060	Rocket, Rucola (Wild rocket (Diplotaxis spp.))	3
251070	Red mustard	3
251080	Leaves and sprouts of Brassica spp. including turnip greens (Mizuna, leaves of peas and radish and other babyleaf crops, including brassica crops (crops harvested up to 8 true leaf stage), kohlrabi leaves)	3
251990	Others	3
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, amaranthus spinach (pak-khom, tampara), tajar leaves, bitterblad/bitawiri)	0,05*
252020	Purslane (Winter purslane/miner's lettuce, garden purslane, common purslane, sorrel, glasswort, agretti (Salsola soda))	1
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves) (Malabar nightshade, banana leaves, climbing wattle (Acacia pennata))	0,05*
254000	(d) Water cress (Morning glory/Chinese convolvulus/water convolvulus/water spinach/kangkung (Ipomea aquatica), water clover, water mimosa)	0,05*
255000	(e) Witloof	0,3
256000	(f) Herbs	2
256010	Chervil	2
256020	Chives	2
256030	Celery leaves (Fennel leaves, coriander leaves, dill leaves,	2

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/metalaxyl-M ⁽⁶⁾
	caraway leaves, lovage, angelica, sweet cicely and other Apiacea leaves, culantro/stinking/long coriander/stink weed (Eryngium foetidum))	
256040	Parsley (leaves of root parsley)	2
256050	Sage (Winter savory, summer savory, Borago officinalis leaves)	2
256060	Rosemary	2
256070	Thyme (Marjoram, oregano)	2
256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil, edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)	2
256090	Bay leaves (laurel) (Lemon grass)	2
256100	Tarragon (Hyssop)	2
256990	Others	2
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean/French beans/snap beans, scarlet runner bean, slicing bean, yard long beans, guar beans, soya beans)	0,05*
260020	Beans (without pods) (Broad beans, flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout/sugar peas/snow peas)	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,05*
270020	Cardoons (Borago officinalis stems)	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes (Banana flower)	0,05*
270060	Leek	0,2
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated fungi (Common mushroom, oyster mushroom, shitake, fungus mycelium	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/metalaxyl-M ⁽⁶⁾
	(vegetative parts))	
280020	Wild fungi (Chanterelle, truffle, morel, cep)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0,1*
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds (Other seeds of Cucurbitaceae)	0,1*
401110	Safflower	0,1*
401120	Borage (Purple viper's bugloss/Canary flower (Echium plantagineum), Com Gromwell (Buglossoides arvensis))	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	0,05*
500010	Barley	0,05*
500020	Buckwheat (Amaranthus, quinoa)	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff, finger	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/metalaxyl-M ^(a)
	millet, pearl millet)	
500050	Oats	0,05*
500060	Rice (Indian/wild rice (<i>Zizania aquatica</i>))	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt, triticale)	0,05*
500990	Others (Canary grass seeds (<i>Phalaris canariensis</i>))	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers (Elderflowers (<i>Sambucus nigra</i>))	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves (<i>Ginkgo</i> leaves)	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoabeans (fermented or dried)	0,1*
650000	(v) Carob (st.johns bread)	0,1*
700000	7. HOPS (dried)	10
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/metalaxyl-M ^(a)
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Sichuan pepper (Anise pepper, Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black, green 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	Cinamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (<i>Curcuma</i>)	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	
900010	Sugar beet (root)	0,1
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0,05*
1010000	(i) Tissue	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/metalaxyl-M ^(a)
1011000	(a) Swine	0,05*
1011010	Muscle	0,05*
1011020	Fat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Muscle	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Muscle	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Muscle	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Muscle	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Muscle	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Metalaxyl/metalaxyl-M ^(a)
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, kangaroo, deer)	0,05*
1017010	Muscle	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Bird eggs	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen, honey comb with honey (comb honey))	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products (Wild game)	0,05*

(*). Indicates lower limit of analytical determination.

^(a) Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)).

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation, <i>French</i>)
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
DE	Germany
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC-MS	gas chromatography with mass spectrometry detection
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
i.e.	that is (id est, <i>Latin</i>)
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
LOQ	limit of quantification
MRL	maximum residue level
NEU	northern European Union
NL	The Netherlands
OECD	Organisation 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
RMS	rapporteur Member State
RNA	ribonucleic acid
SC	suspension concentrate
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UK	United Kingdom
WHO	World Health Organisation
yr	year