

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for dimethoate in olives for oil production and table olives¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Greece, herewith referred as the evaluating Member State (EMS), received an application from Cheminova A/S, on behalf of the Dimethoate Task Force, to modify the existing MRLs for the active substance dimethoate in olives for oil production and table olives. In order to accommodate for the intended use of dimethoate, Greece proposed to raise the existing MRLs in olives from the value of 2 mg/kg to 3 mg/kg. Greece 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. According to EFSA the data are sufficient to derive a MRL of 4 mg/kg on table olives and olives for oil production for the intended foliar use of dimethoate in Southern Europe according to the enforcement residue definition as sum of dimethoate and omethoate, expressed as dimethoate. Adequate analytical enforcement methods are available to control the residues of dimethoate and omethoate in olives at the validated LOQ of 0.01 mg/kg for each analyte. Based on the risk assessment results, EFSA concludes that the proposed use of dimethoate on olive trees for oil production and table olives will not result in a consumer exposure exceeding the toxicological reference values. However, the risk assessment in the framework of this opinion should be considered as provisional and may underestimate the actual consumer risk. The final evaluation of the toxicological relevance of metabolites III, XII and XX is still to be provided. To perform a more accurate calculation, the confirmation of the supported authorised use pattern and the results from residue trials conducted according to the final agreed residue definition for risk assessment are needed.

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KEY WORDS

Dimethoate, olives, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, organophosphate, omethoate

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005³, Greece, herewith referred as the evaluating Member State (EMS), received an application from Cheminova A/S, on behalf of the Dimethoate Task Force, to modify the existing MRLs for the active substance dimethoate in olives for oil production and table olives. In order to accommodate for the intended use of dimethoate, Greece proposed to raise the existing MRLs in olives from the value of 2 mg/kg to 3 mg/kg. Greece 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 11 July 2011.

EFSA bases its assessment on the evaluation report, the Draft Assessment Report (DAR) and its addenda prepared by the United Kingdom under Council Directive 91/414/EEC⁴, the Commission Review Report on dimethoate, EFSA conclusion on the peer review, the JMPR Evaluation reports, EFSA previous reasoned opinion on dimethoate as well as additional information submitted in the framework of Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of dimethoate was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.001 mg/kg bw per day and an ARfD of 0.01 mg/kg bw. In addition separate toxicological reference values were set for omethoate, a metabolite considerably more toxic than dimethoate.

The metabolism of dimethoate in primary plants was investigated after foliar application in potatoes and wheat at time of the peer review and in olives under a previous MRL application. In the crop groups investigated dimethoate formed a wide range of metabolites, among which omethoate is the primary metabolism product. Even though omethoate is the more toxic metabolite, other metabolites, in particular (*O*-desmethyl omethoate carboxylic acid (metabolite XX), *O*-desmethyl *iso*-dimethoate (metabolite XII) and dimethoate carboxylic acid (metabolite III)), can potentially contribute to the toxicological burden given their presence in significant amounts. Therefore, further information to determine the toxicological relevance of these metabolites was requested as part of the response to the confirmatory data requirements. The peer review concluded on a residue definition for enforcement as dimethoate and omethoate to be determined separately. Since a change of the residue definition as established in Regulation (EC) No 396/2005 (dimethoate, sum of dimethoate and omethoate, expressed as dimethoate) would have had an impact on the existing MRLs for dimethoate, EFSA recommended to implement the change in the framework of the comprehensive MRL review for dimethoate under Article 12 of this Regulation. Pending the assessment of the data on the toxicity of metabolites XX, XII and III, a provisional residue definition for risk assessment was proposed as “sum of dimethoate and 6 times omethoate expressed as dimethoate (for acute risk assessment)” and “sum of dimethoate and 3 times omethoate expressed as dimethoate” (for chronic risk assessment), taking into account that both compounds share a common toxicological mode of action but with different potencies. EFSA concludes that the provisional residue definitions for enforcement and for risk assessment are applicable to the intended use on the crops under consideration.

EFSA considers that the submitted supervised residue trials are sufficient to derive a MRL of 4 mg/kg on table olives and olives for oil production for the intended foliar use of dimethoate in Southern Europe according to the enforcement residue definition as sum of dimethoate and omethoate, expressed as dimethoate. Adequate analytical enforcement methods are available to control the residues of dimethoate and omethoate in olives at the validated LOQ of 0.01 mg/kg for each analyte.

Studies investigating the nature of dimethoate residues in processed commodities were assessed in the framework of the peer review through hydrolysis studies simulating sterilisation, baking, brewing, boiling and pasteurization. The peer review concluded that the nature of residues was affected by processing to a certain extent only when severe conditions such as sterilisation are applied. However, no specific residue definition for processed commodities was set as the metabolism was similar to that

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.

observed in raw agricultural commodities (RAC). Specific studies investigating the magnitude of dimethoate and omethoate residues in olives processed to oil and canned olives were assessed during the peer review. EFSA is not recommending the inclusion of the derived processing factors in Annex VI of Regulation (EC) No 396/2005 as long as the residue definition (dimethoate and omethoate set separately) is not modified.

Since the proposed use of dimethoate is on permanent crops, investigations of residues in rotational crops are not required. Olives are also not usually fed to livestock, therefore the nature and magnitude of residues in commodities of animal origin resulting for the intended use of dimethoate in olive trees were not assessed.

A provisional consumer risk assessment was performed with revision 2 of the EFSA PRIMo. It is based on the assumption that metabolites XX, XII and III do not contribute to the overall toxicological burden taking into account the authorised uses of dimethoate as notified by the Member States for the Article 12 review and the existing acceptable CXLs. For the calculation of the chronic exposure, EFSA used the median residue values for dimethoate and omethoate as derived from the residue trials on olives, the median residue values for dimethoate and omethoate from previous reasoned opinions, the risk assessment input values reported by the rapporteur Member States, the United Kingdom, in the framework of Article 12 of Regulation (EC) No 396/2005 and the MRL values. The acute exposure assessment was performed only with regard to the commodities under consideration. The available processing factors were also applied to refine the calculation. The calculated exposure was then compared with the toxicological reference values as derived for dimethoate.

Taking into account the information available to EFSA, 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 79.4 % of the ADI (DE child diet). The contribution of residues in olives for oil production and table olives to the total consumer exposure accounted for a maximum of 8.8 % and 0.2 % of the ADI, respectively (WHO Cluster diet B). No acute consumer risk was identified in relation to the MRL proposal for olives for oil production and table olives. The calculated maximum exposure in percentage of the ARfD was 6.9 % for olives for oil production and 6.1 % for table olives.

EFSA concludes that the proposed use of dimethoate on olive trees for oil production and table olives will not result in a consumer exposure exceeding the toxicological reference values. However, the risk assessment in the framework of this opinion should be considered as provisional and may underestimate the actual consumer risk. The final evaluation of the toxicological relevance of metabolites III, XII and XX is still to be provided. To perform a more accurate calculation, the confirmation of the supported authorised use pattern and the results from residue trials conducted according to the final agreed residue definition for risk assessment are needed.

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

Summary table

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: sum of dimethoate and omethoate expressed as dimethoate (Regulation (EC) No 396/2005)				
161030	Table olives	2	4	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended foliar spraying use of dimethate based on the available information.
402010	Olives for oil production	2	4	

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
				based on the final agreed residue definition for risk assessment and the supported uses.

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

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	5
Background	6
Terms of reference.....	6
The active substance and its use pattern.....	7
Assessment	8
1. Method of analysis.....	8
1.1. Methods for enforcement of residues in food of plant origin	8
1.2. Methods for enforcement of residues in food of animal origin	8
2. Mammalian toxicology.....	9
3. Residues.....	10
3.1. Nature and magnitude of residues in plant.....	10
3.1.1. Primary crops.....	10
3.1.2. Rotational crops.....	13
3.2. Nature and magnitude of residues in livestock	13
4. Consumer risk assessment	14
Conclusions and recommendations	18
References	20
Appendices	22
A. Good Agricultural Practice (GAPs).....	22
B. Pesticide Residues Intake Model (PRIMo).....	23
C. List of metabolites and related structural formula	29
Abbreviations	30

BACKGROUND

Regulation (EC) No 396/2005 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/EEC, 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.

Greece, hereafter referred to as the evaluating Member State (EMS), received an application from the company Cheminova A/S⁶ on behalf of the Dimethoate Task Force to modify the existing MRLs for the active substance dimethoate in olives for oil production and table olives. 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 11 July 2011.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2011-00886 and the following subject:

Dimethoate - Application to modify the existing MRLs in olives

Greece proposed to raise the existing MRLs of dimethoate in olives for oil production and table olives from the value of 2 mg/kg to 3 mg/kg. EFSA identified some data gaps or points which needed further clarifications which were addressed by the EMS in an updated evaluation report provided on 15 February 2012. The report replaces the previous document dated April 2011.

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.

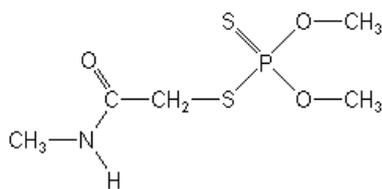
In this particular case the calculated deadline for providing the reasoned opinion is 11 October 2011.

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 Cheminova A/S, on behalf of Dimethoate Task Force, P.O. Box 9, 7620 Lemvig, Denmark.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Dimethoate is the ISO common name for *O,O*-dimethyl *S*-methylcarbamoylmethyl phosphorodithioate or 2-dimethoxyphosphinothioylthio-*N*-methylacetamide (IUPAC). The chemical structure of the compound is herewith reported.



Molecular weight: 229.3 g/mol

Dimethoate is a contact and systemic organophosphate insecticide and acaricide for the control of a wide range of pests. It acts by inhibiting the enzyme acetylcholinesterase. Dimethoate main plant metabolite, its oxygen analogue omethoate⁷, has a similar biochemical mode of action, but showed to be more toxic.

Dimethoate was evaluated in the framework of Council Directive 91/414/EEC with the United Kingdom designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission Directive 2007/25/EC⁸ which entered into force on 1st October 2007 with the provision to submit confirmatory data. In accordance with Commission Implementing Regulation (EU) No 540/2011⁹ dimethoate is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The representative uses considered in the Annex I inclusion were foliar applications of dimethoate on sugar beets and protected lettuce (EC, 2006). The Draft Assessment Report (DAR) of dimethoate included also uses on olives, wheat and tomatoes and was peer reviewed by EFSA (EFSA, 2006). According to the provisions set in the Annex I inclusion Directive, the RMS evaluated the toxicological relevance of certain metabolites potentially present in crops in view of their possible contribution to the consumer safety in a DAR Addendum (United Kingdom, 2011) and addressed the comments received from EFSA and MSs in a reporting table that was submitted to the European Commission for consideration in October 2011. In accordance with the procedure for confirmatory data, the European Commission has to take further action. To date, the European Commission has not requested additional advice from EFSA and a final decision on the toxicological relevance of metabolites III, XII and XX is still to be provided.

Omethoate is no longer used as pesticide at European level. Since no manufacturer supported the active substance it was not evaluated under Directive 91/414/EEC. A non-inclusion decision was taken in 2002 by Regulation (EC) No 2076/2002¹⁰.

The existing EU MRLs for dimethoate are included in Annexes II and IIIB of Regulation (EC) No 396/2005 (Appendix C). MRL proposals for barley, oats, broccoli, cauliflower, Brussels sprouts and cherry were recently assessed by EFSA (EFSA, 2011) but not yet voted by the Standing Committee on the Food Chain and Animal Health (SCFCAH). The existing MRLs on olives for oil production and on table olives are set at the value of 2 mg/kg. Codex Alimentarius has established CXLs for a wide range of commodities, including olives for which the CXL is set at 0.5 mg/kg.

The details of the intended GAPs for dimethoate in Southern Europe are given in Appendix A. The Member States for which the authorisation was requested were not specified by the notifier.

⁷ Omethoate. See Appendix D.

⁸ Commission Directive 2007/25/EC of 23 April 2007. OJ L 106, 24.04.1007, p.34-42.

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

¹⁰ Commission Regulation (EC) No 2076/2002 of 20 November 2002. OJ L 319, 23.11.2002, p.3-11.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Greece, 2012), the Draft Assessment Report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2004, 2006, 2011), the Commission Review Report on dimethoate (EC, 2006), the conclusion on the peer review of the pesticide risk assessment of the active substance dimethoate (EFSA, 2006), the JMPR Evaluation reports (FAO, 2004a, 2004b), the conclusions from previous EFSA opinion on dimethoate (EFSA, 2008, 2010a, 2010b, 2011) as well as the information submitted by the RMS in the framework of the review of the existing MRLs for dimethoate according to Article 12 of Regulation (EC) No 396/2005 (United Kingdom, 2010). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011¹¹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

Since the review of the studies on the toxicological relevance of the metabolites identified in the crop metabolism as requested according to Commission Directive 2007/25/EC (confirmatory data) is not yet finalised, the conclusions reached in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the review.

1. Method of analysis

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

The analytical methods for the determination of dimethoate and omethoate residues (both are part of the residue definition for enforcement set in Regulation (EC) No 396/2005) in plant commodities were assessed during the peer review (EFSA, 2006) and in a previous reasoned opinion on dimethoate (EFSA, 2011). Methods for the determination of dimethoate and omethoate in matrices with high water content (lettuce, tomatoes, sugar beet), oil content (olives, olive oil) and dry matrices (wheat) by means of liquid chromatography with mass detection (LC-MS) were sufficiently validated at the LOQ of 0.01 mg/kg for each analyte. Thus, the LOQ for the residue definition (sum of dimethoate and omethoate, expressed as dimethoate) is 0.02 mg/kg. Alternative methods based on gas-chromatography (GC) were reported with similar LOQ values (oranges, lettuce, potatoes, tomatoes, olives, peas, sugar beet, sorghum, wheat and maize).

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 is also validated for the determination of dimethoate and omethoate in matrices with high water content, high acid content, oil content and in dry matrices. The LOQ for oily fruits is of 0.01 mg/kg for each compound (CEN, 2008).

Since the commodity under consideration belongs to the group of high oil content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for dimethoate on the crop under consideration are available.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since olives and their by-products are normally not fed to livestock.

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

2. Mammalian toxicology

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

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
<i>Dimethoate</i>					
ADI	EC	2006	0.001 mg/kg bw per day	Overall NOAEL from: 2 yr rat, multigeneration rat, rat neurotoxicity and rat developmental neurotoxicity study	100
ARfD	EC	2006	0.01 mg/kg bw	Rat, acute dietary neurotoxicity	100
<i>Omethoate</i>					
ADI	EFSA	2006	0.0003 mg/kg bw per day	Rat, multigeneration study and 2 yr study	100
ARfD	EFSA	2006	0.002 mg/kg bw	Rat, acute neurotoxicity	100

Omethoate, which exerts a similar mode of toxicological action, showed to be more toxic than dimethoate. By comparison of the most sensitive toxicological endpoint for inhibition of the cholinesterase activity, the toxicity equivalence factors (TEFs) of three for the chronic risk assessment and of six for the acute risk assessment were agreed by the peer review (EFSA, 2006).

Even though omethoate was expected to be the most toxic metabolite of dimethoate, also other metabolites, in particular *O*-desmethyl omethoate carboxylic acid (metabolite XX¹²), *O*-desmethyl *iso*-dimethoate (metabolite XII¹³) and dimethoate carboxylic acid (metabolite III¹⁴) can bring a significant contribution to the toxicological burden given their presence in significantly amounts in certain crops parts. Therefore further information on the potential for cholinesterase inhibition to determine the toxicological relevance of metabolites III, XII and XX was requested as part of the response to the confirmatory data requirements (EC, 2006). New data have been evaluated by the RMS in an addendum to the DAR (United Kingdom, 2011). EFSA and MSs have provided comments to the RMS in a reporting table that was submitted to the European Commission for consideration in October 2011. EFSA is of the opinion that the toxicity of metabolites III, XII and XX is still not fully elucidated. EFSA's view is shared by some Member States. However, the European Commission has not yet taken any further steps on the subject and the final evaluation on the toxicological relevance of metabolites III, XII and XX is still to be provided.

¹² Metabolite XX. See Appendix D.

¹³ Metabolite XII. See Appendix D.

¹⁴ Metabolite III. See Appendix D.

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 dimethoate after foliar application was assessed in potatoes and wheat during the peer review under Directive 91/414/EEC (United Kingdom, 2004; EFSA, 2006) and in olives during the assessment of a previous MRL application (EFSA, 2011). The overview of the metabolism study designs is presented in the table below.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application details				Remarks
			Method, F or G ^(a)	Rate	No/Interval	Sampling	
Fruits and fruiting vegetable	Olive	[methoxy- ¹⁴ C]-dimethoate	F	0.72 kg a.s./ha	4	After each appl., 28 DALA	Not evaluated in the peer review.
Root and tuber vegetables	Potato			0.34 kg a.s./ha	2 (14 d)	0, 2, 7, 14, 21, 28 DALA	Samples: tubers, foliage.
Cereals	Wheat			0.68 kg a.s./ha at BBCH 24 (1 st appl.), 0.4 kg a.s./ha at BBCH 69 (2 nd appl.)	2 (41 d)	0, 14, 26 d, (after 1 st appl.), 21, 32 DALA	Samples: whole plant, grains, hails, straw.

(a): Outdoor/field use (F) or glasshouse/protected crops/indoor application (G)

The results of the metabolism studies are detailed in a previous reasoned opinion (EFSA, 2011). The metabolic pattern of dimethoate consisted of a complex mixture of compounds, depending on the crop and plant part and varied with time. Apart from the formation of omethoate, other metabolites, such as metabolites XXIII¹⁵ and XV¹⁶ as well as metabolites XX, XII, III were observed at relevant levels. This is in particular the case for cereal grains, potato tubers and green olives. Quantitatively, the metabolite XXIII was the major residue at harvest in potato tubers, wheat grains and straw and in olives. According to the toxicological studies, metabolite XXIII has not shown anticholinesterase activity in the rat and metabolite XV is not expected to be a cholinesterase inhibitor on the basis of its structure. Insufficient toxicological information was available for metabolites III, XII and XX, and further data were requested (EFSA, 2006).

The peer review concluded on a residue definition for enforcement as dimethoate and omethoate to be determined separately. Since a change of the residue definition for enforcement as established in Regulation (EC) No 396/2005 (sum of dimethoate and omethoate, expressed as dimethoate) would have had an impact on the existing MRLs for dimethoate, EFSA recommended to implement the change in the framework of the comprehensive MRL review for dimethoate under Article 12 of this Regulation (EFSA, 2010a). Pending the final decision on the inclusion in the residue definition of metabolites XX, XII and III with appropriate toxicity equivalence factors, the peer review proposed a provisional residue definition for risk assessment as “sum of dimethoate and 6 times omethoate

¹⁵ Metabolite XXIII: See Appendix D.

¹⁶ Metabolite XV: See Appendix D.

expressed as dimethoate (acute risk assessment)” and “sum of dimethoate and 3 times omethoate expressed as dimethoate” (chronic risk assessment) (EFSA, 2006).

For the uses on olives, EFSA concludes that the metabolism of dimethoate is sufficiently addressed and the proposed provisional residue definitions are applicable.

3.1.1.2. Magnitude of residues

a. Foliar spray application on olives

Nine supervised residue trials (six designed as residue decline studies) on olives conducted in Spain, Italy, Greece and Southern France were submitted. Extrapolation of residue data from table olives (minor crop in SEU) to olives for oil production (major crop in SEU) and *vice-versa* is acceptable (EC, 2011). Samples were analysed for dimethoate and omethoate concentrations. All trials were in compliance with the intended GAP. The data are sufficient to derive the MRL proposal and the risk assessment input values.

b. Bait spray application on olives

Two side-by-side decline studies on olive trees were submitted. On one plot a single bait spray solution containing 0.65 L/hL of proteins was applied to approximately 25 % (Spanish trial) and 12.5 % (Greek trial) of each individual tree (mainly branches) according to the intended GAP. A single foliar broadcast spray dose (0.04 kg a.s./hL; 1200 L/ha; 0.48 kg a.s./ha) was applied on the other plot. At harvest, total residues (sum of dimethoate and omethoate) were lower (0.13 mg/kg) in olives receiving the bait spray application compared to the concentrations (0.32 mg/kg) obtained after the foliar spray application (Spanish trial). Thus, the intended bait application GAP can be regarded as less critical, provided that the product is applied to olive trees according to the tested use pattern.

The residue data obtained following dimethoate foliar spray application were used to derive the values for the risk assessment (highest residue, median residue) and the MRL proposal according to the different residue definitions (see Table 3-2).

The storage stability of dimethoate and omethoate in primary crops was assessed under the peer reviewed (EFSA, 2006). Residues of both compounds were found to be stable when stored at temperatures between -10°C to -20°C in a range of commodities (potatoes, oranges, sorghum grain and forage, cotton seed and cherries) for up to 27 months (6 months in the case of cherries). In addition, dimethoate and omethoate proved to be stable in olives for up to 6 months at about -18°C (Greece, 2012). As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability. The QuEChERS method was used to analyse the supervised residue trial samples and was proven to fit for purpose (Greece, 2012).

EFSA considers that the data are sufficient to derive a MRL proposal of 4 mg/kg for the intended foliar use on table olives and olives for oil productions in SEU according to the enforcement residue definition as sum of dimethoate and omethoate, expressed as dimethoate.

In view of the implementation of the separated enforcement residue definitions for dimethoate as established during the peer review, the MRL of 3 mg/kg is proposed for dimethoate and the MRL of 1 mg/kg is proposed for omethoate.

Table 3-2: Overview of the available residues trials data

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results ^(b) (mg/kg)	Median residue (mg/kg) (c)	Highest residue (mg/kg) (d)	MRL proposal (mg/kg)	Median CF (e)	Comments (f)
			Enforcement residue definition (see below)					
Proposed enforcement residue definition: dimethoate (EFSA, 2006).								
Table olives ↔ Olives for oil production	SEU	Outdoor	0.02 ^(g) ; 0.08 ^(g) ; 3 x 0.12; 0.54; 0.55; 0.94; 1.69 ^(h)	0.12	1.69	3	n.a.	R _{ber} = 1.49 R _{max} = 2.14 MRL _{OECD} = 2.67/3
Proposed enforcement residue definition: omethoate (EFSA, 2006)								
Table olives ↔ Olives for oil production	SEU	Outdoor	<0.01; 0.24; 0.30; 0.32; 0.33; 0.44; 0.46; 0.48 ^(g) ; 0.50	0.33	0.50	1	n.a.	R _{ber} = 0.94 R _{max} = 0.81 MRL _{OECD} = 0.96/1
Enforcement residue definition: dimethoate, sum of dimethoate and omethoate⁽ⁱ⁾ expressed as dimethoate (Regulation (EC) No 396/2005)								
Table olives ↔ Olives for oil production	SEU	Outdoor	0.03 ^(g) ; 0.44; 0.45; 0.56; 0.56 ^(g) ; 0.79; 1.01; 1.24; 2.19 ^(h)	0.56	2.19	4	n.a.	R _{ber} = 2.25 R _{max} = 2.71 MRL _{OECD} = 3.31/4

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

(b): Residues expressed as fruit without stone (flesh). Since the weight ratio of the stone and the flesh for each sample was not recorded, no recalculation to the whole fruit was possible.

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

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

(e): Median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial. However, for dimethoate the CF is not applicable as the input value for risk assessment is established based on fixed toxicological equivalence factors applicable to all crops.

(f): 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).

(g): Highest values measured at a longer PHI of 35 days.

(h): Statistically detected as potential outlier (Dixon's Q-test) but no information and no obvious defects in the trial justified the exclusion of the value from the calculation (EC, 1997g; FAO, 2009).

(i): Based on the molecular weight ratio relatively close to the value of 1 (exactly 1.075), it was considered not necessary to convert omethoate residues in dimethoate equivalents (EFSA, 2006).

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of dimethoate was investigated during the peer review in studies performed at three test conditions representing pasteurization, 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 peer review concluded that the nature of residues was affected by processing to a certain extent only when severe conditions such as sterilisation are applied. However, no specific residue definitions for processed commodities were set as the metabolites formed were similar to those observed in raw agricultural commodities (EFSA, 2006).

Studies investigating the magnitude of dimethoate residues in the processing of olives into canned olives and oil were assessed in the framework of the peer review. Olives were treated four times with dimethoate at about 4.5-8N the intended rate and collected at a shorter PHI (21 days). Separate processing factors for dimethoate and omethoate were calculated (EFSA, 2006). It is noted that the processing study (Doc No 532-5005) reported as an additional experiment by the EMS (Greece, 2012) was assessed during the peer review (listed in the references relied on, United Kingdom, 2004).

The processing factors derived are reported in Table 3-3.

Table 3-3: Overview of the available processing factors (EFSA, 2006)

Processed commodity	Number of studies	PF derived for dimethoate ^a	PF derived for omethoate ^a
Olive, crude oil	3	0.3	< 0.01
Olive, refined oil	3	0.27	0.01
Olives, 6 months canned olives	3	0.3	0.12
Olives, 6 months canned olives (sterilised)	3	0.09	0.01
Olives, 6 months canned brine	3	0.16	0.08
Olives, 6 months canned brine (sterilised)	3	0.04	0.01

(a): Mean PFs calculated for dimethoate and omethoate separately on the basis of the ratio between the residue values of dimethoate (or of omethoate) in processed commodity and in the RAC prior to processing.

As long as the residue definition established in Regulation (EC) No 396/2005 is not changed to reflect the separated definitions for omethoate and dimethoate proposed during the peer review (EFSA, 2006), EFSA does not recommend the inclusion of the derived processing factors in Annex VI of Regulation (EC) No 396/2005.

3.1.2. Rotational crops

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

3.2. Nature and magnitude of residues in livestock

Since olives and their by-products are not normally fed to livestock, the nature and magnitude of dimethoate residues in livestock is not assessed in the framework of this application (EC, 1996).

4. Consumer risk assessment

The consumer risk assessment is 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 population¹⁷ (EFSA, 2007). The consumer risk assessment is based on the assumption that metabolites XX, XII and III do not contribute to the overall toxicological burden taking into account the authorised uses of dimethoate as notified by the Member States for the Article 12 review and the existing acceptable CXLs (United Kingdom, 2010).

For the calculation of the chronic exposure, EFSA used the median residue values of dimethoate and omethoate as derived from the residue trials on olives (see Table 3-2). The risk assessment input value (RA value) was recalculated according to the provisional residue definition for chronic risk assessment. For the remaining commodities of plant origin, EFSA adopted the same approach as in previous reasoned opinion (EFSA, 2011). In particular:

- For the crops for which the existing EU MRL is above the LOQ and residue trials are available (cherries, broccoli, cauliflower, Brussels sprout, celeriac, spring onions, rye, wheat, sugar beets), the median residue values of dimethoate and omethoate as reported in the EFSA conclusion of the peer review (EFSA, 2006) and in previous reasoned opinions (EFSA, 2008, 2011) were used. The risk assessment input value was calculated according to the provisional residue definition for chronic risk assessment (median residue_{dimethoate}+3*median residue_{omethoate});
- For the crops for which the existing EU MRL is above the LOQ but no residue trials are available (dried herbal infusions) and for bark of spices (MRL at the LOQ of 0.05 mg/kg). It was assumed that the total residue contains exclusively the more toxic omethoate compound. Thus, the existing MRL value was multiplied by a factor of 3 and used as risk assessment input value (MRL*3);
- For the crops for which the existing EU MRL is based on the CXL (spices: seeds, fruits and berries, roots and rhizome), the median residue value reported by the JMPR (FAO, 2004b) was used. Since there was no information available on the amounts of omethoate in the crop, it was assumed that omethoate is present in food at the levels of dimethoate, to account for the worst case situation (median residue_{dimethoate}+3*median residue_{dimethoate});
- For the crops for which the existing EU MRL is at the LOQ and for which residue trials supporting the current MRL (LOQ) have been provided for the Article 12 MRL review (citrus fruits, beetroots, onion, head cabbage, peas without pods), the risk assessment input value as reported by the RMS was used (United Kingdom, 2010). The risk assessment input value was calculated according to the provisional residue definition for chronic risk assessment (median residue_{dimethoate}+3*median residue_{omethoate});
- For the crops for which the EU MRL is at the LOQ and the GAP has been notified for the Article 12 MRL review without providing residue trials (apples, pears, peaches, grapes, strawberries, radishes, witloof, sage, rosemary, thyme, basil, bay leaves, tarragon, cotton seed, chicory roots) (United Kingdom, 2010). It was assumed that residues of both dimethoate and omethoate are present in food at the single LOQ of 0.01 mg/kg or at the LOQ of 0.05 mg/kg (cotton seed), to account for the worst case situation (LOQ_{dimethoate}+3 LOQ_{omethoate});

¹⁷ 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).

- The crops for which the existing EU MRL is at the LOQ and a requested use was previously rejected (carrots, parsnips, parsley roots, lettuce, tomatoes, aubergines, asparagus, globe artichokes) by EFSA (EFSA, 2010a, 2010b) or no GAP has not been notified for the Article 12 MRL review (United Kingdom, 2010) were excluded from the exposure calculation.

The processing factors (PFs) for raw oil (dimethoate: 0.3; omethoate: 0.01) and for sterilised canned olives (dimethoate: 0.09; omethoate: 0.01) as derived from the processing trials (see Table 3-3) were applied. In addition, the median PFs (dimethoate: 0.18; omethoate: 0.5) for flour (type 550 flour) calculated from the available processing studies on wheat (United Kingdom, 2004), the peeling factor of 0.065 for citrus fruits (FAO, 2004a) and the yield factor for wine grapes were taken into account to refine the chronic risk assessment.

It is noted that the model for the long-term exposure assessment is affected by some uncertainties. It is based upon the information on the existing uses of dimethoate collected by the RMS for the Article 12 review, which is not yet fully validated. Since there was no information available on the residues of omethoate in several crops, conservative assumptions are used to avoid an underestimation of the risk. Furthermore, metabolites XX, XII and III were considered as not contributing to the overall toxicological burden (applied also to the acute risk assessment).

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the highest level (see Table 3-2) according to the provisional acute risk assessment residue definition: sum of the highest residue value_{dimethoate} + 6 x the highest residue value_{omethoate}. The values were refined by using the PFs for olives applied in the chronic risk assessment.

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
Provisional risk assessment residue definition (RA RD):				
Acute: sum of dimethoate and 6 times omethoate, expressed as dimethoate				
Chronic: sum of dimethoate and 3 times omethoate, expressed as dimethoate				
Table olives	0.02 (0.12*0.09) + 3*(0.33*0.01)	Median residue*PF _{dimethoate} +3*Median residue* PF _{omethoate}	0.18 (1.69*0.09) + 6*(0.5*0.01)	Highest residue*PF _{dimethoate} +6*Highest residue *PF _{omethoate}
Olives for oil production	0.05 (0.12*0.3) + 3*(0.33*0.01)	Median residue*PF _{dimethoate} +3*Median residue * PF _{omethoate}	0.54 (1.69*0.3) + 6*(0.5*0.01)	Highest residue*PF _{dimethoate} +6*Highest residue *PF _{omethoate}
Cherries	0.16 (0.025+3*0.045)	RA input value (EFSA, 2011)	Acute risk assessment was undertaken only with regard to the crop under consideration.	
Broccoli	0.04 (0.01+3*0.01)	RA input value (EFSA, 2011)		
Cauliflower	0.04 (0.01+3*0.01)	RA input value (EFSA, 2011)		
Brussels sprouts	0.05 (0.02+3*0.01)	RA input value (EFSA, 2011)		
Barley, oat grain	0.004 (0.001+3*0.001)	RA input value (EFSA, 2011)		

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Citrus fruits	0.003 (0.04*0.065)	RA input value*Peeling Factor (orange,UK, 2010; FAO, 2004a)		
Beetroot	0.04	RA input value (sugar beet, UK, 2010)		
Celeriac	0.02	RA input value (EFSA, 2008, 2011)		
Spring onions	0.54	RA input value (EFSA, 2008, 2011)		
Onions, Head cabbage	0.08	RA input value (UK, 2010)		
Peas without pods	0.04	RA input value (UK, 2010)		
Rye, wheat	0.01 (0.01*0.18)+3* (0.006*0.5)	Median residue*PF _{dimethoate} +3*Median residue* PF _{omethoate} (EFSA, 2006; FAO, 2004a)		
Sugar beets	0 ^(b)	See footnote (EFSA, 2011)		
Apples, pears; peaches; table grapes; strawberries; radishes; witloof; sage, rosemary, thyme, basil, bay leaves, tarragon; chicory roots	0.04 (0.01+3*0.01)	LOQ+3*LOQ (UK, 2010)		
Wine grapes	0.03 (0.01+3*0.01*0.7)	LOQ+3*LOQ*YF ^(c) (UK, 2010)		
Cotton seed	0.2 (0.05+3*0.05)	LOQ+3*LOQ (UK, 2010)		
Camomile flowers	3 (1*3)	MRL*3 (EFSA, 2011)		
Herbal infusions (dried flowers (except camomile), dried leaves, dried roots)	0.3 (0.1*3)	MRL*3 (EFSA, 2011)		
Spices (bark)	0.15 (0.05*3)	MRL*3 (EFSA, 2011)		
Spices (seeds, fruits and berries, roots or rhizome)	0.68 (0.17+3*0.17)	Median Residue (FAO, 2004b) +3*median residue		

(a): RA input value calculated according to the provisional residue definition for chronic risk assessment (sum of the median residue_{dimethoate} +3 x the median residue_{omethoate}) (United Kingdom, 2010; EFSA, 2011).

(b): No residue is expected in sugar. Therefore sugar beet is not included in the intake calculation (EFSA, 2011).

(c): Consumption figures in the EFSA PRIMo are expressed as wine grapes. Since it is assumed that all wine grapes are consumed as wine, the consumption is recalculated to wine using a yield factor (1 kg of wine grapes is needed to produce 0.7 kg of wine) to perform the refined intake calculation for wine grapes.

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

Taking into account the information available to EFSA, 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 79.4 % of the ADI (DE child diet). The contribution of residues in olives for oil production and table olives to the total consumer exposure accounted for a maximum of 8.8 % and 0.2 % of the ADI, respectively (WHO Cluster diet B).

No acute consumer risk was identified in relation to the MRL proposal for olives for oil production and table olives. The calculated maximum exposure in percentage of the ARfD was 6.9 % for olives for oil production and 6.1 % for table olives.

EFSA concludes that the intended use of dimethoate on olives for oil production and table olives will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern.

However, the risk assessment in the framework of this opinion should be considered as provisional and may underestimate the actual consumer risk. The final evaluation of the toxicological relevance of metabolites III, XII and XX is still to be provided. To perform a more accurate calculation, the confirmation of the supported authorised use pattern and the results from residue trials conducted according to the final agreed definition for risk assessment are needed.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of dimethoate was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.001 mg/kg bw per day and an ARfD of 0.01 mg/kg bw. In addition separate toxicological reference values were set for omethoate, a metabolite considerably more toxic than dimethoate.

The metabolism of dimethoate in primary plants was investigated after foliar application in potatoes and wheat at time of the peer review and in olives under a previous MRL application. In the crop groups investigated dimethoate formed a wide range of metabolites, among which omethoate is the primary metabolism product. Even though omethoate is the more toxic metabolite, other metabolites, in particular (O-desmethyl omethoate carboxylic acid (metabolite XX), O-desmethyl iso-dimethoate (metabolite XII) and dimethoate carboxylic acid (metabolite III)), can potentially contribute to the toxicological burden given their presence in significant amounts. Therefore, further information to determine the toxicological relevance of these metabolites was requested as part of the response to the confirmatory data requirements. The peer review concluded on a residue definition for enforcement as dimethoate and omethoate to be determined separately. Since a change of the residue definition as established in Regulation (EC) No 396/2005 (dimethoate, sum of dimethoate and omethoate, expressed as dimethoate) would have had an impact on the existing MRLs for dimethoate, EFSA recommended to implement the change in the framework of the comprehensive MRL review for dimethoate under Article 12 of this Regulation. Pending the assessment of the data on the toxicity of metabolites XX, XII and III, a provisional residue definition for risk assessment was proposed as “sum of dimethoate and 6 times omethoate expressed as dimethoate (for acute risk assessment)” and “sum of dimethoate and 3 times omethoate expressed as dimethoate” (for chronic risk assessment), taking into account that both compounds share a common toxicological mode of action but with different potencies. EFSA concludes that the provisional residue definitions for enforcement and for risk assessment are applicable to the intended use on the crops under consideration.

EFSA considers that the submitted supervised residue trials are sufficient to derive a MRL of 4 mg/kg on table olives and olives for oil production for the intended foliar use of dimethoate in Southern Europe according to the enforcement residue definition as sum of dimethoate and omethoate, expressed as dimethoate. Adequate analytical enforcement methods are available to control the residues of dimethoate and omethoate in olives at the validated LOQ of 0.01 mg/kg for each analyte.

Studies investigating the nature of dimethoate residues in processed commodities were assessed in the framework of the peer review through hydrolysis studies simulating sterilisation, baking, brewing, boiling and pasteurization. The peer review concluded that the nature of residues was affected by processing to a certain extent only when severe conditions such as sterilisation are applied. However, no specific residue definition for processed commodities was set as the metabolism was similar to that observed in raw agricultural commodities (RAC). Specific studies investigating the magnitude of dimethoate and omethoate residues in olives processed to oil and canned olives were assessed during the peer review. EFSA is not recommending the inclusion of the derived processing factors in Annex VI of Regulation (EC) No 396/2005 as long as the residue definition (dimethoate and omethoate set separately) is not modified.

Since the proposed use of dimethoate is on permanent crops, investigations of residues in rotational crops are not required. Olives are also not usually fed to livestock, therefore the nature and magnitude of residues in commodities of animal origin resulting for the intended use of dimethoate in olive trees were not assessed.

A provisional consumer risk assessment was performed with revision 2 of the EFSA PRIMo. It is based on the assumption that metabolites XX, XII and III do not contribute to the overall toxicological burden taking into account the authorised uses of dimethoate as notified by the Member States for the Article 12 review and the existing acceptable CXLs. For the calculation of the chronic exposure, EFSA used the median residue values for dimethoate and omethoate as derived from the residue trials

on olives, the median residue values for dimethoate and omethoate from previous reasoned opinions, the risk assessment input values reported by the rapporteur Member States, the United Kingdom, in the framework of Article 12 of Regulation (EC) No 396/2005 and the MRL values. The acute exposure assessment was performed only with regard to the commodities under consideration. The available processing factors were also applied to refine the calculation. The calculated exposure was then compared with the toxicological reference values as derived for dimethoate.

Taking into account the information available to EFSA, 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 79.4 % of the ADI (DE child diet). The contribution of residues in olives for oil production and table olives to the total consumer exposure accounted for a maximum of 8.8 % and 0.2 % of the ADI, respectively (WHO Cluster diet B). No acute consumer risk was identified in relation to the MRL proposal for olives for oil production and table olives. The calculated maximum exposure in percentage of the ARfD was 6.9 % for olives for oil production and 6.1 % for table olives.

EFSA concludes that the proposed use of dimethoate on olive trees for oil production and table olives will not result in a consumer exposure exceeding the toxicological reference values. However, the risk assessment in the framework of this opinion should be considered as provisional and may underestimate the actual consumer risk. The final evaluation of the toxicological relevance of metabolites III, XII and XX is still to be provided. To perform a more accurate calculation, the confirmation of the supported authorised use pattern and the results from residue trials conducted according to the final agreed residue definition for risk assessment are needed.

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: sum of dimethoate and omethoate expressed as dimethoate (Regulation (EC) No 396/2005)				
161030	Table olives	2	4	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended foliar spraying use of dimethate based on the available information.
402010	Olives for oil production	2	4	The risk assessment is to be considered as provisional and may need to be reconsidered based on the final agreed residue definition for risk assessment and the supported uses.

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

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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		
Olive	SEU	F	Olive fly (<i>Bactrocera oleae</i>), olive moth (<i>Prays oleae</i>)	EC	400 g/L	Foliar spraying	From infestation to BBCH 85	1-2	10 d	0.04	1200	0.48	28	
Olive	SEU	F	Olive fly (<i>Bactrocera oleae</i>)	EC	400 g/L	Bait spraying	From infestation to BBCH 85	1	n.a.	0.25 + 0.65 L/hL protein	20	0.05	28	Could be combined with 1 foliar application with spray interval of 10 d

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

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Dimethoate									
Status of the active substance:		included		Code no.					
LOQ (mg/kg bw):				proposed LOQ:					
Toxicological end points									
ADI (mg/kg bw/day):		0.001		ARfD (mg/kg bw):		0.01			
Source of ADI:		EC		Source of ARfD:		EC			
Year of evaluation:		2006		Year of evaluation:		2006			
Provisional risk assessment residue definition: Acute = sum of dimethoate and 6 times omethoate, expressed as dimethoate; Chronic = sum of dimethoate and 3 times omethoate, expressed as dimethoate (EFSA, 2006).									
Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI minimum - maximum					
				7 79					
				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)	
79.4	DE child	48.3	Apples	5.7	Cherries	5.1	Table grapes		
51.8	WHO Cluster diet B	9.2	Wheat	8.8	Olives for oil production	6.2	Onions		
50.9	NL child	25.3	Apples	5.1	Wheat	3.0	Table grapes		
28.0	DK child	9.3	Apples	5.9	Wheat	4.8	Rye		
27.7	IE adult	3.9	Wine grapes	3.3	Apples	2.7	Pears		
27.0	WHO cluster diet E	5.0	Wine grapes	4.3	Wheat	3.4	Apples		
26.0	PT General population	7.7	Wine grapes	4.2	Wheat	4.2	Apples		
24.8	FR toddler	10.5	Apples	2.8	Wheat	2.5	Strawberries		
24.6	WHO cluster diet D	7.0	Wheat	4.1	Onions	2.7	Apples		
23.9	FR all population	12.4	Wine grapes	3.6	Wheat	1.9	Apples		
21.8	SE general population 90th percentile	5.0	Head cabbage	4.2	Apples	3.6	Onions		
21.0	WHO regional European diet	3.4	Onions	3.2	Wheat	2.9	Head cabbage		
20.3	ES child	4.8	Wheat	4.6	Apples	3.4	Olives for oil production		
19.5	UK Toddler	6.8	Apples	4.2	Wheat	1.9	Onions		
19.4	UK Infant	6.3	Apples	2.8	Wheat	2.3	Peas (without pods)		
19.3	PL general population	8.2	Apples	2.9	Head cabbage	2.6	Onions		
19.2	NL general	4.7	Apples	2.2	Wheat	2.0	Wine grapes		
18.7	FR infant	10.0	Apples	2.0	Strawberries	1.3	Pears		
18.1	IT kids/toddler	7.2	Wheat	3.5	Apples	1.4	Cherries		
18.0	WHO Cluster diet F	3.9	Wheat	2.6	Apples	2.2	Head cabbage		
15.5	ES adult	3.1	Apples	2.5	Wheat	1.9	Olives for oil production		
14.9	DK adult	4.3	Wine grapes	3.1	Apples	2.2	Wheat		
14.9	LT adult	7.5	Apples	3.2	Head cabbage	1.2	Rye		
13.8	IT adult	4.5	Wheat	3.2	Apples	1.5	Peaches		
13.6	UK vegetarian	2.5	Wine grapes	2.4	Apples	2.2	Wheat		
11.3	UK Adult	3.4	Wine grapes	1.8	Wheat	1.6	Apples		
7.3	FI adult	1.6	Apples	1.1	Onions	1.1	Wheat		
Conclusion:									
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Dimethoate is unlikely to present a public health concern.									

Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations						
The acute risk assessment is based on the ARfD.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.												
Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1 *)		**)	IESTI 2 *)		**)	IESTI 1 *)		**)	IESTI 2 *)		**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	6.9	Olives for oil	0.537 / -	6.9	Olives for oil	0.537 / -	4.2	Olives for oil	0.537 / -	4.2	Olives for oil production	0.537 / -
6.1	Table olives	0.1821 / -	6.1	Table olives	0.1821 / -	2.4	Table olives	0.1821 / -	2.4	Table olives	0.1821 / -	
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	***) pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)
<p>*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.</p> <p>**) pTMRL: provisional temporary MRL</p> <p>***) pTMRL: provisional temporary MRL for unprocessed commodity</p>												
<p>Conclusion:</p> <p>For Dimethoate IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.</p> <p>No exceedance of the ARfD/ADI was identified for any unprocessed commodity.</p> <p>For processed commodities, no exceedance of the ARfD/ADI was identified.</p>												

Existing EU maximum residue levels (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 18/04/2012 10:30))

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0.02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0.02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.02*
110030	Lemons (Citron, lemon)	0.02*
110040	Limes	0.02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0.02*
110990	Others	0.02*
120000	(ii) Tree nuts (shelled or unshelled)	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	0.02*
130010	Apples (Crab apple)	0.02*
130020	Pears (Oriental pear)	0.02*
130030	Quinces	0.02*
130040	Medlar	0.02*
130050	Loquat	0.02*
130990	Others	0.02*
140000	(iv) Stone fruit	
140010	Apricots	0.02*
140020	Cherries (sweet cherries, sour cherries)	0,2 (ft) (0,3) ⁽ⁱ⁾
140030	Peaches (Nectarines and similar hybrids)	0.02*
140040	Plums (Damson, greengage, mirabelle)	0.02*
140990	Others	0.02*
150000	(v) Berries & small fruit	0.02*
151000	(a) Table and wine grapes	0.02*
151010	Table grapes	0.02*
151020	Wine grapes	0.02*
152000	(b) Strawberries	0.02*
153000	(c) Cane fruit	0.02*
153010	Blackberries	0.02*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0.02*
153030	Raspberries (Wineberries)	0.02*
153990	Others	0.02*
154000	(d) Other small fruit & berries	0.02*
154010	Blueberries (Bilberries cowberries (red bilberries))	0.02*
154020	Cranberries	0.02*
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 (mediteranean medlar)	0.02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0.02*
154990	Others	0.02*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	
161010	Dates	0.02*
161020	Figs	0.02*
161030	Table olives	2
161040	Kumquats (Marumi kumquats, nagami kumquats)	0.02*
161050	Carambola (Bilimbi)	0.02*
161060	Persimmon	0.02*
161070	Jambolan (java plum) (Java apple (water apple), pomeac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0.02*
161990	Others	0.02*
162000	(b) Inedible peel, small	0.02*
162010	Kiwi	0.02*
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 mammey sapote)	0.02*
162990	Others	0.02*
163000	(c) Inedible peel, large	0.02*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
163010	Avocados	0.02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0.02*
163030	Mangoes	0.02*
163040	Papaya	0.02*
163050	Pomegranate	0.02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0.02*
163070	Guava	0.02*
163080	Pineapples	0.02*
163090	Bread fruit (Jackfruit)	0.02*
163100	Durian	0.02*
163110	Soursop (guanabana)	0.02*
163990	Others	0.02*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0.02*
212000	(b) Tropical root and tuber vegetables	0.02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0.02*
212020	Sweet potatoes	0.02*
212030	Yams (Potato bean (yam bean), 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	0.02*
213030	Celeriac	0,1
213040	Horseradish	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)	0.02*
213090	Salsify (Scorzoner, Spanish salsify (Spanish oysterplant))	0.02*
213100	Swedes	0.02*
213110	Turnips	0.02*
213990	Others	0.02*
220000	(ii) Bulb vegetables	
220010	Garlic	0.02*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
220020	Onions (Silverskin onions)	0.02*
220030	Shallots	0.02*
220040	Spring onions (Welsh onion and similar varieties)	2
220990	Others	0.02*
230000	(iii) Fruiting vegetables	0.02*
231000	(a) Solanacea	0.02*
231010	Tomatoes (Cherry tomatoes,)	0.02*
231020	Peppers (Chilli peppers)	0.02*
231030	Aubergines (egg plants) (Pepino)	0.02*
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* (0.03) ^(a)
241020	Cauliflower	0.02* (0.03) ^(a)
241990	Others	0.02*
242000	(b) Head brassica	0.02*
242010	Brussels sprouts	0.02* (0.1) ^(a)
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*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0.02*
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, sorrel, 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	Tamagon (Hyssop)	0.02*
256990	Others	0.02*
260000	(vi) Legume vegetables (fresh)	0.02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0.02*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0.02*
260030	Peas (with pods) (Mangetout (sugar peas))	0.02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.02*
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*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
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	0.02*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0.02*
300020	Lentils	0.02*
300030	Peas (Chickpeas, field peas, chickling vetch)	0.02*
300040	Lupins	0.02*
300990	Others	0.02*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0.05*
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	0.05*
401080	Mustard seed	0.05*
401090	Cotton seed	0.05*
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	2
402020	Palm nuts (palmoil kernels)	0.05*
402030	Palmfruit	0.05*
402040	Kapok	0.05*
402990	Others	0.05*
500000	5. CEREALS	
500010	Barley	0.02* (0.03) ^(a)
500020	Buckwheat	0.02*
500030	Maize	0.02*
500040	Millet (Foxtail millet, teff)	0.02*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
500050	Oats	0.02* (0.03) ^(a)
500060	Rice	0.02*
500070	Rye	0,05
500080	Sorghum	0.02*
500090	Wheat (Spelt Triticale)	0,05
500990	Others	0.02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i>)	0.05*
620000	(ii) Coffee beans	0.05*
630000	(iii) Herbal infusions (dried)	
631000	(a) Flowers	
631010	Camomille flowers	1
631020	Hybiscus flowers	0,1
631030	Rose petals	0,1
631040	Jasmine flowers	0,1
631050	Lime (linden)	0,1
631990	Others	0,1
632000	(b) Leaves	
632010	Strawberry leaves	0,1
632020	Rooibos leaves	0,1
632030	Maté	0,1
632990	Others	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	0.05*
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	
810000	(i) Seeds	5
810010	Anise	5
810020	Black caraway	5
810030	Celery seed (Lovage seed)	5
810040	Coriander seed	5
810050	Cumin seed	5
810060	Dill seed	5
810070	Fennel seed	5
810080	Fenugreek	5
810090	Nutmeg	5
810990	Others	5
820000	(ii) Fruits and berries	0,5
820010	Allspice	0,5
820020	Anise pepper (Japan pepper)	0,5
820030	Caraway	0,5

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
820040	Cardamom	0,5
820050	Juniper berries	0,5
820060	Pepper, black and white (Long pepper, pink pepper)	0,5
820070	Vanilla pods	0,5
820080	Tamarind	0,5
820990	Others	0,5
830000	(iii) Bark	0.05*
830010	Cinnamon (Cassia)	0.05*
830990	Others	0.05*
840000	(iv) Roots or rhizome	0,1
840010	Liquorice	0,1
840020	Ginger	0,1
840030	Turmeric (Curcuma)	0,1
840040	Horseradish	0,1
840990	Others	0,1
850000	(v) Buds	0.05*
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)	1
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	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	
1014010	Meat	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others	
1030000	(iii) Birds' eggs, fresh preserved or cooked	

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
	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	
1030010	Chicken	
1030020	Duck	
1030030	Goose	

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

(*) Indicates lower limit of analytical determination.

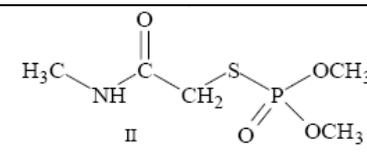
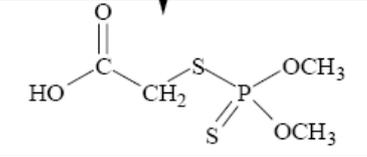
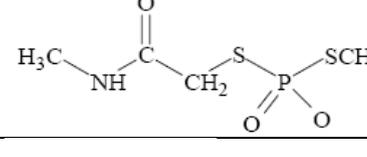
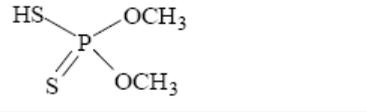
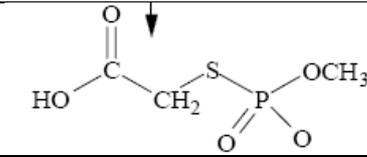
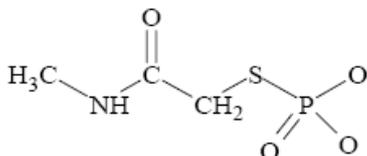
Footnotes:

0140020 Cherries (sweet cherries, sour cherries)

Dimethoate - code 0140020: The maximum residue level has been established temporarily pending the finalisation of the review under article 12(2).

^(a) The MRL values proposed by EFSA in its reasoned opinion (EFSA, 2011) are under brackets. These values are not yet voted at SCFCAH by 18 April 2012.

C. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Metabolite	Common name	Structure
Metabolite II	Omethoate O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate or 2-dimethoxyphosphinoylthio-N-methylacetamide (IUPAC)	 <p>Molecular weight: 213.2</p>
Metabolite III	Dimethoate carboxylic acid	
Metabolite XII	O-desmethyl iso-dimethoate	
Metabolite XV	O,O-dimethyl dithiophosphoric acid	
Metabolite XX	O-desmethyl omethoate carboxylic acid	
Metabolite XXIII	O-desmethyl-N-desmethyl omethoate	

Adapted from Figure B.7.1. Proposed metabolic pathway for dimethoate in plants and domestic animals. Draft Assessment Report (United Kingdom, 2004).

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
CEN	European Committee for Standardisation (Comité Européen de Normalisation, <i>French</i>)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CIRCA	(EU) Communication & Information Resource Centre Administrator
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
EC	European Community
EC	emulsifiable concentrate
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (former GIFAP)
GLP	Good Laboratory Practice
ha	hectare
hL	hectolitre
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography

kg	kilogram
L	litre
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry
NOAEL	no observed adverse effect level
OECD	Organization for Economic Co-operation and Development
PF	processing factor
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
SCFCAH	Standing Committee on the Food Chain and Animal Health
SEU	Southern European Union
STMR	supervised trials median residue
TEF	toxicity equivalence factor
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UK	the United Kingdom
WHO	World Health Organisation
YF	yield factor
yr	year